LANNETT CO INC Form 10-K September 13, 2006

#### U.S. SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2006

OR

#### • TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_\_to \_\_\_\_\_

Commission File No. 001-31298 LANNETT COMPANY, INC.

(Exact name of registrant as specified in its charter)

**State of Delaware** 

State of Incorporation

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 oNo þ

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 oNo þ

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 pNo 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 b 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 oNo  $\natural$ 

Aggregate market value of Common stock held by non-affiliates of the Registrant, as of December 31, 2005 was \$104,663,020 based on the closing price of the stock on the American Stock Exchange.

Table of Contents

23-0787699

I.R.S. Employer I.D. No.

#### Edgar Filing: LANNETT CO INC - Form 10-K

As of August 25, 2006, there were 24,148,014 shares of the issuer s common stock, \$.001 par value, outstanding.

#### **TABLE OF CONTENTS**

<u>PART I</u>

ITEM 1. DESCRIPTION OF BUSINESS

ITEM 1A. RISK FACTORS

ITEM 1b. UNRESOLVED STAFF COMMENTS

ITEM 2. DESCRIPTION OF PROPERTY

ITEM 3. LEGAL PROCEEDINGS

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

<u>PART II</u>

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

ITEM 6. SELECTED FINANCIAL DATA

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND

**RESULTS OF OPERATIONS** 

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

ITEM 9A. CONTROLS AND PROCEDURES

ITEM 9B. OTHER INFORMATION

<u>PART III</u>

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

ITEM 11. EXECUTIVE COMPENSATION

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND

MANAGEMENT AND RELATED STOCKHOLDER MATTERS

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K SIGNATURES

Annual Report on Form 10-K

Subsidiaries of the Company

Consent of Grant Thornton

Certification of Chief Executive Officer

Certification of Chief Financial Officer

Certification of CEO and CFO Pursuant to Section 906

#### 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, continue, or pursue, or the negative other 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 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 fiscal year basis, the most recent being the fiscal year ended June 30, 2006. 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 and operating income during fiscal 2006 by adding new products, as well as by improved results from existing distribution agreements. The Company plans to continue to focus on improved financial performance though additions to our line of generic products, additional sales to current customers, higher unit sales, and a focus on minimizing 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 recovered in future years as it submits applications to the Food and Drug Administration (FDA), and when it receives marketing approval from the

would

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 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 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 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 with 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. An ANDA filer must certify, with respect to each patent that claims the listed drug for the bioequivalent of which the ANDA filer is seeking approval, [FN3] 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. These legal activities can trigger an automatic 30 month stay of the ANDA if the innovator company files a claim and it will delay the approval of the generic company s ANDA. Currently, Lannett has no 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. Please refer to the following section entitled Products for more descriptive information on the 24 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. 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. The mail order segment continued to be one of the fastest growing classes in the Company s distribution efforts. Companies such 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.

#### 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	<b>Medical Indication</b>	<b>Equivalent Brand</b>
1	Acetazolamide Tablets	Glaucoma	Diamox®
2	Baclofen Tablets (a)	Muscle Relaxer	Lioresal®
3	Butalbital, Aspirin and Caffeine Capsules	Migraine Headache	Fiorinal®
4	Butalbital, Aspirin, Caffeine with Codeine Phosphate	Migraine Headache	Fiorinal w/ Codeine
	Capsules		#3®
5	Clindamycin HCl Capsules (a)	Antibiotic	Cleocin®
6	Danazol Capsules (a)	Endometriosis	Danocrine®
7	Dicyclomine Tablets/Capsules	Irritable Bowels	Bentyl®
8	Digoxin Tablets	<b>Congestive Heart</b>	Lanoxin®
		Failure	
9	Diphenoxylate with Atropine Sulfate Tablets	Diarrhea	Lomotil®
10	Doxycyline Tablets (a)	Antibiotic	Adoxa®
11	Doxycyline Hyclate Tablets (a)	Antibiotic	Periostat®
12	Hydromorphone HCl Tablets	Pain Management	Dilaudid®
13	Levothyroxine Sodium Tablets	Thyroid Deficiency	Levoxyl <sup>®</sup> / Synthroid <sup>®</sup>
14	Methocarbamol Tablets	Muscle Relaxer	Robaxin®
15	Methyltestoterone/Esterified Estrogens Tablets	Hormone Replacement	Estratest®
16	Morphine Sulfate Oral Solution (a)	Pain Management	Roxanol®
17	Oxycodone HCl Oral Solution (a)	Pain Management	Roxicodone®
18	Phentermine HCl Tablets	Weight Loss	Adipex-P <sup>®</sup>
19	Pilocarpine Tablets (a)	Dryness of the Mouth	Salagen <sup>®</sup>
20	Primidone Tablets	Epilepsy	Mysoline®
21	Probenecid Tablets (a)	Gout	Benemid®
22	Sulfamethoxazole w/ Trimethoprim (a)	Antibiotic	Bactrim®
	5		

23 24	<b>Name of Product</b> Terbutaline Sulfate Tablets Unithroid <sup>®</sup> Tablets	<b>Medical Indication</b> Bronchospasms Thyroid Deficiency	<b>Equivalent Brand</b> Brethine <sup>®</sup> N/A
(a)	product		

launched during fiscal 2006.

#### **Key Products**

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 more than 80%, 93% and 97% of the Company s total net sales in Fiscal 2006, 2005 and 2004 respectively. The decline in this percentage during 2006 is testament 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 eight 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<sup>®</sup>, 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. 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<sup>®</sup>. In December 2004, JSP received a letter from the FDA approving its supplemental application for generic bioequivalence to Synthroid<sup>®</sup>. 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<sup>®</sup> Monarch Pharmaceutical s Levoxy<sup>¶</sup> as well as generic competition from Mylan Laboratories and Sandoz.

#### **New Products**

Lannett received 10 ANDA approvals from the FDA during the fiscal year ended June 30, 2006. We received 2 approvals in the previous year ended June 30, 2005. Following are more specific details regarding our latest approvals. Market data is obtained from NDC Health (now known as Per-Sé).

In September 2005, Lannett received a letter from the FDA with approval to market and launch Clindamycin HCL Tablets. Clindamycin capsules are the generic equivalent of Cleocin<sup>®</sup>, marketed by Pharmacia Corporation. Annual sales for Clindamycin capsules totaled \$334 million in 2004. Clindamycin is used to treat serious bacterial infections. In September 2005, Lannett received a letter from the FDA with approval to market and launch Danazol 200mg Capsules. Danazol is the generic version of Danocrine<sup>®</sup> and is used for the treatment of endometriosis amenable to hormonal management. The market size for Danazol is \$14.4 million.

In September 2005, Lannett received a letter from the FDA with approval to market and launch Sulfamethoxazole with Trimethoprim. According to Per-Sé, sales for generic Sulfamethoxazole with Trimethoprim tablets totaled \$260 million in 2004. Sulfamethoxazole with Trimethoprim is used to treat infections such as urinary tract infections, bronchitis, ear infections (otitis), traveler s diarrhea, and Pneumocystis carinii pneumonia and is the generic equivalent of Bactrim<sup>®</sup> and Bactrim DS<sup>®</sup>, marketed by United Research Laboratories, Inc.

In October 2005, Lannett received a letter from the FDA with approval to market and launch Pilocarpine 5mg tablets. Pilocarpine is indicated for the treatment of dry mouth symptoms from salivary gland hypofunction from cancer radiotherapy or Sjogren s Syndrome. Pilocarpine is the generic version of Salagen and has a market of \$36 million. In November 2005, Lannett received a letter from the FDA with approval to market and launch Doxycycline Hyclate 20mg tablets. Doxycycline Hyclate is indicated for use as an adjunct to scaling and root planning to promote attachment level gain and to reduce pocket depth in patients with adult periodontitis. Doxycycline Hyclate is the generic version of Periostat<sup>®</sup> and the total market is estimated at \$67 million.

In December 2005, Lannett received a letter from the FDA with approval to market and launch Baclofen 20mg tablets. According to Per-Sé, total sales in 2005 of Baclofen were approximately \$89.5 million. Baclofen is useful for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.

In December 2005, Lannett received a letter from the FDA as the first generic with approval to market and launch Doxycycline tablets. Doxycycline Monohydrate is the generic version of Adoxa<sup>®</sup>, marketed by Doak Dermatologics, a subsidiary of Bradley Pharmaceuticals, Inc. According to Per-Sé, total sales of Adoxa were \$32 million in 2004. Doxycycline Monohydrate is a tetracycline-type antibiotic used to treat many different bacterial infections, such as urinary tract infections, acne, gonorrhea, Chlamydia, and periodontitis among others.

In January 2006, Lannett launched Morphine Sulfate Solution. Morphine Sulfate is used for the treatment of chronic and acute pain and is a generic version of Roxanol<sup>®</sup>.

In January 2006, Lannett launched Oxycodone HCL Oral Solution. Oxycodone HCL Solution is a generic version of Roxicodone<sup>®</sup> and is used for treating pain.

In May 2006, Lannett received a letter from the FDA with approval to market and launch Probenecid Tablets. According to Per-Sé, total sales in 2005 of Probenecid were approximately \$26.0 million. Probenecid is indicated for the treatment of hyperuicemia associated with gout and gouty arthritis. Probenecid is also used as an adjunctive therapy with some antibiotics such as penicillin, ampicillin, methicillin, oxacillin, cloxacillin, or nafcillin, for the elevation and prolongation of plasma levels by whatever route the antibiotic is given.

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	<b>Regulatory Requirement</b>	Number of Products
FDA Review	ANDA	7
FDA Review	ANDA supplement	3
Clinical Testing	ANDA	2
Scale-Up	Grand-fathered	0
Scale-Up	ANDA supplement	2
Scale-Up	ANDA	4
Formulation/Method Development	ANDA	37

#### **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 76% of the Company s inventory purchases in Fiscal 2006, 62% in Fiscal 2005 and 81% in Fiscal 2004. 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<sup>®</sup>. 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 two 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 11% of the Company s costs of purchased inventory in Fiscal 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.

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. The Company signed supply and development agreements with Olive Healthcare, of India; Orion Pharma, of Finland; Azad Pharma AG, of Switzerland, and is in negotiations with companies in Israel and Greece 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 such products, and increase future revenues and income.

The Company has also contracted with an 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 industry s largest wholesale distributors McKesson, Cardinal Health, and Amerisource Bergen accounted for 17%, 15%, and 5%, respectively, of net sales in Fiscal 2006. 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 2006, 2005, and 2004, 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	Watson Pharmaceuticals, Breckenridge Pharmaceutical
without Codeine Phosphate Capsules	(manufactured by Anabolic Laboratories)
	11

Product	<b>Primary Competitors</b>
Digoxin Tablets	GlaxoSmithKline, Amide (marketed by Bertek Pharmaceuticals), Caraco Pharmaceutical Laboratories
Doxycycline Tablets	Par Pharmaceuticals, Ranbaxy
Levothyroxine Sodium Tablets	Abbott Laboratories, Monarch Pharmaceuticals, Mylan Laboratories, Sandoz, Forest
Primidone Tablets	Watson Pharmaceuticals, Qualitest Pharmaceuticals, URL
Sulfamethoxazole w/ Trimethoprim	URL/Mutual Pharmaceuticals, Sandoz, Vista
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. 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. **Research and Development** 

The Company incurred research and development (R&D) expenses of approximately \$8,102,000 in 2006, \$6,266,000 in 2005, and \$5,896,000 in 2004. 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. **Employees** 

The Company currently has 193 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. *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 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.

#### 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 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, 2006, our three largest customers accounted for 17%, 15% and 5% 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 1b. UNRESOLVED STAFF COMMENTS**

The Company has received written comments from the Securities and Exchange Commission staff during the current fiscal year. The comments relate to Form 10K dated June 30, 2005, and the Forms 10O as of September 30, 2005. December 31, 2005 and March 31, 2006. Lannett believes these comments will be resolved in the near future. The Company does not expect the resolution to have any material effect on the financial statements or disclosures. **ITEM 2. DESCRIPTION OF PROPERTY** 

Lannett owns two facilities in Philadelphia, Pennsylvania, from where all operations are based. 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 December 2005, the Company refinanced the mortgages on these two properties. As of June 30, 2006, the mortgage balance was approximately \$6 million.

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 will hold the warehouse, and will become the future headquarters of the Company. We expect to

begin occupying the building in December 2006, with full conversion of the facility to take place over another 6 to 9 months. The existing facilities will continue to operate, giving the Company the ability to broaden its manufacturing and pharmaceutical development.

#### **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 monitoring costs were incurred during the years ended June 30, 2006, 2005 and 2004.

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, 2006.

#### 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 2006 and 2005, 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, 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
<u>Fiscal Year</u>	<u>Ended June 30, 2005</u>	
	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
Holders		
As of August 25, 2006, there were connecting taly 227	holdow of record of the Commons. a common star	J.

As of August 25, 2006, there were approximately 237 holders of record of the Company s common stock. **Dividends** 

The Company did not pay cash dividends in Fiscal 2006 or Fiscal 2005. 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, 2006.

	Number of securities to be		Number of securities remaining available for future issuance under equity
	issued upon	Weighted average exercise price	compensation plans
	exercise of outstanding options, warrants and rights	of outstanding options, warrants and rights	(excluding securities reflected in column (a))
Plan Category	(a)	(b)	(c)
Equity Compensation plans approved by security holders	792,003	\$ 12.98	1,613,144
Equity Compensation plans not approved by security holders			
Total 2	792,003 3	\$ 12.98	1,613,144

#### ITEM 6. SELECTED FINANCIAL DATA

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

As of and for the Fiscal Year Ended June 30,		2006		2005	2004	2	2003	2	2002
<b>Operating Highlights</b>									
Net Sales		64,060,375		,901,645	\$ 63,781,219	-	486,758	-	126,214
Gross Profit		30,160,330		,484,737	\$ 36,924,344	-	228,964	-	573,537
Operating Income/(Loss)	\$	8,453,918		,639,658)	\$ 20,830,969	\$19,060,106		\$11,425,483	
Net Income/(Loss)	\$	4,968,922	\$(32	,779,596)	\$ 13,215,454	\$11,	666,887	\$7,	195,990
Basic Earnings/(Loss) Per									
Share	\$	0.21	\$	(1.36)	\$ 0.63	\$	0.58	\$	0.36
Diluted Earnings/(Loss) Per									
Share	\$	0.21	\$	(1.36)	\$ 0.63	\$	0.58	\$	0.36
Weighted Average Shares									
Outstanding, Basic		24,130,224	24	,097,472	20,831,750	19,9	968,633	19,	895,757
Weighted Average Shares									
Outstanding, Diluted		24,154,409	24	,097,472	21,053,944	20,	121,314	20,0	018,548
Balance Sheet Highlights									
Current Assets	\$ 4	43,486,847	\$ 33	,938,115	\$ 48,862,443	\$23,	930,048	\$10,4	439,630
Working Capital*	\$ 2	22,862,419	\$ 17	,542,553	\$ 28,923,814	\$17,	185,052	\$ 6,	891,998
Total Assets		05,992,064		,917,060	\$ 131,904,084	-	834,544	\$17,	338,503
Total Debt	\$	8,196,692		,532,448	\$ 10,092,857	\$ 3,0	097,802	\$ 4,	142,538
Deferred Tax Liabilities	\$	2,545,734	\$ 2	,009,582	\$ 1,614,323	\$ 1,	112,369	\$ (	581,489
Total Stockholders Equity	\$ ´	75,755,916	\$ 69	,249,244	\$ 102,246,991	\$21,	597,710	\$ 9,	766,049
* Working capital equals current assets less current liabilities				24					
				∠ <del>'1</del>					

## 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.

#### **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 accruals as they are the primary recipient of chargebacks and rebates. Incentives offered to secure sales vary from product to product. Provisions for estimated rebates and promotional credits are estimated based upon contractual terms. Provisions for other customer credits, such as price adjustments, returns, and chargebacks, require management to make subjective judgments on customer mix. Unlike branded innovator drug companies, Lannett does not use information about product levels in distribution channels from third-party sources, such as IMS and NDC Health, in estimating future returns and other credits. Lannett calculates a chargeback/rebate rate based on contractual terms with its customers and applies this rate to customer sales. The only variable is customer mix, and this is based on historical data and sales expectations. The chargeback/rebate reserve is reviewed on a monthly basis by management using several ratio and calculated metrics. Lannett s methodology for estimating reserves has been consistent with previous periods.

*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 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. Return periods will vary by customer and product.

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 of returns from a major wholesaler that was unable to sell a significant amount of Levothyroxine Sodium tablets that it had purchased a year earlier. The product was returned to the Company in December 2005, and concurrently written off as slow moving and short-dated inventory. *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 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. When competitors enter the market of existing products in 2006, shelf stock adjustments are issued to maintain price competitiveness. Management foresaw this occurrence and appropriately reserved for it as seen in the table below.

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, 2006, 2005 and 2004: **For the Year Ended June 30, 2006** 

**Reserve Category** Chargebacks **Rebates** Returns Other Total Reserve Balance as of June 30, 7,999,700 \$ 10,750,000 2005 \$ \$ 1,028,800 \$ 1,692,000 \$ 29,500 Actual Credits Issued-Related To Sales Recorded in Fiscal 2005 (7,920,500)(1,460,500)(1,272,400)(59,300)(10,712,700)Additional Reserves Charged to Net Sales During Fiscal 2006 28,237,000 6,188,500 36,221,000 497,300 1,298,200 Actual Credits Issued-Related To Sales Recorded in Fiscal 2006 (18, 178, 800)(3,573,700)(500,900)(992, 800)(23, 246, 200)Reserve Balance as of June 30. 2006 \$ 10,137,400 \$ 2,183,100 \$ 416,000 \$ 275,600 \$ 13,012,100

#### 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 Fiscal 2004	(4,978,300)	(1,970,000)	(523,100)	(95,800)	(7,567,200)		
Additional Reserves Charged to Net Sales During Fiscal 2005	21,028,100	7,100,100	2,933,900	623,400	31,685,500		
Actual Credits Issued-Related To Sales Recorded in Fiscal 2005	(14,534,600)	(5,965,500)	(1,166,800)	(586,400)	(22,253,300)		
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		

#### Table of Contents

### Edgar Filing: LANNETT CO INC - Form 10-K

Actual Credits Issued-Related To Sales Recorded in Fiscal 2003	(1,604,000)	(1,166,400)	(182,700)		(2,953,100)
Actual Credits Issued-Related To Sales Recorded in Fiscal 2004	(12,447,000)	(2,723,200)	(60,100)	(410,000)	(15,640,300)
Additional Reserves Charged to Net Sales During Fiscal 2004	18,897,500	4,863,900	480,600	464,400	24,706,400
Reserve Balance as of June 30, 2004	\$ 6,484,500	\$ 1,864,200	\$ 448,000	\$ 88,300	\$ 8,885,000
Reserve Activity 2006 vs. 2005					

The chargeback reserve increased from \$10,750,000 at June 30, 2005 to \$13,012,100 at June 30, 2006 due to an increased level of sales in the months of May and June as compared to prior year. Historically,

the ratio of the reserve to gross sales is between 30% and 40%. The fiscal years ended June 30, 2006 and 2005 were 36% and 40%, respectively. In fiscal 2005, there were additional reserves taken for an expected Levothyroxine return. This accounted for an additional \$1.4 million or 1.8%. There were no additional reserves charged to net sales in fiscal 2006 that relate to prior year sales. Rebates have decreased both in amount and as a percentage of the reserve in the

additional credits issued-related to sales recorded in Fiscal 2006 due to the classification of rebates from wholesale customers. When the reserve is calculated for the wholesale/distribution customers, it is calculated in aggregate since they submit the amounts together. This is in part the reason why the chargeback amount has increased. However there is a large rebate reserve as of June 30, 2006 as direct customers (those who receive the only rebates) were a larger than usual portion of sales in the month of June 58%, typically 50%. Other increased due to an increase in shelf stock adjustments. Additional competitors in the Primidone 50 market have caused Lannett to give more of this type of credit.

Fluctuations in the amount of sales through the wholesaler channel will have an impact on the amount of reserve being charged. Due to the fact that wholesale sales result in greater chargebacks, an increase in wholesale sales will result in a higher level of chargebacks. For the first, second, third and fourth quarters of Fiscal 2006, reserves recorded against sales amounted to \$7.5 million, \$7.9 million, \$12.5 million and \$10.0 million, respectively. Wholesaler sales were \$9.3 million, \$9.9 million, \$16.7 million and \$15.8 million, respectively. The increase in the dollar value of the reserves corresponds to the increase in wholesale sales.

#### Reserve Activity 2005 vs. 2004

Actual credits processed against fiscal year 2004 chargebacks during fiscal year 2005 are nearly \$1.5 million less than the June 30, 2004 balance of \$6,484,500, a result of overestimating the required reserve at June 30, 2004. The large majority of chargebacks occur from sales to wholesalers. Sales through these wholesalers were beginning to decline by the end of fiscal 2004. This decline resulted in lower chargebacks. In addition, the competition within the generic industry, by competitors introducing similar pharmaceuticals, led to pressures on product sales and pricing. Often these competitors product introductions are not known in advance, and require the Company to maintain flexible pricing strategies in order to not lose market share. At this point, the sales decline through wholesalers was a result of greater competition. Due to the relatively small size of Lannett s product offerings, the sales through the wholesalers may decline without much notice. Lannett s ability to compete will depend on the ability to add new products to offer wholesalers as well as pharmacy customers. The Company continued to estimate higher chargebacks than needed. By the end of the fiscal year, sales through the wholesalers had increased again, the result of customers buying greater quantities before the fiscal year ended, and requiring a reserve of nearly \$8 million.

The rebates reserve of \$1,864,000 at June 30, 2004 had \$1,970,000 of credits issued against it during fiscal year 2005. This difference of \$106,000 is an underestimate of rebates, which was corrected in the additional reserves taken in fiscal year 2005. By June 30, 2005, the rebates reserve is estimated to be \$1,029,000, a result of declining overall sales during the last quarter of fiscal year 2005.

The returns reserve balance at June 30, 2004, \$448,000, had actual credits of \$523,000 issued against it during fiscal year 2005. This difference of \$75,000 is not related to any one product. By June 30, 2005 the returns reserve was increased to \$1,692,000 as the company was anticipating a significant return from one customer on its Levothyroxine Sodium tablets.

The Company ships its products to the warehouses of its wholesale, mail order, distributor and retail chain customers. When the Company and a customer come to an agreement for the supply of a product, the customer will generally continue to purchase the product, stock its warehouse(s), and resell the

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

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

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

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

In the fourth quarter of fiscal year 2005, the Company recorded a \$4,000,000 write-down of slow moving and short dated inventory primarily related to Levothyroxine Sodium tablets, which had been returned by a wholesaler during the quarter.

*Intangible Asset* On March 23, 2004, the Company entered into an agreement with Jerome Stevens Pharmaceuticals, Inc. (JSP) for the exclusive marketing and distribution rights in the United States to the current line of JSP products in exchange for four million (4,000,000) shares of the Company s common stock. As a result of the JSP agreement, the Company recorded an intangible asset of \$67,040,000 for the exclusive marketing and distribution rights obtained from JSP. The intangible asset was recorded based upon the fair value of the four million (4,000,000) shares at the time of issuance to JSP. The agreement was included as an Exhibit in the Form 8-K filed by the Company on May 5, 2004, as subsequently amended.

In June 2004, JSP s Levothyroxine Sodium tablet product received from the FDA an AB rating to the brand drug Levoxyl<sup>®</sup>. In December 2004, the product received from the FDA a second AB rating to the brand drug Synthroid<sup>®</sup>. As a result of the dual AB ratings, the Company was required to pay JSP an additional \$1.5 million in cash to reimburse JSP for expenses related to obtaining the AB ratings. As of March 31, 2005, the Company recorded an addition to the intangible asset of \$1.5 million.

During Fiscal 2005, events occurred which indicated that the carrying value of the intangible asset was not recoverable. In accordance with Statement of Financial Accounting Standards No. 144 (FAS 144), *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company engaged a third party valuation specialist to assist in the performance of an impairment test for the quarter ended March 31, 2005. The impairment test was performed by discounting forecasted future net cash flows for the JSP products covered under the agreement and then comparing the discounted present value of those cash flows to the carrying value of the asset (inclusive of the \$1.5 million paid to JSP for the dual AB ratings). As a result of the testing, the Company recorded a non-cash impairment loss of approximately \$46,093,000 to write the asset down to its fair value of approximately \$16,062,000 as of the date of the impairment. This impairment loss is shown on the statement of operations as a component of operating loss. Management concluded that, as of June 30, 2006, the intangible asset is correctly stated at fair value and, therefore, no additional adjustment is required.

*New Accounting Pronouncements* In November 2004, the FASB issued FASB Statement No. 151, Inventory Costs an amendment of ARB No. 43, Chapter 4 (SFAS No. 151), which is the result of its efforts to converge U.S. accounting standards for inventories with International Accounting Standards. SFAS No. 151 requires abnormal amounts of idle facility expense, freight, handling costs and wasted material or spoilage to be recognized as current-period charges. It also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 was effective for inventory costs incurred

beginning January 1, 2006. The adoption of this standard did not have any impact on the Company. In March 2005, the FASB issued FIN 47 Accounting for Conditional Asset Retirement Obligations, an Interpretation of FASB Statement No. 143. This Interpretation clarifies that a conditional retirement obligation refers to a legal obligation to perform an asset retirement activity in which the timing and (or) method of settlement are conditional on a future event that may or may not be within the control of the entity. The obligation to perform the asset retirement activity is unconditional even though uncertainty exists about the timing and (or) method of settlement. Accordingly, an entity is required to recognize a liability for the fair value of a conditional asset retirement obligation if the fair value of the liability can be reasonably estimated. The liability should be recognized when incurred, generally upon acquisition, construction or development of the asset. FIN 47 is effective no later than the end of fiscal years ending after December 15, 2005. The adoption of FIN 47 had no impact on our financial statements.

In May 2005, the FASB issued FASB Statement No. 154, Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3 (SFAS No. 154). Previously, APB Opinion No. 20, Accounting Changes and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements required the inclusion of the cumulative effect of changes in accounting principle in net income of the period of the change. SFAS No. 154 requires companies to recognize a change in accounting principle, including a change required by a new accounting pronouncement when the pronouncement does not include specific transition provisions retrospectively to prior period financial statements. SFAS No. 154 was effective as of January 1, 2006. The adoption of this standard did not have any impact on the Company in the current fiscal year.

In September 2005, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 04-13, Accounting for Purchases and Sales of Inventory with the Same Counterparty (EITF 04-13). EITF 04-13 provides guidance on whether two or more inventory purchase and sales transactions with the same counterparty should be viewed as a single exchange transaction within the scope of APB No. 29, Accounting for Nonmonetary Transactions. In addition, EITF 04-13 indicates whether nonmonetary exchanges of inventory within the same line of business should be recognized at cost or fair value. EITF 04-13 was effective as of April 1, 2006. There has been no impact on the Company s financial statements, effective from April 1, 2006 to date..

In April 2006, the FASB issued FASB Staff Position No. FIN 46(R)-6, Determining the Variability to Be Considered in Applying FASB Interpretation No. 46(R) (FSP No. 46(R)-6). This pronouncement provides guidance on how a reporting enterprise should determine the variability to be considered in applying FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities, which could impact the assessment of whether certain variable interest entities are consolidated. FSP No. 46(R)-6 will be effective for the Company on July 1, 2006. The provisions of FSP No. 46(R)-6 are applied prospectively. FSP No. 46(R)-6 has had no impact on the Company in the current year.

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), to clarify the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS 109, Accounting for Income Taxes. Effective January 1, 2007, FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company is currently evaluating the impact, if any, that FIN 48 will have on its financial statements.

#### Results of Operations Fiscal 2006 compared to Fiscal 2005

Net sales increased by 43%, from \$44,901,645 in Fiscal 2005 to \$64,060,375 in Fiscal 2006. The increase was due in part from a rebound in Levothyroxine sales which increased \$6.4 million, or 75%. The Company also had additional growth with the introduction of several new products which accounted for \$12.6 million in sales. Several other products besides Levothyroxine Sodium experienced increased sales over prior year including Digoxin 29%, Acetazolamide 8%, Unithroid 38%, and Hydromorphone 398%. Volume and price increases attributed to increased sales 33% due to increase in volume (new sales are included in volume increases) and 11% increase in prices. Prices rebounded in the sales of Levothyroxine and Digoxin. Both saw increased price pressure in the prior year as several competitors entered into the market.

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

Customer Category	Fiscal 2006 Net Sales	Fiscal 2005 Net Sales	Fiscal 2004 Net Sales
Wholesaler/Distributor	\$44.0 million	\$24.8 million	\$43.0 million
Retail Chain	\$10.6 million	\$10.5 million	\$12.1 million
Mail-Order Pharmacy	\$ 7.0 million	\$ 5.9 million	\$ 4.3 million
Private Label	\$ 2.5 million	\$ 3.7 million	\$ 4.4 million
Total	\$64.1 million	\$44.9 million	\$63.8 million

Wholesaler/Distributor sales increased due to a rebound in Levothyroxine Sodium sales and sales of new products. Levothyroxine Sodium sales increased as Wholesalers reduced their inventories and began to reorder the product in larger volumes in Fiscal 2006. Mail Order Pharmacy sales increased due to new product sales and the fact that this area of the industry is growing at a faster rate than the other areas. Retail Chain sales remained unchanged from the prior year, as new products sales replaced the loss of any existing products. Private label sales decreased due to our largest private label customer, Qualitest, receiving FDA approval in late November 05 to manufacture its own Primidone 50mg. Sales to the Private Label category may continue to decline, as Lannett does not actively pursue additional private label customers because of the lower margins and product label inventories required to service the category.

Cost of sales increased 8%, from \$31,416,908 in Fiscal 2005 to \$33,900,045 in Fiscal 2006. This increase is due in part to higher production volumes to meet increased sales demand. Gross margins were 47% in 2006, an improvement over 30% in 2005. Improvement was, in part, affected by the prior year write-off of short-dated Levothyroxine Sodium. , The prior year also experienced an increased return accrual, taken in anticipation of an unusually large return of Levothyroxine. The Levothyroxine related write-offs accounted for 10% of cost of sales in the prior year. Aside from the prior year one-time incidents related to Levothyroxine, the margins increased due to additional product offerings and higher effective pricing. Despite new entrants to the Primidone market, the Company was able to maintain its market share and competitive price. The Company was also able to take advantage of its new products and the higher margin on these products. Depending on future market conditions for each of the Company s products, changes in the future sales product mix may occur. These changes may affect the gross profit percentage in future periods.

Research and development ( R&D ) expenses increased by \$1,836,943, or 29%. The increase in R&D is primarily due to an increase in raw material consumption for production of experimental batches.

Selling, general and administrative expenses increased \$2.6 million, or 28%. The increase is primarily due to the adoption of SFAS 123(R) which contributed stock compensation expense of \$1.4 million.

Amortization expense decreased \$3.7 million from \$5.5 million to \$1.8 million due to the write down of the intangible asset that occurred in March 2005. Please see further description of this event in Note 1 of the Notes to Consolidated Financial Statements, under the heading Intangible Assets.

As a result of the revaluation of the intangible asset, the Company s financial results changed from an operating loss of (\$53,639,659) in Fiscal 2005 to an operating income of \$8,453,918 in Fiscal 2006.

The Company s income tax classification changed to an income tax expense of \$3,561,175 from an income tax benefit of (\$21,045,902) in Fiscal 2005. The effective tax rate increased slightly from 39% in 2005 to 41% in 2006.

The Company reported net income of \$4,968,922 for Fiscal 2006, or \$.21 basic and diluted income per share, compared to net loss of (\$32,779,596) for Fiscal 2005, or (\$1.36) basic and diluted loss per share.

#### Results of Operations Fiscal 2005 compared to Fiscal 2004

Net sales decreased by 30%, from \$63,781,219 in Fiscal 2004 to \$44,901,645 in Fiscal 2005. The decrease was generally due to increased competition in the generic drug market that affected most of the Company s products. The increased competition, both from existing competitors and new entrants, has resulted in significant price pressures. Sales of the Levothyroxine Sodium line of products declined by \$4,948,000 due in part to a delay in the AB rating, which gave the competition a market advantage. The sales of Unithroid tablets declined \$2,036,000. Sales of Butalbital with Aspirin and Caffeine capsules declined \$3,240,000. Sales of Primidone tablets, seeing competition for the first time, declined \$4,390,000. Sales of Digoxin tablets declined \$3,480,000. New product sales contributed \$500,000 to the sales in Fiscal 2005. Year over year decline in existing product sales were a result of volume declines of 8% and price reductions of 22%.

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

Customer Category	Fiscal 2005 Net Sales	Fiscal 2004 Net Sales	Fiscal 2003 Net Sales
Wholesaler/Distributor	\$24.8 million	\$43.0 million	\$20.6 million
Retail Chain	\$10.5 million	\$12.1 million	\$ 9.9 million
Mail-Order Pharmacy	\$ 5.9 million	\$ 4.3 million	\$ 2.6 million
Private Label	\$ 3.7 million	\$ 4.4 million	\$ 9.4 million

Total

\$44.9 million

\$63.8 million

\$42.5 million

Sales in every category, with the exception of Mail-Order Pharmacy, decreased in Fiscal 2005. This is a result of the factors described in the previous paragraph. Sales to mail order pharmacy increased due to an increase in product lines offered, and a general increase across the business sector. Sales to wholesalers/distributors declined mainly due to the loss of primary position on the Amerisource Bergen pro-generic contract and a decrease in pricing with all wholesalers and distributors due to the competitive market.

Cost of sales increased by 17%, from \$26,856,875 in Fiscal 2004 to \$31,416,908 in Fiscal 2005. These costs include raw materials/cost of finished goods purchased and resold, production expenses, and shipping expenses. The cost of purchased materials increased approximately \$4,071,000, shipping expenses increased by approximately \$199,000 and other miscellaneous production-related expenses increased by approximately \$290,000. Gross margin (exclusive of amortization of intangible assets) decreased from 58% in Fiscal 2004 to 30% in Fiscal 2005. The decrease in gross profit margin was a result of the accrual of additional return of Levothyroxine Sodium. In addition to decreases in net weighted average prices of some of the Company s products due to increased market competition, increases in direct and indirect costs as well as a change in the product sales mix also resulted in lower gross margins. Please see additional information regarding the Company s gross margin in Note 1 of the Notes to Consolidated Financial Statements, under the heading Intangible Assets.

Research and development ( R&D ) expenses increased by 6%, from \$5,895,096 in Fiscal 2004 to \$6,265,522 in Fiscal 2005. The increase in R&D is a result of contracting formulation development out to a third party laboratory for product development for \$940,000 in Fiscal 2005, and an increase of raw material consumption of approximately \$1,200,000 used in the development and formulation of new products not yet

approved by the FDA. These costs were offset by a decrease in Bio studies of \$1,185,000 from Fiscal 2004 to Fiscal 2005.

Selling, general and administrative expenses increased by 4%, from \$8,863,966 in Fiscal 2004 to \$9,194,377 in Fiscal 2005. This increase is primarily a result of Sarbanes-Oxley related accounting and consulting costs of approximately \$520,000 and an increase in insurance of \$160,000. These increases were partially offset by savings in various other expense accounts.

The Company s interest expense increased from approximately \$45,000 in Fiscal 2004 to approximately \$351,000 in Fiscal 2005 as a result of the borrowing under the 2003 Loan Financing which included a mortgage loan, equipment loan and construction loan, each of which started in Fiscal 2005. Interest income increased from approximately \$24,000 in Fiscal 2004 to approximately \$165,622 in Fiscal 2005, as a result of an investment of excess cash in marketable securities and a higher cash balance.

As a result of the items discussed above, and the impairment charge of \$46,147,000 taken on the intangible asset (see note 1 of the consolidated financial statements), the Company s financial results changed from an operating income of \$20,830,969 in Fiscal 2004 to an operating loss of (\$53,639,659) in Fiscal 2005.

The Company s income tax classification changed from an income tax expense of \$7,594,316 in Fiscal 2004 to an income tax benefit of (\$21,045,902) in Fiscal 2005 as a result of the Company s pre-tax loss. The effective tax rate increased slightly from 36.5% in 2004 to 39.1% in 2005.

The Company reported net loss of (\$32,779,596) for Fiscal 2005, or (\$1.36) basic and diluted loss per share, compared to net income of \$13,215,454 for Fiscal 2004, or \$0.63 basic and diluted earnings per share.

#### **Liquidity and Capital Resources**

Net cash provided by operating activities of \$3,529,949 for the year ended June 30, 2006 was attributable to net income of \$4,968,922 as adjusted for the effects of non-cash items of \$8,140,312 and net changes in operating assets and liabilities totaling (\$9,579,285). Significant changes in operating assets and liabilities are described below.

- 1. An increase in trade accounts receivable of \$11,924,058 was partially due to increased sales in the most recent months of Fiscal 2006. The May to June sales figures for 2006 were \$7.2 million greater than the same period in Fiscal 2005. Also, the prior year had 3 customers with substantial credit balances at June 30, 2005. The Company monitors its liquidity in a number of ways. A Days Sales Outstanding (DSO) calculation is used to determine our ability to collect accounts receivable. DSO is analyzed in two ways, Gross A/R compared to Average Daily Gross Sales, and Net A/R (net of reserve for chargebacks and rebates) compared to Average Daily Net Sales. For the first, second, third and fourth quarters of Fiscal 2006, this Gross DSO amounted to 64 days, 68 days, 76 days and 78 days, respectively. The increase is due to delayed processing of credits from wholesale customers. Some delays were the result of customers failing to report all credits, while some were the responsibility of the Company to act upon. For the first, second, third and fourth quarters of Fiscal 2006, this Net DSO amounted to 26 days, 49 days, 52 days and 56 days, respectively. Net DSO was low in the first quarter of Fiscal 2006 due to two significant customers that had credit balances at September 30, 2005. These customers balances returned to normal balances due from the customers as additional sales were made.
- 2. Inventory increased \$1,487,734 due to the increase in quantity of products offered by the Company. The Company offers 11 more drugs than was offered in the previous year. As a result, inventory increases were needed to be prepared for increasing product launches. As our product offerings increase, higher inventory levels are expected, both in dollars and quantities. This investment in inventory is vital to Lannett s strategy of maintaining our reputation of always in-stock.

- 3. A decrease in prepaid taxes of \$745,482 is primarily attributable to taxable income in Fiscal 2006 compared to a loss in Fiscal 2005.
- 4. An increase in accrued expenses of \$3,550,257 was due to increased personnel expenses, professional expenses, and a receiving accrual for materials received at the end of the fiscal year. These fluctuations are in the normal course of business.

The net cash used in investing activities of \$6,035,726 for the twelve months ended June 30, 2006 was attributable to the Company s loan to an API provider of \$3,182,498. The Company also had capital expenditures of \$5,114,626 primarily related to several investments in production equipment and facility improvements. This was offset by the sale of \$2,219,848 of its marketable securities.

On December 13, 2005 the Company refinanced \$5,750,000 of its debt through the Philadelphia Industrial Development Corporation (PIDC) and the Pennsylvania Industrial Development Authority (PIDA). With the proceeds from the refinancing, the Company paid off its Mortgage and Construction Loan, as well as a portion of the Equipment Ioan. These Ioans were with Wachovia Bank. The Company financed \$4,500,000 through the Immigrant Investor Program (PIDC Regional Center, LP III). The Company will pay a bi-annual interest payment at a rate equal to two and one-half percent per annum. The outstanding principal balance shall be due and payable 5 years (60 months) from January 1, 2006. The remaining \$1,250,000 is financed through the PIDA Loan. The Company is required to make equal payments each month for 180 months starting February 1, 2006 with interest of two and three-quarter percent per annum. The PIDA Loan has \$1,221,780 outstanding as of June 30, 2006 with \$69,090 currently due. None of the PIDC Loan is currently due.

An additional \$500,000 was financed through the Pennsylvania Department of Community and Economic Development Machinery and Equipment Loan Fund. The Company is required to make equal payments for 60 months starting May 1, 2006 with interest of two and three quarter percent per annum. As of June 30, 2006, \$476,560 is outstanding and \$95,019 is currently due.

In April 1999, the Company entered into a loan agreement (the Agreement ) with a governmental authority, the Philadelphia Authority for Industrial Development (the Authority or PAID ), to finance future construction and growth projects of the Company. The Authority issued \$3,700,000 in tax-exempt variable rate demand and fixed rate revenue bonds to provide the funds to finance such growth projects pursuant to a trust indenture ( the Trust Indenture ). A portion of the Company s proceeds from the bonds was used to pay for bond issuance costs of approximately \$170,000. The Trust Indenture requires that the Company repay the Authority loan through installment payments beginning in May 2003 and continuing through May 2014, the year the bonds mature. The bonds bear interest at the floating variable rate determined by the organization responsible for selling the bonds (the remarketing agent ). The interest rate fluctuates on a weekly basis. The effective interest rate at June 30, 2006 was 4.13%. At June 30, 2006, the Company has \$955,566 outstanding on the Authority loan, of which \$654,996 is classified as currently due. The remainder is classified as a long-term liability. In April 1999, an irrevocable letter of credit of \$3,770,000 was issued by Wachovia Bank, National Association (Wachovia) to secure payment of the Authority Loan and a portion of the related accrued interest. At June 30, 2006, no portion of the letter of credit has been utilized.

The Equipment Loan consists of a term loan with a maturity date of five years. The Company, as part of the 2003 Loan Financing agreement with Wachovia, is required to make equal payments of principal and interest. As of June 30, 2006, the Company has outstanding \$1,042,786 under the Equipment Loan, of which \$320,520 is classified as currently due.

The financing facilities under the 2003 Loan Financing, of which only the Equipment Loan is left, bear interest at a variable rate equal to the LIBOR rate plus 150 basis points. The LIBOR rate is the rate per annum, based on a 30-day interest period, quoted two business days prior to the first day of such interest period for the offering by leading banks in the London interbank market of dollar deposits. As of June 30, 2006, the interest rate for the 2003 Loan Financing (of which only the Equipment loan remains) was 6.85%.

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

The terms of the Equipment loan require that the Company meet certain financial covenants and reporting standards, including the attainment of standard financial liquidity and net worth ratios. As of June 30, 2006, the Company has complied with such terms, and successfully met its financial covenants.

The following table represents annual contractual obligations as of June 30, 2006

**Contractual Obligations** 

	Total	Ι	less than 1 year	1 3 years	3 5 years	n	nore than 5 years
Long-Term Debt Operational Leases Purchase Obligations Other	\$ 8,196,692 1,983,288 164,000,000	\$	1,130,706 331,972 17,000,000	\$ 1,283,600 783,802 37,000,000	\$ 4,924,653 799,570 41,000,000	\$	857,733 67,944 69,000,000
Total	\$ 174,179,980	\$	18,462,678	\$ 39,067,402	\$46,724,223	\$	69,925,677

#### **Prospects for the Future**

The Company has several generic products under development. These products are all orally-administered topical and parenteral products designed to be generic equivalents to brand named innovator drugs. The Company s developmental drug products are intended to treat a diverse range of indications. As the oldest generic drug manufacturer 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, so as to make it attractive for Lannett to reconsider manufacturing and selling it. If the Company makes the determination to introduce one of these products into the consumer marketplace, it must review the ANDA and related documentation to ensure that the approved product specifications, formulation and other factors meet current FDA requirements for the marketing of that drug. The Company would then redevelop the product and submit it to the FDA for supplemental approval. The FDA is approval process for ANDA supplements is similar to that of a new ANDA. Generally, in these situations, the Company must file a supplement to the FDA for the applicable ANDA, informing the FDA of any significant changes in the manufacturing process, the formulation, or the raw material supplier of the previously-approved ANDA.

A majority of the products in development represent either previously approved ANDAs that the Company is planning to reintroduce (ANDA supplements), or new formulations (new ANDAs). The products under development are at various stages in the development cycle formulation, scale-up, and/or clinical testing. Depending on the complexity of the active ingredient s chemical characteristics, the cost of the raw material, the FDA-mandated requirement of bioequivalence studies, the cost of such studies and other developmental factors, the cost to develop a new generic product varies. It can range from \$100,000 to \$1 million. Some of Lannett s developmental products will require bioequivalence studies, while others will not depending on the FDA s Orange Book classification. Since the Company has no control over the FDA review process, management is unable to anticipate whether or when it will be able to begin producing and shipping additional products.

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.

Occasionally the Company will work on developing a drug product that does not require FDA approval. The FDA allows generic manufacturers to manufacture and sell products which are equivalent to innovator drugs which are grand-fathered, under FDA rules, prior to the passage of the Hatch-Waxman Act of 1984. The FDA allows generic manufacturers to produce and sell generic versions of such grand-fathered products by simply performing and internally documenting the product stability over a period of time. Under this scenario, a generic company can forego the time required for FDA ANDA approval.

The Company signed supply and development agreements with Olive Healthcare, of India; Orion Pharma, of Finland; Azad Pharma AG, of Switzerland, and is in negotiations with companies in Israel and Greece 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 such products, and increase future revenues and income. The majority of the Company s R&D projects are being developed in-house under Lannett s direct supervision and with Company personnel. Hence, the Company does not believe that its outside contracts for product development and manufacturing supply are material in nature, nor is the Company substantially dependent on the services rendered by such outside firms. 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.

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

The Company plans to enhance relationships with strategic business partners, including providers of product development research, raw materials, active pharmaceutical ingredients as well as finished goods. Management believes that mutually beneficial strategic relationships in such areas, including potential financing arrangements, partnerships, joint ventures or acquisitions, could allow for potential competitive advantages in the generic pharmaceutical market. For example, the Company has entered into prepayment arrangements in exchange for discounted purchase prices on certain active pharmaceutical ingredients (API) and oral dosage forms. The Company has also arranged for a loan to a certain API provider as well as continued funding of recent operations of this API provider that should facilitate the availability of difficult to source material in the future. The Company plans to continue to explore such areas for potential opportunities to enhance shareholder value.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Consolidated Financial Statements and Report of the Independent Registered Public Accounting Firm filed as a part of this Form 10-K are listed in the Exhibit Index filed herewith.

# ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.



#### **ITEM 9A. CONTROLS AND PROCEDURES**

#### Disclosure Controls and Procedures

We carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 (the Exchange Act ), as amended for financial reporting as of June 30, 2006. Based on that evaluation, our chief executive officer and chief financial officer concluded that these controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported as specified in Securities and Exchange Commission rules and forms. There were no changes in these controls or procedures identified in connection with the evaluation of such controls or procedures that occurred during our last fiscal quarter, or in other factors that have materially affected, or are reasonably likely to materially affect these controls or procedures.

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

#### Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the chief executive officer and chief financial officer and effected by the board of directors and management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of our management and board of directors;

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2006. In making this assessment, our management used the criteria set forth by the Committee of

Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on our assessment, our management believes that, as of June 30, 2006, our internal control over financial reporting is effective. Please see the Report of Independent Registered Public Accounting Firm at the beginning of the Company s Financial Statements. **ITEM 9B. OTHER INFORMATION** 

ITEM 9B. OTHER INFORMATION None

#### PART III ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT Directors and Executive Officers

The directors and executive officers of the Company are set forth below:

	Age	Position
Directors:		
William Farber	74	Chairman of the Board
Ronald A. West	72	Vice Chairman of the Board, Director
Myron Winkelman	68	Director
Albert Wertheimer	63	Director
Garnet Peck	76	Director
Kenneth Sinclair	60	Director
Jeffrey Farber	46	Director
Officers:		
Arthur P. Bedrosian	60	President and Chief Executive Officer
Brian J. Kearns	40	Vice President of Finance, Treasurer, Secretary and Chief Financial Officer
Kevin Smith	46	Vice President of Sales and Marketing
Bernard Sandiford	77	Vice President of Operations
William Schreck William Farber <b>B</b> Ph. wa	57 as elected as C	Vice President of Logistics hairman of the Board of Directors in August 1991 From April 1993 to the

**William Farber R. Ph.** was elected as Chairman of the Board of Directors in August 1991. From April 1993 to the end of 1993, Mr. Farber was the President and a director of Auburn Pharmaceutical Company. From 1990 through March 1993, Mr. Farber served as Director of Purchasing for Major Pharmaceutical Corporation. From 1965 through 1990, Mr. Farber was the Chief Executive Officer of Michigan Pharmacal Corporation. Mr. Farber is a registered pharmacist in the State of Michigan.

Albert I. Wertheimer was elected a Director of the Company in September 2004. Dr. Wertheimer has a long and distinguished career in various aspects of pharmacy, health care, education and pharmaceutical research. Since 2000, Dr. Wertheimer has been a professor at the School of Pharmacy at Temple University, and director of its Center for Pharmaceutical Health Services Research. From 1997 to 2000, Dr. Wertheimer was Director of Outcomes Research and Management at Merck & Co., Inc. In addition to his academic responsibilities, he is the author of 22 books and more than 360 journal articles. Dr. Wertheimer also provides consulting services to institutions in the pharmaceutical industry. Dr. Wertheimer s academic experience includes professorships and other faculty and administrative positions at several educational institutions, including the Medical College of Virginia, St. Joseph s University, Philadelphia College of Pharmacy and Science and the University of Minnesota. Dr. Wertheimer s

previous professional experience includes pharmacy services in commercial and non-profit environments. Professor Wertheimer is a licensed pharmacist in five states, and is a member of several health associations, including the American Pharmacists Association and the American Public Health Association. Dr. Wertheimer is the editor of the

Journal of Pharmaceutical Finance and Economic Policy ; and he has been on the editorial board of the Journal of Managed Pharmaceutical Care, Medical Care, and other healthcare journals. Dr. Wertheimer has a Bachelor of Science Degree in Pharmacy from the University of Buffalo, a Master of Business Administration from the State University of New York at Buffalo, a Physical Science Doctorate from Purdue University and a Post Doctoral Fellowship from the University of London, St. Thomas Medical School.

Ronald A. West was elected a Director of the Company in January 2002. In September 2004, Mr. West was elected Vice Chairman of the Board of Directors. Mr. West is currently a Director of Beecher Associates, an industrial real estate investment company, R&M Resources, an investment and consulting services company and North East Staffing, Inc., an employee services company. Prior to this, from 1983 to 1987, Mr. West, financial expert for the audit committee at Lannett, served as Chairman and Chief Executive Officer of Dura Corporation, an original equipment manufacturer of automotive products and other engineered equipment components. In 1987, Mr. West sold his ownership position in Dura Corporation, at which time he retired from active management positions. Mr. West was employed at Dura Corporation since 1969. Prior to this, he served in various financial management positions with TRW, Inc., Marlin Rockwell Corporation and National Machine Products Group, a division of Standard Pressed Steel Company. Mr. West studied Business Administration at Michigan State University and the University of Detroit. Myron Winkelman, R. Ph. was elected a Director of the Company in June 2003. Mr. Winkelman has significant career experience in various aspects of pharmacy and health care. He is currently President of Winkelman Management Consulting (WMC), which provides consulting services to both commercial and governmental clients. He has served in this position since 1994. Mr. Winkelman has recently managed multi-state drug purchasing initiatives for both Medicaid and state entities. Prior to creating WMC, he was a senior executive with ValueRx, a large pharmacy benefits manager, and served for many years as a senior executive for the Revco, Rite Aid and Perry Drug chains. While at ValueRx, Mr. Winkelman served on the Board of Directors of the Pharmaceutical Care Management Association. He belongs to a number of pharmacy organizations, including the Academy of Managed Care Pharmacy and the Michigan Pharmacy Association. Mr. Winkelman is a registered pharmacist and holds a Bachelor of Science Degree in Pharmacy from Wayne State University.

**Garnet Peck, PhD**, was elected a director of the Company in September 2005. Dr. Peck is Professor Emeritus of the Industrial and Physical Pharmacy department at Purdue University, where he has held numerous positions since 1967. Earlier in his career, Dr. Peck served as senior scientist and group leader at Mead Johnson Research Center and as a Pharmacist in the United States Army. Dr. Peck has also consulted for some of the largest pharmaceutical companies in the world and served on several committees of the United States Food and Drug Administration. Dr. Peck has chaired numerous pharmaceutical conferences and is a published author and frequent lecturer. He earned his Bachelor of Science Degree in Pharmacy, with distinction, from Ohio Northern University, and a Master of Science degree and Doctorate Degree in Industrial Pharmacy from Purdue University.

**Kenneth Sinclair, PhD**, was elected director of the Company in September 2005. Dr. Sinclair is currently Professor and Chair of the Accounting Department at Lehigh University, where he began his academic career in 1972. Dr. Sinclair has been recognized for his teaching innovation, held leadership positions with professional accounting organizations and served on numerous academic and advisory committees. He has received a number of awards and honors for teaching and service, and has researched and written on a myriad of subjects related to accounting. Dr. Sinclair earned a Bachelor of Business Administration degree in Accounting, a Master of Science degree in accounting and a Doctorate Degree in Business Administration from the University of Massachusetts.

Jeffrey Farber was elected director of the Company, Inc in May 2006. Jeffrey Farber joined the Company in August 2003 as Secretary. For the past 13 years, Mr. Farber has been President and the owner of Auburn Pharmaceutical ( Auburn ), a national generic pharmaceutical distributor. Prior to starting Auburn, Mr. Farber served in various positions at Major Pharmaceutical ( Major ), where he was employed for over 15 years. At Major, Mr. Farber was involved in sales, purchasing and eventually served as President of the mid-west division. Mr. Farber also spent time working at Major s manufacturing division Vitarine Pharmaceuticals where he served on its Board of Directors. Mr. Farber graduated from Western Michigan University with a Bachelors of Science Degree in Business Administration and participated in the Pharmacy Management Graduate Program at Long Island University. Mr. Farber is the son of William Farber, the Chairman of the Board of Directors and the principal shareholder of the Company.

**Arthur P. Bedrosian, J.D.** was elected President of the Company in May 2002 and CEO in January of 2006. Prior to this, he served as the Company s Vice President of Business Development from January 2002 to April 2002, and as a Director from February 2000 to January 2002. Mr. Bedrosian has operated generic drug manufacturing, sales, and marketing businesses in the healthcare industry for many years. Prior to joining the Company, from 1999 to 2001, Mr. Bedrosian served as President and Chief Executive Officer of Trinity Laboratories, Inc., a medical device and drug manufacturer. Mr. Bedrosian also operated Pharmaceutical Ventures Ltd, a healthcare consultancy and Interal Corporation, a computer consultancy to Fortune 100 companies. Mr. Bedrosian holds a Bachelor of Arts Degree in Political Science from Queens College of the City University of New York and a Juris Doctorate from Newport University in California.

**Brian J. Kearns** was elected Vice President of Finance, Treasurer and Chief Financial Officer of the Company in March 2005 and Secretary in May 2005. Prior to joining the Company, Mr. Kearns served as the Executive Vice President, Treasurer and Chief Financial Officer of MedQuist Inc., a healthcare information management company, from 2000 through 2004. Prior to joining MedQuist, Mr. Kearns was Vice President and Senior Health Care IT analyst at Banc of America Securities from 1999 trough 2000. Mr. Kearns also held various positions with Salomon Smith Barney from 1994 through 1998, including Senior Analyst of Business Services Equity Research. Prior to that, Mr. Kearns held several financial management positions during his seven years at Johnson & Johnson. Mr. Kearns holds a Bachelor of Science degree in Finance from Lehigh University and a Master of Business Administration degree from Rider University, where he matriculated with distinction.

**Kevin Smith** joined the Company in January 2002 as Vice President of Sales and Marketing. Prior to this, from 2000 to 2001, he served as Director of National Accounts for Bi-Coastal Pharmaceutical, Inc., a pharmaceutical sales representation company. Prior to this, from 1999 to 2000, he served as National Accounts Manager for Mova Laboratories Inc., a pharmaceutical manufacturer. Prior to this, from 1991 to 1999, Mr. Smith served as National Sales Manager at Sidmak Laboratories, a pharmaceutical manufacturer. Mr. Smith has extensive experience in the generic sales market, and brings to the Company a vast network of customers, including retail chain pharmacies, wholesale distributors, mail-order wholesalers and generic distributors. Mr. Smith has a Bachelor of Science Degree in Business Administration from Gettysburg College.

**Bernard Sandiford** joined the Company in November 2002 as Vice President of Operations. Prior to this, from 1998 to 2002, he was the President of Sandiford Consultants, a firm specializing in providing consulting services to drug manufacturers for Good Manufacturing Practices and process validations. His previous employment included senior operating positions with Halsey Drug Company, Barr Laboratories, Inc., Duramed Pharmaceuticals, Inc., and Revlon Health Care Group. In addition to these positions, Mr. Sandiford performed various consulting assignments regarding Good Manufacturing Practices for several companies in the pharmaceutical industry. Mr. Sandiford has a Bachelor of Science Degree in Chemistry from Long Island University.

**William Schreck** joined the Company in January 2003 as Materials Manager. In May 2004, he was promoted to Vice President of Logistics. Prior to this, from 1999 to 2001, he served as Vice President of Operations at Nature s Products, Inc., an international nutritional and over-the-counter drug product manufacturing and distribution company. Mr. Schreck s prior experience also includes executive management positions at Ivax Pharmaceuticals, Inc., a division

of Ivax Corporation, Zenith-Goldline Laboratories and Rugby-Darby Group Companies, Inc. Mr. Schreck has a Bachelor of Arts Degree from Hofstra University.

To the best of the Company s knowledge, there have been no events under any bankruptcy act, no criminal proceedings and no judgments or injunctions that are material to the evaluation of the ability or integrity of any director, executive officer, or significant employee during the past five years.

## Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires the Company s directors, officers, and persons who own more than 10% of a registered class of the Company s equity securities to file with the SEC reports of ownership and changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater-than-10% stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file.

Based solely on review of the copies of such reports furnished to the Company or written representations that no other reports were required, the Company believes that during Fiscal 2006, all filing requirements applicable to its officers, directors and greater-than-10% beneficial owners were complied with.

## **Code of Ethics and Financial Expert**

The Company has adopted the Code of Professional Conduct (the code of ethics ), a code of ethics that applies to the Company s Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and Corporate Controller, and other finance organization employees. The code of ethics is publicly available on our website at <u>www.lannett.com.</u> If the Company makes any substantive amendments to the finance code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to our Chief Executive Officer, Chief Financial Officer, or Chief Accounting Officer and Corporate Controller, we will disclose the nature of such amendment or waiver on our website or in a report on Form 8-K.

The Board of Directors has determined that Mr. West, current director of Lannett as well as director of Beecher Associates, an industrial real estate investment company, R&M Resources, an investment and consulting services company and North East Staffing, Inc., an employee services company and previously the Chief Executive Officer of Dura Corporation, is the audit committee financial expert as defined in section 3(a)(58) of the Exchange Act and the related rules of the Commission.

## **ITEM 11. EXECUTIVE COMPENSATION**

#### **Summary Compensation Table**

The following table summarizes all compensation paid to or earned by the named executive officers of the Company for Fiscal 2006, Fiscal 2005 and Fiscal 2004.

	Annua	l Compensation			•	Term Compens Awards	sation Payouts	
(a)	(b)	(c)	( <b>d</b> )	(e)	( <b>f</b> )	(g)	(h)	(i)
Name and	~ /				~ /	Securities	LTIP	All Other
				Other	Restricted	Under-lying		
Principal				Annual	Stock	Options/	PayoutsC	ompensation
	Fiscal							
Position	Year	Salary <sup>1</sup>	Bonus	Compensati	Ønward(s)	SARs	Amount	Amounts
Arthur P.								
Bedrosian <sup>2</sup>	2006	278,641	92,970	0	0	25,000	0	3,003
President and								
Chief	2005	236,709	168,750	0	0	0	0	0
Executive Officer	2004	212,548	240,000	0	0	177,900	0	0
Brian Kearns	2006	193,572	20,712	0	0	0	0	1,526
Chief Financial								
Officer,	2005	47,115	0	0	0	100,000	0	0
Treasurer <sup>3</sup>	2004	0	0	0	0	0	0	0
Bernard								
Sandiford	2006	178,883	54,898	0	0	12,000	0	5,146
Vice President of	2005	140,932	58,500	0	0	0	0	0
Operations	2004	159,440	78,000	0	0	0	0	0
Kevin Smith	2006	191,810	66,895	0	0	12,000	0	6,212
Vice President of	2005	171,578	95,518	0	0	0	0	0
Sales and								
Marketing	2004	160,488	158,410	0	0	0	0	0
William Schreck	2006	169,134	60,000	0	0	12,000	0	6,604
Vice President of	2005	140,862	73750	0	0	0	0	0
Logistics	2004	103,927	37,500	0	0	0	0	0

- Includes car allowance, and for Bernard Sandiford, salary contains apartment allowance.
- 2 Mr. Bedrosian joined the Company on January 24, 2002 as Vice President of Business Development. On May 5, 2002, he was elected President of the Company. On January 3, 2006, he was promoted to President and Chief Executive Officer.
- <sup>3</sup> Brian Kearns was hired March 14, 2005 as Chief Financial Officer.

#### Aggregated Options/SAR Exercises and Fiscal Year-end Options/SAR Values

(a)	(b)	(c)	(d) Number of Securities	(e) Value of Unexercised
	Shares		Underlying Unexercised	In-the-Money Options at
	Acquired On	Value	Options at FY-End Exercisable/	FY-End Exercisable/
Name	Exercise	Realized	Unexercisable	Unexercisable
Arthur P. Bedrosian				
President and Chief Executive Officer	0	0	167,900/35,000	\$18,360/0
	0	0	33,333/66,667	\$ 0/0

## Edgar Filing: LANNETT CO INC - Form 10-K

Brian Kearns				
Chief Financial Officer, Treasurer				
Bernard Sandiford				
Vice President of Operations	0	0	30,380/19,500	\$ 0/0
*				
	45			

(a) Name	(b) Shares Acquired On Exercise	(c) Value Realized	(d) Number of Securities Underlying Unexercised Options at FY-End Exercisable/ Unexercisable	(e) Value of Unexercised In-the-Money Options at FY-End Exercisable/ Unexercisable
Kevin Smith Vice President of Sales and Marketing	0	0	54,093/29,667	\$ 0/0
William Schreck Vice President of Logistics <b>Compensation of Directors</b>	0	0	17,745/12,000	\$ 0/0

Non-employee directors received a retainer of \$2,500 per month as compensation for their services during Fiscal 2006. They also were compensated \$1,000 per Board meeting. There were twelve Board meetings held during Fiscal 2006. Additional committees of the Board of Directors include the Audit Committee, the Compensation Committee and the Strategic Planning Committee. Committee members received \$1,000 and the Chairman received \$1,500 per Committee meetings attended. There were seven Audit Committee meetings, six Strategic Planning Committee meetings and seven Compensation Committee meetings held during Fiscal 2006. Directors are also reimbursed for expenses incurred in attending Board and Committee meetings. There were no stock options granted to directors in Fiscal 2006.

#### **Employment Agreements**

The Company has entered into employment agreements with Arthur P. Bedrosian, Brian Kearns, Kevin Smith, Bill Schreck, and Bernard Sandiford (the Named Executives ). Each of the agreements provide for an annual base salary and eligibility to receive a bonus. The salary and bonus amounts of the Named Executives are determined by the Board of Directors. Additionally, the Named Executives are eligible to receive stock options, which are granted at the discretion of the Board of Directors, and in accordance with the Company s policies regarding stock option grants. Under the agreements, the Named Executive employees may be terminated at any time with or without cause, or by reason of death or disability. In certain termination situations, the Company is liable to pay severance compensation to the Named Executive of between one year and three years.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth, as of June 30, 2006, information regarding the security ownership of the directors and certain executive officers of the Company and persons known to the Company to be beneficial owners of more than five (5%) percent of the Company s common stock:

		Excluding Op Debentu		Including Options (*)		
Name and Address of		Number	Percent	Number		
Beneficial Owner	Office	of Shares	of Class	of Shares	Percent of Class	
Directors/Executive Office	ers:					
William Farber 9000 State Road Philadelphia, PA 19136	Chairman of the Board	<b>13,619,129</b> <sup>1</sup>	56.41%	13,689,963 <sup>2</sup>	55.66%	
Albert Wertheimer 9000 State Road Philadelphia, PA 19136	Director	1,000	0.00%	7,667 <sup>3</sup>	0.03%	
Myron Winkelman 9000 State Road Philadelphia, PA 19136	Director	1,000	0.00%	24,3334	0.10%	
Ronald A. West 9000 State Road Philadelphia, PA 19136	Director	7,310	0.03%	<b>43,925</b> <sup>5</sup>	0.18%	
Jeffrey Farber 9000 State Road Philadelphia, PA 19136	Director	147,120	0.61%	162,1206	0.66%	
Arthur Bedrosian 9000 State Road Philadelphia, PA 19136	President and Chief Executive Officer	<b>460,997</b> <sup>7</sup>	1.91%	617,897 <sup>8</sup>	2.51%	
Brian Kearns 9000 State Road Philadelphia, PA 19136	Chief Financial Officer	0	0.00%	33,333 <sup>9</sup>	0.14%	
Kevin Smith 9000 State Road Philadelphia, PA 19136	Vice President of Sales and Marketing	1,236	0.00%	61,996 <sup>10</sup>	0.25%	
		Δ	0.000	17 74511	0.07.07	
		0	0.00%	17,745 <sup>11</sup>	0.07%	

William Schreck 9000 State Road Philadelphia, PA 19136	Vice President of Logistics				
Bernard Sandiford 9000 State Road Philadelphia, PA 19136	Vice President of Operations	287	0.00%	30,667 <sup>12</sup>	0.12%
All directors and executive officers as a group (10 persons)		14,238,079	58.97%	14,689,646	59.73%
		47			

- Includes 300,000 shares owned jointly by William Farber and his spouse Audrey Farber.
- 2 Includes 37,500 vested options to purchase common stock at an exercise price of \$7.97 per share. 16,667 vested options to purchase common stock at an exercise price of \$17.36. 16,667 vested options to purchase common stock at an exercise price of \$16.04.
- <sup>3</sup> Includes 6,666 vested options to purchase common stock at an exercise price of \$9.02 per share.
- <sup>4</sup> Includes 10,000 vested options to purchase common stock at an exercise price of \$17.36. 13,333 vested options to purchase common stock at an exercise price of \$16.04.

5 Includes 9,948 vested options to purchase common stock at an exercise price of \$7.97 per share, 10,000 vested options to purchase common stock at an exercise price of \$17.36 per share, and 16,667 vested options to purchase common stock at an exercise price of \$16.04.

<sup>6</sup> Includes 6,667 vested options to purchase common stock at an exercise price of \$17.36 per share and 8,333 vested options to purchase common stock at an exercise price of \$16.04.

7 Includes 27,450 shares owned by Arthur Bedrosian s wife, Shari Bedrosian and 9,000 shares owned by Arthur Bedrosian s daughter, Talin Bedrosian. Mr. Bedrosian disclaims beneficial

ownership of these shares.

8

Includes 18,000 vested options to purchase common stock at an exercise price of \$4.63 per share, 96,900 vested options to purchase common stock at an exercise price of \$7.97 per share, 22,000 vested options to purchase common stock at an exercise price of \$17.36, and 20,000 vested options to purchase common stock at an exercise price of \$16.04.

- <sup>9</sup> Includes 33,333 vested options to purchase common stock at an exercise price of \$6.75 per share.
- Includes 38,760 vested options to purchase common stock at an exercise price of \$7.97 per share, 8,667 vested options to purchase common stock at an exercise price of \$17.36, and 13,333

vested options to purchase common stock at an exercise price of \$16.04 per share.

Includes 17,745 vested options to purchase common stock at an exercise price of \$11.27 per share.

12 Includes 15,380 vested options to purchase common stock at an exercise price of \$11.27 per share, 6,667 vested options to purchase common stock at an exercise price of \$17.36, and 8,333 vested options to purchase common stock at an exercise price of \$16.04.

\* Assumes that all options exercisable within sixty days have been exercised, which results in 24,593,892 shares outstanding.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The Company had sales of approximately \$1,143,000, \$590,000, and \$590,000 during the fiscal years ended June 30, 2006, 2005 and 2004, respectively, to a generic distributor, Auburn Pharmaceutical Company. Jeffrey Farber (the related party), a board member and the son of the Chairman of the Board of Directors and principal shareholder of the Company, William Farber, is the owner of Auburn Pharmaceutical Company. Accounts receivable includes amounts due from the related party of approximately \$191,000 and \$179,000 at June 30, 2006 and 2005, respectively. In the Company s opinion, the terms of these transactions were not more favorable to the related party than would have been to a non-related party.

In January 2005, Lannett Holdings, Inc. entered into an agreement pursuant to which it purchased for \$100,000 and future royalty payments the proprietary rights to manufacture and distribute a product for which Pharmeral, Inc. owns the ANDA. This agreement is subject to Lannett Holdings, Inc. s ability to obtain FDA approval to use the proprietary rights. In the event that such FDA approval cannot be obtained, Pharmeral, Inc. must repay the \$100,000 to Lannett Holdings, Inc. Accordingly, the Company has treated this payment as a prepaid asset. Arthur Bedrosian, President of Lannett, was formerly the President and Chief Executive Officer of Pharmeral, Inc and currently owns 100% of Pharmeral, Inc. This transaction was approved by the Board of Directors of Lannett and, in its opinion, the terms were not more favorable to the related party than they would have been to a non-related party.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Grant Thornton LLP served as the independent auditors of the Company during Fiscal 2006, 2005 and 2004. No relationship exists other than the usual relationship between independent public accountant and client. The following table identifies the fees paid to Grant Thornton LLP in Fiscal 2006, 2005 and 2004.

		Audit-Related	<b>Tax Fees</b>	All Other	
	Audit Fees	<b>Fees</b> (1)	(2)	<b>Fees (3)</b>	<b>Total Fees</b>
Fiscal 2006:	\$282,000	\$	\$43,209	\$ 56,217	\$381,426
Fiscal 2005:	\$260,500	\$ 2,850	\$52,475	\$ 53,895	\$369,720
Fiscal 2004:	\$ 92,124	\$ 5,000	\$29,621	\$ 38,325	\$165,070

(1) Audit-related

fees include fees paid for preparation and participation in Board of Director meetings, and Audit Committee meetings.

- (2) Tax fees include fees paid for preparation of annual federal, state and local income tax returns, quarterly estimated income tax payments, and various tax planning services. Fiscal 2006 and 2005 include fees paid to Grant Thornton for services rendered during an IRS audit.
- (3) Other fees

include:

Fiscal 2006 Fees paid for services rendered in connection with quarterly reviews of the Company s SEC filings, assurance services, fixed asset review, a cost segregation study and review of various SEC correspondence.

## Edgar Filing: LANNETT CO INC - Form 10-K

Fiscal 2005 Other fees were for review of various SEC correspondence and fees for services rendered in connection with the Company s application to various local and state entities for benefits related to the Company s facility expansion.

Fiscal 2004 Fees paid for services rendered in connection with arbitrage calculations on certain tax exempt bond issues, review of stock option documentation, review of S-3 registration statement filing for the four million shares granted to JSP, review of various SEC correspondence and fees for services rendered in connection with the Company s application to various local and state entities for benefits related to the Company s facility expansion. The non-audit services provided to the Company by Grant Thornton LLP were pre-approved by the Company s audit committee. Prior to engaging its auditor to perform non-audit services, the Company s audit committee reviews the particular service to be provided and the fee to be paid by the Company for such service and assesses the impact of the service on the auditor s independence.

## PART IV

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

- (a) A list of the exhibits required by Item 601 of Regulation S-K to be filed as of this Form 10-K is shown on the Exhibit Index filed herewith
- (b) Consolidated Financial Statements and Supplementary Data

The following are included herein:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of June 30, 2006 and 2005

Consolidated Statements of Operations for each of the three years in the period ended June 30, 2006 Consolidated Statements of Changes in Shareholders Equity for each of the three years in the period ended June 30, 2006

Consolidated Statements of Cash Flows for each of the three years in the period ended June 30, 2006 Notes to Consolidated Financial Statements

Supplementary Data (Unaudited)

(c) On May 22, 2006, the Company filed a Form 8-K disclosing Item 5 and Item 9 thereof and including as an exhibit the press release announcing that Jeffrey Farber was elected to the Board of Directors of the Company.

On May 10, 2006, the Company filed a Form 8-K disclosing Item 2 and Item 9 thereof and including as an exhibit the press release announcing the Company s results of operations for the quarter and nine months ended March 31, 2006.

On January 17, 2006, the Company filed a Form 8-K disclosing Item 5 and Item 9 thereof and including as an exhibit the press release announcing that Arthur P. Bedrosian, Lannett Company s president, was appointed chief executive officer and director, succeeding William Farber.

#### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

#### LANNETT COMPANY, INC.

Vice President of Finance, Treasurer,

and Chief Financial Officer

Date: September 13, 2006	By:	/s/ Arthur P. Bedrosian Arthur P. Bedrosian, President and Chief Executive Officer
Date: September 13, 2006	By:	/s/ Brian Kearns Brian Kearns,

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: September 13, 2006	By: /s/ William Farber William Farber, Chairman of the Board of Directors
Date: September 13, 2006	By: /s/ Ronald West Ronald West, Director, Vice Chairman of the Board, Chairman of Compensation Committee
Date: <u>September 13, 2006</u>	By: /s/ Arthur P Bedrosian Arthur P. Bedrosian, Director, President and Chief Executive Officer
Date: September 13, 2006	By: /s/ Jeffrey Farber Jeffrey Farber, Director
Date: September 13, 2006	By: /s/ Garnet Peck Garnet Peck, Director
Date: September 13, 2006	By: /s/ Kenneth Sinclair Kenneth Sinclair,

Director, Chairman of Audit Committee

Date: September 13, 2006

Date: September 13, 2006

- By: /s/ Albert Wertheimer Albert Wertheimer, Director
- By: /s/ Myron Winkelman Myron Winkelman, Director, Chairman of Strategic Plan Committee