LANNETT CO INC
Form 10-K/A
September 12, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(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, 2005

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	**23-0787-699**
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 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.

Yes o No x

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes x No 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, 2004 was $99,942,641 based on the closing price of the stock on the American Stock Exchange.

As of August 25, 2005, there were 24,118,674 shares of the issuer s common stock, $.001 par value, outstanding.

EXPLANATORY NOTE

This amendment on Form 10-K/A (the Amendment) amends Lannett Company Inc. s annual report on Form 10-K for the fiscal year ended June 30, 2005, as initially filed with the Securities and Exchange Commission on September 13, 2005 (the Form 10-K).

The Company has expanded and enhanced the disclosure in the text and tables located in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, (MD&A) relating to chargebacks, rebates and returns. Similarly, tables in the Notes to the Financial Statements have also been expanded to reflect enhanced disclosure.

The Company has added disclosure of its methods of tracking Days Sales Outstanding (DSO) in the section under Critical Accounting Policies titled Accounts Receivables within the MD&A. This has been included to provide enhanced disclosure relating to the Company s ability to manage receivables.

Additional disclosure has also been made in the section titled Results of Operations within Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations. This has been undertaken to provide enhanced disclosure relating to the changes in sales year over year.

The filing of this Amendment shall not be deemed an admission that the original Form 10-K, when filed, included any untrue statement of material fact or omitted to state a material fact necessary to make a statement not misleading.

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. In 1991, the Company merged into Lannett Company, Inc., a Delaware corporation. The sole purpose of the merger was to reincorporate the Company as a Delaware corporation. The Company develops, manufactures, packages, markets and distributes pharmaceutical products sold under generic chemical names. References herein to a fiscal year refer to the Company s fiscal year ending June 30.

Historically, the Company has competed for an increasing share of the generic market. Although net sales and operating income declined in fiscal 2005, the Company plans to improve future financial performance as a result of additions to the Company s line of generic products, additional sales to current customers, higher unit sales and a management focus on minimizing unnecessary overhead and administrative costs. Some of the new generic products sold by Lannett were developed and are manufactured by Lannett while others are manufactured by others. 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 paid back 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 for additional cash when it is 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 an industrious 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

There are numerous stages in the generic drug development process:

1.) Formulation and Analytical Method Development: Once a drug candidate is selected for future sales, product development scientists perform various experiments on the incorporation of active ingredients into a dosage form. These experiments include 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 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. 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 to the Generic Pharmaceutical Association on February 26, 2005, Lester M. Crawford, D.V.M., Ph.D., and the Acting Commissioner of Food and Drugs at the FDA, said that the median approval time for a new ANDA for the FDA s Fiscal 2004 year was 16.2 months. 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 to the FDA, it must certify that no patents are listed in the Orange Book, the FDA s reference listing of approved drugs, or listed patents have expired. If there are patents covering some aspect of the innovator drug, the applicant must state whether it is seeking approval for marketing after the expiration of the Orange Book patents; or the patents listed therein are invalid, unenforceable, or not infringed usually referred to as a Paragraph IV Certification. ANDAs containing Paragraph IV certifications frequently result in legal actions by the innovator drug companies. These legal activities can trigger an automatic 30 month stay of our ANDA if the innovator company files a claim and it will delay the approval of the generic company s ANDA. Currently, Lannett has filed two Paragraph IV certifications in 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. 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 July 2003, the Company signed a lease/purchase option agreement for a 63,000 square foot building located at 9001 Torresdale Avenue, Philadelphia, Pennsylvania. On November 26, 2003, the Company exercised its option to purchase the facility. The initial renovation of the building is complete and the Company moved some of its staff and operations into that building in the fall of 2004. Lannett currently plans to move certain additional non manufacturing personnel into the 9001 Torresdale building over the next year.

Many FDA regulations relating to cGMP (current Good Manufacturing Practices) 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 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 reduced the number of observations in its latest FDA inspection. The Company believes that such observations are minor in nature, and will be remediated in a timely fashion with no material effect on its future 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.

Despite the decline of Company sales in Fiscal 2005, the Company continues to expand its sales to the major chain drug stores, including CVS, Brooks, Rite Aid and Walgreen s. The mail order

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segment continued to be one of the fastest growing classes in the Company s distribution efforts. Such companies, as Medco Health, Express Scripts and Caremark are leaders in sales growth in the pharmaceutical market. Lannett also increased distribution in the wholesaler segment led by Cardinal Health and McKesson Corporation. 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.

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Management

As the Company continues to grow, additional managers will be hired to complement the skilled team. These new managers will serve in a variety of functions, including Research, Sales, Finance, Quality Control, Quality Assurance, Regulatory Compliance and Production. Ultimately, the execution of a sound business strategy requires a capable and knowledgeable management team.

Products

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

Name of Product	Manufacture Source	Medical Indication	Equivalent Brand
1) Acetazolamide Tablets	Lannett	Glaucoma	Diamox®
2) Butalbital, Aspirin and Caffeine Capsules	Lannett	Migraine Headache	Fiorinal®
3) Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules	JSP	Migraine Headache	Fiorinal w/ Codeine #3®
4) Ciprofloxacin Tablets	Spectrum	Antibiotic	Cipro®
5) Digoxin Tablets	JSP	Congestive Heart Failure	Lanoxin®
6) Dicyclomine Tablets/Capsules	Lannett	Irritable Bowels	Bentyl®
7) Diphenoxylate with Atropine Sulfate Tablets	Lannett	Diarrhea	Lomotil®
8) Hydromorphone HCl Tablets	Lannett	Pain Management	Dilaudid
9) Levothyroxine Sodium Tablets	JSP	Thyroid Deficiency	Levoxyl®/ Synthroid®
10) Methocarbamol Tablets	Lannett	Muscle Relaxer	Robaxin®
11) Methyltestoterone/Esterified Estrogens Tablets	Lannett	Hormone Replacement	Estratest®
12) Phentermine HCl Tablets	Lannett	Weight Loss	Adipex-P®
13) Phenylpropanolamine Tablets-Vet	Lannett	Incontinence	Propagest®
14) Primidone Tablets	Lannett	Epilepsy	Mysoline®
15) Terbutaline Sulfate Tablets	Lannett	Bronchospasms	Brethine®
16) Unithroid Tablets	JSP	Thyroid Deficiency	N/A

All of the products currently manufactured and/or sold by the Company are prescription products. Of the products listed above, Unithroid and those containing butalbital, digoxin, primidone and

levothyroxine sodium were the Company s key products, contributing to more than 93%, 97% and 95% of the Company s total net sales in Fiscal 2005, 2004 and 2003, respectively.

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 seven years. The other butalbital product, Butalbital with Aspirin, Caffeine and Codeine Phosphate capsules is manufactured by 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 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 (0.025, 0.05, 0.075, 0.088, 0.1, 0.112, 0.125, 0.15, 0.175, 0.2, and 0.3 milligrams per tablet). 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.

In April 2005, Lannett received a letter from the FDA with approval to market and launch Phentermine Hydrochloride tablets 37.5 mg., which is a central nervous system stimulant and anorexiant. Phentermine HCl tablets are the generic version of Adipex-P manufactured and sold by TEVA through its Gate Pharmaceutical division. It is indicated for the short-term management of obesity.

In March 2005, Lannett received approval from the FDA for the ANDA of Terbutaline Sulfate tablets 2.5mg and 5 mg. Terbutaline Sulfate is indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema, and is the generic equivalent of Brethine(R) tablets marketed by Novartis Pharmaceuticals and aaiPharma Inc.

Additional products are currently under development. These products are all orally administered, solid-dosage (i.e. tablet/capsule) products designed to be generic equivalents to brand named innovator drugs. The Company s developmental drug products are intended to treat a diverse range of indications. 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 Company has contracted with Spectrum Pharmaceuticals Inc., based in California, to market generic products developed and manufactured by Spectrum and/or its partners. The first applicable product under this agreement is ciprofloxacin tablets, the generic version of Cipro®, an anti-bacterial drug, marketed by Bayer Corporation, prescribed to treat infections. The Company has also initiated discussions with other firms for similar new product initiatives, in which Lannett will market and distribute products manufactured by third parties. Lannett intends to use its strong customer relationships to build its market share for these third party products, and increase future revenues and income.

The majority of the Company s R&D projects are being developed in-house under Lannett s direct supervision and with Company personnel. Hence, the Company does not believe that its outside contracts for product development or manufacturing supply, including Spectrum Pharmaceuticals Inc., 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	11
FDA Review	ANDA supplement	3
Clinical Testing	ANDA	7
Scale-Up	Grand-fathered	2
Scale-Up	ANDA supplement	0
Scale-Up	ANDA	0
Formulation/Method Development	ANDA	25

Raw Material(s) and Finished Good(s) 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 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.

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 42% of the Company s inventory purchases in Fiscal 2005, 81% in Fiscal 2004 and 62% in Fiscal 2003. 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 Material Contract with Supplier footnote in the Company s June 30, 2005 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 is $15 million. Thereafter, the minimum quantity to be purchased increases by $1 million per year up to $24 million for the last year of the ten-year contract. The Company has met the minimum purchase requirement for the first year 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.

The Company has also contracted with Spectrum Pharmaceuticals (Spectrum), based in California, to purchase and distribute Ciprofloxacin tablets which are manufactured by Spectrum and/or its partners. Ciprofloxacin tablets are the generic version of the brand Cipro®, an anti-bacterial drug marketed by Bayer Corporation and prescribed to treat infections. The Company began selling Ciprofloxacin tablets in February 2005.

In October 2004, the Company signed an agreement with Orion Pharma (Orion), based in Finland, to purchase and distribute three drug products. Under the terms of the agreement, Orion will supply Lannett with the finished products and all laboratory documentation, and Lannett will coordinate the completion of the clinical biostudies necessary to submit Abbreviated New Drug Applications (ANDAs) to the FDA.

Another supplier, Siegfried (USA), Inc. (Siegfried), supplies primidone and butalbital, the raw materials in the Company s commercial products of the same name, and accounted for 4% of the Company s inventory purchases in Fiscal 2005, 6% in Fiscal 2004 and 12% in Fiscal 2003. This includes building a satisfactory inventory level, and obtaining contractual supply commitments. The agreement is a standard supply agreement evidencing the terms of the supply of material. There are no guaranteed purchase volume commitments; however the agreement does require Lannett to purchase 100% of its primidone raw material requirements from Siegfried. The price of the material may vary depending on the quantity of material purchased during the term of the agreement. The term of the agreement was October 1, 2002 through December 31, 2003. As of June 30, 2005, a new agreement with Siegfried had not yet been executed. The Company continues to purchase raw materials from Siegfried under the terms of the expired purchase agreement which is included in Exhibit 10.9 of the Company s Form 10-KSB for the year ended June 30, 2004. The Company is in the process of finalizing a new agreement with Siegfried.

The Company has also contracted with API Provider for the supply of raw materials and oral dosage forms relating to future products. The agreements are standard supply agreements evidencing the terms of the supply of material. There are no guaranteed purchase volume commitments. The price of the material may vary depending on the quantity of material purchased during the term of the agreement.

Customers and Marketing

The Company sells its products primarily to wholesale distributors, generic drug distributors, mail-order pharmacies, group purchasing organizations, drug chains, and other pharmaceutical companies. The wholesale distributors McKesson, Cardinal Health, and Amerisource Bergen accounted for 17%, 14%, and 9%, respectively, of net sales in Fiscal 2005. 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. This has the effect of over-emphasizing the sales volume attributable to such wholesaler 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 2005, 2004 and 2003, 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, as well as by flexibility (reacting to customer needs quickly and decisively for example shipping product via overnight delivery when the customer is in critical need of inventory), availability of inventory, and by the fact that the Company s products are available only from a limited number of suppliers. 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.

Product	**Primary Competitors**
Butalbital with Aspirin and Caffeine, with and without Codeine Phosphate Capsules	Watson Pharmaceuticals, Breckenridge Pharmaceutical mfd. by Anabolic Laboratories,
Digoxin Tablets	GlaxoSmithKline, Amide (marketed by Bertek Pharmaceuticals), Caraco Pharmaceutical Laboratories
Levothyroxine Sodium Tablets	Abbott Laboratories, Monarch Pharmaceuticals, Mylan Laboratories, Sandoz
Methyltestoterone/Esterified Estrogens Tablets	Solvay Pharmaceuticals, Syntho Pharmaceuticals (marketed by Breckenridge Pharmaceutical)
Phentermine HCL Tablets	Eon Laboratories, Amide Pharmaceutical, Purepac Pharmaceutical Co.
Primidone Tablets	Watson Pharmaceuticals, Qualitest Pharmaceuticals
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 Drug Price 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 Drug Price 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. 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 Practices (cGMP Regulations). 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.

Research and Development

The Company incurred research and development expenses of approximately $6,266,000 in 2005, $5,896,000 in 2004 and $2,575,000 in 2003.

Employees

The Company currently has 172 employees, of which 167 are full-time.

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 2. DESCRIPTION OF PROPERTY

The Company s headquarters, administrative offices, quality control laboratory, and manufacturing and production facilities, consisting of approximately 31,000 square feet, are located at 9000 State Road, Philadelphia, Pennsylvania.

On July 1, 2003, the Company entered into a lease/purchase option agreement for a 63,000 square foot facility at 9001 Torresdale Avenue, Philadelphia, Pennsylvania, approximately 1 mile from the Company s headquarters. On November 26, 2003, the Company exercised its option to purchase the facility. The Company s research laboratory, warehousing and distribution operations, and sales and accounting departments are now housed there.

In December 1997, the Company entered into a three-year and three-month lease for a 23,500 square foot facility located at 500A State Road, Bensalem, Pennsylvania. This facility housed laboratory research, warehousing and distribution operations. The leased facility is located approximately 2 miles from the Company headquarters. In January 2001, the Company extended this lease through April 30, 2004. After that time, the Company renewed the lease again through April 30, 2005. The Company no longer utilizes nor has any lease obligations related to the 500A State Road, Bensalem, Pennsylvania facility.

ITEM 3. LEGAL PROCEEDINGS

Regulatory Proceedings

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

In 2004 and 2005, the Company entered into three, separate confidential agreements with ThePharmaNetwork, LLC (TPN) pursuant to which the company agreed to collaborate to develop, manufacture, supply, and commercialize a certain generic pharmaceutical drug product. In August 2005, TPN filed a lawsuit against various defendants, including the Company, seeking, among other things, to terminate the three agreements between the Company and TPN. The matter is currently pending before the United States District Court for the District of New Jersey. The Company has filed an answer denying the allegations. The Company has also filed counterclaims against TPN and its principal, Jonathan B. Rome, for, among other things, breach of contract. Because of the confidential nature of the agreements and the generic pharmaceutical drug product at issue, the Company has requested that the Court place all documents under seal to prevent the wrongful disclosure of the Company s sensitive, confidential, and proprietary information. The Company s request for a temporary restraining order was granted. As a result, TPN is temporarily restrained from competing against Lannett or collaborating with Lannett s competitors with respect to the drug product at issue. TPN is also temporarily restrained from using, disclosing or disseminating any confidential information about this drug product until after the hearing on the preliminary injunction, which is scheduled for Sept. 14, 2005. TPN received a temporary restraining order prohibiting Lannett from disclosing TPN s confidential information until after the preliminary injunction hearing on Sept. 14, 2005. At this time, Management is unable to estimate a range of loss, if any, related to this action. Management believes that the outcome of this litigation will not have a material adverse impact on the financial position or results of operation of the Company.

DES Cases

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. The Company was represented in many of these actions by the insurance company with which the Company maintained coverage 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.

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, 2005.

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 2005 and 2004, 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, 2005

	High	Low
First quarter	$ 15.19	$ 9.50
Second quarter	$ 12.80	$ 8.25
Third quarter	$ 10.05	$ 5.95
Fourth quarter	$ 6.45	$ 3.88

Fiscal Year Ended June 30, 2004

	High	Low
First quarter	$ 25.09	$ 15.65
Second quarter	$ 18.88	$ 16.40
Third quarter	$ 19.00	$ 15.10
Fourth quarter	$ 17.00	$ 13.18

Holders

As of August 25, 2005, there were approximately 249 holders of record of the Company s common stock.

Dividends

The Company did not pay cash dividends in Fiscal 2005, Fiscal 2004 or Fiscal 2003. 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, 2005.

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	857,108	$ 13.72	1,395,267
Equity Compensation plans not approved by security holders			
Total	857,108	$ 13.72	1,395,267

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ITEM 6. SELECTED FINANCIAL DATA

Lannett Company, Inc. and Subsidiaries

Financial Highlights

As of or for the Year Ended June 30,	2005	2004	2003	2002	2001
Operating Highlights					
Net Sales	$ 44,901,645	$ 63,781,219	$ 42,486,758	$ 25,126,214	$ 12,090,993
Gross Profit	$ 13,484,737	$ 36,924,344	$ 26,228,964	$ 16,673,537	$ 5,556,229
Operating (Loss)/Income	$ (53,639,658)	$ 20,830,969	$ 19,060,106	$ 11,425,483	$ 2,042,585
Net (Loss)/Income	$ (32,779,596)	$ 13,215,454	$ 11,666,887	$ 7,195,990	$ 1,829,915
Basic (Loss)/Earnings Per Share	$ (1.36)	$ 0.63	$ 0.58	$ 0.36	$ 0.14
Diluted (Loss)/Earnings Per Share	$ (1.36)	$ 0.63	$ 0.58	$ 0.36	$ 0.14
Weighted Average Shares Outstanding, Basic	24,097,472	20,831,750	19,968,633	19,895,757	13,206,128
Weighted Average Shares Outstanding, Diluted	24,097,472	21,053,944	20,121,314	20,018,548	13,206,128
Balance Sheet Highlights					
Current Assets	$ 33,938,115	$ 48,862,443	$ 23,930,048	$ 10,439,630	$ 8,884,835
Working Capital*	$ 17,542,553	$ 28,923,814	$ 17,185,052	$ 6,891,998	$ (69,920)
Total Assets	$ 94,917,060	$ 131,904,084	$ 31,834,544	$ 17,338,503	$ 15,931,617
Total Debt	$ 9,532,448	$ 10,092,857	$ 3,097,802	$ 4,142,538	$ 10,773,222
Deferred Tax Liabilities	$ 2,009,582	$ 1,614,323	$ 1,112,369	$ 681,489	$ 641,285
Total Stockholders Equity	$ 69,249,244	$ 102,246,991	$ 21,597,710	$ 9,766,049	$ 2,515,685

*Working capital equals current assets less current liabilities

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Any statements made in this 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, o variations thereof or comparable 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 Section entitled Risks

Related to Our Business, and other risks and uncertainties detailed herein and from time to time in our Securities and Exchange Commission filings, may affect its actual results.

We disclaim any obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. We also may make additional disclosures in our quarterly reports on Form 10-Q and current reports on Form 8-K that we may file 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.

Risks Related to Our Business

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

RISKS ASSOCIATED WITH INVESTING IN THE BUSINESS OF LANNETT

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;

- 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 product manufacturers, including us, 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. 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 wholesale customers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other retail customers. A chargeback is the difference between the price the wholesale customer pays and the price that the wholesale customer 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 most 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 JSP s 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.

RISKS RELATING TO INVESTING IN THE PHARMACEUTICAL INDUSTRY

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 and warning letters 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, 2005, our three largest customers accounted for 17%, 14% and 9% respectively, of our net revenues. 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 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 2006, and any current reports on Form 8-K filed by the Company. All share and per share amounts on this Form 10-K have been adjusted to reflect a three-for-two stock split effective on February 14, 2003.

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.

Revenue Recognition - The Company recognizes revenue when its products are shipped. At this point, title and risk of loss have transferred to the customer and provisions for estimates, including rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable. Accruals for these provisions are presented in the consolidated financial statements as rebates and chargebacks payable and reductions to net sales. The change in the reserves for various sales adjustments may not be proportionally equal to the change in sales because of changes in both the product and the customer mix. Increased sales to wholesalers will generally require additional rebates. Incentives offered to secure sales vary from product to product. Provisions for estimated rebates and promotional and other credits are estimated based on historical payment experience, customer inventory levels, and contract terms. Provisions for other customer credits, such as price adjustments, returns, and chargebacks, require management to make subjective judgments. Unlike branded innovator drug companies,

Lannett does not use information about product levels in distribution channels from third-party sources, such as IMS and NDC Health, in estimating future returns and other credits.

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

Rebates Rebates are offered to the Company s key customers to promote customer loyalty and encourage greater product sales. These rebate programs provide customers with rebate credits upon attainment of pre-established volumes or attainment of net sales milestones for a specified period. Other promotional programs are incentive programs offered to the customers. At the time of shipment, the Company estimates reserves for rebates and other promotional credit programs based on the specific terms in each agreement. The reserve for rebates increases as sales to certain wholesale and retail customers increase. However, these rebate programs are tailored to the customers individual programs. Hence, the reserve will depend on the mix of customers that comprise such rebate programs.

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

In the fourth quarter of fiscal year 2005, the Company recorded a $1,500,000 write-down in sales to account for expected returns. This additional reserve came about because excess inventory existed with a major wholesaler that was unable to sell a significant amount of Levothyroxine Sodium tablets that it had purchased a year earlier. The Company considered extending the shelf-life of the product in March 2005, but decided against this extension. In May 2005, the conclusion was ultimately reached to reserve for all estimated returns. The date that all unsold

products would eventually be returned was through December 2005, and the $1,500,000 included the estimate of all returns through December 2005.

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

The following tables identify the reserves for each major category of revenue allowance and a summary of the activity for the years ended June 30, 2005 and 2004:

For the Year Ended June 30, 2005

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2004	$ 6,484,500	$ 1,864,200	$ 448,000	$ 88,300	$ 8,885,000
Actual credits issued related to sales recorded in prior fiscal years	(4,978,300)	(1,970,000)	(523,100)	(95,800)	(7,567,200)
Reserves or (reversals) charged during Fiscal 2005 related to sales recorded in prior fiscal years	(1,420,000)	130,000	1,400,000		110,000
Reserves charged to net sales in fiscal 2005 related to sales recorded in fiscal 2005	21,028,100	6,970,100	1,533,900	623,400	30,155,500
Actual credits issued related to sales in fiscal 2005	(13,114,600)	(5,965,500)	(1,166,800)	(586,400)	(20,833,300)
Reserve Balance as of June 30, 2005	$ 7,999,700	$ 1,028,800	$ 1,692,000	$ 29,500	$ 10,750,000

For the Year Ended June 30, 2004

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2003	$ 1,638,000	$ 889,900	$ 210,200	$ 33,900	$ 2,772,000
Actual credits issued related to sales recorded in prior fiscal years	(1,604,000)	(1,166,400)	(182,700)		(2,953,100)
Reserves or (reversals) charged during Fiscal 2004 related to sales recorded in prior fiscal years		300,000			300,000
	18,897,500	4,563,900	480,600	464,400	24,406,400

Reserves charged to net sales in fiscal 2004 related to sales recorded in fiscal 2004					
Actual credits issued related to sales in fiscal 2004	(12,447,000)	(2,723,200)	(60,100)	(410,000)	(15,640,300)
Reserve Balance as of June 30, 2004					