LANNETT CO INC
Form 10-K
September 09, 2011
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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, 2011

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 x

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

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, 2010 was $90,607,745 based on the closing price of the stock on the NYSE - AMEX.

As of September 2, 2011, there were 28,338,037 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.

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, 2011. 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 August 2011, we are currently among the top 20 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 15th most prescribed pharmaceutical product, including both branded and generic products, in the U.S. over the past year, reaching approximately 25 million prescriptions for the twelve months ended June 2011. This product line represents approximately 0.6% of the domestic prescription market.

Over the last year, we have experienced a 1% growth in prescriptions for our products while Levo has experienced a 7% annual growth during that period.

Over the past five years, we have experienced a 29% growth in our revenues from approximately $83 million in fiscal year 2007 to approximately $107 million in fiscal year 2011. This growth has been achieved primarily through strategic partnerships and launches of additional manufactured drugs as well as opportunities resulting from our exceptional compliance with regulatory issues.

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 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 Hydromorphone HCl 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

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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. 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 55% of our net sales in fiscal year 2011 and both products have experienced significant market growth in sales over the past few years. Distribution agreements with other manufacturers have also increased our net sales in recent years.

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.

Strong Track Record of Obtaining Regulatory Approvals for New Products. During the past two fiscal years, we have received five approved Abbreviated New Drug Applications (each, an ANDA) and one NDA 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.

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). 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 of these market opportunities.

In addition, narcotics or controlled drugs are subject to a rigorous regulatory compliance regimen. 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 can 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 four 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, (3) purchasing ANDAs from other generic manufacturers that no longer seek to manufacture a specific product and (4) marketing drugs under brand names where we see no generic opportunity. 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.

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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 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 will allow 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. Market indicators have shown us that the aging domestic population will likely result in a higher demand for pain management pharmaceutical products.

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, Cocaine and Morphine Sulfate were our key products, collectively accounting for approximately 69%, 75% and 71% of our net sales in fiscal years 2011, 2010 and 2009, respectively. In fiscal year 2009, we began selling our prenatal vitamin, OB Natal One, which was the generic version to a brand name prenatal vitamin. During the launch year of 2009, we sold approximately $12.6 million in net sales of the product. During our fiscal year 2009, the brand equivalent was withdrawn from the marketplace. Due to the brand company withdrawing their detailing sales force from the marketplace, we saw a significant drop in sales of our OB Natal One product during fiscal years 2010 and 2011. As part of our lawsuit settlement with the brand company in March 2009, Lannett withdrew this product from the marketplace by December 2010.

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 patients of various ages and demographic backgrounds. 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 Levo have grown rapidly in recent years from approximately $35 million in 2007 to almost $46.2 million in 2011. 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. Net sales of this product have increased from approximately $4.7 million in 2007 to $12.4 million in 2011. In our distribution of these products, we compete with three similar generic products from GlaxoSmithKline, Impax, and Westward.

We distribute two products containing Butalbital. We have manufactured and sold one of the products, Butalbital with Aspirin and Caffeine capsules, for more than nineteen 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. Although new innovator drugs to

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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.

Morphine Sulfate liquid oral solution is produced and marketed in three different size containers (20 mgs per mL in 30, 120 and 240 mL bottles). We manufacture these liquid dosage forms at our Cody Labs subsidiary and we are currently finishing the manufacturing methods and capabilities to make the API form also at Cody. This drug is prescribed primarily for the management of pain in adults where other products or delivery methods are not tolerable to the patient. As recently as March of 2009, seven different companies, including Lannett, were manufacturing and/or distributing this product. As a result of actions by the FDA during fiscal years 2009 and 2010 (see Item 1. Government Regulation), six of those companies, including Lannett, left the market by July 2010. From July 2010 through June 2011, only one company had an approved NDA for this product and enjoyed market exclusivity selling it. In June 2011, Lannett became the second approved manufacturer of this product. Lannett expects to resume sales of this product during the first fiscal quarter of 2012.

Cocaine Topical Solution (C-Topical) is produced and marketed under a preliminary new drug application (PIND) in two different strengths and two different size containers. (4% per 4 and 10 ml bottles, and 10% per 4 and 10 ml bottles). We manufacture these liquid dosage forms at our Cody Labs subsidiary and we expect to complete finishing the manufacturing methods and capabilities to make the API form also at Cody within the next fiscal year. Sales of C-Topical approximated 5% of Lannett s Net Sales during Fiscal 2011. This drug is utilized primarily for the anesthetization of the patient during ear, nose or throat surgery. It also works as a vasoconstrictor during the surgery.

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, research and development and possibly additional manufacturing space in the future. In June 2006, we leased a third building located several miles from our manufacturing facility, consisting of 66,000 square feet on approximately 7.3 acres. We purchased this building in October 2009 for approximately $3.8 million, plus the cost of fit out of approximately $2.0 million. A significant portion of the purchase price and fit out costs were financed through a series of loans with Wells Fargo N.A. bank and a Pennsylvania state run development agency. These loans could not be put in place until all construction had been completed and a proper certificate of occupancy had been obtained, due to a requirement by the state run development agency. Construction was substantially complete by June 30, 2010 and the configuration of the warehouse was substantially completed by September 2010. A certificate of occupancy was obtained in September 2010. The series of financings were completed and funded as of May 31, 2011. This new facility is being used for certain administrative functions, warehouse space, shipping and possibly additional manufacturing space in the future.

The manufacturing facility of our wholly-owned subsidiary, Cody Labs, consists of an approximately 73,000 square foot structure located on approximately 15 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 outside the current structure.

We have adopted many new aspects in support of 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 entitled Quality by Design 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 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.

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Research and Development Process

Over the past several years, we have heavily invested our 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 costs 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, our Specialty Pharma unit 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. Over the past several years, we have hired additional personnel in product development, production, formulation and the R&D laboratory. 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 sale, 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 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 the 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 information obtained from the FDA, the current FDA average review time for ANDAs exceeds 26 months. While we have received approval for some of our ANDAs in 14 months, we have also waited longer than 36 months before receiving approval.

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Subsequently, the FDA advised that electronic submissions of applications may shorten the approval process. We currently file our ANDAs and NDAs electronically. ANDAs and NDAs 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 which would delay the approval of the generic company s ANDA. Currently, we have filed no paragraph IV certifications with our ANDAs.

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 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.

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
1	Acetazolamide Tablets	Glaucoma	Diamox®
2	Amantadine SoftGel Capsules	Parkinson s Disease	Symmetrel ®
3	Bethanechol Chloride Tablets	Urinary Retention	Urecholine®
4	Butalbital, Aspirin and Caffeine Capsules	Migraine Headache	Fiorinal®
5	Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules	Migraine Headache	Fiorinal w/ Codeine #3®
6	Clindamycin HCl Capsules	Antibiotic	Cleocin®
7	C-Topical Solution	Anesthetic	N/A
8	Codeine Sulfate Tablets	Pain Management	N/A
9	Danazol Capsules	Endometriosis	Danocrine®
10	Dicyclomine Tablets	Irritable Bowels	Bentyl®
11	Dicyclomine Capsules	Irritable Bowels	Bentyl®
12	Digoxin Tablets	Congestive Heart Failure	Lanoxin®
13	Dipyridamole Tablets	Anticoagulant	Persantine ®
14	Doxycycline Tablets	Antibiotic	Adoxa®
15	Doxycycline Hyclate Tablets	Antibiotic	Periostat®

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16	Fluphenazine Tablets	Antipsychotic	Prolixin®
17	Hydrochlorothiazide Tablet	Diuretic	Hydrodiuril®
18	Hydromorphone HCl Tablets	Pain Management	Dilaudid®
19	Levothyroxine Sodium Tablets	Thyroid Deficiency	Levoxyl®/ Synthroid®
20	Morphine Sulfate Oral Solution	Pain Management	Roxanol®
21	Oxycodone HCl Oral Solution	Pain Management	Roxicodone®
22	Phentermine HCl Tablets	Obesity	Adipex-P®
23	Phentermine HCl Capsules	Obesity	Fastin®
24	Pilocarpine HCl Tablets	Dryness of the Mouth	Salagen®
25	Primidone Tablets	Epilepsy	Mysoline®
26	Probenecid Tablets	Gout	Benemid®
27	Rifampin Capsules	Antibiotic	Rifadin®
28	Terbutaline Sulfate Tablets	Bronchospasms	Brethine®
29	Unithroid® Tablet	Thyroid Deficiency	N/A
30	Ursodiol Capsules	Gallstone	Actigall ®

Unlike the branded, innovator companies, we do not develop new molecules. However, we have filed and received two patents for APIs at our Cody, Wyoming manufacturing facility, with an additional patent pending.

In fiscal years 2011 and 2010, we received two and three ANDA approvals from the FDA, respectively. The following summary contains more specific details regarding our latest ANDA approvals. Market data is obtained from Wolters Kluwer.

In December 2009, we received a letter from the FDA with approval to market and launch Hydromorphone Hydrochloride Tablets USP, 2 mg, 4 mg and 8 mg, the generic equivalent of Purdue Pharmaceuticals (formerly Abbott s) Dilaudid® Tablets 2 mg, 4 mg and 8 mg. According to Wolters Kluwer, U.S. sales in 2008 of both generic and brand Hydromorphone Hcl Tablets, 2 mg, 4 mg and 8 mg were $170 million at Average Wholesale Price. Hydromorphone Hcl tablets are indicated for the management of pain in patients where an opioid analgesic is appropriate.

In April 2010, we received a letter from the FDA with approval to market and launch Ondansetron Injection USP, 2 mg/mL, Multi-Dose Vials. Ondansetron Injection USP, 2 mg/mL is the generic equivalent of GlaxoSmithKline s Zofran® Injection, 2 mg/mL. Ondansetron Injection, USP 2 mg/mL is indicated for the prevention of postoperative nausea and vomiting and for the prevention of chemotherapy-induced nausea and vomiting. For the 12 months ended December 2009 U.S. sales of Ondansetron Injection USP, 2 mg/mL, were approximately $58 million at Average Wholesale Price (AWP). A launch date for the product has not yet been set.

In July 2010, we received a letter from the FDA with approval to market and launch Phentermine Hydrochloride Blue/White Seed Capsules USP, 30 mg, the generic equivalent of Sandoz, Inc. s Reference Listed Drug (RLD) Phentermine Hcl Capsules USP, 30 mg. According to Wolters Kluwer, U.S. sales of Phentermine Hcl Capsules USP, 30 mg in 2009 were approximately $36.5 million at Average Wholesale Price (AWP). This does not include sales of Phentermine made directly to consumers through clinics. Phentermine Hcl is indicated as a short-term adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index $\geq$ 30 kg/m2, or $\geq$ 27 kg/m2 in the presence of other risk factors (e.g., hypertension, diabetes, and hyperlipidemia).

In August 2010, we received a letter from the FDA with approval to market and launch Ondansetron Injection USP, 2 mg/mL, Single-Dose Vials. Ondansetron Injection USP, 2 mg/mL is the generic version of GlaxoSmithKline s Zofran Injection, 2 mg/mL. Ondansetron Injection, USP

2 mg/mL is indicated for the prevention of postoperative nausea and vomiting and for the prevention of chemotherapy-induced nausea and vomiting. For the 12 months ended December 2009, Ondansetron Injection USP, 2 mg/mL had U.S. sales of approximately $58 million at Average Wholesale Price. A launch date for the product has not been set.

We have additional products 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. Our 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 that we are currently developing is dependent on numerous factors, including but not limited to, the complexity of the active ingredient s chemical characteristics, the price of the raw materials and the FDA-mandated requirement of bioequivalence studies (depending on the FDA s Orange Book classification). The estimated cost to develop a new generic product ranges from approximately $100,000 to $1.7 million.

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In addition, we currently own several ANDAs that are dormant for products which we currently do not manufacture and market. Occasionally, we review such ANDAs to determine if the market potential for any of these older drugs has recently changed to make it attractive for us to reconsider manufacturing and selling. If we decide to introduce one of these products into the consumer market, we must review the original ANDA and related documentation to ensure that the approved product specifications, formulation and other factors meet current FDA requirements for the marketing of the applicable drug. Generally, in these situations, we 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. We would then redevelop the product and submit it to the FDA for supplemental approval. The FDA s approval process for an ANDA supplement is similar to that of a new ANDA.

In addition to the efforts of our internal product development group, we have 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 include orally administered solid dosage products, injectables and nasal delivery products that are intended to treat a diverse range of medical indications. We intend to ultimately transfer the formulation technology and manufacturing process for some of these R&D products to our own commercial manufacturing sites. We initiated these outsourced R&D efforts to complement the progress of our own internal R&D efforts.

The majority of our R&D projects are being developed in-house under our direct supervision and with our own personnel. Accordingly, we do not believe that our outside contracts for product development or manufacturing supply are material in nature, nor are we substantially dependent on the services rendered by such outside firms. Since we have no control over the FDA review process, our 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 our 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 Form 10-K.

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	16
FDA Review	ANDA supplement	2
Clinical Testing	ANDA	4
Scale-Up	ANDA	20
Scale-Up	ANDA supplement	2
Formulation/Method Development	ANDA	16

We incurred R&D expenses of approximately $8,587,000 in fiscal year 2011, $11,251,000 in fiscal year 2010, and $8,427,000 in fiscal year 2009. The R&D spending includes spending on bioequivalence studies, internal development resources as well as outsourced development. While we manage all R&D from our principal executive office in Philadelphia, we have also been taking advantage of favorable development costs in other countries. We have strategic partnerships with various companies that either act as contract research organizations or API suppliers as well as dosage form manufacturers. In addition, U.S.-based research organizations have been engaged for product development to enhance our internal development. Fixed payment arrangements are established with Lannett and these development partners, and can range up to almost $900,000 to develop a drug, and in some cases include a royalty provision. Development payments are normally scheduled in advance, based on attaining development milestones.

Raw Materials and Finished Goods Inventory Suppliers

Our use of raw materials in the production process consists of using pharmaceutical chemicals in various forms that 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 we purchase for the production process, we purchase certain finished dosage inventories, including capsule, tablet and oral liquid products. We sell these finished dosage products directly to our customers along with the finished

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dosage products manufactured in-house. If suppliers of a certain material or finished product are limited, we will generally take certain precautionary steps to avoid a disruption in supply, such as finding a secondary supplier or ordering larger quantities.

Our primary finished product inventory supplier is JSP in Bohemia, New York. Purchases of finished goods inventory from JSP accounted for approximately 64% of our inventory purchases in fiscal year 2011, 77% in fiscal year 2010 and 71% in fiscal year 2009. On March 23, 2004, we entered into the JSP Distribution Agreement 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 our common stock. The products covered under the JSP Distribution Agreement include Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules, Digoxin Tablets and Levo Tablets, sold generically and under the brand name Unithroid®. The initial term of the JSP Distribution Agreement is ten years, beginning on March 23, 2004 and continuing through March 22, 2014. See note 18 to our consolidated financial statements for more information on the terms, conditions and financial impact of the JSP Distribution Agreement.

During the term of the JSP Distribution Agreement, we are required to use commercially reasonable efforts to purchase minimum dollar quantities of JSP s products that we distribute. The minimum quantity to be purchased in the first year of the JSP Distribution 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 JSP Distribution Agreement. We have met each applicable minimum purchase requirement to date, but there is no guarantee that we will be able to continue to do so in the future. If we do not meet the minimum purchase requirements, JSP s sole remedy is to terminate the JSP Distribution Agreement.

We have entered into definitive supply and development agreements with certain international companies, including Wintac of India, Orion Pharma of Finland, Azad Pharma AG, Swiss Caps of Switzerland and Pharma 2B (formerly Pharmaseed) and The GC Group of Israel, as well as certain domestic companies, including JSP, Banner Pharmacaps, Cerovene, and Summit Bioscience LLC. We are currently in negotiations on similar agreements with other international companies, through which we will market and distribute future products manufactured in-house or by third parties. We intend to capitalize on our strong customer relationships to build our market share for such products, and increase future revenues and income.

Customers and Marketing

We sell our products primarily to wholesale distributors, generic drug distributors, mail-order pharmacies, group purchasing organizations, chain drug stores and other pharmaceutical companies. The pharmaceutical industry s largest wholesale distributors, McKesson, Cardinal Health and Amerisource Bergen, accounted for 9%, 6%, and 10%, respectively, of our net sales in fiscal year 2011 and 9%, 7% and 11%, respectively, of our net sales in fiscal year 2010. Our largest chain drug store customer, Walgreens, accounted for 17% and 26% of net sales in fiscal year 2011 and fiscal year 2010, respectively. We perform ongoing credit evaluations of our customers financial condition, and have experienced no significant collection problems to date. Generally, we require no collateral from our customers.

Sales to 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. We enter into definitive agreements with our indirect customers to establish pricing for certain covered products. Under such agreements, the indirect customers independently select a wholesaler from which to purchase the products at these agreed-upon prices. We 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, see 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 our books as sales to the

wholesale customers.

We believe 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, we believe that consumer demand will be fulfilled by other wholesale or retail sources of supply. As a result, we attempt to develop and maintain strong relationships with most of the major retail chains, wholesale distributors and mail-order pharmacies in order to facilitate the supply of our products through whatever channel the consumer prefers. Although we have agreements with customers governing the transaction terms of our sales, there are no minimum purchase quantities applicable to these agreements.

We promote our products through direct sales, trade shows and bids. We also market our products through private label arrangements, under which we manufacture our products with a label containing the name and logo of a customer. This practice is commonly referred to as private label business. Private label business allows us to leverage our internal sales efforts by using the marketing services from other well-respected pharmaceutical dosage suppliers. The focus of our sales efforts is the relationships we create with our customer accounts. Strong and dependable customer relationships have created a positive platform for us to increase our 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 years 2011, 2010 and 2009, our

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advertising expenses were immaterial. When our sales representatives make contact with a customer, we will generally offer to supply the customer our 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 our supply of a product, the customer typically expects a high standard of service, including timely receipt of products ordered, availability of convenient, user-friendly and effective customer service functions and maintaining open lines of communication.

Competition

The manufacturing and distribution of generic pharmaceutical products is a highly competitive industry. Competition is based primarily on price, service and quality. Our competitive advantage is based on our ability to provide strong and dependable customer service by maintaining adequate inventory levels, employing a responsive order filling system and prioritizing timely fulfillment of those orders. We ensure that our products are available from national suppliers as well as our own warehouse. The modernization of our facilities, hiring of experienced staff and implementation of inventory and quality control programs have improved our competitive cost position over the past five years.

We compete with other manufacturers and marketers of generic and brand drugs. Each product manufactured and/or sold by us has a different set of competitors. The list below identifies the companies with which we primarily compete with respect to each of our major products.

Product	Primary Competitors
Butalbital with Aspirin and Caffeine, with and without Codeine Phosphate Capsules	Watson and Breckenridge
C_Topical Solution	None
Digoxin Tablets	GlaxoSmithKline, Impax, and Westward
Doxycycline Hyclate and Monohydrate Tablets	Par, Mylan, Sandoz and Ranbaxy
Hydromorphone HCl Tablets	Mallinckrodt, Roxane and Purdue
Levothyroxine Sodium Tablets	Abbott, Monarch, Mylan, Sandoz and Forest
Morphine Sulfate Liquid Oral Solution	Roxane
Primidone Tablets	Watson, Qualitest, URL, Westward, Amneal and Impax
Rifampin Capsules	Sandoz and Versapharm
Unithroid® Tablets	Abbott, Monarch, Mylan and Sandoz
Ursodiol Capsules	Corepharma, Epic, Mylan, Teva and Watson

Government Regulation

Pharmaceutical manufacturers are subject to extensive regulation by the federal government, principally by the FDA, and, in cases of controlled drugs the DEA, and to a lesser extent by other federal regulatory bodies and state governments. The FDCA, the Controlled Substance Act (the CSA) and other federal statutes and regulations govern or influence the testing, manufacture, safety, labeling, storage, record keeping, approval, pricing, advertising, and promotion of our 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 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.

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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. The new drug approval process generally involves:

- completion of preclinical laboratory and animal testing in compliance with the FDA s GLP regulations;

- submission to the FDA of an Investigational New Drug (IND) application for human clinical testing, which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product for each intended use;

- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA s cGMP regulations; and

- submission to and approval by the FDA of an NDA.

The results of preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. Further, each clinical trial must be reviewed and approved by an independent Institutional Review Board. Human clinical trials are typically conducted in three sequential phases that may overlap. These phases generally include:

- Phase I, during which the drug is introduced into healthy human subjects or, on occasion, patients and is tested for safety, stability, dose tolerance, and metabolism;

- Phase II, during which the drug is introduced into a limited patient population to determine the efficacy of the product in specific targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks; and

- Phase III, during which the clinical trial is expanded to a larger and more diverse patient group at geographically dispersed clinical trial sites to further evaluate clinical efficacy, optimal dosage, and safety.

The drug sponsor, the FDA, or the independent Institutional Review Board at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

The results of preclinical animal studies and human clinical studies, together with other detailed information, are submitted to the FDA as part of the NDA. The NDA also must contain extensive manufacturing information. The FDA may approve or disapprove the NDA if applicable FDA regulatory criteria are not satisfied or it may require additional clinical data. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained or if problems occur or are identified after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

Satisfaction of FDA new drug approval requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer s activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be subject to varying interpretations that could delay, limit, or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

- ***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

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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. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

In addition to establishing a new ANDA procedure, the Hatch-Waxman Act created statutory protections for approved brand name drugs. Under the Hatch-Waxman 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. Upon NDA approval, the FDA lists in its Orange Book the approved drug product and any patents identified by the NDA applicant that relate to the drug product. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the FDA s Orange Book before expiration of the referenced patent(s), must certify to the FDA that (1) no patent information on the drug product that is the subject of the ANDA has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the ANDA is submitted. This last certification is known as a Paragraph IV certification. A notice of the 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 NDA to which the ANDA refers. Before the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the MMA), which amended the Hatch-Waxman Act, if the NDA holder or patent owner(s) asserted a patent challenge within 45 days of its receipt of the certification notice, the FDA was prevented from approving that ANDA until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in an ANDA applicant s favor, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In some cases, NDA owners and patent holders have obtained additional patents for their products after an ANDA had been filed but before that ANDA received final marketing approval, and then initiated a new patent challenge, which resulted in more than one 30-month stay.

The MMA amended the Hatch-Waxman Act to eliminate certain unfair advantages of patent holders in the implementation of the Hatch-Waxman Act. As a result, the NDA owner remains entitled to an automatic 30-month stay if it initiates a patent infringement lawsuit within 45 days of its receipt of notice of a paragraph IV certification, but only if the patent infringement lawsuit is directed to patents that were listed in the FDA s Orange Book before the ANDA was filed. An ANDA applicant is now permitted to take legal action to enjoin or prohibit the listing of certain of these patents as a counterclaim in response to a claim by the NDA owner that its patent covers its approved drug product.

If an ANDA applicant is the first-to-file a substantially complete ANDA with a paragraph IV certification and provides appropriate notice to the FDA, the NDA holder, and all patent owner(s) for a particular generic product, the applicant may be awarded a 180-day period of marketing exclusivity against other companies that subsequently file ANDAs for that same product. A substantially complete ANDA is one that contains all the information required by the Hatch-Waxman Act and the FDA s regulations, including the results of any required bioequivalence studies. The FDA may refuse to accept the filing of an ANDA that is not substantially complete or may determine during substantive review of the ANDA that additional information, such as an additional bioequivalence study, is required to support approval. Such a determination may affect an applicant s first to file status and eligibility for a 180-day period of marketing exclusivity for the generic product. The MMA also modified the rules governing when the 180-day marketing exclusivity period is triggered or forfeited and shared exclusivity. Prior to the legislation, the 180-day marketing exclusivity period was triggered upon the first commercial marketing of the ANDA or a court decision holding the patent invalid, unenforceable, or not infringed. For ANDAs accepted for filing before March 2000, that court decision had to be final and non-appealable (other than a petition to the U.S. Supreme Court for a writ of certiorari). In March 2000, the FDA changed its position in response to two court cases that challenged the FDA s original interpretation of what constituted a court decision under the Hatch-Waxman Act. Under the changed policy, the 180-day marketing exclusivity period began running immediately upon a district court decision holding the patent at issue invalid, unenforceable, or not infringed, regardless of whether the ANDA had been approved and the generic product had been marketed. In codifying the FDA s original policy, the MMA retroactively applies a final and non-appealable court decision trigger for all ANDAs filed before December 8, 2003 leaving intact the first commercial marketing trigger. As for ANDAs filed after December 8, 2003, the marketing exclusivity period is only triggered upon the first commercial marketing of the ANDA product, but that exclusivity may be forfeited under

certain circumstances, including, if the ANDA is not marketed within 75 days after a final and non-appealable court decision by the first-to-file or other ANDA applicant, or if the FDA does not tentatively approve the first-to-file applicant s ANDA within 30 months.

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In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an ANDA. If the listed drug is a new chemical entity, the FDA may not accept an ANDA for a bioequivalent product for up to five years following approval of the NDA for the new chemical entity. If the listed drug is not a new chemical entity but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve an ANDA for a bioequivalent product before expiration of three years. Certain other periods of exclusivity may be available if the listed drug is indicated for treatment of a rare disease or is studied for pediatric indications.

- ***Section 505(b)(2) New Drug Applications:*** 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 where at least some of information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon certain preclinical or clinical studies conducted for an approved product. The manufacturer must also submit, if the FDA so requires, bioavailability or bioequivalence data illustrating that the generic drug formulation produces the same effects, within an acceptable range, as the previously approved innovator drug. Because published literature to support the safety and efficacy of post-1962 drugs may not be available, this procedure is of limited utility to generic drug manufacturers and the resulting approved product will not be interchangeable with the innovator drug as an ANDA drug would be unless bioeqivalency testing were undertaken and approved by FDA. Moreover, the utility of Section 505(b)(2) applications have with the exception of Grandfathered drugs been diminished by the availability of the ANDA process, as described above.

Additionally, certain products, marketed prior to the Federal Food, Drug and Cosmetic Act may be considered GRASE (Generally Recognized As Safe and Effective) or Grandfathered. GRASE products are those old drugs that do not require prior approval from FDA in order to be marketed because they are generally recognized as safe and effective based on published scientific literature. Similarly, Grandfathered products are those which entered the market before the passage of the 1938 act or the 1962 amendments to the act. Under the grandfather clause, such a product is exempted from the effectiveness requirements [of the act] if its composition and labeling have not changed since 1962 and if, on the day before the 1962 amendments became effective, it was (1) used or sold commercially in the United States, (2) not a new drug as defined by the act at that time, and (3) not covered by an effective application. Recently, the FDA has increased its efforts to force companies to file and seek FDA approval for these GRASE products. Efforts have included granting market exclusivity to approved GRASE products and issuing notices to companies currently producing these products. One such current FDA effort includes our currently marketed product, Morphine Sulfate Oral Solution. Please see additional discussion regarding our Morphine Sulfate Oral Solution product in Item 1A. Risk Factors, Item 3 Legal Proceedings and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations.

Manufacturing cGMP Requirements

Among the requirements for new drug approval is the requirement that the prospective manufacturer s methods conform to the FDA s cGMP regulations to the satisfaction of the FDA pursuant to a pre-approval inspection before the facility may be used to manufacture the product. The cGMP regulations must be followed at all times during which the approved drug is manufactured and the manufacturing facilities are subject to periodic inspections by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with application regulations. FDA s cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. In complying with the standards set forth in the cGMP regulations, we must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. In March 2011, the FDA completed its inspection of the Company s manufacturing facilities in both Philadelphia and Cody, Wyoming. The inspections concluded with only minor observations, seven at the Philadelphia location and five at the Cody facility.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including but not limited to, the seizure or recall of non-complying drug products injunctions, consent decrees placing significant restrictions on or suspending

manufacturing operations, and/or civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Other Regulatory Requirements

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, off-label

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promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and/or federal civil and criminal investigations and prosecutions.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Outside of the United States, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing, and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of safety, quality and efficacy.

DEA Regulation

We maintain registrations with the DEA that enable us to receive, manufacture, store, and distribute controlled substances in connection with our operations. Controlled substances are those drugs that appear on one of five schedules promulgated and administered by the DEA under the CSA. The CSA governs, among other things, the distribution, recordkeeping, handling, security, and disposal of controlled substances. We are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess our ongoing compliance with DEA s regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation or a denial of renewal of our DEA registration, injunctions, or civil or criminal penalties.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws whose purpose is to eliminate fraud and abuse in federal health care programs. Our business is subject to compliance with these laws.

Anti-Kickback Statutes and Federal False Claims Act

The federal health care programs Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as Medicare or Medicaid. The definition of remuneration has been broadly interpreted to include anything of value, including for example gifts, certain discounts, the furnishing of free

supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment, and possible exclusion from Medicare, Medicaid, and other federal health care programs. In addition some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) to issue a series of regulations, known as safe harbors. These safe harbors, issued by the OIG beginning in July 1991, set forth provisions that, if all their applicable requirements are met, will assure health care providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

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Government officials have focused their enforcement efforts on marketing of health care services and products, among other activities, and recently have brought cases against companies, and certain sales, marketing, and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Another development affecting the health care industry is the increased use of the federal Civil False Claims Act, and in particular, action brought pursuant to the False Claims Act s whistleblower or qui tam provisions. The False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought against health care providers by private individuals has increased dramatically. In addition, various states have enacted false claims law analogous to the Civil False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal health care program.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $5,500 to $11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits or causes another to submit a false claim for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, kickbacks, and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the False Claims Act in connection with off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of discount and rebate information and other information affecting federal, state, and third-party reimbursement of our products, and the sale and marketing of our products may be subject to scrutiny under these laws. We are unable to predict whether we will be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act of 1977, as amended (FCPA), was enacted for the purpose of making it unlawful for certain classes of persons and entities to make payments to foreign government officials to assist in obtaining or retaining business. Specifically, the anti-bribery provisions of the FCPA prohibit the bribery of government officials. Lannett believes it is in compliance with the FCPA.

HIPAA and Other Fraud and Privacy Regulations

Among other things, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) created two new federal crimes: health care fraud and false statements relating to health care matters. The HIPAA health care fraud statute prohibits, among other things, knowing and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment, and/or exclusion from government-sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement or representation in connection with the delivery of or payment for health care benefits, items, or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

Pricing

In the United States, our sales are dependent upon the availability of coverage and reimbursement for our products from third-party payers, including federal and state programs such as Medicare and Medicaid, and private organizations such as commercial health insurance and managed care companies. Such third-party payers are increasingly challenging the price of medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. This includes the placement of our pharmaceutical products on drug formularies or lists of medications.

Over the past several years, the rising costs of providing health care services has triggered legislation to make certain changes to the way in which pharmaceuticals, including our products, are covered and reimbursed, particularly by governmental programs. For instance, recent federal legislation and regulations have created a voluntary prescription drug benefit, Medicare Part D, revised the formula used to reimburse health care providers and physicians under Part B and have imposed significant revisions to the Medicaid Drug Rebate Program. These changes have resulted in, and may continue to result in, coverage and reimbursement restrictions and increased rebate obligations by manufacturers. In addition, there continue to be legislative and regulatory proposals at the federal and

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state levels directed at containing or lowering the cost of health care. Examples of how limits on drug coverage and reimbursement in the United States may cause reduced payments for drugs in the future include:

- changing Medicare reimbursement methodologies;
- revising drug rebate calculations under the Medicaid program;
- reforming drug importation laws;
- fluctuating decisions on which drugs to include in formularies; and
- requiring pre-approval of coverage for new or innovative drug therapies.

We cannot predict the likelihood or pace of such additional changes or whether there will be significant legislative or regulatory reform impacting our products. Nor can we predict with precision what effect such governmental measures would have if they were ultimately enacted into law. However, in general, we believe that legislative and regulatory reform activity likely will continue.

We are also subject to federal, state and local laws of general applicability, including laws regulating working conditions and the storage, transportation, or discharge of items that may be considered hazardous substances, hazardous waste, or environmental contaminants. We monitor our compliance with all environmental laws. We are in substantial compliance with all regulatory bodies.

As a publicly-traded company, we are also subject to significant regulations and laws, including the Sarbanes-Oxley Act of 2002. Since its enactment, we have developed and instituted a corporate compliance program based on what we believe are the current best practices and we continue to update the program in response to newly implemented or changing regulatory requirements.

We operate in a highly regulated environment and are responsible for maintaining compliance with many regulatory requirements. The U.S. Department of Justice, acting on behalf of the DEA, issued us a letter in August 2008 requesting additional information on certain record keeping matters regarding a DEA inspection of our facilities. We fully complied with their request and intend to fully comply with all requests for information that occur from time to time as a normal course of business.

Employees

As of June 30, 2011, we had 310 employees, comprised of 221 employees at Lannett and 89 employees at Cody Labs.

Securities and Exchange Act Reports

We maintain a website at *www.lannett.com*. We make available on or through our website our current and periodic reports, including any amendments to those reports, that are filed with the Securities and Exchange Commission (the SEC) in accordance with the Securities Exchange Act of 1934, as amended (the Exchange Act). These reports 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 our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. The contents of our website are not incorporated by reference in this Form 10-K and shall not be deemed filed under the Exchange Act.

ITEM 1A.