

LANNETT CO INC
Form 10-K
September 29, 2008
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

**For the fiscal year ended June 30,
2008**

OR

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES
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
State of Incorporation

23-0787699
I.R.S. Employer I.D. No.

9000 State Road

Philadelphia, Pennsylvania 19136

Edgar Filing: LANNETT CO INC - Form 10-K

Registrant's telephone number, including area code: (215) 333-9000

(Address of principal executive offices and telephone number)

Securities registered under Section 12(b) of the Exchange Act:

None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, \$.001 Par Value

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes No

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

Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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

Edgar Filing: LANNETT CO INC - Form 10-K

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

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12B-12 of the Exchange Act).

Yes

No

Aggregate market value of Common stock held by non-affiliates of the Registrant, as of December 31, 2007 was \$30,654,552 based on the closing price of the stock on the American Stock Exchange.

As of September 25, 2008, there were 24,340,402 shares of the issuer's common stock, \$.001 par value, outstanding.

Table of Contents

TABLE OF CONTENTS

PART I

<u>ITEM 1. DESCRIPTION OF BUSINESS</u>	3
<u>ITEM 1A. RISK FACTORS</u>	16
<u>ITEM 2. DESCRIPTION OF PROPERTY</u>	22
<u>ITEM 3. LEGAL PROCEEDINGS</u>	22
<u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	22

PART II

<u>ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	23
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	24
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	25
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	42
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	42
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	43
<u>ITEM 9B. OTHER INFORMATION</u>	44

PART III

<u>ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT</u>	45
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	49
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	62
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	65
<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	66

PART IV

<u>ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K</u>	67
<u>SIGNATURES</u>	68
<u>Annual Report on Form 10-K</u>	
<u>Subsidiaries of the Company, Exhibit 21</u>	
<u>Consent of Grant Thornton LLP, Exhibit 23.1</u>	
<u>Certification of Chief Executive Officer, Exhibit 31.1</u>	
<u>Certification of Chief Financial Officer, Exhibit 31.2</u>	
<u>Certification of CEO and CFO Pursuant to Section 906, Exhibit 32</u>	

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements in Item 1A Risk Factors , Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and in other statements located elsewhere in this Annual Report. Any statements made in this Annual Report that are not statements of historical fact or that refer to estimated or anticipated future events are forward-looking statements. We have based our forward-looking statements on our management s beliefs and assumptions based on information available to them at this time. Such forward-looking statements reflect our current perspective of our business, future performance, existing trends and information as of the date of this filing. These include, but are not limited to, our beliefs about future revenue and expense levels and growth rates, prospects related to our strategic initiatives and business strategies, express or implied assumptions about government regulatory action or inaction, anticipated product approvals and launches, business initiatives and product development activities, assessments related to clinical trial results, product performance and competitive environment, and anticipated financial performance. Without limiting the generality of the foregoing, words such as may, will, expect, believe, anticipate, intend, could, would, estimate, continue, or pursue, or the negative other variations thereof or c terminology, are intended to identify forward-looking statements. The statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We caution the reader that certain important factors may affect our actual operating results and could cause such results to differ materially from those expressed or implied by forward-looking statements. We believe the risks and uncertainties discussed under the Item 1A - Risk Factors and other risks and uncertainties detailed herein and from time to time in our SEC filings, may affect our actual results.

We disclaim any obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. We also may make additional disclosures in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and in other filings that we may make from time to time with the SEC. Other factors besides those listed here could also adversely affect us. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995, as amended.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

General

Lannett Company, Inc. (the Company, Lannett, we, or us) was incorporated in 1942 under the laws of the Commonwealth of Pennsylvania, and reincorporated in 1991 as a Delaware corporation. We develop, manufacture, market and distribute generic versions of pharmaceutical products. The Company reports financial information on a quarterly and fiscal year basis, the most recent being the fiscal year ended June 30, 2008. All references herein to a fiscal year refer to the Company s fiscal year ending June 30.

Edgar Filing: LANNETT CO INC - Form 10-K

The Company is focused on increasing our share of the generic pharmaceutical market. We plan to improve our financial performance by expanding our line of generic products, increasing unit sales to current customers and reducing overhead and administrative costs. In addition, our recent acquisition of Cody Laboratories, Inc. allows us to work toward vertically integrating our dosage form manufacturing in order to reduce active pharmaceutical ingredients (API) costs. Some of the new generic products sold by Lannett were developed and are manufactured by Lannett while other products are manufactured by other companies. The products manufactured or distributed by Lannett and their brand name equivalents are identified in the section entitled **Products** in Item 1 of this Form 10-K.

Table of Contents

Over the past several years, Lannett has consistently devoted resources to research and development (R&D) projects, including new generic product offerings. The costs of these R&D efforts are expensed during the periods incurred. The Company believes that such investments may be recovered in future years as it submits applications to the Food and Drug Administration (FDA), and when it receives marketing approval from the FDA to distribute such products. In addition to using cash generated from its operations, the Company has entered into financing agreements with third parties to provide additional cash when needed. These financing agreements are more fully described in the section entitled **Liquidity and Capital Resources** in Item 7 of this Form 10-K. The Company has embarked on a plan to grow in future years. In addition to organic growth to be achieved through its own R&D efforts, the Company has also initiated marketing projects with other companies in order to expand future revenue. The Company expects that its growing list of generic drugs under development will drive future growth. The Company also intends to use the infrastructure it has created, and to continually devote resources to additional R&D projects. The following steps outline Lannett's efforts:

Research and Development Process

There are numerous stages in the generic drug development process:

- 1.) **Formulation and Analytical Method Development:** After a drug candidate is selected for future sales, product development chemists perform various experiments on the incorporation of active ingredients into a dosage form. These experiments will result in the creation of a number of product formulations to determine which formula will be most suitable for the Company's subsequent development process. Various formulations are tested in the laboratory to measure results against the innovator drug. During this time, the Company may use reverse engineering methods on samples of the innovator drug to determine the type and quantity of inactive ingredients. During the formulation phase, the Company's research and development chemists begin to develop an analytical, laboratory testing method. The successful development of this test method will allow the Company to test developmental and commercial batches of the product in the future. All of the information used in the final formulation, including the analytical test methods adopted for the generic drug candidate, will be included as part of the Chemical, Manufacturing and Controls section of the Abbreviated New Drug Application (ANDA) submitted to the FDA in the generic drug application.

- 2.) **Scale-up:** After the product development scientists and the R&D chemists agree on a final formulation to use in moving the drug candidate forward in the developmental process, the Company will attempt to increase the batch size of the product. The batch size represents the standard magnitude to be used in manufacturing a batch of the product. The determination of batch size will affect the amount of raw material that is input into the manufacturing process and the number of expected tablets or capsules to be created during the production cycle. The Company attempts to determine batch size based on the amount of active ingredient in each dosage, the available production equipment and unit sales projections. The scaled-up batch is then generally produced in the Company's commercial manufacturing facilities. During this manufacturing process, the Company will document the equipment used, the amount of time in each major processing step and any other steps needed to consistently produce a batch of that product. This information generally referred to as the validated manufacturing process, will be included in the Company's generic drug application submitted to the FDA.

3.) Clinical testing: After a successful scale-up of the generic drug batch, the Company then schedules and performs clinical testing procedures on the product if required by the FDA. These procedures, which are generally outsourced to third parties, include testing the absorption of the generic product in the human bloodstream compared to the absorption of the innovator drug. The results of this testing are then documented and reported to the Company to determine the success of the generic drug product. Success, in this context, means the successful comparison of the Company's product related to the innovator product. Since bioequivalence and a stable

Table of Contents

formula are the primary requirements for a generic drug approval (assuming the manufacturing plant is in compliance with the FDA's good manufacturing quality standards), lengthy and costly clinical trials proving safety and efficacy, which are generally required by the FDA for innovator drug approvals, are unnecessary for generic companies. If the results are successful, the Company will continue the collection of documentation and information for assembly of the drug application.

4.) Submission of the ANDA for FDA review and approval: The ANDA process became formalized under The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act (Hatch-Waxman Act). An ANDA represents a generic drug company's application to the FDA to manufacture and/or distribute a drug that is the generic equivalent to an already-approved brand named (innovator) drug. Once bioequivalence studies are complete, the generic drug company submits an ANDA to the FDA for marketing approval.

According to the September 2008 issue of Generics Bulletin the current review time exceeds 19 months. While we have received approvals in 14 months we have also gone well beyond the 19 as discussed in the article. We see no improvement in this in the short term.

When a generic drug company files an ANDA with the FDA, it must certify that no patents are listed in the Orange Book, the FDA's reference listing of approved drugs and listed patents. An ANDA filer must certify, with respect to each application, whether the filer is challenging a patent that no patent was filed for the listed drug (a paragraph I certification), that the patent has expired (a paragraph II certification), that the patent will expire on a specified date and the ANDA filer will not market the drug until that date (a paragraph III certification), or that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new drug (a paragraph IV certification). A paragraph IV certification can trigger an automatic 30 month stay of the ANDA if the innovator company files a claim. It will delay the approval of the generic company's ANDA. Currently, Lannett has filed no paragraph IV certifications with its ANDAs.

Over the past several years, the Company has hired additional personnel in product development, production, formulation and the R&D laboratory. Lannett believes that its ability to select appropriate products for development, develop such products on a timely basis, obtain FDA approval, and achieve economies in production will be critical for its success in the generic industry. The strategy involves a combination of decisions focusing on long-term profitability and a secure market position with fewer challenges from competitors.

Competition in generic pharmaceutical manufacturing should continue to grow as more pharmaceutical products lose patent protection. However, the Company believes that with strong technical know-how, low overhead expenses, and efficient product development, manufacturing and marketing, it can remain competitive. It is the intention of the Company to reinvest as much capital as possible to develop new products as the success of any generic pharmaceutical manufacturer depends on its ability to continually introduce new generic products to the market. Over time, if a generic drug market for a specific product remains stable and consumer demand remains consistent, it is likely that additional generic manufacturing companies will pursue the generic product by developing it, submitting an ANDA, and potentially receiving marketing approval from the FDA. If this occurs, the generic competition for the drug increases, and a company's market share may drop. In addition to reduced unit sales, the unit selling price may also drop due to the product's availability from additional suppliers. This may have the effect of reducing a generic company's future net sales of the product. Due to these factors that may potentially affect a generic company's future results of operations, the ability to properly assess the competitive effect of new products, including market share, the number of competitors and the generic unit price erosion, is critical to a generic company's R&D plan. A generic company may be able to reduce the potential exposure to competitive influences that negatively affect its sales and profits by having several drug candidates in its R&D pipeline. As such, a generic company may be able to avoid becoming materially dependent on the sales of one drug. Please refer to the following section entitled **Products**

Table of Contents

for more descriptive information on the 28 products the Company currently produces or sells. Unlike the branded, innovator companies, Lannett does not develop new molecules nevertheless it has filed and received 2 patents at its Cody Wyoming facility with an additional one pending. However, the typical intellectual property in the generic drug industry are the ANDAs that generic drug companies own.

Validated Pharmaceutical Capabilities

Lannett's manufacturing facility consists of 31,000 square feet on 3.5 acres owned by the Company. In addition, the Company owns a 63,000 square foot building located within 1 mile of the manufacturing facility, which houses packaging, warehousing, shipping, R&D and a number of administrative functions. In addition, we lease a third building located several miles from the manufacturing facility, consisting of 65,000 square feet. This building is currently being used as a warehouse.

The manufacturing facility of Lannett's wholly-owned subsidiary, Cody Laboratories, Inc. (Cody) consists of 73,000 square feet on 16.2 acres in Cody, Wyoming. Cody leases the facility from Cody LCI Realty, LLC, Wyoming, which is 50% owned by Lannett and 50% by an officer of Cody.

Many FDA regulations relating to current Good Manufacturing Practices (cGMP) have been adopted by the Company in the last several years. In designing its facilities, full attention was given to material flow, equipment and automation, quality control and inspection. A granulator, an automatic film coating machine, high-speed tablet presses, blenders, encapsulators, fluid bed dryers, high shear mixers and high-speed bottle filling are a few examples of the sophisticated product development, manufacturing and packaging equipment the Company uses. In addition, the Company's Quality Control laboratory facilities are equipped with high precision instruments, such as automated high-pressure liquid chromatographs, gas chromatographs, robots and laser particle sizers.

Lannett continues to pursue its comprehensive plan for improving and maintaining quality control and quality assurance programs for its pharmaceutical development and manufacturing facilities. The FDA periodically inspects the Company's production facilities to determine the Company's compliance with the FDA's manufacturing standards. Typically, after the FDA completes its inspection, it will issue the Company a report, entitled a Form 483, containing the FDA's observations of possible violations of cGMP which may be minor or severe in nature. The degree of severity of the observation is generally determined by the time necessary to remediate the cGMP violation, any consequences on the consumer of the products, and whether the observation is subject to a Warning Letter from the FDA. By strictly enforcing the various FDA guidelines, namely current Good Manufacturing Practices (cGMPs) and Good Laboratory Practices (cGLPs), as well as adherence to Lannett's Standard Operating Procedures (SOPs) the Company has successfully minimized the number of observations in its FDA inspections.

Sales and Customer Relationships

The Company sells its pharmaceutical products to generic pharmaceutical distributors, drug wholesalers, chain drug retailers, private label distributors, mail-order pharmacies, other pharmaceutical manufacturers, managed care organizations, hospital buying groups and health maintenance organizations. It promotes its products through direct sales, trade shows, trade publications, and bids. The Company also licenses the marketing of its products to other manufacturers and/or marketers in private label agreements.

Edgar Filing: LANNETT CO INC - Form 10-K

The Company continues to expand its sales to the major chain drug stores. Its policy of maintaining an adequate inventory and fulfilling orders in a timely manner has contributed to the Company's reputation among its customers as a dependable supplier of high quality generic pharmaceuticals. Its Cody Labs subsidiary sells to dosage form manufacturers.

Table of Contents

Management

The Company has been focused on increasing the size and quality of its management team in anticipation of continued growth. Managers from large, established, brand pharmaceutical companies as well as competing generic companies have been brought in to complement the skills and knowledge of the existing management team. As the Company continues to grow, additional managers may need to be added to the team. We intend to hire the best people available to expand the knowledge and expertise within the Company, in order to achieve the Company's goals.

Table of Contents**Products**

As of the date of this filing, the Company manufactured and/or distributed the following products:

	Name of Product	Medical Indication	Equivalent Brand
1	Acetazolamide Tablets	Glaucoma	Diamox®
2	Baclofen Tablets	Muscle Relaxer	Lioresal®
3	Bethanechol Chloride Tablets	Urinary Retention	Urecholine®
4	Butalbital, Aspirin and Caffeine Capsules	Migraine Headache	Fiorinal®
5	Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules	Migraine Headache	Fiorinal w/ Codeine #3®
6	Clidamycin HCl Capsules	Antibiotic	Cleocin®
7	Danazol Capsules	Endometriosis	Danocrine®
8	Dicyclomine Tablets/Capsules	Irritable Bowels	Bentyl®
9	Digoxin Tablets	Congestive Heart Failure	Lanoxin®
10	Dipyridamole Tablets	Blood Clot Reduction	Persantine®
11	Doxycycline Tablets	Antibiotic	Adoxa®
12	Doxycycline Hyclate Tablets	Antibiotic	Periostat®
13	Hydrochlorothiazide Tablet	Water Retention	Hydrodiuril®
14	Hydromorphone HCl Tablets	Pain Management	Dilaudid®
15	Levothyroxine Sodium Tablets	Thyroid Deficiency	Levoxyl®/ Synthroid®
16	Esterified Estrogen & Methyltestosterone Tablets	Hormone Replacement	Estratest®
17	Morphine Sulfate Oral Solution	Pain Management	Roxanol®
18	Multivitamin with Minerals	Prenatal Vitamin	PrimaCare ONE ®
19	Oxycodone HCl Oral Solution	Pain Management	Roxicodone®
20	Phentermine HCl Tablets	Weight Loss	Adipex-P®
21	Phentermine HCl Capsules	Weight Loss	Fastin®
22	Pilocarpine HCl Tablets	Dryness of the Mouth	Salagen®
23	Primidone Tablets	Epilepsy	Mysoline®
24	Probenecid Tablets	Gout	Benemid®
25	Rifampin Capsules	Antibiotic	Rifadin®
26	Sulfamethoxazole with Trimethoprim	Antibacterial	Bactrim®
27	Terbutaline Sulfate Tablets	Bronchospasms	Brethine®
28	Unithroid® Tablet	Thyroid Deficiency	N/A

Table of Contents

Key Products

All of the products currently manufactured and/or sold by the Company are prescription products. Of the products listed above, those containing Butalbital, Digoxin, Primidone, and Levothyroxine Sodium were the Company's key products, contributing approximately 76%, 63% and 71% of the Company's total net sales in fiscal 2008, 2007 and 2006 respectively. In Fiscal 2006, the Company began selling Sulfamethoxazole w/ Trimethoprim (SMZ/TMP). Because of a market opportunity, sales of SMZ/TMP grew from 3% of sales in 2006 to 19% of sales in 2007, but declined to 9% of net sales in 2008. This product is not included in the above key products because the supply agreement for the product expired in August 2008 and was not renewed.

The Company has two products containing Butalbital. One of the products, Butalbital with Aspirin and Caffeine capsules, has been manufactured and sold by Lannett for more than nine years. The other Butalbital product, Butalbital with Aspirin, Caffeine and Codeine Phosphate capsules is manufactured by Jerome Stevens Pharmaceuticals, Inc. (JSP). Lannett began buying this product from JSP and selling it to its customers in December 2002. Both products, which are in orally administered capsule dosage forms, are prescribed to treat tension headaches caused by contractions of the muscles in the neck and shoulder area and migraine. The drug is prescribed primarily for adults of various demographic backgrounds. Migraine headache is an increasingly prevalent condition in the United States. As conditions continue to grow, the demand for effective medical treatments will continue to grow. Common side effects of drugs which contain Butalbital include dizziness and drowsiness. The Company notes that although new innovator drugs to treat migraine headaches have been introduced by brand name drug companies, there is still a loyal following of doctors and consumers who prefer to use Butalbital products for treatment. As the brand name companies continue to promote products containing Butalbital, like Fiorinal®, the Company expects to continue to produce and sell its generic Butalbital products.

Digoxin tablets are produced and marketed with two different potencies (0.125 and 0.25 milligrams per tablet). This product is manufactured by JSP. Lannett began buying this product from JSP and selling it to its customers in September 2002. Digoxin tablets are used to treat congestive heart failure in patients of various ages and demographic backgrounds. The beneficial effects of Digoxin result from direct actions on the cardiac muscle, as well as indirect actions on the cardiovascular system mediated by effects on the autonomic nervous system. Side effects of Digoxin may include apathy, blurred vision, changes in heartbeat, confusion, dizziness, headaches, loss of appetite, nausea, vomiting and weakness.

Primidone tablets are produced and marketed with two different potencies (50 and 250 milligrams per tablet). This product was developed and is manufactured by Lannett. Lannett has been manufacturing and selling Primidone 250-milligram tablets for more than seven years. Lannett began selling Primidone 50-milligram tablets in June 2001. Both products, which are in orally administered tablet dosage forms, are prescribed to treat convulsion and seizures in epileptic patients of all ages and demographic backgrounds. Common side effects of Primidone include lack of muscle coordination, vertigo and severe dizziness.

The Company's products containing Levothyroxine Sodium tablets are produced and marketed with eleven different potencies. In addition to generic Levothyroxine Sodium tablets, the Company also markets and distributes Unithroid tablets, a branded version of Levothyroxine Sodium tablets, which is produced and marketed with eleven different potencies. Both Levothyroxine Sodium products are manufactured by JSP. Lannett began buying generic Levothyroxine Sodium tablets from JSP and selling it to its customers in April 2003. In September 2003, the Company began buying the branded Unithroid tablets from JSP and selling it to its customers. Levothyroxine Sodium tablets are used to treat hypothyroidism and other thyroid disorders. It remains one of the most prescribed drugs in the United States with over 13 million patients of various ages and demographic backgrounds. Side effects from Levothyroxine Sodium are rare, but may include allergic reactions, such as rash or hives. In late June of 2004, JSP received a letter from the FDA approving its supplemental application for generic bioequivalence to Levoxyl®. In December 2004, JSP received a letter from the FDA approving its supplemental application for generic bioequivalence

Table of Contents

to Synthroid®. With its distribution of these products, Lannett competes in a market which is currently controlled by two branded Levothyroxine Sodium tablet products Abbott Laboratories Synthroid® and Monarch Pharmaceutical's Levoxyl® as well as generic competition from Mylan Laboratories and Sandoz.

New Products

In Fiscal 2008, Lannett received 9 ANDA approvals from the FDA. We received only 1 ANDA approval in Fiscal 2007. The following contains more specific details regarding our latest approvals. Market data is obtained from Wolters Kluwer.

In July 2007, Lannett received a letter from the FDA with approval to market and launch Baclofen 10mg tablets. Baclofen is the generic version of Lioresal® and is a muscle relaxer used to treat symptoms of multiple sclerosis. According to Wolters Kluwer, total sales of generic Baclofen 10mg tablets were \$151 million at average wholesale price (AWP) in 2007.

In August 2007, Lannett received two letters from the FDA with approval to market and launch Hydrochlorothiazide 25mg & 50mg tablets. Hydrochlorothiazide is the generic version of Hydrodiuril® and is a thiazide diuretic (water pill) that helps prevent your body from absorbing too much salt. According to Wolters Kluwer, total sales of generic Hydrochlorothiazide 25mg & 50mg tablets was \$182 million at AWP in 2007.

In December 2007, Lannett received a letter from the FDA with approval to market and launch Phentermine HCl 30mg capsules. Phentermine HCl is the generic version of Fastin® and is an appetite suppressant. According to Wolters Kluwer, total sales of generic Phentermine HCl 30mg capsules were \$37.5 million at AWP in 2007.

In March 2008, Lannett received three letters from the FDA with approval to market and launch Bethanechol Chloride 5mg, 10mg & 25mg tablets. Bethanechol Chloride is the generic version of Urecholine® and is indicated for the treatment of acute postoperative and postpartum non obstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention. According to Wolters Kluwer, total sales of generic Bethanechol Chloride 5mg, 10mg & 25mg tablets at AWP was \$56 million in 2007.

In March 2008, Lannett received a letter from the FDA with approval to market and launch Rifampin 150mg & 300mg capsules. Rifampin is the generic version of Rifadin® and is used to reduce the number of meningococcal bacteria in the nose and throat. According to Wolters Kluwer, total sales of generic Rifampin 150mg & 300mg capsules at AWP was \$35 million in 2007.

In April 2008, Lannett received a letter from the FDA with approval to market and launch Dipyridamole 25mg, 50mg & 75mg tablets. Dipyridamole is the generic version of Persantine® and is used to reduce the formation of blood clots in people who have had heart valve surgery. According to Wolters Kluwer, total sales of generic Dipyridamole 25mg, 50mg & 75mg tablets at AWP was \$45 million in 2007.

Edgar Filing: LANNETT CO INC - Form 10-K

Additional products are currently under development. These products are either orally administered, solid-dosage products (i.e. tablet/capsule) or oral solutions, topicals or parenterals 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. The products under development are at various stages in the development cycle - formulation, scale-up, clinical testing and FDA review.

The cost associated with each product currently under development is dependent on numerous factors not limited to the following: the complexity of the active ingredient's chemical characteristics, the price of the raw materials, the FDA-mandated requirement of bioequivalence studies depending on the FDA's Orange Book classification and other developmental factors. The estimated cost to develop a new generic product ranges from \$100,000 to \$1 million.

Table of Contents

In addition, as one of the oldest generic drug manufacturers in the country formed in 1942, Lannett currently owns several ANDAs that are dormant on the Company's records for products which it does not manufacture and market. Occasionally, the Company reviews such ANDAs to determine if the market potential for any of these older drugs has recently changed to make it attractive for Lannett to reconsider manufacturing and selling them. If the Company decides to introduce one of these products into the consumer market, 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. 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, the raw material supplier or another major feature of the previously approved ANDA. The Company would then redevelop the product and submit it to the FDA for supplemental approval. The FDA's approval process for an ANDA supplement is similar to that of a new ANDA.

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 intended to treat a diverse range of medical indications. It is the Company's intention to ultimately transfer the formulation technology and manufacturing process for all of these R&D products to the Company's own commercial manufacturing sites. The Company initiated these outsourced R&D efforts to complement the progress of its own internal R&D efforts.

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 or manufacturing supply are material in nature, nor is the Company substantially dependent on the services rendered by such outside firms. 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 such additional products.

The following table summarizes key information related to the Company's R&D products. The column headings are defined as follows:

- 1.) **Stage of R&D** Defines the current stage of the R&D product in the development process, as of the date of this filing.
- 2.) **Regulatory Requirement** Defines whether the R&D product is or is expected to be a new ANDA submission, an ANDA supplement, or a grand-fathered product not requiring specific FDA approval.
- 3.) **Number of Products** Defines the number of products in R&D at the stage noted. In this context, a product means any finished dosage form, including all potencies, containing the same API or combination of APIs and which represents a generic version of the same Reference Listed Drug (RLD) or innovator drug, identified in the FDA's Orange Book.

Stage of R&D	Regulatory Requirement	Number of Products
FDA Review	ANDA	10

Edgar Filing: LANNETT CO INC - Form 10-K

FDA Review	ANDA supplement	3
Clinical Testing	ANDA	1
Scale-Up	Grand-fathered	0
Scale-Up	ANDA supplement	0
Scale-Up	ANDA	12
Formulation/Method Development	ANDA	29

Table of Contents

Raw Materials and Finished Goods Inventory Suppliers

The raw materials used by the Company in the production process consist of pharmaceutical chemicals in various forms and are generally available from several sources. FDA approval is required in connection with the process of using most active ingredient suppliers. In addition to the raw materials purchased for the production process, the Company purchases certain finished dosage inventories, including capsule, tablet, and oral liquid products. The Company then sells these finished dosage products directly to its customers along with the finished dosage products internally manufactured. If suppliers of a certain material or finished product are limited, the Company will generally take certain precautionary steps to avoid a disruption in supply, such as finding a secondary supplier or ordering larger quantities.

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 71% of the Company's inventory purchases in Fiscal 2008, 63% in Fiscal 2007 and 76% in Fiscal 2006. 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. Refer to the Materials Contract footnote to our consolidated financial statements for more information on the terms, conditions, and financial impact of this agreement.

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 purchase quantity 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 four 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.

In August 2005, the Company signed an agreement with a finished goods provider to purchase, at fixed prices, and distribute a certain generic pharmaceutical product in the United States. Purchases of finished goods inventory from this provider accounted for approximately 14% of the Company's costs of purchased inventory in Fiscal 2008, 23% in 2007, and 11% in 2006. The term of the agreement was three years, beginning on August 22, 2005 and continuing through August 21, 2008. Following its expiration on August 21, 2008, the agreement was not renewed.

The Company signed supply and development agreements with Olive Healthcare, Wintac and Unichem of India; Orion Pharma of Finland; Azad Pharma AG of Switzerland, Pharmaseed in Israel and Banner Pharmacaps and Catalent in the United States. The Company is also in negotiations with companies in Israel for similar new product initiatives in which Lannett will market and distribute products manufactured by third parties.

Customers and Marketing

The Company sells its products primarily to wholesale distributors, generic drug distributors, mail-order pharmacies, group purchasing organizations, chain drug stores, and other pharmaceutical companies. The

Table of Contents

industry's largest wholesale distributors, McKesson, Cardinal Health, and Amerisource Bergen, accounted for 6%, 10%, and 6%, respectively, of net sales in Fiscal 2008. The Company's largest chain drug store customer, Walgreens, accounted for 36% of net sales in Fiscal 2008. The Company performs ongoing credit evaluations of its customers' financial condition, and has experienced no significant collection problems to date. Generally, the Company requires no collateral from its customers.

Sales to these wholesale customers include indirect sales, which represent sales to third-party entities, such as 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. This credit is called a chargeback. For more information on chargebacks, refer to the section entitled Chargebacks in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Form 10-K. These indirect sale transactions are recorded on Lannett's books as sales to the wholesale customers.

The Company believes that retail-level consumer demand dictates the total volume of sales for various products. In the event that wholesale and retail customers adjust their purchasing volumes, the Company believes that consumer demand will be fulfilled by other wholesale or retail sources of supply. As such, Lannett attempts to develop and maintain strong relationships with most of the major retail chains, wholesale distributors, and mail-order pharmacies in order to facilitate the supply of the Company's products through whatever channel the consumer prefers. Although the Company has agreements with customers governing the transaction terms of its sales, there are no minimum purchase quantities with these agreements.

The Company promotes its products through direct sales, trade shows, trade publications, and bids. The Company also markets its products through private label arrangements, under which Lannett produces its products with a label containing the name and logo of a customer. This practice is commonly referred to as private label business. It allows the Company to leverage its internal sales efforts by using the marketing services from other well-respected pharmaceutical dosage suppliers. The focus of the Company's sales efforts is the relationships it creates with its customer accounts. Strong customer relationships have created a positive platform for Lannett to increase its sales volumes. Advertising in the generic pharmaceutical industry is generally limited to trade publications, read by retail pharmacists, wholesale purchasing agents and other pharmaceutical decision-makers. Historically and in Fiscal 2008, 2007, and 2006, the Company's advertising expenses were immaterial. When the customer and the Company's sales representatives make contact, the Company will generally offer to supply the customer its products at fixed prices. If accepted, the customer's purchasing department will coordinate the purchase, receipt and distribution of the products throughout its distribution centers and retail outlets. Once a customer accepts the Company's supply of product, the customer typically expects a high standard of service, including shipping product in a timely manner, maintaining convenient and effective customer service functions, and retaining a mutually beneficial dialogue of communication. The Company believes that although the generic pharmaceutical industry is a commodity industry where price is the primary factor for sales success, these additional service standards are also important to the customers that rely on a consistent source of supply.

Competition

The manufacture and distribution of generic pharmaceutical products is a highly competitive industry. Competition is based primarily on price, service and quality. Our competitive advantage is based on our ability to provide superior customer service (fulfilling customer's in critical need of inventory, carrying excess finished goods inventory and providing added value) by insuring the Company's products are available from national suppliers as well as our own warehouse. The modernization of our facilities, hiring of

Table of Contents

experienced staff, and implementation of inventory and quality control programs have improved our competitive cost position over the past five years.

The Company competes with other manufacturers and marketers of generic and brand drugs. Each product manufactured and/or sold by Lannett has a different set of competitors. The list below identifies the companies with which Lannett primarily competes for each of its major products.

Product	Primary Competitors
Butalbital with Aspirin and Caffeine, with and without Codeine Phosphate Capsules	Watson Pharmaceuticals, Breckenridge Pharmaceutical (manufactured by Anabolic Laboratories)
Digoxin Tablets	GlaxoSmithKline, Caraco Pharmaceutical Laboratories, Westward Pharmaceuticals
Doxycycline	Par Pharmaceuticals, Ranbaxy Laboratories
Levothyroxine Sodium Tablets	Abbott Laboratories, Monarch Pharmaceuticals, Mylan Laboratories, Sandoz, Forest Laboratories
Primidone Tablets	Watson Pharmaceuticals, Qualitest Pharmaceuticals, URL, Westward Pharmaceuticals, Amneal Pharmaceuticals, Impax Labs
Sulfamethoxazole w/ Trimethoprim	URL/Mutual Pharmaceuticals, Sandoz, Vista, Teva
Unithroid Tablets	Abbott Laboratories, Monarch Pharmaceuticals, Mylan Laboratories, Sandoz

Government Regulation

Pharmaceutical manufacturers are subject to extensive regulation by the federal government, principally by the FDA and the Drug Enforcement Agency (DEA) and to a lesser extent, by other federal regulatory bodies and state governments. The Federal Food, Drug and Cosmetic Act, the Controlled Substance Act, and other federal statutes and regulations govern or influence the testing, manufacture, safety, labeling, storage, record keeping, approval, pricing, advertising, and promotion of the Company's generic drug products. Noncompliance with applicable regulations can result in fines, recall and seizure of products, total or partial suspension of production, personal and/or corporate prosecution and debarment, and refusal of the government to approve new drug applications. The FDA also has the authority to revoke previously approved drug products.

Generally, FDA approval is required before a prescription drug can be marketed. A new drug is one not generally recognized by qualified experts as safe and effective for its intended use. New drugs are typically developed and submitted to the FDA by companies expecting to brand the product and sell it as a new medical treatment. The FDA review process for new drugs is very extensive and requires a substantial investment to research and test the drug candidate. However, less burdensome approval procedures may be used for generic equivalents. Typically, the investment required to develop a generic drug is less costly than the brand innovator drug.

Table of Contents

There are currently three ways to obtain FDA approval of a drug:

- ***New Drug Applications (NDA)***: Unless one of the two procedures discussed in the following paragraphs is available, a manufacturer must conduct and submit to the FDA complete clinical studies to establish a drug's safety and efficacy.
- ***Abbreviated New Drug Applications (ANDA)***: An ANDA is similar to an NDA except that the FDA generally waives the requirement of complete clinical studies of safety and efficacy. However, it may require bioavailability and bioequivalence studies. Bioavailability indicates the rate of absorption and levels of concentration of a drug in the bloodstream needed to produce a therapeutic effect. Bioequivalence compares one drug product with another and indicates if the rate of absorption and the levels of concentration of a generic drug in the body are within prescribed statistical limits to those of a previously approved drug. Under the Hatch-Waxman Act, an ANDA may be submitted for a drug on the basis that it is the equivalent of an approved drug regardless of when such other drug was approved. In addition to establishing a new ANDA procedure, this Act created statutory protections for approved brand name drugs. Under the Hatch-Waxman Act, an ANDA for a generic drug may not be made effective until all relevant product and use patents for the brand name drug have expired or have been determined to be invalid. Prior to this act, the FDA gave no consideration to the patent status of a previously approved drug. Additionally, the Hatch-Waxman Act extends for up to five years the term of a product or use patent covering a drug to compensate the patent holder for the reduction of the effective market life of a patent due to federal regulatory review. With respect to certain drugs not covered by patents, the act sets specified time periods of two to ten years during which ANDAs for generic drugs cannot become effective or, under certain circumstances, cannot be filed if the branded drug was approved after December 31, 1981. Lannett, like most other generic drug companies, uses the ANDA process for the submission of its developmental generic drug candidates.
- ***Paper New Drug Applications (Paper NDA also known as a 505(b)(2))***: For a drug that is identical to a drug first approved after 1962, a prospective manufacturer need not go through the full NDA procedure. Instead, it may demonstrate safety and efficacy by relying on published literature and reports. The manufacturer must also submit, if the FDA so requires, bioavailability or bioequivalence data illustrating that the generic drug formulation produces the same effects, within an acceptable range, as the previously approved innovator drug. Because published literature to support the safety and efficacy of post-1962 drugs may not be available, this procedure is of limited utility to generic drug manufacturers and the resulting approved product will not be interchangeable with the innovator drug as an ANDA drug would be unless bioequivalency testing were undertaken and approved by FDA. Moreover, the utility of Paper NDAs has been further diminished by the recently broadened availability of the ANDA process, as described above.

Among the requirements for new drug approval is the requirement that the prospective manufacturer's methods conform to the FDA's current Good Manufacturing Practice. The cGMP Regulations must be followed at all times during which the approved drug is manufactured. In complying with the standards set forth in the cGMP Regulations, the Company must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Failure to comply with the cGMP Regulations risks possible FDA action, including but not limited to, the seizure of noncomplying drug products or, through the Department of Justice, enjoining the manufacture of such

products.

The Company is also subject to federal, state, and local laws of general applicability, such as laws regulating working conditions and the storage, transportation, or discharge of items that may be considered hazardous substances, hazardous waste, or environmental contaminants. The Company monitors its compliance with all environmental laws. The Company is in substantial compliance with all regulatory bodies.

As a publicly traded company we are also subject to significant regulations, including the Sarbanes-Oxley Act of 2002. Since its enactment, we have developed and instituted a corporate compliance program based on what we believe are the current best practices and we continue to update the program in response to newly implemented or changing regulatory requirements.

Table of Contents

Lannett operates in a highly regulated environment and is responsible for maintaining compliance with many regulatory requirements. The U.S. Department of Justice, acting on behalf of the U.S. Drug Enforcement Administration (DEA), recently issued a letter to the Company requesting additional information on certain record keeping matters regarding a DEA inspection of Lannett's facilities. The Company intends to fully comply with this and all requests for information that occur from time to time as a normal course of business.

Research and Development

The Company incurred research and development (R&D) expenses of approximately \$5,173,000 in 2008, \$7,459,000 in 2007, and \$8,102,000 in 2006. The R&D spending includes spending on bioequivalence studies, internal development resources, as well as outsourced development. While the Company manages all R&D from our offices in Philadelphia, we have also been taking advantage of favorable development costs in other countries. We have alliances with various companies that either act as contract research organizations or active pharmaceutical ingredient suppliers as well as dosage form manufacturers. In addition, US based Clinical Research Organizations have been engaged for product development to enhance our internal development. Fixed payment arrangements are established with these development partners, and can range from \$150,000 to \$250,000 to develop a drug. Development payments are normally scheduled in advance, based on milestones.

Employees

The Company currently has 187 employees at Lannett and an additional 35 employees at Cody.

Securities Exchange Act Reports

The Company maintains an Internet website at the following address: www.lannett.com. The Company makes available on or through its Internet website certain reports and amendments to those reports that are filed with the Securities and Exchange Commission (SEC) in accordance with the Securities Exchange Act of 1934. These include annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. This information is available on the Company's website free of charge as soon as reasonably practicable after the Company electronically files the information with, or furnishes it to, the SEC. The contents of the Company's website are not incorporated by reference in this Form 10-K and shall not be deemed filed under the Securities Exchange Act of 1934.

ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks and others are discussed elsewhere in this report. These and other risks could materially and adversely affect our business, financial condition, operating results or cash flows.

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;

Table of Contents

- receiving requisite regulatory approvals for such products in a timely manner;
- the availability, on commercially reasonable terms, of raw materials, including active pharmaceutical ingredients 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 issued and been 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.

If KV were to prevail in its countersuit against us, and the Company were subject to paying damages or were prohibited from selling the Prenatal Multivitamin in the future, it could have an adverse impact on the Company.

In early June 2008, the Company filed a declaratory judgment suit 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. The case is currently in its discovery phase with a hearing expected in January 2009. The Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position.

The 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.

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.

Table of Contents

Our future results of operations, financial condition and cash flows depend to a significant extent upon our product sales mix. Our sales of 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:

- 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 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

Table of Contents

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.

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.

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

Table of Contents

Lannett, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Rising insurance costs 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 coverages to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverages, could have a negative impact on our results of operations, financial condition and cash flows.

The loss of our 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 key personnel. 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 of our senior executive officers.

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.

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, principally the FDA and to a lesser extent by the DEA, and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products.

Edgar Filing: LANNETT CO INC - Form 10-K

Under these regulations, we are subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable regulations. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with current Good Manufacturing Practice, or cGMP, and other FDA regulations. Following such inspections, the FDA may issue notices on Form 483 that could cause us 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. FDA guidelines specify that a Warning Letter is issued only for violations of

Table of Contents

regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. Any such sanctions, if imposed, could materially harm our operating results and financial condition. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Similar sanctions as detailed above may be available to the FDA under a consent decree, depending upon the actual terms of such decree. 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. Certain of our vendors are subject to similar regulation and periodic inspections.

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. 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.

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 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.

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 year ended June 30, 2008, our three largest customers accounted for 36%, 10% and 6% 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 which would require them to purchase our products.

Table of Contents

ITEM 2. DESCRIPTION OF PROPERTY

Lannett owns two facilities in Philadelphia, Pennsylvania. The administrative offices, quality control laboratory, and manufacturing and production facilities are located in a 38,000 square foot facility at 9000 State Road in Philadelphia. The second facility consists of 65,000 square feet, and is located within 1 mile of the State Road location, 9001 Torresdale Avenue in Philadelphia. Our research laboratory, package, warehousing and distribution operations, sales and accounting departments are located in the second building.

In June 2006, Lannett signed a lease agreement on a 66,000 square foot facility in Philadelphia. An additional agreement which gives us the option to buy the facility was also signed. This new facility is initially going to be used for warehouse space with the expectation of making this facility our headquarters in addition to manufacturing and warehousing. The other Philadelphia locations will continue to be utilized as manufacturing, packaging, and as a research laboratory. This gives Lannett the space to fit its desire to expand.

Cody, a subsidiary of Lannett, 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, Wyoming, which is 50% owned by Lannett and 50% by an affiliate of Cody Labs.

ITEM 3. LEGAL PROCEEDINGS

In early June 2008, the Company filed a declaratory judgment suit 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. The case is currently in its discovery phase with a hearing expected in January 2009. The Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position.

In or about July 2008, Albion International and Albion, Inc. filed suit against Lannett asserting claims for patent and trademark infringement, as well as unfair competition, arising out of Lannett's use of product that it purchased from Albion and used as an ingredient in its MMC. Lannett filed a motion to dismiss the complaint on the basis that it purchased the product from Albion and, as such, was authorized to use the product in its MMC. The Court has not ruled on the motion. Lannett is no longer purchasing product from Albion. If Albion were to prevail on its claims, it may be entitled to a reasonable royalty on the Lannett product that contained the Albion ingredient. The Company believes that Albion's claims have no merit and Lannett intends to vigorously defend the suit.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Edgar Filing: LANNETT CO INC - Form 10-K

No matters have been submitted to a vote of the Company's security holders during the quarter ended June 30, 2008.

Table of Contents**PART II****ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Market Information**

On April 15, 2002, the Company's common stock began trading on the American Stock Exchange. Prior to this, the Company's common stock traded in the over-the-counter market through the use of the inter-dealer "pink-sheets" published by Pink Sheets LLC. The following table sets forth certain information with respect to the high and low daily closing prices of the Company's common stock during Fiscal 2008 and 2007, as quoted by the American Stock Exchange. Such quotations reflect inter-dealer prices without retail mark-up, markdown, or commission and may not represent actual transactions.

Fiscal Year Ended June 30, 2008

	High	Low
First quarter	\$ 6.20	\$ 3.65
Second quarter	\$ 5.14	\$ 3.05
Third quarter	\$ 3.55	\$ 2.34
Fourth quarter	\$ 4.80	\$ 2.05

Fiscal Year Ended June 30, 2007

	High	Low
First quarter	\$ 6.38	\$ 4.55
Second quarter	\$ 6.94	\$ 5.28
Third quarter	\$ 6.83	\$ 5.09
Fourth quarter	\$ 7.15	\$ 5.08

 Holders

As of September 25, 2008, there were approximately 258 holders of record of the Company's common stock.

Dividends

The Company did not pay cash dividends in Fiscal 2008 or Fiscal 2007. The Company intends to use available funds for working capital, plant and equipment additions, and various product extension ventures. The Company does not expect to pay, nor should shareholders expect to receive, cash dividends in the foreseeable future.

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA**

The following financial information as of and for the five years ended June 30, 2008, has been derived from the Company's Consolidated Financial Statements. This information should be read in conjunction with the Consolidated Financial Statements and related notes thereto included elsewhere herein.

The comparability of information is affected by the write-off of a portion of a note receivable due from Cody Labs, and the subsequent acquisition of Cody Labs (a provider of active pharmaceutical ingredients (API)) in Fiscal 2007. Approximately \$7.8 million of notes were written-off prior to the Cody Labs acquisition, representing the excess of the note receivable over the fair value of assets received of approximately \$4.4 million.

Statement of Financial Accounting Standards (SFAS) 123(R), *Share-Based Payment*, was adopted on July 1, 2005 using the modified prospective transition method. Because the modified prospective transition method was elected, results for prior periods have not been restated to include share-based compensation expense for stock options or the Company's Employee Stock Purchase Plan. See Note 1 to the financial statements in Item 8 for more information.

In Fiscal 2005, the Company determined that an intangible asset related to acquired product rights was impaired. At that time, the Company determined that this intangible was impaired and a \$46.1 million impairment charge was recorded.

Lannett Company, Inc. and Subsidiaries**Financial Highlights**

As of and for the Fiscal Year Ended June 30,	2008	2007	2006	2005	2004
Operating Highlights					
Net Sales	\$ 72,403,283	\$ 82,577,591	\$ 64,060,375	\$ 44,901,645	\$ 63,781,219
Gross Profit	\$ 16,301,071	\$ 21,424,987	\$ 28,375,665	\$ 7,968,320	\$ 35,609,834
Operating (Loss)/Income	\$ (5,430,534)	\$ (5,964,409)	\$ 8,453,918	\$ (53,639,658)	\$ 20,830,969
Net (Loss)/Income	\$ (2,318,059)	\$ (6,929,008)	\$ 4,968,922	\$ (32,779,596)	\$ 13,215,454
Basic (Loss)/Earnings Per Share	\$ (0.10)	\$ (0.29)	\$ 0.21	\$ (1.36)	\$ 0.63
Diluted (Loss)/Earnings Per Share	\$ (0.10)	\$ (0.29)	\$ 0.21	\$ (1.36)	\$ 0.63
Balance Sheet Highlights					
Total Assets	\$ 116,858,608	\$ 104,656,100	\$ 105,992,064	\$ 94,917,060	\$ 131,904,084
Total Debt	\$ 8,978,834	\$ 9,679,965	\$ 8,196,692	\$ 9,532,448	\$ 10,092,857
Long Term Debt	\$ 8,186,922	\$ 8,987,846	\$ 7,649,806	\$ 7,262,672	\$ 8,104,141
Total Stockholders' Equity	\$ 69,271,480	\$ 70,183,175	\$ 75,755,916	\$ 69,249,244	\$ 102,246,991

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In addition to historical information, this Form 10-K contains forward-looking information. The forward-looking information is subject to certain risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. Important factors that might cause such a difference include, but are not limited to, those discussed in the following section, entitled Management's Discussion and Analysis of Financial Condition and Results of Operations. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. The Company undertakes no obligation to publicly revise or update these forward-looking statements to reflect events or circumstances that may occur. Readers should carefully review the risk factors described in other documents the Company files from time to time with the SEC, including the quarterly reports on Form 10-Q to be filed by the Company in Fiscal 2009, and any current reports on Form 8-K filed by the Company.

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. For a detailed discussion on the application of these and other accounting policies, refer to Note 1 in the Notes to the Consolidated Financial Statements included herein.

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 June 30, 2008 and 2007 balance sheets are consolidated VIE assets of \$1.9 and \$1.8 million, respectively, which is comprised mainly of land and a building. VIE liabilities consist of a mortgage on that property in the amount of \$1.7 and \$1.8 million at June 30, 2008 and 2007, 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.

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,

Table of Contents

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. 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.

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 and chargebacks 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

Table of Contents

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 and chargebacks 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 fiscal years ended June 30, 2008, 2007 and 2006. Unless we have specific information to indicate otherwise, actual credits issued in a given year are assumed to be related to sales recorded in prior years based on the Company's returns policy. The following tables have been revised to conform to this assumption.

For the Year Ended June 30, 2008

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2007	\$ 4,649,478	\$ 871,339	\$ 113,313	\$ 52,234	\$ 5,686,364
Actual credits issued related to sales recorded in prior fiscal years	(4,556,488)	(1,741,804)	(4,909,659)		(11,207,951)
Reserves or (reversals) charged during Fiscal 2008 related to sales in prior fiscal years		870,465	5,892,805	(50,000)	6,713,270
Reserves charged to net sales during Fiscal 2008 related to sales recorded in Fiscal 2008	26,126,995	7,999,232	12,546,130	473,423	47,145,780
Actual credits issued related to sales recorded in Fiscal 2008	(22,170,578)	(7,366,918)		(473,550)	(30,011,046)
Reserve Balance as of June 30, 2008	\$ 4,049,407	\$ 632,314	\$ 13,642,589	\$ 2,107	\$ 18,326,417

For the Year Ended June 30, 2007

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2006	\$ 10,137,400	\$ 2,183,100	\$ 416,000	\$ 275,600	\$ 13,012,100
Actual credits issued related to sales recorded in prior fiscal years	(10,170,000)	(1,800,000)	(5,578,000)	(250,000)	(17,798,000)
Reserves or (reversals) charged during Fiscal 2007 related to sales recorded in prior fiscal years		(300,000)	3,572,313		3,272,313
Reserves charged to net sales in fiscal 2007 related to sales recorded in fiscal 2007	28,034,000	9,562,000	1,703,000	1,044,800	40,343,800
Actual credits issued related to sales in fiscal 2007	(23,351,922)	(8,773,761)		(1,018,166)	(33,143,849)
Reserve Balance as of June 30, 2007	\$ 4,649,478	\$ 871,339	\$ 113,313	\$ 52,234	\$ 5,686,364

For the Year Ended June 30, 2006

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2005	\$ 7,999,700	\$ 1,028,800	\$ 1,692,000	\$ 29,500	\$ 10,750,000
Actual credits issued related to sales recorded in prior fiscal years	(7,920,500)	(1,460,500)	(1,273,300)	(59,300)	(10,713,600)
Reserves or (reversals) charged during Fiscal 2006 related to sales recorded in prior fiscal years		500,000	(500,000)		
Reserves charged to net sales in fiscal 2006 related to sales recorded in fiscal 2006	28,237,000	5,688,500	497,300	1,298,200	35,721,000
Actual credits issued related to sales in fiscal 2006	(18,178,800)	(3,573,700)	0	(992,800)	(22,745,300)
Reserve Balance as of June 30, 2006	\$ 10,137,400	\$ 2,183,100	\$ 416,000	\$ 275,600	\$ 13,012,100

Reserve Activity 2008 vs. 2007

The total reserve for chargebacks, rebates, returns and other adjustments increased from \$5,686,364 at June 30, 2007 to \$18,326,415 at June 30, 2008. The increase in the reserve balance was primarily the result of our decision to record during the fourth quarter of Fiscal 2008 a \$10,536,000 provision for the expected return of 100% of the shipments of Prenatal Multivitamin. Our expectation that all of the product would be returned was based on our inability to have the product specified as a brand equivalent, and information from our customers regarding their intentions to return the product. Also during our fiscal year 2008 we increased our estimated returns reserve by approximately \$3.0 million, based on an analysis of our historical returns experience, the average lag time between sales and returns and our understanding of the buying patterns and inventory practices of both our direct and indirect customers. This change in estimate incorporated new information that has

Edgar Filing: LANNETT CO INC - Form 10-K

allowed us to better estimate the average length of time between product sales and returns. As this change resulted from new information that has allowed us to better estimate the average length of time between product sales and returns, we consider it to be a change in estimate as defined in SFAS 154: *Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3*.

During fiscal year 2008, we also experienced an unanticipated increase in our returns compared to historical experience that required us to record a provision of approximately \$3.0 million in fiscal year 2008 for returns related to sales in prior years. We believe, however, that this increase in return was largely related to certain specific nonrecurring events.

The decline in chargeback and rebate reserves between June 30, 2007 and June 30, 2008 was due in part to a change in our sales mix away from wholesalers and toward the chain drug stores as well as a decrease in inventory levels at wholesaler distribution centers. The following tables compare the year-end reserve balances in fiscal 2008 and 2007 and the sales mix in fiscal 2008 and fiscal 2007.

	Fiscal Year Ended June 30,			
	2008	%	2007	%
Chargeback reserve	\$ 4,049,407	22%	\$ 4,649,478	82%
Rebate reserve	632,314	3%	871,339	15%
Return reserve	13,642,589	74%	113,313	2%
Other reserve	2,107	0%	52,234	1%
	\$ 18,326,417	100%	\$ 5,686,364	100%

	Fiscal Year ended June 30,		Fiscal Fourth Quarter	
	2008	2007	2008	2007
Chain drug stores	34%	24%	35%	34%
Mail Order	3%	4%	4%	4%
Wholesalers	62%	72%	61%	62%
Private Label	0%	0%	0%	0%
	100%	100%	100%	100%

Reserve Activity 2007 vs. 2006

The total reserves for chargebacks, rebates, returns and other adjustments decreased from \$13,012,100 at June 30, 2006 to \$5,686,364 at June 30, 2007. The decrease reflected a change in customer sales mix away from wholesalers and toward the chain drug stores which reduces total chargebacks because wholesalers are typically the only customers who are eligible for chargebacks and rebates. The decrease in rebate reserve to \$871,339 from \$2,183,100 at June 30, 2006 was also due to the decrease in sales to wholesalers as well as a decrease in sales in the fourth quarter of Fiscal 2007. There was a large rebate reserve as of June 30, 2006 as direct customers (only direct customers are eligible to receive rebates) represented a larger-than-usual percentage of sales in the month of June.

The following tables compare the year-end reserve balances for fiscal 2007 and 2006, and the customer sales mix in Fiscal 2007 and Fiscal 2006.

Edgar Filing: LANNETT CO INC - Form 10-K

	Fiscal Year Ended 6/30,			
	2007		2006	
		%		%
Chargeback reserve	\$ 4,649,478	82%	\$ 10,137,400	78%
Rebate reserve	871,339	15%	2,183,100	17%
Return reserve	113,313	2%	416,000	3%
Other reserve				