LANNETT CO INC
Form 10-K
September 24, 2010
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2010

OR

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

For the transition period from to

Commission File No. 001-31298

LANNETT COMPANY, INC.

(Exact name of registrant as specified in its charter)

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

9000 State Road

Philadelphia, Pennsylvania 19136

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

(Address of principal executive offices and telephone number)

Securities registered under Section 12(b) of the Exchange Act: **None**

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

Common Stock, $.001 Par Value

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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

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

Large accelerated filer o	Accelerated filer o

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

Smaller reporting company x

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

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

Aggregate market value of common stock held by non-affiliates of the registrant, as of December 31, 2009 was $60,310,315 based on the closing price of the stock on the NYSE - AMEX.

As of September 17, 2010, there were 25,238,882 shares of the registrant s common stock, $.001 par value, outstanding.

Table of Contents

TABLE OF CONTENTS

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 n variations thereof or comparable terminology, are intended to identify forward-looking statements. The statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We caution the reader that certain important factors may affect our actual operating results and could cause such results to differ materially from those expressed or implied by forward-looking statements. We believe the risks and uncertainties discussed under the Item 1A - Risk Factors and other risks and uncertainties detailed herein and from time to time in our SEC filings, may affect our actual results.

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

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, 2010. All references herein to a fiscal year or Fiscal refer to the applicable fiscal year ending June 30.

According to data reported by IMS Health in August 2010, we are currently among the top 20 companies, based on number of prescription transactions, for unbranded generic products in the United States. We intend to grow our business organically as well as through strategic partnerships. Additionally, our Levothyroxine Sodium tablets (Levo) were recognized by IMS Health as the 18th most prescribed pharmaceutical product, including both branded and generic products, in the U.S. over the past year, reaching approximately 23 million prescriptions through June 2010. This product line represents approximately 0.6% of the domestic prescription market. Over the last year, we have experienced a 6% growth in prescriptions for our products. In addition, Levo has experienced a 11% annual growth during that period.

Over the past five years, we have experienced a 95% growth in our revenues from approximately $64 million in fiscal year 2006 to over $125 million in fiscal year 2010. This rapid growth has been achieved primarily through strategic partnerships and opportunities resulting from certain difficulties that a number of our competitors have experienced with regulatory compliance issues.

Competitive Strengths

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

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

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

Mutually Beneficial Supply and Distribution Arrangements. In 2004, we entered into an exclusive distribution agreement with Jerome Stevens Pharmaceuticals (JSP) covering four different product lines. Two of these product lines, Levo and Digoxin, collectively accounted for approximately 58% of our net sales in fiscal year 2010 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.

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

Strong Track Record of Obtaining Regulatory Approvals for New Products. During the past two fiscal years, we have received 5 approved Abbreviated New Drug Applications (each, an ANDA) from the Food and Drug Administration (the FDA). We expect

Table of Contents

to receive several more during the next fiscal year. These regulatory approvals will enable us to manufacture and supply a broader portfolio of generic pharmaceutical products.

Reputation for Regulatory Compliance. We have a strong track record of regulatory compliance and we believe that we have strong effective regulatory compliance capabilities and practices through hiring qualified individuals and implementing strong current Good Manufacturing Practices (cGMP). 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 of these market opportunities.

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

Business Strategies

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

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

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

Improve our Operating Profile in Certain Targeted Specialty Markets. In certain situations, we may increase our focus on certain specialty markets within the generic pharmaceutical industry. By narrowing our focus to specialty markets, we can provide increased product alternatives in categories with relatively few other market participants. We plan to strengthen our relationships with strategic partners, including providers of product development research, raw materials, API and finished products. We believe that mutually 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, Cocaine and Morphine Sulfate were our key products, collectively accounting for approximately 75%, 71% and 74% of our net sales in fiscal years 2010, 2009 and 2008, respectively. In fiscal year

Table of Contents

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. In fiscal year 2009, we began selling our prenatal vitamin, OB Natal One, which was the generic version to a brand name prenatal vitamin. During the launch year of 2009, we sold approximately $12.6 million in net sales of the product. During our fiscal year 2009, the brand equivalent was withdrawn from the marketplace. Since the brand company withdrew their detailing salesforce, we have seen a significant drop in sales of our OB Natal One product. OB Natal One is not factored among our key products because the Company expects to see continued declining sales for this product as obstetricians prescribe other available prenatal vitamins.

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 $51 million in 2010. 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, nausea, vomiting and weakness. Net sales of this product have increased from approximately $4.7 million in 2007 to $21.0 million in 2010.

We distribute two products containing Butalbital. We have manufactured and sold one of the products, Butalbital with Aspirin and Caffeine capsules, for more than eighteen 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.

Morphine Sulfate liquid oral solution is produced and marketed in three different size containers (20 mgs per mL in 30, 120 and 240 mL bottles). We manufacture these liquid dosage forms at our Cody Labs subsidiary and we are currently finishing the manufacturing methods and capabilities to make the API form also at Cody. Sales of Morphine Sulfate approximated 5% of Lannett s Net Sales during Fiscal 2010. This drug is prescribed primarily for the management of pain in adults where other products or delivery methods are not tolerable to the patient. Common side effects of this drug include respiratory and circulatory depression. As recently as March of 2009, seven different companies, including Lannett, were manufacturing and/or distributing this product. As a result of recent actions by the FDA (see Item 1. Government

Regulation), at least five of those companies, including Lannett, have left the market by July 2010. Only one company has an approved NDA for this product and is currently selling it, and Lannett expects to become the second approved manufacturer within the next several months. If the FDA approves our current NDA application on Morphine Sulfate (see Item 1A. Risk Factors), Lannett will be vertically integrated on this product line.

Cocaine Topical Solution (C-Topical) is produced and marketed in two different strengths and two different size containers. (4% per 4 and 10 ml bottles, and 10% per 4 and 10 ml bottles). We manufacture these liquid dosage forms at our Cody Labs subsidiary and we expect to complete finishing the manufacturing methods and capabilities to make the API form also at Cody within the next fiscal year. Sales of C-Topical approximated 5% of Lannett s Net Sales during Fiscal 2010. This drug is utilized primarily for the

Table of Contents

anesthetization of the patient during ear, nose or throat surgery. It also works as a vasoconstrictor during the surgery. The only other company that was marketing this product announced during our fiscal 2010 year that they were withdrawing from the marketplace.

Validated Pharmaceutical Capabilities

Our manufacturing facility consists of 31,000 square feet on an approximately 3.5-acre parcel of land that we own. In addition, we own a 63,000 square foot building on approximately 3.0 acres located within one mile of our manufacturing facility that houses packaging, research and development and possibly additional manufacturing space in the future. In June 2006, we leased a third building located several miles from our manufacturing facility, consisting of 66,000 square feet on approximately 7.3 acres. We purchased this building in October 2009 for approximately $3.8 million, plus the cost of fit out of approximately $2.0 million. A significant portion of the purchase price and fit out costs are expected to be financed through a series of loans with a bank and a Pennsylvania state run development agency. Construction was substantially complete by June 30, 2010. The financing will be competed shortly. This new facility is being used for certain administrative functions, warehouse space, shipping and possibly additional manufacturing space in the future.

The manufacturing facility of our wholly-owned subsidiary, Cody Labs, consists of an approximately 73,000 square foot structure located on approximately 16 acres in Cody, Wyoming. Cody Labs leases the facility from Cody LCI Realty, LLC, Wyoming, which is 50% owned by us and 50% by an officer of Cody Labs and his former spouse. Cody Labs manufacturing facility currently has capacity for further expansion, both inside the existing structure, as well as by building outside the current structure.

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

We continue to pursue our comprehensive plan for improving and maintaining quality control and quality assurance programs for our pharmaceutical development and manufacturing facilities. The FDA periodically inspects our production facilities to determine our compliance with the FDA s manufacturing standards. Typically, after completing its inspection, the FDA will issue us a report, entitled a Form 483, containing observations of any possible violations of cGMPs. The FDA s observations may be minor or severe in nature and the degree of severity is generally determined by the time necessary to remediate the cGMP violation, any consequences to the consumer of the products, and whether the observation is subject to a Warning Letter from the FDA. By strictly complying with cGMPs and the various FDA 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. Over the past several years, we have hired additional personnel in product development, production, formulation and the R&D laboratory. We also intend to use our R&D infrastructure to continually devote resources to additional R&D projects. The following steps outline the numerous stages in the generic drug development process:

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

Table of Contents

adopted for the generic drug candidate, will be included as part of the Chemistry, Manufacturing and Controls section of the ANDA submitted to the FDA in the generic drug application.

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

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

4.) *Submission of the ANDA for FDA review and approval*. The ANDA process became formalized under The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act (Hatch-Waxman Act). The Hatch-Waxman Act amended the Federal Food, Drug and Cosmetic Act (FDCA) to permit 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 a June 2010 presentation given by the FDA s Office of Generic Drugs, the current FDA review time for ANDAs exceeds 26 months. While we have received approval for some of our ANDAs in 14 months, we have also waited longer than 3 years before receiving approval. Subsequently, the FDA advised that electronic submissions of applications may shorten the approval process. We currently file our ANDAs and NDAs electronically. ANDAs and NDAs submitted for our products may not receive FDA approval on a timely basis, if at all.

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

certifications with our ANDAs.

Sales and Customer Relationships

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

Table of Contents

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

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

Management

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

Current Products

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

	Name of Product	**Medical Indication**	**Equivalent Brand**
1	Acetazolamide Tablets	Glaucoma	Diamox®
2	Amantadine SoftGel Capsules	Parkinson s Disease	Symmetrel ®
3	Baclofen Tablets	Muscle Relaxer	Lioresal®
4	Bethanechol Chloride Tablets	Urinary Retention	Urecholine®
5	Butalbital, Aspirin and Caffeine Capsules	Migraine Headache	Fiorinal®
6	Butalbital, Aspirin, Caffeine with Codeine Phosphate Capsules	Migraine Headache	Fiorinal w/ Codeine #3®
7	Clindamycin HCl Capsules	Antibiotic	Cleocin®
8	C-Topical Solution	Anesthetic	N/A
9	Codeine Sulfate Tablets	Pain Management	N/A
10	Danazol Capsules	Endometriosis	Danocrine®
11	Dicyclomine Tablets	Irritable Bowels	Bentyl®
12	Dicyclomine Capsules	Irritable Bowels	Bentyl®
13	Digoxin Tablets	Congestive Heart Failure	Lanoxin®
14	Dipyridamole Tablets	Anticoagulant	Persantine ®
15	Doxycycline Tablets	Antibiotic	Adoxa®
16	Doxycycline Hyclate Tablets	Antibiotic	Periostat®
17	Esterified Estrogen & Methyltestoterone Tablets	Hormone Replacement	Estratest®
18	Hydrochlorothiazide Tablet	Diuretic	Hydrodiuril®
19	Hydromorphone HCl Tablets	Pain Management	Dilaudid®
20	Levothyroxine Sodium Tablets	Thyroid Deficiency	Levoxyl®/ Synthroid®
21	Morphine Sulfate Oral Solution	Pain Management	Roxanol®

22	OB-Natal ® ONE SoftGel Capsules	Pregnancy	N/A
23	Oxycodone HCl Oral Solution	Pain Management	Roxicodone®
24	Phentermine HCl Tablets	Obesity	Adipex-P®
25	Phentermine HCl Capsules	Obesity	Fastin®
26	Pilocarpine HCl Tablets	Dryness of the Mouth	Salagen®
27	Primidone Tablets	Epilepsy	Mysoline®
28	Probenecid Tablets	Gout	Benemid®
29	Rifampin Capsules	Antibiotic	Rifadin®
30	Terbutaline Sulfate Tablets	Bronchospasms	Brethine®
31	Unithroid® Tablet	Thyroid Deficiency	N/A
32	Ursodiol Capsules	Gallstone	Actigall ®

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

In fiscal years 2010 and 2009, we received five and four 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.

Table of Contents

In March 2008, we received a letter from the FDA with approval to market and launch Rifampin Capsules 150mg and 300mg. 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 Capsules 150mg and 300mg at AWP were $35 million in 2007.

In April 2008, we received a letter from the FDA with approval to market and launch Dipyridamole Tablets 25mg, 50mg and 75mg. 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 Tablets 25mg, 50mg and 75mg at AWP were $45 million in 2007.

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

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 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 HCI Tablets 7.5 mg, the generic equivalent of Salagen®. Pilocarpine HCI tablets are indicated for (1) the treatment of symptoms of dry mouth from salivary gland hyprfunction 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 HCI Tablets 7.5mg at AWP were $2.5 million in 2008.

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

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

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

and hyperlipidemia).

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

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

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

Table of Contents

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. Accordingly, we do not believe that our outside contracts for product development or manufacturing supply are material in nature, nor are we substantially dependent on the services rendered by such outside firms. Since we have no control over the FDA review process, our management is unable to anticipate whether or when it will be able to begin producing and shipping such additional products.

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

1.) Stage of R&D defines the current stage of the R&D product in the development process, as of the date of this Form 10-K.

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

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

Stage of R&D	Regulatory Requirement	Number of Products
FDA Review	ANDA	21
FDA Review	ANDA supplement	10
Clinical Testing	ANDA	5
Scale-Up	Preliminary Investigational New Drug	3
Scale-Up	ANDA supplement	3

Scale-Up	ANDA	4
Formulation/Method Development	ANDA	35

We incurred R&D expenses of approximately $11,251,000 in fiscal year 2010, $8,427,000 in fiscal year 2009, and $5,173,000 in fiscal year 2008. 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 $90,000 to $575,000 to develop a drug. Development payments are normally scheduled in advance, based on milestones.

Table of Contents

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 77% of our inventory purchases in fiscal year 2010, 71% in fiscal year 2009 and 71% in fiscal year 2008. 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 17 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.

We have entered into definitive supply and development agreements with certain international companies, including Wintac of India, Orion Pharma of Finland, Azad Pharma AG, Swiss Caps of Switzerland and Pharma 2B (formerly Pharmaseed) and The GC Group of Israel, as well as certain domestic companies, including 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-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 9%, 7%, and 11%, respectively, of our net sales in fiscal year 2010 and 7%, 9% and 7%, respectively, of our net sales in fiscal year 2009. Our largest chain drug store customer, Walgreens, accounted for 26% and 28% of net sales in fiscal year 2010 and fiscal year 2009, 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

Table of Contents

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 2010, 2009 and 2008, our advertising expenses were immaterial. When our sales representatives make contact with a customer, we will generally offer to supply the customer our products at fixed prices. If accepted, the customer s purchasing department will coordinate the purchase, receipt and distribution of the products throughout its distribution centers and retail outlets. Once a customer accepts our supply of a product, the customer typically expects a high standard of service, including timely receipt of products ordered, availability of convenient, user-friendly and effective customer service functions and maintaining open lines of communication.

Competition

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

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

Product	Primary Competitors
Butalbital with Aspirin and Caffeine, with and without Codeine Phosphate Capsules	Watson and Breckenridge
C_Topical Solution	None
Digoxin Tablets	GlaxoSmithKline, Impax, Caraco and Westward
Doxycycline Hyclate and Monohydrate Tablets	Par, Mylan, Sandoz and Ranbaxy
Levothyroxine Sodium Tablets	Abbott, Monarch, Mylan, Sandoz and Forest
Morphine Sulfate Liquid Oral Solution	Roxane and Mallinckrodt
Primidone Tablets	Watson, Qualitest, URL, Westward, Amneal and Impax

Rifampin Capsules	Sandoz and Versapharm
Unithroid® Tablets	Abbott, Monarch, Mylan 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

Table of Contents

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;

- 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.

Table of Contents

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

- ***Abbreviated New Drug Applications (ANDA):*** An ANDA is similar to an NDA except that the FDA generally waives the requirement of complete clinical studies of safety and efficacy. However, it may require bioavailability and bioequivalence studies. Bioavailability indicates the rate of absorption and levels of concentration of a drug in the bloodstream needed to produce a therapeutic effect. Bioequivalence compares one drug product with another and indicates if the rate of absorption and the levels of concentration of a generic drug in the body are within prescribed statistical limits to those of a previously approved drug. Under the Hatch-Waxman Act, an ANDA may be submitted for a drug on the basis that it is the equivalent of an approved drug regardless of when such other drug was approved. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

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

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

If an ANDA applicant is the first-to-file a substantially complete ANDA with a paragraph IV certification and provides appropriate notice to the FDA, the NDA holder, and all patent owner(s) for a particular generic product, the applicant may be awarded a 180-day period of marketing exclusivity against other companies that subsequently file ANDAs for that same product. A substantially complete ANDA is one that contains

all the information required by the Hatch-Waxman Act and the FDA s regulations, including the results of any required bioequivalence studies. The FDA may refuse to accept the filing of an ANDA that is not substantially complete or may determine during substantive review of the ANDA that additional information, such as an additional bioequivalence study, is required to support approval. Such a determination may affect an applicant s first to file status and eligibility for a 180-day period of marketing exclusivity for the generic product. The MMA also modified the rules governing when the 180-day marketing exclusivity period is triggered or forfeited and shared exclusivity. Prior to the legislation, the 180-day marketing exclusivity period was triggered upon the first commercial

Table of Contents

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 bioeqivalency testing were undertaken and approved by FDA. Moreover, the utility of Section 505(b)(2) applications have with the exception of Grandfathered drugs been diminished by the availability of the ANDA process, as described above.

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

Manufacturing cGMP Requirements

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

Table of Contents

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 FFDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and/or federal civil and criminal investigations and prosecutions.

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

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

DEA Regulation

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

Fraud and Abuse Laws

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

Anti-Kickback Statutes and Federal False Claims Act

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

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial

Table of Contents

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

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

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

Table of Contents

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.

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

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

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

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

Employees

As of June 30, 2010, we had 305 employees, comprised of 218 employees at Lannett and 87 employees at Cody Labs.

Securities and Exchange Act Reports

We maintain a website at *www.lannett.com*. We make available on or through our website our current and periodic reports, including any amendments to those reports, that are filed with the Securities and Exchange Commission (the SEC) in accordance with the Securities Exchange Act of 1934, as amended (the Exchange Act). These reports include annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. This information is available on our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. The contents of our website are not incorporated by reference in this Form 10-K and shall not be deemed filed under the Exchange Act.

ITEM 1A. 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 69% of our fiscal year 2010 sales are of distributed products, primarily manufactured by JSP. Two of theses products are Levo and Digoxin, which accounted for 41% and 17%, respectively, of our Fiscal 2010 net sales, and 40% and 22%, respectively, of our net sales for Fiscal 2009. If the supply of these products is interrupted in any way by any form of temporary or permanent business interruption to JSP, including but not limited to fire or other naturally-occurring, damaging event to their physical plant and/or equipment, condemnation of their facility, legislative or regulatory cease and desist declaration regarding their operations,

Table of Contents

and any interruption in their source of API for their products, our operating results could be materially adversely affected. We do not have, at this time, a second source for these products.

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 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.

Recently, the FDA has increased its efforts to force companies to file and seek FDA approval for GRASE products. Efforts have included granting market exclusivity to approved GRASE products and issuing notices to companies currently producing these products. Lannett currently manufactures and markets several products that are considered GRASE products, including Morphine Sulfate. The FDA is currently undertaking activities to force all companies who manufacture Morphine Sulfate to file applications and seek approval for this product or remove their product from the market. As of July 24, 2010, Lannett has stopped manufacturing and distributing Morphine Sulfate Oral Solution and as of the date of this Form 10-K, the Company has approximately $2 million of Morphine Sulfate Oral Solution finished goods inventory. Lannett has filed such an application and currently awaits FDA approval on the submission. The Company expects approval on this application within the next seven months. But, if the Company is rejected on its current application, or if the current application takes significantly longer than seven months to be approved, the Company is at risk of losing the $2 million of Morphine Sulfate Oral Solution inventory recorded on its books as of July 24, 2010, and approximately 5% to 8 % in future annual Net Sales.

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

Table of Contents

manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of sales, and/or criminal prosecution., Any of these or other regulatory actions could materially harm our operating results and financial condition. Although we have instituted internal compliance programs, if these programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business**.** Additionally, if the FDA were to undertake additional enforcement activities with any of Lannett s GRASE products, their actions could result in, among other things, removal of some of our products from the market, seizure of products and total or partial suspension of sales. Any of these regulatory actions could materially harm our operating results and financial condition.

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 were unable to successfully renew its FDA and/or DEA licenses, the financial results of Lannett would be negatively impacted.

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

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

- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;

- receiving requisite regulatory approvals for such products in a timely manner;

- the availability, on commercially reasonable terms, of raw materials, including APIs and other key ingredients;

- developing and commercializing a new product is time consuming, costly and subject to numerous factors that may delay or prevent the successful commercialization of new products; and

- commercializing generic products may be substantially delayed by the listing with the FDA of patents that have the effect of potentially delaying approval of the off-patent product by up to 30 months, and in some cases, such patents have been issued and listed with the FDA after the key chemical patent on the branded drug product has expired or been litigated, causing additional delays in obtaining approval.

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

The 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.

Table of Contents

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 if 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 certain products that we manufacture tend to create higher gross margins than do the products we purchase and resell. As a result, our sales mix will significantly impact our gross profit from period to period.

Factors that may cause our sales mix to vary include:

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

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

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

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

- pursuing new patents for existing products which may be granted just before the expiration of one patent which could extend patent protection for additional years or otherwise delay the launch of generics;

- using the Citizen Petition process to request amendments to FDA standards;

- seeking changes to U.S. Pharmacopoeia, an organization which publishes industry recognized compendia of drug standards;

- attaching patent extension amendments to non-related federal legislation; and

- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing.

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

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

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may have to defend against charges that we violated patents or proprietary rights of third parties. This is

Table of Contents

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

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

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

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

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

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

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

third-party payors and the growth of organizations such as HMOs and MCOs could result in lower prices and a reduction in demand for our products.

In addition, legislative and regulatory proposals and enactments to reform health care and government insurance programs could significantly influence the manner in which pharmaceutical products and medical devices are prescribed and purchased. We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could limit the amounts that federal and state governments will pay for health care products and services. The extent to which future legislation or regulations, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted or what effect such legislation or regulation would have on our business remains uncertain. For example, the American Recovery and Reinstatement Act of 2009, also known as the stimulus package, includes $1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. 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.

Table of Contents

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

We are subject to various federal and state laws pertaining to health care fraud and abuse, including the federal fraud and abuse law (sometimes referred to as the Anti-Kickback Statute) which apply to our sales and marketing practices and our relationships with physicians. At the federal level, the Anti-Kickback Statute prohibits any person or entity from knowingly and willfully soliciting, receiving, offering, or paying any remuneration, including a bribe, kickback, or rebate, directly or indirectly, in return for or to induce the referral of patients for items or services covered by federal health care programs, or the furnishing, recommending, or arranging for products or services covered by federal health care programs. Federal health care programs have been defined to include plans and programs that provide health benefits funded by the federal government, including Medicare and Medicaid, among others. The definition of remuneration has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, and waivers of payments. Several courts have interpreted the federal Anti-Kickback Statute s intent requirement to mean that if even one purpose in an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under federal health care programs, the statute has been violated. The federal government has issued regulations, commonly known as safe harbors that set forth certain provisions which, if fully met, will assure parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement will be illegal or that prosecution under the federal Anti-Kickback Statute will be pursued, but such transactions or arrangements face an increased risk of scrutiny by government enforcement authorities and an ongoing risk of prosecution. If our sales and marketing practices or our relationships with physicians (such as physicians serving on our Scientific Advisory Board) are considered by federal or state enforcement authorities to be knowingly and willfully soliciting, receiving, offering, or providing any remuneration in exchange for arranging for or recommending our products and services, and such activities do not fit within a safe harbor, then these arrangements could be challenged under the federal Anti-Kickback Statute. If our operations are found to be in 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 statue 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 best price to the states under the Medicaid program. We are not currently subject to any such investigations or actions and having not used AWP pricing since 2000 would not likely become subject to these investigations.

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

We are subject to state and federal laws that govern the submission of claims for reimbursement. The federal False Claims Act imposes civil liability and criminal fines on individuals or entities that knowingly submit, or cause to be submitted, false or

Table of Contents

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, 2010, our three largest customers accounted for 26%, 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 Lannett, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

The cost of insurance, including workers compensation, product liability and general liability insurance, 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.

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

Significant balances of intangible assets, including product rights acquired, are subject to impairment testing and may result in impairment charges, which 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

Table of Contents

products in the market, various other competitive and regulatory issues and contractual terms. Significant changes to any of these factors would require us to perform an additional impairment test on the affected asset and, if evidence of impairment exists, we would be required to take an impairment charge with respect to the asset. Such a charge would adversely affect our results of operations and financial condition.

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

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

ITEM 2. DESCRIPTION OF PROPERTY

Lannett owns three facilities in Philadelphia, Pennsylvania. Certain administrative functions, manufacturing and production facilities and our quality control laboratory are located in a 31,000 square foot facility at 9000 State Road 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 and packaging functions are located in the second building, which may be used for additional manufacturing space in the future.

In June 2006, we leased a third building located several miles from our manufacturing facility in Philadelphia, consisting of 66,000 square feet on approximately 7.3 acres. We purchased this building in October 2009 for approximately $3.8 million, plus the cost of fit out of approximately $2.0 million. A significant portion of the purchase price and fit out costs are expected to be financed through a series of loans with a bank and a Pennsylvania state run development agency. Construction was substantially complete by June 30, 2010. The financing will be competed shortly. This new facility is being used for certain administrative functions, warehouse space, shipping and possibly additional manufacturing space in the future.

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 January 2010, the Company initiated an arbitration proceeding against Olive Healthcare (Olive) for damages arising out of Olive s delivery of defective soft-gel prenatal vitamin capsules. The Company seeks damages in excess of $3.5 million. Olive has denied liability and filed a counterclaim in February 2010 for breach of contract.

In 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. In March 2009, the Company and KV settled the litigation. In light of the withdrawal of KV s innovator prenatal product due to FDA enforcement actions, 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 is to 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 May 2010, the Company filed an action for declaratory relief in the Delaware Superior Court against KV seeking a declaration that KV breached its obligations under a settlement agreement entered into with the

Table of Contents

Company (the Binding Agreement). In June 2010, KV filed a counterclaim to the complaint and asserted claims for breach of contract, declaratory judgment, negligent misrepresentation and fraud in connection with the Binding Agreement, alleging among other things that the Company has improperly withheld royalties from KV arising out of its sales of a pre-natal vitamin product.

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. In January 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. In July 2009, the settlement agreement was signed and the case was dismissed.

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 2010 and 2009, 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, 2010

	High	Low
First quarter	$ 9.67	$ 6.70
Second quarter	$ 8.19	$ 4.95
Third quarter	$ 6.45	$ 4.17
Fourth quarter	$ 5.12	$ 4.23

Fiscal Year Ended June 30, 2009

	High	Low
First quarter	$ 4.20	$ 2.25
Second quarter	$ 5.00	$ 1.79
Third quarter	$ 5.86	$ 4.60
Fourth quarter	$ 7.52	$ 4.86

Holders

As of September 17, 2010, there were approximately 249 holders of record of the Company s common stock.

Table of Contents

Dividends

The Company did not pay cash dividends in Fiscal 2010 or Fiscal 2009. The Company intends to use available funds for working capital, plant and equipment additions, and various product extension ventures. The Company does not expect to pay, nor should shareholders expect to receive, cash dividends in the foreseeable future.

Share Repurchase Program

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

ISSUER PURCHASES OF EQUITY SECURITIES

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
April 1 to April 30, 2010	8,799	$ 4.47	8,799	$ 4,348,587
May 1 to May 31, 2010				
June 1 to June 30, 2010				
	8,799		8,799	

On January 27, 2005, the Company s Board of Directors approved a stock repurchase program which was reauthorized by the Board of Directors on November 20, 2009. Under the program, the Company is authorized to repurchase up to $5 million of its outstanding common stock. As of June 30, 2010, the Company has repurchased 110,108 shares of its common stock under the program at an aggregate purchase price of $651,413.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following financial information as of and for the five years ended June 30, 2010, has been derived from our consolidated financial statements. This information should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere herein. The comparability of information is affected by the items described below.

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

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.

Lannett Company, Inc. and Subsidiaries

Financial Highlights

As of and for the Fiscal Year Ended June 30,	2010	2009	2008	2007	2006
Operating Highlights					
Net Sales	$ 125,177,949	$ 119,002,215	$ 72,403,283	$ 82,577,591	$ 64,060,375
Gross Profit	$ 41,339,807	$ 45,244,469	$ 16,301,071	$ 21,424,987	$ 28,375,665
Operating Income/(Loss)	$ 13,030,019	$ 10,780,869	$ (5,430,534)	$ (5,964,409)	$ 8,453,918
Net Income/(Loss) Lannett Company, Inc.	$ 7,821,067	$ 6,534,245	$ (2,318,059)	$ (6,929,008)	$ 4,968,922
Basic Earnings/(Loss) Per Share Lannett Company, Inc.	$ 0.32	$ 0.27	$ (0.10)	$ (0.29)	$ 0.21
Diluted Earnings/(Loss) Per Share Lannett Company, Inc.	$ 0.31	$ 0.27	$ (0.10)	$ (0.29)	$ 0.21
Balance Sheet Highlights					
Total Assets	$ 139,963,797	$ 124,577,121	$ 113,679,264	$ 104,656,100	$ 105,992,064
Total Debt	$ 7,719,827	$ 8,138,768	$ 8,978,834	$ 9,679,965	$ 8,196,692
Long Term Debt, less Current Portion	$ 2,868,549	$ 7,703,382	$ 8,186,922	$ 8,987,846	$ 7,649,806
Total Stockholders Equity	$ 88,957,715	$ 77,647,623	$ 69,321,789	$ 70,183,175	$ 75,755,916

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 2011, 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

Table of Contents

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.

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 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 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.

Table of Contents

The following tables identify the reserves for each major category of revenue allowance and a summary of the activity for fiscal years 2010, 2009 and 2008. 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, 2010

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2009	$ 6,089,802	$ 2,537,746	$ 5,106,992	$	$ 13,734,540
Actual credits issued related to sales recorded in prior fiscal years	(6,068,639)	(2,537,746)	(3,832,652)		(12,439,037)
Reserves or (reversals) charged during Fiscal 2010 related to sales in prior fiscal years			(401,203)		(401,203)
Reserves charged to net sales during Fiscal 2010 related to sales recorded in Fiscal 2010	48,539,403	16,353,467	4,528,118	1,226,614	70,647,601
Actual credits issued related to sales recorded in Fiscal 2010	(42,278,440)	(12,787,436)		(1,226,614)	(56,292,489)
Reserve Balance as of June 30, 2010	$ 6,282,127	$ 3,566,031	$ 5,401,254	$	$ 15,249,412

For the Year Ended June 30, 2009

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
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

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
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

Reserve Activity 2010 vs. 2009

The total reserve for chargebacks, rebates, returns and other adjustments increased from $13,734,540 at June 30, 2009 to $15,249,412 at June 30, 2010. The increase in total reserves was due to an increase in the rebates reserve as a result of the timing of credits being processed by the customers and by the Company, an increase in chargeback reserves due primarily to an increase in inventory levels at wholesaler distribution centers, and an increase in the return reserves due to an increase in overall sales.

During Fiscal 2010 approximately $424,000 of the original $10,545,000 return reserve recorded in the fourth quarter of Fiscal 2008 for the Prenatal Multivitamin product was applied to accounts receivable for customers who had returned the Prenatal Multivitamin product during 2010. In addition, the Company reversed approximately $387,000 to net sales in the fourth quarter of Fiscal 2010 as a result of new information that the Company had received regarding the amount of Multivitamin product that remained to be returned to the Company. This adjustment left a balance of approximately $17,000 of Multivitamin returns reserve on the consolidated balance sheet at June 30, 2010.

The following tables compare the year-end reserve balances in fiscal years 2010 and 2009 and the gross sales mix in Fiscal 2010 and Fiscal 2009.

	Fiscal Year Ended June 30,			
	2010	%	2009	%
Chargeback reserve	$ 6,282,127	41%	$ 6,089,802	44%
Rebate reserve	3,566,031	23%	2,537,746	19%
Return reserve	5,401,254	36%	5,106,992	37%
Other reserve		0%		0%

$	15,249,412	100%	$ 13,734,540	100%

	Fiscal Year ended June 30,		Fiscal Fourth Quarter	
	2010	2009	2010	2009
Chain drug stores	32%	37%	31%	33%
Mail Order	4%	4%	4%	3%
Wholesalers	64%	59%	65%	64%
	100%	100%	100%	100%

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 $10,545,000 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, product complaints and information from our customers regarding their intentions to return the product. Substantially all of these products were returned in Fiscal 2009 leaving a balance of approximately $828,000 in the Multivitamin return reserve at June 30, 2009. Partially offsetting this decrease was an increase primarily due to an increase in sales volume in Fiscal 2009.

Table of Contents

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 compare the year-end reserve balances in fiscal years 2009 and 2008 and the gross sales mix for the fourth quarters and full years 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%

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 day s 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 DSO 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, 2010, 2009 and 2008:

Fiscal Year Ended June 30,	2010	2009	2008
Net DSO (in days)	77	55	65
Gross DSO (in days)	69	53	70

The level of net DSO at June 30, 2010 is slightly higher 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. The increase is due to a higher percentage of sales being shipped at the end of the quarter.

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.

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

Table of Contents

consolidating a VIE do not represent additional assets that could be used to satisfy claims against our general assets. Reflected in the June 30, 2010 and 2009 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 $1.6 million and $1.7 million at June 30, 2010 and 2009, 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.

New Accounting Pronouncements -

In December 2007, the FASB issued authoritative guidance which 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 the guidance, 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, updated guidance was issued to address application issues regarding the accounting and disclosure provisions for contingencies. The authoritative guidance applies 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 this authoritative guidance 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 authoritative guidance 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. We adopted this authoritative guidance effective July 1, 2009. As a result of the adoption, the Company presents noncontrolling interests as a component of equity on its consolidated balance sheets. Minority interest expense is now shown below net income under the heading net income attributable to noncontrolling interest . Prior year financial statements have been reclassified to reflect the adoption of this guidance. The adoption of this guidance did not have any other significant impact on our consolidated financial statements.

In April 2008, the FASB issued authoritative guidance which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. The guidance is intended to improve the consistency between the useful life of a recognized intangible asset and the period of expected cash flows used to measure the fair value of the asset. We adopted this authoritative guidance effective July 1, 2009. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In June 2009, the FASB issued authoritative guidance for determining whether an entity is a variable interest entity and modifies the methods allowed for determining the primary beneficiary of a variable interest entity. This guidance requires 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 requires ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. The authoritative guidance is effective for the annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period and annual reporting periods thereafter. We do not expect the adoption of this authoritative guidance to have a significant impact on our consolidated financial statements.

In January 2010, the FASB issued authoritative guidance which requires reporting entities to make new disclosures about recurring or nonrecurring fair value measurements including significant transfers into and out of Level 1 and Level 2 fair value measurements and

information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. The authoritative guidance is effective for interim and annual reporting periods beginning after December 15, 2009, except for Level 3 reconciliation disclosures which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. We do not anticipate that this update will have a material impact on our consolidated financial statements.

Table of Contents

Results of Operations Fiscal 2010 compared to Fiscal 2009

Net sales increased 5% from $119,002,215 in Fiscal 2009 to $125,177,949 in Fiscal 2010. The following factors contributed to the $6,175,734 increase in sales:

Medical indication	Sales volume change %	Sales price change %
Migraine Headache	(6)%	9%
Antibiotics	5%	(5)%
Prescription Vitamin	(47)%	(15)%
Pain Management	138%	44%
Epilepsy	(10)%	26%
Heart Failure	(19)%	(1)%
Thyroid Deficiency	9%	0%

Sales of drugs used for pain management increased by approximately $9,974,000 for Fiscal 2010 compared to Fiscal 2009. This increase is due to an increased number of products offered as well as a market withdrawal by one of our major competitors. Sales of drugs used in the treatment of thyroid deficiency increased by approximately $4,485,000 as a result of a continued shift away from branded drugs towards generic prescriptions. Partially offsetting these increases was a decrease in sales of our prescription vitamins of approximately $6,929,000 due to a lack of selling activities by the branded drug company. The overall increase in sales was also affected by a decrease in sales of drugs for the treatment of congestive heart failure by approximately $5,425,000 in Fiscal 2010 compared to Fiscal 2009. This decrease was due to a prior year product recall by several of our major competitors which increased our Fiscal 2009 revenues. Additional sales can also be attributed to new drugs used for the treatment of gallstones totaling approximately $2,190,000.

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 2010 compared to Fiscal 2009.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 2010 Net Sales	Fiscal 2009 Net Sales
Wholesaler/Distributor	$ 58.2 million	$ 53.8 million
Retail Chain	$ 60.3 million	$ 59.0 million
Mail-Order Pharmacy	$ 6.7 million	$ 5.8 million
Private Label	$ 0.0 million	$ 0.4 million
Total	$ 125.2 million	$ 119.0 million

The sales to wholesaler/distributor and retail chain customer categories 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.

Cost of sales increased 14% to $83,838,142 in Fiscal 2010 from $73,757,746 in Fiscal 2009. The increase reflected the impact of the 5% increase in sales as well as additional royalties of approximately $455,180 primarily related to the sale of the prescription vitamins, our Amantadine product and the final payments under the Provell termination agreement. Additionally, the increase in cost of sales is attributable to two months of idle capacity costs at our Cody Labs subsidiary being directly expensed to the income statement during the second quarter of fiscal 2010. In March of 2009, the FDA issued a warning letter to nine companies including Lannett to remove Morphine Sulfate Oral Solution from the market until someone could submit an application and receive approval on such application. In April 2009, due to shortages of this fairly necessary drug in the marketplace, the FDA reversed their position and allowed all seven companies to continue manufacturing and/or marketing Morphine Sulfate up until 180 days after someone received approval on a Morphine Sulfate application. These actions by the FDA caused the DEA to withhold purchasing and manufacturing quota from some or all of these nine companies, including Lannett. Although the Company had quota at the time and quota issues were resolved by December 2009, the Cody Labs facility was left idle for the months of October and November 2009 due to the lack of Morphine Sulfate quota.

Table of Contents

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

Gross profit margins for Fiscal 2010 and Fiscal 2009 were 33% and 38%, respectively. Gross profit percentage decreased due to the decline in sales of the prescription vitamin, the commencement of the related royalty and the Cody Labs idle capacity costs discussed above. While the Company is continuously striving to keep product costs low, there can be no guarantee that profit margins will not fluctuate in future periods. Pricing pressure from competitors and costs of producing or purchasing new drugs may also fluctuate in the future. Changes in the future sales product mix may also occur. These changes may affect the gross profit percentage in future periods.

Research and development (R&D) expenses increased 34% to $11,251,421 in Fiscal 2010 from $8,427,135 in Fiscal 2009. The increase was primarily due to an increase in the number of drugs in development and preparation for submission to the FDA as well as increased costs for biostudies. The Company expenses all production costs as R&D until the drug is approved by the FDA. R&D expenses may fluctuate from period to period, based on R&D plans for submission to the FDA.

Selling, general and administrative (S, G & A) expenses decreased 33% to $17,375,320 in Fiscal 2010 from $26,059,104 in Fiscal 2009. The decrease is primarily due to litigation expenses in Fiscal 2009 related to the patent challenge with KV Pharmaceuticals of approximately $6,537,000 which were not incurred in Fiscal 2010 as the litigation was settled in March 2009. In the third quarter of Fiscal 2009, the Company also incurred severance costs related to the departure of the Company s former chief financial officer of approximately $452,000 which were not incurred in Fiscal 2010. Most of the remaining decrease in S, G &A expense is due to the reallocation of personnel at Cody Labs during 2010 to production due to their transition during this fiscal year into a more fully functional manufacturing facility. The costs incurred during fiscal 2009 of getting the Cody facility compliant with FDA cGMP requirements, as well as the personnel and related expenses incurred to set up laboratories and manufacturing space, and writing and establishing all policies and procedures were expensed to S, G &A. While the Company is focused on controlling costs, increases in personnel costs may have an ongoing and longer lasting impact on the administrative cost structure. 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 $275,870 in Fiscal 2010 from $321,751 in Fiscal 2009, due to lower levels of long term debt. Interest income decreased to $62,328 in Fiscal 2010 from $209,188 in Fiscal 2009 due to lower interest earned on smaller investment securities balances.

The Company recorded income tax expense totaling $4,813,044 in Fiscal 2010 compared to $4,090,716 in Fiscal 2009. The effective tax rate for Fiscal 2010 was 37.5% compared to 38.3% for Fiscal 2009. The effective tax rate for Fiscal 2010 includes the impact of a change in Pennsylvania tax law which lowered the Company s apportionment factor within this state. The impact of this change caused the Company to reduce its deferred tax assets by approximately $650,000, and therefore increased the effective tax rate by approximately 5% for Fiscal 2010. The increase in effective tax rate related to this change in Pennsylvania tax law was essentially offset by the impact of the settlement reached with the IRS related to its review of the federal income tax return for Fiscal 2008. As a result of the settlement, the Company recorded a refund receivable totaling approximately $421,000 and reduced its liability for unrecognized tax benefits by approximately $216,000. In addition, the Company amended its Fiscal 2005 income tax return to claim additional federal income tax credits, which was accepted as timely filed by the IRS. As a result, the Company reduced its income taxes payable by approximately $528,000 related to this amended income tax return.

At June 30, 2010, the Company has recognized a net deferred tax asset of $17,881,721. The net deferred tax asset is net of a valuation allowance of $2,016,620 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 attributable to Lannett of $7,821,067 for Fiscal 2010, or $0.32 basic and $0.31 diluted earnings per share, compared to net income attributable to Lannett of $6,534,245 for Fiscal 2009, or $0.27 basic and diluted earnings per share.

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 prescription vitamins during Fiscal 2009 which was the first year that the Company has offered this product. In addition to the sales of the prescription vitamins, the following factors contributed to the $46,598,932 increase in sales:

Table of Contents

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 prescription 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 addition 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

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.

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 term 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 prescription 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,

Table of Contents

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 an 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 noncontrolling interest of $10,624,961 as compared to an income tax benefit of $3,376,011 in Fiscal 2008 on a pretax loss after noncontrolling 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 attributable to Lannett of $6,534,245 for Fiscal 2009, or $0.27 basic and diluted earnings per share, compared to a net loss attributable to Lannett of $2,318,059 for Fiscal 2008, or $0.10 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, 2010, working capital was $40,104,705 as compared to $38,632,170 at June 30, 2009, an increase of $1,472,535.

Net cash provided by operating activities of $6,941,231 for the year ended June 30, 2010 reflected net income of $8,008,028 after adjusting for non-cash items of $6,787,846, as well as cash used by changes in operating assets and liabilities of $7,854,643. Significant changes in operating assets and liabilities are comprised of:

- An increase in trade accounts receivable of approximately $8,802,000 primarily as a result of increased sales in Fiscal 2010 as well as the timing of those shipments resulting in a higher DSO at June 30, 2010. The change in the accounts receivable balance from June 30, 2009

to June 30, 2010 includes a non-cash decrease of approximately $424,000 related to the issuance of credits for the returns of the multivitamin product received by the Company through June 30, 2010.

- An increase in inventories of approximately $2,862,000 due to increased stocking levels at both Lannett and Cody Labs for certain products as of June 30, 2010 that are being carried in order to respond to the increased order volume we are currently experiencing.

- An increase in income taxes payable of approximately $769,000 primarily related to federal tax provisions in excess of estimated tax payments made in Fiscal 2010.

- An increase in prepaid expenses and other current assets of approximately $1,908,000 primarily related to the Company s payment of $1,406,000 to the FDA that accompanied an initial application for approval of a currently marketed GRASE product. The Company is currently awaiting a response from the FDA as to whether part or all of the fee is refundable. The FDA normally has up to six months from date of submission in order to determine if any amounts are refundable. Accordingly the Company is recording this amount in Other Current Assets. If any part of the fee is not refundable, and the Company receives approval to market the related product, the Company expects to record the amount as an intangible asset and amortize it over the estimated product life. If this application is not approved, the Company has the right to re-file an application for this specific product with no additional fee due.

- An increase in accrued expenses of approximately $1,622,000 due to the timing of payments related to biostudies and royalties.

Table of Contents