

LANNETT CO INC
Form 10-K
September 12, 2012
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2012

OR

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

For the transition period from to

Commission File No. 001-31298

LANNETT COMPANY, INC.

(Exact name of registrant as specified in its charter)

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State of Delaware
State of Incorporation

23-0787699
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 No

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 No

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 No

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.

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

Accelerated filer

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

Smaller reporting company

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 No

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

Aggregate market value of common stock held by non-affiliates of the registrant, as of December 31, 2011 was \$72,293,776 based on the closing price of the stock on the NYSE MKT.

As of August 31, 2012, there were 28,314,697 shares of the registrant's common stock, \$.001 par value, outstanding.

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CAUTIONARY STATEMENT FOR PURPOSES OF THE SAFE HARBOR PROVISIONS OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995.

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 throughout the 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, growth rates, prospects related to our strategic initiatives and business strategies, express or implied assumptions about government regulatory action or inaction, anticipated product approvals and launches, business initiatives and product development activities, assessments related to clinical trial results, product performance and competitive environment, and anticipated financial performance. Without limiting the generality of the foregoing, words such as may, will, expect, believe, anticipate, intend, could, would, estimate, continue, or pursue, or the negative other variations thereof or comparative 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. and subsidiaries (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, 2012. 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 2012, we are currently among the top 25 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 11th most prescribed pharmaceutical product, including both branded and generic products, in the U.S. over the past year, reaching approximately 25.0 million

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prescriptions for the twelve months ended June 2012. This product line represents approximately 0.6% of the domestic prescription market.

Over the past five years, we have experienced a 71% growth in net sales from approximately \$72.0 million in fiscal year 2008 to approximately \$123.0 million in fiscal year 2012. 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 regulations.

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 into certain markets and achieve economies of scale in production are 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.

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Efficient Development Systems and Manufacturing Expertise for New Products. We believe that our manufacturing expertise, low overhead expenses, 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. Competition from new and other market participants for the manufacture and distribution of certain products would likely affect 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 market 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.

Mutually Beneficial Supply and Distribution Arrangements. In 2004, we entered into an exclusive ten-year distribution agreement with Jerome Stevens Pharmaceuticals (JSP) covering four different product lines. Two of these product lines, Levo and Digoxin, collectively accounted for approximately 50% of our net sales in fiscal year 2012 and both products have experienced significant market growth in sales over the past few years. Preliminary discussions have been held with JSP over contract renewal. 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 ten 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, position us to avail ourselves of market opportunities.

In addition, narcotics which are classified by the DEA as 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 concentrated poppy straw for conversion into active pharmaceutical ingredients (API). Such licenses are renewed annually, and 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

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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 other controlled drugs. We continue our efforts to improve our financial performance by expanding our line of generic products, increasing unit sales to current customers, creating manufacturing efficiencies, and managing our 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 and (4) marketing drugs under brand names. 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

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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 Drugs. 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 concentrated poppy straw for conversion into API. 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 and controlled substances.

Cody Labs' manufacturing expertise in narcotic APIs will allow us to build a market with limited domestic competition. We anticipate that demand for narcotics and other controlled drugs will continue to grow as the Baby Boomer generation ages. We are well-positioned to take advantage of these opportunities by concentrating additional resources in the narcotics and other controlled drugs 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, our top five products in each fiscal year collectively accounted for approximately 69%, 69% and 75% of our net sales in fiscal years 2012, 2011 and 2010, respectively.

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 in recent years from approximately \$36.6 million in 2008 to almost \$50.0 million in 2012. 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. 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 \$7.6 million in 2008 to \$10.9 million in 2012. In our distribution of these products, we compete with three similar generic products from Caraco, Impax, and West-Ward.

We distribute two products containing Butalbital. We have manufactured and sold one of the products, Butalbital with Aspirin and Caffeine capsules, for more than 19 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 migraines. The drug is prescribed primarily for adults of various demographic backgrounds. Migraine headaches are an increasingly prevalent condition in the United States. As conditions continue to grow, we believe the demand for effective medical treatments will continue to grow. 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.

Morphine Sulfate Oral Solution is produced and marketed in three different size containers. We manufacture these solution dosage forms at our Cody Labs subsidiary and are currently finishing the manufacturing methods and capabilities to make the API. 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 2009, nine different companies, including Lannett, were manufacturing and/or distributing this product. As a

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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 resumed 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. 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 commercially within the next fiscal year. Sales of C-Topical approximated 8% of Lannett's net sales during Fiscal 2012. This drug is utilized primarily for the anesthetization of the patient during ear, nose or throat surgery. It also works as a vasoconstrictor.

Validated Pharmaceutical Capabilities

Our 31,000 square foot manufacturing facility sits on approximately 3.5 acres of company owned land. In addition, we own a 63,000 square foot building residing on approximately 3.0 acres of company owned land. This facility is located within one mile of our manufacturing facility. The facility houses packaging, research and development, and has capacity for additional manufacturing space, if needed. In October 2009, we purchased a 66,000 square foot building on 7.3 acres of land, for approximately \$3.8 million, plus the cost of fit out of approximately \$2.0 million. This facility is being used for certain administrative functions, warehouse space and shipping and has capacity for additional manufacturing space, if needed.

The manufacturing facility of our wholly-owned subsidiary, Cody Labs, consists of an approximately 73,000 square foot facility located on approximately 15.0 acres of land in Cody, Wyoming. Cody Labs leases the facility from Cody LCI Realty, LLC, which is 50% owned by Lannett and 50% by an officer of Cody Labs. Cody Labs' manufacturing facility currently has capacity for further expansion, both inside and outside the existing structure.

We have adopted many new processes 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 used in the production process. In addition, our Quality Control laboratory facilities are equipped with high precision instruments, such as automated 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 in 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 a report, entitled a Form 483, containing observations arising from an inspection. 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, and in 70 years of business have never received a cGMP Warning Letter.

Research and Development Process

Over the past several years, we have heavily invested in 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, which includes organic growth to be achieved through R&D efforts, as well as efforts in our Specialty Pharma unit which has initiated marketing projects 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

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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 product development scientists and the R&D chemists agree on a final formulation for use in moving the drug candidate forward in the developmental process, we then 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 affects 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 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, is included in the 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 equivalent of a new 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 33 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. 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.

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,

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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.

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 Butalbital, Aspirin and Caffeine Capsules	Migraine Headache	Fiorinal®
4 Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules	Migraine Headache	Fiorinal w/ Codeine #3®
5 Clindamycin HCl Capsules	Antibiotic	Cleocin®
6 C-Topical Solution	Anesthetic	N/A
7 Danazol Capsules	Endometriosis	Danocrine®
8 Dicyclomine Tablets	Irritable Bowels	Bentyl®
9 Dicyclomine Capsules	Irritable Bowels	Bentyl®
10 Diethylpropion HCl IR and ER Tablets	Obesity	Tenuate® and Dospan®
11 Digoxin Tablets	Congestive Heart Failure	Lanoxin®
12 Doxycycline Tablets	Antibiotic	Adoxa®
13 Doxycycline Hyclate Tablets	Antibiotic	Periostat®
14 Fluphenazine Tablets	Antipsychotic	Prolixin®
15 Hydrochlorothiazide Capsules	Diuretic	Microzide®

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16	Hydrochlorothiazide Tablet	Diuretic	Hydrodiuril®
17	Hydromorphone HCl Tablets	Pain Management	Dilaudid®
18	Levothyroxine Sodium Tablets	Thyroid Deficiency	Levoxyol®/ Synthroid®
19	Loxapine Succinate Capsules	Antipsychotic	Loxitane®
20	Morphine Sulfate Oral Solution	Pain Management	N/A
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	Triamterene w/Hydrochlorothiazide Capsules	Hypertension	Dyazide®
30	Unithroid® Tablet	Thyroid Deficiency	N/A
31	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.

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In fiscal years 2012 and 2011, we received eight and two ANDA approvals from the FDA, respectively. Additionally, we received one NDA approval from the FDA in FY2011. The following summary contains more specific details regarding our latest ANDA and NDA approvals. Market data was obtained from Wolters Kluwer.

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'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 ≥ 30 kg/m², or ≥ 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 \$58.0 million at AWP.

In June 2011, we received a letter from the FDA with approval to market and launch Morphine Sulfate Oral Solution. Sales of Morphine Sulfate Oral Solution for the last 12 months at AWP were approximately \$31.7 million. The Company commenced shipping shortly after product approval.

In July 2011, we received a letter from the FDA with approval to market and launch Diethylpropion HCl Tablets, 25 mg. Diethylpropion HCl Tablets, 25 mg, is therapeutically equivalent to the reference listed drug, Tenuate® Tablets, 25 mg, of Watson Pharmaceuticals. Retail pharmacy sales of Diethylpropion HCl Tablets, 25 mg, at AWP were approximately \$3.3 million for the year ending May, 2011. Additional sales of this drug are made through bariatric clinics.

In July 2011, we received a letter from the FDA with approval to market and launch Phentermine HCl capsules, 37.5 mg. Phentermine HCl capsules, 37.5 mg, is therapeutically equivalent to the reference listed drug, Adipex-P® Capsules, 37.5 mg, of Teva Pharmaceuticals USA. Sales of Phentermine HCl Capsules, 37.5 mg, at AWP were approximately \$8.8 million for the year ending May 2011. Additional sales of this drug are made through bariatric centers.

In July 2011, we received a letter from the FDA with approval to market and launch Phentermine Resin Extended-Release Capsules, 15 mg and 30 mg. Phentermine Resin Extended-Release Capsules, 15 mg and 30 mg, are therapeutically equivalent to the reference listed drug, Ionamin® Capsules, 15 mg and 30 mg, of UCB Inc. This product was not launched due to a loss of an ingredient supplier.

In September 2011, we received a letter from the FDA with approval to market and launch Loxapine Succinate Capsules, 5 mg, 10 mg, 25 mg, and 50 mg. Loxapine Capsules, 5 mg, 10 mg, 25 mg, and 50 mg are therapeutically equivalent to the reference listed drug, Loxitane® Capsules, 5 mg, 10 mg, 25 mg, and 50 mg from Watson Pharmaceuticals. Retail pharmacy sales of Loxapine Capsules at AWP were approximately \$22.3

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million for the 12-month period ending June 2011.

In October 2011, we received a letter from the FDA with approval to market and launch Diethylpropion HCl Extended Release Tablets, 75 mg. Sales of Diethylpropion HCl Extended Release Tablets, 75 mg, at AWP were approximately \$7.6 million on an annual basis. Diethylpropion HCl, as with most anti-obesity drugs, primarily is sold to bariatric clinics.

In December 2011, we received a letter from the FDA with approval to market and launch Triamterene with Hydrochlorothiazide 37.5/25 mg Capsules. Triamterene with Hydrochlorothiazide 37.5/25 mg Capsules is therapeutically equivalent to the reference listed drug, Dyazide® Capsules, 25/37.5 mg, of SmithKline Beecham. Sales of Triamterene Hydrochlorothiazide 37.5/25 mg Capsules, at AWP were approximately \$111.0 million for the 12 months ending October 2011.

In January 2012, we received a letter from the FDA with approval to market and launch Hydrochlorothiazide Capsules, 12.5 mg. Hydrochlorothiazide Capsules, 12.5 mg, is therapeutically equivalent to the reference listed drug, Microzide® Capsules, 12.5 mg, of Watson Pharmaceuticals. Sales of Hydrochlorothiazide Capsules, 12.5 mg, at AWP were approximately \$204.0 million for the 12 months ending October 2011. Hydrochlorothiazide is indicated in the management of hypertension.

In January 2012, we received a letter from the FDA with approval of a supplemental Abbreviated New Drug Application for Phentermine HCl Capsules, 15 mg. Sales of Phentermine HCl Capsules, 15 mg, at AWP were approximately \$11.0 million for the year ending December 2011. Additional sales of this drug are made through bariatric centers.

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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 parenterals 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 average estimated cost to develop a new generic product ranges from approximately \$0.1 million to \$1.7 million.

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.

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

Stage of R&D	Regulatory Requirement	Number of Products
FDA Review	ANDA	14
FDA Review	ANDA supplement	5
Clinical Testing	ANDA	3
Scale-Up	ANDA	19
Scale-Up	ANDA supplement	3
Formulation/Method Development	ANDA	11

We incurred R&D expenses of approximately \$11.8 million in fiscal year 2012, \$8.6 million in fiscal year 2011, and \$11.3 million in fiscal year 2010. 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

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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 \$0.9 million 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 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 2012, 64% in fiscal year 2011 and 77% in fiscal year 2010. 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 4.0 million 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 22 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 \$15.0 million. Thereafter, the minimum purchase quantity increases by \$1.0 million per year up to \$24.0 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 market share for such products, and increase future revenues and income.

Customers and Marketing

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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%, 12%, and 11%, respectively, of our net sales in fiscal year 2012 and 9%, 6% and 10%, respectively, of our net sales in fiscal year 2011. Our largest chain drug store customer, Walgreens, accounted for 18% and 17% of net sales in fiscal year 2012 and fiscal year 2011, 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 promote our products through direct sales, trade shows and group purchasing organizations bidding processes. We also market our products through private label arrangements, under which we manufacture our products with a label containing the name and logo of our customer. This practice is commonly referred to as private label business. Private label business allows us to leverage our

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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 2012, 2011 and 2010, our 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.

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, generally there are no minimum purchase quantities applicable to these agreements.

Competition

The manufacturing and distribution of generic pharmaceutical products is a highly competitive industry. Competition is based primarily on price. In addition to competitive pricing our competitive advantages are 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 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 name 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	Alternative products to meet the need
Digoxin Tablets	GlaxoSmithKline, Impax, West-Ward and Caraco
Doxycycline Hyclate and Monohydrate Tablets	Par, Mylan, Sandoz and Ranbaxy
Hydromorphone HCl Tablets	Mallinckrodt, Roxane and Purdue
Levothyroxine Sodium Tablets	Abbott, Monarch, Mylan and Sandoz
Morphine Sulfate Oral Solution	Roxane and Mallinckrodt

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Primidone Tablets	Watson, Qualitest, West-Ward, Amneal and Impax
Rifampin Capsules	Sandoz and Versapharm
Triamterene w/Hydrochlorothiazide	Sandoz and Mylan
Unithroid® Tablets	Abbott, Monarch, Mylan and Sandoz
Ursodiol Capsules	Corepharma, Epic, Mylan, Teva and Watson

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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. 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 are generally used for generic equivalents. Typically, the investment required to develop a generic drug is less costly than the innovator drug.

There are currently three ways to obtain FDA approval of a drug:

- ***New Drug Applications (NDA)***: Unless one of the two procedures discussed in the following sections 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.

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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

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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 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.

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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

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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. 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.

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 (NCE), the FDA may not accept an ANDA for a bioequivalent product for up to five years following approval of the NDA for the NCE. 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 bioequivalency 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 FDCA 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. Please see additional discussion regarding GRASE and Grandfathered products in Item 1A. Risk Factors and Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations.

Manufacturing cGMP Requirements

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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. These inspections include reviews of procedures and operations used in the testing and manufacture of our products to assess 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.

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Failure to comply with statutory and regulatory requirements subject 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 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 combination of FDA regulatory or enforcement actions against the Company could have a material adverse effect on our financial results.

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 the 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

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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, such as Sarbanes-Oxley Act of 2002, Dodd-Frank, and the Foreign Corrupt Practices Act (FCPA).

Anti-Kickback Statutes and Federal False Claims Act

The federal health care programs Anti-Kickback Statutes prohibit 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.

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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.

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 (FFCA), and in particular, action brought pursuant to the FFCA's Whistleblower or Qui Tam provisions. The FFCA 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 FFCA 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 FFCA, 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 FFCA, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of \$6,000 to \$11,000 for each separate false claim. There are many potential bases for liability under the FFCA. 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 FFCA 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 FFCA 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 FFCA 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, knowingly 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.

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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 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 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, 2012, we had 324 employees, including 220 employees at Lannett and 104 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.

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ITEM 1A. RISK FACTORS

A major portion of our revenue is derived from sales of finished products manufactured by Jerome Stevens Pharmaceuticals (JSP). If our contract with JSP is not renegotiated prior to its March 22, 2014 expiration date, our operating results would be materially adversely affected.

Approximately 51% of our fiscal year 2012 net sales are of distributed products, primarily manufactured by JSP. Two of these products are Levo and Digoxin, which accounted for 41% and 9%, respectively, of our Fiscal 2012 net sales, and 43% and 12%, respectively, of our net sales for Fiscal 2011. Our agreement with JSP currently expires on March 22, 2014. The Company is currently engaged in discussions to renew the contract, however there is no guarantee that the contract will be renewed or extended. If the Company fails to renegotiate the agreement with JSP or it renews its contract with JSP with terms less favorable than those included in the existing agreement, our operating results would be materially adversely affected.

We materially rely on an uninterrupted supply of finished products from JSP for a majority of our sales. If we were to experience an interruption of that supply, our operating results would suffer.

If the supply of these products is interrupted in any way by any form of temporary or permanent business interruption to JSP, including but not limited to fire or other naturally-occurring, damaging event to their physical plant and/or equipment, condemnation of their facility, legislative or regulatory cease and desist declaration regarding their operations, FDA action, and any interruption in their source of API for their products, our operating results could be materially adversely affected. We do not have, at this time, a second source for these products.

The generic pharmaceutical industry is highly competitive.

We face strong competition in our generic product business. Revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents for brand name products and related exclusivity periods expire or fall under patent challenges, the first generic manufacturer to receive regulatory approval for generic equivalents of such products is generally able to achieve significant market penetration. As competing off-patent manufacturers receive regulatory approvals on similar products or as brand manufacturers launch generic versions of such products (for which no separate regulatory approval is required), market share, revenues and gross profit typically decline, in some cases dramatically. Accordingly, the level of market share, revenue and gross profit attributable to a particular generic product is normally related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. Consequently, we must continue to develop and introduce new products in a timely and cost-effective manner to maintain our revenues and gross margins.

During the first quarter of Fiscal 2011, Lannett faced significant pricing challenges on its top two selling products. In order to keep the volume of business with the specific customer involved, Lannett chose to reduce its selling price on both of the products. This price reduction has had and may continue to have a significant impact to the gross profit margins and profitability of Lannett in the future.

Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

All pharmaceutical companies, including Lannett, are subject to extensive, complex, costly and evolving regulation by the federal government, including the FDA and in the case of controlled drugs, the DEA, and state government agencies. The FDCA, the CSA and other federal statutes and regulations govern or influence the development, testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products.

The process for obtaining governmental approval to manufacture and market pharmaceutical products is rigorous, time-consuming and costly, and we cannot predict the extent to which we may be affected by legislative and regulatory developments. We are dependent on receiving FDA and other governmental or third-party approvals prior to manufacturing, marketing and shipping our products. The FDA approval process for a particular product candidate can take several years and requires us to dedicate substantial resources to securing approvals, and we may not be able to obtain regulatory approval for our product candidates in a timely manner, or at all. In order to obtain approval for our generic product candidates, we must demonstrate that our drug product is bioequivalent to a drug previously approved by the FDA through the new drug approval process, known as an innovator drug. Bioequivalency may be demonstrated in vivo or in vitro by comparing the generic product candidate to the innovator drug product in dosage form, strength, route of administration, quality, dissolution performance characteristics, and intended use. The FDA may not agree that the bioequivalence studies we submit in the ANDA applications for our generic drug products are adequate to support approval. If it determines that an ANDA application is not adequate to support approval, the FDA could deny our application or request additional

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information, including clinical trials, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product.

Consequently, there is always the chance that we will not obtain FDA or other necessary approvals, or that the rate, timing and cost of such approvals, will adversely affect our product introduction plans or results of operations. We carry inventories of certain product(s) in anticipation of launch, and if such product(s) are not subsequently launched, we may be required to write-off the related inventory. Furthermore, the FDA also has the authority to revoke drug approvals previously granted and remove these products from the market for a variety of reasons, including a failure to comply with applicable regulations, the discovery of previously unknown problems with the product, or because the ingredients in the drug are no longer approved by the FDA.

Additionally, certain products, marketed prior to the FDCA may be considered GRASE 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 1906 Act, 1938 Act or the 1962 amendments to the Act. Under the Grandfathered drug 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 GRASE or Grandfathered products. Efforts have included issuing notices to companies currently producing these products to cease its distribution of said products. Lannett currently manufactures and markets two products that are considered GRASE or Grandfathered products, including C-Topical Solution and Oxycodone HCl Solution. The FDA is currently undertaking activities to force all companies who manufacture certain GRASE products to file applications and seek approval for these products or remove their products from the market. As of July 24, 2010, Lannett stopped manufacturing and distributing Morphine Sulfate Oral Solution (MS) as part of one the FDA s enforcement actions. Lannett filed a 505(b)(2) New Drug Application (MS NDA) in February 2010 and was granted FDA approval on the submission in June 2011. Due to the length of time it took to receive approval on this application, the Company fully reserved its MS inventory as of June 30, 2011.

The Company submitted, as part of the MS NDA, a \$1.4 million application fee at the time of submission. Lannett is currently working with the FDA to get part of this fee returned to the Company. As of June 30, 2012, the Company has not received a final determination on whether any of the fee is refundable. An estimate of the un-returned amount was reclassified from other long-term assets on the Company s balance sheet as of June 30, 2011 into intangible assets upon shipment of the product which commenced in August 2011. The Company began amortizing the intangible asset over its useful life upon shipment of the product in August 2011. Amortization will be adjusted prospectively once the un-returned amount is finalized. Lannett also has approximately \$1.7 million of net inventory value at June 30, 2012 of other Grandfathered products which would also be at risk if the FDA were to pursue enforcement actions on these products similar to their actions on Morphine Sulfate Oral Solution and Oxycodone HCl Oral Solution.

In addition, Lannett, as well as many of our significant suppliers of distributed product and raw materials, are subject to periodic inspection of facilities, procedures and operations and/or the testing of the finished products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that pharmaceutical companies are in compliance with all applicable regulations. The FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether systems and processes are in compliance with cGMP, and other FDA regulations. Following such inspections, the FDA may issue notices on Form 483 that could cause us or our suppliers to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of a FDA inspection and lists conditions the FDA inspectors believe may violate cGMP or other FDA regulations. The DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, record-keeping, and distribution of drugs that are considered controlled substances. Some of the pain management products we manufacture contain controlled substances. The DEA periodically inspects facilities for compliance with its rules and regulations. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs.

Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, delays in or denials of new product approvals, warning letters, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of sales, and/or criminal prosecution. Any of these or other regulatory actions could materially harm our operating results and financial condition. Although we have instituted internal compliance programs, if these programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business. Additionally, if the FDA were to undertake additional enforcement activities with any of Lannett's GRASE products, their actions could result in, among other things, removal of some of our products from the market, seizure of products and total or partial suspension of sales. Any of these regulatory actions could materially harm our operating results and financial condition.

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Our manufacturing operations as well as our suppliers manufacturing are subject to licensing by the FDA and/or DEA. If we or our suppliers are unable to maintain the proper agency licensing arrangements, our operating results would be materially negatively impacted.

All of our manufacturing operations as well as those of our suppliers rely on maintaining active licenses to produce and develop generic drugs. Specifically, our Cody Labs operations rely on a DEA license to directly import and convert raw concentrated poppy straw into several APIs or dosage forms. This license is granted for a one year period and must be renewed successfully each year in order for us to maintain Cody's current operations and allow the Company to continue to work towards becoming a fully integrated narcotics supplier. If the Company is unable to successfully renew its FDA and/or DEA licenses, the financial results of Lannett would be negatively impacted.

If we are unable to successfully develop or commercialize new products, our operating results will suffer.

Our future results of operations will depend to a significant extent upon our ability to successfully commercialize new generic products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;
- receiving requisite regulatory approvals for such products in a timely manner;
- the availability, on commercially reasonable terms, of raw materials, including APIs and other key ingredients;
- developing and commercializing a new product is time consuming, costly and subject to numerous factors that may delay or prevent the successful commercialization of new products; and
- commercializing generic products may be substantially delayed by the listing with the FDA of patents that have the effect of potentially delaying approval of the off-patent product by up to 30 months, and in some cases, such patents have been issued and listed with the FDA after the key chemical patent on the branded drug product has expired or been litigated, causing additional delays in obtaining approval.

As a result of these and other difficulties, products currently in development by Lannett may or may not receive the regulatory approvals necessary for marketing. If any of our products, when developed and approved, cannot be successfully or timely commercialized, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

The loss of key personnel could cause our business to suffer.

The success of our present and future operations will depend, to a significant extent, upon the experience, abilities and continued services of our key personnel. If we lose the services of our key personnel, or if they are unable to devote sufficient attention to our operations for any other reason, our business may be significantly impaired. If the employment of any of our current key personnel is terminated, we cannot assure you that we will be able to attract and replace the employee with the same caliber of key personnel. As such, we have entered into employment agreements with all of our senior executive officers in order to help retain these key individuals.

Our gross profit may fluctuate from period to period depending upon our product sales mix, our product pricing and our costs to manufacture or purchase products.

Our future results of operations, financial condition and cash flows depend to a significant extent upon our product sales mix. Our sales of certain products that we manufacture tend to create higher gross margins than do the products we purchase and resell. As a result, our sales mix will significantly impact our gross profit from period to period.

Factors that may cause our sales mix to vary include:

- the amount of new product introductions;

- marketing exclusivity, if any, which may be obtained on certain new products;

- the level of competition in the marketplace for certain products;

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- the availability of raw materials and finished products from our suppliers; and
- the scope and outcome of governmental regulatory action that may involve us.

The profitability of our product sales is also dependent upon the prices we are able to charge for our products, the costs to purchase products from third parties, and our ability to manufacture our products in a cost effective manner.

If branded pharmaceutical companies are successful in limiting the use of generics through their legislative and regulatory efforts, our sales of generic products may suffer.

Many branded pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

- pursuing new patents for existing products which may be granted just before the expiration of one patent which could extend patent protection for additional years or otherwise delay the launch of generics;
- using the Citizen Petition process to request amendments to FDA standards;
- seeking changes to U.S. Pharmacopoeia, an organization which publishes industry recognized compendia of drug standards;
- attaching patent extension amendments to non-related federal legislation; and
- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing.

If branded pharmaceutical companies are successful in limiting the use of generic products through these or other means, our sales may decline. If we experience a material decline in product sales, our results of operations, financial condition and cash flows will suffer.

Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may have to defend against charges that we violated patents or proprietary rights of third parties. This is especially true in the case of generic products on which the patent covering the branded product is expiring, an area where infringement litigation is prevalent, and in the case of new branded products where a competitor has obtained patents for similar products. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. In addition, if we infringe on the rights of others, we could lose our right to develop or manufacture products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. Although the parties to patent and intellectual property disputes in the pharmaceutical industry have often settled their disputes through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, we cannot be certain that the necessary licenses would be available to us on terms we believe to be acceptable. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling a number of our products, which could harm our business, financial condition, results of operations and cash flows.

If we are unable to obtain sufficient supplies from key suppliers that in some cases may be the only source of finished products or raw materials, our ability to deliver our products to the market may be impeded.

We are required to identify the supplier(s) of all the raw materials for our products in our applications with the FDA. To the extent practicable, we attempt to identify more than one supplier in each drug application. However, some products and raw materials are available only from a single source and, in some of our drug applications, only one supplier of products and raw materials has been identified, even in instances where multiple sources exist. To the extent any difficulties experienced by our suppliers cannot be resolved within a reasonable time, and at reasonable cost, or if raw materials for a particular product become unavailable from an approved supplier and we are required to qualify a new supplier with the FDA, our profit margins and market share for the affected product could decrease, and our development and sales and marketing efforts could be delayed.

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Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce our revenues in future fiscal periods.

Based on industry practice, generic drug manufacturers have liberal return policies and have been willing to give customers post-sale inventory allowances. Under these arrangements, from time to time, we give our customers credits on our generic products that our customers hold in inventory after we have decreased the market prices of the same generic products due to competitive pricing. Therefore, if new competitors enter the marketplace and significantly lower the prices of any of their competing products, we would likely reduce the price of our product. As a result, we would be obligated to provide credits to our customers who are then holding inventories of such products, which could reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesalers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other customers. A chargeback is the difference between the price the wholesaler pays and the price that the wholesaler's end-customer pays for a product. Although we establish reserves based on our prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates.

Health care initiatives and other third-party payor cost-containment pressures could cause us to sell our products at lower prices, resulting in decreased revenues.

Some of our products are purchased or reimbursed by state and federal government authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs, and managed care organizations, or MCOs. Third-party payors increasingly challenge pharmaceutical product pricing. There also continues to be a trend toward managed health care in the United States. Pricing pressures by third-party payors and the growth of organizations such as HMOs and MCOs could result in lower prices and a reduction in demand for our products.

In addition, legislative and regulatory proposals and enactments to reform health care and government insurance programs could significantly influence the manner in which pharmaceutical products and medical devices are prescribed and purchased. We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could limit the amounts that federal and state governments will pay for health care products and services. The extent to which future legislation or regulations, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted or what effect such legislation or regulation would have on our business remains uncertain. For example, the American Recovery and Reinstatement Act of 2009, also known as the stimulus package, includes \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. The stimulus package funding is expected to be used for, among other things, to conduct, support or synthesize research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of products. Although Congress has indicated that this funding is intended for improvement in quality of health care, it remains unclear how the research will impact coverage, reimbursement or other third-party payor policies. Such measures or other health care system reforms that are adopted could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on development projects and affect our ultimate profitability.

We may need to change our business practices to comply with changes to fraud and abuse laws.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including the federal fraud and abuse law (sometimes referred to as the Anti-Kickback Statute) which apply to our sales and marketing practices and our relationships with physicians. At the federal level, the Anti-Kickback Statute prohibits any person or entity from knowingly and willfully soliciting, receiving, offering, or paying any remuneration, including a bribe, kickback, or rebate, directly or indirectly, in return for or to induce the referral of patients for items or services

covered by federal health care programs, or the furnishing, recommending, or arranging for products or services covered by federal health care programs. Federal health care programs have been defined to include plans and programs that provide health benefits funded by the federal government, including Medicare and Medicaid, among others. The definition of remuneration has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, and waivers of payments. Several courts have interpreted the federal Anti-Kickback Statute's intent requirement to mean that if even one purpose in an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under federal health care programs, the statute has been violated. The federal government has issued regulations, commonly known as safe harbors that set forth certain provisions which, if fully met, will assure parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement will be illegal or that prosecution under the federal Anti-Kickback Statute will be pursued, but such transactions or arrangements face an increased risk of scrutiny by government enforcement authorities and an ongoing risk of prosecution. If our sales and marketing practices or our relationships with physicians (such as physicians serving on our Scientific Advisory Board) are considered by federal or state enforcement authorities to be knowingly and willfully soliciting, receiving, offering, or providing any remuneration in exchange for arranging for or recommending our products and services, and such activities do not fit within a safe harbor, then these arrangements could be challenged under the federal Anti-Kickback Statute. If our operations are found to be in

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violation of the federal Anti-Kickback Statute we may be subject to civil and criminal penalties including fines of up to \$25,000 per violation, civil monetary penalties of up to \$50,000 per violation, assessments of up to three times the amount of the prohibited remuneration, imprisonment, and exclusion from participating in the federal health care programs. In addition, HIPAA and its implementing regulations 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, knowingly 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. A number of states also have anti-fraud and anti-kickback laws similar to the federal Anti-Kickback Statute that prohibit certain direct or indirect payments if such arrangements are designed to induce or encourage the referral of patients or the furnishing of goods or services. Some states' anti-fraud and anti-kickback laws apply only to goods and services covered by Medicaid. Other states' anti-fraud and anti-kickback laws apply to all health care goods and services, regardless of whether the source of payment is governmental or private. Due to the breadth of these laws and the potential for changes in laws, regulations, or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could materially adversely affect our business.

Certain federal and state governmental agencies, including the U.S. Department of Justice and the U.S. Department of Health and Human Services, have been investigating issues surrounding pricing information reported by drug manufacturers and used in the calculation of reimbursements as well as sales and marketing practices. For example, many government and third-party payors, including Medicare and Medicaid, reimburse doctors and others for the purchase of certain pharmaceutical products based on the product's AWP reported by pharmaceutical companies. While Lannett has only used Suggested Wholesale Prices since 2000, the federal government, certain state agencies, and private payors are investigating and have begun to file court actions related to pharmaceutical companies' reporting practices with respect to AWP, alleging that the practice of reporting prices for pharmaceutical products has resulted in a false and overstated AWP, which in turn is alleged to have improperly inflated the reimbursement paid by Medicare beneficiaries, insurers, state Medicaid programs, medical plans, and others to health care providers who prescribed and administered those products. In addition, some of these same payors are also alleging that companies are not reporting their best price to the states under the Medicaid program. We are not currently subject to any such investigations or actions and having not used AWP pricing since 2000 would not likely become subject to these investigations.

We may become subject to federal and state false claims litigation brought by private individuals and the government.

We are subject to state and federal laws that govern the submission of claims for reimbursement. The Federal False Claims Act (FFCA), also known as Qui Tam, imposes civil liability and criminal fines on individuals or entities that knowingly submit, or cause to be submitted, false or fraudulent claims for payment to the government. Violations of the FFCA and other similar laws may result in criminal fines, imprisonment, and civil penalties for each false claim submitted and exclusion from federally funded health care programs, including Medicare and Medicaid. The FFCA also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the FFCA. These suits, also known as Qui Tam actions, may be brought by, with only a few exceptions, any private citizen who has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the FFCA allows an individual to share in any amounts paid to the federal government in fines or settlement as a result of a successful Qui Tam action. If our past or present operations are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs, and/or the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results, action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Sales of our products may continue to be adversely affected by the continuing consolidation of our distribution network and the concentration of our customer base.

Our principal customers are wholesale drug distributors and major retail drug store chains. These customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. We expect that consolidation of drug wholesalers and retailers will increase pricing and other competitive pressures on drug manufacturers, including Lannett.

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Our three largest customers accounted for 18%, 12% and 11%, respectively, of our net sales for the fiscal year ended June 30, 2012, and 17%, 10% and 9%, respectively, of our net sales for the fiscal year ended June 30, 2011. The loss of any of these customers could materially adversely affect our business, results of operations and financial condition and our cash flows. In addition, the Company generally does not enter into long-term supply agreements with its customers that would require them to purchase our products.

The design, development, manufacture and sale of our products involves the risk of product liability claims by consumers and other third parties, and insurance against such potential claims is expensive and may be difficult to obtain.

The design, development, manufacture and sale of our products involve an inherent risk of product liability claims and the associated adverse publicity. Insurance coverage is expensive and may be difficult to obtain, and may not be available in the future on acceptable terms, or at all. Although we currently maintain product liability insurance for our products in amounts we believe to be commercially reasonable, if the coverage limits of these insurance policies are not adequate, a claim brought against Lannett, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Rising insurance costs, as well as the inability to obtain certain insurance coverage for risks faced by Lannett, could negatively impact profitability.

The cost of insurance, including workers compensation, product liability and general liability insurance, has risen in prior years and may increase in the future. In response, we may increase deductibles and/or decrease certain coverage to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverage, could have a negative impact on our results of operations, financial condition and cash flows.

Additionally, certain insurance coverages may not be available to Lannett for risks faced by Lannett. Sometimes the coverages obtained by Lannett for certain risks may not be adequate to fully reimburse the amount of damage that Lannett could possibly sustain. Should either of these events occur, the lack of insurance to cover the entire cost to the Company would adversely affect our results of operations and financial condition.

Significant balances of intangible assets, including product rights acquired, are subject to impairment testing and may result in impairment charges, which would adversely affect our results of operations and financial condition.

Our acquired contractual rights to market and distribute products are stated at cost, less accumulated amortization and related impairment charges identified to date. We determined the initial cost by referring to the original fair value of the assets exchanged. Future amortization periods for product rights are based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired products. Such factors include the product's position in its life cycle, the existence or absence of like products in the market, various other competitive and regulatory issues and contractual terms. Significant changes to any of these factors would require us to perform an additional impairment test on the affected asset and, if evidence of impairment exists, we would be required to take an impairment charge with respect to the asset. Such a charge would adversely affect our results of operations and financial condition.

Federal regulation of arrangements between manufacturers of branded and generic products could adversely affect our business.

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, companies are now required to file with the Federal Trade Commission (FTC) and the Department of Justice certain types of agreements entered into between brand and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs. This new requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with branded pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities. The impact of this new requirement and the potential private-party lawsuits associated with arrangements between brand name and generic drug manufacturers is uncertain, and could adversely affect our business.

ITEM 2. DESCRIPTION OF PROPERTY

Lannett owns three facilities in Philadelphia, Pennsylvania. Certain administrative functions, manufacturing and production facilities and our quality control laboratory are located in a 31,000 square foot facility at 9000 State Road Philadelphia, PA. The second facility consists of 63,000 square feet, and is located within one mile of the State Road facility at 9001 Torresdale Avenue Philadelphia, PA. Our research laboratory and packaging functions are located at this location. Additionally, the facility has capacity for additional manufacturing space, if needed. In October 2009, we purchased a building consisting of 66,000 square feet on approximately 7.3

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acres of land for approximately \$3.8 million, plus the cost of fit out of approximately \$2.0 million. This facility is being used for certain administrative functions, warehouse space, shipping and has capacity for additional manufacturing space, if needed.

The manufacturing facility of our wholly-owned subsidiary, Cody Labs, consists of an approximately 73,000 square foot structure located on approximately 15.0 acres in Cody, Wyoming. Cody Labs leases the facility from Cody LCI Realty, LLC, which is 50% owned by us and 50% by an officer of Cody Labs. Cody Labs' manufacturing facility currently has capacity for further expansion, both inside and outside the existing structure.

ITEM 3. LEGAL PROCEEDINGS

In January 2010, the Company initiated an arbitration proceeding against Olive Healthcare (Olive) for damages arising out of Olive's delivery of defective soft-gel prenatal vitamin capsules. The Company sought damages in excess of \$3.5 million. Olive denied liability and filed a counterclaim in February 2010 for breach of contract. Olive also filed a lawsuit against the Company in Daman, India seeking to enjoin the United States arbitration and claiming damages of approximately \$6.8 million for compensatory damages and an additional approximately \$6.8 million for loss of business. The Company engaged Indian counsel to actively defend that suit. The parties reached a settlement agreement which was signed and executed on August 13, 2012. The agreement is favorable to Lannett and includes the dismissal with prejudice of all legal proceedings between the Company and Olive in the U.S. and India.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

On April 15, 2002, the Company's common stock began trading on the American Stock Exchange (now the NYSE MKT). Prior to this, the Company's common stock traded in the over-the-counter market through the use of the inter-dealer "pink-sheets" published by Pink Sheets LLC. The following table sets forth certain information with respect to the high and low daily closing prices of the Company's common stock during Fiscal 2012 and 2011, as quoted by the NYSE MKT. Such quotations reflect inter-dealer prices without retail mark-up, markdown, or commission and may not represent actual transactions.

Fiscal Year Ended June 30, 2012

		High		Low
First quarter	\$	5.11	\$	3.50
Second quarter	\$	4.50	\$	3.53
Third quarter	\$	5.24	\$	4.01
Fourth quarter	\$	4.34	\$	3.76

Fiscal Year Ended June 30, 2011

		High		Low
First quarter	\$	4.92	\$	4.06
Second quarter	\$	6.75	\$	4.61
Third quarter	\$	5.75	\$	5.08
Fourth quarter	\$	5.77	\$	4.98

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Holders

As of August 31, 2012, there were approximately 218 holders of record of the Company's common stock.

Dividends

The Company did not pay cash dividends in Fiscal 2012 or Fiscal 2011. The Company intends to use available funds for working capital, plant and equipment additions, and various product extension ventures. The Company does not expect to pay, nor should shareholders expect to receive, cash dividends in the foreseeable future.

Share Repurchase Program

On January 27, 2005, the Company's Board of Directors approved a stock repurchase program which was reauthorized by the Board of Directors on November 20, 2009. Under the program, the Company is authorized to repurchase up to \$5.0 million of its outstanding common stock. As of June 30, 2012, the Company has repurchased 342,245 shares of its common stock under the program at an aggregate purchase price of \$1,594,285.

The following table sets forth certain information with respect to the Company's Share Repurchase Program.

ISSUER PURCHASES OF EQUITY SECURITIES

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
April 1 to April 30, 2012	20,215	\$ 3.89	20,215	\$ 3,569,672
May 1 to May 31, 2012	24,103	3.96	24,103	3,474,296
June 1 to June 30, 2012	17,458	3.93	17,458	3,405,715
	61,776		61,776	

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Stock Performance Chart

The following graph presents a comparison of the cumulative total stockholder return on the Company's stock with the cumulative total return of the NYSE MKT Composite Index and the Morningstar Drug Manufacturers Specialty and Generic Index for the period of five years commencing July 1, 2007 and ending June 30, 2012. The graph assumes that \$100 was invested on July 1, 2007 in each of Lannett Company, Inc. common stock, NYSE MKT Composite Index and the Morningstar Drug Manufacturers Specialty and Generic Index.

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA**

The following financial information as of and for the five years ended June 30, 2012, has been derived from our consolidated financial statements. This information should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere herein. The comparability of information is affected by the items described below.

In Fiscal 2008, we increased our returns reserve by \$10.5 million, reflecting our expectation that 100% of the shipments of Prenatal Multivitamin made in the fourth quarter of Fiscal 2008 would be returned. Our expectation that all of the product would be returned was based on our inability to have the product specified as a brand equivalent, product complaints and information from our customers regarding their intentions to return the product.

Lannett Company, Inc. and Subsidiaries**Financial Highlights****(In thousands, except per share data)****As of and for the Fiscal Year Ended June 30,****Operating Highlights**

	2012	2011	2010	2009	2008
Net Sales	\$ 122,990	\$ 106,835	\$ 125,178	\$ 119,002	\$ 72,043
Gross Profit	\$ 38,947	\$ 23,320	\$ 41,340	\$ 45,244	\$ 16,301
Operating Income (loss)	\$ 6,910	\$ (1,179)	\$ 12,713	\$ 10,758	\$ (5,425)
Net Income (loss) Lannett Company, Inc.	\$ 3,948	\$ (277)	\$ 7,821	\$ 6,534	\$ (2,318)
Basic Earnings (loss) Per Share Lannett Company, Inc.	\$ 0.14	\$ (0.01)	\$ 0.32	\$ 0.27	\$ (0.10)
Diluted Earnings (loss) Per Share Lannett Company, Inc.	\$ 0.14	\$ (0.01)	\$ 0.31	\$ 0.27	\$ (0.10)

Balance Sheet Highlights

Total Assets	\$ 158,218	\$ 147,744	\$ 139,964	\$ 124,577	\$ 113,679
Total Debt	\$ 7,161	\$ 7,822	\$ 7,720	\$ 8,139	\$ 8,979
Long Term Debt, less Current Portion	\$ 6,513	\$ 7,193	\$ 2,869	\$ 7,703	\$ 8,187
Total Stockholders Equity	\$ 111,313	\$ 105,689	\$ 88,958	\$ 77,648	\$ 69,322

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In addition to historical information, this Form 10-K contains forward-looking information. The forward-looking information is subject to certain risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. Important factors that might cause such a difference include, but are not limited to, those discussed in the following section, entitled

Management's Discussion and Analysis of Financial Condition and Results of Operations. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. The Company undertakes no

obligation to publicly revise or update these forward-looking statements to reflect events or circumstances that may occur. Readers should carefully review the risk factors described in other documents the Company files from time to time with the SEC, including the Quarterly Reports on Form 10-Q to be filed by the Company in Fiscal 2013, and any Current Reports on Form 8-K filed by the Company.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities at the date of our financial statements. Actual results may differ from these estimates under different assumptions or conditions.

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Critical accounting policies are defined as those that are reflective of significant judgments and uncertainties and potentially result in materially different results under different assumptions and conditions. We believe that our critical accounting policies include those described below:

Revenue Recognition - The Company recognizes revenue when its products are shipped. At this point, title and risk of loss have transferred to the customer and provisions for estimates, including rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable. Accruals for these provisions are presented in the consolidated financial statements as rebates, chargebacks and returns payable and reductions to net sales. The change in the reserves for various sales adjustments may not be proportionally equal to the change in sales because of changes in both the product and the customer mix. Increased sales to wholesalers will generally require additional accruals as they are the primary recipient of chargebacks and rebates. Incentives offered to secure sales vary from product to product. Provisions for estimated rebates and promotional credits are estimated based upon contractual terms. Provisions for other customer credits, such as price adjustments, returns, and chargebacks, require management to make subjective judgments on customer mix. Unlike branded innovator drug companies, Lannett does not use information about product levels in distribution channels from third-party sources, such as IMS and Wolters Kluwer, in estimating future returns and other credits. Lannett calculates a chargeback/rebate rate based on contractual terms with its customers and applies this rate to customer sales. The only variable is customer mix, and this assumption is based on historical data and sales expectations.

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

Rebates Rebates are offered to the Company's key chain drug store, distributor and wholesaler customers to promote customer loyalty and increase product sales. These rebate programs provide customers with rebate credits upon attainment of pre-established volumes or attainment of net sales milestones for a specified period. Other promotional programs are incentive programs offered to the customers. As a result of the Patient Protection and Affordable Care Act (PPACA) enacted in the U.S. in March 2010, the Company participates in a new cost sharing program for certain Medicare Part D beneficiaries designed primarily for the sale of brand drugs and certain generic drugs if their FDA approval was granted under a New Drug Application (NDA) or 505(b) NDA versus an Abbreviated New Drug Application (ANDA). Because our drugs used for the treatment of thyroid deficiency and our Morphine Sulfate Oral Solution product were approved by the FDA as a 505(b)(2) NDA, they are considered branded drugs for purposes of the PPACA. Drugs purchased under this program during Medicare Part D coverage gap (commonly referred to as the donut hole) result in additional rebates. At the time of shipment, the Company estimates reserves for rebates and other promotional credit programs based on the specific terms in each agreement. The reserve for rebates increases as sales to certain wholesale and retail customers increase. However, since these rebate programs are not identical for all customers, the size of the reserve will depend on the mix of customers that are eligible to receive rebates.

Returns Consistent with industry practice, the Company has a product returns policy that allows customers to return product within a specified period prior to and subsequent to the product's lot expiration date in exchange for a credit to be applied to future purchases. The Company's policy requires that the customer obtain pre-approval from the Company for any qualifying return. The Company estimates its provision for

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returns based on historical experience, changes to business practices, and credit terms. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future returns. The Company continually monitors the provisions for returns and makes adjustments when management believes that actual product returns may differ from established reserves. Generally, the reserve for returns increases as net sales increase. The reserve for returns is included in the rebates, chargebacks and returns payable account on the balance sheet.

Other Adjustments Other adjustments consist primarily of price adjustments, also known as shelf stock adjustments, which are credits issued to reflect decreases in the selling prices of the Company's products that customers have remaining in their inventories at the time of the price reduction. Decreases in selling prices are discretionary decisions made by management to reflect competitive

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market conditions. Amounts recorded for estimated shelf stock adjustments are based upon specified terms with direct customers, estimated declines in market prices, and estimates of inventory held by customers. The Company regularly monitors these and other factors and evaluates the reserve as additional information becomes available. Other adjustments are included in the rebates, chargebacks and returns payable account on the balance sheet.

The following tables identify the reserves for each major category of revenue allowance and a summary of the activity for fiscal years 2012, 2011 and 2010. Unless we have specific information to indicate otherwise, actual credits issued in a given year are assumed to be related to sales recorded in prior years based on the Company's returns policy.

For the Year Ended June 30, 2012

(In thousands)										
Reserve Category	Chargebacks		Rebates		Returns		Other		Total	
Reserve Balance as of June 30, 2011	\$	5,497	\$	2,925	\$	5,142	\$		\$	13,564
Actual credits issued related to sales recorded in prior fiscal years		(5,354)		(3,084)		(4,294)		(152)		(12,884)
Reserves or (reversals) charged during Fiscal 2012 related to sales in prior fiscal years		(143)		159				152		168
Reserves charged to net sales during Fiscal 2012 related to sales recorded in Fiscal 2012		68,576		21,019		4,692		1,981		96,268
Actual credits issued related to sales recorded in Fiscal 2012		(61,513)		(16,583)				(1,981)		(80,077)
Reserve Balance as of June 30, 2012	\$	7,063	\$	4,436	\$	5,540	\$		\$	17,039

For the Year Ended June 30, 2011

(In thousands)										
Reserve Category	Chargebacks		Rebates		Returns		Other		Total	
Reserve Balance as of June 30, 2010	\$	6,282	\$	3,566	\$	5,401	\$		\$	15,249
Actual credits issued related to sales recorded in prior fiscal years		(6,100)		(3,947)		(4,592)				(14,639)
Reserves or (reversals) charged during Fiscal 2011 related to sales in prior fiscal years				381						381
Reserves charged to net sales during Fiscal 2011 related to sales recorded in Fiscal 2011		53,687		16,587		6,715		3,502		80,491

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Actual credits issued related to sales recorded in Fiscal 2011	(48,372)	(13,662)	(2,382)	(3,502)	(67,918)
Reserve Balance as of June 30, 2011	\$ 5,497	\$ 2,925	\$ 5,142	\$	\$ 13,564

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(In thousands) Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2009	\$ 6,090	\$ 2,538	\$ 5,107	\$	\$ 13,735
Actual credits issued related to sales recorded in prior fiscal years	(6,069)	(2,538)	(3,833)		(12,440)
Reserves or (reversals) charged during Fiscal 2010 related to sales in prior fiscal years			(401)		(401)
Reserves charged to net sales during Fiscal 2010 related to sales recorded in Fiscal 2010	48,539	16,353	4,528	1,227	70,647
Actual credits issued related to sales recorded in Fiscal 2010	(42,278)	(12,787)		(1,227)	(56,292)
Reserve Balance as of June 30, 2010	\$ 6,282	\$ 3,566	\$ 5,401	\$	\$ 15,249

Reserve Activity 2012 vs. 2011

The total reserve for chargebacks, rebates, returns and other adjustments increased from \$13,564,000 at June 30, 2011 to \$17,039,000 June 30, 2012. The increase in total reserves was due to an increase in the rebates reserve as a result of increased gross sales to customers who participate in rebate programs, the timing of actual rebate credits issued, as well as an additional rebate program the Company became obligated to participate in under Medicare Part D. The increase in chargeback reserves is due primarily to an increase in inventory levels at wholesale distribution centers as a result of increased gross sales during Fiscal 2012 as compared to Fiscal 2011. The activity in the Other category for the year ended June 30, 2012 includes shelf-stock, shipping and other sales adjustments.

The following tables compare the year-end reserve balances in fiscal years 2012 and 2011 and the gross sales mix in Fiscal 2012 and Fiscal 2011.

(In thousands)	Fiscal Year Ended June 30,		Fiscal Year Ended June 30,	
	2012	%	2011	%
Chargeback reserve	\$ 7,063	41%	\$ 5,497	40%
Rebate reserve	4,436	26%	2,925	22%
Return reserve	5,540	33%	5,142	38%
Other reserve		%		%
	\$ 17,039	100%	\$ 13,564	100%

	Fiscal Year ended June 30,	
	2012	2011
Chain drug stores	24%	28%

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Mail Order	4%	2%
Wholesalers	72%	70%
	100%	100%

Reserve Activity 2011 vs. 2010

The total reserve for chargebacks, rebates, returns and other adjustments decreased from \$15,249,000 at June 30, 2010 to \$13,564,000 at June 30, 2011. The decrease in total reserves was due to a decrease in the rebates reserve as a result of the timing of credits being processed by the customers and by the Company, a decrease in chargeback reserves due primarily to a decrease in inventory levels at wholesale distribution centers, and a decrease in return reserve primarily due to timing of credits processed by the customer.

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During Fiscal 2011, the Company issued credits totaling \$2,382,000 related to Fiscal 2011 gross sales of Morphine Sulfate Oral Solution which were returned as a result of the FDA's action to force the Company to cease manufacturing and distributing this product as of July 24, 2010.

The following tables compare the year-end reserve balances in fiscal years 2011 and 2010 and the gross sales mix in Fiscal 2011 and Fiscal 2010.

(In thousands)	Fiscal Year Ended June 30,			
	2011	%	2010	%
Chargeback reserve	\$ 5,497	40%	\$ 6,282	41%
Rebate reserve	2,925	22%	3,566	23%
Return reserve	5,142	38%	5,401	36%
Other reserve		%		%
	\$ 13,564	100%	\$ 15,249	100%

	Fiscal Year ended June 30,	
	2011	2010
Chain drug stores	28%	32%
Mail Order	2%	4%
Wholesalers	70%	64%
	100%	100%

Inventories - The Company values its inventory at the lower of cost (determined by the first-in, first-out method) or market, regularly reviews inventory quantities on hand, and records a provision for excess and obsolete inventory based primarily on estimated forecasts of product demand and production requirements. The Company's estimates of future product demand may prove to be inaccurate, in which case it may have understated or overstated the provision required for excess and obsolete inventory.

Income Taxes - The Company accounts for income taxes in accordance with FASB ASC 740. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities as measured by presently enacted tax rates which will be in effect when these differences reverse. Deferred tax expense/(benefit) is the result of changes in deferred tax assets and liabilities. The Company may recognize the tax benefit from an uncertain tax position claimed on a tax return only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The authoritative standards issued by the FASB also provide guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. The factors used to assess the likelihood of realization of its net deferred tax assets are the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in applicable tax jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

Intangible Assets - Indefinite-lived intangible assets are tested for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. Definite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable.

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Indefinite-lived intangible assets are considered impaired if the carrying value of the asset is greater than fair value. The fair value is determined by using a discounted cash flow analysis. Definite-lived intangible assets are considered impaired if the carrying value of the asset is greater than the undiscounted cash flows related to the assets. Our cash flow models are highly reliant on various assumptions which are considered level 3 inputs, including estimates of future cash flow (including long-term growth rates), discount rates, and expectations about variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows. As of June 30, 2012 and 2011, the Company had one indefinite-lived intangible asset in the amount of \$149,000. The Company performed the annual impairment test in the fourth quarter and determined that no impairment charges were required. No events or changes in circumstances were identified during Fiscal 2012 or Fiscal 2011 that would indicate a need to perform impairment analyses for definite-lived intangible assets. As such, no impairment charges were required.

Definite-lived intangible assets are amortized over the estimated useful lives, generally for periods ranging from 10 to 15 years. The Company continually evaluates the reasonableness of the useful lives of these assets. For the fiscal years ended June 30, 2012, 2011 and 2010, the Company incurred amortization expense of \$1,879,000, \$1,875,000, and \$1,833,000, respectively.

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Share-based Compensation - Share-based compensation costs are recognized over the vesting period based on the fair value of the instrument on the date of grant less an estimate for forfeitures. The Company uses the Black-Scholes option-pricing model to determine the fair value of stock options and the share price on the grant date to value restricted stock. The fair value model includes various assumptions, including the expected volatility, expected life of the awards, and risk-free interest rates. These assumptions involve inherent uncertainties based on market conditions which are generally outside the Company's control. Changes in these assumptions could have a material impact on share-based compensation costs recognized in the financial statements. Refer to Note 18 of our Consolidated Financial Statements for a detailed description of our Black-Scholes weighted average assumptions for fiscal 2012, 2011, and 2010.

New Accounting Pronouncements -

In June 2011, the FASB issued authoritative guidance which allows an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both options, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. This guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. This guidance does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. This authoritative guidance must be applied retrospectively, and is effective for fiscal years and interim periods within those years, beginning after December 15, 2011. In December 2011, the FASB issued an update deferring the effective date for amendments to the presentation of reclassifications of items out of accumulated other comprehensive income. The adoption of this guidance by the Company on July 1, 2012 will not have a significant impact on the Company's consolidated financial statements as it only requires a change in the format of the current presentation.

In July 2012, the FASB issued authoritative guidance which allows an entity the option to first assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that an indefinite-lived intangible asset is impaired. If, after assessing the totality of events and circumstances, an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to take further action. An entity also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. An entity will be able to resume performing the qualitative assessment in any subsequent period. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted, including for annual and interim impairment tests performed as of a date before July 27, 2012, if a public entity's financial statements for the most recent annual or interim period have not yet been issued or, for nonpublic entities, have not yet been made available for issuance. The Company adopted this guidance effective July 1, 2012. The adoption of this guidance by the Company is not expected to have a significant impact on the Company's consolidated financial statements.

Results of Operations Fiscal 2012 compared to Fiscal 2011

Net sales increased 15% from \$106,835,000 in Fiscal 2011 to \$122,990,000 in Fiscal 2012. The following factors contributed to the \$16,155,000 increase in sales:

Medical indication	Sales volume change %	Sales price change %
Antibiotic	57%	(47)%
Cardiovascular	58%	(13)%

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Gallstone Prevention	26%	(15)%
Glaucoma	13%	23%
Migraine Headache	(29)%	(2)%
Obesity	26%	(8)%
Pain Management	(2)%	44%
Thyroid Deficiency	7%	1%

Sales of drugs used for pain management increased by \$6,123,000 for Fiscal 2012 compared to Fiscal 2011 due mainly to a price increase as well as additional volume of C-Topical Solution shipped to wholesale distributors. The Company also commenced shipments of Morphine Sulfate Oral Solution in the first quarter of Fiscal 2012 based on its June 2011 FDA approval which contributed to the overall increase in pain management sales. Partially offsetting these increases was decreases in volume of Oxycodone sold during Fiscal 2012. Sales of drugs for cardiovascular treatment increased by approximately \$5,589,000 compared to Fiscal 2011 mainly due to a recently approved product for the treatment of hypertension which commenced shipping at the end of December 2011 partially offset by a competitive price reduction for another cardiovascular product during the third quarter of Fiscal

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2011 in order to retain one of our major customers. Sales of drugs used in the treatment of thyroid deficiency increased by approximately \$3,798,000 for Fiscal 2012 compared to Fiscal 2011 primarily as a result of increased sales volume to one of our major retail customers, partially offset by a decrease in price related to Medicare Part D coverage gap rebates totaling approximately \$1,797,000. Sales of drugs used for anti-psychosis treatment increased by \$1,286,000 during Fiscal 2012 mainly due to the Loxapine product launch. Additional sales can also be attributed to drugs used for the treatment of glaucoma prevention which accounted for an increase in net sales of \$1,134,000 for Fiscal 2012 compared to Fiscal 2011. The overall increase in sales was partially offset by a decrease in sales of drugs used for the treatment of migraine headaches by \$2,683,000 for Fiscal 2012 compared to Fiscal 2011 primarily as a result of decreased volumes to both chain drug stores and wholesale distributors. Sales of prescription vitamins decreased by \$1,838,000 due to the settlement agreement reached with KV on December 15, 2010 which required the Company to cease selling products covered by the licensed patents.

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

(In thousands) Customer Category	Fiscal 2012 Net Sales	Fiscal 2011 Net Sales
Wholesaler/Distributor	\$ 68,082	\$ 56,632
Retail Chain	45,633	46,270
Mail-Order Pharmacy	9,275	3,933
Total	\$ 122,990	\$ 106,835

The sales to wholesaler/distributor increased primarily as a result of the increase in sales of pain management products discussed above, partially offset by a decrease in demand for migraine headache products for which the company is no longer the primary supplier. The sales to retail chains decreased due to the discontinuation of sales of prescription vitamins, lower volumes of drugs used for the treatment of migraine headaches, in addition to a Medicare Part D coverage gap rebate totaling approximately \$1,797,000 related to sales of drugs used for the treatment of thyroid deficiency. Mail-order pharmacy sales increased primarily as a result of increased sales due to a recently approved product for the treatment of hypertension which commenced shipping in January 2012.

Cost of sales increased slightly to \$84,043,000 in Fiscal 2012 from \$83,515,000 in Fiscal 2011. The increase reflected the impact of the 15% increase in sales as well as a change in the mix of products sold, partially offset by manufacturing efficiencies. Cost of sales for Fiscal 2011 included additional inventory reserves totaling \$1,738,000 related to Morphine Sulfate Oral Solution and the reversal of royalty expense totaling \$618,000 as a result of the settlement agreement reached with KV in December 2010.

Amortization expense included in cost of sales change above primarily relates to the JSP Distribution Agreement. For the remaining term of the JSP Distribution Agreement, the Company will incur annual amortization expense of approximately \$1,785,000 related to this agreement.

Gross profit margins for Fiscal 2012 and Fiscal 2011 were 32% and 22%, respectively. Gross profit percentage increased due to a change in the mix of products sold as discussed above, in addition to manufacturing efficiencies. Gross profit margins in Fiscal 2011 were negatively impacted by additional inventory reserves totaling \$1,738,000 related to Morphine Sulfate Oral Solution partially offset by the reversal of royalty expense totaling \$618,000 as a result of the settlement agreement reached with KV in December 2010. Pricing pressure from competitors and costs of producing or purchasing new drugs may also fluctuate in the future. Changes in the future sales product mix may also

occur. These changes may affect the gross profit percentage in future periods.

Research and development (R&D) expenses increased 38% to \$11,844,000 in Fiscal 2012 from \$8,587,000 in Fiscal 2011. The increase is primarily due to compensation related costs incurred during Fiscal 2012 but not incurred in Fiscal 2011, in addition to increased internal research and development activities partially offset by a decrease in costs related to biostudies as a result of the timing of milestone achievements for costs of products in development. The Company expenses all production costs as R&D until the drug is approved by the FDA. R&D expenses may fluctuate from period to period, based on R&D plans for submission to the FDA.

Selling, general and administrative (S,G&A) expenses increased 27% to \$20,193,000 in Fiscal 2012 from \$15,912,000 in Fiscal 2011. The increase is primarily due to compensation related costs incurred during Fiscal 2012 but not incurred in Fiscal 2011, in addition to an increase in outsourced sales and marketing expenses. Fiscal 2011 also includes the reversal of the remaining Fiscal 2010 accrued bonuses totaling \$1,391,000, of which \$1,010,000 was included in SG&A. While the Company is focused on controlling costs, increases in personnel costs may have an ongoing and longer lasting impact on the administrative cost structure.

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Other costs are being incurred to facilitate improvements in the Company's infrastructure. These costs are expected to be temporary investments in the future of the Company and may not continue at the same level.

Interest expense increased to \$273,000 in Fiscal 2012 from \$214,000 in Fiscal 2011, due to higher average levels of long-term debt outstanding during Fiscal 2012. Interest and dividend income increased to \$142,000 in Fiscal 2012 from \$91,000 in Fiscal 2011 due to higher interest earned on larger average investment securities balances throughout Fiscal 2012. The Company recorded losses on trading investment securities during Fiscal 2012 totaling \$103,000, of which \$236,000 was realized gains and \$339,000 was unrealized losses compared to realized and unrealized gains totaling \$206,000 in Fiscal 2011.

The Company recorded income tax expense totaling \$2,600,000 in Fiscal 2012 compared to an income tax benefit totaling \$461,000 in Fiscal 2011. The effective tax rate for Fiscal 2012 was 39.3% compared to 65.8% for Fiscal 2011. The effective tax rate for Fiscal 2012 includes the impact of nondeductible incentive stock option compensation expense relative to pretax income for Fiscal 2012 partially offset by the impact of income tax credits. The effective tax rate for Fiscal 2012 was lower compared to Fiscal 2011 due primarily to the impact in Fiscal 2011 of income tax credits and the reversal of a portion of our liability for unrecognized tax benefits totaling \$264,000 related to a settlement with the IRS. These increases were partially offset by the effect of nondeductible incentive stock option compensation expenses relative to the pretax income for Fiscal 2011.

At June 30, 2012, the Company has recognized a net deferred tax asset of \$13,902,000. The net deferred tax asset is net of a valuation allowance of \$2,112,000 that is primarily related to the Cody notes receivable impairment incurred in conjunction with the acquisition of Cody Labs. The Company has provided for the valuation allowance related to the notes receivable impairment as this benefit will be realized only upon the disposition of Cody Labs. As the Company has no current plans to dispose of its holdings in Cody, a full valuation allowance has been established. The Company expects the remaining net deferred tax assets to be fully realizable based on the Company's history and future expectations of generating sufficient taxable income.

The Company reported a net income attributable to Lannett of \$3,948,000 for Fiscal 2012, or \$0.14 basic and diluted earnings per share, compared to a net loss attributable to Lannett of \$277,000 for Fiscal 2011, or \$0.01 basic and diluted loss per share.

Results of Operations Fiscal 2011 compared to Fiscal 2010

Net sales decreased 15% from \$125,178,000 in Fiscal 2010 to \$106,835,000 in Fiscal 2011. The following factors contributed to the \$18,343,000 decrease in sales:

Medical indication	Sales volume change %	Sales price change %
Antibiotics	(10)%	5%
Cardiovascular	(22)%	(19)%
Gallstone Prevention	175%	(30)%
Glaucoma	27%	27%
Migraine Headache	(1)%	(11)%

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Obesity	(19)%	7%
Pain Management	(22)%	33%
Prescription Vitamin	(73)%	22%
Thyroid Deficiency	7%	(16)%

Sales of drugs used in the treatment of thyroid deficiency decreased by \$5,174,000 for Fiscal 2011 compared to Fiscal 2010 primarily as a result of a competitive price reduction in order to retain one of our major customers. Included in this amount is a one-time shelf stock adjustment totaling \$1,500,000. The overall decrease in sales was also affected by a decrease in sales of drugs for cardiovascular treatment of \$8,443,000 for Fiscal 2011 compared to Fiscal 2010 mainly due to a decrease in the volume of bottles shipped, as well as a result of a competitive price reduction in order to retain one of our major customers. Included in this amount is a one-time shelf stock adjustment totaling \$638,000. Net sales of our prescription vitamins also decreased by \$3,802,000 due to the settlement agreement reached with KV on December 15, 2010 which requires the Company to cease selling products covered by the licensed patents. Sales of drugs used for the treatment of migraine headaches decreased by \$1,201,000 for Fiscal 2011 compared to Fiscal 2010 primarily as a result of a price reduction. The overall decrease in sales was partially offset by an increase in sales of drugs used for pain management which increased by \$618,000 for Fiscal 2011 compared to Fiscal 2010. This increase is primarily the result of an increase in demand for pain management products including Hydromorphone HCl and Oxycodone HCl which increased \$4,044,000 and \$3,205,000, respectively for Fiscal 2011 compared to Fiscal 2010. Partially offsetting this increase were Fiscal 2010 revenues of Morphine Sulfate Oral Solution totaling \$6,337,000 which were not recognized in Fiscal 2011 as a result of the FDA's action to force Lannett and all but one competitor to cease manufacturing and/or distributing Morphine Sulfate Oral Solution effective July 24, 2010.

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

(In thousands) Customer Category	Fiscal 2011 Net Sales	Fiscal 2010 Net Sales
Wholesaler/Distributor	\$ 56,632	\$ 58,166
Retail Chain	46,270	60,321
Mail-Order Pharmacy	3,933	6,691
Total	\$ 106,835	\$ 125,178

The sales to wholesaler/distributor decreased as a result of the decrease in sales of Morphine Oral Solution discussed above, partially offset by an increase in demand for products for which the Company is a major supplier such as drugs used for the treatment of gallstones. The sales to retail chains decreased primarily as a result of the competitive price reductions on two products in order to retain one of our major customers as discussed above. Sales to retail chains also declined as a result of the settlement agreement reached with KV which requires the Company to cease selling products covered by the licensed patents as discussed above.

Cost of sales decreased slightly to \$83,515,000 in Fiscal 2011 from \$83,838,000 in Fiscal 2010. The decrease reflected the impact of the 15% decrease in sales as well as a change in the mix of products sold. Cost of sales includes the additional inventory reserves totaling \$1,738,000 related to Morphine Sulfate Oral Solution. The Company increased its reserves related to Morphine Sulfate Oral Solution as a result of new information obtained during the January 2011 meeting with the FDA in that the FDA required a pre-approval inspection (PAI) as part of the MS NDA approval process. The Company received FDA approval in June 2011 to begin selling Morphine Sulfate Oral Solution although existing inventories totaling \$2,063,000 are fully reserved as of June 30, 2011 based on their expiration dates. Cost of sales also included the reversal of royalty expense in Fiscal 2011 totaling \$618,000 as a result of the settlement agreement reached with KV whereas Fiscal 2010 includes additional royalties of \$455,000 primarily related to the sale of the prescription vitamins, our Amantadine product and the final payments under the Provell termination agreement.

Amortization expense included in cost of sales change above primarily relates to the JSP Distribution Agreement. For the remaining term of the JSP Distribution Agreement, the Company will incur annual amortization expense of approximately \$1,785,000 related to this agreement.

Gross profit margins for Fiscal 2011 and Fiscal 2010 were 22% and 33%, respectively. Gross profit percentage decreased due to the overall decline in sales described above. Gross profit margins were also reduced by the additional inventory reserves recorded during Fiscal 2011 totaling \$1,738,000 related to Morphine Sulfate Oral Solution as discussed above. Partially offsetting the decrease was an increase due to the reversal of royalty expense totaling \$618,000 as a result of the settlement agreement reached with KV. While the Company is continuously striving to keep product costs low, there can be no guarantee that profit margins will not fluctuate in future periods. Pricing pressure from competitors and costs of producing or purchasing new drugs may also fluctuate in the future. Changes in the future sales product mix may also occur. These changes may affect the gross profit percentage in future periods.

Research and development (R&D) expenses decreased 24% to \$8,587,000 in Fiscal 2011 from \$11,252,000 in Fiscal 2010. The decrease is primarily due to the timing of milestone achievements for costs of products in development and completed phases for several biostudies. The Company expenses all production costs as R&D until the drug is approved by the FDA. R&D expenses may fluctuate from period to period,

based on R&D plans for submission to the FDA.

Selling, general and administrative (S,G&A) expenses decreased 8% to \$15,912,000 in Fiscal 2011 from \$17,375,000 in Fiscal 2010. The decrease is primarily due to incentive compensation costs incurred in Fiscal 2010, but not incurred in Fiscal 2011, as well as the reversal of the remaining Fiscal 2010 accrued bonuses totaling approximately \$1,391,000 in the second quarter of Fiscal 2011 (see Note 14 to the Consolidated Financial Statements), of which approximately \$1,010,000 was included in S,G &A. Partially offsetting the overall decrease are increased legal costs of \$784,000 related to the litigation with the FDA regarding the status of Grandfathered products, including our Morphine Sulfate Oral Solution. While the Company is focused on controlling costs, increases in personnel costs may have an ongoing and longer lasting impact on the administrative cost structure. Other costs are being incurred to facilitate improvements in the Company's infrastructure. These costs are expected to be temporary investments in the future of the Company and may not continue at the same level.

Grant income of \$410,000 recognized in Fiscal 2011 is related to the grant funding received in July 2004 totaling \$500,000 from the Commonwealth of Pennsylvania (the Commonwealth), acting through the Department of Community and Economic Development.

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The grant funding program required the Company to use the funds for machinery and equipment located at their Pennsylvania locations, hire additional full-time employees, operate its Pennsylvania locations a minimum of five years and meet certain matching investment requirements. If the Company failed to comply with any of the requirements above, the Company would be liable to repay the full amount of the grant funding. In June 2011, the Company reached a formal agreement with the Commonwealth as to whether it complied with all of the requirements of the grant funding program. Based on the terms of the agreement, the Company was required to repay \$90,000 to the Commonwealth, which resulted in the recognition of the remaining \$410,000 of the funding as grant income (see Note 10 to the Consolidated Financial Statements).

Interest expense decreased to \$214,000 in Fiscal 2011 from \$276,000 in Fiscal 2010, due to lower levels of long-term debt outstanding during Fiscal 2011. Interest and dividend income increased to \$91,000 in Fiscal 2011 from \$62,000 in Fiscal 2010 due to higher interest earned on larger investment securities balances.

The Company recorded an income tax benefit totaling \$461,000 in Fiscal 2011 compared to income tax expense totaling \$4,813,000 in Fiscal 2010. The effective tax rate for Fiscal 2011 was 65.8% compared to 37.5% for Fiscal 2010. The effective tax rate for Fiscal 2011 was higher compared to Fiscal 2010 due primarily to the impact in Fiscal 2011 of income tax credits and the reversal of a portion of our liability for unrecognized tax benefits totaling \$264,000 related to a settlement with the IRS. These increases were partially offset by the effect of nondeductible incentive stock option compensation expenses relative to the pretax income for Fiscal 2011. The effective tax rate for Fiscal 2010 includes the impact of a change in Pennsylvania tax law which lowered the Company's apportionment factor within this state. The impact of this change caused the Company to reduce its deferred tax assets by \$650,000, and therefore increased the effective tax rate by approximately 5% for Fiscal 2010. The increase in effective tax rate related to this change in Pennsylvania tax law was essentially offset by the impact of the settlement reached with the IRS related to its review of the federal income tax return for Fiscal 2008. As a result of the settlement, the Company recorded a refund receivable totaling \$421,000 and reduced its liability for unrecognized tax benefits by \$216,000. In addition, the Company amended its Fiscal 2005 income tax return during Fiscal 2010 to claim additional federal income tax credits, which was accepted as timely filed by the IRS. As a result, the Company reduced its income taxes payable for Fiscal 2010 by \$528,000 related to this amended income tax return.

At June 30, 2011, the Company has recognized a net deferred tax asset of \$14,984,000. The net deferred tax asset is net of a valuation allowance of \$2,032,000 that is primarily related to the Cody notes receivable impairment incurred in conjunction with the acquisition of Cody Labs. The Company has provided for the valuation allowance related to the notes receivable impairment as this benefit will be realized only upon the disposition of Cody Labs. As the Company has no current plans to dispose of its holdings in Cody, a full valuation allowance has been established. The Company expects the remaining net deferred tax assets to be fully realizable based on the Company's history and future expectations of generating sufficient taxable income.

The Company reported a net loss attributable to Lannett of \$277,000 for Fiscal 2011, or \$0.01 basic and diluted loss per share, compared to net income attributable to Lannett of \$7,821,000 for Fiscal 2010, or \$0.32 basic and \$0.31 diluted earnings per share.

Liquidity and Capital Resources

The Company has historically financed its operations with cash flow generated from operations, supplemented with borrowings from various government agencies and financial institutions. At June 30, 2012, working capital was \$66,089,000 as compared to \$59,282,000 at June 30, 2011, an increase of \$6,807,000.

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Net cash from operating activities of \$11,121,000 for the fiscal year ended June 30, 2012 reflected net income of \$4,018,000 after adjustments for non-cash items of \$9,093,000, as well as cash used by changes in operating assets and liabilities of \$1,990,000. Significant changes in operating assets and liabilities are comprised of:

- An increase in trade accounts receivable of \$8,751,000 primarily as a result of increased sales in the fourth quarter of Fiscal 2012 compared to the fourth quarter of Fiscal 2011. The Company's days sales outstanding (DSO), based on gross sales, for Fiscal 2012 was 61 days. The level of DSO at June 30, 2012 is comparable to the Company's expectation that DSO will be in the 60 to 70 day range based on 60 day payment terms for most customers.
- A decrease in income taxes receivable of \$1,516,000 primarily as a result of Fiscal 2012 taxable income.
- An increase in rebates, chargebacks and returns payable of \$3,475,000 primarily due to an increase in rebates reserve as a result of increased sales to customers who participate in rebate programs, the timing of credits taken by customers, as well as an additional rebate program the Company became obligated to participate in under Medicare Part D, and an increase in chargeback reserves due primarily to an increase in inventory levels at wholesale distribution centers.
- An increase in accrued payroll and payroll related costs of \$2,209,000 primarily related to accrued incentive compensation costs in Fiscal 2012.

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Net cash provided by investing activities of \$7,379,000 for the year ended June 30, 2012 is mainly the result of proceeds from the sale of investment securities of \$35,910,000, partially offset purchases of investment securities of \$23,301,000 and purchases of property, plant and equipment of \$5,237,000.

Net cash used in financing activities of \$1,130,000 for Fiscal 2012 was primarily due to scheduled repayments of debt of \$661,000 and purchases of treasury stock of \$722,000, partially offset by proceeds from the issuance of stock pursuant to stock compensation plans of \$272,000.

The Company has entered into agreements with various government agencies and financial institutions to provide additional cash to help finance the Company's various capital investments and potential strategic opportunities. These borrowing arrangements as of June 30, 2012 are as follows:

The Company has a \$3,000,000 line of credit from Wells Fargo Bank, N.A. (Wells Fargo) that was scheduled to expire on March 31, 2012. The line of credit was renewed and extended until April 30, 2013 and bears interest of 1-month LIBOR Market Index Rate plus 2.00%. The interest rate at June 30, 2012 and 2011 was 2.25% and 3.00%, respectively. Availability under the line of credit is reduced by outstanding letters of credit totaling \$5,000 at June 30, 2012 and June 30, 2011. As of June 30, 2012 and 2011, the Company had \$2,995,000 of availability under the line of credit. The availability fee on the unused balance of the line of credit is 0.375%. The line of credit is collateralized by the working capital assets of the Company. As of June 30, 2012, the Company was in compliance with the financial covenants under the agreement.

The Company borrowed \$1,250,000 through the Pennsylvania Industrial Development Authority (PIDA). The Company is required to make equal payments each month for 180 months starting February 1, 2006 with interest of 2.75% per annum. The PIDA Loan has \$777,000 outstanding as of June 30, 2012 with \$81,000 currently due.

In April 1999, the Company entered into a loan agreement with the Philadelphia Authority for Industrial Development (the Authority or PAID), to finance future construction and growth projects of the Company. The Authority issued \$3,700,000 in tax-exempt variable rate demand and fixed rate revenue bonds to provide the funds to finance such growth projects pursuant to a trust indenture (the Trust Indenture). A portion of the Company's proceeds from the bonds was used to pay for bond issuance costs of \$170,000. The Trust Indenture requires that the Company repay the Authority loan through installment payments beginning in May 2003 and continuing through May 2014, the year the bonds mature. The bonds bear interest at the floating variable rate determined by the organization responsible for selling the bonds (the remarketing agent). The interest rate fluctuates on a weekly basis. The effective interest rate at June 30, 2012 and 2011 was 0.38% and 0.40%, respectively. At June 30, 2012, the Company has \$290,000 outstanding on the Authority loan, of which \$140,000 is classified as currently due. In April 1999, an irrevocable letter of credit of \$3,770,000 was issued by Wells Fargo. This letter of credit is renewed annually to secure payment of the outstanding Authority loan balance and a portion of the related accrued interest. At June 30, 2012, no portion of the letter of credit has been utilized.

The Company has negotiated a set of mortgages on its Townsend Road facility with both Wells Fargo and PIDA. The Wells Fargo portion of the loan is for \$3,056,000, bears a floating interest rate of the 1-Month LIBOR rate plus 2.95%, amortizes the loan over a 15 year term and has an 8 year maturity date. The effective interest rate at June 30, 2012 and 2011 was 3.20% and 3.14%, respectively. The PIDA portion of the loan is for \$2,000,000, bears an interest rate of 3.75% and matures in 15 years. Both loans closed and were funded in May 2011. At June 30, 2012, the Company has \$2,818,000 outstanding on the Wells Fargo portion of the loan, of which \$204,000 is classified as currently due. The PIDA Loan has \$1,899,000 outstanding as of June 30, 2012 with \$105,000 currently due.

The Company has executed Security Agreements with Wells Fargo, PIDA and PIDC in which the Company has agreed to pledge its working capital, some equipment and its Townsend Road property to collateralize the amounts due.

The Company consolidates Cody LCI Realty, LLC, a variable interest entity (VIE), for which Cody Labs is the primary beneficiary. See Note 12 to our Consolidated Financial Statements for Consolidation of Variable Interest Entities. A mortgage loan with First National Bank of Cody related to the purchase of land and building by the VIE has also been consolidated in the Company's consolidated balance sheets. The mortgage requires monthly principal and interest payments of \$15,000. Effective February 2011, the interest rate was modified from a fixed rate of 7.5% to a floating rate with a floor of 4.5% and a ceiling of 9.0%, with payments to be made through April 2022. As of June 30, 2012, \$1,377,000 is outstanding under the mortgage loan, of which \$118,000 is classified as currently due with a rate of 4.5%. The mortgage is collateralized by the land and building.

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The following table represents annual contractual obligations as of June 30, 2012:

(In thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 Years
Long-Term Debt	\$ 7,161	\$ 648	\$ 1,202	\$ 1,103	\$ 4,208
Purchase Obligations	41,250	23,250	18,000		
Interest on Obligations	1,595	240	421	342	592
Total	\$ 50,006	\$ 24,138	\$ 19,623	\$ 1,445	\$ 4,800

The purchase obligations above are primarily due to the agreement with Jerome Stevens Pharmaceuticals, Inc. (JSP). If the minimum purchase requirement is not met, JSP has the right to terminate the contract within 60 days of Lannett's failure to meet the requirement. If JSP terminates the contract, Lannett does not pay any fee, but could lose its exclusive distribution rights in the United States. If Lannett's management believes that it is not in the Company's best interest to fulfill the minimum purchase requirements, it can also terminate the contract without any penalty. If either party were to terminate the purchase agreement, there would be a significant impact on the operating cash flows of the Company from the termination. See Note 22 to our Consolidated Financial Statements for more information on the terms, conditions and financial impact of the JSP Distribution Agreement.

Prospects for the Future

Generic pharmaceutical manufacturers and distributors are constantly faced with pricing pressures in the marketplace as competitors attempt to lure business from distributors, wholesalers and chain retailers by offering lower prices than the incumbent supplier. Lannett tries to differentiate itself in the marketplace by complementing its lower cost offerings with higher levels of customer service and quality of the products. But as Lannett enters Fiscal Year 2013, there is an increasing number of competitors on our key products that are attempting to supplant Lannett as the preferred vendor.

Beginning in the first quarter of Fiscal 2011, Lannett faced significant pricing challenges on its top two selling products. In order to keep the volume of business with the specific customers involved, Lannett chose to reduce its selling price on both of the products. These price reductions had and may continue to have a significant impact to the gross profit margins and profitability of Lannett expected in the future.

The Company has had difficulty marketing its Oxycodone HCl Solution product starting in the third quarter of Fiscal 2011 due to the current limitations by the DEA to grant additional manufacturing quota to Cody Labs for its production. This product contributed approximately \$3.8 million in revenue in Fiscal 2012 and \$4.6 million in Fiscal 2011. The loss of this product would have a significant impact to the gross profit margins and profitability of Lannett expected in the future.

The Company has several generic products under development. These products are all orally-administered, topical, injectable and parenteral products designed to be generic equivalents to brand named innovator drugs. The Company's developmental drug products are intended to treat a diverse range of indications. As one of the oldest generic drug manufacturers in the country, formed in 1942, Lannett currently owns several ANDAs for products which it does not manufacture and market. These ANDAs are dormant on the Company's records. Occasionally, the Company reviews such ANDAs to determine if the market potential for any of these older drugs has recently changed, so as to make it attractive for Lannett to reconsider manufacturing and selling it. If the Company makes the determination to introduce one of these products into the

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consumer marketplace, it must review the ANDA and related documentation to ensure that the approved product specifications, formulation and other factors meet current FDA requirements for the marketing of that drug. The Company would then redevelop the product and submit it to the FDA for supplemental approval. The FDA's approval process for ANDA supplements is similar to that of a new ANDA. Generally, in these situations, the Company must file a supplement to the FDA for the applicable ANDA, informing the FDA of any significant changes in the manufacturing process, the formulation, or the raw material supplier of the previously-approved ANDA. Recently, the FDA has announced that it will prioritize its review of 3,800 Chemistry Manufacturing and Control (CMC) supplements in order to make progress on reviewing a backlog of over 2,200 ANDAs. This could negatively impact the sales of future products.

The products under development are at various stages in the development cycle—formulation, scale-up, and/or clinical testing. Depending on the complexity of the active ingredient's chemical characteristics, the cost of the raw material, the FDA-mandated requirement of bioequivalence studies, the cost of such studies and other developmental factors, the cost to develop a new generic product varies and on average can range from \$0.1 million to \$1.7 million. Some of Lannett's developmental products will require bioequivalence studies, while others will not—depending on the FDA's Orange Book classification. Since the Company has no control over the FDA review process, management is unable to anticipate whether or when it will be able to begin producing and shipping additional products.

The Company views its 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 it to concentrate on developing and completing its dosage

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form manufacturing in order to reduce 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 the Company to avoid increased costs associated with buying narcotic API from other manufacturers. The Company anticipates that it can use this license to become a vertically integrated manufacturer of narcotic products, as well as a supplier of API to the pharmaceutical industry. The Company believes that the aging domestic population may result in a higher demand for pain management pharmaceutical products and that it will be well-positioned to take advantage of this increased demand.

Cody Labs' manufacturing expertise in narcotic APIs will allow Lannett to build a market with limited domestic competition. The Company anticipates that the demand for narcotics and controlled drugs will continue to grow as the Baby Boomer generation ages and that it is well-positioned to take advantage of these opportunities by concentrating additional resources in the narcotics and controlled drugs area. The sale of pain management products approximated 17% of net sales for the year Fiscal 2012 and 14% of net sales for the Fiscal 2011. Due to the FDA's actions against Morphine Sulfate Oral Solution and a slow down in the demand for one other product that is manufactured at Cody, Lannett incurred a decrease in the percentage of sales related to pain management products during Fiscal 2011. Since the Company received the FDA approval for its 505(b)(2) New Drug Application for Morphine Sulfate Oral Solution in June 2011, net sales related to pain management products have increased.

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

Occasionally, the Company will work on developing a drug product that does not require FDA approval. Certain prescription drugs do not require prior FDA approval before marketing. They include, for instance, drugs listed as DESI drugs (Drug Efficacy Study implementation) which are under evaluation by FDA, Grandfathered Drugs, and prescription multivitamin drugs. A generic manufacturer may sell products which are chemically equivalent to innovator drugs, under FDA rules by simply performing and internally documenting the normal research and development involved in bringing a new product to market. Under this scenario, a generic company can forego the time required for FDA approval.

More specifically, certain products, marketed prior to the Federal Food, Drug and Cosmetic Act may be considered GRASE 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.

The Company has entered supply and development agreements with certain international companies, including Wintac of India, Orion Pharma of Finland, Azad Pharma AG and Swiss Caps of Switzerland, Pharma 2B (formerly Pharmaseed) of Israel and the GC Group, as well as certain domestic companies, including JSP, Banner Pharmacaps, Cerovene and Summit Bioscience. The Company is currently in negotiations on similar agreements with other international companies, through which Lannett will market and distribute products manufactured by Lannett or

by third parties. Lannett intends to use its strong customer relationships to build its market share for such products, and increase future revenues and income.

The majority of the Company's R&D projects are being developed in-house under Lannett's direct supervision and with Company personnel. Hence, the Company does not believe that its outside contracts for product development and manufacturing supply are material in nature, nor is the Company substantially dependent on the services rendered by such outside firms.

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

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The Company plans to enhance relationships with strategic business partners, including providers of product development research, raw materials, active pharmaceutical ingredients as well as finished goods. Management believes that mutually beneficial strategic relationships in such areas, including potential financing arrangements, partnerships, joint ventures or acquisitions, could allow for potential competitive advantages in the generic pharmaceutical market. The Company plans to continue to explore such areas for potential opportunities to enhance shareholder value.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company has debt instruments with variable interest rates. The Company has a \$3,000,000 line of credit from Wells Fargo Bank, N.A. (Wells Fargo) that was scheduled to expire on March 31, 2012. The line of credit was renewed and extended until April 30, 2013 and bears interest of 1-month LIBOR Market Index Rate plus 2.00%. The interest rate at June 30, 2012 and 2011 was 2.25% and 3.00%. Availability under the line of credit is reduced by outstanding letters of credit totaling \$5,000 at June 30, 2012 and June 30, 2011. As of June 30, 2012 and June 30, 2011, the Company had \$2,995,000 of availability under the line of credit. The availability fee on the unused balance of the line of credit is 0.375%. The line of credit is collateralized by the working capital assets of the Company. As of June 30, 2012, the Company was in compliance with the financial covenants under the agreement.

The Company has negotiated a set of mortgages on its Townsend Road facility with both Wells Fargo and PIDA. The Wells Fargo portion of the loan is for \$3,056,000, bears a floating interest rate of the 1-Month LIBOR rate plus 2.95%, amortizes the loan over a 15 year term and has an 8 year maturity date. The effective interest rate at June 30, 2012 and 2011 was 3.20% and 3.14%, respectively. At June 30, 2012, the Company has \$2,818,000 outstanding on the loan, of which \$204,000 is classified as currently due.

A mortgage loan with First National Bank of Cody related to the purchase of land and building by Cody LCI Realty, LLC, a variable interest entity, has also been consolidated in the Company's consolidated balance sheets. The mortgage requires monthly principal and interest payments of \$15,000. Effective February 2011, the interest rate was modified from a fixed rate of 7.5% to a floating rate with a floor of 4.5% and a ceiling of 9.0%, with payments to be made through April 2022. As of June 30, 2012, \$1,377,000 is outstanding under the mortgage loan with a rate of 4.5%. The mortgage is collateralized by the land and building.

The Company invests in equity securities, U.S. government agency securities and corporate bonds, which are exposed to market and interest rate fluctuations. The interest and dividends earned on these investments may vary based on fluctuations in interest rate and market conditions.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 (the Exchange Act), as amended, for financial reporting as of June 30, 2012. Based on that evaluation, our chief executive officer and chief financial officer concluded that these controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported as specified in Securities and Exchange Commission rules and forms. There were no changes in these controls or procedures identified in connection with the evaluation of such controls or procedures that occurred during our last fiscal quarter, or in other factors that have materially affected, or are reasonably likely to materially affect these controls or procedures.

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is

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accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

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

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

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2012. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*.

Based on our assessment, our management believes that, as of June 30, 2012, our internal control over financial reporting is effective.

The effectiveness of our internal control over financial reporting as of June 30, 2012 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their report included in this Annual Report on Form 10-K under Item 15. Exhibits, Financial Statement Schedules.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2012, there were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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

	Age	Position
<u>Directors:</u>		
William Farber	80	Chairman Emeritus
Jeffrey Farber	52	Chairman of the Board
Ronald A. West	78	Vice Chairman of the Board
Arthur P. Bedrosian	66	Director
Kenneth Sinclair Ph.D.	65	Director
Albert I. Wertheimer, Ph.D.	69	Director
Myron Winkelman	74	Director
David Drabik	44	Director
Paul Taveira	52	Director
<u>Officers:</u>		
Arthur P. Bedrosian	66	President and Chief Executive Officer
Martin P. Galvan	60	Vice President of Finance and Chief Financial Officer
William F. Schreck	63	Chief Operating Officer
Kevin R. Smith	52	Vice President of Sales and Marketing
Ernest J. Sabo	64	Vice President of Regulatory Affairs and Chief Compliance Officer
Robert Ehlinger	54	Vice President of Logistics and Chief Information Officer

William Farber was elected as Chairman of the Board of Directors in August 1991. From April 1993 to the end of 1993, Mr. Farber was the President and a director of Auburn Pharmaceutical Company. From 1990 through March 1993, Mr. Farber served as Director of Purchasing for

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Major Pharmaceutical Corporation. From 1965 through 1990, Mr. Farber was the Chief Executive Officer of Michigan Pharmacal Corporation. Mr. Farber was previously a registered pharmacist in the State of Michigan for more than 40 years until his retirement from active employment in the pharmaceutical industry. On June 1, 2011, Mr. Farber retired from his position as Chairman of the Board and was appointed Chairman Emeritus.

Jeffrey Farber was elected a Director of the Company in May 2006 and was appointed Chairman of the Board of Directors in July 2012. Jeffrey Farber joined the Company in August 2003 as Secretary. Since 1994, Mr. Farber has been President and the owner of Auburn Pharmaceutical (Auburn), a national generic pharmaceutical distributor. Prior to starting Auburn, Mr. Farber served in various positions at Major Pharmaceutical (Major), where he was employed for over 15 years. At Major, Mr. Farber was involved in sales, purchasing and eventually served as President of the mid-west division. Mr. Farber also spent time working at Major's manufacturing division Vitarine Pharmaceuticals where he served on its Board of Directors. Mr. Farber graduated from Western Michigan University with a Bachelors of Science Degree in Business Administration and participated in the Pharmacy Management Graduate Program at Long Island University. Mr. Farber is the son of William Farber, the Chairman Emeritus of the Board of Directors of the Company.

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The Nominating and Governance Committee concluded that Mr. Farber is qualified and should continue to serve, due, in part, to his significant experience in the generic drug industry and his ongoing role as the owner of a highly regarded and successful generic drug distributor. His skills include a thorough knowledge of the generic drug marketplace and drug supply chain management.

Ronald A. West was elected a Director of the Company in January 2002. In September 2004, Mr. West was elected Vice Chairman of the Board of Directors and Lead Independent Director and on June 1, 2011 was elected to serve as Chairman of the Board. In July 2012 Mr. West stepped down as Chairman of the Board and is now Vice Chairman. Mr. West is currently a Director of Beecher Associates, an industrial real estate investment company. Prior to this, from 1983 to 1987, Mr. West, member of the Audit and Compensation committees at Lannett, served as Chairman and Chief Executive Officer of Dura Corporation, an original equipment manufacturer of automotive products and other engineered equipment components. In 1987, Mr. West sold his ownership position in Dura Corporation, at which time he retired from active management positions. Mr. West was employed at Dura Corporation since 1969. Prior to this, he served in various financial management positions with TRW, Inc., Marlin Rockwell Corporation and National Machine Products Group, a division of Standard Pressed Steel Company. Mr. West studied Business Administration at Michigan State University and the University of Detroit.

The Nominating and Governance Committee concluded that Mr. West is qualified and should continue to serve, due, in part, because of his long and successful career in the manufacturing sector, both as a senior executive and as a financial manager. In addition to his financial analytic skills, he is a natural leader with solid experience in corporate governance.

Kenneth Sinclair, Ph.D. was elected a Director of the Company in September 2005. Dr. Sinclair is currently Professor of Accounting and Senior Advisor to the College of Business and Economics Dean at Lehigh University, where he began his academic career in 1972. Dr. Sinclair had served as Chair of Lehigh's Accounting Department from 1988 to 1994 and 1998 to 2007. He has taught a variety of accounting courses, including financial and managerial accounting at both the undergraduate and graduate level. He has been recognized for his teaching innovation, held leadership positions with professional accounting organizations and served on numerous academic and advisory committees. He has received a number of awards and honors for teaching and service, and has researched and written on a myriad of subjects related to accounting. He has also been heavily involved with strategic planning at both the College and Department level at Lehigh. Dr. Sinclair earned a Bachelor of Business Administration degree in Accounting, a Master of Science degree in Accounting and a Doctorate Degree in Business Administration with a concentration in Accounting from the University of Massachusetts.

The Nominating and Governance Committee concluded that Dr. Sinclair is qualified and should continue to serve, due, in part to his long and distinguished career as an accounting academic and his deep understanding of accounting and financial reporting. His skills also include organizational planning and interpersonal relations.

Albert I. Wertheimer, Ph.D., was elected a Director of the Company in September 2004. Dr. Wertheimer has a long and distinguished career in various aspects of pharmacy, health care, education and pharmaceutical research. Since 2000, Dr. Wertheimer has been a professor at the School of Pharmacy at Temple University, and director of its Center for Pharmaceutical Health Services Research. From 1997 to 2000, Dr. Wertheimer was Director of Outcomes Research and Management at Merck & Co., Inc. In addition to his academic responsibilities, he is the author of 28 books and more than 380 journal articles. Dr. Wertheimer also provides consulting services to institutions in the pharmaceutical industry. Dr. Wertheimer's academic experience includes professorships and other faculty and administrative positions at several educational institutions, including the Medical College of Virginia, St. Joseph's University, Philadelphia College of Pharmacy and Science and the University of Minnesota. Dr. Wertheimer's previous professional experience includes pharmacy services in commercial and non-profit environments. Professor Wertheimer is a licensed pharmacist in five states, and is a member of several health associations, including the American Pharmacists Association and the American Public Health Association. Dr. Wertheimer is the editor of the *Journal of Pharmaceutical Health Services Research*; and he has been on the editorial board of *the Journal of Managed Pharmaceutical Care, Medical Care*, and other healthcare journals. Dr. Wertheimer has a Bachelor of Science Degree in Pharmacy from the University of Buffalo, a Master of Business Administration from the

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State University of New York at Buffalo, a Doctorate from Purdue University and a Post Doctoral Fellowship from the University of London, St. Thomas Medical School.

The Nominating and Governance Committee concluded that Dr. Wertheimer is qualified and should continue to serve, due, in part to his deep understanding of all aspects of pharmacy practice, including retail and manufacturing. His skills include business planning and a sound knowledge of drug regulation and distribution.

Myron Winkelman, R. Ph. was elected a Director of the Company in June 2003. Mr. Winkelman has significant career experience in various aspects of pharmacy and health care. He is currently President of Winkelman Management Consulting (WMC), which provides consulting and audit services to both commercial and governmental clients. He has served in this position since 1994. Prior to creating WMC, he was a senior executive with ValueRx, a large pharmacy benefits manager, and served for many years as a senior executive for the Revco, Rite Aid and Perry Drug chains. While at ValueRx, Mr. Winkelman served on the Board of Directors of the Pharmaceutical Care Management Association. He belongs to a number of pharmacy organizations, including the Academy of

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Managed Care Pharmacy and the Michigan Pharmacy Association. Mr. Winkelman is a registered pharmacist and holds a Bachelor of Science Degree in Pharmacy from Wayne State University.

The Nominating and Governance Committee concluded that Mr. Winkelman is qualified and should continue to serve, due, in part to his experiences with and knowledge of Pharmacy Benefit Administration and Mail Order Pharmacy. His skills include a deep understanding of government pharmacy benefits and the drug supply chain.

David Drabik was elected a Director of the Company in January 2011. Mr. Drabik is a National Association of Corporate Directors Governance Fellow. Since 2002, Mr. Drabik has been President of Cranbrook & Co., LLC (Cranbrook), an advisory firm primarily serving the private equity and venture capital community. At Cranbrook, Mr. Drabik assists and advises its clientele on originating, structuring, and executing private equity and venture capital transactions. From 1995 to 2002, Mr. Drabik served in various roles and positions with UBS Capital Americas (and its predecessor UBS Capital LLC), a New York City based private equity and venture capital firm that managed \$1.5 billion of capital. From 1992 to 1995, Mr. Drabik was a banker with Union Bank of Switzerland's Corporate and Institutional Banking division in New York City. Mr. Drabik graduated from the University of Michigan with a Bachelors of Business Administration degree.

The Nominating and Governance Committee concluded that Mr. Drabik is well qualified and should be nominated to serve as a Director due, in part to his understanding and involvement in investment banking. As a global investment bank professional with extensive experience advising senior management, his skills include business analytics, financing and a strong familiarity with SEC documentation.

Paul Taveira, was elected a Director of the Company in May 2012. Mr. Taveira has been Chief Executive Officer of A&D Environmental Services Inc., an environmental and industrial services company, since 2009. He currently serves on their Board of Directors. From 2007 to 2009, Mr. Taveira was a Managing Partner of Precision Source LLC, a manufacturer of precision parts for various industries across the United States. From 1997 to 2007, Mr. Taveira held several positions at PSC Inc., a national provider of environmental services, including President, Vice President and Regional General Manager. From 1987 to 1997, Mr. Taveira held several management positions with Clean Harbors Inc., an international provider of environmental and energy services. Mr. Taveira graduated from Worcester State University with a Bachelor of Science degree in Biology.

The Nominating and Governance Committee concluded that Mr. Taveira is well qualified and should be nominated to serve as a Director due, in part to his understanding and experience as a Chief Executive Officer and Director of A&D Environmental Services Inc. Additionally, Mr. Taveira has experience as a Managing Partner of Precision Source LLC, a manufacturer of precision parts for various industries across the United States.

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

The Nominating and Governance Committee concluded that Mr. Bedrosian is qualified to serve as a director, in part, because his experience as our President and Chief Executive Officer has been instrumental in the company's growth and provides the board with a compelling understanding of our operations, challenges and opportunities. In addition, his background includes over 40 years in the generic pharmaceutical industry that encompasses a broad background and knowledge in the underlying scientific, sales, marketing and supply chain management which brings special expertise to the board in developing our business strategies. His recent qualification to FINRA's list of arbitrators recognizes his expertise and experience.

Martin P. Galvan, CPA was appointed as the Company's Vice President of Finance and Chief Financial Officer in August 2011. Most recently, he was Chief Financial Officer of CardioNet, Inc., a medical technology and service company. From 2001 to 2007, Mr. Galvan was employed by Viasys Healthcare Inc., a healthcare technology company that was acquired by Cardinal Health, Inc. in June 2007. Prior to the acquisition, he served as Executive Vice President, Chief Financial Officer and Director Investor Relations. From 1999 to 2001, Mr. Galvan served as Chief Financial Officer of Rodel, Inc., a precision surface technologies company in the semiconductor industry. From 1979 to 1998, Mr. Galvan held several positions with Rhone-Poulenc Rorer Inc., a pharmaceutical company, including Vice President, Finance - The Americas; President & General Manager, RPR Mexico & Central America; Vice President, Finance, Europe/Asia Pacific; and Chief Financial Officer, United Kingdom & Ireland. Mr. Galvan began his career with the international accounting firm Ernst & Young LLP. He earned a Bachelor of Arts degree in economics from Rutgers University and is a member of the American Institute of Certified Public Accountants.

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William F. Schreck joined the Company in January 2003 as Materials Manager. In May 2004, he was promoted to Vice President of Logistics. In August 2009, Mr. Schreck was promoted to Senior Vice President and General Manager. In January 2011, Mr. Schreck was promoted to Chief Operating Officer. Prior to this, from 1999 to 2001, he served as Vice President of Operations at Nature's Products, Inc., an international nutritional and over-the-counter drug product manufacturing and distribution company. From 2001 to 2002 he served as an independent consultant for various companies. Mr. Schreck's prior experience also includes comprehensive executive management positions at Ivax Pharmaceuticals, Inc., a division of Ivax Corporation, Zenith-Goldline Laboratories and Rugby-Darby Group Companies, Inc. Mr. Schreck has a Bachelor of Arts Degree from Hofstra University.

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

Ernest J. Sabo joined the Company in March 2005 as Director of Quality Assurance. In May 2008, Mr. Sabo was promoted to Vice President of Regulatory Affairs and Chief Compliance Officer. Prior to this, he served at Wyeth Pharmaceuticals as Manager of QA Compliance from 2001 to 2003 and as Associate Director of QA Compliance from 2003 to 2005. Mr. Sabo held former positions as Director of Validation, Quality Assurance, Quality Control and R&D at Delavau/Accucorp, Inc. from 1993 thru 2001. He has over 30 years of experience in the pharmaceutical industry, his background spans from Quality Assurance, Quality Control, Cleaning/Process Validation and Manufacturing turn-key operations. Mr. Sabo holds a Bachelor of Arts in Biology from Trenton State College (now known as The College of New Jersey).

Robert Ehlinger joined the Company in July 2006 as Chief Information Officer. In June 2011, Mr. Ehlinger was promoted to Vice President of Logistics and Chief Information Officer. Prior to joining Lannett, Mr. Ehlinger was the Vice President of Information Technology at MedQuist, Inc., a healthcare services provider, where his career spanned 10 years in progressive operational and technology roles. Prior to MedQuist, Mr. Ehlinger was with Kennedy Health Systems as their Corporate Director of Information Technology supporting acute care and ambulatory care health information systems and biomedical support services. Earlier on, Mr. Ehlinger was with Dowty Communications where he held various technical and operational support roles prior to assuming the role of International Distribution Sales Executive managing the Latin America sales distribution channels. Mr. Ehlinger received a Bachelor's of Arts degree in Physics from Gettysburg College in Gettysburg, PA.

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

Section 16(a) Beneficial Ownership Reporting Compliance

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

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Based solely on review of the copies of such reports furnished to the Company or written representations that no other reports were required, the Company believes that during Fiscal 2012 all filing requirements applicable to its officers, directors and greater-than-10% beneficial owners under Section 16(a) of the Exchange Act were complied with in a timely manner, except for a Form 3 for Mr. Ehlinger; Form 4s related to option grants to Mr. Schreck and Mr. Ehlinger on July 8, 2011 and to Mr. Galvan on July 15, 2011; Form 4s relating to option grants to officers and restricted stock grants to directors on August 25, 2011; a Form 4 relating to purchase of common stock by Mr. Drabik on September 12, 2011; a Form 4 relating to a restricted stock grant to Mr. Bedrosian on October 13, 2011; Form 4s relating to shares withheld to pay taxes for restricted stock vesting by certain officers on October 29, 2011; Form 4s relating to a sale of common stock on November 23, 2011 by Mr. Sabo and by Mr. West on February 29, 2012; and Form 5s for Mr. Bedrosian, Mr. Smith and Mr. Ehlinger.

Table of Contents**Code of Ethics and Financial Expert**

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

The Board of Directors has determined that Mr. Sinclair, current director of Lannett, is the audit committee financial expert as defined in section 3(a)(58) of the Exchange Act and the related rules of the Commission.

ITEM 11. EXECUTIVE COMPENSATION

The following table summarizes all compensation paid to or earned by the named executive officers ("NEOs" or "Named Executive Officers") of the Company for Fiscal 2012, Fiscal 2011 and Fiscal 2010.

Name and Principal Position (a)	Fiscal Year (b)	Salary (c)	Stock Awards (e)	Option Awards (f)	Non-equity incentive plan compensation (g)	All Other Compensation (i)	Total (j)
Arthur P. Bedrosian President and Chief Executive Officer	2012	\$ 425,096	\$ 20,250	\$ 171,315	\$ 198,908	\$ 22,542	\$ 838,111
	2011	416,763				22,556	439,319
	2010	407,410	359,384	297,390	269,750	22,367	1,356,301
Martin P. Galvan Vice President of Finance and Chief Financial Officer (1)	2012	235,577		107,364	116,320	14,873	474,134
	2011						
	2010						
Keith R. Ruck Former Vice President of Finance and Chief Financial Officer (2)	2012	15,833				152,665	168,498
	2011	190,000				15,617	205,617
	2010	189,293	89,550	243,090	123,500	11,257	656,690
William F. Schreck Chief Operating Officer	2012	250,000		205,292	116,320	18,263	589,875
	2011	219,231				19,592	238,823
	2010	196,681	177,791	302,729	130,000	28,159	835,360
Robert Ehlinger Vice President of Logistics and Chief Information Officer	2012	170,000		147,044	79,098	16,677	412,819
	2011	156,656				6,008	162,664
	2010	147,485	93,333	59,478	74,158	6,758	381,212
Kevin R. Smith Vice President of Sales and	2012	212,755		95,707	99,549	22,013	430,024
	2011	207,722				21,888	229,610

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Marketing	2010	206,564	179,455	198,260	135,019	21,985	741,283
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* Note Effective February 28, 2010 for fiscal years ending on or after December 20, 2009, the SEC amended its rules related to the Summary Compensation and Director Compensation Tables. The new rules require issuers to report as compensation the aggregate grant date fair-value of stock and option awards issued during the fiscal year to NEOs, rather than the dollar amount recognized for financial statement purposes for that fiscal year under the previous rules. Amounts are computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718. Fiscal 2010 amounts have been restated.

(1) Martin P. Galvan was appointed and assumed the role of Vice President of Finance and Chief Financial Officer on August 8, 2011. He did not earn any compensation from the Company during FY2011 and FY 2010.

(2) Mr. Ruck resigned as Vice President of Finance and Chief Financial Officer effective August 1, 2011.

Table of Contents**All Other Compensation**

The following summarizes the components of column (i) of the Summary Compensation Table:

Arthur P. Bedrosian	2012	\$	8,280	\$	13,500	\$		\$	762	\$		\$	22,542
President and	2011		8,294		13,500				762				22,556
Chief Executive Officer	2010		8,219		13,500				648				22,367
Martin P. Galvan	2012		4,327		10,177				369				14,873
Vice President of Finance and	2011												
Chief Financial Officer (1)	2010												
Keith R. Ruck	2012				900						151,765		152,665
Former Vice President of Finance	2011		4,703		10,800				114				15,617
and	2010		2,499		8,668				90				11,257
Chief Financial Officer (2)													
William F. Schreck	2012		7,067		10,800				396				18,263
Chief Operating Officer	2011		8,327		10,800				465				19,592
	2010		7,918		10,800		9,030		411				28,159
Robert Ehlinger	2012		5,654		10,800				223				16,677
Vice President of Logistics and	2011		5,846						162				6,008
Chief Information Officer	2010		6,620						138				6,758
Kevin R. Smith	2012		8,375		13,500				138				22,013
Vice President of Sales and	2011		8,250		13,500				138				21,888
Marketing	2010		8,371		13,500				114				21,985

(1) Martin P. Galvan was appointed and assumed the role of Vice President of Finance and Chief Financial Officer on August 8, 2011. He did not earn any compensation from the Company during FY2011 and FY 2010.

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Aggregated Options/SAR Exercises and Fiscal Year-end Options/SAR Values**GRANTS OF PLAN-BASED AWARDS**

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Name (a)	Grant Date (b)	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stocks or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Awards Price of Fair Value of Option Awards (\$/sh)	Grant Date of Stock and Options Awards (i)
		Threshold (\$) (c)	Target (\$) (d)	Maximum (\$) (e)	Threshold (\$) (f)	Target (\$) (g)	Maximum (\$) (h)	(i)	(j)	(k)	(i)
Arthur P. Bedrosian President and Chief Executive Officer	8/25/2011 10/13/2011								89,500	\$ 3.55	\$ 171,315