

LANNETT CO INC  
Form 10-K  
September 28, 2009  
Table of Contents

# 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, 2009

OR

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

For the transition period from            to

Commission File No. 001-31298

## LANNETT COMPANY, INC.

(Exact name of registrant as specified in its charter)

State of Delaware  
State of Incorporation

23-0787699  
I.R.S. Employer I.D. No.

9000 State Road

Philadelphia, Pennsylvania 19136

Edgar Filing: LANNETT CO INC - Form 10-K

**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

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

Edgar Filing: LANNETT CO INC - Form 10-K

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

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

As of September 15, 2009, there were 24,459,953 shares of the registrant's common stock, \$.001 par value, outstanding.

---

Table of Contents

**TABLE OF CONTENTS**

PART I

<u>ITEM 1. DESCRIPTION OF BUSINESS</u>	4
<u>ITEM 1A. RISK FACTORS</u>	23
<u>ITEM 2. DESCRIPTION OF PROPERTY</u>	30
<u>ITEM 3. LEGAL PROCEEDINGS</u>	31
<u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	32

PART II

<u>ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	33
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	34
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	35
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	51
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	51
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	52
<u>ITEM 9B. OTHER INFORMATION</u>	53

PART III

<u>ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT</u>	54
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	58
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	73
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	78
<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	79

PART IV

<u>ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES,</u>	80
--	----

SIGNATURES

81

Table of Contents

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

Table of Contents

**PART I**

**ITEM 1. DESCRIPTION OF BUSINESS**

**Business Overview**

Lannett Company, Inc. (the Company, Lannett, we, or us ) was incorporated in 1942 under the laws of the Commonwealth of Pennsylvania, and reincorporated in 1991 as a Delaware corporation. We develop, manufacture, market and distribute generic versions of branded pharmaceutical products. We report financial information on a quarterly and fiscal year basis with the most recent being the fiscal year ended June 30, 2009. All references herein to a fiscal year or Fiscal refer to the applicable fiscal year ending June 30.

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

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

**Competitive Strengths**

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

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

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

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

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

Table of Contents

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

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

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

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

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

**Business Strategies**

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

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



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

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

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

Table of Contents

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

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

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

**Key Products**

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

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

Digoxin tablets are produced and marketed with two different potencies (0.125 and 0.25 milligrams ( mg ) per tablet). This product is manufactured by JSP and we distribute it under the JSP Distribution Agreement. We began buying this product from JSP and selling it to our customers in September 2002. Digoxin tablets are used to treat congestive heart failure in patients of various ages and demographic

backgrounds. The beneficial effects of Digoxin result from direct actions on the cardiac muscle, as well as indirect actions on the cardiovascular system mediated by effects on the autonomic nervous system. Side effects of Digoxin may include apathy, blurred vision, changes in heartbeat, confusion, dizziness, headaches, loss of appetite,

Table of Contents

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

We distribute two products containing Butalbital. We have manufactured and sold one of the products, Butalbital with Aspirin and Caffeine capsules, for more than nine years. The other Butalbital product, Butalbital with Aspirin, Caffeine and Codeine Phosphate capsules, is manufactured by JSP. We began buying this product from JSP and selling it to our customers in December 2002. Both Butalbital products, which are in orally administered capsule dosage forms, are prescribed to treat tension headaches caused by contractions of the muscles in the neck and shoulder area and migraine. The drug is prescribed primarily for adults of various demographic backgrounds. Migraine headache is an increasingly prevalent condition in the United States. As conditions continue to grow, the demand for effective medical treatments will continue to grow. Common side effects of drugs which contain Butalbital include dizziness and drowsiness. Although new innovator drugs to treat migraine headaches have been introduced by brand name drug companies, we believe that there is still a loyal following of doctors and consumers who prefer to use Butalbital products for treatment. As the brand name companies continue to promote products containing Butalbital, like Fiorinal®, we expect to continue to produce and sell our generic Butalbital products.

Primidone tablets are produced and marketed with two different potencies (50mg and 250mg tablets). We developed and manufacture Primidone tablets and began selling Primidone 50mg tablets in June 2001. In addition, we have been manufacturing and selling Primidone 250mg tablets for more than seven years. Both Primidone products, which are in orally administered tablet dosage forms, are prescribed to treat convulsion and seizures in epileptic patients of all ages and demographic backgrounds. Common side effects of Primidone include lack of muscle coordination, vertigo and severe dizziness.

**Validated Pharmaceutical Capabilities**

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

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

We have adopted many FDA regulations relating to cGMPs in the last several years, and we believe we are operating our facilities in material compliance with the FDA's cGMP regulations. In designing our facilities, full attention was given to material flow, equipment and automation, quality control and inspection. A granulator, an automatic film coating machine, high-speed tablet presses, blenders, encapsulators, fluid bed dryers, high shear mixers and high-speed bottle filling are a few examples of the sophisticated product development, manufacturing and packaging equipment we use. In addition, our Quality Control laboratory facilities are equipped with high precision instruments, such as automated high-pressure liquid chromatographs, gas chromatographs, robots and laser particle size analyzers.

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

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

Table of Contents

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

**Research and Development Process**

Over the past several years, we have consistently devoted resources to R&D projects, including new generic product offerings. The costs of these R&D efforts are expensed during the periods incurred. We believe that such investment expense may be recovered in future years when we receive marketing approval from the FDA to distribute such products. In addition to using cash generated from our operations, we have entered into financing agreements with third parties to provide additional cash when needed. These financing agreements are more fully described in the section entitled **Liquidity and Capital Resources** in Item 7 of this Form 10-K. We have embarked on a plan to grow in future years. In addition to organic growth to be achieved through our own R&D efforts, we have also initiated marketing projects with other companies in order to expand future revenue. We expect that our growing list of generic products under development will drive future growth. We also intend to use our R&D infrastructure to continually devote resources to additional R&D projects. The following steps outline the numerous stages in the generic drug development process:

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

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

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



Table of Contents

innovator drug approvals, are typically unnecessary for generic companies. If the results are successful, we will continue the collection of documentation and information for assembly of the drug application.

4.) *Submission of the ANDA for FDA review and approval.* The ANDA process became formalized under The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act ( Hatch-Waxman Act ). The Hatch-Waxman Act amended the Federal Food, Drug and Cosmetic Act ( FDCA ) to permit FDA to review and approve an ANDA for a generic copy of a drug product, which previously received FDA approval through its new drug approval process, without having the generic drug company conduct costly clinical trials. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data, and quality control procedures.

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

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

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

**Sales and Customer Relationships**

We sell our pharmaceutical products to generic pharmaceutical distributors, drug wholesalers, chain drug retailers, private label distributors, mail-order pharmacies, other pharmaceutical manufacturers, managed care organizations, hospital buying groups, governmental entities and health maintenance organizations. We promote our products through direct sales, trade shows, trade publications and bids. We also license the marketing of our products to other manufacturers and/or marketers in private label agreements.



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

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

Table of Contents**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:

<b>Name of Product</b>	<b>Medical Indication</b>	<b>Equivalent Brand</b>
1Acetazolamide Tablets	Glaucoma	Diamox®
2Amantadine Gel Capsules	Parkinson s Disease	Symmetrel ®
3Baclofen Tablets	Muscle Relaxer	Lioresal®
4Bethanechol Chloride Tablets	Urinary Retention	Urecholine®
5Butalbital, Aspirin and Caffeine Capsules	Migraine Headache	Fiorinal®
6Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules	Migraine Headache	Fiorinal w/ Codeine #3®
7Clindamycin HCl Capsules	Antibiotic	Cleocin®
8Cocaine Topical Solution	Anesthetic	N/A
9Danazol Capsules	Endometriosis	Danocrine®
10Dicyclomine Tablets	Irritable Bowels	Bentyl®
11Dicyclomine Capsules	Irritable Bowels	Bentyl®
12Digoxin Tablets	Congestive Heart Failure	Lanoxin®
13Dipyridamole Tablets	Anticoagulant	Persantine ®
14Doxycycline Tablets	Antibiotic	Adoxa®
15Doxycycline Hyclate Tablets	Antibiotic	Periostat®
16Esterified Estrogen & Methyltestosterone Tablets	Hormone Replacement	Estratest®
17Hydrochlorothiazide Tablet	Water Retention	Hydrodiuril®
18Hydromorphone HCl Tablets	Pain Management	Dilaudid®
19Levothyroxine Sodium Tablets	Thyroid Deficiency	Levoxy®/ Synthroid®
20Morphine Sulfate Oral Solution	Pain Management	Roxanol®
21OB-Natal ® ONE Gel Capsules	Pregnancy	PrimaCare ONE®
22Oxycodone HCl Oral Solution	Pain Management	Roxicodone®
23Phentermine HCl Tablets	Weight Loss	Adipex-P®
24Phentermine HCl Capsules	Weight Loss	Fastin®
25Pilocarpine HCl Tablets	Dryness of the Mouth	Salagen®
26Primidone Tablets	Epilepsy	Mysoline®
27Probenecid Tablets	Gout	Benemid®
28Rifampin Capsules	Antibiotic	Rifadin®
29Terbutaline Sulfate Tablets	Bronchospasms	Brethine®
30Unithroid® Tablet	Thyroid Deficiency	N/A
31Ursodiol Capsules	Gallstone	Actigall ®



Table of Contents

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

In fiscal years 2009 and 2008, we received four and eight ANDA approvals from the FDA, respectively. The following summary contains more specific details regarding our latest ANDA approvals. Market data is obtained from Wolters Kluwer.

In July 2007, we received a letter from the FDA with approval to market and launch Baclofen 10mg tablets. Baclofen is the generic version of Lioresal® and is a muscle relaxer used to treat symptoms of multiple sclerosis. According to Wolters Kluwer, total sales of generic Baclofen 10mg tablets were \$151 million at average wholesale price ( AWP ) in 2007.

In August 2007, we received two letters from the FDA with approval to market and launch Hydrochlorothiazide 25mg and 50mg tablets. Hydrochlorothiazide is the generic version of Hydrodiuril® and is a thiazide diuretic (water pill) that helps prevent your body from absorbing too much salt. According to Wolters Kluwer, total sales of generic Hydrochlorothiazide 25mg and 50mg tablets were \$182 million at AWP in 2007.

In December 2007, we received a letter from the FDA with approval to market and launch Phentermine HCl 30mg capsules. Phentermine HCl is the generic version of Fastin® and is an appetite suppressant. According to Wolters Kluwer, total sales of generic Phentermine HCl 30mg capsules were \$37.5 million at AWP in 2007.

In March 2008, we received three letters from the FDA with approval to market and launch Bethanechol Chloride 5mg, 10mg and 25mg tablets. Bethanechol Chloride is the generic version of Urecholine® and is indicated for the treatment of acute postoperative and postpartum non obstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention. According to Wolters Kluwer, total sales of generic Bethanechol Chloride 5mg, 10mg and 25mg tablets at AWP were \$56 million in 2007.

In March 2008, we received a letter from the FDA with approval to market and launch Rifampin 150mg and 300mg capsules. Rifampin is the generic version of Rifadin® and is used to reduce the number of meningococcal bacteria in the nose and throat. According to Wolters Kluwer, total sales of generic Rifampin 150mg and 300mg capsules at AWP were \$35 million in 2007.

In April 2008, we received a letter from the FDA with approval to market and launch Dipyridamole 25mg, 50mg and 75mg tablets. Dipyridamole is the generic version of Persantine® and is used to reduce the formation of blood clots in people who have had heart valve surgery. According to Wolters Kluwer, total sales of generic Dipyridamole 25mg, 50mg and 75mg tablets at AWP were \$45 million in 2007.

In August 2008, we received a letter from the FDA with approval to market and launch Doxycycline Tablets, 75mg and 150 mg, the generic equivalent of Adoxa® and is used for the treatment of bacterial infections. According to Wolters Kluwer, combined sales of generic Doxycycline Tablets, 75 mg and 150mg, were \$25.8 million in 2007.

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

In December 2008, we received a letter from the FDA with approval to market and launch Ursodiol 300 mg Capsules, the generic equivalent of Actigall® and are indicated for patients with radiolucent noncalcified gallbladder stones, and for the prevention of gallstone formation in obese patients experiencing rapid weight loss. According to Wolters Kluwer, combined sales of generic and brand Ursodiol were \$128.2 million for the 12 months ending October 2008.

In May 2009, we received a letter from the FDA with approval to market and launch Pilocarpine HCl 7.5 mg tablets, the generic equivalent of Salagen®. Pilocarpine HCl tablets are indicated for (1) the treatment of symptoms of dry mouth from salivary gland dysfunction caused by radiotherapy for cancer of the head and neck and (2) the treatment of symptoms of dry mouth in patients with Sjogren's syndrome. According to Wolters Kluwer, combined sales of generic and brand Pilocarpine HCl 7.5mg tablets at AWP were \$2.5 million in 2008.

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

Table of Contents

range of indications. The products under development are at various stages in the development cycle formulation, scale-up, clinical testing and FDA review.

The cost associated with each product that we are currently developing is dependent on numerous factors, including but not limited to, the complexity of the active ingredient's chemical characteristics, the price of the raw materials and the FDA-mandated requirement of bioequivalence studies (depending on the FDA's Orange Book classification). The estimated cost to develop a new generic product ranges from \$100,000 to \$1.5 million.

In addition, as one of the oldest generic drug manufacturers in the country formed in 1942, we currently own several ANDAs that are dormant on our records for products which we 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 are orally administered solid dosage products intended to treat a diverse range of medical indications. We intend to ultimately transfer the formulation technology and manufacturing process for all 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. Hence, 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.

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

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	9
FDA Review	ANDA supplement	9
Clinical Testing	ANDA	11
Scale-Up	Grand-fathered	4
Scale-Up	ANDA supplement	1

Table of Contents

Scale-Up	ANDA	10
Formulation/Method Development	ANDA	38

We incurred R&D expenses of approximately \$8,427,000 in fiscal year 2009, \$5,173,000 in fiscal year 2008, and \$7,459,000 in fiscal year 2007. The R&D spending includes spending on bioequivalence studies, internal development resources as well as outsourced development. While we manage all R&D from our principal executive office in Philadelphia, we have also been taking advantage of favorable development costs in other countries. We have strategic partnerships with various companies that either act as contract research organizations or API suppliers as well as dosage form manufacturers. In addition, U.S.-based research organizations have been engaged for product development to enhance our internal development. Fixed payment arrangements are established with these development partners, and can range from \$150,000 to \$250,000 to develop a drug. Development payments are normally scheduled in advance, based on 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 71% of our inventory purchases in fiscal year 2009, 71% in fiscal year 2008 and 63% in fiscal year 2007. On March 23, 2004, we entered into the JSP Distribution Agreement for the exclusive distribution rights in the United States to the current line of JSP products in exchange for four million (4,000,000) shares of our common stock. The products covered under the JSP Distribution Agreement include Butalbital, Aspirin, Caffeine with Codeine Phosphate capsules, Digoxin tablets and Levo tablets, sold generically and under the brand name Unithroid®. The initial term of the JSP Distribution Agreement is ten years, beginning on March 23, 2004 and continuing through March 22, 2014. See note 18 to our consolidated financial statements for more information on the terms, conditions and financial impact of the JSP Distribution Agreement.

During the term of the JSP Distribution Agreement, we are required to use commercially reasonable efforts to purchase minimum dollar quantities of JSP's products that we distribute. The minimum quantity to be purchased in the first year of the JSP Distribution Agreement was \$15 million. Thereafter, the minimum purchase quantity increases by \$1 million per year up to \$24 million for the last year of the JSP Distribution Agreement. We have met each applicable minimum purchase requirement to date, but there is no guarantee that we will be able to continue to do so in the future. If we do not meet the minimum purchase requirements, JSP's sole remedy is to terminate the JSP Distribution Agreement.

In August 2005, we entered into a three year agreement with a finished goods provider to purchase, at fixed prices, and distribute a certain generic pharmaceutical product in the United States. Purchases of finished goods inventory from this provider accounted for approximately 1%, 14% and 23% of our costs of purchased inventory in fiscal years 2009, 2008 and 2007, respectively. Following its expiration on August 21, 2008, the agreement was not renewed.



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

We have entered into definitive supply and development agreements with certain international companies, including Wintac of India, Orion Pharma of Finland, Azad Pharma AG and Swiss Caps of Switzerland and Pharma 2B (formerly Pharmaseed) of Israel, as well as certain domestic companies, including Banner Pharmacaps, Cerovene and Inverness. We are currently in negotiations on similar agreements with other international companies, through which we will market and distribute future products manufactured in-

Table of Contents

house or by third parties. We intend to capitalize on our strong customer relationships to build our market share for such products.

**Customers and Marketing**

We sell our products primarily to wholesale distributors, generic drug distributors, mail-order pharmacies, group purchasing organizations, chain drug stores and other pharmaceutical companies. The pharmaceutical industry's largest wholesale distributors, McKesson, Cardinal Health and Amerisource Bergen, accounted for 8%, 11%, and 9%, respectively, of our net sales in fiscal year 2009 and 6%, 9% and 5%, respectively, of our net sales in fiscal year 2008. Our largest chain drug store customer, Walgreens, accounted for 31% and 36% of net sales in fiscal year 2009 and fiscal year 2008, respectively. We perform ongoing credit evaluations of our customers' financial condition, and have experienced no significant collection problems to date. Generally, we require no collateral from our customers.

Sales to wholesale customers include indirect sales, which represent sales to third-party entities, such as independent pharmacies, managed care organizations, hospitals, nursing homes, and group purchasing organizations, collectively referred to as indirect customers. We enter into definitive agreements with our indirect customers to establish pricing for certain covered products. Under such agreements, the indirect customers independently select a wholesaler from which to purchase the products at these agreed-upon prices. We will provide credit to the wholesaler for the difference between the agreed-upon price with the indirect customer and the wholesaler's invoice price. This credit is called a chargeback. For more information on chargebacks, see the section entitled Chargebacks in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Form 10-K. These indirect sale transactions are recorded on our books as sales to the wholesale customers.

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

We promote our products through direct sales, trade shows and bids. We also market our products through private label arrangements, under which we manufacture our products with a label containing the name and logo of a customer. This practice is commonly referred to as private label business. Private label business allows us to leverage our internal sales efforts by using the marketing services from other well-respected pharmaceutical dosage suppliers. The focus of our sales efforts is the relationships we create with our customer accounts. Strong and dependable customer relationships have created a positive platform for us to increase our sales volumes. Advertising in the generic pharmaceutical industry is generally limited to trade publications, read by retail pharmacists, wholesale purchasing agents and other pharmaceutical decision-makers. Historically and in fiscal years 2009, 2008 and 2007, our advertising expenses were immaterial. When our sales representatives makes contact with a customer, we will generally offer to supply the customer our products at fixed prices. If accepted, the customer's purchasing department will coordinate the purchase, receipt and distribution of the products throughout its distribution centers and retail outlets. Once a customer accepts our supply of a product, the customer typically expects a high standard of service, including timely receipt of products ordered, availability of convenient, user-friendly and effective customer service functions and maintaining open lines of communication.

**Competition**

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

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

Table of Contents

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

Product	Primary Competitors
Butalbital with Aspirin and Caffeine, with and without Codeine Phosphate Capsules	Watson Pharmaceuticals and Breckenridge Pharmaceutical (manufactured by Anabolic Laboratories)
Digoxin Tablets	GlaxoSmithKline, Caraco Pharmaceutical Laboratories and Westward Pharmaceuticals
Doxycycline	Par Pharmaceuticals and Ranbaxy Laboratories
Levothyroxine Sodium tablets	Abbott Laboratories, Monarch Pharmaceuticals, Mylan Laboratories, Sandoz and Forest Laboratories
Primidone tablets	Watson Pharmaceuticals, Qualitest Pharmaceuticals, URL, Westward Pharmaceuticals, Amneal Pharmaceuticals and Impax Labs
Rifampin capsules	Sandoz and Versapharm
Unithroid tablets	Abbott Laboratories, Monarch Pharmaceuticals, Mylan Laboratories and Sandoz

**Government Regulation**

Pharmaceutical manufacturers are subject to extensive regulation by the federal government, principally by the FDA, and, in cases of controlled drugs, the DEA, and to a lesser extent, by other federal regulatory bodies and state governments. The FDCA, the Controlled Substance Act (the CSA ) and other federal statutes and regulations govern or influence the testing, manufacture, safety, labeling, storage, record keeping, approval, pricing, advertising, and promotion of our generic drug products. Noncompliance with applicable regulations can result in fines, recall and seizure of products, total or partial suspension of production, personal and/or corporate prosecution and debarment, and refusal of the government to approve new drug applications. The FDA also has the authority to revoke previously approved drug products.

Generally, FDA approval is required before a prescription drug can be marketed. A new drug is one not generally recognized by qualified experts as safe and effective for its intended use. New drugs are typically developed and submitted to the FDA by companies expecting to brand the product and sell it as a medical treatment. The FDA review process for new drugs is very extensive and requires a substantial investment to research and test the drug candidate. However, less burdensome approval procedures may be used for generic equivalents. Typically, the investment required to develop a generic drug is less costly than the brand innovator drug.

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

- **New Drug Applications (NDA):** Unless one of the two procedures discussed in the following paragraphs is available, a manufacturer must conduct and submit to the FDA complete clinical studies to establish a drug's safety and efficacy. The new drug approval process generally

involves:

- completion of preclinical laboratory and animal testing in compliance with the FDA's GLP regulations;
- submission to the FDA of an Investigational New Drug ( IND ) application for human clinical testing, which must become effective before human clinical trials may begin;

Table of Contents

- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's cGMP regulations; and
- submission to and approval by the FDA of an NDA.

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

- Phase I, during which the drug is introduced into healthy human subjects or, on occasion, patients and is tested for safety, stability, dose tolerance, and metabolism;
- Phase II, during which the drug is introduced into a limited patient population to determine the efficacy of the product in specific targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks; and
- Phase III, during which the clinical trial is expanded to a larger and more diverse patient group at geographically dispersed clinical trial sites to further evaluate clinical efficacy, optimal dosage, and safety.

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

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

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

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

Table of Contents

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.

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



Table of Contents

exclusivity against other companies that subsequently file ANDAs for that same product. A substantially complete ANDA is one that contains all the information required by the Hatch-Waxman Act and the FDA's regulations, including the results of any required bioequivalence studies. The FDA may refuse to accept the filing of an ANDA that is not substantially complete or may determine during substantive review of the ANDA that additional information, such as an additional bioequivalence study, is required to support approval. Such a determination may affect an applicant's first to file status and eligibility for a 180-day period of marketing exclusivity for the generic product. The MMA also modified the rules governing when the 180-day marketing exclusivity period is triggered or forfeited and shared exclusivity. Prior to the legislation, the 180-day marketing exclusivity period was triggered upon the first commercial marketing of the ANDA or a court decision holding the patent invalid, unenforceable, or not infringed. For ANDAs accepted for filing before March 2000, that court decision had to be final and non-appealable (other than a petition to the U.S. Supreme Court for a writ of certiorari). In March 2000, the FDA changed its position in response to two court cases that challenged the FDA's original interpretation of what constituted a court decision under the Hatch-Waxman Act. Under the changed policy, the 180-day marketing exclusivity period began running immediately upon a district court decision holding the patent at issue invalid, unenforceable, or not infringed, regardless of whether the ANDA had been approved and the generic product had been marketed. In codifying the FDA's original policy, the MMA retroactively applies a final and non-appealable court decision trigger for all ANDAs filed before December 8, 2003 leaving intact the first commercial marketing trigger. As for ANDAs filed after December 8, 2003, the marketing exclusivity period is only triggered upon the first commercial marketing of the ANDA product, but that exclusivity may be forfeited under certain circumstances, including, if the ANDA is not marketed within 75 days after a final and non-appealable court decision by the first-to-file or other ANDA applicant, or if the FDA does not tentatively approve the first-to-file applicant's ANDA within 30 months.

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

- **Section 505(b)(2) New Drug Applications:** For a drug that is identical to a drug first approved after 1962, a prospective manufacturer need not go through the full NDA procedure. Instead, it may demonstrate safety and efficacy by relying on published literature and reports where at least some of information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon certain preclinical or clinical studies conducted for an approved product. The manufacturer must also submit, if the FDA so requires, bioavailability or bioequivalence data illustrating that the generic drug formulation produces the same effects, within an acceptable range, as the previously approved innovator drug. Because published literature to support the safety and efficacy of post-1962 drugs may not be available, this procedure is of limited utility to generic drug manufacturers and the resulting approved product will not be interchangeable with the innovator drug as an ANDA drug would be unless 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.

Table of Contents

*Manufacturing cGMP Requirements*

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

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including but not limited to, the seizure or recall of noncomplying 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 more of which could have a material adverse effect on us.

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

*DEA Regulation*

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

Table of Contents

Fraud and Abuse Laws

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

*Anti-Kickback Statutes and Federal False Claims Act*

The federal health care programs Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as Medicare or Medicaid. The definition of remuneration has been broadly interpreted to include anything of value, including for example gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment, and possible exclusion from Medicare, Medicaid, and other federal health care programs. In addition some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

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

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

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

Another development affecting the health care industry is the increased use of the federal Civil False Claims Act, and in particular, action brought pursuant to the False Claims Act's whistleblower or qui tam provisions. The False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the

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

number of suits brought against health care providers by private individuals has increased dramatically. In addition, various states have enacted false claims law analogous to the Civil False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal health care program.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim

Table of Contents

for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, kickbacks, and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the False Claims Act in connection with off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of discount and rebate information and other information affecting federal, state, and third-party reimbursement of our products, and the sale and marketing of our products may be subject to scrutiny under these laws. We are unable to predict whether we will be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

*HIPAA and Other Fraud and Privacy Regulations*

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

*Pricing*

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

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

Table of Contents

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, 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, 2009, we had 277 employees, comprised of 217 employees at Lannett and an additional 60 employees at Cody Labs.

**Securities 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.



Table of Contents

**ITEM 1A. RISK FACTORS**

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

Approximately 75% of our sales are of distributed products, primarily manufactured by JSP. Two of these products are Levo and Digoxin, which accounted for 40% and 22%, respectively, of our Fiscal 2009 net sales, and 51% and 10%, respectively, of our net sales for Fiscal 2008. If the supply of these products is interrupted in any way, including any form of temporary or permanent business interruption to JSP, our operating results could be materially adversely affected. We do not have, at this time, a second source for these products.

**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 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

Table of Contents

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.

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 to us.

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.

**Our manufacturing operations as well as our suppliers manufacturing are subject to licensing by the FDA and/or DEA. If we or our suppliers were 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 opium 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 was 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;

Table of Contents

- 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 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, 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.

**The loss of Arthur P. Bedrosian or our other 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 Arthur P. Bedrosian and our other key personnel. If we lose the services of Mr. Bedrosian or our other key personnel, or he or 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 to help prevent the loss of our key personnel.

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

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

Factors that may cause our sales mix to vary include:

- the amount of new product introductions;
- marketing exclusivity, if any, which may be obtained on certain new products;
- the level of competition in the marketplace for certain products;
- the availability of raw materials and finished products from our suppliers; and
- the scope and outcome of governmental regulatory action that may involve us.

Table of Contents

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

Table of Contents

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.

**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 pending 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. If the stimulus package is approved in its current form, this funding will be used, 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

Table of Contents

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 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 average wholesale price (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

Table of Contents

best price to the states under the Medicaid program. We are not currently subject to any such investigations or actions, but if we do become subject or if these investigations and actions were to result in changes to our operations, it could materially adversely affect our results of operations.

**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 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 False Claims Act 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 False Claims Act also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the False Claims Act. These suits, 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 False Claims Act 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.

For the fiscal year ended June 30, 2009, our three largest customers accounted for 31%, 11% and 9%, respectively, of our net sales. The loss of any of these customers could materially adversely affect our business, results of operations and financial condition and our cash flows. In addition, the Company has no long-term supply agreements with its customers 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

Table of Contents

Lannett, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

**Rising insurance costs could negatively impact profitability.**

The cost of insurance, including workers compensation, product liability and general liability insurance, have risen in prior years and may increase in the future. In response, we may increase deductibles and/or decrease certain 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.

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

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

**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 two facilities in Philadelphia, Pennsylvania. The administrative offices, quality control laboratory and manufacturing and production facilities are located in a 31,000 square foot facility at 9000 State Road in Philadelphia. The second facility consists of 63,000 square feet, and is located within one mile of the State Road location at 9001 Torresdale Avenue in Philadelphia. Our research laboratory, package, warehousing and distribution operations, sales and accounting departments are located in the second building.



Table of Contents

In June 2006, Lannett signed a lease agreement on a 66,000 square foot facility in Philadelphia. An additional agreement which gives us the option to buy the facility was also signed. The Company expects to purchase this building in fall 2009 for approximately \$3.8 million plus the cost of fit out estimated to be approximately \$2 million. A significant portion of the purchase price and fit out costs are expected to be financed through a series of loans with a bank and a Pennsylvania state run development agency. This new facility is initially going to be used for warehouse space with the expectation of making this facility our headquarters and possibly additional manufacturing space. The other Philadelphia locations will continue to be utilized as manufacturing, packaging, and as a research laboratory. This gives Lannett the space to fit its desire to expand.

Cody, a wholly-owned subsidiary of Lannett, leases a 73,000 square foot facility in Cody, Wyoming. This location houses Cody's manufacturing and production facilities. Cody leases the facility from Cody LCI Realty, LLC, Wyoming, which is 50% owned by Lannett and 50% by an officer of Cody Laboratories and his former spouse.

**ITEM 3. LEGAL PROCEEDINGS**

In early June 2008, the Company filed a declaratory judgment suit in the Federal District Court of Delaware (Civil Action No. 08-338 (JJF)) against KV Pharmaceuticals, DrugTech Corp. and Ther-Rx Corp (collectively, KV). The complaint sought declaratory judgment for non-infringement and invalidity of certain patents owned by KV. The complaint further sought declaratory judgment of anti-trust violations and federal and state unfair competition violations for actions taken by KV in securing and enforcing these patents. After the complaint was filed, KV countered with a motion for a Temporary Restraining Order (TRO) to prevent the Company from launching its Multivitamin with Mineral Capsules (MMCs), due to alleged patent and trademark infringement issues. The TRO was heard and, ultimately, resulted in a conclusion by the court that the Company's product label on the MMCs should be modified. KV also countered with claims of infringement by the Company of KV's patents seeking the Company's profits for sales of MMCs or other monetary relief, preliminary and permanent injunctive relief, attorney's fees and a finding of willful infringement. On March 17, 2009, the Company and KV settled the litigation. In light of the withdrawal of KV's innovator prenatal product, and the resulting anticipated decline in sales and declining market for written prescription, the Company decided it was pointless to continue the litigation and entered into the settlement arrangement with KV. Pursuant to the settlement, the Company received a license from KV and became an authorized generic provider. During the terms of the license, the Company will pay KV a royalty on all future sales of its Prenatal vitamin product. Lannett will cease offering its Prenatal vitamin product if and when the brand is restored to the marketplace.

In or about July 2008, Albion International and Albion, Inc. filed suit in the United States District Court, District of Utah (Case No. 2:08cv00515) against Lannett asserting claims for patent and trademark infringement, as well as unfair competition, arising out of Lannett's use of product that it purchased from Albion and used as an ingredient in its MMC. Lannett filed a motion to dismiss the complaint on the basis that it purchased the product from Albion and, as such, was authorized to use the product in its MMC. The Court granted the motion and dismissed the complaint but gave Albion leave to file an amended complaint. On January 20, 2009, Albion filed an amended complaint. Lannett filed an answer to the complaint and counterclaim, asserting, among other things, that Albion tortuously interfered with Lannett's contracts. Subsequent to the filing of the answer and counterclaim, Lannett and Albion reached an agreement in principal to settle the case. Under terms of the settlement, the parties would each dismiss their claims against each other and provide releases. On July 6, 2009, the settlement agreement was signed and on July 13, 2009, the case was dismissed.

Table of Contents

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

No matters have been submitted to a vote of the Company's security holders during the quarter ended June 30, 2009.



Table of Contents**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 AMEX). 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 2009 and 2008, as quoted by the NYSE AMEX. Such quotations reflect inter-dealer prices without retail mark-up, markdown, or commission and may not represent actual transactions.

**Fiscal Year Ended June 30, 2009**

	<b>High</b>	<b>Low</b>
First quarter	\$ 4.20	\$ 2.25
Second quarter	\$ 5.00	\$ 1.79
Third quarter	\$ 5.86	\$ 4.60
Fourth quarter	\$ 7.52	\$ 4.86

**Fiscal Year Ended June 30, 2008**

	<b>High</b>	<b>Low</b>
First quarter	\$ 6.20	\$ 3.65
Second quarter	\$ 5.14	\$ 3.05
Third quarter	\$ 3.55	\$ 2.34
Fourth quarter	\$ 4.80	\$ 2.05

 **Holders**

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

As of September 15, 2009, there were approximately 249 holders of record of the Company's common stock.

### **Dividends**

The Company did not pay cash dividends in Fiscal 2009 or Fiscal 2008. 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.

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

The following financial information as of and for the five years ended June 30, 2009, 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, and information from our customers regarding their intentions to return the product.

In Fiscal 2007, the Company wrote-off of a portion of a note receivable due from Cody Labs, and subsequently acquired Cody Labs (a provider of API). Approximately \$7.8 million of notes were written-off prior to the Cody Labs acquisition, representing the excess of the note receivable over the fair value of assets received of approximately \$4.4 million.

Statement of Financial Accounting Standards (SFAS) 123(R), *Share-Based Payment*, was adopted on July 1, 2005 using the modified prospective transition method. Because the modified prospective transition method was elected, results for prior periods have not been restated to include share-based compensation expense for stock options or the Company's Employee Stock Purchase Plan. See note 1 to our consolidated financial statements for more information.

In Fiscal 2005, the Company determined that an intangible asset related to acquired product rights was impaired. At that time, the Company determined that this intangible was impaired and a \$46.1 million impairment charge was recorded.

**Lannett Company, Inc. and Subsidiaries****Financial Highlights****As of and for the Fiscal Year Ended**

<b>June 30,</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>Operating Highlights</b>					
Net Sales	\$ 119,002,215	\$ 72,403,283	\$ 82,577,591	\$ 64,060,375	\$ 44,901,645
Gross Profit	\$ 45,244,469	\$ 16,301,071	\$ 21,424,987	\$ 28,375,665	\$ 7,968,320
Operating Income/(Loss)	\$ 10,780,869	\$ (5,430,534)	\$ (5,964,409)	\$ 8,453,918	\$ (53,639,658)
Net Income/(Loss)	\$ 6,534,245	\$ (2,318,059)	\$ (6,929,008)	\$ 4,968,922	\$ (32,779,596)
Basic Earnings/(Loss) Per Share	\$ 0.27	\$ (0.10)	\$ (0.29)	\$ 0.21	\$ (1.36)
Diluted Earnings/(Loss) Per Share	\$ 0.27	\$ (0.10)	\$ (0.29)	\$ 0.21	\$ (1.36)

**Balance Sheet Highlights**

Edgar Filing: LANNETT CO INC - Form 10-K

Total Assets	\$	124,577,121	\$	113,679,264	\$	104,656,100	\$	105,992,064	\$	94,917,060
Total Debt	\$	8,138,768	\$	8,978,834	\$	9,679,965	\$	8,196,692	\$	9,532,448
Long Term Debt	\$	7,703,382	\$	8,186,922	\$	8,987,846	\$	7,649,806	\$	7,262,672
Total Stockholders Equity	\$	77,553,969	\$	69,271,480	\$	70,183,175	\$	75,755,916	\$	69,249,244

Table of Contents

**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 2010, and any Current Reports on Form 8-K filed by the Company.

**Critical Accounting Policies**

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

Critical accounting policies are defined as those that are reflective of significant judgments and uncertainties and potentially result in materially different results under different assumptions and conditions. We believe that our critical accounting policies include those described below. For a detailed discussion on the application of these and other accounting policies, refer to Note 1 in the Notes to the Consolidated Financial Statements included herein.

**Consolidation of Variable Interest Entity** The Company consolidates any Variable Interest Entity ( VIE ) of which we are the primary beneficiary. The liabilities recognized as a result of consolidating a VIE do not represent additional claims on our general assets; rather, they represent claims against the specific assets of the consolidated VIE. Conversely, assets recognized as a result of consolidating a VIE do not represent additional assets that could be used to satisfy claims against our general assets. Reflected in the June 30, 2009 and 2008 balance sheets are consolidated VIE assets of \$1.9 million and \$1.9 million, respectively, which is comprised mainly of land and a building. VIE liabilities primarily consist of a mortgage on that property in the amount of \$1.7 million and \$1.7 million at June 30, 2009 and 2008, respectively. This VIE was initially consolidated by Cody, as Cody has been the primary beneficiary. Cody has then been consolidated within Lannett's financial statements since its acquisition in April 2007.

**Revenue Recognition** The Company recognizes revenue when its products are shipped. At this point, title and risk of loss have transferred to the customer and provisions for estimates, including rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable. Accruals for these provisions are presented in the consolidated financial statements as rebates and chargebacks payable and reductions to net sales. The change in the reserves for various sales adjustments may not be proportionally equal to the change in sales because of changes in both the product and the customer mix. Increased sales to wholesalers will generally require additional accruals as they are the primary recipient of chargebacks and rebates. Incentives offered to secure sales vary from product to product. Provisions for estimated rebates and promotional credits are estimated based upon contractual terms. Provisions for other customer credits, such as price adjustments, returns, and chargebacks, require management to make subjective judgments on customer mix. Unlike branded



Table of Contents

innovator drug companies, Lannett does not use information about product levels in distribution channels from third-party sources, such as IMS Health 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. The chargeback/rebate reserve is reviewed on a monthly basis by management using several ratios and calculated metrics. As we continue to obtain additional information about our historical experience for chargebacks, rebates and returns, we also update our estimates of the required reserves.

**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 by the Company 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 expected mix of product sales to the indirect customers. The Company continually monitors the reserve for chargebacks and makes adjustments when management believes that expected chargebacks on actual sales may differ from the amounts that were assumed in the establishment of the chargeback reserves.

**Rebates** Rebates are offered to the Company's key chain drug store 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. 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 rebate-eligible customers are recognized and decreases when actual rebate payments are made. However, since rebate programs are not identical for all customers, the size of the reserve will depend on the mix of sales to customers that are eligible to receive rebates.

**Returns** Consistent with industry practice, the Company has a product returns policy that allows certain customers to return product within a specified period prior to and subsequent to the product's lot expiration date in exchange for a credit to be applied to future purchases. The Company's policy requires that the customer obtain pre-approval from the Company for any qualifying return. The Company estimates its provision for returns based on historical experience, adjusted for any changes in business practices or conditions that would cause management to believe that future product returns may differ from those returns assumed in the establishment of reserves. Generally, the reserve for returns increases as sales increase and decrease when credits are issued or payments are made for actual returns received. 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 a price reduction. Decreases in selling prices are discretionary decisions made by management to reflect competitive market conditions. Amounts recorded for estimated shelf stock adjustments are based upon specified terms with direct





Table of Contents

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. When competitors enter the market for existing products, shelf stock adjustments may be issued to maintain price competitiveness.

The following tables identify the reserves for each major category of revenue allowance and a summary of the activity for fiscal years 2009, 2008 and 2007. 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, 2009**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
Reserve Balance as of June 30, 2008	\$ 4,049,407	\$ 632,314	\$ 13,642,589	\$ 2,107	\$ 18,326,417
Actual credits issued related to sales recorded in prior fiscal years	(3,954,794)	(632,314)	(12,853,342)		(17,440,450)
Reserves or (reversals) charged during Fiscal 2009 related to sales in prior fiscal years			2,107	(2,107)	
Reserves charged to net sales during Fiscal 2009 related to sales recorded in Fiscal 2009	35,391,475	12,141,204	4,315,638	204,119	52,052,436
Actual credits issued related to sales recorded in Fiscal 2009	(29,396,286)	(9,603,458)		(204,119)	(39,203,863)
Reserve Balance as of June 30, 2009	\$ 6,089,802	\$ 2,537,746	\$ 5,106,992	\$	\$ 13,734,540

Table of Contents**For the Year Ended June 30, 2008**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
Reserve Balance as of June 30, 2007	\$ 4,649,478	\$ 871,339	\$ 113,313	\$ 52,234	\$ 5,686,364
Actual credits issued related to sales recorded in prior fiscal years	(4,556,488)	(1,741,804)	(4,909,659)		(11,207,951)
Reserves or (reversals) charged during Fiscal 2008 related to sales in prior fiscal years		870,465	5,892,805	(50,000)	6,713,270
Reserves charged to net sales during Fiscal 2008 related to sales recorded in Fiscal 2008	26,126,995	7,999,232	12,546,130	473,423	47,145,780
Actual credits issued related to sales recorded in Fiscal 2008	(22,170,578)	(7,366,918)		(473,550)	(30,011,046)
Reserve Balance as of June 30, 2008	\$ 4,049,407	\$ 632,314	\$ 13,642,589	\$ 2,107	\$ 18,326,417

**For the Year Ended June 30, 2007**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
Reserve Balance as of June 30, 2006	\$ 10,137,400	\$ 2,183,100	\$ 416,000	\$ 275,600	\$ 13,012,100
Actual credits issued related to sales recorded in prior fiscal years	(10,170,000)	(1,800,000)	(5,578,000)	(250,000)	(17,798,000)
Reserves or (reversals) charged during Fiscal 2007 related to sales in prior fiscal years		(300,000)	3,572,313		3,272,313
Reserves charged to net sales during Fiscal 2007 related to sales recorded in Fiscal 2007	28,034,000	9,562,000	1,703,000	1,044,800	40,343,800
Actual credits issued related to sales recorded in Fiscal 2007	(23,351,922)	(8,773,761)		(1,018,166)	(33,143,849)
Reserve Balance as of June 30, 2007	\$ 4,649,478	\$ 871,339	\$ 113,313	\$ 52,234	\$ 5,686,364

**Reserve Activity 2009 vs. 2008**

The total reserve for chargebacks, rebates, returns and other adjustments decreased from \$18,326,417 at June 30, 2008 to \$13,734,540 at June 30, 2009. The decrease in the reserve balance was primarily the result of our decision to record during the fourth quarter of Fiscal 2008 a \$10,536,000 provision for the expected return of 100% of the shipments of Prenatal Multivitamin. Our expectation that all of the product would

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

be returned was based on our inability to have the product specified as a brand equivalent, and information from our customers regarding their intentions to return the product. Substantially all of these products were returned in Fiscal 2009. Partially offsetting this decrease was an increase primarily due to an increase in sales volume in Fiscal 2009.

The increase in chargeback and rebate reserves between June 30, 2008 and June 30, 2009 was primarily due to an increase in sales volume in 2009, as well as a change in our sales mix. The following tables

Table of Contents

compare the year-end reserve balances in fiscal years 2009 and 2008 and the gross sales mix in Fiscal 2009 and Fiscal 2008.

	Fiscal Year Ended June 30,			
	2009	%	2008	%
Chargeback reserve	\$ 6,089,802	44%	\$ 4,049,407	22%
Rebate reserve	2,537,746	19%	632,314	3%
Return reserve	5,106,992	37%	13,642,589	74%
Other reserve		0%	2,107	0%
	\$ 13,734,540	100%	\$ 18,326,417	100%

	Fiscal Year ended June 30,		Fiscal Fourth Quarter	
	2009	2008	2009	2008
Chain drug stores	37%	34%	33%	35%
Mail Order	4%	4%	3%	4%
Wholesalers	59%	62%	64%	61%
	100%	100%	100%	100%

**Reserve Activity 2008 vs. 2007**

The total reserve for chargebacks, rebates, returns and other adjustments increased from \$5,686,364 at June 30, 2007 to \$18,326,417 at June 30, 2008. The increase in the reserve balance was primarily the result of our decision to record during the fourth quarter of Fiscal 2008 a \$10,536,000 provision for the expected return of 100% of the shipments of Prenatal Multivitamin. Our expectation that all of the product would be returned was based on our inability to have the product specified as a brand equivalent, and information from our customers regarding their intentions to return the product. Also during Fiscal 2008 we increased our estimated returns reserve by approximately \$3.0 million, based on an analysis of our historical returns experience, the average lag time between sales and returns and our understanding of the buying patterns and inventory practices of both our direct and indirect customers. This change in estimate incorporated new information that has allowed us to better estimate the average length of time between product sales and returns. As this change resulted from new information that has allowed us to better estimate the average length of time between product sales and returns, we consider it to be a change in estimate as defined in SFAS 154: *Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3.*

During Fiscal 2008, we also experienced an unanticipated increase in our returns compared to historical experience that required us to record a provision of approximately \$3.0 million in fiscal year 2008 for returns related to sales in prior years. We believe, however, that this increase in returns was largely related to certain specific nonrecurring events.

The decline in chargeback and rebate reserves between June 30, 2007 and June 30, 2008 was due in part to a change in our sales mix away from wholesalers and toward the chain drug stores as well as a decrease in inventory levels at wholesaler distribution centers. The following tables compare the year-end reserve balances in Fiscal 2008 and Fiscal 2007 and the sales mix in Fiscal 2008 and Fiscal 2007.

Table of Contents

	Fiscal Year Ended June 30,			
	2008	%	2007	%
Chargeback reserve	\$ 4,049,407	22%	\$ 4,649,478	82%
Rebate reserve	632,314	3%	871,339	15%
Return reserve	13,642,589	74%	113,313	2%
Other reserve	2,107	0%	52,234	1%
	\$ 18,326,417	100%	\$ 5,686,364	100%

	Fiscal Year ended June 30,		Fiscal Fourth Quarter	
	2008	2007	2008	2007
Chain drug stores	34%	24%	35%	34%
Mail Order	4%	4%	4%	4%
Wholesalers	62%	72%	61%	62%
	100%	100%	100%	100%

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

The Company also regularly monitors accounts receivable ( AR ) balances by reviewing both net and gross days sales outstanding ( DSO ). Net DSO is calculated by dividing gross accounts receivable less the reserve for rebates, chargebacks, returns and other adjustments by the average daily net sales for the period. Gross DSO shows the result of the same calculation without regard to rebates, chargebacks, returns and other adjustments.

The Company monitors both net DSO and gross DSO as an overall check on collections and to assess the reasonableness of the reserves. Gross DSO provides management with an understanding of the frequency of customer payments, and the ability to process customer payments and deductions. The net DSO calculation provides management with an understanding of the relationship of the AR balance net of the reserve liability compared to net sales after charges to the reserves during the period. Standard payment terms offered to customers are consistent with industry practice at 60 days. Net eliminates the effect of timing of processing, which is inherent in the gross DSO calculation.

The following table shows the results of these calculations for the fiscal years ended June 30, 2009, 2008 and 2007:

Fiscal Year Ended June 30,	2009	2008	2007
Net DSO (in days)	55	65	72
Gross DSO (in days)	53	70	74

Table of Contents

The level of both net and gross DSO at June 30, 2009 is slightly lower than the Company's expectation that DSO will be in the 60 to 70 day range based on 60 day payment terms for most customers due to significantly higher average daily sales in the fourth quarter of Fiscal 2009 which were collected by June 30, 2009.

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

***New Accounting Pronouncements -***

In June 2007, the Emerging Issues Task Force ( EITF ) reached a final consensus on EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ( EITF 07-3 ). EITF 07-3 was effective for our fiscal year beginning July 1, 2008. EITF 07-3 requires non-refundable advance payments for future research and development activities to be capitalized until the goods have been delivered or related services have been performed. As the guidance in EITF 07-03 is consistent with our existing policy, EITF 07-03 did not have any impact on our financial statements or related disclosures.

In November 2007, the EITF reached a final consensus on EITF Issue No. 07-1, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property ( EITF 07-1 ). EITF 07-1 will be effective for our fiscal year beginning July 1, 2009 and interim periods within that fiscal year. Adoption is on a retrospective basis to all prior periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the impact of adopting EITF 07-1 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations ( FAS 141(R) ). FAS 141(R) significantly changes the accounting for business combinations in a number of areas including the treatment of contingent consideration, contingencies, acquisition costs, in-process research and development and restructuring costs. In addition, under FAS 141(R), changes in deferred tax asset valuation allowances and acquired income tax uncertainties in a business combination after the measurement period will impact income tax expense. In April 2009, FAS 141(R) was amended by FASB Staff Position FAS 141R-1, Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies, ( FSP FAS 141(R)-1 ) to address application issues regarding the accounting and disclosure provisions for contingencies. FSP FAS 141(R) amends FAS 141R by replacing the guidance on the initial recognition and measurement of assets and liabilities arising from contingencies acquired or assumed in a business combination. FSP FAS 141(R)-1 also amends FAS 141R's subsequent accounting guidance for contingent assets and liabilities recognized at the acquisition date and amends the disclosure requirements for contingencies. FAS 141(R) and FSP FAS 141(R)-1 apply prospectively to business combinations for which the acquisition date is on or after the beginning of the fiscal year beginning July 1, 2009. Early application is not permitted. The effect of these standards on our consolidated financial statements will depend on the nature and terms of any business combinations that occur after the effective date.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements ( FAS 160 ). FAS 160 amends Accounting Research Bulletin No. 51 to establish accounting



Table of Contents

and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements and establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation. FAS 160 is effective for our fiscal year beginning July 1, 2009. We do not expect the adoption of FAS 160 to have a significant impact on our consolidated financial statements.

In April 2008, the FASB issued FASB Staff Position No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP FAS 142-3 ). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *Goodwill and Other Intangible Assets*. The FSP is intended to improve the consistency between the useful life of a recognized intangible asset under Statement 142 and the period of expected cash flows used to measure the fair value of the asset under FAS 141(R) and other U.S. generally accepted accounting principles. The new standard is effective for our financial statements issued for fiscal years and interim periods beginning July 1, 2009. We do not expect the adoption of FSP FAS 142-3 to have a significant impact on our consolidated financial statements.

In April 2009, the FASB issued FASB Staff Position (FSP) FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, to make the guidance on other-than-temporary impairments of debt securities more operational and improve the financial statement disclosures related to other-than-temporary impairments for debt and equity securities. The FSP clarifies the interaction of the factors that should be considered when determining whether a debt security is other-than-temporarily impaired. FSP FAS 115-2 and FAS 124-2 are effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. If an entity adopts either FSP FAS 157-4 or FSP FAS 107-1 and APB 28-1 for periods ending after March 15, 2009, then it must adopt this FSP at the same time. The Company adopted FSP FAS 115-2 and FAS 124-2 effective June 30, 2009. The adoption of these standards did not have a significant impact on our consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* ( FAS 165 ). FAS 165 defines the period after the balance sheet date during which a reporting entity's management should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements. The statement is effective for interim and annual periods ending after June 15, 2009. The Company adopted FAS 165 effective with its financial statements as of and for the year ended June 30, 2009. In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through September 28, 2009, the date the financial statements were issued.

In June 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)* ( FAS 167 ). FAS 167 amends Interpretation 46(R) to require an enterprise to perform an analysis to determine whether the enterprise's variable interest or interests give it a controlling financial interest in a variable interest entity. It also amends Interpretation 46(R) to require ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. The statement is effective for the annual reporting period that begins after November 15, 2009. We do not expect the adoption of FAS 167 to have a significant impact on our consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification TM and the Hierarchy of Generally Accepted Accounting Principles*, a replacement of FASB Statement No. 162 ( SFAS 168 ), which establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied in the preparation of financial statements in conformity with generally accepted accounting principles. SFAS 168 explicitly recognizes rules and interpretive releases of the Securities and Exchange Commission ( SEC ) under federal securities laws as authoritative GAAP for SEC registrants. SFAS 168 will become effective in the first





Table of Contents

quarter of fiscal year 2010 and will not have a material impact on the Company's consolidated financial statements.

**Results of Operations Fiscal 2009 compared to Fiscal 2008**

Net sales increased 64% from \$72,403,283 in Fiscal 2008 to \$119,002,215 in Fiscal 2009. The increase was partly due to sales of approximately \$12,569,000 of our Prenatal vitamins during Fiscal 2009 which was the first year that the Company has offered this product. In addition to the sales of the Prenatal vitamins, the following factors contributed to the \$46,598,932 increase in sales:

Medical indication	Sales volume change %	Sales price change %
Migraine Headache	(3)%	(4)%
Antibiotics	51%	(43)%
Epilepsy	2%	(53)%
Heart Failure	159%	36%
Thyroid	28%	(3)%

The increase in product sales can be attributed primarily to three products. Sales of drugs for the treatment of congestive heart failure increased by approximately \$18,847,000 for Fiscal 2009 compared to Fiscal 2008 due to a product recall by several of our major competitors. For Fiscal 2009, the Company had sales of approximately \$12,569,000 of the Prenatal vitamins, which was the first year the Company offered this product. Sales of drugs used in the treatment of thyroid deficiency increased by approximately \$9,311,000. The main reason for this increase was due to an increase in sales to one large existing retail chain customer along with the pick up of several new customers at our existing prices.

The Company expects to continue increasing the number of products available for sale to its customers, which will require additional FDA approvals. The Company's receipt of several approvals by the FDA to offer new products has resulted in more sales of new products in Fiscal 2009 compared to Fiscal 2008.

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

Customer Category	Fiscal 2009 Net Sales	Fiscal 2008 Net Sales
Wholesaler/Distributor	\$53.8 million	\$30.5 million
Retail Chain	\$59.0 million	\$37.1 million
Mail-Order Pharmacy	\$5.8 million	\$4.5 million
Private Label	\$0.4 million	\$0.3 million
Total	\$119.0 million	\$72.4 million

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

The sales to all customer categories except private label increased significantly as a result of an increase in the demand for products for which the Company is the major supplier and also an increase in the number of products available for sale.

Table of Contents

Cost of sales increased 31%, from \$56,102,212 in Fiscal 2008 to \$73,757,746 in Fiscal 2009. The increase reflected the impact of the 64% increase in net sales as well as the overall fixed nature of some production costs.

Amortization expense primarily relates to the JSP Distribution Agreement. For the remaining five years of the JSP Distribution Agreement, the Company will incur annual amortization expense of approximately \$1,785,000.

Gross profit as a percent of net sales increased to 38% in Fiscal 2009 from 23% in Fiscal 2008, due to strong profit margins on the new Prenatal vitamin, increased margins for our congestive heart failure medication, and the overall fixed nature of some production costs versus the 64% increase in revenues. While the Company is continuously striving to keep product costs low, there can be no guarantee that profit margins will not decline in future periods due to pricing pressure from competitors and costs of producing or purchasing new drugs. Changes in the product mix may also occur which could affect gross profit as a percent of sales in future periods.

Research and development ( R&D ) expenses increased 63% to \$8,427,135 in Fiscal 2009 from \$5,172,715 in Fiscal 2008. The increase was primarily due to a increase in the production of drugs in development and preparation for submission to the FDA. 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 planned submissions to the FDA.

Selling, general and administrative expenses increased 57% to \$26,059,104 in Fiscal 2009 from \$16,552,859 in Fiscal 2008. The increase is primarily due to litigation expenses related to the patent challenge with KV Pharmaceuticals of approximately \$6,537,000, incentive compensation costs totaling approximately \$4,200,000, and severance costs related to the departure of the Company's former chief financial officer of approximately \$452,000. 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.

Interest expense decreased to \$321,751 in Fiscal 2009 from \$383,267 in Fiscal 2008, due to lower levels of long term debt. Interest income increased to \$209,188 in Fiscal 2009 from \$170,040 in Fiscal 2008 due to interest income received on a large income tax refund as well as interest earned on a higher level of investment securities.

The Company recorded income tax expense of \$4,090,716 in Fiscal 2009 on a pretax income after minority interest of \$10,624,961 as compared to an income tax benefit of \$3,376,011 in Fiscal 2008 on a pretax loss after minority interest of \$5,694,070. The inclusion of nondeductible expenses, state income taxes, the effects of federal income tax credits, and a reduction in the valuation allowance for deferred tax assets were the principal reasons for the effective tax rate of 38.3% in fiscal year 2009.

At June 30, 2009, the Company has recognized a net deferred tax asset of \$18,054,474. The net deferred tax asset is net of a valuation allowance of \$2,097,175 that is 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 net income of \$6,534,245 for Fiscal 2009, or \$0.27 basic and diluted earnings per share, compared to a net loss of \$2,318,059 for Fiscal 2008, or \$0.10 basic and diluted loss per share.

Table of Contents**Results of Operations Fiscal 2008 compared to Fiscal 2007**

Net sales decreased 12% from \$82,577,591 in Fiscal 2007 to \$72,403,283 in Fiscal 2008. The decrease reflected increased competition in the generic drug market which adversely affected Lannett's sales of certain antibacterial drugs as well as sales of drugs used in the treatment of epilepsy. Prices of antibiotic drugs declined 34% from prior year levels due to increased competition, which partly offset higher sales volumes. Prices of Lannett's heart failure drugs increased slightly from prior year levels and sales volumes increased 49% from the prior year level, largely due to the impact of a product recall of one of Lannett's competitors during the quarter ended June 30, 2008. Thyroid medication, our largest product in terms of sales, showed a continued growth in both volume and in price. The following table presents the percentage changes in process and volumes for the Company's products, by medical indication.

Medical indication	Sales volume change %	Sales price change %
Migraine Headache	18%	(17)%
Antibiotics	136%	(34)%
Epilepsy	(20)%	(36)%
Heart Failure	49%	8%
Thyroid	5%	4%

We plan to continue to increase the number of products available for sale to our customers, although FDA approvals are needed to achieve this growth.

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

Customer Category	Fiscal 2008 Net Sales	Fiscal 2007 Net Sales
Wholesaler/Distributor	\$30.5 million	\$49.4 million
Retail Chain	\$37.1 million	\$27.9 million
Mail-Order Pharmacy	\$4.5 million	\$5.1 million
Private Label	\$0.3 million	\$0.2 million
Total	\$72.4 million	\$82.6 million

Wholesaler/Distributor sales decreased as a result of one of Lannett's major wholesalers withdrawing from the one-stop program which used Lannett as a first call supplier. Retail chain sales increased significantly as a result of an increase in the number of products available for sale and a significant increase in the number of retail stores of one of our customers. Mail order pharmacy sales decreased from the prior year due mainly to the market shift toward retail chains at the expense of mail order pharmacy sales. Private label sales increased slightly from the prior year, although this channel is not expected to contribute significantly to Lannett's sales in the future as we have decided not to actively pursue additional private label customers because of the lower margins for this business.

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

In 2006, prior to its acquisition by Lannett, Cody received an FDA warning letter, and stopped operations to remediate their facility. This remediation occurred from August 2006 through February 2007. Upon completion of the remediation, Cody requested an FDA inspection. Subsequent FDA inspection resulted in relatively minor Form 483 observations, which have since been remediated. In March 2008, Cody Labs recommenced manufacturing operations after management concluded that certain regulatory deficiencies identified by the FDA prior to Lannett's acquisition were substantially remediated.

Table of Contents

Cost of sales decreased 8%, from \$61,152,604 in Fiscal 2007 to \$56,102,212 in Fiscal 2008. The decrease reflected the 12% decrease in net sales, partly offset by the impact of normal inflationary pressures on labor and material costs and expenses related to the Company's prenatal vitamin with mineral product.

Amortization expense relate to the JSP Distribution Agreement. For the remaining six years of the JSP Distribution Agreement, the Company will incur annual amortization expense of approximately \$1,785,000.

Gross profit as a percent of net sales declined to 23% in Fiscal 2008 from 26% in Fiscal 2007, due in part to expenses related to the prenatal multivitamin with mineral product, and price erosion for antibiotics, heart failure products and epilepsy medications. While the Company is continuously striving to keep product costs low, there can be no guarantee that profit margins will not decline in future periods due to pricing pressure from competitors and costs of producing or purchasing new drugs. Changes in the product mix may also occur which could affect gross profit as a percent of sales in future periods.

R&D expenses decreased 31% to \$5,172,715 in Fiscal 2008 from \$7,459,432 in Fiscal 2007. The decrease was primarily due to a decrease in the production of drugs in development and preparation for submission to the FDA. 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 planned submissions to the FDA.

Selling, general and administrative expenses increased 36% to \$16,552,859 in Fiscal 2008 from \$12,161,187 in Fiscal 2007, primarily due to the inclusion of a full year of general and administrative expenses of Cody, which was acquired in the fourth quarter of Fiscal 2007. The remaining increase in expense reflects increased legal expenses and higher professional fees. While the Company is focused on controlling costs, increases in personnel costs may have an ongoing impact on the administrative cost structure. Other costs are being incurred to facilitate improvements in the Company's infrastructure.

On March 31, 2007, the Company recorded an impairment charge of \$7,775,890 on a note receivable owed by Cody. On April 10, 2007, it was decided to complete the acquisition of Cody by forgiving the remaining balance of the receivable. At that point, Cody owed Lannett approximately \$11.7 million, in the form of notes receivable and prepayments on products and services. The remaining value of the amounts owed, or \$4.4 million was approximately the net asset value of Cody at the time of the acquisition.

The Note was determined to be uncollectible due to FDA reviews and operational delays by Cody to return to operation. In 2006, Cody received an FDA warning letter, and stopped operations to remediate their facility. This remediation occurred from the months of August 2006 through February 2007. Upon completion of the remediation, Cody requested a future FDA inspection. The timing of that inspection was, at that time, unknown, and Cody management was unable to conclude as to the outcome of that inspection. With such a limited outlook, Cody management suggested that the full note was not likely to be satisfied, and Lannett management was not willing to loan further funds to Cody to keep it in operation. Both companies agreed to complete the acquisition for the value of the Cody's net assets. The uncollected portion of debt was extinguished prior to the acquisition.

Upon acquisition, the fair value of Cody's assets was added to the Company's Consolidated Balance Sheets, and the results of operations were included in the Consolidated Statements of Operations from the acquisition date forward. Due to the fact that most of the value of Cody consisted of physical assets that were recently acquired as part of the remediation, the fair value closely approximated the book value of net



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

assets. In accordance with the Financial Accounting Standards Board Statement No. 141, Business Combinations, measurement is based on the fair value of the consideration given or the fair value of the asset (or net assets) acquired, whichever is more clearly evident and, thus, more reliably measurable.

Interest expense increased to \$383,267 in Fiscal 2008 from \$273,633 in Fiscal 2007, reflecting full year impact of the interest expense on a mortgage held by Cody LCI Realty LLC. Effective with the acquisition of Cody Labs on April 10, 2007, the Company consolidated the operations of Cody LCI Realty LLC, a variable interest entity that had been fully consolidated by Cody Labs. See note 13 to our Consolidated Financial Statements.

Table of Contents

The Company recorded an income tax benefit of \$3,376,011 in Fiscal 2008 on a pretax loss after minority interest of \$5,694,070 as compared to tax expense of \$1,007,929 in Fiscal 2007 on a pretax loss of \$5,921,079. The inclusion of state income taxes, federal income tax credits, and a reduction in the valuation allowance for deferred tax assets were the principal reasons for the effective tax rate of 59.3% in fiscal 2008.

At June 30, 2008, the Company has recognized a net deferred tax asset of \$21,198,706. The net deferred tax asset is net of a valuation allowance of \$2,314,498 for the specific total tax asset of \$2,106,798 related to the Cody notes receivable impairment incurred in conjunction with the acquisition of Cody Labs and the \$207,700 tax benefit associated with the state income tax net operating loss carryforwards. 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 valuation allowance related to the tax benefit of the state operating loss carryforwards has been established as the Company does not expect these carryforwards to be utilized due to the Company's tax planning strategies at the state and local levels. 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 of \$2,318,059 for Fiscal 2008, or \$0.10 basic and diluted loss per share, compared to net loss of \$6,929,008 for Fiscal 2007, or \$0.29 basic and diluted loss 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, 2009, working capital was \$38,632,170, as compared to \$25,944,623 at June 30, 2008, an increase of \$12,687,547.

Net cash provided by operating activities of \$20,572,848 for the year ended June 30, 2009 reflected net income of \$6,534,245 after adjusting for non-cash items of \$9,404,639, as well as cash provided from changes in operating assets and liabilities of \$4,633,964. Significant changes in operating assets and liabilities are comprised of:

1. An increase in trade accounts receivable of \$5,548,253 primarily as a result of increased sales in Fiscal 2009, offset by the collection of approximately \$10,545,000 of receivables outstanding at June 30, 2008 related to sales of multivitamins for which related reserves were accrued subsequent to collection. The change in the accounts receivable balance from June 30, 2008 to June 30, 2009 includes a non-cash decrease of approximately \$9,717,000 related to the issuance of credits for the returns of the multivitamin product received by the Company through June 30, 2009.
2. An increase in inventories of \$4,578,103 due to increased stocking levels at both Lannett and Cody Labs for several products as of June 30, 2009 that are being carried in order to respond to the increased order volume we are currently experiencing.
3. An increase in income taxes payable of \$711,073 related to Fiscal 2009 taxable income as well as the Fiscal 2009 receipt of prior year overpayments and credit refund claims totaling \$1,598,937 which were reflected as prepaid taxes at June 30, 2008.
4. An increase in accounts payable of \$3,719,696 due to the timing of payments at the end of the month.
5. An increase in rebates, chargebacks and returns payable of \$5,125,610 primarily associated with the increase in Fiscal 2009 sales offset by a non-cash decrease of approximately \$9,717,000 related to the issuance of credits for the returns of the multivitamin product received by the Company through June 30, 2009.



Table of Contents

6. An increase in accrued payroll and payroll related costs of \$4,505,949 primarily related to Fiscal 2009 accrued incentive compensation costs totaling approximately \$4,200,000.

Net cash used in investing activities of \$173,576 for the year ended June 30, 2009 reflected the purchase of property, plant and equipment of \$1,604,114, partially offset by \$1,429,038 of net proceeds related to the sale of the Company's marketable securities.

Net cash used in financing activities for the year ended June 30, 2009 was \$823,528 primarily due to scheduled debt repayments of \$840,066. Proceeds from the issuance of stock of \$160,766 were partially offset by the purchase of treasury stock and repurchase of stock options totaling \$20,228 and \$124,000, respectively.

The Company has entered into agreements with various government agencies and financial institutions to provide additional cash to help finance the Company's operations. These borrowing arrangements as of June 30, 2009 are as follows:

The Company had a \$3,000,000 line of credit from Wachovia Bank, N.A. ( Wachovia ) that bears interest at the prime interest rate less 0.25% (3% at June 30, 2009). The Company had \$3,000,000 available under this line of credit at June 30, 2009. The line of credit was renewed and extended to November 30, 2009.

The Company borrowed \$4,500,000 from the Philadelphia Industrial Development Corporation ( PIDC ). The Company will pay a bi-annual interest payment at a rate equal to two and one-half percent per annum. The outstanding principal balance shall be due and payable 60 months from January 1, 2006.

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 two and three-quarter percent per annum. The PIDA Loan has \$1,002,607 outstanding as of June 30, 2009 with \$75,017 currently due.

The Company borrowed \$500,000 from the Pennsylvania Department of Community and Economic Development Machinery and Equipment Loan Fund. The Company is required to make equal payments for 60 months starting May 1, 2006 with interest of two and three quarter percent per annum. As of June 30, 2009, \$182,831 is outstanding and \$103,100 is 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 approximately \$170,000. The Trust Indenture requires that the Company repay the Authority loan through installment payments beginning in May 2003 and continuing through May 2014, the year the bonds mature. The bonds bear interest at the floating variable rate determined by the organization responsible for selling the bonds (the remarketing agent ). The interest rate fluctuates on a weekly basis. The effective interest rate at June 30, 2009 was 0.62%. At June 30, 2009, the Company has \$680,000 outstanding on the Authority loan, of which \$125,000 is classified as currently due. The remainder is classified as a long-term liability. In April 1999, an irrevocable letter of credit of \$3,770,000 was issued by Wachovia to secure payment of the Authority Loan

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

and a portion of the related accrued interest. At June 30, 2009, no portion of the letter of credit has been utilized.

The Company entered into agreements (the 2003 Loan Financing ) with Wachovia to finance the purchase of the Torresdale Avenue facility, the renovation and setup of the building, and other anticipated capital expenditures. The Company, as part of the 2003 Loan Financing agreement, is required to make equal payments of principal and interest. The only portion of the loan that remains outstanding at June 30, 2009 was the Equipment Loan which consists of a term loan with a term of five years and had an outstanding balance of \$80,130, all of which is classified as current. The terms of the Equipment loan require that the Company meet certain financial covenants and reporting standards, including the attainment of specific

Table of Contents

financial liquidity and net worth ratios. As of June 30, 2009, the Company was in compliance with all financial covenants under this agreement.

The Company is required to maintain and comply with a debt service coverage ratio of not less than two to one (to be measured quarterly). Debt service coverage is defined as the ratio of earnings before interest, taxes, depreciation and amortization (EBITDA) to the sum of interest expenses plus scheduled current maturities of long-term debt and current capitalized lease obligations. The terms of the agreement require the Company to at all times maintain deposit balances in excess of \$3,500,000 with the Wachovia. Additionally, the Company is required pay to Wachovia an availability fee equal to 0.50% per annum calculated daily, on the available but unused balance of the line of credit instead of the previous 0.25% per annum rate. The financing facilities under the 2003 Loan Financing bear interest at a variable rate equal to the LIBOR rate plus 150 basis points. As of June 30, 2009, the effective interest rate for the 2003 Loan Financing (of which only the Equipment loan remains) was 1.81%.

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

Also as a result of the acquisition of Cody, the Company consolidates Cody LCI Realty, LLC, a variable interest entity ( VIE ), for which Cody Labs is the primary beneficiary. See note 13 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 has approximately 17 years of principal and interest payments remaining, with monthly payments of \$14,782, at a fixed rate of 7.5%, to be made through June 2026. As of June 30, 2009, the Company has \$1,693,200 outstanding under the mortgage loan, of which \$52,139 is classified as currently due. The mortgage is collateralized by the land and building.

In July 2004, the Company received \$500,000 of grant funding from the Commonwealth of Pennsylvania, acting through the Department of Community and Economic Development. The grant funding program requires the Company to use the funds for machinery and equipment located at their Pennsylvania locations, hire an additional 100 full-time employees by June 30, 2006, operate its Pennsylvania locations a minimum of five years and meet certain matching investment requirements. If the Company fails to comply with any of the requirements above, the Company would be liable to repay the full amount of the grant funding (\$500,000). The Company has recorded the unearned grant funds as a liability until the Company complies with all of the requirements of the grant funding program. As of June 30, 2009, the Company has had preliminary discussions with the Commonwealth of Pennsylvania to determine whether it will be required to repay any of the funds provided under the grant funding program. Based on information available at June 30, 2009, the Company has recorded the grant funding as a long-term liability under the caption of Unearned Grant Funds.

The following table represents annual contractual obligations as of June 30, 2009:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-Term Debt	\$ 8,138,768	\$ 435,386	\$ 5,117,119	\$ 579,694	\$ 2,006,569
Operating Leases	217,551	133,675	83,876		
Purchase Obligations	105,752,500	20,572,500	43,930,000	41,250,000	
Interest on Obligations	1,649,684	274,907	346,295	261,682	766,800
Total	\$ 115,758,503	\$ 21,416,468	\$ 49,477,290	\$ 42,091,376	\$ 2,773,369



Table of Contents

Purchase obligations primarily relate to the JSP Distribution Agreement. See note 18 to our Consolidated Financial Statements for more information on the terms, conditions and financial impact of the JSP Distribution Agreement.

**Prospects for the Future**

The Company has several generic products under development. These products are all orally-administered, topical and parenteral products designed to be generic equivalents to brand named innovator drugs. The Company's developmental drug products are intended to treat a diverse range of indications. As 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 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.

A majority of the products in development represent either previously approved ANDAs that the Company is planning to reintroduce (ANDA supplements), or new formulations (new ANDAs). The products under development are at various stages in the development cycle—formulation, scale-up, and/or clinical testing. Depending on the complexity of the active ingredient's chemical characteristics, the cost of the raw material, the FDA-mandated requirement of bioequivalence studies, the cost of such studies and other developmental factors, the cost to develop a new generic product varies and can range from \$100,000 to \$1.5 million. Some of Lannett's developmental products will require bioequivalence studies, while others will not—depending on the FDA's Orange Book classification. Since the Company has no control over the FDA review process, management is unable to anticipate whether or when it will be able to begin producing and shipping additional products.

In addition to the efforts of its internal product development group, Lannett has contracted with several outside firms for the formulation and development of several new generic drug products. These outsourced R&D products are at various stages in the development cycle—formulation, analytical method development and testing and manufacturing scale-up. These products are orally-administered solid dosage products, topical or parenterals intended to treat a diverse range of medical indications. We intend to ultimately transfer the formulation technology and manufacturing process for all 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. 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 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 1938 act or the 1962 amendments to the act. Under





Table of Contents

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.

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, as well as certain domestic companies, including Banner Pharmacaps, Cerovene and Inverness. 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.

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 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.



Table of Contents

**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, 2009. Based on that evaluation, our chief executive officer and chief financial officer concluded that these controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported as specified in Securities and Exchange Commission rules and forms. There were no changes in these controls or procedures identified in connection with the evaluation of such controls or procedures that occurred during our last fiscal quarter, or in other factors that have materially affected, or are reasonably likely to materially affect these controls or procedures.

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

*Management's Report on Internal Control over Financial Reporting*

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

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of our management and board of directors;
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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

Table of Contents

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2009. 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, 2009, our internal control over financial reporting is effective.

*Changes in Internal Control over Financial Reporting*

During the quarter ended June 30, 2009, 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.

*Registered Public Accounting Firm Report on Internal Control over Financial Reporting*

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the SEC that require only management's report in this Annual Report.

**ITEM 9B. OTHER INFORMATION**

None.

Table of Contents**PART III****ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE****Directors and Executive Officers**

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

	Age	Position
<b><u>Directors:</u></b>		
William Farber	78	Chairman of the Board
Ronald A. West	75	Vice Chairman of the Board, Director
Arthur P. Bedrosian	63	Director
Jeffrey Farber	49	Director
Kenneth Sinclair	63	Director
Albert Wertheimer	67	Director
Myron Winkelman	71	Director
<b><u>Officers:</u></b>		
Arthur P. Bedrosian	63	President and Chief Executive Officer
Keith R. Ruck	48	Interim Chief Financial Officer and Corporate Controller
Stephen Kovary	52	Vice President of Operations
William Schreck	60	Senior Vice President and General Manager
Kevin Smith	49	Vice President of Sales and Marketing
Ernest Sabo	61	Vice President of Regulatory Affairs and Chief Compliance Officer

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

**Ronald A. West** was elected a Director of the Company in January 2002. In September 2004, Mr. West was elected Vice Chairman of the Board of Directors. Mr. West is currently a Director of Beecher Associates, an industrial real estate investment company. Prior to this, from 1983 to 1987, Mr. West, member of the audit committee at Lannett, served as Chairman and Chief Executive Officer of Dura Corporation, an original equipment manufacturer of automotive products and other engineered equipment components. In 1987, Mr. West sold his ownership position in Dura Corporation, at which time he retired from active management positions. Mr. West was employed at Dura Corporation since 1969. Prior to this, he served in various financial management positions with TRW, Inc., Marlin Rockwell Corporation and National Machine



Table of Contents

Products Group, a division of Standard Pressed Steel Company. Mr. West studied Business Administration at Michigan State University and the University of Detroit.

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

**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 has been recognized for his teaching innovation, held leadership positions with professional accounting organizations and served on numerous academic and advisory committees. He has received a number of awards and honors for teaching and service, and has researched and written on a myriad of subjects related to accounting. Dr. Sinclair earned a Bachelor of Business Administration degree in Accounting, a Master of Science degree in accounting and a Doctorate Degree in Business Administration from the University of Massachusetts.

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

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

Table of Contents

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

**Arthur P. Bedrosian, J.D.** was promoted to President of the Company in May 2002 and CEO in January of 2006. Prior to this, he served as the Company's Vice President of Business Development from January 2002 to April 2002. 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 Interal Corporation, a computer consultancy to Fortune 100 companies. Mr. Bedrosian holds a Bachelor of Arts Degree in Political Science from Queens College of the City University of New York and a Juris Doctorate from Newport University in California.

**Keith R. Ruck** joined the Company in September 2008 as Corporate Controller. As of March 23, 2009, the Company named Mr. Ruck Interim Chief Financial Officer. Mr. Ruck, a Certified Public Accountant (CPA), has more than 26 years of public company financial management experience. Prior to joining Lannett, he served as Corporate Controller of Optium Corporation from April 2007 to September 2008. From 2000 to 2007, he was Vice President - Finance of MAAX KSD Corporation and from 1998 to 2000, he served as Vice President of Finance and Chief Financial Officer of Total Containment, Inc. Mr. Ruck earned a bachelor of science degree in business administration and a master of finance degree from LaSalle University.

**Stephen Kovary** joined the Company in September 2009 as Vice President of Operations. Prior to joining Lannett, Mr. Kovary was the Vice President, Plant Manager for PF Laboratories, a division of Purdue Pharma, LP, since 2003. Formerly, Mr. Kovary held senior level management positions at Pliva, Inc, Abbott Laboratories and Parke-Davis. Mr. Kovary holds a Bachelor of Science in Pharmacy from the Rutgers University Ernest Mario School of Pharmacy and a Masters in Business Administration in Management from Fairleigh Dickenson University. Mr. Kovary is a member of the American and New Jersey Pharmaceutical Associations, the International Society of Pharmaceutical Engineers and the Parenteral Drug Association. Mr. Kovary is a registered pharmacist in the State of New Jersey and a member of the Alumni Association of the Rutgers University Ernest Mario School of Pharmacy.

**William 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 has been promoted to Senior Vice President and General Manager. 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 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 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.



Table of Contents

**Ernest Sabo** joined Lannett 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 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.

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

**Section 16(a) Beneficial Ownership Reporting Compliance**

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

Based solely on review of the copies of such reports furnished to the Company or written representations that no other reports were required, the Company believes that during Fiscal 2009, 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, except for certain Form 4s that were filed late related to certain stock option and restricted share grants in the current and prior years and except for transactions for which no filings were made by Mr. Bedrosian with respect to trades made by a family member.

**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, and other finance organization employees. The code of ethics is publicly available on our website at [www.lannett.com](http://www.lannett.com). If the Company makes any substantive amendments to the finance code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to our Chief Executive Officer, Chief Financial Officer, or 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 as well as current 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, is the audit committee financial expert as defined in section 3(a)(58) of the Exchange Act and the related rules of the Commission.



Table of Contents**ITEM 11. EXECUTIVE COMPENSATION**

The following table summarizes all compensation paid to or earned by the named executive officers of the Company for Fiscal 2009, Fiscal 2008 and Fiscal 2007.

Name and Principal Position (a)	Fiscal Year (b)	Salary (c)	Stock Awards (e)	Options Awards (f)	Non-equity incentive plan compensation (g)	All Other Compensation (i)	Total (j)
Arthur P. Bedrosian President and Chief Executive Officer	2009	\$ 367,202	\$ 244,155	\$	\$ 244,365	\$ 43,796	\$ 899,518
	2008	324,825		42,381		22,099	389,305
	2007	301,016	122,234	158,303	43,358	34,159	659,070
Brian Kearns (1) Chief Financial Officer, Treasurer	2009	176,484	8,680			690,274	875,438
	2008	210,361		28,254		18,460	257,075
	2007	202,678	83,021	161,830	27,719	22,841	498,089
Keith R. Ruck (2) Interim Chief Financial Officer and Corporate Controller	2009	128,854	30,308	5,202	60,617	1,234	226,215
	2008						
	2007						
Bernard Sandiford (3) Vice President of Operations	2009	170,190	111,673		111,508	17,476	410,847
	2008	166,547		2,825		17,493	186,865
	2007	154,525	64,799	161,830	16,628	41,888	439,670
William Schreck Senior Vice President and General Manager	2009	180,722	118,485		118,947	18,341	436,495
	2008	170,670		22,603		18,044	211,317
	2007	162,871	68,021	161,830	16,724	25,334	434,780
Kevin Smith Vice President of Sales and Marketing	2009	200,180	129,362		130,825	21,502	481,869
	2008	192,005		22,603		21,495	236,103
	2007	183,230	61,490	161,830	18,814	24,076	449,440

(1) Mr. Kearns resigned effective March 23, 2009. As part of his separation agreement, he will receive a total of \$669,440. See Employment Agreements section below.

(2) Mr. Ruck assumed the title of Interim Chief Financial Officer on March 23, 2009.

(3) Mr. Sandiford retired effective July 3, 2009



Table of Contents

## (i) Supplemental All Other Compensation Table

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

Name and Principal Position	Fiscal Year	Company Match Contributions 401(k) Plan	Auto Allowance	Pay in Lieu of Vacation	Housing Allowance	Excess Life Insurances	Termination related	Total
Arthur P. Bedrosian President and Chief Executive Officer	2009	\$ 8,823	\$ 13,500	\$ 20,993	\$	\$ 480	\$	\$ 43,796
	2008	8,195	13,500			404		22,099
	2007	10,935	13,265	9,540		419		34,159
Brian Kearns Chief Financial Officer, Treasurer	2009	12,052	8,723			59	669,440	690,274
	2008	7,590	10,800			70		18,460
	2007	12,222	10,559			60		22,841
Keith R. Ruck Interim Chief Financial Officer and Corporate Controller	2009	1,182				52		1,234
	2008 2007							
Bernard Sandiford Vice President of Operations	2009	6,676	10,800					17,476
	2008	6,693	10,800					17,493
	2007	9,212	10,601	11,258	10,817			41,888
William Schreck Senior Vice President and General Manager	2009	7,114	10,800			427		18,341
	2008	6,872	10,800			372		18,044
	2007	9,382	10,589	5,095		268		25,334
Kevin Smith Vice President of Sales and Marketing	2009	7,905	13,500			97		21,502
	2008	7,889	13,500			106		21,495
	2007	9,309	13,188	1,486		93		24,076



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

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 (#) (i)	All Other Option Awards: Number of Securities Underlying Options (#) (j)	Exercise or Base Price of Option Awards (\$/sh) (k)	Grant Date Fair Value of Stock and Options Awards (i)
		Threshold (\$) (c)	Target (\$) (d)	Maximum (\$) (e)	Threshold (\$) (f)	Target (\$) (g)	Maximum (\$) (h)				
Arthur P. Bedrosian President and Chief Executive Officer	9/18/2008								30,000	\$ 2.80	\$ 42,390
Brian Kearns Chief Financial Officer and Treasurer	9/18/2008								20,000	\$ 2.80	\$ 28,260
Keith R. Ruck Interim Chief Financial Officer and Corporate Controller	10/17/2008								15,000	\$ 2.79	\$ 22,170
Bernard Sandiford Vice President of Operations	9/18/2008								2,000	\$ 2.80	\$ 2,826
William Schreck Vice President of Logistics	9/18/2008								16,000	\$ 2.80	\$ 22,608
Kevin Smith Vice President of Sales and Marketing	9/18/2008								16,000	\$ 2.80	\$ 22,608

**Employment Agreements**

The Company has entered into employment agreements with Arthur P. Bedrosian, President and Chief Executive Officer, Kevin Smith, Vice President of Sales and Marketing, William Schreck, Senior Vice President and General Manager, Ernest Sabo, Vice President of Regulatory Affairs and Chief Compliance Officer and Stephen Kovary, Vice President of Operations. Each of the agreements provide for an annual base salary and eligibility to receive a bonus. The salary and bonus amounts of these executives are determined by the Board of Directors. Additionally, these executives are eligible to receive stock options, which are granted at the discretion of the Board of Directors, and in

accordance with the Company's policies regarding stock option grants. Under the agreements, these executive employees may be terminated at any time with or without cause, or by reason of death or disability. In certain termination situations, the Company is liable to pay severance compensation to these executives of between 18 months and three years.

Table of Contents

During the third quarter of Fiscal Year 2009, the Company's Vice President of Finance, Treasurer, Secretary and Chief Financial Officer resigned. As part of his separation agreement, the Company is obligated to pay to him approximately \$670,000 to settle any outstanding obligations from his employment agreement, including any salary, bonus, vacation, stock options and medical benefits. Of this amount, \$300,440 was paid in Fiscal 2009 with \$165,000 designated for the payment of pro rated bonus, and \$11,440 was designated for the payment of accrued but unused paid time off. As part of the settlement, \$124,000 was designated as the portion of the settlement related to the repurchase of his outstanding stock options. The Company therefore charged this amount to Additional Paid in Capital, as it represents the fair value of the options repurchased on the repurchase date. Additional payments totaling \$369,000 for severance and benefits will be paid in Fiscal 2010 and Fiscal 2011 pursuant to the separation agreement.

**Compensation of Directors****DIRECTOR COMPENSATION**

<b>Name</b>	<b>Fees Earned</b>	<b>Stock Awards</b>	<b>Options Awards</b>	<b>Non-Equity Incentive Plan Compensation</b>	<b>Change in Pension Value and Nonqualified Deferred Compensation</b>	<b>All Other Compensation</b>	<b>Total</b>
<b>(a)</b>	<b>(\$) (b)</b>	<b>(\$) (c)</b>	<b>(\$) (d)</b>	<b>(\$) (e)</b>	<b>(\$) (f)</b>	<b>(\$) (g)</b>	<b>(\$) (h)</b>
William Farber	\$ 3,000	\$ 16,900	\$	\$	\$	\$	\$ 19,900
Ronald A. West	22,000	16,900					38,900
Jeffrey Farber	9,000	16,900					25,900
Kenneth Sinclair	24,500	16,900					41,400
Albert Wertheimer	23,000	16,900					39,900
Myron Winkelman	11,500	16,900					28,400

**COMPENSATION DISCUSSION AND ANALYSIS****Overview of Our Compensation Program**

A fundamental goal of our compensation program is to maximize stockholder value. In order to accomplish this goal, we must attract and retain talented and capable executives, and we must provide those executives with incentives that motivate and reward them for achieving Lannett's short and longer-term goals. To this end, our executive compensation is guided by the following key principles:

- that executive compensation should depend upon group and individual performance factors;
- that the interests of executives should be closely aligned with those of stockholders through equity-based compensation; and

Table of Contents

- that compensation should be appropriate and fair in comparison to the compensation provided to similarly situated executives within the pharmaceutical industry and within other publicly-traded companies similar in market capitalization to Lannett.

Important to our compensation program are the decisions of, and guidance from, the Compensation Committee of our Board of Directors. The Compensation Committee (which we refer to, for purposes of this analysis, as the Committee ) is composed entirely of directors who are independent of Lannett under the independence standards established by the American Stock Exchange, the securities exchange where our common stock is traded. The Committee operates pursuant to a written charter adopted by the Board. If you would like to review the Committee's charter, it is available to any stockholder who requests a copy from our Chief Financial Officer, at 9000 State Road, Philadelphia, Pennsylvania 19136.

The Committee has the authority and responsibility to establish and periodically review our executive compensation principles, described above. Importantly, the Committee also has sole responsibility for approving the corporate goals and objectives upon which the compensation of the chief executive officer (the CEO ) is based, for evaluating the CEO's performance in light of these goals and objectives, and for determining the CEO's compensation, including his equity-based compensation.

The Committee also reviews and approves the recommendations of the CEO with regard to the compensation and benefits of other executive officers. In accomplishing this responsibility, the Committee meets regularly with the CEO, approves cash and equity incentive objectives of the executive officers, reviews with the CEO the accomplishment of these objectives and approves the base salary and other elements of compensation for the executive officers. The Committee has full discretion to modify the recommendations of the CEO in the course of its approval of executive officer compensation.

The Committee also annually reviews recommendations from their consultant, and makes recommendations to the Board about, the compensation of non-employee directors.

During Fiscal 2007, the Committee recommended the adoption of a new Incentive Plan to supplement our existing stock option plans. The Incentive Plan was approved by our stockholders in January 2007. The Incentive Plan provides for the grant of various equity awards, including stock options and restricted stock, to Lannett employees and directors. The Committee is responsible for administering this Plan and it has sole authority to make grants to the CEO or any other executive officer.

In conjunction with its responsibilities related to executive compensation, the Committee also oversees the management development process, reviews plans for executive officer succession and performs various other functions.

The Committee consults as needed with an outside compensation consulting firm retained by the Committee. As it makes decisions about executive compensation, the Committee obtains data from its consultant regarding current compensation practices and trends among United States companies in general and pharmaceutical companies in particular, and reviews this information with its consultant. In addition, the Chairman of the Committee is in contact with management outside of Committee meetings regarding matters being considered or expected to be considered by the Committee.

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

The individuals who served as Chief Executive Officer and Chief Financial Officer during Fiscal 2009, as well as the other individuals included in the Summary Compensation Table on page 58, are referred to as the named executive officers.

### **Our Fiscal 2009 Compensation Program**

In Fiscal 2009, the Committee's approach to compensation was intended to focus our executives on accomplishing our short and longer-term objectives, and it had as its ultimate objective sustained growth

Table of Contents

in stockholder value. This approach was intended to compensate executives at levels at or near the median levels of compensation offered by other pharmaceutical companies similar in size to Lannett and with whom we compete.

In making decisions about the elements of Fiscal 2009 compensation, the Committee not only considered available market information about each element but also considered aggregate compensation for each executive. Base salary provided core compensation to executives, but it was accompanied by:

- the potential for incentive-based cash compensation based upon our attainment of Fiscal 2009 operating income, other targeted corporate goals and individual or departmental objectives,
- various forms of equity compensation, including some grants based upon Fiscal 2009 sales growth results and upon our return on invested capital results,
- various benefits and perquisites, and
- the potential for post-termination compensation under certain circumstances.

*Summary of Fiscal 2009 Compensation Elements*

The table below provides detailed information regarding each element of the Fiscal 2009 compensation program.

	<b>Compensation Element Overview</b>	<b>Purpose of the Compensation Element</b>
<b>Base Salary</b>	Base salary pays for competence in the executive role. An executive's salary level depends on the decision making responsibilities, experience, work performance, achievement of key goals and team building skills of each position, and the relationship to amounts paid to other executives at peer companies.	To provide competitive fixed compensation based on sustained performance in the executive's role and competitive market practice.
<b>Short-Term Incentives</b>	<b>Annual Incentive Bonus Plan (AIBP)</b> The AIBP program rewards with cash awards for annual achievement of overall corporate objectives, and specific individual or departmental operational objectives. In Fiscal 2009, objectives for the Officers were tied to Lannett's achievement of operating income targets, other targeted corporate goals and individual	To motivate and focus our executive team on the achievement of our annual performance goals.

objectives.



Table of Contents

Compensation Element Overview		Purpose of the Compensation Element
<b>Long-Term Incentives</b>	<b>Stock Options</b>	We strive to deliver a balanced long-term incentive portfolio to executives, focusing on (a) share price appreciation, (b) retention, and (c) internal financial objectives.
	Stock options reward sustained stock price appreciation and encourage executive retention during a three-year vesting term and a ten-year option life.	The primary objectives of the overall design are:
	<b>Restricted Stock</b>	
	Restricted stock rewards sustained stock price appreciation and encourages executive retention during its three-year vesting term.	to align management interests with those of stockholders,
	The value of participants' restricted stock increases and decreases according to Lannett's stock price performance during the vesting period and thereafter.	to increase management's potential for stock ownership opportunities (all awards are earned in shares),
		to attract and retain excellent management talent, and
		to reward growth of the business, increased profitability, and sustained stockholder value.

Compensation Element Overview		Purpose of the Compensation Element
<b>Benefits</b>	<b>In General</b>	
	Executives participate in employee benefit plans available to all employees of Lannett, including health, life insurance and disability plans. The cost of these benefits is partially borne by the employee, but mostly paid by the Company.	These benefits are designed to attract and retain employees and provide security for their health and welfare needs. We believe that these benefits are reasonable, competitive and consistent with Lannett's overall executive compensation program.

Table of Contents

**401(k) Plan**

Executives may participate in Lannett's 401(k) retirement savings plan, which is available to all employees. In calendar 2006, the Company matched employees contributions to the plan, on a dollar for dollar basis, up to 3% of their base salary, subject to regulatory limits. Beginning in calendar 2007, Lannett began matching contributions, at a rate of \$.50 on the dollar up to 8% of base salary.

**Life Insurance**

Lannett provides life insurance benefits to all employees. The coverage amount for executives is one times base compensation up to a limit of \$115,000 and premiums paid for coverage above \$50,000 are treated as imputed income to the executive.

**Disability Insurance**

Lannett provides short-term and long-term disability insurance to employees which would, in the event of disability, pay an employee 60% of his or her base salary with limits.

**Compensation Element Overview**

**Purpose of the Compensation Element**

**Perquisites**

Lannett does not utilize perquisites or personal benefits extensively. The few perquisites that are provided complement other compensation vehicles and enable the Company to attract and retain key executives. These perquisites include:

We believe these benefits better allow us to attract and retain superior employees for key positions.

automobile allowances in various amounts to key executives.

**Compensation Element Overview**

**Purpose of the Compensation Element**

**Post-Termination Pay**

**Severance Plan**

Lannett's Severance Pay Plan is designed to pay severance benefits to an executive for a qualifying separation. For the Chief Executive Officer, the Severance Pay Plan provides for a payment of three times the sum of base salary plus a pro rated annual cash bonus for the current year calculated as if all targets and goals are achieved.

The Severance Pay Plan is intended (1) to allow executives to concentrate on making decisions in the best interests of Lannett (or any successor organization in the event that a change of control is to occur), and (2) generally alleviate an executive's concerns about the loss of his or her position without cause.



Table of Contents

For the other named executive officers, the Severance Pay Plan provides for a payment of eighteen months of base salary plus a pro rated annual cash bonus for the current year calculated as if all targets and goals are achieved.

The use of the above compensation tools enables Lannett to reinforce its pay for performance philosophy as well as to strengthen its ability to attract and retain high-performing executive officers. The Committee believes that this combination of programs provides an appropriate mix of fixed and variable pay, balances short-term operational performance with long-term stockholder value creation, and encourages executive recruitment and retention in a high-performance culture.

***Market Data and Our Peer Group***

In determining 2008 and 2009 compensation for the named executive officers, the Committee relied on market data provided by its consultant. This information was principally related to a group of 13 peer companies similar in size to Lannett with median revenues of \$40 million to \$133 million (we refer to this group of companies as the Peer Group ). Information on these companies was derived from two sources: (1) the consultant and broader market survey data analysis, and (2) publicly-available information appearing in the proxy statements of these companies. The members of the Peer Group were:

Bradley Pharmaceutical

Savient Pharm. Inc.

Hi Tech Pharm. Co. Inc.

Quigley Corp.

Noven Pharmaceuticals Inc.

Viropharma Inc.

Balchem Corp.

Orasure Technologies Inc.

Interpharm Holdings Inc

Able Laboratories Inc

Caraco Pharm. Labs

Neogen Corp.

Akorn Inc.

The Committee plans to evaluate the Peer Group periodically and revise it as necessary to ensure that it continues to be appropriate for benchmarking our executive compensation program.

*Base Salary*

Base salaries for the named executive officers are intended, in general, to approach median salaries for similarly situated executives among Peer Group companies. A number of additional factors are considered, however, in determining base salary, such as the executive's individual performance, his or her experience, competencies, skills, abilities, contribution and tenure, internal compensation consistency, the need to attract new, talented executives, and the Company's overall annual budget. Base salaries are generally reviewed on an annual basis.

Base salary increases were granted to Mr. Bedrosian for \$43,200 effective on September 1, 2008, Mr. Kearns for \$8,482 effective on September 1, 2008, Mr. Smith for \$7,757, effective on September 1, 2008, Mr. Schreck for \$10,342 effective on September 1, 2008, and Mr. Sandiford for \$3,350 effective on September 1, 2008, based on their performance.

Table of Contents***Fiscal 2009 Annual Incentive Bonus Plan******Design***

In November 2006, the Committee approved the 2007 Annual Incentive Bonus Plan (or AIBP) program. This program allowed executive officers the opportunity to earn cash awards upon the accomplishment of the Fiscal 2009 operating income goal, other targeted corporate goals and a number of individual objectives. The relative weighting of these objectives for each executive was fifty percent (50%) for operating income, twenty-five percent (25%) for other targeted corporate goals, twenty percent (20%) for individual objectives and five percent (5%) based on CEO and Committee discretion. For the CEO, the five percent (5%) discretionary portion will be determined by the Committee.

Based on market data provided by its consultant, and considering the relatively low base salaries of the named executive officers, the Committee formulated potential AIBP awards which exceeded the 50th percentile among Peer Group companies, expressed as percentages of base salary. Actual payouts depended upon the degree to which objectives were accomplished as well as the weight accorded to each objective, as described above. The table below shows the potential payout amounts for each of the named executive officers, expressed as percentages of base salary.

<b>Performance Level</b>	<b>Arthur Bedrosian</b>	<b>Brian Kearns</b>	<b>Bernard Sandiford</b>	<b>William Schreck</b>	<b>Kevin Smith</b>
Superior Level	120-150%	120-150%	120-150%	120-150%	120-150%
Goal Level	100-120%	100-120%	100-120%	100-120%	100-120%
Threshold Level	50-100%	50-100%	50-100%	50-100%	50-100%

The Committee also determined that, if results for any objectives were between the minimum and maximum of the ranges, the Committee would determine appropriate payout percentage.

As discussed above, each named executive officer's objectives for Fiscal 2009 included Company operating income targets and other targeted corporate goals. The Committee reviewed and approved these targets following discussions with management, a review of our historical results, consideration of the various circumstances facing the Company during Fiscal 2009 and taking into account the expectations of our annual plan. The Fiscal 2009 operating income and other corporate goals AIBP targets approved by the Committee are detailed in the table below.

<b>Objective</b>	<b>Superior</b>	<b>Goal</b>	<b>Target</b>
Operating Income*	\$ 6.0M	\$ 5.0M	\$ 4.0M
R&D Submissions	9	8	7
R&D Acceptances	8	7	6
R&D Launches	7	6	5

\* For purposes of determining achievement of the AIBP targets, these measures exclude certain categories of non-recurring items that the Committee believes do not reflect the performance of Lannett's core continuing operations.



Table of Contents

Operational objectives for Mr. Bedrosian related to finalizing a production and sales contract with acceptable returns and a successful launch of a specific new product and achieving profitability for its subsidiary operations. Mr. Kearns' objectives related to achieving cash flow targets, establishing internal controls, developing and achieving SAP implementation. Objectives for Mr. Smith included achieving sales targets and margin targets in addition to obtaining new customers in new channels and reducing short dated goods in inventory. For Mr. Schreck, the objectives included reducing obsolete inventory and utilizing SAP more efficiently along with the warehouse relocation. Mr. Sandiford's objectives related to assisting Cody achieve Divisional goals, zero 483 deficiencies and no batch rejections.

All payouts to executive officers under the 2009 AIBP were contingent upon the Committee's review and certification of the degree to which Lannett achieved the 2009 AIBP objectives, and upon the Committee's certification of the degree to which individual objectives had been achieved. The program provided that payout for any objective would be limited to 20% of the actual operating income attained by Lannett.

The 2009 AIBP program provided that the Committee could, in its discretion: modify, amend, suspend or terminate the Plan at any time.

**Results**

In September 2009, the Committee reviewed and certified Lannett's Fiscal 2009 results for purposes of the AIBP program, determining that the objectives for operating income and other corporate objectives far surpassed the goals set at the beginning of the year. The Committee also reviewed and certified the performance of the executive officer individual objectives, determining that these objectives were achieved to varying degrees. In calculating the 2009 bonus payments to the named executives as well as the other employees, it was determined that the Superior Level bonuses could not be paid because the accumulated total of payments to all employees would exceed 20% of the actual operating income achieved by the Company in Fiscal 2009 (20% cap). The Committee, in its discretion, altered the 2009 bonus payments in two ways as a one-time adjustment: First, the Committee lowered the overall calculation of the payout to the high end of the Goal Level. Second, it decided to grant unrestricted shares of stock that would make up the difference between the 20% cap and the amount that employees would have received if the 20% cap were not in place. These unrestricted shares will immediately vest upon grant, which is anticipated to occur in November 2009. The total value of the 2009 bonus payouts, including the unrestricted stock grant is expected to approximate 27.7% of the pre-bonus actual operating profit for the 2009 Fiscal Year. The Company expects to review and possibly alter its current compensation structure, including the AIBP program in the fall of 2009 so that fair compensation can be paid to its employees while still respecting the 20% cap requirement.

**2009 Long Term Incentive Awards (LTIA)**

**Design**

The Committee believes that long-term equity incentives are an important part of a complete compensation package because they focus executives on: increasing the value of the assets that are entrusted to them by the stockholders, achieving Lannett's long-term goals, aligning the interests of executives with those of stockholders, encouraging sustained stock performance and helping to retain executives.



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

Prior to the approval of the Incentive Plan by stockholders in 2007, Lannett's equity grants consisted only of stock options. The Incentive Plan expanded the types of equity vehicles which the Committee could grant to executives by including restricted stock. In September 2009, the Committee determined the amount of both stock options and restricted stock to be granted to executives, each designed to emphasize

Table of Contents

particular elements of the Company's immediate and long-term objectives and to retain key executives. As of the date of the filing of this Form 10-K, these options and restricted stock shares had not yet been granted. We refer to these grants collectively as the 2009 Long Term Incentive Awards (LTIA). The types of grants were:

- stock options, becoming exercisable over three years (approximately one-third increments on each anniversary) from the date of the grant and having a total term of ten years,
- shares of restricted stock, vesting over three years (approximately one-third increments on each anniversary) from the date of grant,

The Committee assessed the appropriate overall value of these equity grants to executives by reviewing survey results and other market data provided by its consultant. This information included the value of equity grants made to similarly situated executives among the Peer Group. The overall value of LTIA grants for each executive was determined by the Committee with assistance from their consultant.

In determining the overall value of LTIA grants, the Committee also considered the potential value of equity compensation relative to other elements of compensation for each named executive officer. It likewise assessed the appropriate distribution of equity value among the grant types, as well as the corporate objectives each type of grant was intended to encourage.

***Stock Options and Restricted Stock***

The stock options and restricted stock granted as part of the 2009 LTIA were designed to reward sustained stock price appreciation and to encourage executive retention during a three-year vesting term and, in the case of stock options, a ten-year option life. Stock option and restricted stock awards are intended to align executives' motivation with stockholders' best interests. Grants of stock options were not contingent upon any conditions. They are to be granted independent of organizational performance. Stock options become exercisable approximately in one-third increments on the first three anniversaries of the date of grant. Restricted stock was contingent upon Lannett achieving annual sales growth and return on invested capital goals. Restricted stock will vest in approximately one-third increments on the first three anniversaries of the date of the grant. The Committee determined for each executive officer a target number of options and restricted shares and those targets appear in the tables below.

Restricted Stock Targets:

Performance Level	Bedrosian	Kearns	Sandiford	Schreck	Smith
Superior	16,600	8,300	8,300	8,300	8,300
Goal	12,500	6,600	6,600	6,600	6,600
Threshold	8,300	5,000	5,000	5,000	5,000

Stock Option Targets:

Edgar Filing: LANNETT CO INC - Form 10-K

<b>Range</b>	<b>Bedrosian</b>	<b>Kearns</b>	<b>Sandiford</b>	<b>Schreck</b>	<b>Smith</b>
High	50,000	25,000	25,000	25,000	25,000
Medium	37,500	20,000	20,000	20,000	20,000
Low	25,000	15,000	15,000	15,000	15,000

Table of Contents**Results**

In September 2009, the Committee reviewed and certified the Fiscal 2009 financial results for purposes of the Restricted Share Grants and determined that the performance levels surpassed the superior performance level. As a result of the Committee's review, the Committee expects to grant 70,000 restricted shares and 200,000 options to be apportioned in the following manner:

Awards	Bedrosian	Ruck	Kovary	Schreck	Smith
Options	75,000	15,000		60,000	50,000
Restricted Shares	30,000	10,000		15,000	15,000

**Perquisites and Other Benefits**

We provide named executive officers with perquisites and other personal benefits that we believe are reasonable and consistent with our overall compensation program to better enable us to attract and retain superior employees for key positions. The Committee periodically reviews the levels of perquisites and other personal benefits provided to named executive officers.

During calendar year 2006, Lannett matched employees' contributions to the Lannett Company, Inc. 401(k) Retirement Savings Plan on a dollar for dollar basis up to 3% of an employee's base salary, subject to regulatory limits. Contributions by the named executive officers were matched in this way, subject to the limitations of the Plan and applicable law. Beginning in calendar year 2007 and continuing to present, Lannett matched contributions to the 401(k) plan on a fifty cents on the dollar basis up to 8% of the contributing employee's base salary. The named executive officers are also provided with car allowances, for which the taxes are also paid by the Company.

Lannett provides life insurance for executive officers which would, in the event of death, pay \$115,000 to designated beneficiaries. Premiums paid for coverage above \$50,000 are treated as imputed income to the executive. Lannett also provides short-term and long-term disability insurance which would, in the event of disability, pay the executive officer sixty percent (60%) of his base salary up to the plan limits of \$2,000/week for short term disability and \$15,000/month for long term disability. Executive officers participate in other qualified benefit plans, such as medical insurance plans, in the same manner as all other employees.

Attributed costs of the personal benefits available to the named executive officers for the fiscal year ended June 30, 2009, are included in column (i) of the Summary Compensation Table on page 58.

**Severance and Change of Control Benefits**

We believe that reasonable severance and change in control benefits are necessary in order to recruit and retain qualified senior executives and are generally required by the competitive recruiting environment within our industry and the marketplace in general. These severance benefits reflect the fact that it may be difficult for such executives to find comparable employment within a short period of time, and are designed to

alleviate an executive's concerns about the loss of his or her position without cause. We also believe that a change in control arrangement will provide an executive security that will likely reduce the reluctance of an executive to pursue a change in control transaction that could be in the best interests of our stockholders. Lannett's Severance Pay Plan is designed to pay severance benefits to an executive for a qualifying separation. For the Chief Executive Officer, the Severance Pay Plan provides for a payment of three times the sum of base salary plus a pro-rated annual cash bonus for the current year calculated as if all targets and goals are achieved. For the other named executive officers, the Severance Pay Plan

Table of Contents

provides for a payment of eighteen months of base salary plus a pro rated annual cash bonus for the current year calculated as if all targets and goals are achieved.

**Timing of Committee Meetings and Grants; Option and Share Pricing**

The Committee typically holds four regular meetings each year, and the timing of these meetings is generally established during the year. The Committee holds special meetings from time to time as its workload requires. Historically, annual grants of equity awards have typically been accomplished at a meeting of the Committee in September of each year. Individual grants (for example, associated with the hiring of a new executive officer or promotion to an executive officer position) may occur at any time of year. We expect to coordinate the timing of equity award grants to be made within thirty (30) days of Lannett's earnings release announcement following the completion of the fiscal year. The exercise price of each stock option and restricted share awarded to our executive officers is the closing price of our common stock on the date of grant.

**Tax and Accounting Implications**

*Deductibility of Executive Compensation*

Section 162(m) of the Internal Revenue Code of 1986, as amended, precludes the deductibility of an executive officer's compensation that exceeds \$1.0 million per year unless the compensation is paid under a performance-based plan that has been approved by stockholders. The Committee believes that it is generally preferable to comply with the requirements of Section 162(m) through, for example, the use of our Incentive Plan. However, to maintain flexibility in compensating executive officers in a manner that attracts, rewards and retains high quality individuals, the Committee may elect to provide compensation outside of those requirements when it deems appropriate. The Committee believes that stockholder interests are best served by not restricting the Committee's discretion in this regard, even though such compensation may result in non-deductible compensation expenses to the Company.

Table of Contents

**REPORT OF THE COMPENSATION COMMITTEE**

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis set forth above with management. Taking this review and discussion into account, the undersigned Committee members recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this annual report on Form 10-K.

**The Compensation Committee**

Ronald West (Chair)  
Albert Wertheimer  
Myron Winkelman

Table of Contents**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth, as of September 15, 2009, information regarding the security ownership of the directors and certain executive officers of the Company and persons known to the Company to be beneficial owners of more than five (5%) percent of the Company's common stock:

Name and Address of Beneficial Owner	Office	Excluding Options and Restricted Shares		Including Options (*) and Restricted Shares	
		Number of Shares	Percent of Class	Number of Shares	Percent of Class
<u>Directors/Executive Officers:</u>					
William Farber 9000 State Road Philadelphia, PA 19136	Chairman of the Board	8,675,796(1)	35.46%	8,768,296(1),(2)	35.71%
Ronald A. West 9000 State Road Philadelphia, PA 19136	Vice Chairman of the Board, Director	5,977(3)	0.02%	60,925(3),(4)	0.25%
Jeffrey Farber 9000 State Road Philadelphia, PA 19136	Interim Chairman of the Board, Director	5,158,787(5)	21.08%	5,206,287(5),(6)	21.24%
Kenneth Sinclair 9000 State Road Philadelphia, PA 19136	Director	6,667(7)	0.03%	31,667(7),(8)	0.13%
Albert Wertheimer 9000 State Road Philadelphia, PA 19136	Director	7,667(9)	0.03%	32,667(9),(10)	0.13%
Myron Winkelman 9000 State Road Philadelphia, PA 19136	Director	7,667(11)	0.03%	47,667(11),(12)	0.19%
Arthur P. Bedrosian 9000 State Road Philadelphia, PA 19136	President and Chief Executive Officer	542,530(13)	2.22%	830,964(13),(14)	3.36%
William Schreck 9000 State Road Philadelphia, PA 19136	Senior Vice President of Logistics	6,657(15)	0.03%	88,169(15),(16)	0.36%
Kevin Smith 9000 State Road	Vice President of Sales and Marketing	11,033(17)	0.05%	146,560(17),(18)	0.60%



Edgar Filing: LANNETT CO INC - Form 10-K

Philadelphia, PA 19136					
Ernest Sabo 9000 State Road Philadelphia, PA 19136	Vice President of Regulatory Affair and Chief Compliance Officer	3,604(19)	0.01%	33,197(19),(20)	0.14%
David Farber 6884 Brook Hollow Ct West Bloomfield, MI 48322					
		5,160,708(21)	21.10%	5,183,208(21),(22)	21.17%
Keith R. Ruck 9000 State Road Philadelphia, PA 19136	Interim Chief Financial Officer and Corporate Controller	767(23)	0.00%	5,767(23),(24)	0.02%
Farber Properties 1775 John R Road Troy, MI 48083					
		5,000,000(25)	20.44%	5,000,000	20.44%
All directors and executive officers as a group (11 persons)					
		14,427,150	58.98%	15,252,165	62.36%

Table of Contents

---

(1) Includes 197,825 shares owned by William Farber's spouse, Audrey Farber; 10,000 shares owned by William Farber's mother, Doris Farber, whose affairs Mr. Farber controls; and 132,212 shares held by William Farber as custodian for his seven minor grandchildren. Mr. Farber disclaims beneficial ownership of these shares. Includes 26,250 shares held in William Farber's IRA account. Includes 1,667 vested shares received pursuant to a restricted stock award granted in September 2007 and 5,000 vested shares received pursuant to a restricted stock award granted in September 2008.

(2) Includes 37,500 vested options to purchase common stock at an exercise price of \$7.97 per share, 25,000 vested options to purchase common stock at an exercise price of \$17.36 per share, 25,000 vested options to purchase common stock at an exercise price of \$16.04 per share, 3,333 vested options to purchase common stock at an exercise price of \$6.89 per share and includes 1,667 restricted shares vesting September 18, 2009.

(3) Includes 1,667 vested shares received pursuant to a restricted stock award granted in September 2007 and 5,000 vested shares received pursuant to a restricted stock award granted in September 2008.

(4) Includes 9,948 vested options to purchase common stock at an exercise price of \$7.97 per share, 15,000 vested options to purchase common stock at an exercise price of \$17.36 per share, 25,000 vested options to purchase common stock at an exercise price of \$16.04 and 3,333 vested options to purchase common stock at an exercise price of \$6.89 and includes 1,667 restricted shares vesting September 18, 2009.

(5) Includes 5,000,000 shares held by Farber Properties Group LLC ( FPG ). Farber Properties Group, LLC is managed and jointly owned by Jeffrey Farber and David Farber. David Farber and Jeffrey Farber each disclaim beneficial ownership of 2,500,000 shares held by FPG. Indirect shares include 150 shares held by Jeffrey Farber as custodian for his son. Also includes 9,500 shares held by Farber Investment Company, LLC ( FIC ), which holds 38,000 shares of common stock. Jeffrey Farber and David Farber each beneficially owns 25% of FIC and each disclaims beneficial ownership of all but 9,500 shares held by FIC. Also includes 1,667 vested shares received pursuant to a restricted stock award granted in September 2007 and 5,000 vested shares received pursuant to a restricted stock award granted in September 2008.

(6) Includes 10,000 vested options to purchase common stock at an exercise price of \$17.36 per share, 12,500 vested options to purchase common stock at an exercise price of \$16.04, 20,000 vested options to purchase common stock at an exercise price of \$4.55, and 3,333 vested options to purchase common stock at an exercise price of \$6.89 and includes 1,667 restricted shares vesting September 18, 2009.

(7) Includes 1,667 vested shares received pursuant to a restricted stock award granted in September 2007 and 5,000 vested shares received pursuant to a restricted stock award granted in September 2008.

(8) Includes 20,000 vested options to purchase common stock at an exercise price of \$4.55 per share and 3,333 vested options to purchase common stock at an exercise price of \$6.89 per share and includes 1,667 restricted shares vesting September 18, 2009.

Edgar Filing: LANNETT CO INC - Form 10-K

(9) Includes 1,667 vested shares received pursuant to a restricted stock award granted in September 2007 and 5,000 vested shares received pursuant to a restricted stock award granted in September 2008.

(10) Includes 20,000 vested options to purchase common stock at an exercise price of \$9.02 per share and 3,333 vested options to purchase common stock at an exercise price of \$6.89 per share and includes 1,667 restricted shares vesting September 18, 2009.

Table of Contents

- (11) Includes 1,667 vested shares received pursuant to a restricted stock award granted in September 2007 and 5,000 vested shares received pursuant to a restricted stock award granted in September 2008.
- (12) Includes 15,000 vested options to purchase common stock at an exercise price of \$17.36, 20,000 vested options to purchase common stock at an exercise price of \$16.04 and 3,333 vested options to purchase common stock at an exercise price of \$6.89 per share and includes 1,667 restricted shares vesting September 18, 2009.
- (13) Includes 33,150 shares owned by Arthur Bedrosian's wife, Shari, and 1,000 shares owned by his daughter Talin. Mr. Bedrosian disclaims beneficial ownership of these shares. Includes 19,264 vested shares received pursuant to a restricted stock award granted in September 2007. Also includes 25,452 shares of common stock held through employee stock purchase plan.
- (14) Includes 18,000 vested options to purchase common stock at an exercise price of \$4.63 per share, 96,900 vested options to purchase common stock at an exercise price of \$7.97 per share, 33,000 vested options to purchase common stock at an exercise price of \$17.36 per share, 30,000 vested options to purchase common stock at an exercise price of \$16.04 per share, 25,000 vested options to purchase common stock at an exercise price of \$8.00 per share, 20,000 vested options to purchase common stock at an exercise price of \$6.89 per share, 50,000 vested options to purchase common stock at an exercise price of \$4.03 per share, and 10,000 vested options to purchase common stock at an exercise price of \$2.80 per share and includes 5,533 restricted shares vesting September 18, 2009.
- (15) Includes 6,657 vested shares received pursuant to a restricted stock award granted in September 2007.
- (16) Includes 17,745 vested options to purchase common stock at an exercise price of \$11.27 per share, 12,000 vested options to purchase common stock at an exercise price of \$5.18 per share and 10,000 vested options to purchase common stock at an exercise price of \$6.89 per share, 33,333 vested options to purchase common stock at an exercise price of \$4.03 per share, and 5,333 vested options to purchase common stock at an exercise price of \$2.80 per share and 3,100 restricted shares vesting September 18, 2009.
- (17) Includes 6,697 vested shares received pursuant to a restricted stock award granted in September 2007.

Table of Contents

(18) Includes 38,760 vested options to purchase common stock at an exercise price of \$7.97 per share, 13,000 vested options to purchase common stock at an exercise price of \$17.36 per share, 20,000 vested options to purchase common stock at an exercise price of \$16.04 per share, 12,000 vested options to purchase common stock at an exercise price of \$5.18 per share, 10,000 vested options to purchase common stock at an exercise price of \$6.89 per share, 33,333 vested options to purchase common stock at an exercise price of \$4.03 per share, and 5,333 vested options to purchase common stock at an exercise price of \$2.80 per share and includes 3,100 restricted shares vesting September 18, 2009.

(19) Includes 3,604 vested shares received pursuant to a restricted stock award granted in September 2007.

(20) Includes 3,260 vested options to purchase common stock at an exercise price of \$7.48 per share, 4,000 vested options to purchase common stock at an exercise price of \$5.18 per share, 5,000 vested options to purchase common stock at an exercise price of \$6.89 per share, 10,000 vested options to purchase common stock at an exercise price of \$4.03 per share, and 5,333 vested options to purchase common stock at an exercise price of \$2.80 per share and includes 2,000 restricted shares vesting September 18, 2009.

(21) Includes 5,000,000 shares held by Farber Properties Group LLC ( FPG ). Farber Properties Group, LLC is managed and jointly owned by Jeffrey Farber and David Farber. David Farber and Jeffrey Farber each disclaim beneficial ownership of 2,500,000 shares held by FPG. Indirect shares include 7,488 shares held by David Farber as custodian for his children, and 2,850 shares held by David Farber's spouse. Also includes 9,500 shares held by Farber Investment Company, LLC ( FIC ), which holds 38,000 shares of common stock. Jeffrey Farber and David Farber each beneficially owns 25% of FIC and each disclaims beneficial ownership of all but 9,500 shares held by FIC.

(22) Includes 10,000 vested options to purchase common stock at an exercise price of \$17.36 per share and 12,500 vested options to purchase common stock at an exercise price of \$16.04 per share.

(23) Includes 767 shares of common stock held through employee stock purchase plan.

(24) Includes 5,000 vested options to purchase common stock at an exercise price of \$2.79 per share.

(25) Farber Properties Group, LLC is managed and jointly owned by Jeffrey Farber and David Farber.

\* Assumes that all options exercisable within sixty days have been exercised, and all restricted shares vesting within sixty days have vested, which results in 25,284,968 shares outstanding.

Table of Contents

**Equity Compensation Plan Information**

The following table summarizes the equity compensation plans as of June 30, 2009:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation plans approved by security holders	1,585,681	\$ 7.54	3,181,471
Equity Compensation plans not approved by security holders			
<b>Total</b>	<b>1,585,681</b>	<b>\$ 7.54</b>	<b>3,181,471</b>

Table of Contents

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

The Company had sales of approximately \$786,000, \$787,000, and \$763,000 during the fiscal years ended June 30, 2009, 2008 and 2007, respectively, to a generic distributor, Auburn Pharmaceutical Company. Jeffrey Farber (the related party), a board member and the son of the Chairman of the Board of Directors and principal shareholder of the Company, William Farber, is the owner of Auburn Pharmaceutical Company. Accounts receivable includes amounts due from the related party of approximately \$125,000 and \$305,000 at June 30, 2009 and 2008, respectively. In the Company's opinion, the terms of these transactions were not more favorable to the related party than would have been to a non-related party.

In January 2005, Lannett Holdings, Inc. entered into an agreement in which the Company purchased for \$100,000 and future royalty payments the proprietary rights to manufacture and distribute a product for which Pharmeral, Inc. owned the ANDA. In Fiscal 2008, the Company obtained FDA approval to use the proprietary rights. Accordingly, the Company originally capitalized this purchased product right as an indefinite lived intangible asset and tested this asset for impairment on a quarterly basis. During the fourth quarter of Fiscal 2009, it was determined that this intangible asset no longer has an indefinite life. No impairment existed because the estimated fair value exceeded the carrying amount on that date. Accordingly, the \$100,000 carrying amount of this intangible asset will be amortized on a straight line basis prospectively over its 10 year remaining estimated useful life.

Arthur Bedrosian, President and Chief Executive Officer of the Company, Inc. currently owns 100% of Pharmeral, Inc. This transaction was approved by the Board of Directors of the Company and in their opinion the terms were not more favorable to the related party than they would have been to a non-related party. In May 2008, Mr. Bedrosian and Pharmeral waived their rights to any royalty payments on the sales of the drug by Lannett under Lannett's current ownership structure. Should Lannett undergo a major change in control where a third party is involved, this royalty would be reinstated.

At June 30, 2009 and 2008, respectively, the Company had \$0 and approximately \$983,000 of deferred revenue as a result of prepayments on inventory received from Provell Pharmaceuticals, LLC (Provell). The Company recognized revenues of approximately \$29,000, \$141,000 and \$45,000 during the fiscal years ended June 30, 2009, 2008 and 2007, respectively. Accounts receivable includes amounts due from Provell of approximately \$55,000 and \$60,000 at June 30, 2009 and 2008, respectively. Provell is a joint venture to distribute pharmaceutical products through mail order outlets. In exchange for access to Lannett's drug providers, Lannett received a 33% ownership of this venture. After June 30, 2008, Lannett's ownership portion of this venture decreased to 25% due to outside investment in the venture from a third party. The investment is valued at zero, due to losses incurred to date by Provell. During June 2009, the Company terminated its participation in this joint venture.

Table of Contents**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Grant Thornton LLP served as the independent auditors of the Company during Fiscal 2009, 2008 and 2007. No relationship exists other than the usual relationship between independent public accountant and client. The following table identifies the fees incurred for services rendered by Grant Thornton LLP in Fiscal 2009, 2008 and 2007.

	<b>Audit Fees</b>	<b>Audit-Related (1)</b>	<b>Tax Fees (2)</b>	<b>All Other Fees (3)</b>	<b>Total Fees</b>
Fiscal 2009:	\$ 295,084	\$	\$ 179,677	\$ 10,932	\$ 485,693
Fiscal 2008:	\$ 335,894	\$ 5,900	\$ 78,880	\$ 49,964	\$ 470,638
Fiscal 2007:	\$ 338,660	\$	\$ 36,528	\$ 70,300	\$ 445,460

(1) Audit-related fees include fees paid for preparation of an S-8 filing.

(2) Tax fees include fees paid for preparation of annual federal, state and local income tax returns, quarterly estimated income tax payments, Cody tax issues, sales and use tax review and various tax planning services.

(3) Other fees include:

Fiscal 2009 Fees paid for review of various SEC correspondences.

Fiscal 2008 Fees paid for review of various SEC correspondences.

Fiscal 2007 Fees paid for review of various SEC correspondences, disclosures, and fixed asset review.

The non-audit services provided to the Company by Grant Thornton LLP were pre-approved by the Company's audit committee. Prior to engaging its auditor to perform non-audit services, the Company's audit committee reviews the particular service to be provided and the fee to be paid by the Company for such service and assesses the impact of the service on the auditor's independence.



Table of Contents

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a) Consolidated Financial Statements and Supplementary Data

(1) The following financial statements are included herein:

Consolidated Balance Sheets as of June 30, 2009 and 2008

Consolidated Statements of Operations for each of the three years ended June 30, 2009

Consolidated Statements of Changes in Shareholders' Equity for each of the three years ended June 30, 2009

Consolidated Statements of Cash Flows for each of the three years ended June 30, 2009

Notes to Consolidated Financial Statements for the three years ended June 30, 2009

Supplementary Data

(2) The following financial statement schedule is included herein

Schedule II Valuation and Qualifying Accounts

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

Table of Contents

**SIGNATURES**

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

LANNETT COMPANY, INC.

Date: September 28, 2009 By: / s / Arthur P. Bedrosian  
Arthur P. Bedrosian,  
President and Chief Executive Officer

Date: September 28, 2009 By: / s / Keith R. Ruck  
Keith R. Ruck  
Interim Chief Financial Officer and  
Corporate Controller

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

Date: September 28, 2009 By: / s / William Farber  
William Farber,  
Chairman of the Board of Directors

Date: September 28, 2009 By: / s / Ronald West  
Ronald West,  
Director, Vice Chairman of the Board,  
Chairman of Compensation Committee

Date: September 28, 2009 By: / s / Arthur P. Bedrosian  
Arthur P. Bedrosian,  
Director, President and Chief Executive Officer

Date: September 28, 2009 By: / s / Jeffrey Farber  
Jeffrey Farber,  
Director

Date: September 28, 2009 By: / s / Kenneth Sinclair  
Kenneth Sinclair,  
Director, Chairman of Audit Committee

Date: September 28, 2009 By: / s / Albert Wertheimer  
Albert Wertheimer,  
Director

Date: September 28, 2009 By: / s / Myron Winkelman  
Myron Winkelman,  
Director, Chairman of Strategic Plan Committee



Table of Contents

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders

Lannett Company, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Lannett Company, Inc. (a Delaware corporation) and Subsidiaries (collectively, the Company) as of June 30, 2009 and 2008, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the three years in the period ended June 30, 2009. Our audits of the basic financial statements included the financial statement schedule listed in the index appearing under Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Lannett Company, Inc. and Subsidiaries as of June 30, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended June 30, 2009 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 16 to the consolidated financial statements, the Company has adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Tax Positions*, in 2008.

/s/ GRANT THORNTON LLP

Philadelphia, Pennsylvania

Management

September 28, 2009

Table of Contents

## LANNETT COMPANY, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

	June 30, 2009	June 30, 2008
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 25,832,456	\$ 6,256,712
Investment securities - available for sale	347,921	354,155
Trade accounts receivable (net of allowance of \$132,000 and \$207,151, respectively)	29,945,748	34,114,982
Inventories, net	16,195,361	11,617,258
Interest receivable	90,425	51,781
Prepaid taxes		1,598,937
Deferred tax assets	4,296,929	6,997,935
Other current assets	602,335	591,415
<b>Total Current Assets</b>	<b>77,311,175</b>	<b>61,583,175</b>
Property, plant and equipment	41,431,158	39,996,008
Less accumulated depreciation	(18,533,773)	(15,261,905)
	22,897,385	24,734,103
Construction in progress	591,685	458,046
Investment securities - available for sale	801,748	2,145,980
Intangible assets (product rights) - net of accumulated amortization	9,118,710	10,361,835
Deferred tax assets	13,757,545	14,200,771
Other assets	98,873	195,354
<b>Total Assets</b>	<b>\$ 124,577,121</b>	<b>\$ 113,679,264</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>LIABILITIES</b>		
Current Liabilities		
Accounts payable	\$ 16,805,468	\$ 13,085,772
Accrued expenses	1,842,434	1,807,628
Accrued payroll and payroll related	5,150,104	644,155
Deferred revenue		982,668
Income taxes payable	711,073	
Current portion of long-term debt	435,386	791,912
Rebates, chargebacks and returns payable	13,734,540	18,326,417
<b>Total Current Liabilities</b>	<b>38,679,005</b>	<b>35,638,552</b>
Long-term debt, less current portion	7,703,382	8,186,922
Unearned grant funds	500,000	500,000
Other long-term liabilities	47,111	32,001
<b>Total Liabilities</b>	<b>46,929,498</b>	<b>44,357,475</b>
Commitment and Contingencies, See notes 9 and 10		
Minority Interest in Cody LCI Realty, LLC, net of taxes	93,654	50,309
<b>SHAREHOLDERS' EQUITY</b>		
Common stock - authorized 50,000,000 shares, par value \$0.001; issued and outstanding, 24,517,696 and 24,283,963 shares, respectively	24,518	24,284
Additional paid in capital	76,250,309	74,497,100
Retained earnings / (accumulated deficit)	1,743,565	(4,790,680)
Accumulated other comprehensive income	24,751	9,722
	78,043,143	69,740,426

Edgar Filing: LANNETT CO INC - Form 10-K

Less: Treasury stock at cost - 82,228 and 74,970 shares, respectively	(489,174)	(468,946)
<b>Total Shareholders Equity</b>	<b>77,553,969</b>	<b>69,271,480</b>
<b>Total Liabilities and Shareholders Equity</b>	<b>\$ 124,577,121</b>	<b>\$ 113,679,264</b>

The accompanying notes to consolidated financial statements are an integral part of these statements.

Table of Contents

**LANNETT COMPANY, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	2009	Fiscal Year Ended June 30, 2008		2007
Net sales	\$ 119,002,215	\$ 72,403,283	\$ 82,577,591	
Cost of sales	71,272,859	54,080,947	57,394,751	
Amortization of intangible assets	1,787,167	1,784,664	1,784,664	
Product royalties	697,720	236,601	1,973,189	
Gross profit	45,244,469	16,301,071	21,424,987	
Research and development expenses	8,427,135	5,172,715	7,459,432	
Selling, general, and administrative expenses	26,059,104	16,552,859	12,161,187	
Loss on impairment			7,775,890	
(Gain) loss on sale of investments	(53,524)	4,338		
Loss (gain) on sale of assets	30,885	1,693	(7,113)	
Operating income (loss)	10,780,869	(5,430,534)	(5,964,409)	
Other income (expense):				
Interest income	209,188	170,040	316,963	
Interest expense	(321,751)	(383,267)	(273,633)	
	(112,563)	(213,227)	43,330	
Income (loss) before income tax expense (benefit) and minority interest	10,668,306	(5,643,761)	(5,921,079)	
Income tax expense (benefit)	4,090,716	(3,376,011)	1,007,929	
Minority interest in Cody LCI Realty, LLC, net of taxes	43,345	50,309		
Net income (loss)	\$ 6,534,245	\$ (2,318,059)	\$ (6,929,008)	
Basic net income (loss) per common share	\$ 0.27	\$ (0.10)	\$ (0.29)	
Diluted net income (loss) per common share	\$ 0.27	\$ (0.10)	\$ (0.29)	
Basic weighted average number of shares outstanding	24,447,016	24,227,181	24,159,251	
Diluted weighted average number of shares outstanding	24,587,378	24,227,181	24,159,251	

The accompanying notes to consolidated financial statements are an integral part of these statements.



Table of Contents

## LANNETT COMPANY, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY

	Common Stock		Additional	Retained	Treasury	Accum. Other	Shareholders
	Shares	Amount	Paid-in	earnings /	Stock	Comp. Income (Loss)	Equity
	Issued		Capital	(accumulated			
				deficit)			
<b>Balance, June 30, 2006</b>	24,141,325	\$ 24,141	\$ 71,742,402	\$ 4,456,387	\$ (394,570)	\$ (72,444)	\$ 75,755,916
Exercise of stock options	375		281				281
Shares issued in connection with employee stock purchase plan	29,517	30	134,860				134,890
Share based compensation							
Stock options			1,176,235				1,176,235
Other comprehensive income, net of income tax						44,861	44,861
Net loss				(6,929,008)			(6,929,008)
<b>Balance, June 30, 2007</b>	24,171,217	\$ 24,171	\$ 73,053,778	\$ (2,472,621)	\$ (394,570)	\$ (27,583)	\$ 70,183,175
Shares issued in connection with employee stock purchase plan	38,282	38	138,592				138,630
Share based compensation							
Restricted stock			134,794				134,794
Stock options			869,921				869,921
Shares issued in connection with restricted stock grant	74,464	75	300,015				300,090
Purchase of treasury stock					(74,376)		(74,376)
Other comprehensive income, net of income tax						37,305	37,305
Net loss				(2,318,059)			(2,318,059)
<b>Balance, June 30, 2008</b>	24,283,963	\$ 24,284	\$ 74,497,100	\$ (4,790,680)	\$ (468,946)	\$ 9,722	\$ 69,271,480
Exercise of stock options	10,800	11	45,801				45,812
Shares issued in connection with employee stock purchase plan	49,331	49	114,905				114,954
Share based compensation							
Restricted stock			172,028				172,028
Stock options			930,878				930,878
Employee stock purchase plan			81,871				81,871
Shares issued in connection with restricted stock grant	68,602	69	101,331				101,400
Shares issued for contingent consideration for Cody Labs							
Acquisition	105,000	105	430,395				430,500
Stock options repurchased			(124,000)				(124,000)
Purchase of treasury stock					(20,228)		(20,228)

Edgar Filing: LANNETT CO INC - Form 10-K

Other comprehensive income, net of income tax							15,029	15,029					
Net income					6,534,245			6,534,245					
<b>Balance, June 30, 2009</b>	24,517,696	\$	24,518	\$	76,250,309	\$	1,743,565	\$	(489,174)	\$	24,751	\$	77,553,969

The accompanying notes to consolidated financial statements are an integral part of these statements.

Table of Contents

## LANNETT COMPANY, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	2009	Fiscal Year Ended June 30, 2008	2007
<b>OPERATING ACTIVITIES:</b>			
Net income (loss)	\$ 6,534,245	\$ (2,318,059)	\$ (6,929,008)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	5,099,108	5,229,358	4,465,393
Deferred tax expense (benefit)	2,983,538	(4,743,854)	1,779,843
Stock compensation expense	1,286,177	1,029,923	1,176,235
Loss on disposal/impairment of assets	30,885		7,774,098
(Gain) loss on sale of assets	(53,524)	1,693	
Other noncash expenses	15,110	13,339	
Interest income accrued on note			(267,672)
Minority interest in Cody LCI Realty, LLC, net of taxes	43,345	50,309	
Changes in assets and liabilities which provided (used) cash:			
Trade accounts receivable	(5,548,253)	(14,641,004)	5,447,693
Inventories	(4,578,103)	2,901,226	(2,716,610)
Prepaid and income taxes payable	2,310,010	1,594,748	18,826
Prepaid expenses and other assets	46,917	(69,679)	140,195
Accounts payable	3,719,696	1,968,824	9,441,359
Accrued expenses	34,806	563,992	448,096
Rebates, chargebacks and returns payable	5,125,610	12,640,053	(7,325,720)
Accrued payroll and payroll related	4,505,949	(447,322)	(2,415,401)
Deferred revenue	(982,668)	(655,325)	1,637,993
Net cash provided by operating activities	20,572,848	3,118,222	12,675,320
<b>INVESTING ACTIVITIES:</b>			
Cash paid for acquisition of business, net cash received			167,728
Purchases of property, plant and equipment (including construction in progress)	(1,604,114)	(2,295,817)	(2,465,075)
Proceeds from sale of assets	1,500	21,380	10,000
Proceeds from sale of investment securities - available for sale	7,408,295	2,023,616	1,845,838
Purchase of investment securities - available for sale	(5,979,257)	(1,140,945)	
Issuance of note receivable			(7,059,567)
Net cash used in investing activities	(173,576)	(1,391,766)	(7,501,076)
<b>FINANCING ACTIVITIES:</b>			
Repayments of debt	(840,066)	(701,131)	(585,433)
Proceeds from issuance of stock	160,766	113,422	135,171
Purchase of treasury stock	(20,228)	(74,376)	
Repurchase of stock options	(124,000)		
Net cash used in financing activities	(823,528)	(662,085)	(450,262)
NET INCREASE IN CASH AND CASH EQUIVALENTS	19,575,744	1,064,371	4,723,982
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	6,256,712	5,192,341	468,359

Edgar Filing: LANNETT CO INC - Form 10-K

CASH AND CASH EQUIVALENTS, END OF YEAR	\$	25,832,456	\$	6,256,712	\$	5,192,341
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION						
Interest paid	\$	217,463	\$	270,691	\$	194,656
Income taxes paid	\$	250,000	\$		\$	684,670
Lannett stock issued - contingent consideration - Cody Labs acquisition	\$	581,175	\$		\$	

The accompanying notes to consolidated financial statements are an integral part of these statements.

**Table of Contents**

**LANNETT COMPANY, INC. AND ITS SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Summary of Significant Accounting Policies**

Lannett Company, Inc., a Delaware corporation, and subsidiaries (the Company), develops, manufactures, packages, markets and distributes pharmaceutical products sold under generic chemical names.

The Company is engaged in an industry which is subject to considerable government regulation related to the development, manufacturing and marketing of pharmaceutical products. In the normal course of business, the Company periodically responds to inquiries or engages in administrative and judicial proceedings involving regulatory authorities, particularly the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA).

*Use of Estimates* - The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Principles of Consolidation* - The consolidated financial statements include the accounts of the operating parent company, Lannett Company, Inc., and its wholly owned subsidiaries, Lannett Holdings, Inc. and Cody Laboratories, Inc. Cody Laboratories, Inc includes the consolidation of Cody LCI Realty, LLC, a variable interest entity, as a result of the acquisition of Cody Laboratories, Inc. See Note 13 regarding the consolidation of this variable interest entity. All intercompany accounts and transactions have been eliminated.

*Reclassifications* - Certain prior year amounts have been reclassified to conform to the current year financial statement presentation.

*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 NDC Health, in estimating future returns and other credits. Lannett calculates a chargeback/rebate rate based on contractual terms with its customers and applies this rate to customer sales. The only variable is customer mix, and this 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

Table of Contents

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 by the Company to the large wholesale customers, such as Cardinal Health, AmerisourceBergen, and McKesson, increase, the reserve for chargebacks will also generally increase. However, the size of the increase depends on the product mix. The Company continually monitors the reserve for chargebacks and makes adjustments when management believes that expected chargebacks on actual sales may differ from actual chargeback reserves.

**Rebates** Rebates are offered to the Company's key chain drug store 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. 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 before and after the product's lot expiration date in exchange for a credit to be applied to future purchases. The Company's policy requires that the customer obtain pre-approval from the Company for any qualifying return. The Company estimates its provision for returns based principally on historical experience. However, the Company continually monitors the provisions for returns and makes adjustments when management believes that future product returns may differ from historical experience. Generally, the reserve for returns increases as net sales increase. During our fiscal year 2008 we increased our estimated returns reserve approximately \$3.0 million, of which \$1.5 million occurred in the fourth quarter. This adjustment was based on an analysis of our historical returns experience, the average lag time between sales and returns and an evaluation of changing buying and inventory trends of both our direct and indirect customers. As this change resulted from new information that has allowed us to better estimate the average length of time between product sales and returns, we consider it to be a change in estimate as defined in SFAS 154: *Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3*. 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 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.

Table of Contents

The following tables identify the reserves for each major category of revenue allowance and a summary of the activity for the fiscal years ended June 30, 2009, 2008 and 2007:

**For the Year Ended June 30, 2009**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
Reserve Balance as of June 30, 2008	\$ 4,049,407	\$ 632,314	\$ 13,642,589	\$ 2,107	\$ 18,326,417
Actual credits issued related to sales recorded in prior fiscal years	(3,954,794)	(632,314)	(12,853,342)		(17,440,450)
Reserves or (reversals) charged during Fiscal 2009 related to sales in prior fiscal years			2,107	(2,107)	
Reserves charged to net sales during Fiscal 2009 related to sales recorded in Fiscal 2009	35,391,475	12,141,204	4,315,638	204,119	52,052,436
Actual credits issued related to sales recorded in Fiscal 2009	(29,396,286)	(9,603,458)		(204,119)	(39,203,863)
Reserve Balance as of June 30, 2009	\$ 6,089,802	\$ 2,537,746	\$ 5,106,992	\$	\$ 13,734,540

**For the Year Ended June 30, 2008**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
Reserve Balance as of June 30, 2007	\$ 4,649,478	\$ 871,339	\$ 113,313	\$ 52,234	\$ 5,686,364
Actual credits issued related to sales recorded in prior fiscal years	(4,556,488)	(1,741,804)	(4,909,659)		(11,207,951)
Reserves or (reversals) charged during Fiscal 2008 related to sales in prior fiscal years		870,465	5,892,805	(50,000)	6,713,270
Reserves charged to net sales during Fiscal 2008 related to sales recorded in Fiscal 2008	26,126,995	7,999,232	12,546,130	473,423	47,145,780
Actual credits issued related to sales recorded in Fiscal 2008	(22,170,578)	(7,366,918)		(473,550)	(30,011,046)
Reserve Balance as of June 30, 2008	\$ 4,049,407	\$ 632,314	\$ 13,642,589	\$ 2,107	\$ 18,326,417





Table of Contents**For the Year Ended June 30, 2007**

<b>Reserve Category</b>	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Other</b>	<b>Total</b>
Reserve Balance as of June 30, 2006	\$ 10,137,400	\$ 2,183,100	\$ 416,000	\$ 275,600	\$ 13,012,100
Actual credits issued related to sales recorded in prior fiscal years	(10,170,000)	(1,800,000)	(5,578,000)	(250,000)	(17,798,000)
Reserves or (reversals) charged during Fiscal 2007 related to sales recorded in prior fiscal years		(300,000)	3,572,313		3,272,313
Reserves charged to net sales in fiscal 2007 related to sales recorded in fiscal 2007	28,034,000	9,562,000	1,703,000	1,044,800	40,343,800
Actual credits issued related to sales in fiscal 2007	(23,351,922)	(8,773,761)		(1,018,166)	(33,143,849)
Reserve Balance as of June 30, 2007	\$ 4,649,478	\$ 871,339	\$ 113,313	\$ 52,234	\$ 5,686,364

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

The products that the Company sells are generic versions of brand named drugs. The consumer markets for such drugs are well-established markets with many years of historically-confirmed consumer demand. Such consumer demand may be affected by several factors, including alternative treatments and costs, etc. However, the effects of changes in such consumer demand for the Company's products, like generic products manufactured by other generic companies, are gradual in nature. Any overall decrease in consumer demand for generic products generally

Table of Contents

occurs over an extended period of time. This is because there are thousands of doctors, prescribers, third-party payers, institutional formularies and other buyers of drugs that must change prescribing habits and medicinal practices before such a decrease would affect a generic drug market. If the historical data the Company uses and the assumptions management makes to calculate its estimates of future returns, chargebacks, and other credits do not accurately approximate future activity, its net sales, gross profit, net income and earnings per share could change. However, management believes that these estimates are reasonable based upon historical experience and current conditions.

**Cash and cash equivalents** - The Company considers all highly liquid securities purchased with original maturities of 90 days or less to be cash equivalents. Cash equivalents are stated at cost, which approximates market value, and consist of certificates of deposit that are readily converted to cash.

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

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

**Property, Plant and Equipment** - Property, plant and equipment are stated at cost. Depreciation is provided for by the straight-line method for financial reporting purposes over the estimated useful lives of the assets. Depreciation expense for the fiscal years ended June 30, 2009, 2008, and 2007 was approximately \$3,275,000, \$3,444,000 and \$2,765,000, respectively.

**Investment Securities** - The Company's investment securities consist of marketable debt securities, primarily in U.S. government and agency obligations. All of the Company's marketable debt securities are classified as available-for-sale and recorded at fair value, based on quoted market prices. Unrealized holding gains and losses are recorded, net of any tax effect, as a separate component of accumulated other comprehensive income (loss). No gains or losses on marketable debt securities are realized until they are sold or a decline in fair value is determined to be other-than-temporary. In accordance with Financial Accounting Standards Board (FASB) Staff Position Nos. FAS 115-1 and FAS 124-1 The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments (FSP 115-1), the Company periodically reviews its marketable securities and determines whether the investments are other-than-temporarily impaired. If the investments are deemed to be other-than-temporarily impaired, the investments are written down to their then current fair market value with a new cost basis being established. There were no securities determined by management to be other-than-temporarily impaired for the fiscal years ended June 30, 2009, 2008 and 2007.



Table of Contents

**Shipping and Handling Costs** The cost of shipping products to customers is recognized at the time the products are shipped, and is included in cost of sales.

**Research and Development** Research and development costs are charged to expense as incurred.

**Intangible Assets** In March 2004, the Company entered into an agreement with Jerome Stevens Pharmaceuticals, Inc. (JSP) for the exclusive marketing and distribution rights in the United States to the current line of JSP products in exchange for four million (4,000,000) shares of the Company's common stock. As a result of the JSP agreement, the Company recorded an intangible asset of \$67,040,000 for the exclusive marketing and distribution rights obtained from JSP. The intangible asset was recorded based upon the fair value of the four million (4,000,000) shares at the time of issuance to JSP. During the quarter ended March 31, 2005, the Company recorded a non-cash impairment loss of approximately \$46,093,000 in accordance with SFAS 144, *Accounting for Impairment or Disposal of Long-lived Assets* to reduce the carrying value of the intangible asset to its fair value of approximately \$16,062,000 as of the date of the impairment. As of June 30, 2009 and 2008, management concluded the carrying value of the intangible asset was less than its fair value and, therefore, no further impairment was required. The Company will incur annual amortization expense of approximately \$1,785,000 for the JSP intangible asset over the remaining term of the agreement.

On April 10, 2007, the Company entered into a Stock Purchase Agreement to acquire Cody by purchasing all of the remaining shares of common stock of Cody. The consideration for the April 10, 2007 acquisition was approximately \$4,438,000, which represented the fair value of the tangible net assets acquired. The agreement also required Lannett to issue to the sellers up to 120,000 shares of unregistered common stock of the Company contingent upon the receipt of a license from a regulatory agency. This license was subsequently received in July 2008 and triggered the payment of 105,000 shares (87.5% of the 120,000 shares as the Company already owned 12.5%) of Lannett stock to the former owners of Cody Labs, which was completed in October 2008. Therefore, the Company recorded an intangible asset related to the acquisition of a drug import license in the original amount of \$581,175 and recorded a corresponding deferred tax liability of approximately \$150,700 due to the non-deductibility of the amortization for tax purposes. The Company has assigned a 15 year life to this intangible asset based on average life cycles of Lannett products. See Note 12.

In January 2005, Lannett Holdings, Inc. entered into an agreement in which the Company purchased for \$100,000 and future royalty payments the proprietary rights to manufacture and distribute a product for which Pharmeral, Inc. owned the ANDA. In May 2008, the Company and Pharmeral waived their rights to any royalty payments on the sales of the drug by Lannett, under Lannett's current ownership structure. Should Lannett undergo a major change in control where a third party is involved, this royalty will be reinstated. In Fiscal 2008, the Company obtained FDA approval to use these proprietary rights. Accordingly, the Company has capitalized this purchased product right as an indefinite lived intangible asset which is tested for impairment at least on an annual basis. During the fourth quarter of fiscal 2009, it was determined that this intangible asset no longer has an indefinite life. No impairment existed because the estimated fair value exceeded the carrying amount on that date. Accordingly, the \$100,000 carrying amount of this intangible asset will be amortized on a straight line basis prospectively over its 10 year remaining estimated useful life. See Note 17.

For the fiscal years ended June 30, 2009, 2008 and 2007, the Company incurred amortization expense of approximately \$1,824,000, \$1,785,000, and \$1,785,000, respectively.

Table of Contents

Future annual amortization expense consists of the following:

Fiscal Year Ending June 30,	Annual Amortization Expense	
2010	\$	1,833,412
2011		1,833,412
2012		1,833,412
2013		1,833,412
2014		1,387,245
Thereafter		397,817
	\$	9,118,710

**Advertising Costs** - The Company charges advertising costs to operations as incurred. Advertising expense for the fiscal years ended June 30, 2009, 2008 and 2007 was approximately \$48,000, \$9,000, and \$75,000, respectively.

**Income Taxes** - The Company uses the liability method specified by Statement of Financial Accounting Standards No. 109 (FAS), *Accounting for Income Taxes*. 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 the enacted tax rates which are expected to be in effect when these differences reverse. Deferred tax expense/ (benefit) is the result of changes in deferred tax assets and liabilities. In July 2006, the FASB issued FIN 48, which addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FIN 48, the Company may recognize the tax benefit from an uncertain tax position 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. FIN 48 also provides guidance on derecognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. We adopted the provisions of FIN 48 on July 1, 2007.

**Segment Information** - The Company reports segment information in accordance with Statement of Financial Accounting Standard No. 131 (FAS 131), *Disclosures about Segments of an Enterprise and Related Information*. The Company operates one business segment - generic pharmaceuticals, accordingly the Company has one reporting segment. In accordance with FAS 131, the Company aggregates its financial information for all products and reports as one operating segment. The following table identifies the Company's approximate net product sales by medical indication for the fiscal years ended June 30, 2009, 2008 and 2007:

Table of Contents

Medical Indication	For the Fiscal Year Ended June 30,		
	2009	2008	2007
Migraine Headache	\$ 9,553,143	\$ 10,302,868	\$ 10,738,109
Epilepsy	1,777,820	3,811,963	7,593,547
Pre Natal Vitamin	12,569,304		
Heart Failure	26,421,467	7,574,240	4,728,907
Thyroid Deficiency	47,740,834	38,429,663	35,350,388
Antibiotic	6,483,190	3,449,429	3,095,241
Other	14,456,457	8,835,120	21,071,399
<b>Total</b>	<b>\$ 119,002,215</b>	<b>\$ 72,403,283</b>	<b>\$ 82,577,591</b>

**Concentration of Market and Credit Risk** Six of the Company's products, defined as generics containing the same active ingredient or combination of ingredients, accounted for approximately 40%, 22%, 11%, 8%, 3%, and 2% of net sales for the fiscal year ended June 30, 2009. Those same products accounted for 53%, 10%, 0%, 14%, 4%, and 0%, respectively, of net sales for the fiscal year ended June 30, 2008, and 43%, 6%, 0%, 12%, 3%, and 0%, respectively, for the fiscal year ended June 30, 2007.

Four of the Company's customers accounted for 31%, 11%, 9%, and 8%, respectively, of net sales for the fiscal year ended June 30, 2009; 36%, 9%, 5%, and 6%, respectively, of net sales for the fiscal year ended June 30, 2008; and 15%, 12%, 6%, and 24%, respectively, of net sales for the fiscal year ended June 30, 2007.

Credit terms are offered to customers based on evaluations of the customers' financial condition. Generally, collateral is not required from customers. Accounts receivable payment terms vary and are stated in the financial statements at amounts due from customers net of an allowance for doubtful accounts. Accounts remaining outstanding longer than the payment terms are considered past due. The Company determines its allowance by considering a number of factors, including the length of time trade accounts receivable are past due, the Company's previous loss history, the customer's current ability to pay its obligation to the Company, and the condition of the general economy and the industry as a whole. The Company writes-off accounts receivable when they become uncollectible.

**Share-based Payments** - The Company follows the guidance in Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 123 (R), Share-Based Payment (SFAS 123(R)). SFAS 123(R) addresses the accounting for share-based compensation in which we receive employee services in exchange for our equity instruments. Under the standard, the Company recognizes compensation cost for share-based compensation issued to or purchased by employees, net of estimated forfeitures, under share-based compensation plans using a fair value method. Compensation cost related to share-based payments is included in the income statement in the same line item as the related other compensation costs.

At June 30, 2009, the Company had three stock-based employee compensation plans (the Old Plan, the 2003 Plan, and the Long-term Incentive Plan, or LTIP).

During the fiscal year ended June 30, 2009, the Company awarded 30,000 shares of restricted stock under the LTIP which vested immediately. Stock compensation expense of \$101,400 was recognized during the fiscal year ended June 30, 2009, related to these shares of restricted stock.





Table of Contents

During the fiscal year ended June 30, 2008, the Company awarded 209,264 shares of restricted stock under the LTIP of which, 74,464 of these shares vested 100% on January 1, 2008, the remainder vest in equal portions on September 18, 2008, 2009 and 2010. Stock compensation expense of \$172,028 and \$134,794 was recognized during the fiscal years ended June 30, 2009 and 2008, related to the vesting of these shares of restricted stock.

The Company is required to record compensation expense for all awards granted after the date of adoption of SFAS 123(R) and for the unvested portion of previously granted awards that remain outstanding as of the beginning of the period of adoption. The Company measures share-based compensation cost for options using the Black-Scholes option pricing model. The following table presents the weighted average assumptions used to estimate fair values of the stock options granted during the years ended June 30 and the estimated annual forfeiture rates used to recognize the associated compensation expense:

	Incentive Stock Options FY 2009	Non- qualified Stock Options FY 2009	Incentive Stock Options FY 2008	Non- qualified Stock Options FY 2008	Incentive Stock Options FY 2007	Non- qualified Stock Options FY 2007
Risk-free interest rate	2.46%	2.52%	4.15%	4.21%	4.71%	4.79%
Expected volatility	61%	56%	56%	56%	59%	59%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Forfeiture rate	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Expected term (in years)	5.0 years	5.0 years	5.0 years	5.0 years	5.0 years	5.0 years
Weighted average fair value	\$ 2.20	\$ 1.41	\$ 2.11	\$ 2.11	\$ 3.36	\$ 3.20

Approximately 147,000 options were issued under the LTIP during the year ended June 30, 2009. This compares to approximately 582,000 options issued during the year ended June 30, 2008 and approximately 354,000 options issued during the year ended June 30, 2007. 10,800 options were exercised in the year ended June 30, 2009, resulting in proceeds of \$45,812 to the Company. There were no shares under option that were exercised in the year ended June 30, 2008. 375 options were exercised in the year ended June 30, 2007, resulting in proceeds of \$281 to the Company. At June 30, 2009, there were 1,585,681 options outstanding. Of those, 602,900 were options issued under the LTIP, 771,548 were issued under the 2003 Plan, and 211,233 under the Old Plan. There are no further shares authorized to be issued under the Old Plan. 1,125,000 shares were authorized to be issued under the 2003 Plan, with 12,090 shares under option having already been exercised under that plan. 2,500,000 shares were authorized to be issued under the LTIP, with 6,400 shares under option having already been exercised under that plan.

Expected volatility is based on the historical volatility of the price of our common shares since the date we commenced trading on the NYSE - Amex, April 2002, or a historical period equal to the expected term of the option, whichever is shorter. We use historical information to estimate expected term within the valuation model. The expected term of awards represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. Compensation cost is recognized using a straight-line method over the vesting or service period and is net of estimated forfeitures.

The forfeiture rate assumption is the estimated annual rate at which unvested awards are expected to be forfeited during the vesting period. This assumption is based on our historical forfeiture rate. Periodically, management will assess whether it is necessary to adjust the estimated rate to reflect changes in actual forfeitures or changes in expectations. For example, adjustments may be needed if, historically, forfeitures were affected mainly by turnover that resulted from a business restructuring that is not expected to recur. The forfeiture rate used to calculate compensation expense was 5% for fiscal years 2009, 2008 and 2007. Under the provisions of FAS 123R, the



Table of Contents

Company will incur additional expense if the actual forfeiture rate is lower than originally estimated. A recovery of prior expense will be recorded if the actual rate is higher than originally estimated.

The following table presents all share-based compensation costs recognized in our statements of income as part of selling, general and administrative expenses:

	Twelve months ended June 30,		
	2009	2008	2007
Share based compensation			
Stock options	\$ 930,878	\$ 869,921	\$ 1,142,912
Employee stock purchase plan	\$ 81,871	\$ 25,208	\$ 33,323
Restricted stock	\$ 273,428	\$ 134,794	\$
Tax benefit at effective rate	\$ 79,560	\$ 108,127	\$ 187,762

As part of the former CFO's resignation, the Company repurchased all of his 185,000 outstanding stock options. Therefore, the Company recorded, as incremental stock compensation expense, the previously unrecognized compensation cost totaling approximately \$83,000 related to options for which the requisite service period had not been rendered as of the repurchase date. See Note 10 for additional information.

Options outstanding that have vested and are expected to vest as of June 30, 2009 are as follows:

	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Options vested	986,237	\$ 9.53	\$ 723,174	5.5
Options expected to vest	569,472	\$ 4.27	\$ 1,474,106	8.5
Total vested and expected to vest	1,555,709	\$ 7.60	\$ 2,197,280	6.6

A summary of nonvested restricted stock award activity as of June 30, 2009, 2008, and 2007 and changes during the years then ended, is presented below:

	Awards	Weighted Average Grant - date Fair Value
Nonvested at June 30, 2007		\$
Granted	209,264	843,334
Vested	(74,464)	(300,090)
Forfeited	(10,000)	(40,300)
Nonvested at June 30, 2008	124,800	502,944
Granted	30,000	101,400
Vested	(68,602)	(256,966)
Forfeited	(9,000)	(36,270)

Edgar Filing: LANNETT CO INC - Form 10-K

Nonvested at June 30, 2009	77,198	\$	311,108
----------------------------	--------	----	---------

A summary of stock option award activity under the Plans as of June 30, 2009, 2008 and 2007 and changes during the years then ended, is presented below:

Table of Contents

	Incentive Stock Options				Nonqualified Stock Options			
	Awards	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life	Awards	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Outstanding at July 1, 2008	991,267	\$ 5.76			703,064	\$ 10.16		
Granted	187,102	\$ 4.03			37,998	\$ 2.80		
Exercised	(10,800)	\$ 4.24						
Forfeited, expired or repurchased	(208,660)	\$ 5.06			(114,290)	\$ 5.75		
Outstanding at June 30, 2009	958,909	\$ 5.60	\$ 1,844,125	7.4	626,772	\$ 10.52	\$ 430,739	5.5
Outstanding at June 30, 2009 and not yet vested	478,551	\$ 4.27	\$ 1,234,175	8.6	120,893	\$ 4.23	\$ 317,515	8.2
Exercisable at June 30, 2009	480,358	\$ 6.91	\$ 609,950	6.2	505,879	\$ 12.02	\$ 113,224	4.9
	Incentive Stock Options				Nonqualified Stock Options			
	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Outstanding at July 1, 2007	501,349	\$ 7.48			617,982	\$ 11.00		
Granted	496,818	\$ 4.03			85,082	\$ 4.03		
Exercised								
Forfeited or expired	(6,900)	\$ 5.67						
Outstanding at June 30, 2008	991,267	\$ 5.76	\$ 6,300	8.0	703,064	\$ 10.16	\$	6.5
Outstanding at June 30, 2008 and not yet vested	660,538	\$ 4.54	\$	9.0	183,651	\$ 5.05	\$	8.7
Exercisable at June 30, 2008	330,729	\$ 8.21	\$ 6,300	6.1	519,413	\$ 11.96	\$	5.8
	Incentive Stock Options				Nonqualified Stock Options			
	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life	Awards	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Outstanding at July 1, 2006	307,541	\$ 8.47			484,462	\$ 12.42		
Granted	220,263	\$ 6.14			133,520	\$ 5.84		
Exercised	(375)	\$ 0.75	\$ 2,063					
Forfeited or expired	(26,080)	\$ 7.84						
Outstanding at June 30, 2007	501,349	\$ 7.48	\$ 201,763	7.8	617,982	\$ 11.00	\$ 103,320	7.1
Outstanding at June 30, 2007 and not yet vested	276,222	\$ 6.11	\$ 133,375	9.0	177,817	\$ 6.16	\$ 99,680	8.9
Exercisable at June 30, 2007	225,127	\$ 9.16	\$ 68,388	6.3	440,165	\$ 12.96	\$ 3,640	6.4

Options with a fair value of approximately \$786,000 completed vesting during 2009. As of June 30, 2009, there was approximately \$1,129,000 of total unrecognized compensation cost related to nonvested share-based compensation awards granted under the Plans. That cost is expected to be recognized over a weighted average period of 1.4 years. As of June 30, 2008, there was

Table of Contents

approximately \$1,790,000 of total unrecognized compensation cost related to non-vested share-based compensation awards granted under the Plans. The Company issues new shares when stock options are exercised.

**Unearned Grant Funds** The Company records all grant funds received as a liability until the Company fulfills all the requirements of the grant funding program.

**Earnings per Common Share** SFAS No. 128, *Earnings per Share*, requires a dual presentation of basic and diluted earnings per share on the face of the Company's consolidated statement of income and a reconciliation of the computation of basic earnings per share to diluted earnings per share. Basic earnings per share excludes the dilutive impact of common stock equivalents and is computed by dividing net income by the weighted-average number of shares of common stock outstanding for the period. Diluted earnings per share include the effect of potential dilution from the exercise of outstanding common stock equivalents into common stock using the treasury stock method. Earnings per share amounts for all periods presented have been calculated in accordance with the requirements of SFAS No. 128. A reconciliation of the Company's basic and diluted earnings per share follows:

	2009		2008		2007	
	Net Income (Numerator)	Shares (Denominator)	Net Loss (Numerator)	Shares (Denominator)	Net Loss (Numerator)	Shares (Denominator)
Basic earnings/(loss) per share factors	\$ 6,534,245	24,447,016	\$ (2,318,059)	24,227,181	\$ (6,929,008)	24,159,251
Effect of potentially dilutive options		140,361				
Diluted earnings/(loss) per share factors	\$ 6,534,245	24,587,378	\$ (2,318,059)	24,227,181	\$ (6,929,008)	24,159,251
Basic earnings/(loss) per share	\$ 0.27		\$ (0.10)		\$ (0.29)	
Diluted earnings/(loss) per share	\$ 0.27		\$ (0.10)		\$ (0.29)	

Dilutive shares have been excluded in the weighted average shares used for the calculation of earnings per share in periods of net loss because the effect of such securities would be anti-dilutive. The number of anti-dilutive shares that have been excluded in the computation of diluted earnings per share for the fiscal years ended June 30, 2009, 2008 and 2007 were 980,781, 1,949,131, and 1,119,331, respectively.

As disclosed in Note 12, the Company entered into a Stock Purchase Agreement on April 10, 2007 to acquire Cody Laboratories, Inc. (Cody) by purchasing all of the remaining shares of common stock of Cody. As part of the consideration, the agreement required Lannett to issue to the sellers up to 120,000 shares of unregistered common stock of the Company contingent upon the receipt of a license from a regulatory agency. In accordance with paragraph 30 of SFAS 128, these contingently issuable shares were not included in the calculation of diluted EPS because the conditions necessary for the issuance of the shares had not been satisfied at the end of the reporting period. In July, 2008, the license was received from the regulatory agency and the contingent shares were issued to the sellers in accordance with the Stock Purchase Agreement.

**Table of Contents**



**Note 2. New Accounting Standards**

In June 2007, the Emerging Issues Task Force ( EITF ) reached a final consensus on EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ( EITF 07-3 ). EITF 07-3 was effective for our fiscal year beginning July 1, 2008. EITF 07-3 requires non-refundable advance payments for future research and development activities to be capitalized until the goods have been delivered or related services have been performed. As the guidance in EITF 07-03 is consistent with our existing policy, EITF 07-03 did not have any impact on our financial statements or related disclosures.

In November 2007, the EITF reached a final consensus on EITF Issue No. 07-1, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property ( EITF 07-1 ). EITF 07-1 will be effective for our fiscal year beginning July 1, 2009 and interim periods within that fiscal year. Adoption is on a retrospective basis to all prior periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the impact of adopting EITF 07-1 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations ( FAS 141(R) ). FAS 141(R) significantly changes the accounting for business combinations in a number of areas including the treatment of contingent consideration, contingencies, acquisition costs, in-process research and development and restructuring costs. In addition, under FAS 141(R), changes in deferred tax asset valuation allowances and acquired income tax uncertainties in a business combination after the measurement period will impact income tax expense. In April 2009, FAS 141(R) was amended by FASB Staff Position FAS 141R-1, Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies, ( FSP FAS 141(R)-1 ) to address application issues regarding the accounting and disclosure provisions for contingencies. FSP FAS 141(R) amends FAS 141R by replacing the guidance on the initial recognition and measurement of assets and liabilities arising from contingencies acquired or assumed in a business combination. FSP FAS 141(R)-1 also amends FAS 141R's subsequent accounting guidance for contingent assets and liabilities recognized at the acquisition date and amends the disclosure requirements for contingencies. FAS 141(R) and FSP FAS 141(R)-1 apply prospectively to business combinations for which the acquisition date is on or after the beginning of the fiscal year beginning July 1, 2009. Early application is not permitted. The effect of these standards on our consolidated financial statements will depend on the nature and terms of any business combinations that occur after the effective date.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements ( FAS 160 ). FAS 160 amends Accounting Research Bulletin No. 51 to establish accounting and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements and establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation. FAS 160 is effective for our fiscal year beginning July 1, 2009. We do not expect the adoption of FAS 160 to have a significant impact on our consolidated financial statements.

In April 2008, the FASB issued FASB Staff Position No. FAS 142-3, Determination of the Useful Life of Intangible Assets ( FSP FAS 142-3 ). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, Goodwill and Other Intangible Assets . The FSP is intended to improve the consistency between the useful life of a recognized intangible asset under Statement 142 and the period of expected cash flows used to measure the fair value of the asset under FAS 141(R) and other U.S. generally accepted

Table of Contents

accounting principles. The new standard is effective for our financial statements issued for fiscal years and interim periods beginning July 1, 2009. We do not expect the adoption of FSP FAS 142-3 to have a significant impact on our consolidated financial statements.

In April 2009, the FASB issued FASB Staff Position (FSP) FAS 115-2 and FAS 124-2, Recognition and Presentation of Other-Than-Temporary Impairments, to make the guidance on other-than-temporary impairments of debt securities more operational and improve the financial statement disclosures related to other-than-temporary impairments for debt and equity securities. The FSP clarifies the interaction of the factors that should be considered when determining whether a debt security is other-than-temporarily impaired. FSP FAS 115-2 and FAS 124-2 are effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. If an entity adopts either FSP FAS 157-4 or FSP FAS 107-1 and APB 28-1 for periods ending after March 15, 2009, then it must adopt this FSP at the same time. The Company adopted FSP FAS 115-2 and FAS 124-2 effective June 30, 2009. The adoption of these standards did not have a significant impact on our consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events ( FAS 165 ). FAS 165 defines the period after the balance sheet date during which a reporting entity's management should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements. The statement is effective for interim and annual periods ending after June 15, 2009. The Company adopted FAS 165 effective with its financial statements as of and for the year ended June 30, 2009. In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through September 28, 2009, the date the financial statements were issued.

In June 2009, the FASB issued SFAS No. 167, Amendments to FASB Interpretation No. 46(R) ( FAS 167 ). FAS 167 amends Interpretation 46(R) to require an enterprise to perform an analysis to determine whether the enterprise's variable interest or interests give it a controlling financial interest in a variable interest entity. It also amends Interpretation 46(R) to require ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. The statement is effective for the annual reporting period that begins after November 15, 2009. We do not expect the adoption of FAS 167 to have a significant impact on our consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification TM and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162 ( SFAS 168 ), which establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied in the preparation of financial statements in conformity with generally accepted accounting principles. SFAS 168 explicitly recognizes rules and interpretive releases of the Securities and Exchange Commission ( SEC ) under federal securities laws as authoritative GAAP for SEC registrants. SFAS 168 will become effective in the first quarter of fiscal year 2010 and will not have a material impact on the Company's consolidated financial statements.

**Table of Contents**

**Note 3. Inventories**



Inventories at June 30, 2009 and 2008 consist of the following:

Edgar Filing: LANNETT CO INC - Form 10-K

	2009	2008
Raw Materials	\$ 5,755,982	\$ 3,530,951
Work-in-process	2,846,600	1,034,360
Finished Goods	6,664,193	6,767,718
Packaging Supplies	928,586	284,229
	\$ 16,195,361	\$ 11,617,258

The preceding amounts are net of inventory obsolescence reserves of \$2,744,305 and \$1,642,668 at June 30, 2009 and 2008, respectively.

**Note 4. Property, Plant and Equipment**





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

Property, plant and equipment at June 30, 2009 and 2008 consist of the following:

	Useful Lives	2009		2008	
Land	-	\$	918,314	\$	918,314
Building and improvements	10 - 39 years		17,048,351		16,806,057
Machinery and equipment	5 - 10 years		22,573,324		21,434,375
Furniture and fixtures	5 - 7 years		891,169		837,262
			41,431,158		39,996,008
Less accumulated depreciation			(18,533,773)		(15,261,905)
Total		\$	22,897,385	\$	24,734,103

### **Note 5. Investment Securities - Available-for-Sale**

On July 1, 2008, the Company adopted FAS 157, which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. In February 2008, the FASB issued FSP 157-1 which amends FAS 157 to remove certain leasing transactions from its scope and FSP 157-2 that deferred the effective date of FAS 157 for one year for nonfinancial assets and liabilities recorded at fair value on a non-recurring basis. In October 2008, the FASB issued FSP 157-3, which clarifies the application of FAS 157 in a market that is not active. In April 2009, the FASB issued FSP 157-4 which provides additional guidance when the volume and level of activity for the asset or liability have significantly decreased. FAS 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. FAS 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. FAS 157 describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities. The Company does not have any level 1 available-for-sale securities as of June 30, 2009.

Table of Contents

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar instruments in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable. The Company's Level 2 assets and liabilities primarily include debt securities with quoted prices that are traded less frequently than exchange-traded instruments, corporate bonds, U.S. government and agency securities and certain mortgage-backed and asset-backed securities whose values are determined using pricing models with inputs that are observable in the market or can be derived principally from or corroborated by observable market data. The fair value of the Company's available-for-sale securities in the table below are derived solely from level 2 inputs.

Level 3 Unobservable inputs that are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation. The Company does not have any level 3 available-for-sale securities as of June 30, 2009.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The amortized cost, gross unrealized gains and losses, and fair value of the Company's available-for-sale securities as of June 30, 2009 and June 30, 2008:

June 30, 2009

Available-for-Sale

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Government Agency	\$ 928,910	\$ 40,352	\$	\$ 969,262
Corporate Bonds	179,507	900		180,407
	\$ 1,108,417	\$ 41,252	\$	\$ 1,149,669

June 30, 2008

Available-for-Sale

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Government Agency	\$ 2,036,039	\$ 48,059	\$ (9,854)	\$ 2,074,244
Asset-Backed Securities	447,893	1,013	(23,015)	425,891
	\$ 2,483,932	\$ 49,072	\$ (32,869)	\$ 2,500,135



Table of Contents

The amortized cost and fair value of the Company's current available-for-sale securities by contractual maturity at June 30, 2009 and June 30, 2008 are summarized as follows:

	June 30, 2009 Available for Sale		June 30, 2008 Available for Sale	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in one year or less	\$ 338,159	\$ 347,921	\$ 343,638	\$ 354,155
Due after one year through five years	770,258	801,748	1,692,401	1,720,089
Due after five years through ten years			121,608	121,769
Due after ten years			326,285	304,122
Total available-for-sale securities	1,108,417	1,149,669	2,483,932	2,500,135
Less current portion	338,159	347,921	343,638	354,155
Long-term available-for-sale securities	\$ 770,258	\$ 801,748	\$ 2,140,294	\$ 2,145,980

The Company uses the specific identification method to determine the cost of securities sold. For the fiscal years ended June 30, 2009, the Company had realized gains of \$53,524, whereas for fiscal years 2008 and 2007, the Company had realized losses of \$4,338 and \$0, respectively.

As of June 30, 2009 and 2008, there were no securities held from a single issuer that represented more than 10% of shareholders' equity. As of June 30, 2009, there were no individual securities in a continuous unrealized loss position.

**Note 6. Bank Line of Credit**

The Company has a \$3,000,000 line of credit from Wachovia Bank, N.A. (now a subsidiary of Wells Fargo & Co.) that bears interest at the prime interest rate less 0.25% (3.00% and 4.75% at June 30, 2009 and 2008, respectively). As of June 30, 2009 and 2008, the Company has \$3,000,000 and \$2,912,247 of availability under this line of credit. The Company entered into a letter of credit in the amount of \$917,000 of which \$87,753 was outstanding as of June 30, 2008. There were no outstanding letters of credit as of June 30, 2009. The line of credit was renewed and extended to November 30, 2009. The line of credit is collateralized by substantially all of the Company's assets. The agreement contains covenants with respect to working capital, net worth and certain ratios, as well as other covenants. As of June 30, 2009, the Company was in compliance with all financial covenants under the agreement.

The Company is required to maintain and comply with a debt service coverage ratio of not less than 2 to 1 (to be measured quarterly). Debt service coverage is defined as the ratio of earnings before interest, taxes, depreciation and amortization (EBITDA) to the sum of interest expenses plus scheduled current maturities of long-term debt and current capitalized lease obligations. The terms of the agreement require the Company to at all times maintain deposit balances in excess of \$3,500,000 with the Wachovia for the balance of the arrangement. Additionally, the Company is now required to pay Wachovia an availability fee equal to 0.50% per annum calculated daily, on the available but unused balance of the line of credit instead of the previous 0.25% per annum rate.

Table of Contents

**Note 7. Unearned Grant Funds**

In July 2004, the Company received \$500,000 of grant funding from the Commonwealth of Pennsylvania, acting through the Department of Community and Economic Development. The grant funding program requires the Company to use the funds for machinery and equipment located at their Pennsylvania locations, hire an additional 100 full-time employees by June 30, 2006, operate its Pennsylvania locations a minimum of five years and meet certain matching investment requirements. If the Company fails to comply with any of the requirements above, the Company would be liable to repay the full amount of the grant funding (\$500,000). The Company has recorded the unearned grant funds as a liability until the Company complies with all of the requirements of the grant funding program. As of June 30, 2009, the Company has had preliminary discussions with the Commonwealth of Pennsylvania to determine whether it will be required to repay any of the funds provided under the grant funding program. Based on information available at June 30, 2009, the Company has recorded the grant funding as a long-term liability under the caption of Unearned Grant Funds.

Table of Contents**Note 8. Long-Term Debt**

Long-term debt at June 30, 2009 and 2008 consists of the following:

	June 30, 2009	June 30, 2008
PIDC Regional Center, LP III loan	\$ 4,500,000	\$ 4,500,000
Pennsylvania Industrial Development Authority loan	1,002,607	1,075,732
Pennsylvania Department of Community & Economic Development loan	182,831	283,475
Tax-exempt bond loan (PAID)	680,000	795,000
Equipment loan	80,130	400,653
SBA loan		183,750
First National Bank of Cody mortgage	1,693,200	1,740,224
<b>Total debt</b>	<b>8,138,768</b>	<b>8,978,834</b>
Less current portion	435,386	791,912
<b>Long term debt</b>	<b>\$ 7,703,382</b>	<b>\$ 8,186,922</b>

## Current Portion of Long Term Debt

	June 30, 2009	June 30, 2008
PIDC Regional Center, LP III loan	\$	\$
Pennsylvania Industrial Development Authority loan	75,017	73,132
Pennsylvania Department of Community & Economic Development loan	103,100	100,614
Tax-exempt bond loan (PAID)	125,000	115,000
Equipment loan	80,130	400,653
SBA loan		54,025
First National Bank of Cody mortgage	52,139	48,488
<b>Total current portion of long term debt</b>	<b>\$ 435,386</b>	<b>\$ 791,912</b>

The Company financed \$4,500,000 through the Philadelphia Industrial Development Corporation (PIDC). The Company pays a bi-annual interest payment at a rate equal to two and one-half percent per annum. The outstanding principal balance is due and payable January 1, 2011.

The Company financed \$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 two and three-quarter percent per annum.

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





Table of Contents

In April 1999, the Company entered into a loan agreement (the Agreement) with a governmental authority, the Philadelphia Authority for Industrial Development (the Authority or PAID), to finance future construction and growth projects of the Company. The Authority issued \$3,700,000 in tax-exempt variable rate demand and fixed rate revenue bonds to provide the funds to finance such growth projects pursuant to a trust indenture (the Trust Indenture). A portion of the Company's proceeds from the bonds was used to pay for bond issuance costs of approximately \$170,000. The Trust Indenture requires that the Company repay the Authority loan through installment payments beginning in May 2003 and continuing through May 2014, the year the bonds mature. The bonds bear interest at the floating variable rate determined by the organization responsible for selling the bonds (the remarketing agent). The interest rate fluctuates on a weekly basis. The effective interest rate at June 30, 2009 and 2008 was 0.62% and 1.67%, respectively.

The Company entered into agreements (the 2003 Loan Financing) with Wachovia to finance the purchase of the Torresdale Avenue facility, the renovation and setup of the building, and other anticipated capital expenditures. The Company, as part of the 2003 Loan Financing agreement, is required to make equal payments of principal and interest. The only portion of the loan that remains outstanding at June 30, 2009 was the Equipment Loan which consists of a term loan with a term of five years and had an outstanding balance of \$80,130 and \$400,653 at June 30, 2009 and 2008, respectively. The terms of the Equipment loan require that the Company meet certain financial covenants and reporting standards, including the attainment of specific financial liquidity and net worth ratios. As of June 30, 2009, the Company was in compliance with all financial covenants under this agreement.

The Company is required to maintain and comply with a debt service coverage ratio of not less than 2 to 1 (to be measured quarterly). Debt service coverage is defined as the ratio of earnings before interest, taxes, depreciation and amortization (EBITDA) to the sum of interest expenses plus scheduled current maturities of long-term debt and current capitalized lease obligations. The terms of the agreement require the Company to at all times maintain deposit balances in excess of \$3,500,000 with Wachovia for the balance of the arrangement. Additionally, the Company now pays to Wachovia an availability fee equal to 0.50% per annum calculated daily, on the available but unused balance of the line of credit instead of the previous 0.25% per annum rate.

The financing facilities under the 2003 Loan Financing, of which only the Equipment Loan is left, bear interest at a variable rate equal to the LIBOR rate plus 150 basis points. The LIBOR rate is the rate per annum, based on a 30-day interest period, quoted two business days prior to the first day of such interest period for the offering by leading banks in the London interbank market of dollar deposits. As of June 30, 2009 and 2008, the interest rate for the 2003 Loan Financing (of which only the Equipment loan remains) was 1.81% and 3.89%, respectively.

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

Included in the acquisition of Cody was a loan from the Small Business Administration (SBA). The loan required fixed monthly payments, with an effective interest rate of 8.75%, through July 31, 2012. This loan was paid off in the third quarter of fiscal 2009.

Also as part of the Cody acquisition, the Company became primary beneficiary to a variable interest entity (VIE) called Cody LCI Realty, LLC. See Note 13, Consolidation of Variable Interest Entity for additional description. The VIE owns land and a building which is being leased to Cody. A mortgage loan with First National Bank of Cody has been consolidated in the Company's financial statements, along with the related land and building. The mortgage has 17 years remaining. Principal and interest payments of \$14,782, at a fixed interest rate of 7.5%, are being made on a monthly basis through June 2026. The mortgage loan is collateralized by the land and building.



Table of Contents

Long-term debt amounts are due as follows:

Fiscal Year Ending June 30,	Amounts Payable to Institutions
2010	\$ 435,386
2011	4,842,534
2012	274,585
2013	280,706
2014	298,988
Thereafter	2,006,569
	\$ 8,138,768

Some of the Company's debt instruments are fixed rate, with a lower interest rate than the prevailing market rates. The Company has been able to obtain favorable rates through Philadelphia and Pennsylvania Industrial Development Authorities.

**Note 9. Contingencies**



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

In early June 2008, the Company filed a declaratory judgment suit in the Federal District Court of Delaware (Civil Action No. 08-338 (JJF)) against KV Pharmaceuticals, DrugTech Corp., and Ther-Rx Corp (collectively KV). The complaint sought declaratory judgment for non-infringement and invalidity of certain patents owned by KV. The complaint further sought declaratory judgment of anti-trust violations and federal and state unfair competition violations for actions taken by KV in securing and enforcing these patents. After the complaint was filed, KV countered with a motion for a Temporary Restraining Order (TRO) to prevent the Company from launching its Multivitamin with Mineral Capsules (MMCs), due to alleged patent and trademark infringement issues. The TRO was heard and, ultimately, resulted in a conclusion by the court that the Company's product label on the MMCs should be modified. KV also countered with claims of infringement by the Company of KV's patents seeking the Company's profits for sales of MMCs or other monetary relief, preliminary and permanent injunctive relief, attorney's fees and a finding of willful infringement. On March 17, 2009 the Company and KV settled the litigation. In light of the withdrawal of KV's innovator prenatal product, and the resulting anticipated decline in sales and declining market for written prescription, the Company decided it was pointless to continue the litigation and entered into the settlement arrangement with KV. Pursuant to the settlement, the Company received a license from KV and became an authorized generic provider. During the terms of the license, the Company will pay KV a royalty on all future sales of its Prenatal vitamin product. Lannett will cease offering its Prenatal vitamin product if and when the brand is restored to the marketplace.

In or about July 2008, Albion International and Albion, Inc. filed suit in the United States District Court, District of Utah (Case No. 2:08cv00515) against Lannett asserting claims for patent and trademark infringement, as well as unfair competition, arising out of Lannett's use of product that it purchased from Albion and used as an ingredient in its MMC. Lannett filed a motion to dismiss the complaint on the basis that it purchased the product from Albion and, as such, was authorized to use the product in its MMC. The Court granted the motion and dismissed the complaint but gave Albion leave to file an amended complaint. On January 20, 2009, Albion filed an amended complaint. Lannett filed an answer to the complaint and counterclaim, asserting, among other things, that Albion tortuously interfered with Lannett's contracts. Subsequent to the filing of the answer and counterclaim, Lannett and Albion reached an

Table of Contents

agreement in principle to settle the case. Under terms of the settlement, the parties would each dismiss their claims against each other and provide releases. On July 6, 2009, the settlement agreement was signed and on July 13, 2009, the case was dismissed.

**Note 10. Commitments**



*Leases*

In June 2006, Lannett signed a lease agreement on a 66,000 square foot facility located on approximately seven acres in Philadelphia. An additional agreement which gives the Company the option to buy the facility was also signed. The Company expects to purchase this building in the Fall of 2009 for approximately \$3.8 million plus the cost of fit out. A significant portion of the purchase price and fit out costs are expected to be financed through a series of loans with a bank and a Pennsylvania state run development agency. This new facility is initially going to be used for warehouse space with the expectation of making this facility the Company's headquarters and possibly additional manufacturing space. This purchase and potential fit out of this new facility is expected to be financed either through a bank, a state development agency or both. The other Philadelphia locations will continue to be utilized as manufacturing, packaging, and as a research laboratory.

Lannett's subsidiary, Cody leases a 73,000 square foot facility in Cody, Wyoming. This location houses Cody's manufacturing and production facilities. Cody leases the facility from Cody LCI Realty, LLC, a Wyoming limited liability company which is 50% owned by Lannett. See Note 13.

Rental and lease expense for the years ended June 30, 2009, 2008 and 2007 was approximately \$449,000, \$449,000, and \$380,000, respectively.

*Contractual Obligations*

The following table represents annual contractual obligations as of June 30, 2009:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-Term Debt	\$ 8,138,768	\$ 435,386	\$ 5,117,119	\$ 579,694	\$ 2,006,569
Operating Leases	217,551	133,675	83,876		
Purchase Obligations	105,752,500	20,572,500	43,930,000	41,250,000	
Interest on Obligations	1,649,684	274,907	346,295	261,682	766,800
Total	\$ 115,758,503	\$ 21,416,468	\$ 49,477,290	\$ 42,091,376	\$ 2,773,369

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.



Table of Contents***Employment Agreements***

The Company has entered into employment agreements with Arthur P. Bedrosian, President and Chief Executive Officer, Kevin Smith, Vice President of Sales and Marketing, William Schreck, Senior Vice President and General Manager, Ernest Sabo, Vice President of Regulatory Affairs and Chief Compliance Officer and Stephen Kovary, Vice President of Operations. Each of the agreements provide for an annual base salary and eligibility to receive a bonus. The salary and bonus amounts of these executives are determined by the Board of Directors. Additionally, these executives are eligible to receive stock options, which are granted at the discretion of the Board of Directors, and in accordance with the Company's policies regarding stock option grants. Under the agreements, these executive employees may be terminated at any time with or without cause, or by reason of death or disability. In certain termination situations, the Company is liable to pay severance compensation to these executives of between 18 months and three years.

During the third quarter of Fiscal Year 2009, the Company's Vice President of Finance, Treasurer, Secretary and Chief Financial Officer resigned. As part of his separation agreement, the Company is obligated to pay to him approximately \$670,000 to settle any outstanding obligations from his employment agreement, including any salary, bonus, vacation, stock options and medical benefits. Of this amount, \$300,440 was paid in Fiscal 2009 with \$165,000 designated for the payment of pro rated bonus, and \$11,440 was designated for the payment of accrued but unused paid time off. As part of the settlement, \$124,000 was designated as the portion of the settlement related to the repurchase of his outstanding stock options. The Company therefore charged this amount to Additional Paid in Capital, as it represents the fair value of the options repurchased on the repurchase date. Additional payments totaling approximately \$369,000 for severance and benefits will be paid in Fiscal 2010 and Fiscal 2011 pursuant to the separation agreement.

**Note 11. Comprehensive Income (Loss)**

The Company's other comprehensive income (loss) is comprised of unrealized gains (losses) on investment securities classified as available-for-sale. The components of comprehensive income (loss) and related taxes consisted of the following as of June 30, 2009, 2008 and 2007:

	2009	For Fiscal Year Ended June 30, 2008	2007
Other Comprehensive Income (Loss):			
Net Income (Loss)	\$ 6,534,245	\$ (2,318,059)	\$ (6,929,008)
Unrealized Holding Gain on Securities	25,049	62,174	74,769
Add: Tax savings at statutory rate	(10,020)	(24,869)	(29,908)
Total Other Comprehensive Income	15,029	37,305	44,861
Total Comprehensive Income (Loss)	\$ 6,549,274	\$ (2,280,754)	\$ (6,884,147)

Table of Contents

**Note 12. Acquisition of Cody Laboratories, Inc.**

On March 31, 2007, the Company wrote down \$7,775,890 of a note receivable owed by Cody Laboratories, Inc. The Company determined that the value of the note receivable was impaired, and on April 10, 2007, it was decided to complete the acquisition of Cody by forgiving the amount of loans that exceeded the fair value of assets received. The remaining value of the amounts owed to Lannett approximated the value of Cody at the acquisition date.

On April 10, 2007, the Company entered into a Stock Purchase Agreement to acquire Cody by purchasing all of the remaining shares of common stock of Cody. The Company initially acquired a 12.5% direct interest in Cody Labs in July 2005. The consideration for the April 10, 2007 acquisition was approximately \$4,438,000, which represented the fair value of the tangible net assets acquired. The agreement also required Lannett to issue to the sellers up to 120,000 shares of unregistered common stock of the Company contingent upon the receipt of a license from a regulatory agency. This license was subsequently received in July 2008 and triggered the payment of 105,000 shares (87.5% of the 120,000 shares as the Company already owned 12.5%) of Lannett stock to the former owners of Cody Labs, which was completed in October 2008. Therefore, the Company recorded an intangible asset related to the acquisition of a drug import license in the original amount of \$581,175 and recorded a corresponding deferred tax liability of \$150,675 due to the non-deductibility of the amortization for tax purposes. The Company has assigned a 15 year life to this intangible asset based on average life cycles of Lannett products.

Cody was a privately owned manufacturer and supplier of bulk active pharmaceutical ingredients (API). The Company acquired all outstanding stock in this supplier in order to expand the breadth of its product offerings, and to maximize the profit margin on these products being offered.

The Company accounted for the transaction by following the guidance under SFAS 15, *Accounting by Debtors and Creditors for Troubled Debt Restructuring* and under the purchase method of accounting as provided in SFAS 141, *Business Combinations*. The operating results of the acquired business have been included in the consolidated statements of operations, financial condition and cash flows since the April 10, 2007 acquisition date. During Fiscal 2008, the Company adjusted the original purchase price allocation for Cody Labs, as a result of a study and additional analysis of assets acquired. The result of this study was to increase the deferred tax assets by \$1,255,000 and decrease the value of Cody Labs' property, plant and equipment by the same amount.

Table of Contents

A condensed balance sheet of Cody at the date of acquisition, April 10, 2007, is as follows:

Cash	\$	157,962
Inventory		325,372
Other current assets		89,445
Total current assets		572,779
Property, plant and equipment, net		3,202,455
Deferred tax asset		1,255,000
Total assets	\$	5,030,234
Accounts payable	\$	258,660
Current portion of long-term debt		48,524
Accrued expenses		91,476
Total current liabilities		398,660
Long term debt, less current portion		193,417
Total shareholders' equity		4,438,157
Total liabilities and shareholders' equity	\$	5,030,234

The following pro forma historical results of operations for the year ended June 30, 2007 is presented as if the Company had acquired Cody on July 1, 2006.

		(Unaudited) Year Ended June 30, 2007
Net Sales	\$	82,578,000
Net loss	\$	(3,197,000)
Loss per common share - basic and diluted	\$	(0.13)
Weighted average common shares outstanding - basic		24,159,251
Weighted average common shares outstanding - diluted		24,159,251

The unaudited pro forma financial information is presented for informational purposes only and does not purport to represent what the operating results actually would have been had the acquisition occurred on that date.

**Note 13. Consolidation of Variable Interest Entity**

Lannett consolidates any Variable Interest Entity ( VIE ) of which we are the primary beneficiary. The liabilities recognized as a result of consolidating a VIE do not represent additional claims on our general assets rather, they represent claims against the specific assets of the consolidated VIE. Conversely, assets recognized as a result of consolidating a VIE do not represent additional assets that could be used to satisfy

claims against our general assets. Reflected in each of the June 30, 2009 and 2008 balance sheets are consolidated VIE assets of approximately \$1.9 million and \$1.9 million, which are comprised mainly of land and a building. VIE liabilities consist primarily of a mortgage on that property in the amount of \$1.7 million and \$1.7 million at June 30, 2009 and 2008, respectively.

Table of Contents

Cody LCI Realty LLC ( Realty ) is the only VIE that is consolidated. Realty has been consolidated by Cody prior to its acquisition by Lannett. Realty is a 50/50 joint venture with a former shareholder of Cody. Its purpose was to acquire the facility used by Cody. Until the acquisition of Cody in April 2007, Lannett had not consolidated the VIE because Cody had been the primary beneficiary of the VIE. The risks associated with our interests in this VIE is limited to a decline in the value of the land and building as compared to the balance of the mortgage note on that property, up to Lannett's 50% share of the venture. Realty owns the land and building, and Cody leases the building and property from Realty for \$15,000 per month. All intercompany rent expense is eliminated upon consolidation with Cody.

The Company is not involved in any other VIE of which Lannett is primary beneficiary.

**Note 14. Employee Benefit Plan**

The Company has a defined contribution 401k plan (the Plan ) covering substantially all employees. During calendar year 2006, Lannett matched employees' contributions to the Lannett Company, Inc. 401(k) Retirement Savings Plan on a dollar for dollar basis up to 3% of an employee's base salary, subject to regulatory limits. Beginning in calendar year 2007 and continuing to present, Lannett matched contributions to the 401(k) plan on a fifty cents on the dollar basis up to 8% of the contributing employee's base salary. Contributions to the Plan during the years ended June 30, 2009, 2008 and 2007 were approximately \$330,000, \$350,000, and \$375,000, respectively.

**Note 15. Employee Stock Purchase Plan**

In February 2003, the Company's shareholders approved an Employee Stock Purchase Plan ( ESPP ). Employees eligible to participate in the ESPP may purchase shares of the Company's stock at 85% of the lower of the fair market value of the common stock on the first day of the calendar quarter, or the last day of the calendar quarter. Under the ESPP, employees can authorize the Company to withhold up to 10% of their compensation during any quarterly offering period, subject to certain limitations. The ESPP was implemented on April 1, 2003 and is qualified under Section 423 of the Internal Revenue Code. The Board of Directors authorized an aggregate total of 1,125,000 shares of the Company's common stock for issuance under the ESPP. As of June 30, 2009, 175,591 shares have been issued under the ESPP. Compensation expense of \$81,871, \$25,208, and \$33,322 was recognized in fiscal years 2009, 2008 and 2007, respectively, relating to the ESPP.

Table of Contents**Note 16. Income Taxes**

The provision (benefit) for income taxes consists of the following for the years ended June 30:

	2009	2008	2007
<b>Current Income Taxes</b>			
Federal	\$ 1,074,723	\$ 1,367,843	\$ (771,913)
State and Local Taxes	32,455		
Total	1,107,178	1,367,843	(771,913)
<b>Deferred Income Taxes</b>			
Federal	3,151,911	(3,986,449)	1,503,322
State and Local Taxes	(168,373)	(757,405)	276,520
Total	2,983,538	(4,743,854)	1,779,842
Total	\$ 4,090,716	\$ (3,376,011)	\$ 1,007,929

A reconciliation of the differences between the effective rates and federal statutory rates is as follows:

	2009	2008	2007
Federal income tax at statutory rate	34.0%	35.0%	35.0%
State and local income tax, net	(0.4)%	2.4%	0%
Nondeductible expenses	2.3%	(3.5)%	(4.4)%
Change in valuation allowance	(0.7)%	6.2%	(45.1)%
Income tax credits	(1.6)%	15.3%	0%
Other	4.7%	3.9%	(2.5)%
Income tax expense	38.3%	59.3%	(17.0)%

The principal types of differences between assets and liabilities for financial statement and tax return purposes are accruals, reserves, impairment of intangibles, accumulated amortization, accumulated depreciation and stock compensation which began in Fiscal 2006. A deferred tax asset is recorded for the future benefits created by the timing of accruals and reserves and the application of different amortization lives for financial statement and tax return purposes. In addition to the deferred tax assets shown in the table below, a \$16,501 and \$6,482 current deferred tax liability is also included on the balance sheet related to the tax effect of accumulated other comprehensive income at June 30, 2009 and 2008, respectively. A deferred tax asset valuation allowance was established based on the likelihood that it is more likely than not that the Company will be unable to realize certain of the deferred tax assets. A deferred tax liability is recorded for the future liability created by different depreciation methods for financial statement and tax return purposes.

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

### Table of Contents

As of June 30, 2009 and 2008, temporary differences which give rise to deferred tax assets and liabilities are as follows:

	2009	2008
<b>Deferred tax assets:</b>		
Accrued expenses	\$ 118,965	\$ 30,550
Stock compensation expense	740,687	673,154
Unearned grant funds	194,109	195,000
Reserve for returns	1,982,629	5,321,431
Reserves for accounts receivable and inventory	2,748,381	1,707,006
Intangible impairment	11,929,502	13,182,667
State net operating loss	74,255	207,700
Income tax credit carryforwards		63,083
Federal net operating loss	1,156,131	1,255,065
Impairment on Cody note receivable	2,097,175	2,106,798
Accumulated amortization on intangible asset	1,977,804	2,011,146
	23,019,638	26,753,600
Valuation allowance	(2,097,175)	(2,314,498)
<b>Total</b>	<b>20,922,463</b>	<b>24,439,102</b>
<b>Deferred tax liabilities:</b>		
Prepaid expenses	69,199	54,570
Property, plant and equipment	2,756,793	3,179,344
Other	25,496	
<b>Net deferred tax asset</b>	<b>\$ 18,070,975</b>	<b>\$ 21,205,188</b>

On April 10, 2007, the Company entered into a Stock Purchase Agreement to acquire Cody by purchasing all of the remaining shares of common stock of Cody. The consideration for the April 10, 2007 acquisition was approximately \$4,438,000, which represented the fair value of the tangible net assets acquired. The agreement also required Lannett to issue to the sellers up to 120,000 shares of unregistered common stock of the Company contingent upon the receipt of a license from a regulatory agency. This license was subsequently received in July 2008 and triggered the payment of 105,000 shares of Lannett stock to the former owners of Cody Labs, which was completed in October 2008. Therefore, the Company recorded an intangible asset related to the acquisition of a drug import license in the original amount of \$581,175 and recorded a corresponding deferred tax liability in the amount of \$150,675 due to the non-deductibility of the amortization for tax purposes.

In the third quarter of Fiscal 2008, the Company adjusted the original purchase price allocation for Cody, as a result of a study and additional analysis of assets acquired. The result of this study was to increase the deferred tax assets by \$1,255,065 and decrease the value of Cody's property, plant and equipment by the same amount. This adjustment was made in accordance with SFAS No. 141, Business Combinations. The increase in deferred tax assets related to Cody's federal net operation loss (NOL) carry forwards totaling approximately \$3,774,000 at the date of acquisition with \$1,902,000 expiring in 2026 and \$1,872,000 in 2027. At June 30, 2009, the remaining gross deferred tax asset is \$3,400,385. The income tax benefit associated with the NOL carry forwards has been recognized in accordance with Section 382 of the Internal Revenue Code of 1986.

On July 1, 2007, we adopted the provisions of FIN 48, Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109 (FIN 48), which provides a financial statement recognition threshold and measurement attribute for a tax position taken or expected to





Table of Contents

be taken in a tax return. Under FIN 48, we may recognize the tax benefit from an uncertain tax position 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. FIN 48 also provides guidance on de-recognition of income tax assets and liabilities, classification of current and deferred income tax assets and liabilities, accounting for interest and penalties associated with tax positions, and income tax disclosures. The Company did not recognize any additional current or deferred income tax assets or liabilities as a result of the implementation of FIN 48.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits (exclusive of interest and penalties) is as follows:

Balance at June 30, 2008	\$	
Additions for tax positions of the current year		65,033
Additions for tax positions of prior years		232,630
Reductions for tax positions of prior years		
Settlements		
Lapse of statute of limitations		
Balance at June 30, 2009	\$	297,663

As of June 30, 2009, the Company reported total unrecognized benefits of \$297,663, all of which would affect the Company's effective tax rate if recognized. As a result of the positions taken during the year, the Company has not recorded any interest and penalties for the year ended June 30, 2009 in the statement of operations and no cumulative interest and penalties have been recorded either in the Company's statement of financial position as of June 30, 2009. The Company will recognize interest accrued on unrecognized tax benefits in interest expense and any related penalties in operating expenses. The Company does not believe that the total unrecognized tax benefits will significantly increase or decrease in the next twelve months.

The Company files tax returns in the United States federal jurisdiction, Pennsylvania, New Jersey and California. The Company's tax returns for Fiscal 2005 and prior generally are no longer subject to review as such years generally are closed. The Company has been notified that its federal income tax return for Fiscal 2008 will be reviewed by the IRS during Fiscal 2010. The Company believes that an unfavorable resolution for open tax years would not be material to the financial position of the Company.

**Note 17. Related Party Transactions**

The Company had sales of approximately \$786,000, \$787,000, and \$763,000 during the fiscal years ended June 30, 2009, 2008 and 2007, respectively, to a generic distributor, Auburn Pharmaceutical Company. Jeffrey Farber (the related party), who is a current board member and the son of the Chairman of the Board of Directors and principal shareholder of the Company, William Farber, is the owner of Auburn Pharmaceutical Company. Accounts receivable includes amounts due from the related party of approximately \$125,000 and 305,000 at June 30, 2009 and 2008, respectively. In the Company's opinion, the terms of these transactions were not more favorable to the related party than would have been to a non-related party.

In January 2005, Lannett Holdings, Inc. entered into an agreement in which the Company purchased for \$100,000 and future royalty payments the proprietary rights to manufacture and distribute a product for which Pharmeral, Inc. owned the ANDA. In Fiscal 2008, the Company



Table of Contents

obtained FDA approval to use the proprietary rights. Accordingly, the Company originally capitalized these rights as an indefinite lived intangible asset and tested this asset for impairment at least on an annual basis. During the fourth quarter of Fiscal 2009, it was determined that this intangible asset no longer has an indefinite life. No impairment existed because the estimated fair value exceeded the carrying amount on that date. Accordingly, the \$100,000 carrying amount of this intangible asset will be amortized on a straight line basis prospectively over its 10 year remaining estimated useful life.

Arthur Bedrosian, President and Chief Executive Officer currently owns 100% of Pharmeral, Inc. This transaction was approved by the Board of Directors of the Company and in their opinion the terms were not more favorable to the related party than they would have been to a non-related party. In May 2008, Mr. Bedrosian and Pharmeral waived their rights to any royalty payments on the sales of the drug by Lannett under Lannett's current ownership structure. Should Lannett undergo a major change in control where a third party is involved, this royalty would be reinstated.

At June 30, 2009 and 2008, respectively, the Company had approximately \$0 and \$983,000 of deferred revenue as a result of prepayments on inventory received from Provell Pharmaceuticals, LLC ( Provell ). The Company recognized revenues of approximately \$29,000, \$141,000 and \$45,000 during the fiscal years ended June 30, 2009, 2008 and 2007, respectively. Accounts receivable includes amounts due from Provell of approximately \$55,000 and \$60,000 at June 30, 2009 and 2008, respectively. Provell is a joint venture to distribute pharmaceutical products through mail order outlets. In exchange for access to Lannett's drug providers, Lannett received a 33% ownership of this venture. After June 30, 2008, Lannett's ownership portion of this venture decreased to 25% due to outside investment in the venture from a third party. The investment is valued at zero, due to losses incurred to date by Provell. During June 2009, the Company terminated its participation in this joint venture.

**Note 18. Material Contracts with Suppliers**

Jerome Stevens Pharmaceuticals agreement:

The Company's primary finished product inventory supplier is Jerome Stevens Pharmaceuticals, Inc. (JSP), in Bohemia, New York. Purchases of finished goods inventory from JSP accounted for approximately 71% of the Company's inventory purchases in Fiscal 2009, 71% in Fiscal 2008 and 63% in Fiscal 2007. On March 23, 2004, the Company entered into an agreement with JSP for the exclusive distribution rights in the United States to the current line of JSP products, in exchange for four million (4,000,000) shares of the Company's common stock. The JSP products covered under the agreement included Butalbital, Aspirin, Caffeine with Codeine Phosphate capsules, Digoxin tablets and Levothyroxine Sodium tablets, sold generically and under the brand name Unithroid®. The term of the agreement is ten years, beginning on March 23, 2004 and continuing through March 22, 2014. Both Lannett and JSP have the right to terminate the contract if one of the parties does not cure a material breach of the contract within thirty (30) days of notice from the non-breaching party.

During the term of the agreement, the Company is required to use commercially reasonable efforts to purchase minimum dollar quantities of JSP's products being distributed by the Company. The minimum quantity to be purchased in the first year of the agreement is \$15.0 million. Thereafter, the minimum quantity to be purchased increases by \$1.0 million per year up to \$24.0 million for the last year of the ten-year contract. The Company has met the minimum purchase requirement for the first five years of the contract, but there is no guarantee that the Company will be able to continue to do so in the future. If the Company does not meet the minimum purchase requirements, JSP's sole remedy is to terminate the agreement.



Table of Contents

Under the agreement, JSP is entitled to nominate one person to serve on the Company's Board of Directors (the Board) provided, however, that the Board shall have the right to reasonably approve any such nominee in order to fulfill its fiduciary duty by ascertaining that such person is suitable for membership on the board of a publicly traded corporation. Suitability is determined by, but not limited to, the requirements of the Securities and Exchange Commission, the American Stock Exchange, and other applicable laws, including the Sarbanes-Oxley Act of 2002. As of June 30, 2009, JSP has not exercised the nomination provision of the agreement.

Management determined that the intangible product rights asset created by this agreement was impaired as of March 31, 2005. See Note 1 Summary of Significant Accounting Policies Intangible Assets for additional disclosure and discussion of this impairment.

The Company's financial condition, as well as its liquidity resources, are very dependent on an uninterrupted supply of product from Jerome Stevens. Should there be an interruption in the supply of product from Jerome Stevens for any reason, this event would have a material impact to the financial condition of Lannett.

Other agreements:

In August 2005, the Company signed an agreement with a finished goods provider to purchase, at fixed prices, and distribute a certain generic pharmaceutical product in the United States. The term of the agreement was three years, beginning on August 22, 2005 and continuing through August 21, 2008. Following its expiration on August 21, 2008, the agreement was not renewed. Purchases of finished goods inventory from this provider accounted for approximately 1% of the Company's costs of purchased inventory in Fiscal 2009, 14% in 2008, and 23% in 2007.

**Note 19. Fair Value of Financial Instruments**

The Company's financial instruments consist primarily of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and debt obligations. The carrying values of these assets and liabilities approximate fair value based upon the short-term nature of these instruments. The Company has estimated that the fair value of long-term debt associated with the 20 year mortgage on its land and building in Cody, Wyoming approximates the discounted amount of future payments to the mortgage-holder.

Table of Contents**Note 20. Quarterly Financial Information (Unaudited)**

Lannett's quarterly consolidated results of operations are shown below:

	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
<b>Fiscal 2009</b>				
Net Sales	\$ 35,448,874	\$ 28,761,316	\$ 29,224,372	\$ 25,567,653
Cost of Goods Sold	21,835,563	17,154,288	18,201,534	16,566,361
Gross Profit	13,613,311	11,607,028	11,022,838	9,001,292
Other Operating Expenses	9,722,714	9,434,449	8,489,249	6,817,188
Operating Income	3,890,597	2,172,579	2,533,589	2,184,104
Other (Expense) Income	(69,110)	2,537	(25,548)	(20,442)
Income Tax Expense	1,393,983	851,310	925,433	919,990
Minority Interest	6,968	9,324	9,546	17,507
Net Income	\$ 2,420,536	\$ 1,314,482	\$ 1,573,062	\$ 1,226,165
Basic Earnings Per Share	\$ 0.10	\$ 0.05	\$ 0.06	\$ 0.05
Diluted Earnings Per Share	\$ 0.10	\$ 0.05	\$ 0.06	\$ 0.05

	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
<b>Fiscal 2008</b>				
Net Sales	\$ 20,748,799	\$ 16,579,512	\$ 17,534,942	\$ 17,540,030
Cost of Goods Sold	17,878,596	12,682,018	13,107,326	12,434,272
Gross Profit	2,870,203	3,897,494	4,427,616	5,105,758
Other Operating Expenses	5,553,598	5,739,007	5,201,499	5,231,858
Operating Loss	(2,683,395)	(1,841,513)	(773,883)	(126,100)
Other (Expense)	(98,691)	(29,786)	(43,647)	(46,746)
Income Tax (Benefit)	(2,554,889)	(615,454)	(159,983)	(45,685)
Minority Interest	50,309			
Net Loss	\$ (277,506)	\$ (1,255,845)	\$ (657,547)	\$ (127,161)
Basic Loss Per Share	\$ (0.01)	\$ (0.05)	\$ (0.03)	\$ (0.01)
Diluted LossPer Share	\$ (0.01)	\$ (0.05)	\$ (0.03)	\$ (0.01)

	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
<b>Fiscal 2007</b>				
Net Sales	\$ 17,390,842	\$ 20,302,576	\$ 22,916,347	\$ 21,967,826
Cost of Goods Sold	14,441,928	15,090,163	17,790,927	13,829,586
Gross Profit	2,948,914	5,212,413	5,125,420	8,138,240
Other Operating Expenses	5,143,647	12,661,477	3,577,296	6,006,976
Operating (Loss) Income	(2,194,733)	(7,449,064)	1,548,124	2,131,264
Other (Expense) Income	(57,978)	22,898	43,828	34,582
Income Tax Expense (Benefit)	322,138	(818,807)	636,781	867,817
Net (Loss) Income	\$ (2,574,849)	\$ (6,607,359)	\$ 955,171	\$ 1,298,029
Basic (Loss) Earnings Per Share	\$ (0.11)	\$ (0.27)	\$ 0.04	\$ 0.05
Diluted (Loss) Earnings Per Share	\$ (0.11)	\$ (0.27)	\$ 0.04	\$ 0.05

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

On March 31, 2007, the Company wrote down \$7,775,890 of a note receivable owed by Cody Laboratories, Inc. The Company determined that the value of the note receivable was impaired, and on April 10, 2007, it was decided to complete the acquisition of Cody by forgiving the amount of loans that exceeded the fair value of assets received. The remaining value of the amounts owed approximated the value of Cody at the time of the acquisition.

Net sales for the fourth quarter of Fiscal 2007 have decreased as a result of change in sales mix and customer mix. The Company was able to increase sales to retail drug stores, however the Company

Table of Contents

experienced declines in sales to wholesaler customers. This change in mix was a result of purchasing patterns of wholesalers and revised purchase agreements with the wholesalers.

In the fourth quarter of Fiscal 2008 net sales increased largely due to a product recall of one of Lannett's competitors. Overall net sales for Fiscal 2008 decreased over Fiscal 2007 as a result of the increased competition in the generic drug market which adversely affected Lannett's sales of drugs used for the treatment of epilepsy and antibiotic drugs. Retail chain sales increased significantly in Fiscal Year 2008 as a result of an increase in the number of products available for sale and a significant increase in the number of retail stores of one of our customers.

Also during the fourth quarter of Fiscal 2008, the Company increased its returns reserve by \$10.5 million, reflecting its expectation that 100% of the shipments of Prenatal Multivitamin made in the fourth quarter would be returned. The Company's expectation that all of the product would be returned was based on its inability to have the product specified as a brand equivalent, and information from its customers regarding their intentions to return the product. In addition, the Company increased the returns reserve in the fourth quarter by approximately \$1.5 million based on an analysis of its historical returns experience, the average lag time between sales and returns and an evaluation of changing buying and inventory trends of both its direct and indirect customers. As this change resulted from new information that has allowed the Company to better estimate the average length of time between product sales and returns, the Company considers it to be a change in estimate as defined in SFAS 154: *Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3*.



Table of Contents**Schedule II - Valuation and Qualifying Accounts**

For the years ended June 30:

Description	Balance at Beginning of Fiscal Year	Charged to (reduction of) Expense	Deductions	Balance at End of Fiscal Year
<b>Allowance for Doubtful Accounts</b>				
2009	\$ 207,151	\$ (87,913)	\$ (12,762)	\$ 132,000
2008	250,000	48,284	91,133	207,151
2007	250,000			250,000
<b>Inventory Valuation</b>				
2009	\$ 1,642,668	\$ 2,004,403	\$ 902,767	\$ 2,744,305
2008	923,920	2,679,902	1,961,154	1,642,668
2007	1,054,499	1,717,357	1,847,936	923,920
<b>Deferred Tax Asset Valuation Allowance</b>				
2009	\$ 2,314,498	\$ (217,323)	\$	\$ 2,097,175
2008	2,667,550	(353,052)		2,314,498
2007		2,667,550		2,667,550

Table of Contents**Exhibit Index**

<b>Exhibit Number</b>	<b>Description</b>	<b>Method of Filing</b>
3.1	Articles of Incorporation	Incorporated by reference to the Proxy Statement filed with respect to the Annual Meeting of Shareholders held on December 6, 1991 (the 1991 Proxy Statement ).
3.2	By-Laws, as amended	Incorporated by reference to the 1991 Proxy Statement.
4	Specimen Certificate for Common Stock	Incorporated by reference to Exhibit 4(a) to Form 8 dated April 23, 1993 (Amendment No. 3 to Form 10-KSB for Fiscal 1992) ( Form 8 )
10.1	Line of Credit Note dated March 11, 1999 between the Company and First Union National Bank	Incorporated by reference to Exhibit 10(ad) to the Annual Report on 1999 Form 10-KSB
10.2	Philadelphia Authority for Industrial Development Taxable Variable Rate Demand/Fixed Rate Revenue Bonds, Series of 1999	Incorporated by reference to Exhibit 10(ae) to the Annual Report on 1999 Form 10-KSB
10.3	Philadelphia Authority for Industrial Development Tax-Exempt Variable Rate Demand/Fixed Revenue Bonds (Lannett Company, Inc. Project) Series of 1999	Incorporated by reference to Exhibit 10(af) to the Annual Report on 1999 Form 10-KSB
10.4	Letter of Credit and Agreements supporting bond issues between the Company and First Union National Bank	Incorporated by reference to Exhibit 10(ag) to the Annual Report on 1999 Form 10-KSB
10.5	2003 Stock Option Plan	Incorporated by reference to the Proxy Statement for Fiscal Year Ending June 30, 2002
10.6	Terms of Employment Agreement with Kevin Smith	Incorporated by reference to Exhibit 10.6 to the Annual Report on 2003 Form 10-KSB
10.7	Terms of Employment Agreement with Arthur Bedrosian	Incorporated by reference to Exhibit 10 to the Quarterly Report on Form 10-Q dated May 12, 2004.
10.9 (Note A)	Agreement between Lannett Company, Inc and Siegfried (USA), Inc.	Incorporated by reference to Exhibit 10.9 to the Annual Report on 2003 Form 10-KSB

Table of Contents

<b>Exhibit Number</b>	<b>Description</b>	<b>Method of Filing</b>
10.10 (Note A)	Agreement between Lannett Company, Inc and Jerome Stevens, Pharmaceutical, Inc.	Incorporated by reference to Exhibit 2.1 to Form 8-K dated April 20, 2004
10.11	Terms of Employment Agreement with Stephen J. Kovary	Filed Herewith
10.12	Agreement of Sale Between Anvil Construction Company, Inc. and Lannett Company, Inc.	Filed Herewith
21	Subsidiaries of the Company	Filed Herewith
23.1	Consent of Grant Thornton, LLP	Filed Herewith
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed Herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed Herewith
32	Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed Herewith