LANNETT CO INC
Form 10-K
September 28, 2009
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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, 2009

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

Registrant s telephone number, including area code: (215) 333-9000

(Address of principal executive offices and telephone number)

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

None

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

Common Stock, $.001 Par Value

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act Yes 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, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o

Accelerated filer o

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

Smaller reporting company x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes o No o**

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12B-12 of the Exchange Act). **Yes o No x**

Aggregate market value of common stock held by non-affiliates of the registrant, as of December 31, 2008 was $50,656,740 based on the closing price of the stock on the NYSE - AMEX.

As of September 15, 2009, there were 24,459,953 shares of the registrant 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 n 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.

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PART I

ITEM 1. DESCRIPTION OF BUSINESS

Business Overview

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 branded pharmaceutical products. We report financial information on a quarterly and fiscal year basis with the most recent being the fiscal year ended June 30, 2009. All references herein to a fiscal year or Fiscal refer to the applicable fiscal year ending June 30.

According to data reported by IMS Health in June 2009, we are among the top 15 companies, based on number of prescription transactions, for unbranded generic products in the United States. We intend to grow our business organically as well as through strategic partnerships. Additionally, our Levothyroxine Sodium tablets (Levo) were recognized by IMS Health as the 19th most prescribed pharmaceutical product, including both branded and generic products, in the U.S., reaching approximately 21 million prescriptions through June 2009. Our product line represents approximately 0.5% of the domestic prescription market. Over the last year, we have experienced a 10% growth in prescriptions for our products. In addition, Levo has experienced a 16% annual growth during that period.

Over the past five years, we have experienced a 164% growth in our revenues from approximately $45 million in fiscal year 2005 to over $119 million in fiscal year 2009. This rapid growth has been achieved through strategic partnerships and opportunities resulting from certain difficulties our various competitors have experienced with regulatory compliance.

Competitive Strengths

Proven Ability to Develop Successful Products and Achieve Scale in Production. We believe that our ability to select viable products for development, efficiently develop such products, including obtaining any applicable regulatory approvals, vertically integrate ourselves into certain specialty markets and achieve economies in production are all critical for our success in the generic pharmaceutical industry in which we operate. We intend to focus on long-term profitability while seeking to secure market positions with fewer challenges from competitors. Two key examples are morphine sulfate oral solution and hydomorphone tablets.

Efficient Development Systems and Manufacturing Expertise for New Products. We believe that our manufacturing expertise, low overhead expenses and efficient product development, manufacturing and marketing capabilities can help us remain competitive in the general pharmaceutical market. We intend to dedicate significant capital toward developing new products because we believe our success is linked to our ability to continually introduce new generic products into the marketplace. Over time, if the market for a specific product remains stable and consumer demand remains consistent, additional generic manufacturing companies will seek to enter and participate in the market by developing the product and seeking regulatory approval for its sale. Competition from new and other market participants for the manufacture and

distribution of certain products would likely harm our market share with respect to such products as well as force us to reduce our selling price for such products due to their increased availability. As a result, we believe that our success depends on our ability to properly assess the competitive effect of new products, including market share, the number of competitors and the generic unit price erosion. We intend to reduce our exposure to competitive influences that may negatively affect our sales and profits, including the potential saturation of the market for certain products, by continuing to emphasize maintenance of a strong research and development (R&D) pipeline. We believe that it is in our best interest to avoid becoming materially dependent on the sale of a single product.

Mutually Beneficial Supply and Distribution Arrangements. In 2004, we entered into an exclusive distribution agreement with Jerome Stevens Pharmaceuticals (JSP) covering four different product lines. Two of these product lines, Levo and Digoxin, collectively accounted for approximately 62% of

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our net sales in fiscal year 2009 and both products have experienced significant growth in sales over the past few years. Distribution agreements with other manufacturers have also increased our net sales in recent years.

Strong Track Record of Obtaining Regulatory Approvals for New Products. During the past two fiscal years, we have received 12 approved Abbreviated New Drug Applications (each, an ANDA) from the Food and Drug Administration (the FDA). We expect to receive several more during the next fiscal year. These regulatory approvals will enable us to manufacture and supply a broader portfolio of generic pharmaceutical products.

Dependable Supplier to our Customers. We believe we are viewed within the generic pharmaceutical industry as a strong, dependable supplier to our customer base. We have cultivated strong and dependable customer relationships by maintaining adequate inventory levels, employing a responsive order filling system and prioritizing timely fulfillment of those orders. A majority of our orders are filled and shipped either on the day of, or the day following, the date that we receive the order.

Reputation for Regulatory Compliance. We have a strong track record of regulatory compliance and we believe that we have strong effective regulatory compliance capabilities and practices through hiring qualified individuals and implementing strong current Good Manufacturing Practices (cGMP). During the last two fiscal years, at least three of our competitors have experienced plant closures and product recalls due to FDA inspections that found violations of cGMPs at their facilities. Two of our competitive strengths, our agility in responding quickly to market events and a strong reputation for regulatory compliance, positioned us to avail ourselves these market opportunities.

In addition, narcotics or controlled drugs are subject to a rigorous regulatory compliance regime. We are one of seven companies in the U.S. that have been granted a license from the U.S. Drug Enforcement Administration (DEA) to import raw poppy straw for conversion into active pharmaceutical ingredients (API). Such licenses are renewed annually, but non-compliance could result in a license not being renewed. As a result, we believe that our strong reputation for regulatory compliance allows us to have a competitive edge in managing the production and distribution of narcotics and controlled drugs.

Business Strategies

Continue to Broaden our Product Lines Through Internal Development and Strategic Partnerships. We are focused on increasing our market share in the generic pharmaceutical industry while concentrating additional resources on the development of new products, including narcotics and controlled drugs. We hope to continue our efforts to improve our financial performance by expanding our line of generic products, increasing unit sales to current customers and reducing overhead and administrative costs.

We have targeted three strategies for expanding our product offerings: (1) deploying our experienced R&D staff to develop products in-house, (2) entering into additional product development agreements or strategic partnerships with third-party product developers and formulators and (3) purchasing ANDAs from other generic manufacturers that no longer seek to manufacture a specific product. We expect that each method will facilitate our identification, selection and development of additional generic pharmaceutical products that we may distribute through our existing network of customers.

We have several existing supply and development agreements with both international and domestic companies, and are currently in negotiations on similar agreements with additional international companies, through which we can market and distribute future products. We intend to capitalize on our strong customer relationships to build our market share for such products.

Improve our Operating Profile in Certain Targeted Specialty Markets. In certain situations, we may increase our focus on certain specialty markets within the generic pharmaceutical industry. By narrowing our focus to specialty markets, we can provide increased product alternatives in categories with relatively few other market participants. We plan to strengthen our relationships with strategic partners, including providers of product development research, raw materials, API and finished products. We believe that mutually

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beneficial strategic relationships in such areas, including potential financing arrangements, partnerships, joint ventures or acquisitions, could enhance our competitive advantages in the generic pharmaceutical market.

Leverage Ability to Vertically Integrate as a Manufacturer, Supplier and Distributor of Narcotics and Controlled Substances. We view our April 2007 acquisition of Cody Laboratories, Inc. (Cody Labs or Cody) as an important step in becoming a vertically integrated narcotics manufacturer and distributor by allowing us to concentrate on developing and completing our dosage form manufacturing in order to reduce our narcotic API costs. In July 2008, the DEA granted Cody Labs a license to directly import raw poppy straw for conversion into API and/or various pharmaceutical products. Only six other companies in the U.S. have been granted this license to date. This license allows us to avoid increased costs associated with buying narcotic API from other manufacturers. We anticipate that we can use this license to become a vertically integrated manufacturer of narcotic products, as well as a supplier of API to the pharmaceutical industry. We believe that the aging domestic population may result in a higher demand for pain management pharmaceutical products and that we will be well-positioned to take advantage of this increased demand.

Cody Labs manufacturing expertise in narcotic APIs will allow us to build a market with limited domestic competition. We anticipate that the demand for narcotics and controlled drugs will continue to grow with the Baby Boomer generation demographics and that we are well-positioned to take advantage of these opportunities by concentrating additional resources in the narcotic area.

Key Products

All of our products currently manufactured and/or sold are prescription products. Of the products listed in the table entitled Current Products below, those containing Levo, Digoxin, Butalbital and Primidone were our key products, collectively accounting for approximately 72%, 83% and 70% of our net sales in fiscal years 2009, 2008 and 2007, respectively. In fiscal year 2006, we began selling Sulfamethoxazole w/ Trimethoprim (SMZ/TMP). Because of a market opportunity, our sales of SMZ/TMP increased from 3% of our net sales in fiscal year 2006 to 19% of our net sales in fiscal year 2007, but declined to 9% of our net sales in fiscal year 2008. SMZ/TMP is not factored among our key products because the applicable supply agreement expired in August 2008 and was not renewed.

Our products containing Levo are produced and marketed with 12 varying potencies. In addition to generic Levo tablets, we also market and distribute Unithroid tablets, a branded version of Levo, which is produced and marketed with 11 varying potencies. Both generic Levo tablets and Unithroid tablets are manufactured by JSP. We began buying generic Levo from JSP and selling it to our customers in April 2003. In September 2003, we began buying the branded Unithroid tablets from JSP and selling them to our customers. Levo tablets are used to treat hypothyroidism and other thyroid disorders. Levo remains one of the most prescribed drugs in the U.S. and is used by over 13 million patients of various ages and demographic backgrounds. Side effects from Levo are rare, but may include allergic reactions, such as rash or hives. We signed a distribution agreement with JSP in March 2004 that granted us exclusive distribution rights to Levo tablets through March 2014 (the JSP Distribution Agreement). In June 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®. Net sales of this product have grown rapidly in recent years from approximately $35 million in 2007 to almost $48 million in 2009. In our distribution of these products, we compete with two branded Levo products Abbott Laboratories Synthroid® and Monarch Pharmaceutical s Levoxyl® as well as generic products from Mylan and Sandoz.

Digoxin tablets are produced and marketed with two different potencies (0.125 and 0.25 milligrams (mg) per tablet). This product is manufactured by JSP and we distribute it under the JSP Distribution Agreement. We began buying this product from JSP and selling it to our 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,

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nausea, vomiting and weakness. Net sales of this product have increased from approximately $4.7 million in 2007 to $26.4 million in 2009.

We distribute two products containing Butalbital. We have manufacturered and sold one of the products, Butalbital with Aspirin and Caffeine capsules, for more than nine years. The other Butalbital product, Butalbital with Aspirin, Caffeine and Codeine Phosphate capsules, is manufactured by JSP. We began buying this product from JSP and selling it to our customers in December 2002. Both Butalbital 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. Although new innovator drugs to treat migraine headaches have been introduced by brand name drug companies, we believe that 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®, we expect to continue to produce and sell our generic Butalbital products.

Primidone tablets are produced and marketed with two different potencies (50mg and 250mg tablets). We developed and manufacture Primidone tablets and began selling Primidone 50mg tablets in June 2001. In addition, we have been manufacturing and selling Primidone 250mg tablets for more than seven years. Both Primidone 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.

Validated Pharmaceutical Capabilities

Our manufacturing facility consists of 31,000 square feet on an approximately 3.5-acre parcel of land that we own. In addition, we own a 63,000 square foot building on approximately 3.0 acres located within one mile of our manufacturing facility that houses packaging, warehousing, shipping, R&D and certain administrative functions. In addition, we lease a third building located several miles from our manufacturing facility, consisting of 66,000 square feet on approximately 7.3 acres. This building is currently being used as a warehouse. We expect to purchase this building in fall 2009 for approximately $3.8 million, plus the cost of fit out estimated to be approximately $2 million. A significant portion of the purchase price and fit out costs are expected to be financed through a series of loans with a bank and a Pennsylvania state government-run development agency.

The manufacturing facility of our wholly-owned subsidiary, Cody Labs, consists of an approximately 73,000 square foot structure located on approximately 16.2 acres in Cody, Wyoming. Cody Labs leases the facility from Cody LCI Realty, LLC, Wyoming, which is 50% owned by us and 50% by an officer of Cody Labs and his former spouse. Cody Labs manufacturing facility currently has capacity for further expansion, both inside the existing structure, as well as by building out the current structure.

We have adopted many FDA regulations relating to cGMPs in the last several years, and we believe we are operating our facilities in material compliance with the FDA s cGMP regulations. In designing our 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 we use. In addition, our Quality Control laboratory facilities are equipped with high precision instruments, such as automated high-pressure liquid chromatographs, gas chromatographs, robots and laser particle size analyzers.

We continue to pursue our comprehensive plan for improving and maintaining quality control and quality assurance programs for our pharmaceutical development and manufacturing facilities. The FDA periodically inspects our production facilities to determine our compliance with the FDA s manufacturing standards. Typically, after completing its inspection, the FDA will issue us a report, entitled a Form 483, containing observations of any possible violations of cGMPs. The FDA s observations may be minor or severe in nature and the degree of severity is generally determined by the time necessary to remediate the cGMP violation, any consequences to the consumer of the products, and whether the observation is subject to a Warning Letter from the FDA. By strictly complying with cGMPs and the various FDA

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guidelines, and Good Laboratory Practices (GLPs), as well as adherence to our Standard Operating Procedures, we have successfully minimized the number of observations in our FDA inspections in recent years.

Research and Development Process

Over the past several years, we have consistently devoted resources to R&D projects, including new generic product offerings. The costs of these R&D efforts are expensed during the periods incurred. We believe that such investment expense may be recovered in future years when we receive marketing approval from the FDA to distribute such products. In addition to using cash generated from our operations, we have entered into financing agreements with third parties to provide additional cash when needed. These financing agreements are more fully described in the section entitled **Liquidity and Capital Resources** in Item 7 of this Form 10-K. We have embarked on a plan to grow in future years. In addition to organic growth to be achieved through our own R&D efforts, we have also initiated marketing projects with other companies in order to expand future revenue. We expect that our growing list of generic products under development will drive future growth. We also intend to use our R&D infrastructure to continually devote resources to additional R&D projects. The following steps outline the 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 scientists 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 our subsequent development process. Various formulations are tested in the laboratory to measure results against the innovator drug. During this time, we may use reverse engineering methods on samples of the innovator drug to determine the type and quantity of inactive ingredients. During the formulation phase, our R&D chemists begin to develop an analytical, laboratory testing method. The successful development of this test method will allow us 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 Chemistry, Manufacturing and Controls section of the 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, we 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 dosages to be created during the production cycle. We attempt 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 our commercial manufacturing facilities. During this manufacturing process, we 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 our ANDA submitted to the FDA.

3.) *Clinical testing*. After a successful scale-up of the generic drug batch, we schedule and perform bioequivalency and in some cases 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 us to determine the success of the generic drug product. Success, in this context, means that we are able to demonstrate that our product is comparable to the innovator product in dosage form, strength, route of administration, quality, performance characteristics and intended use. Since bioequivalence (meaning that the product performs in the same manner and in the same amount of time as the innovator drug) and a stable formula are the primary requirements for a generic drug approval (assuming the manufacturing plant is in compliance with the FDA s cGMPs), lengthy and costly clinical trials proving safety and efficacy, which are required by the FDA for

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innovator drug approvals, are typically unnecessary for generic companies. If the results are successful, we 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). The Hatch-Waxman Act amended the Federal Food, Drug and Cosmetic Act (FDCA) to permit FDA to review and approve an ANDA for a generic copy of a drug product, which previously received FDA approval through its new drug approval process, without having the generic drug company conduct costly clinical trials. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data, and quality control procedures.

According to the September 2008 issue of Generics Bulletin, the current FDA review time for ANDAs exceeds 19 months. While we have received approval for our ANDAs in 14 months, we have also waited longer than 19 months before receiving approval. Subsequently, the FDA advised that electronic submissions of applications may shorten the approval process. We currently file our ANDAs electronically. ANDAs submitted for our products may not receive FDA approval on a timely basis, if at all.

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 (i) that no patent was filed for the listed drug (a paragraph I certification), (ii) that the patent has expired (a paragraph II certification), (iii) 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 (iv) 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 must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved ANDA to which the ANDA refers. 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, we have filed no paragraph IV certifications with our ANDAs.

Over the past several years, we have hired additional personnel in product development, production, formulation and the R&D laboratory.

Sales and Customer Relationships

We sell our 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, governmental entities and health maintenance organizations. We promote our products through direct sales, trade shows, trade publications and bids. We also license the marketing of our products to other manufacturers and/or marketers in private label agreements.

We continue to expand our sales to major chain drug stores. Our policies of maintaining an adequate inventory, employing a responsive order filling system and prioritizing timely fulfillment of those orders have contributed to a strong reputation among our customers as a dependable supplier of high quality generic pharmaceuticals. In addition, our subsidiary, Cody Labs, sells APIs to dosage form manufacturers.

Some of our new generic products were developed and are manufactured by us while other products were developed and manufactured by other companies. The products currently manufactured by us and those manufactured by others are identified in the section entitled **Current Products** in Item 1 of this Form 10-K.

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Management

We have been focused on increasing the size and quality of our management team in anticipation of continuing our growth. We have hired experienced personnel from large, established, brand pharmaceutical companies as well as competing generic companies to complement the skills and knowledge of the existing management team. As we continue to grow, additional personnel may need to be added to our management team. We intend to hire the best people available to expand the knowledge base and expertise within our personnel ranks.

Current Products

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

Name of Product	Medical Indication	Equivalent Brand
1Acetazolamide Tablets	Glaucoma	Diamox®
2Amantadine Gel Capsules	Parkinson s Disease	Symmetrel ®
3Baclofen Tablets	Muscle Relaxer	Lioresal®
4Bethanechol Chloride Tablets	Urinary Retention	Urecholine®
5Butalbital, Aspirin and Caffeine Capsules	Migraine Headache	Fiorinal®
6Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules	Migraine Headache	Fiorinal w/ Codeine #3®
7Clindamycin HCl Capsules	Antibiotic	Cleocin®
8Cocaine Topical		