LANNETT CO INC
Form 10-K
October 09, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2007

OR

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

For the transition period from to

Commission File No. 001-31298

LANNETT COMPANY, INC.

(Exact name of registrant as specified in its charter)

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

9000 State Road

Philadelphia, Pennsylvania 19136

(215) 333-9000

(Address of principal executive offices and telephone number)

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

None

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

Common Stock, $.001 Par Value

(Title of class)

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

Yes o No x

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

Yes o No x

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

Yes x No o

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

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

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

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

Yes o No x

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

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

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

PART I

ITEM 1. DESCRIPTION OF BUSINESS

General

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

The Company is focused on increasing our share of the generic pharmaceutical market. We were able to increase net sales during fiscal 2007 by adding new products, and by increasing sales under existing distribution agreements. We plan to improve our financial performance by expanding our line of generic products, increasing unit sales to current customers and reducing overhead and administrative costs. Some of the new generic products sold by Lannett were developed and are manufactured by Lannett while other products are manufactured by other companies. The products manufactured by Lannett and those manufactured by others are identified in the section entitled **Products** in Item 1 of this Form 10-K.

Over the past several years, Lannett has consistently devoted resources to research and development (R&D) projects, including new generic product offerings. The costs of these R&D efforts are expensed during the

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

Research and Development Process

There are numerous stages in the generic drug development process:

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

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

3.) Clinical testing: After a successful scale-up of the generic drug batch, the Company then schedules and performs clinical testing procedures on the product if required by the FDA. These procedures, which are generally outsourced to third parties, include testing the absorption of the generic product in the human bloodstream compared to the absorption of the innovator drug. The results of this testing are then documented and reported to the Company to determine the success of the generic drug product. Success, in this context, means the successful comparison of the Company s product related to the innovator product. Since bioequivalence and a stable formula are the primary requirements for a generic drug approval (assuming the manufacturing plant is in compliance with the FDA s good manufacturing quality standards), lengthy and costly

clinical trials proving safety and efficacy, which are generally required by the FDA for innovator drug approvals, are unnecessary for generic companies. If the results are successful, the Company will continue the collection of documentation and information for assembly of the drug application.

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

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

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

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

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

Products for more descriptive information on the 23 products the Company currently produces or sells. Unlike the branded, innovator companies, Lannett currently does not own proprietary drug patents. However, the typical intellectual property in the generic drug industry are the ANDAs that generic drug companies own.

Validated Pharmaceutical Capabilities

Lannett s manufacturing facility consists of 31,000 square feet on 3.5 acres owned by the Company. In addition, the Company owns a 63,000 square foot building located within 1 mile of the corporate office. The second building contains packaging, warehouse and shipping functions, R&D and a number of administrative functions.

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

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

Lannett continues to pursue its comprehensive plan for improving and maintaining quality control and quality assurance programs for its pharmaceutical development and manufacturing facilities. The FDA periodically inspects the Company s production facilities to determine the Company s compliance with the FDA s manufacturing standards. Typically, after the FDA completes its inspection, it will issue the Company a report, entitled a Form 483, containing the FDA s observations of possible violations of cGMP. Such observations may be minor or severe in nature. The degree of severity of the observation is generally determined by the time necessary to remediate the cGMP violation, any consequences upon the consumer of the Company s drug products, and whether the observation is subject to a Warning Letter from the FDA. By strictly enforcing the various FDA guidelines, namely Good Laboratory Practices, Standard Operating Procedures and cGMP, the Company has successfully kept the number of observations in its FDA inspection at a minimal level. The Company believes that such observations are minor in nature, and will be remediated in a timely fashion with no material effect on its results of operations.

Sales and Customer Relationships

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

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

Management

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

Products

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

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

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

Key Products

All of the products currently manufactured and/or sold by the Company are prescription products. Of the products listed above, those containing Butalbital, Digoxin, Primidone and Levothyroxine Sodium were the Company s key products, contributing more than 70%, 80% and 93% of the Company s total net sales in Fiscal 2007, 2006 and 2005 respectively. In Fiscal 2006, the Company began selling Sulfamethoxazole w/ Trimethoprim (SMZ/TMP). Because of a market opportunity, sales of SMZ/TMP grew from 3% of sales in 2006 to 19% of sales in 2007. This number is not included in the above key products because the opportunity is no longer available to the Company after prices declined sharply. The decline in this percentage of key products since 2005 is due to our focus on expanding the number of products sold.

The Company has two products containing Butalbital. One of the products, Butalbital with Aspirin and Caffeine capsules, has been manufactured and sold by Lannett for more than nine years. The other Butalbital product, Butalbital with Aspirin, Caffeine and Codeine Phosphate capsules is manufactured by Jerome Stevens Pharmaceuticals, Inc. (JSP). Lannett began buying this product from JSP and selling it to its customers in December 2001. Both products, which are in orally administered capsule dosage forms, are prescribed to treat tension headaches caused by contractions of the muscles in the neck and shoulder area and migraine. The drug is prescribed primarily for adults of various demographic backgrounds. Migraine headache is an increasingly prevalent condition in the United States. As conditions continue to grow, the demand for effective medical treatments will continue to grow. Common side effects of drugs which contain Butalbital include dizziness and drowsiness. The Company notes that although new innovator drugs to treat migraine headaches have been introduced by brand name drug companies, there is still a loyal following of doctors and consumers who prefer to use Butalbital products for treatment. As the brand name companies continue to promote products containing Butalbital, like Fiorinal®, the Company expects to continue to produce and sell its generic Butalbital products.

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

Primidone tablets are produced and marketed with two different potencies (50 and 250 milligrams per tablet). This product was developed and is manufactured by Lannett. Lannett has been manufacturing and selling

Primidone 250-milligram tablets for more than seven years. Lannett began selling Primidone 50-milligram tablets in June 2001. Both products, which are in orally administered tablet dosage forms, are prescribed to treat convulsion and seizures in epileptic patients of all ages and demographic backgrounds. Common side effects of Primidone include lack of muscle coordination, vertigo and severe dizziness.

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

New Products

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

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

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

Additional products are currently under development. These products are either orally administered, solid-dosage products (i.e. tablet/capsule) or oral solutions, topicals or parentarels designed to be generic equivalents to brand named innovator drugs. The Company s developmental drug products are intended to treat a diverse range of indications. The products under development are at various stages in the development cycle formulation, scale-up, clinical testing and FDA review.

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

In addition, as one of the oldest generic drug manufacturers in the country, formed in 1942, Lannett currently owns several ANDAs for products which it does not manufacture and market. These ANDAs are simply dormant on the Company s records. Occasionally, the Company reviews such ANDAs to determine if the market potential for any of these older drugs has recently changed to make it attractive for Lannett to reconsider manufacturing and selling them. If the Company makes the determination to introduce one of these products into the consumer marketplace, it must review the ANDA and related documentation to ensure

that the approved product specifications, formulation and other factors meet current FDA requirements for the marketing of that drug. Generally, in these situations, the Company must file a supplement to the FDA for the applicable ANDA, informing the FDA of any significant changes in the manufacturing process, the formulation, the raw material supplier or another major feature of the previously approved ANDA. The Company would then redevelop the product and submit it to the FDA for supplemental approval. The FDA s approval process for ANDA supplements is similar to that of a new ANDA.

In addition to the efforts of its internal product development group, Lannett has contracted with several outside firms for the formulation and development of several new generic drug products. These outsourced R&D products are at various stages in the development cycle formulation, analytical method development and testing and manufacturing scale-up. These products are orally administered solid dosage products intended to treat a diverse range of medical indications. It is the Company s intention to ultimately transfer the formulation technology and manufacturing process for all of these R&D products to the Company s own commercial manufacturing sites. The Company initiated these outsourced R&D efforts to complement the progress of its own internal R&D efforts.

The majority of the Company s R&D projects are being developed in-house under Lannett s direct supervision and with Company personnel. Hence, the Company does not believe that its outside contracts for product development or manufacturing supply are material in nature, nor is the Company substantially dependent on the services rendered by such outside firms. Since the Company has no control over the FDA review process, management is unable to anticipate whether or when it will be able to begin producing and shipping such additional products.

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

1.) Stage of R&D Defines the current stage of the R&D product in the development process, as of the date of this filing.

2.) Regulatory Requirement Defines whether the R&D product is or is expected to be a new ANDA submission, an ANDA supplement, or a grand-fathered product not requiring specific FDA approval.

3.) Number of Products Defines the number of products in R&D at the stage noted. In this context, a product means any finished dosage form, including all potencies, containing the same API or combination of APIs and which represents a generic version of the same Reference Listed Drug (RLD) or innovator drug, identified in the FDA s Orange Book.

Stage of R&D	Regulatory Requirement	Number of Products
FDA Review	ANDA	14
FDA Review	ANDA supplement	4
Clinical Testing	ANDA	4
Scale-Up	Grand-fathered	1
Scale-Up	ANDA supplement	1
Scale-Up	ANDA	3
Formulation/Method Development	ANDA	47

Raw Materials and Finished Goods Inventory Suppliers

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

The Company s primary finished product inventory supplier is Jerome Stevens Pharmaceuticals, Inc. (JSP), in Bohemia, New York. Purchases of finished goods inventory from JSP accounted for approximately 63% of the Company s inventory purchases in Fiscal 2007, 76% in Fiscal 2006 and 62% in Fiscal 2005. On March 23, 2004, the Company entered into an agreement with JSP for the exclusive distribution rights in the United States to the current line of JSP products in exchange for four million (4,000,000) shares of the Company s common stock. The JSP products covered under the agreement included Butalbital, Aspirin, Caffeine with Codeine Phosphate capsules, Digoxin tablets and Levothyroxine Sodium tablets, sold generically and under the brand name Unithroid®. The term of the agreement is ten years, beginning on March 23, 2004 and continuing through March 22, 2014. Refer to the Materials Contract footnote to our consolidated financial statements for more information on the terms, conditions, and financial impact of this agreement.

During the term of the agreement, the Company is required to use commercially reasonable efforts to purchase minimum dollar quantities of JSP s products being distributed by the Company. The minimum quantity to be purchased in the first year of the agreement was $15 million. Thereafter, the minimum purchase quantity increases by $1 million per year up to $24 million for the last year of the ten-year contract. The Company has met the minimum purchase requirement for the first three years of the contract, but there is no guarantee that the Company will be able to continue to do so in the future. If the Company does not meet the minimum purchase requirements, JSP s sole remedy is to terminate the agreement.

In August 2005, the Company signed an agreement with a finished goods provider to purchase, at fixed prices, and distribute a certain generic pharmaceutical product in the United States. Purchases of finished goods inventory from this provider accounted for approximately 23% of the Company s costs of purchased inventory in Fiscal 2007, and 11% in 2006. The term of the agreement is three years, beginning on August 22, 2005 and continuing through August 21, 2008.

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

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

Customers and Marketing

The Company sells its products primarily to wholesale distributors, generic drug distributors, mail-order pharmacies, group purchasing organizations, chain drug stores, and other pharmaceutical companies. The industry s largest wholesale distributors, McKesson, Cardinal Health, and Amerisource Bergen, accounted for 24%, 12%, and 6%, respectively, of net sales in Fiscal 2007. The Company s largest chain drug store customer, Walgreens, accounted for 15% of net sales in Fiscal 2007. The Company performs ongoing credit evaluations of its customers financial condition, and has experien