

LANNETT CO INC  
Form 10-K/A  
October 01, 2008  
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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-K/A

(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**

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Philadelphia, Pennsylvania 19136

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):

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Large accelerated filer

Accelerated filer

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

Smaller reporting company

Indicate by check mark whether the registrant 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.

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**Explanatory Note:**

This Amendment No. 1 on Form 10-K/A ( this Form 10-K/A ) amends our annual report for the fiscal year ended June 30, 2008, originally filed with the Securities and Exchange Commission ( SEC ) on September 29, 2008 (the Form 10-K ). We are filing this Form 10-K/A to delete an earlier draft of the opinion letter regarding Schedule II Valuation and Qualifying Accounts that was inadvertently included along with the final version of the opinion letter in the September 29, 2008 filing.

No other information contained in the original filing is amended by this Form 10-K/A. The Form 10-K has been corrected and furnished in its entirety in this Form 10-K/A.

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**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 other 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.

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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.

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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

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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**



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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.

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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.

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**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.

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

	<b>Name of Product</b>	<b>Medical Indication</b>	<b>Equivalent Brand</b>
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

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**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





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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.

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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.

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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

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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

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**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



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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





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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.

<b>Product</b>	<b>Primary Competitors</b>
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.



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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.

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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](http://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;

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- 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.**

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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

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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



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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.

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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

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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.





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**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**

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**

	<b>High</b>	<b>Low</b>
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**

	<b>High</b>	<b>Low</b>
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
<b>Operating Highlights</b>					
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
<b>Balance Sheet Highlights</b>					
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

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**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,



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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



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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**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
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**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
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**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
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

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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.

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	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	52,234	1%	275,600	2%
	\$ 5,686,364	100%	\$ 13,012,100	100%

	Fiscal Year ended June 30,		Fiscal Fourth Quarter	
	2007	2006	2007	2006
Chain drug stores	24%	13%	34%	10%
Mail Order	4%	7%	4%	6%
Wholesalers	72%	78%	62%	82%
Private Label	0%	2%	0%	2%
	100%	100%	100%	100%

Other reserves have decreased since June 30, 2006, due to an unusually high level of shelf stock adjustments required in the prior year. Changes in competition in the Primidone 50 market required Lannett to give more of this type of credit in the prior year.

During the year, the Company began to implement improvements to separately calculate the provisions, credits and reserves for chargebacks, rebates and returns including the performance of several types of analysis to ensure reserves are reasonable. These included analysis of wholesaler versus direct (or retail) sales mix; revenue reserve relative to gross sales; comparison of net receivables to net sales; comparison of gross receivables to gross sales; and recalculation of wholesaler inventory levels. Because we were unable to independently verify product sales levels at the final customer, wholesaler inventory reports were used to calculate potential chargebacks and rebates based on known contracted rebate and chargeback rates.

The decrease in the chargeback reserve to \$4,649,478 at June 30, 2007 from \$10,137,400 at June 30, 2006 is due to the decrease in sales to wholesalers. The decrease in rebate reserve to \$871,339 from \$2,183,100 at June 30, 2006 is also due to the decrease in sales to wholesalers plus the decrease in overall sales in the fourth quarter of Fiscal 2007. There was a large rebate reserve as of June 30, 2006 as direct customers (those who receive the only rebates) were a larger than usual portion of sales in the month of June 58%, typically 50%.

During the Fiscal year ended June 30, 2007, the Company began to implement improvements to separately calculate the chargebacks and reserves. Management is continuing to make improvements to the calculation and reconciliation of these amounts. Management performs several types of analysis to ensure reserves are reasonable. This includes ratio analysis of: 1) wholesaler versus direct (or retail) sales mix, 2) revenue reserve to gross sales, 3) comparison of net receivables to net sales, 4) comparison of gross receivables to gross sales and 5) recalculation of wholesaler inventory levels.

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The return and other reserves have decreased since June 30, 2006, due to an unusually high level of shelf stock adjustments required in the prior year. Changes in the competition in the Primidone 50 market required Lannett to give more of this type of credit in the prior year.

Fluctuations in the amount of sales through the wholesaler channel will have an impact on the amount of reserve being charged. Due to the fact that wholesale sales result in greater chargebacks, a change in wholesale sales will directly correlate to change in the chargebacks required. For the first, second, third and fourth quarters of Fiscal 2007, reserves recorded against sales amounted to \$12.0 million, \$10.5 million, \$12.7 million and \$4.7 million, respectively. Wholesaler sales were \$16.2 million, \$12.4 million, \$12.8 million and \$8.7 million, respectively. The decrease in the dollar value of the reserves corresponds to the increase in wholesale sales, most significantly in the fourth quarter. For the first, second, third and fourth quarters of Fiscal 2006, reserves recorded against sales amounted to \$7.1 million, \$7.4 million, \$12.0 million and \$9.7 million, respectively. Wholesaler sales were \$9.3 million, \$9.9 million, \$16.7 million and \$15.8 million, respectively. This third quarter increase in sales and reserves during Fiscal 2006 is a result of increased demand for Levothyroxine Sodium, for which the reserve rebate and chargeback reserve remains consistent, but is higher than most other products. This drug's reserves are higher than other drugs because of the number of competitors in the market. This may change if the number of competitors decline because low prices will force some competitors out of the market, which in turn may lead to higher prices. Fourth quarter sales to wholesalers dropped off slightly from the third quarter. The reserves in the fourth quarter also declined because of the product mix, but were consistent with reserves in the first and second quarters.

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

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

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

The following table shows the results of these calculations for the fiscal years ended June 30, 2008, 2007 and 2006:

Fiscal Year Ended June 30,	2008	2007	2006
Net DSO (in days)	65	72	56
Gross DSO (in days)	70	74	77





The level of both net and gross DSO at June 30, 2008 is consistent with the Company's expectation that DSO will be in the 60 to 70 day range, based on 60 day payment terms for most customers

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

***New Accounting Pronouncements -***

In July 2006, the FASB issued FIN 48, which addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FIN 48, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based solely on position should be measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. FIN 48 also provides guidance on derecognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. FIN 48 is effective for fiscal years beginning after December 15, 2006. We adopted the provisions of FIN 48 on July 1, 2007. See Note 16.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current practice. In February, 2008, the FASB issued FASB Staff Position 157-1, *Application of FASB Statement No. 157 to FASB Statement 13 and Other Accounting Pronouncements That Address Fair value Measurements for Purposes of Lease Classification and Measurement under Statement 13* (FSP FAS 157-1) and FASB Staff Position 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2). FSP FAS 157-1 amends SFAS 157 to remove certain leasing transactions from its scope. FSP FAS 157-2 defers the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis. We adopted the guidance of SFAS 157 as it applies to our financial instruments on July 1, 2008 and do not expect the adoption will have a significant impact on our consolidated financial statements

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS No. 159), which allows companies to choose, at specific election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. If a company elects the fair value option for an eligible item, changes in that item's fair value in subsequent reporting periods must be recognized in current earnings. SFAS 159 is effective for our fiscal year beginning July 1, 2008. We do not expect the adoption of SFAS 159 will have a significant impact on our consolidated financial statements as we have not elected to apply the fair value option to any of our financial assets and liabilities.



In June 2007, the EITF reached a final consensus on EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ( EITF 07-3 ). EITF 07-3 is effective for our fiscal year beginning July 1, 2008. EITF 07-3 requires non-refundable advance payments for future research and development activities to be capitalized until the goods have been delivered or related services have been performed. As the guidance in EITF 07-03 is consistent with our existing policy we do not believe EITF 07-03 will have any impact on our financial statements or related disclosures.

In November 2007, the EITF reached a final consensus on EITF Issue No. 07-1, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property ( EITF 07-1 ). EITF 07-1 will be effective for our fiscal year beginning July 1, 2009 and interim periods within that fiscal year. Adoption is on a retrospective basis to all prior periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the impact of adopting EITF 07-1 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations ( SFAS 141(R) ). SFAS 141(R) will significantly change the accounting for business combinations in a number of areas including the treatment of contingent consideration, contingencies, acquisition costs, in-process research and development and restructuring costs. In addition, under SFAS 141(R), changes in deferred tax asset valuation allowances and acquired income tax uncertainties in a business combination after the measurement period will impact income tax expense. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the fiscal year beginning July 1, 2009. Early application is not permitted. The effect of SFAS 141(R) on our consolidated financial statements will depend on the nature and terms of any business combinations that occur after its effective date.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements ( SFAS 160 ). SFAS 160 amends Accounting Research Bulletin No. 51 to establish accounting and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements and establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation. SFAS 160 is effective for our fiscal year beginning July 1, 2009. We are currently evaluating the impact the adoption of SFAS 160 will have on our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities ( SFAS 161 ). The new standard is intended to help investors better understand how derivative instruments and hedging activities affect an entity's financial position, financial performance and cash flows through enhanced disclosure requirements. The new standard is effective for our fiscal year beginning July 1, 2009 and for all interim periods within that fiscal year. Early adoption is encouraged. We do not expect the adoption of SFAS 161 to have a significant impact on our consolidated financial statements as we do not currently have any derivatives within the scope of SFAS 161.

In April 2008, the FASB issued FASB Staff Position No. FAS 142-3, Determination of the Useful Life of Intangible Assets ( FSP FAS 142-3 ). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, Goodwill and Other Intangible Assets . The FSP is intended to improve the consistency between the useful life of a recognized intangible asset under Statement 142 and the period of expected cash flows used to measure the fair value of the asset under

SFAS 141(R) and other U.S. generally accepted accounting principles. The new standard is effective for our financial statements issued for fiscal years and interim periods beginning July 1, 2009. We are currently evaluating the impact of FSP FAS 142-3.

**Results of Operations Fiscal 2008 compared to Fiscal 2007**

Net sales decreased 12% from \$82,577,591 in Fiscal 2007 to \$72,403,283 in Fiscal 2008. The decrease reflected increased competition in the generic drug market which adversely affected Lannett's sales of certain antibacterial drugs as well as sales of drugs used in the treatment of epilepsy. Prices of antibiotic drugs declined 34% from prior year levels due to increased competition, which partly offset higher sales volumes. Prices of Lannett's heart failure drugs increased slightly from prior year levels and sales volumes increased 49% from the prior year level, largely due to the impact of a product recall of one of Lannett's competitors during the quarter ended June 30, 2008. Thyroid medication, our largest product in terms of sales, showed continued growth in both volume and in price. The following table presents the percentage changes in prices and volumes for the Company's products, by medical indication.

Medical indication	Sales volume change %	Sales price change %
Migraine Headache	18%	(17)%
Antibiotics	136%	(34)%
Epilepsy	(20)%	(36)%
Heart Failure	49%	8%
Thyroid	5%	4%

We plan to continue to increase the number of products available for sale to our customers, although FDA approvals are needed to achieve this growth.

The Company sells its products to customers in various categories. The table below presents the Company's net sales to each category.

Customer Category	Fiscal 2008 Net Sales	Fiscal 2007 Net Sales
Wholesaler/Distributor	\$30.5 million	\$49.4 million
Retail Chain	\$37.1 million	\$27.9 million
Mail-Order Pharmacy	\$4.5 million	\$5.1 million
Private Label	\$0.3 million	\$0.2 million
Total	\$72.4 million	\$82.6 million

Wholesaler/Distributor sales decreased as a result of one of Lannett's major wholesalers withdrawing from the one-stop program which used Lannett as a first call supplier. Retail chain sales increased significantly as a result of an increase in the number of products available for sale and a significant increase in the number of retail stores of one of our customers. Mail order pharmacy sales decreased from the prior year due mainly to the market shift toward retail chains at the expense of mail order pharmacy sales. Private label sales increased slightly from the prior year, although this channel is not expected to contribute significantly to Lannett's sales in the future as we have decided not to actively pursue additional private label customers because of the lower margins for this business.



In 2006, prior to its acquisition by Lannett, Cody received an FDA warning letter, and stopped operations to remediate their facility. This remediation occurred from the months of August 2006 through February 2007. Upon completion of the remediation, Cody requested an FDA inspection. Subsequent FDA inspection resulted in relatively minor Form 483 observations, which have since been remediated. In March 2008 Cody Labs recommenced manufacturing operations after management concluded that certain regulatory deficiencies identified by the FDA prior to Lannett's acquisition were substantially remediated.

Cost of sales (excluding amortization of intangible assets) decreased 6%, from \$57,394,751 in Fiscal 2007 to \$54,080,947 in Fiscal 2008. The decrease reflected the 12% decrease in net sales, partly offset by the impact of normal inflationary pressures on labor and material costs and expenses related to the Company's prenatal vitamin with mineral product.

The amortization expense relates to the March 23, 2004 exclusive marketing and distribution rights agreement with Jerome Stevens Pharmaceutical. For the remaining six years of the contract, the Company will incur annual amortization expense of approximately \$1,785,000.

Gross profit as a percent of net sales declined to 23% in Fiscal 2008 from 26% in Fiscal 2007, due in part to expenses related to the prenatal multivitamin with mineral product, and price erosion for antibiotics, heart failure products and epilepsy medications. While the Company is continuously striving to keep product costs low, there can be no guarantee that profit margins will decline in future periods due to pricing pressure from competitors and costs of producing or purchasing new drugs. Changes in the product mix may also occur which also affect gross profit as a percent of sales in future periods. The Company has changed the presentation of amortization of intangibles and product royalty expenses, in an effort to comply with the SEC's Staff Accounting Bulletin Topic 11-B (SAB 11-B). Accordingly, amortization of intangible assets and product royalty expense is now presented before gross profit in order to align the financial reporting with this SEC guidance, and prior periods have been reclassified in order to be consistent with the current presentation.

Research and development ( R&D ) expenses decreased 31% to \$5,172,715 in Fiscal 2008 from \$7,459,432 in Fiscal 2007. The decrease was primarily due to a decrease in the production of drugs in development and preparation for submission to the FDA. The Company expenses all production costs as R&D until the drug is approved by the FDA. R&D expenses may fluctuate from period to period, based on planned submissions to the FDA.

Selling, general and administrative expenses increased 36% to \$16,552,859 in Fiscal 2008 from \$12,161,187 in Fiscal 2007, primarily due to the inclusion of a full year of general and administrative expenses of Cody, which was acquired in the fourth quarter of Fiscal 2007. The remaining increase in expense reflects increased legal expenses and higher professional fees. While the Company is focused on controlling costs, increases in personnel costs may have an ongoing impact on the administrative cost structure. Other costs are being incurred to facilitate improvements in the Company's infrastructure.

On March 31, 2007, the Company recorded an impairment charge of \$7,775,890 on a note receivable owed by Cody. On April 10, 2007, it was decided to complete the acquisition of Cody by forgiving the remaining balance of the receivable. See discussion below in *Results of Operations - Fiscal 2007 compared to Fiscal 2006*.

Interest expense increased to \$383,267 in Fiscal 2008 from \$273,633 in Fiscal 2007, reflecting full year impact of the interest expense on a mortgage held by Cody Realty LLC. Effective with the acquisition of Cody Labs on April 10, 2007, the Company consolidated the operations of Lannett Realty LLC, a variable interest entity that had been fully consolidated by Cody Labs (see Note 13).

The Company recorded an income tax benefit of \$3,376,011 in Fiscal 2008 on a pretax loss after minority interest of \$5,694,070 as compared to tax expense of \$1,007,929 in Fiscal 2007 on a pretax loss of \$5,921,079. The inclusion of state income taxes, federal income tax credits, and a reduction in the valuation allowance for deferred tax assets were the principal reasons for the effective tax rate of 59.3% in fiscal 2008.



At June 30, 2008, the Company has recognized a net deferred tax asset of \$21,198,706. The net deferred tax asset is net of a valuation allowance of \$2,314,498 for the specific total tax asset of \$2,106,798 related to the Cody notes receivable impairment incurred in conjunction with the acquisition of Cody Labs and the \$207,700 tax benefit associated with the state income tax net operating loss carryforwards. The Company has provided for the valuation allowance related to the notes receivable impairment as this benefit will be realized only upon the disposition of Cody Labs. As the Company has no current plans to dispose of its holdings in Cody, a full valuation allowance has been established. The valuation allowance related to the tax benefit of the state operating loss carryforwards has been established as the Company does not expect these carryforwards to be utilized due to the Company's tax planning strategies at the state and local levels. The Company expects the remaining net deferred tax assets to be fully realizable based on the Company's history and future expectations of generating sufficient taxable income.

The Company reported a net loss of \$2,318,059 for Fiscal 2008, or \$0.10 basic and diluted loss per share, compared to net loss of \$6,929,008 for Fiscal 2007, or \$0.29 basic and diluted loss per share.

### Results of Operations Fiscal 2007 compared to Fiscal 2006

Net sales increased by 29% from \$64,060,375 in Fiscal 2006 to \$82,577,591 in Fiscal 2007. The increase was due in part from continued improvement in sales of Levothyroxine Sodium (Levo), which increased \$18.1 million, or 121% over the prior year sales, and Sulfamethoxazole with Trimethoprim (SMZ) which increased \$14.9 million, a 570% increase. These increases were offset partially by decreases in other existing products, most significantly Primidone tablets, of which sales declined \$5,152,000. The Company is working to offset continued declines in existing products through new product offerings. The increase in Levo sales was due entirely to an increase in the quantity of bottles sold. The increase in SMZ was due to quantity increases of nearly 390% and price increases of 180%.

Overall, product sales quantities increased 100% (including new products), leading to increased sales. Pricing pressure, due to increased competition and new customer demands for lower prices offset the volume increase, resulting in the 29% sales increase over Fiscal 2006. SMZ pricing benefited from the departure of a competitor from the market. Such pricing changes due to competition are not predictable. For that reason, the Company must maintain its focus on developing new products every year to expand the number of products available to supply to customers. Net sales of new products are often impacted by greater incentives to wholesalers. Excluding sales of SMZ in Fiscal 2007, the Company experienced a decline in new product net sales in the year. This is due to the Company receiving fewer approvals from the FDA during the year. At June 30, 2007, the Company had 18 products, as ANDA and ANDA supplements, awaiting approval from the FDA as compared to 10 at June 30, 2006.

The Company sells its products to customers in various categories. The table below identifies the Company's net sales to each category.

Customer Category	Fiscal 2007 Net Sales	Fiscal 2006 Net Sales
Wholesaler/Distributor	\$49.4 million	\$44.0 million
Retail Chain	\$27.9 million	\$10.6 million
Mail-Order Pharmacy	\$5.1 million	\$7.0 million
Private Label	\$0.2 million	\$2.5 million
Total	\$82.6 million	\$64.1 million

Wholesaler/distributor sales increased due to a rebound in Levothyroxine Sodium sales and sales of new products. Levo and SMZ sales increased as wholesalers began to reorder the product in larger volumes in Fiscal 2006. Retail Chain sales increased significantly due to a new significant customer agreement signed during Fiscal 2007. Mail order pharmacy sales decreased slightly from the prior year. Private label sales decreased due to our largest private label customer, Qualitest, receiving FDA approval in late November 2005 to manufacture its own Primidone 50mg. As disclosed previously, private label sales have continued to decline, as Lannett does not actively pursue additional private label customers because of the lower margins and product label inventories required to service the category.

Cost of sales (excluding amortization of intangible assets) increased 69%, from \$33,900,045 in Fiscal 2006 to \$57,394,751 in Fiscal 2007. This increase is due in part to higher production volumes to meet increased sales demand, and increased purchases of finished products for sale. Gross margins were 30% in 2007, a decline from 47% in 2006. In spite of the significant increase in net sales, the Company has increasing sales of drugs made by other companies, and distributed by Lannett. The margins on these drugs are typically lower than margins on produced drugs. The Company also launched a greater amount of new drugs in the prior year, and was able to take advantage of its new products and the higher margin on these products in 2006. Depending on future market conditions for each of the Company's products, changes in the future sales product mix may occur. New drug approvals may increase in future years. Currently, there are 18 products at the FDA review stage. These changes may affect the gross profit percentage in future periods.

Research and development ( R&D ) expenses decreased by \$643,033 or 8%. The decrease in R&D was primarily due to a decrease in raw material consumption for production of experimental batches.

Selling, general and administrative expenses increased \$2,334,382, or 20% from the prior year. A significant portion of the increase is due to expenses incurred in Fiscal 2007 that relate to marketing agreements tied to sales of new generic products.

The amortization expense relates to the March 23, 2004 exclusive marketing and distribution rights agreement with JSP. For the remaining seven years of the contract, the Company will incur annual amortization expense of approximately \$1,785,000.

On March 31, 2007, the Company wrote down \$7,775,890 of a note receivable owed by Cody Laboratories, Inc. The Company determined that the value of the note receivable was impaired, and on April 10, 2007, it was decided to complete the acquisition of Cody by forgiving a portion of the loan. At that point, Cody owed Lannett approximately \$11.7 million, in the form of notes receivable and prepayments on products and services. The remaining value of the amounts owed, or \$4.4 million was approximately the net asset value of Cody at the time of the acquisition.

The Note was determined to be uncollectible due to FDA reviews and operational delays by Cody to return to operation. In 2006, Cody received an FDA warning letter, and stopped operations to remediate their facility. This remediation occurred from the months of August 2006 through February 2007. Upon completion of the remediation, Cody requested a future FDA inspection. The timing of that inspection was, at that time, unknown, and Cody management was unable to conclude as to the outcome of that inspection. With such a limited outlook, Cody management suggested that the full note was not likely to be satisfied, and Lannett management was not willing to loan further funds to Cody to keep it in operation. Both companies agreed to complete the acquisition for the value of the Cody's net assets. The uncollected portion of debt was extinguished prior to the acquisition.

Upon acquisition, the fair value of Cody's assets was added to the Company's Consolidated Balance Sheets, and the results of operations were included in the Consolidated Statements of Operations from the acquisition date forward. Due to the fact that most of the value of Cody consisted of physical assets that were recently acquired as part of the remediation, the fair value closely approximated the book value of net

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assets. In accordance with the Financial Accounting Standards Board Statement No. 141, Business Combinations, measurement is based on the fair value of the consideration given or the fair value of the asset (or net assets) acquired, whichever is more clearly evident and, thus, more reliably measurable.

The Company's net loss for Fiscal 2007 includes an income tax expense of \$1,007,929, as compared to an expense of \$3,561,175 in Fiscal 2006. The Company has set up a valuation allowance on the tax benefit from the write-off of a portion of the Cody loan described above in Fiscal 2007. This has led to an income tax expense despite of the net loss from operations.

The Company reported net loss of \$6,929,008 for Fiscal 2007, or \$.29 basic and diluted loss per share, compared to net income of \$4,968,922 for Fiscal 2006, or \$.21 basic and diluted earnings per share.

### **Liquidity and Capital Resources**

The Company has historically financed its operations with cash flow generated from operations, supplemented with borrowings from various government agencies and financial institutions. At June 30, 2008, working capital was \$25,590,468, as compared to \$22,034,947 at June 30, 2007, an increase of \$3,555,521.

Net cash provided by operating activities of \$3,118,222 for the Fiscal year ended June 30, 2008 reflected cash provided from changes in operating assets and liabilities of \$3,855,513, partly offset by a net loss of \$1,580,768 after adjusting for non-cash items of \$737,291. Significant changes in operating assets and liabilities are comprised of:

1. An increase in trade accounts receivable (excluding the receivables related to the sales of prenatal multivitamins with minerals) of \$2,000,951 was due to a higher level of sales at the end of Fiscal 2008, compared to the end of Fiscal 2007.
2. A decrease in inventory of \$2,901,226 due to higher-than-usual inventories at June 30, 2007 reflecting purchases from Jerome Stevens Pharmaceutical in the quarter ended June 30, 2007 in response to strong demand for Levothyroxine Sodium, Butalbital and Digoxin products.
3. A decrease in prepaid taxes of \$1,594,748 due to the application of an overpayment of taxes in Fiscal 2007 to taxes owed in Fiscal 2008.
4. An increase in accounts payable of \$4,779,328 is due to the timing of payments at the end of the month combined with increased spending on products for resale, primarily Levothyroxine Sodium tablets.
5. A decrease in accrued expenses of \$2,693,834 was due to a high level of accrual for materials received at the end of Fiscal 2007 primarily related to distributed products.

Net cash used in investing activities of \$1,391,766 for the twelve months ended June 30, 2008 reflected the purchase of property, plant and equipment of \$2,295,817, partially offset by \$882,671 of net proceeds related to the sale of the Company's marketable securities.

Net cash used in financing activities for the year ending June 30, 2008 was \$662,085 primarily due to scheduled debt repayments of \$701,131, partially offset by \$113,422 of proceeds from the issuance of stock in connection with the Company's Employee Stock Purchase Plan. In addition, the Company withheld the issuance of shares of stock with a fair value of \$74,376 in connection with the payment of withholding taxes owed by certain employees for vested restricted stock.

During Fiscal 2008, the Company issued restricted stock with a fair value of \$300,090 to settle a liability for employee bonuses that had been earned during Fiscal 2007. This represented a non-cash transaction and is therefore not included on the Consolidated Statement of Cash Flows for Fiscal 2008.

The Company has entered into agreements with various government agencies and financial institutions to provide additional cash to help finance the Company's operations. These borrowing arrangements as of June 30, 2008 are as follows.

The Company had a \$3,000,000 million line of credit from Wachovia Bank, N.A. that bears interest at the prime interest rate less 0.25% (4.75% at June 30, 2008). The Company had \$2,912,247 available under this line of credit at June 30, 2008. The line of credit was renewed and extended to November 30, 2009. The Company also entered into a letter of credit in the amount of \$917,000 of which \$87,753 is outstanding as of June 30, 2008.

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The Company borrowed \$4,500,000 from the Philadelphia Industrial Development Corporation (PIDC). The Company will pay a bi-annual interest payment at a rate equal to two and one-half percent per annum. The outstanding principal balance shall be due and payable 60 months from January 1, 2006.

The Company borrowed \$1,250,000 through the Pennsylvania Industrial Development Authority (PIDA). The Company is required to make equal payments each month for 180 months starting February 1, 2006 with interest of two and three-quarter percent per annum. The PIDA Loan has \$1,075,732 outstanding as of June 30, 2008 with \$73,132 currently due.

The Company had borrowed \$500,000 from the Pennsylvania Department of Community and Economic Development Machinery and Equipment Loan Fund. The Company is required to make equal payments for 60 months starting May 1, 2006 with interest of two and three quarter percent per annum. As of June 30, 2008, \$283,475 is outstanding and \$100,614 is currently due.

In April 1999, the Company entered into a loan agreement with the Philadelphia Authority for Industrial Development (the Authority or PAID), to finance future construction and growth projects of the Company. The Authority issued \$3,700,000 in tax-exempt variable rate demand and fixed rate revenue bonds to provide the funds to finance such growth projects pursuant to a trust indenture (the Trust Indenture). A portion of the Company's proceeds from the bonds was used to pay for bond issuance costs of approximately \$170,000. The Trust Indenture requires that the Company repay the Authority loan through installment payments beginning in May 2003 and continuing through May 2014, the year the bonds mature. The bonds bear interest at the floating variable rate determined by the organization responsible for selling the bonds (the remarketing agent). The interest rate fluctuates on a weekly basis. The effective interest rate at June 30, 2008 was 1.67%. At June 30, 2008, the Company has \$795,000 outstanding on the Authority loan, of which \$115,000 is classified as currently due. The remainder is classified as a long-term liability. In April 1999, an irrevocable letter of credit of \$3,770,000 was issued by Wachovia Bank, National Association (Wachovia) to secure payment of the Authority Loan and a portion of the related accrued interest. At June 30, 2008, no portion of the letter of credit has been utilized.

The Company entered into agreements (the 2003 Loan Financing) with Wachovia to finance the purchase of the Torresdale Avenue facility, the renovation and setup of the building, and other anticipated capital expenditures. The Company, as part of the 2003 Loan Financing agreement, is required to make equal payments of principal and interest. The only portion of the loan that remains outstanding at June 30, 2008 was the Equipment Loan which consists of a term loan with a term of five years and had an outstanding balance of \$400,653. The terms of the Equipment loan require that the Company meet certain financial covenants and reporting standards, including the attainment of specific financial liquidity and net worth ratios. As of June 30, 2008, the Company was not in compliance with one of these covenants, but received a waiver from its lending institution with respect to that covenant as of June 30, 2008. The Company shall maintain and comply with a debt service coverage ratio of not less than 2 to 1 (to be measured quarterly). Debt service coverage is defined as the ratio of earnings before interest, taxes, depreciation and amortization (EBITDA) to the sum of interest expenses plus scheduled current maturities of long-term debt and current capitalized lease obligations. The terms of the waiver require the Company shall at all times maintain deposit balances in excess of \$3,500,000 with the Bank. Additionally, the Company shall now pay to the Bank an availability fee equal to 0.50% per annum calculated daily, on the available but unused balance of the line of credit instead of the previous 0.25% per annum rate. The financing facilities under the 2003 Loan Financing bear interest at a variable rate equal to the LIBOR rate plus 150 basis points. We believe that it is possible that we may not be able to comply with all of the covenants at each measurement date during the twelve month period ending June 30, 2009; therefore we reclassified the \$80,132 long-term portion of the debt to current portion of long-term debt. As of June 30, 2008, the interest rate for the 2003 Loan Financing (of which only the Equipment loan remains) was 3.89%.

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

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As part of the acquisition of Cody Laboratories, the Company assumed the debt owed to the Small Business Administration ( SBA ). The loan requires fixed monthly payments through July 31, 2012.

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The effective interest rate at June 30, 2008 was 8.75%. As of June 30, 2008, \$183,750 is outstanding under the SBA loan, of which \$54,025 is classified as currently due. Cody has pledged inventory, accounts receivable and equipment as collateral for this loan.

Also as a result of the acquisition of Cody, the Company must now consolidate Cody LCI Realty, LLC, a variable interest entity ( VIE ), for which Cody Labs is the primary beneficiary. See Note 13 for Consolidation of Variable Interest Entities. A mortgage loan with First National Bank of Cody related to the purchase of land and building by the VIE has also been consolidated in the Company's consolidated balance sheets. The mortgage has approximately 18 years of principal and interest payments remaining, with monthly payments of \$14,782, at a fixed rate of 7.5%, to be made through June 2026. As of June 30, 2008, the Company has \$1,740,224 outstanding under the mortgage loan, of which \$48,488 is classified as currently due.

In July 2004, the Company received \$500,000 of grant funding from the Commonwealth of Pennsylvania, acting through the Department of Community and Economic Development. The grant funding program requires the Company to use the funds for machinery and equipment located at their Pennsylvania locations, hire an additional 100 full-time employees by June 30, 2006, operate its Pennsylvania locations a minimum of five years and meet certain matching investment requirements. If the Company fails to comply with any of the requirements above, the Company would be liable to repay the full amount of the grant funding (\$500,000). The Company has recorded the unearned grant funds as a liability until the Company complies with all of the requirements of the grant funding program. As of June 30, 2008, the Company has had preliminary discussions with the Commonwealth of Pennsylvania to determine whether it will be required to repay any of the funds provided under the grant funding program. Based on information available at June 30, 2008, the Company has recorded the grant funding as a long-term liability under the caption of Unearned Grant Funds.

The following table represents annual contractual obligations as of June 30, 2008: