LANNETT CO INC
Form 10-K
October 09, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2007

OR

o 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	**23-0787699**
State of Incorporation	I.R.S. Employer I.D. No.

9000 State Road

Philadelphia, Pennsylvania 19136

(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 o No x

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 o No x

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

Yes x No o

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. o

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

Large accelerated filer o Accelerated filer x Non-accelerated filer o

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

Yes o No x

Aggregate market value of Common stock held by non-affiliates of the Registrant, as of December 31, 2006 was $150,967,181 based on the closing price of the stock on the American Stock Exchange.

As of September 21, 2007, there were 24,177,118 shares of the issuer s common stock, $.001 par value, outstanding.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

PART I

ITEM 1. DESCRIPTION OF BUSINESS

General

Lannett Company, Inc. (the Company, Lannett, we, or us) was incorporated in 1942 under the laws of the Commonwealth of Pennsylvania, and reincorporated in 1991 as a Delaware corporation. We develop, manufacture, market and distribute generic versions of pharmaceutical products. The Company reports financial information on a quarterly and fiscal year basis, the most recent being the fiscal year ended June 30, 2007. All references herein to a fiscal year refer to the Company s fiscal year ending June 30.

The Company is focused on increasing our share of the generic pharmaceutical market. We were able to increase net sales during fiscal 2007 by adding new products, and by increasing sales under existing distribution agreements. 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. 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 by Lannett and those manufactured by others are identified in the section entitled **Products** in Item 1 of this Form 10-K.

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 a number of 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 projections. 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 strategies highlight Lannett s plan:

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 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

5

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.

In a presentation entitled, CDER Update, given during the Windhover FDA/CMS Summit, Stephen K. Galson, Director of the Center for Drug Evaluation and Research, cited the median approval time for a new ANDA in fiscal 2006 at 16.6 months. This figure was slightly longer than the 2005 median approval time of 16.3. However, there is no guarantee that the FDA will approve a company s ANDA or that any approval will be given within this time frame.

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 either 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 will 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 since 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 for more descriptive information on the 23 products the Company currently produces or sells. Unlike the branded, innovator companies, Lannett currently does not own proprietary drug patents. 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 corporate office. The second building contains packaging, warehouse and shipping functions, R&D and a number of administrative functions.

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, a Limited Liability Company which is 50% owned by Lannett and 50% by an affiliate of Cody Labs.

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, like 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. Such observations 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 upon the consumer of the Company s drug products, and whether the observation is subject to a Warning Letter from the FDA. By strictly enforcing the various FDA guidelines, namely Good Laboratory Practices, Standard Operating Procedures and cGMP, the Company has successfully kept the number of observations in its FDA inspection at a minimal level. The Company believes that such observations are minor in nature, and will be remediated in a timely fashion with no material effect on its results of operations.

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.

The Company continues to expand its sales to the major chain drug stores. Lannett is recognized by its customers as a dependable supplier of high quality generic pharmaceuticals. The Company s policy of maintaining an adequate inventory and fulfilling orders in a timely manner has contributed to this reputation.

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 further accomplish specific Company goals.

Products

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

	Name of Product	Medical Indication	Equivalent Brand
1	Acetazolamide Tablets	Glaucoma	Diamox®
2	Baclofen Tablets	Muscle Relaxer	Lioresal®
3	Butalbital, Aspirin and Caffeine Capsules	Migraine Headache	Fiorinal®
4	Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules	Migraine Headache	Fiorinal w/ Codeine #3®
5	Clindamycin HCl Capsules	Antibiotic	Cleocin®
6	Danazol Capsules	Endometriosis	Danocrine®
7	Dicyclomine Tablets/Capsules	Irritable Bowels	Bentyl®
8	Digoxin Tablets	Congestive Heart Failure	Lanoxin®
9	Diphenoxylate with Atropine Sulfate Tablets	Diarrhea	Lomotil®
10	Doxycycline Tablets	Antibiotic	Adoxa®
11	Doxycycline Hyclate Tablets	Antibiotic	Periostat®
12	Hydromorphone HCl Tablets	Pain Management	Dilaudid®
13	Levothyroxine Sodium Tablets	Thyroid Deficiency	Levoxyl®/ Synthroid®
14	Methyltestoterone/Esterified Estrogens Tablets	Hormone Replacement	Estratest®
15	Morphine Sulfate Oral Solution	Pain Management	Roxanol®
16	Oxycodone HCl Oral Solution	Pain Management	Roxicodone®
17	Phentermine HCl Tablets	Weight Loss	Adipex-P®

8

	Name of Product	Medical Indication	Equivalent Brand
18	Pilocarpine HCl Tablets	Dryness of the Mouth	Salagen®
19	Primidone Tablets	Epilepsy	Mysoline®
20	Probenecid Tablets	Gout	Benemid®
21	Sulfamethoxazole w/ Trimethoprim	Antibacterial	Bactrim®
22	Terbutaline Sulfate Tablets	Bronchospasms	Brethine®
23	Unithroid® Tablets	Thyroid Deficiency	N/A

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 more than 70%, 80% and 93% of the Company s total net sales in Fiscal 2007, 2006 and 2005 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. This number is not included in the above key products because the opportunity is no longer available to the Company after prices declined sharply. The decline in this percentage of key products since 2005 is due to our focus on expanding the number of products sold.

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 2001. 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 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

Lannett received 1 ANDA approval from the FDA and commenced marketing of 1 additional product during Fiscal 2007. We received 10 approvals in Fiscal 2006. Following are more specific details regarding our latest approvals. Market data is obtained from Wolters-Kluwer.

In January 2007, Lannett began distributing Meloxicam, the generic equivalent of Boehringer Ingelheim s Mobic®. Sales of Meloxicam, a non-steroidal anti-inflammatory drug (NSAID) indicated for the relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis, were approximately $1.4 billion for the twelve months ended November 2006, according to Wolters Kluwer.

In April 2007, Lannett received a letter from the FDA with approval to market and launch Danazol 50mg and 100mg capsules. Danazol is the generic version of Danocrine® and is used for the treatment of endometriosis amenable to hormonal management. According to Wolters Kluwer, total sales of generic Danazol Capsules were $15 million in 2006.

Additional products are currently under development. These products are either orally administered, solid-dosage products (i.e. tablet/capsule) or oral solutions, topicals or parentarels 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 overall cost to develop a new generic product varies in range from $100,000 to $1 million.

In addition, as one of the oldest generic drug manufacturers in the country, formed in 1942, Lannett currently owns several ANDAs for products which it does not manufacture and market. These ANDAs are simply dormant on the Company s records. Occasionally, the Company reviews such ANDAs to determine if the market potential for any of these older drugs has recently changed to make it attractive for Lannett to reconsider manufacturing and selling them. If the Company makes the determination to introduce one of these products into the consumer marketplace, it must review the ANDA and related documentation to ensure that the approved product specifications, formulation and other factors meet current FDA requirements for the marketing of that drug. 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 ANDA supplements 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	14
FDA Review	ANDA supplement	4
Clinical Testing	ANDA	4
Scale-Up	Grand-fathered	1
Scale-Up	ANDA supplement	1
Scale-Up	ANDA	3
Formulation/Method Development	ANDA	47

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 63% of the Company s inventory purchases in Fiscal 2007, 76% in Fiscal 2006 and 62% in Fiscal 2005. 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 three 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 23% of the Company s costs of purchased inventory in Fiscal 2007, and 11% in 2006. The term of the agreement is three years, beginning on August 22, 2005 and continuing through August 21, 2008.

During the term of the agreement, the Company has committed to provide a rolling twelve month forecast of the estimated Product requirements to this provider. The first three months of the rolling twelve month forecast are binding and constitute a firm order.

The Company signed supply and development agreements with Olive Healthcare of India; Orion Pharma of Finland; Azad Pharma AG of Switzerland, Pharmaseed in Israel and Banner Pharmacaps 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 industry s largest wholesale distributors, McKesson, Cardinal Health, and Amerisource Bergen, accounted for 24%, 12%, and 6%, respectively, of net sales in Fiscal 2007. The Company s largest chain drug store customer, Walgreens, accounted for 15% of net sales in Fiscal 2007. 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 obtain 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, whereby 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 expand on its own 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 2007, 2006, and 2005, 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 generally expects a high standard of service. This service standard includes shipping product in a timely manner on receipt of customer purchase orders, 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 equally 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. The Company competes primarily on this basis, for example staying competitive, providing superior customer service (from 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 its facilities, hiring of experienced staff, and implementation of inventory and quality control programs have improved the Company s competitive 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.

13

Product	Primary Competitors
Butalbital with Aspirin and Caffeine, with and without Codeine Phosphate Capsules	Watson Pharmaceuticals, Breckenridge Pharmaceutical (manufactured by Anabolic Laboratories)
Digoxin Tablets	GlaxoSmithKline, Actavis (marketed by Bertek Pharmaceuticals), Caraco Pharmaceutical Laboratories
Doxycycline Tablets	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
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.

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 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):*** 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 bioeqivalency 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.

Research and Development

The Company incurred research and development (R&D) expenses of approximately $7,459,000 in 2007, $8,102,000 in 2006, and $6,266,000 in 2005. 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. In the current fiscal year, we have engaged Olive Healthcare, an India-based manufacturer and exporter of pharmaceutical products. AZAD Pharma AG, a Switzerland-based developer of Active Pharmaceutical Ingredients (APIs), has been contracted with to jointly develop and commercialize one pharmaceutical product. This agreement also includes a supply agreement to provide us with five APIs that we will develop into finished dosage forms for commercialization. The Company has contracted with Banner Pharmacaps and with Pharmaseed of Israel to develop products in other dosage forms. 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. The following table shows the most common development arrangement for payments:

Milestone	Payment	
Signing of Agreement	10	%
First delivery of test results	40	%
Second delivery of test results	40	%
Final Report	10	%

Employees

The Company currently has 198 employees.

Securities Exchange Act Reports

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

ITEM 1A. RISK FACTORS

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

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

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

- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;
- 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;

16

- 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;
- experiencing delays or unanticipated costs; 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.

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

Our future results of operations, financial condition and cash flows depend to a significant extent upon our product sales mix. Our sales of 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 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, as well as delay our development and sales and marketing efforts.

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 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 all 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.

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 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.

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.

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, 2007, our three largest customers accounted for 22%, 20% and 19% 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.

ITEM 1b. UNRESOLVED STAFF COMMENTS

None.

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 located on seven acres 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.

Lannett s subsidiary, Cody Laboratories, Inc. (Cody) leases a 73,000 square foot facility in Cody, Wyoming. This location houses Cody s manufacturing and production facilities. Cody leases the facility from Cody LCI Realty, LLC, a Limited Liability Company which is 50% owned by Lannett and 50% by an affiliate of Cody Labs.

ITEM 3. LEGAL PROCEEDINGS

The Company monitors its compliance with all environmental laws. Any compliance costs which may be incurred are contingent upon the results of future site monitoring and will be charged to operations when incurred. No compliance costs were incurred during the years ended June 30, 2007, 2006 and 2005.

Pursuant to a Pennsylvania Department of Revenue (the Department) Sales and Use Tax audit, the Department assessed Use Tax in the amount of $240,000, plus interest and penalties. The total due per the audit is $347,000, although interest continues to accrue until paid. A Petition for Reassessment has been filed with the Board of Appeals, an administrative board. At this point, management is waiting for a hearing to be scheduled by the Board. Only certain audit issues have been raised in the Petition. Lannett is also contesting the assessed penalties which total approximately $72,000. At this point, management has estimated the minimum liability resulting from this audit will be $219,000, as has accrued this liability as of June 30, 2007.

The Company is currently engaged in several civil actions as a co-defendant with many other manufacturers of Diethylstilbestrol (DES), a synthetic hormone. Prior litigation established that the Company s pro rata share of any liability is less than one-tenth of one percent. Due to the fact that prior litigation established the market share method of prorating liability amongst the companies that manufactured DES during the drug s commercial distribution, which ended in 1971, management has accepted this method as the most reasonably expected method of determining liability for future outcomes of claims. The Company was represented in many of these actions by the insurance company with which the Company maintained coverage (subject to limits of liability) during the time period that damages were alleged to have occurred. The insurance company denies coverage for actions alleging involvement of the Company filed after January 1, 1992. With respect to these actions, the Company paid nominal damages or stipulated to its pro rata share of any liability. The Company has either settled or is currently defending over 500 such claims. At this time, management is unable to estimate a range of loss, if any, related to these actions. Management believes that the outcome of these cases will not have a material adverse impact on the financial position or results of operations of the Company.

In addition to the matters reported herein, the Company is involved in litigation which arises in the normal course of business. In the opinion of management, the resolution of these lawsuits will not have a material adverse effect on the consolidated financial position or results of the Company.

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, 2007.

22

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 2007 and 2006, 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, 2007

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

Fiscal Year Ended June 30, 2006

	High	Low
First quarter	$ 5.70	$ 4.24
Second quarter	$ 8.17	$ 4.75
Third quarter	$ 8.40	$ 7.06
Fourth quarter	$ 7.56	$ 5.45

Holders

As of September 21, 2007, there were approximately 227 holders of record of the Company s common stock.

Dividends

The Company did not pay cash dividends in Fiscal 2007 or Fiscal 2006. 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.

Equity Compensation Plan Information

The following table summarizes the equity compensation plans as of June 30, 2007:

Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)**	**Weighted average exercise price of outstanding options, warrants and rights (b)**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)**
Equity Compensation plans approved by security holders	1,119,331	$ 9.42	3,746,234
Equity Compensation plans not approved by security holders			
Total	1,119,331	$ 9.42	3,746,234

24

ITEM 6. SELECTED FINANCIAL DATA

The following financial information as of and for the five years ended June 30, 2007, 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 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,	**2007**	**2006**	**2005**	**2004**	**2003**
Operating Highlights					
Net Sales	$ 82,577,591	$ 64,060,375	$ 44,901,645	$ 63,781,219	$ 42,486,758
Gross Profit	$ 25,182,840	$ 30,160,330	$ 13,484,737	$ 36,924,344	$ 26,228,964
Operating (Loss)/Income	$ (5,964,409)	$ 8,453,918	$ (53,639,658)	$ 20,830,969	