

AKORN INC
Form 10-K
March 01, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Form 10-K

R Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2012

£ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File Number: 001-32360

AKORN, INC.

(Exact name of registrant as specified in its charter)

LOUISIANA

(State or other jurisdiction of
incorporation or organization)

72-0717400

(I.R.S. Employer Identification No.)

1925 W. Field Court, Suite 300, Lake Forest, Illinois 60045

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (847) 279-6100

Title of each class

Common Stock, No Par Value

Name of each exchange on which registered

The NASDAQ Stock Market LLC

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

(None)

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

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

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 R No £

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 R No £

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

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

Large accelerated filer: ☐ Accelerated filer: ☐ Non-accelerated filer: ☐ Smaller reporting company: ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☐

The aggregate market value of the voting stock of the registrant held by non-affiliates (affiliates being, for these purposes only, directors, executive officers and holders of more than 5% of the registrant's common stock) of the registrant as of June 30, 2012 was approximately \$934,248,000 based on the closing market price of \$15.77 reported on the Nasdaq Stock Market LLC on Friday, June 29, 2012.

The number of shares of the registrant's common stock, no par value per share, outstanding as of February 25, 2013 was 95,921,212.

Documents incorporated by reference: Definitive Proxy Statement for the 2013 Annual Meeting incorporated by reference into Part III, Items 10-14 of this Form 10-K.

Forward-Looking Statements and Factors Affecting Future Results

Certain statements in this Form 10-K constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act. When used in this document, the words “anticipate,” “believe,” “estimate” and “expect” and similar expressions are generally intended to identify forward-looking statements. Any forward-looking statements, including statements regarding our intent, belief or expectations are not guarantees of future performance. These statements are subject to risks and uncertainties and actual results may differ materially from those in the forward-looking statements as a result of various factors, including but not limited to:

Our ability to continue to comply with all of the requirements of the Food and Drug Administration, including current Good Manufacturing Practices regulations;

Our ability to obtain additional funding or financing to operate and grow our business;

The effects of federal, state and other governmental regulation on our business;

Our ability to obtain and maintain regulatory approvals for our products;

Our success in developing, manufacturing, acquiring and marketing new products;

Our ability to generate cash from operations sufficient to meet our working capital requirements;

The success of our strategic partnerships for the development and marketing of new products;

Our ability to bring new products to market and the effects of sales of such products on our financial results;

Our ability to successfully integrate acquired businesses and products;

The effects of competition from other generic pharmaceuticals and from other pharmaceutical companies;

Availability of raw materials needed to produce our products; and

Other factors referred to in this Form 10-K and our other Securities and Exchange Commission filings.

See “Item 1A. Risk Factors”. You should read this report completely with the understanding that our actual results may differ materially from what we expect. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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PART I

Item 1. Business

We manufacture and market a full line of diagnostic and therapeutic ophthalmic pharmaceuticals as well as niche hospital drugs and injectable pharmaceuticals. In addition, we market and distribute vaccines purchased from outside sources. Our customers include physicians, optometrists, hospitals, wholesalers, group purchasing organizations, retail pharmacy chains and other pharmaceutical companies. Akorn, Inc. is a Louisiana corporation founded in 1971 in Abita Springs, Louisiana. In 1997, we relocated our corporate headquarters to the Chicago, Illinois area and currently maintain our corporate offices in Lake Forest, Illinois. We operate pharmaceutical manufacturing facilities in Decatur, Illinois and Somerset, New Jersey, and in Paonta Sahib, Himachal Pradesh, India. We also operated a Research and Development (“R&D”) center in Skokie, Illinois and a distribution warehouse in Gurnee, Illinois.

In this annual report, we have reported results for three operating segments: ophthalmic; hospital drugs & injectables; and contract services. These three segments are described in greater detail below. For information regarding revenues and gross profit for each of our segments, see Item 8. Financial Statements and Supplementary Data, Note 13 — “Segment Information.”

Ophthalmic Segment. We market a full line of diagnostic and therapeutic ophthalmic pharmaceutical products. Diagnostic products, primarily used in the office setting, include mydriatics and cycloplegics, anesthetics, topical stains, gonioscopic solutions, angiography dyes and others. Therapeutic products, sold primarily to wholesalers, chain drug stores and other national account customers, include antibiotics, steroids, steroid combinations, glaucoma medications, decongestants/antihistamines and anti-edema medications. Non-pharmaceutical products include various artificial tear solutions, preservative-free lubricating ointments and eyelid cleansers.

We also market a line of over-the-counter (“OTC”) dry eye and other eye health products principally under the TheraTears® brand name. These products are sold through major chain drug stores and big box retailers, as well as directly to optometrists, ophthalmologists and other eye care practitioners and clinics.

Hospital Drugs & Injectables Segment. We market a line of niche hospital drug and injectable pharmaceutical products, including antidotes, anti-infectives, controlled substances for pain management and anesthesia, and other selected pharmaceutical products. These products are predominately sold to hospitals through the wholesale distribution channel. We target products with limited competition due to difficulty in manufacturing and/or the product’s market size.

We also market Td vaccine from time to time. We ceased the distribution of Td vaccine in early 2010, and restarted their distribution at the end of 2012. In 2010 and prior years, we included Td vaccine sales within the biologics & vaccines segment, which was discontinued in 2010. Due to the non-materiality of Td vaccine sales in 2010 and 2012 and the fact that they are marketed in a similar way and to the same customers as many of our injectable drugs, we are now including Td vaccine sales within the hospital drugs & injectables segment.

Contract Services Segment. We manufacture ophthalmic and injectable pharmaceutical products for third party pharmaceutical customers based on their specifications.

Manufacturing. We operate domestic U.S. manufacturing facilities in Decatur, Illinois and Somerset, New Jersey, and a foreign manufacturing facility in Paonta Sahib, Himachal Pradesh, India. (See Item 2. Properties, for more information.) Through these manufacturing facilities, we manufacture a diverse group of sterile pharmaceutical products, including dye products, liquid injectables, lyophilized injectables, gels, and ophthalmic solutions and ointments for our ophthalmic, hospital drugs & injectables and contract services segments. Our Somerset facility

manufactures ophthalmic solutions and ointment products for our ophthalmic and contract services segments, and gels for our hospital drugs & injectables segment. Our Decatur manufacturing facility manufactures dye products, liquid injectables, lyophilized injectables and ophthalmic solutions for our ophthalmic, hospital drugs & injectables and contract services segments. The manufacturing complex in Paonta Sahib, Himachal Pradesh, India manufactures liquid generic pharmaceutical injectables, injectable and oral cephalosporins, sterile injectable carbapenems, hormones and oncology products. The Paonta Sahib plant currently manufactures product for Indian contract customers and for export to Africa, Asia and other unregulated markets. We are working toward obtaining approval from the U.S. Food and Drug Administration (“FDA”) to manufacture various products from this plant for export to the U.S. and other regulated markets.

Sales and Marketing. We rely on our sales and marketing teams to help us maintain and, where possible, increase our market share in our predominantly non-proprietary product offering. Our sales organization consists of multiple teams, including: (1) regional outside sales teams focused on (a) ophthalmic sales and (b) injectable and other acute care sales; (2) an inside sales team focused on customers in smaller markets; and (3) a national accounts sales team focused on wholesale, retail pharmacy chain and group purchasing organization (“GPO”) markets. Our outside sales representatives sell ophthalmic products directly to retinal surgeons and ophthalmologists, and sell hospital drugs & injectables directly to local hospitals in order to support compliance and pull-through against GPO contracts. Inside sales augments our outside sales teams in the sale of ophthalmic and hospital drugs & injectables products in markets where outside sales would not be cost effective. Our national accounts sales team seeks to establish and maintain contracts with wholesalers, retail pharmacy chains and GPOs that represent hospitals in the United States. To support our sales efforts, we have a customer service team, as well as a marketing department focused on educating current and future customers about our product offerings and manufacturing capabilities.

Research and Development. We seek to continually grow our business by developing new products, either internally or with the assistance of external partners. We have operated an R&D facility in Skokie, Illinois since early 2010, and are relocating to a new, larger facility in Vernon Hills, Illinois during the first quarter of 2013. The majority of our internal product development will take place at the Vernon Hills facility, while our manufacturing plants in Decatur, IL and Somerset, NJ will provide support for the latter phases of product development. We believe that having our own centralized and dedicated R&D facility allows us to significantly increase the size of our product pipeline as well as shorten the time from project start to filing for approval with the FDA. We also continue to work with strategic partners for the external development of certain products. As of December 31, 2012, we had 36 full-time employees directly involved in product research and development activities.

R&D costs are expensed as incurred. Such costs amounted to \$15.9 million, \$11.6 million and \$7.0 million for the years ended December 31, 2012, 2011 and 2010, respectively, and includes both internal R&D expenses and milestone fees paid to our strategic partners. Our strategic partnerships are discussed further in “Business Development.”

We received five Abbreviated New Drug Application (“ANDA”) product approvals from the FDA in 2012, one approval in 2011 and four in 2010. During 2012, we submitted 25 new ANDA filings to the FDA, increasing to 55 the number of our ANDA product filings currently under review by the FDA Office of Generic Drugs: 51 from internal development and four from various strategic agreements with other external partners. In most but not all instances, we own, or will own, the ANDAs that are produced by our strategic partnerships. We plan to continue to file ANDAs on a regular basis in anticipation of selected pharmaceutical products coming off patent, thereby allowing us to compete by marketing generic equivalents. For more information, see “Government Regulation.”

No assurance can be given as to: (1) whether we will file New Drug Applications (“NDAs”) or ANDAs when anticipated; (2) whether or when such NDAs or ANDAs will be approved by the FDA; (3) whether or not we will ultimately develop marketable products based on any filings we do make; (4) the actual size of the market for any such products or (5) whether our participation in such market would be profitable. See “Government Regulation” and Item 1A. Risk Factors – “Our growth depends on our ability to timely develop and successfully integrate new pharmaceutical products.”

Mergers and Acquisitions. We actively seek to expand and enhance our business through strategic acquisitions. We may seek to acquire ANDAs and NDAs from other pharmaceutical companies or pursue acquisition of independent businesses that we believe would complement our existing business and provide us opportunities for growth. During 2011 and early 2012, we completed three significant acquisitions.

On May 3, 2011, we acquired AVR Business Trust and its subsidiaries, Advanced Vision Research, Inc. and Advanced Vision Pharmaceuticals, LLC (collectively, "AVR") for \$26.0 million in cash. AVR is a developer and marketer of a line of OTC eye care products marketed primarily under the TheraTears® brand name. AVR products are carried by major drug retailers throughout the United States and are being marketed in various foreign countries.

On December 22, 2011, we acquired three NDAs from H. Lundbeck A/S ("Lundbeck"). On the date of closing, of the acquisition (the "Lundbeck Acquisition"), we made an initial payment of \$45.0 million and will likely owe a subsequent milestone payment of \$15.0 million in cash on the third anniversary of the closing date. The initial purchase price and the subsequent milestone payment are subject to a reduction if certain sales targets are not met in the first three years and the subsequent three years post closing. The acquired portfolio consists of Nembutal®, a Schedule II controlled drug, Diuril® and Cogentin®. In addition, we signed a transition services agreement with Lundbeck to ensure product availability, and separately paid approximately \$4.6 million for Lundbeck's existing inventory of the three acquired products. This acquisition provided us with three branded, hospital injectables to add to our portfolio.

On February 28, 2012, we acquired selected assets of Kilitch Drugs (India) Limited ("Kilitch") pursuant to a Business Transfer Agreement ("BTA") between our subsidiary, Akorn India Private Limited ("AIPL"), and Kilitch signed on October 6, 2011 (the "Kilitch Acquisition"). We paid approximately \$60.1 million in cash at closing, which included consideration of \$55.2 million and acquisition related costs of \$4.9 million. The primary assets acquired were Kilitch's pharmaceutical manufacturing complex in Paonta Sahib, Himachal Pradesh, India and its ongoing book of business. We also acquired pursuant to the BTA selected assets of NBZ Pharma Limited, a company affiliated with Kilitch, from which we acquired the rights to manufacture and distribute certain pharmaceuticals products. The Paonta Sahib plant currently manufactures pharmaceutical products primarily for contract customers in India and for export to unregulated markets. We plan to obtain FDA and other international certification so that we can manufacture product for export to the U.S. and other regulated markets. See Item 1A. Risk Factors — "Failure to obtain regulatory certification of our manufacturing plant in India for production of pharmaceutical products for export to the United States, as well as other regulated world markets, could impair our ability to grow and adversely affect our business, financial condition and results of operations" and "Failure to comply with the U.S. Foreign Corrupt Practices Act could subject us to, among other things, penalties and legal expenses that could harm our reputation and have a material adverse effect on our business, financial condition and operating results" for more information.

Business Development. In addition to our internal research and development, we also maintain a business development program that identifies potential product acquisition or product licensing opportunities. We have strategically focused our business development efforts on products that complement our existing product lines and which are expected to have few competitors.

In 2004, we entered into a 50/50 strategic partnership with Strides Arcolab Limited (“Strides”) in a new company named Akorn-Strides LLC (the “Joint Venture Company”) for the development and marketing of a number of injectable ANDA products for the hospital and alternate site markets in the United States. Each partner funded the Joint Venture Company with \$1,500,000 for initial development projects. See Item 8. Financial Statements and Supplementary Data, Note 18 – “Unconsolidated Joint Venture” for more information. Strides was responsible for developing, manufacturing and supplying the injectable products, while Akorn was responsible for sales and marketing of these products within the United States. The Joint Venture Company launched its first products in the second half of 2008. To supplement Strides’ manufacturing capabilities, during 2010 Akorn began manufacturing one Joint Venture Company product in our Decatur, Illinois plant. The Joint Venture Company product pipeline was limited to those products identified at the founding of the Joint Venture Company and placed into development shortly thereafter.

On December 29, 2010, the Joint Venture Company entered into a purchase agreement with Pfizer, Inc. (“Pfizer”) to sell all of its ANDAs to Pfizer for a purchase price of \$63.2 million (the “Pfizer Sale Agreement”). Ownership of dormant products and those in development transferred as of the purchase date, while ownership of the actively-marketed ANDAs transferred in the second quarter of 2011. Pursuant to the terms of the Pfizer Sale Agreement, the Joint Venture Company was allowed to sell its actively-marketed ANDA products through April 30, 2011. Subsequent agreement between the parties allowed for the continued sale of one product into June 2011. We recognized \$34.9 million in pre-tax income related to the Pfizer Sale Agreement, of which \$21.5 million was recognized in the fourth quarter of 2010 and \$13.4 million was recognized in the second quarter of 2011. For the years 2011 and 2010, the Joint Venture Company generated net sales of \$6.4 million and \$16.3 million, respectively.

Patents, Trademarks and Proprietary Rights. We consider the protection of our patents, trademarks and proprietary rights important to maintaining and growing our business. Through our acquisitions, we have increased the number and importance of trademarks related to our products and product lines. One of our acquired companies, AVR, maintains a line of OTC eye care products sold under trade names such as TheraTears® and SteriLid®, among others. We are committed to maintaining and defending the trade names of AVR’s products, as they are important in supporting the success and growth of this business. In addition, we maintain and defend trademarks related to a number of internally-developed products, as well as those acquired or licensed from other companies.

We have sought, and intend to continue to seek, patent protection in the United States and selected foreign countries where deemed appropriate and advantageous to us. The importance of these patents does not vary among our business segments. We currently have five patents, none of which expire within the next three years.

We also rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation to maintain and develop our competitive position. We enter into confidentiality agreements with certain of our employees pursuant to which such employees agree to assign to us any inventions relating to our business made by them while in our employ. However, there can be no assurance that others may not acquire or independently develop similar technology or, if patents are not issued with respect to products arising from research, that we will be able to maintain information pertinent to such research as proprietary technology or trade secrets. See Item 1A. Risk Factors — “Our patents and proprietary rights may not adequately protect our products and processes” and “Third parties may claim that we infringe their proprietary rights and may prevent or delay us from manufacturing and selling some of our new products” for more information.

Employee Relations. As of December 31, 2012, we had —759 permanent, full-time employees and eight part-time or temporary employees in the United States and 217 employees working for our subsidiary in India. Of our full-time employees working in the U.S., 409 worked at our manufacturing facilities in Decatur, Illinois, 142 worked at our manufacturing facility in Somerset, New Jersey, 57 were field-based salespersons, 25 worked at our R&D facility in Skokie, Illinois, and the remaining 126 worked in corporate support functions, either at our corporate offices in Lake Forest, Illinois or Ann Arbor, Michigan, or at our distribution facility in Gurnee, Illinois. We believe we have good relations with our employees. None of our employees are represented by a collective bargaining agreement.

Competition. The marketing and manufacturing of pharmaceutical products is highly competitive, with many established manufacturers, suppliers and distributors actively engaged in all phases of the business. Many of our competitors have substantially greater financial and other resources, including greater sales volume, larger sales forces and greater manufacturing capacity. See Item 1A. Risk Factors — “Our industry is very competitive. Additionally, changes in technology could render our products obsolete” for more information.

The companies that compete with our ophthalmic segment include Allergan Pharmaceuticals, Inc., Novartis, Bausch & Lomb, Inc., Apotex and Sun Pharmaceuticals, among others. The ophthalmic segment competes primarily on the basis of price and service.

The companies that compete with our hospital drugs & injectables segment include both generic and name brand companies such as Hospira, Inc., Teva Pharmaceutical Industries, Pfizer, Sagent Pharmaceuticals, Novartis, Fresenius-Kabi, American Regent, Inc., Hikma and Bedford. The hospital drugs & injectables segment competes primarily on the basis of price.

Suppliers and Customers. No supplier represented 10% or more of our purchases in 2012 or 2011. In 2010, purchases from Massachusetts Biologic Laboratories (“MBL”) represented 14% of our total purchases. MBL was the sole supplier of Td vaccine for our former biologics & vaccines segment. Aside from MBL, no other suppliers represented 10% or more of our purchases in 2010.

We require a supply of quality raw materials and components to manufacture and package pharmaceutical products for ourselves and for third parties with which we have contracted. The principal components of our products are active and inactive pharmaceutical ingredients and certain packaging materials. Many of these components are available from only a single source and, in the case of many of our ANDAs and NDAs, only one supplier of raw materials has been identified. Because FDA approval of drugs requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of any new supplier would be required if active ingredients or such packaging materials were no longer available from the specified supplier. The qualification of a new supplier could delay our development and marketing efforts. If for any reason we are unable to obtain sufficient quantities of any of the raw materials or components required to produce and package our products, we may not be able to manufacture our products as planned. See Item 1A. Risk Factors – “Many of the raw materials and components used in our products come from a single source” for more information.

In 2012, 2011 and 2010, a high percentage of our sales were to the three large wholesale drug distributors noted below. These three large wholesale drug distributors account for a large portion of our gross sales, net revenues and accounts receivable in all our business segments except for contract services. The three distributors are:

AmerisourceBergen Corporation (“AmerisourceBergen”);
Cardinal Health, Inc. (“Cardinal”); and
McKesson Drug Company (“McKesson”).

On a combined basis, these three wholesale drug distributors accounted for approximately 58% of our total gross sales and 42% of our net revenue in 2012, and 73% of our gross accounts receivable as of December 31, 2012. The difference between gross sales and net revenue is that gross sales is calculated before allowances for chargebacks, rebates, promotions and product returns (See Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — “Critical Accounting Policies” – “Allowance for Chargebacks and Rebates” for more information).

The table below presents the percentages of our total gross sales, net revenue and gross trade accounts receivable attributed to each of these three wholesale drug distributors as of and for the years ended December 31, 2012, 2011

and 2010:

	2012						2011						2010					
	Gross		Net		Gross		Gross		Net		Gross		Gross		Net		Gross	
	Sales		Revenue		Accounts		Sales		Revenue		Sales		Sales		Revenue		Sales	
					Receivable													
AmerisourceBergen	19	%	14	%	29	%	23	%	23	%	29	%	24	%	17	%	32	%
Cardinal	23	%	17	%	30	%	27	%	25	%	34	%	25	%	17	%	31	%
McKesson	16	%	11	%	14	%	16	%	15	%	9	%	15	%	11	%	7	%
Combined Total	58	%	42	%	73	%	66	%	63	%	72	%	64	%	45	%	70	%

AmerisourceBergen, Cardinal and McKesson are key distributors of our products, as well as a broad range of health care products for many other companies. None of these distributors is an end user of our products. If sales to any one of these distributors were to diminish or cease, we believe that the end users of our products would likely find little difficulty obtaining our products either directly from us or from another distributor. However, the loss of one or more of these distributors, together with a delay or inability to secure an alternative distribution source for end users, could have a material negative impact on our revenue, business, financial condition and results of operations. We consider our business relationships with these three wholesalers to be in good standing and have fee for services contracts with each of them. A change in purchasing patterns, a decrease in inventory levels, an increase in returns of our products, delays in purchasing products and delays in payment for products by one or more of these distributors could have a material negative impact on our revenue, business, financial condition and results of operations. See Item 1A Risk factors – “We depend on a small number of distributors, the loss of any of which could have a material adverse effect” for more information.

Backorders. As of December 31, 2012, we had approximately \$0.8 million of products on backorder as compared to approximately \$2.9 million of backorders as of December 31, 2011. We anticipate filling all open backorders during 2013.

Government Regulation. Pharmaceutical manufacturers and distributors are subject to extensive regulation by government agencies, including the FDA, the Drug Enforcement Administration (“DEA”), the Federal Trade Commission (“FTC”) and other federal, state and local agencies. The Federal Food, Drug and Cosmetic Act (the “FDC Act”), the Controlled Substance Act and other federal statutes and regulations govern or influence the development, testing, manufacture, labeling, storage and promotion of products that we manufacture and market. The FDA inspects drug manufacturers and storage facilities to determine compliance with its current Good Manufacturing Practices (“cGMP”) regulations, non-compliance with which can result in fines, recall and seizure of products, total or partial suspension of production, refusal to approve NDAs and ANDAs and criminal prosecution. The FDA also has the authority to revoke approval of drug products.

FDA approval is required before any application drug product can be manufactured and marketed. New drugs require the application filing of an NDA, including clinical studies demonstrating the safety and efficacy of the drug. Generic drugs, which are equivalents of existing, off-patent brand name drugs, require the application filing of an ANDA. An ANDA does not, for the most part, require clinical studies since safety and efficacy have already been demonstrated by the product originator. However, the ANDA must, for example, provide data demonstrating the equivalency of the generic formulation in terms of bioavailability. The time required by the FDA to review and approve NDAs and ANDAs is variable and, to a large extent, beyond our control.

We are subject to periodic inspections by the FDA and the DEA. Throughout the five year period ended December 31, 2012, there have been no product interruptions associated with regulatory inspection or review activities. The most recent inspections conducted during January/February 2013 at our Somerset, New Jersey plant and August 2012 at our Decatur, Illinois plant, resulted in no significant observations.

Product Recalls. There were no recalls of any of our products during 2012, 2011 or 2010.

DEA Regulation. We also manufacture and distribute several controlled-drug substances, the distribution and handling of which are regulated by the DEA. Failure to comply with DEA regulations can result in fines or seizure of product. There were no DEA citations issued to us in 2012, 2011 or 2010.

Environment. We do not anticipate any material adverse effect from compliance with federal, state and local provisions that have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment.

Foreign Sales. During 2012, 2011 and 2010, approximately \$29.4 million, \$5.3 million, and \$1.1 million of our net revenue, respectively, was related to sales to customers in foreign countries. The 2012 sales figure includes \$16.7 million in sales generated by AIPL, our subsidiary in India, which exclusively sells product to customers in India and other unregulated world markets.

Seasonality and other Cyclical Sales Fluctuations. Most of our business segments do not experience significant seasonality. We do market certain allergy products that typically generate higher sales volume in the warmer months, but these products do not materially impact our overall sales trends. Additionally, we market various antidote products through our hospital drugs & injectables segment, the sales of which are largely timed to the expiration of existing stock held by our ongoing customers. In addition, late in 2012 we restarted the distribution of Td vaccines, which tends to generate higher sales in spring through fall.

Government Contracts. None of our business segments is generally subject to renegotiation of profits or termination of contracts at the election of the Federal government.

Available Information. We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission ("SEC"). Materials filed with the SEC can be read and copied at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet web site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. Our filings are available to the public at the website maintained by the SEC, <http://www.sec.gov>. We also make available, free of charge, through our web site at www.akorn.com, our reports on Forms 10-K, 10-Q, and 8-K, and amendments to those reports, as soon as reasonably practicable after they are filed with or furnished to the SEC. The information contained on our web site is not a part of this document.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. In addition to the other information included in this Annual Report on Form 10-K, you should carefully consider each of the risks described below before purchasing shares of our common stock. The risk factors set forth below are not the only risks that may affect our business. Our business could also be affected by additional risks not currently known to us or that we currently deem to be immaterial. If any of the following risks actually occur, our business, financial condition and results of operations could materially suffer. As a result, the trading price of our common stock could decline, and you may lose all or part of your investment.

Our growth depends on our ability to timely develop and successfully integrate new pharmaceutical products.

Our strategy for growth is dependent upon our ability to develop products that can be promoted through current marketing and distributions channels and, when appropriate, the enhancement of such marketing and distribution channels. We may fail to meet our anticipated time schedule for the filing of ANDAs and NDAs or may decide not to pursue ANDAs or NDAs that we have submitted or anticipate submitting. Our internal development of new pharmaceutical products is dependent upon the research and development capabilities of our personnel and our strategic business alliance infrastructure. There can be no assurance that our strategic business alliance partners or we will successfully develop new pharmaceutical products or, if developed, successfully integrate new products into our existing product lines. In addition, there can be no assurance that we will receive all necessary FDA approvals or that such approvals will not involve delays, which may adversely, affect the marketing and sale of our products. Our failure to develop new products or to receive FDA approval of ANDAs or NDAs could have a material adverse effect on our business, financial condition and results of operations.

Generic and off-patent pharmaceutical products are particularly susceptible to competition, substitution policies and reimbursement policies.

Our success depends, in part, on our ability to identify suitable branded pharmaceutical products to target for development of generic equivalents, determine or anticipate the dates when these branded pharmaceuticals are expected to come off patent, and time our product development activities accordingly so that we will be ready to manufacture and market our generic equivalent products at the most advantageous times. Generic pharmaceuticals must meet the same quality standards as branded pharmaceuticals, even though these equivalent pharmaceuticals are sold at prices that are significantly lower than branded pharmaceuticals. Generic substitution is regulated by the federal and state governments, as is reimbursement for generic drug dispensing. There can be no assurance that substitution will be permitted for newly approved generic drugs or that such products will be subject to government reimbursement. In addition, generic products developed by other third parties may render our generic products noncompetitive or obsolete, or may glut the market with competing products resulting in a reduction in sale price or market share for the generic products we sell. There can be no assurance that we will be able to consistently bring generic pharmaceutical products to market quickly and efficiently in the future. An increase in competition in the sale of generic pharmaceutical products or our failure to bring such products to market before our competitors could have a material adverse effect on our business, financial condition and results of operations.

Further, there is no proprietary protection for most of the branded pharmaceutical products that either we or other pharmaceutical companies sell. In addition, governmental and cost-containment pressures regarding the dispensing of generic equivalents will likely result in generic substitution and competition generally for our branded pharmaceutical products. We attempt to mitigate the effect of this substitution through, among other things, creation of strong brand-name recognition and product-line extensions for our branded pharmaceutical products, but there can be no assurance that we will be successful in these efforts.

We depend on a small number of distributors, the loss of any of which could have a material adverse effect.

A small number of large wholesale drug distributors account for a significant portion of our gross sales, net revenues and accounts receivable. The following three wholesalers –AmerisourceBergen, Cardinal and McKesson – accounted for approximately 58% of total gross sales and 42% of total net revenues in 2012, and 73% of gross trade receivables as of December 31, 2012. In addition to acting as distributors of our products, these three companies also distribute a broad range of health care products on behalf of many other companies. The loss of our relationship with one or more of these wholesalers, together with a delay or inability to secure an alternative distribution source for end users, could have a material adverse impact on our revenue and results of operations. A change in purchasing patterns or inventory levels, an increase in returns of our products, penalties assessed against us for failure to supply or failure to maintain service levels, delays in purchasing products and delays in payment for products by one or more of these distributors also could have a material adverse impact on our revenue, results of operations and cash flows.

Sales of our products may be adversely affected by the continuing consolidation of our customer base.

A significant proportion of our sales is made to relatively few retail drug chains, wholesalers, and managed care purchasing organizations. These customers are continuing to undergo significant consolidation. Such consolidation has provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face. Additionally, the emergence of large buying groups representing independent retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to extract price discounts on our products.

Our net sales and quarterly growth comparisons may also be affected by fluctuations in the buying patterns of retail chains, major distributors and other trade buyers, whether resulting from seasonality, pricing, wholesaler buying decisions or other factors. In addition, since such a significant portion of our revenues is derived from relatively few customers, any financial difficulties experienced by a single customer, or any delay in receiving payments from a single customer, could have a material adverse effect on our business, results of operations and financial condition.

We are subject to extensive government regulations that increase our costs and could subject us to fines, prevent us from selling our products or prevent us from operating our facilities.

Federal and state government agencies regulate virtually all aspects of our business. The development, testing, manufacturing, processing, quality, safety, efficacy, packaging, labeling, record keeping, distribution, storage and advertising of our products, and disposal of waste products arising from such activities, are subject to regulation by the FDA, DEA, FTC, the Consumer Product Safety Commission, the Occupational Safety and Health Administration and the Environmental Protection Agency. Similar state and local agencies also have jurisdiction over these activities. Noncompliance with applicable United States and/or state or local regulatory requirements can result in fines, injunctions, penalties, mandatory recalls or seizures, suspensions of production, recommendations by the FDA against governmental contracts and criminal prosecution. Any of these could have a material adverse effect on our business, financial condition and results of operations. New, modified and additional regulations, statutes or legal interpretation, if any, could, among other things, require changes to manufacturing methods, expanded or different labeling, recall, replacement or discontinuation of certain products, additional record keeping procedures and expanded documentation of the properties of certain products and additional scientific substantiation. Such changes or new legislation could have a material adverse effect on our business, financial condition and results of operations.

We are subject to regulation by the FDA. All pharmaceutical manufacturers, including us, are subject to regulation by the FDA under the authority of the FDC Act. Under the FDC Act, the federal government has extensive administrative and judicial enforcement authority over the activities of finished drug product manufacturers to ensure compliance with FDA regulations. This authority includes, but is not limited to, the authority to initiate judicial action to seize unapproved or non-complying products, to enjoin non-complying activities, to halt manufacturing operations that are not in compliance with cGMP, to recall products, to seek civil and monetary penalties and to criminally prosecute violators. Other enforcement activities include refusal to approve product applications, withdrawal of previously approved applications or prohibition on marketing of certain grandfathered products. Any such enforcement activities, especially the restriction or prohibition on sales of products we market or the halting of our manufacturing operations, could have a material adverse effect on our business, financial condition and results of operations. In addition, the FDA or other government agencies having regulatory authority over pharmaceutical products may request us to voluntarily or involuntarily conduct product recalls due to disputed labeling claims, manufacturing issues, quality defects or for other reasons. Restriction or prohibition on sales, halting of manufacturing operations, recalls of our pharmaceutical products or other enforcement actions could have a material adverse effect on our business, financial condition and results of operations. Further, such actions, in certain circumstances, may constitute an event of default under the terms of our various financing arrangements.

We must obtain approval from the FDA for each pharmaceutical product that we market. The FDA approval process is typically lengthy, and approval is never certain. Our new products could take a significantly longer time than we expect to gain regulatory approval and may never gain approval. Even if the FDA or another regulatory agency approves a product, the approval may limit the indicated uses for a product, may otherwise limit our ability to promote, sell and distribute a product or may require post-marketing studies or impose other post-marketing obligations, which could have a material adverse effect on marketability and profitability of the new products.

We and our third-party manufacturers are subject to periodic inspection by the FDA to assure regulatory compliance regarding the manufacturing, distribution, and promotion of pharmaceutical products. The FDA imposes stringent mandatory requirements on the manufacture and distribution of pharmaceutical products to ensure their safety and efficacy. The FDA also regulates drug labeling and the advertising of prescription drugs. A finding by a governmental agency or court that we are not in compliance with FDA requirements could have a material adverse effect on our business, financial condition and results of operations.

If the FDA changes its regulatory position, it could force us to delay or suspend our manufacturing, distribution or sales of certain products. FDA interpretations of existing or pending regulations and standards may change over time with the advancement of associated technologies, industry trends, and/or prevailing scientific rationale. If the FDA changes its regulatory position due to such factors, it could result in delay or suspension of the manufacturing, distribution or sales of certain of our products. In addition, modifications or enhancements of approved products are in many circumstances subject to additional FDA approvals which may or may not be granted and which may be subject to a lengthy application process. Any change in the FDA's enforcement policy or any decision by the FDA to require an approved NDA or ANDA for one of our products not currently subject to the approved NDA or ANDA requirements or any delay in the FDA approving an NDA or ANDA for one of our products could have a material adverse effect on our business, financial condition and results of operations.

We are subject to extensive DEA regulation, which could result in our being fined or otherwise penalized. We also manufacture and sell drugs which are "controlled substances" as defined in the federal Controlled Substances Act and similar state laws, which impose, among other things, certain licensing, security and record keeping requirements administered by the DEA and similar state agencies, as well as quotas for the manufacture, purchase and sale of controlled substances. The DEA could limit or reduce the amount of controlled substances which we are permitted to manufacture and market or issue fines and penalties against us for purported non-compliance with DEA regulations, which could have a material adverse effect on our business, financial condition and results of operations.

Recently enacted and future healthcare law and policy changes may adversely affect our business.

In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. This health care reform legislation is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. As examples, the current legislation include measures that would (i) significantly increase Medicaid rebates through both the expansion of the program and significant increases in rebates; (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts; (iii) extend the Medicaid rebate rate to a significant portion of Managed Medicaid enrollees; (iv) assess a 50% rebate on Medicaid Part D spending in the coverage gap for branded and authorized generic prescription drugs; and (v) levy a significant excise tax on the industry to fund the healthcare reform.

While the aforementioned healthcare reform legislation may increase the number of patients who have insurance coverage for our products, such insurance mandate does not commence until January 2014, and the healthcare reform legislation also restructures payments to Medicare managed care plans and reduces reimbursements to many third-party payers. Accordingly, the timing on the insurance mandate, the change in the Medicaid rebate levels, the additional fees imposed on us to the extent we market branded drugs, other compliance obligations, and the reduced reimbursement levels to institutional customers may result in a loss of revenue and could adversely affect our business. While we will not know the full effects of this health care reform legislation until applicable federal and state agencies issue regulations or guidance under the new law and the new law has been fully implemented, it appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and to increase our regulatory burdens and operating costs.

The sales of our products depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers, health maintenance organizations including pharmacy benefit managers ("PBMs") and other health care-related organizations. We expect both federal and state governments in the U.S. and foreign governments to continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of healthcare while expanding individual healthcare benefits.

Existing regulations that affect the price of pharmaceutical and other medical products may also change before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for any product we develop in the future. In addition, PBMs and other third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products. Our products may not be considered cost effective, or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investments. All of these may harm our ability to market our products and generate profits.

Our growth and profitability is dependent on our ability to successfully utilize our existing cash reserves and operating cash flows to complete strategic acquisitions or to identify, acquire or develop, new products to market and distribute.

We continue to seek growth opportunities, either by completing strategic acquisitions or by developing and introducing new pharmaceutical products. Continued improvement in our financial performance is dependent on our ability to introduce new products on an ongoing basis, whether developed internally or by third party partners, or acquired from other companies. Any delays or an inability to successfully identify suitable acquisition targets, or acquire or develop, and market and distribute new products, or acquisition or development of new products that do not yield sufficient margins, may result in adverse financial consequences to our business.

We may not achieve the anticipated benefits from our acquisitions and may face difficulties in integrating them, which could adversely affect our operating results, increase costs and place a significant strain on our management.

If we fail to manage the integration of our domestic and international acquisitions and achieve expected synergies, our business could be disrupted and our operating results could be negatively impacted. The operating success of both our domestic and international acquisitions involves the integration of products, processes and personnel into our existing model. In addition, the integration of international acquisitions requires both establishing and training a local management team and overseeing the operations remotely, and can involve cultural, monetary and systems challenges. Our personnel, systems, procedures, or controls may not be adequate to support both our ongoing business and the acquired businesses. If our newly-acquired businesses require a disproportionate share of our resources and management's attention, our overall financial results may suffer.

We have entered into several strategic business alliances that may not result in marketable products.

We have entered into several strategic business alliances that have been formed to supply us with low cost finished dosage form products. We have entered into various purchase and supply agreements and license agreements that are all designed to provide finished dosage form products that can be marketed through our distribution pipeline. There can be no assurance that these agreements will result in additional FDA-approved ANDAs or NDAs, or that we will be able to market any such additional products at a profit. In addition, any clinical trial expenses that we may incur in connection with these strategic business alliances may negatively impact our financial results.

Failure to obtain regulatory certification of our manufacturing plant in India for production of pharmaceutical products for export to the United States, as well as other regulated world markets, could impair our ability to grow and adversely affect our business, financial condition and results of operations.

We operate a manufacturing campus in Paonta Sahib, India, which we acquired through a business combination in 2012. The manufacturing units within this campus were built to the standards of regulated markets, including the United States, but they are not currently approved by the FDA to manufacture products for export to the United States. It is our intention to obtain certification from the FDA and other regulatory authorities to allow this facility to manufacture products for export to the United States and other regulated world markets. Obtaining such certification in a timely manner is critical to our sustaining our growth. An inability to obtain or maintain such certification could restrict our ability to achieve our growth objectives, which would adversely affect our business, financial condition and results of operations.

Further, our operations in India may be adversely affected by general economic conditions and economic and fiscal policy in India, including changes in exchange rates and controls, interest rates and taxation policies; any reversal of India's recent economic liberalization and deregulation policies; as well as social stability and political, economic or diplomatic developments affecting India in the future. In addition, India is known to have experienced governmental corruption to some degree and, in some circumstances, anti-bribery laws may conflict with some local customs and practices. As a result of our policy to comply with the U.S. Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws.

We may not generate cash flow sufficient to pay interest on our outstanding convertible senior notes or repurchase the notes upon a fundamental change.

In June 2011, we issued \$120.0 million aggregate principal amount of 3.50% Convertible Senior Notes due 2016 (the "Notes"). The Notes require us to make semi-annual coupon interest payments of \$2.1 million on June 1 and December 1 of each year until the Notes mature on June 1, 2016. If we do not generate sufficient operating cash flows to fund

these payments or obtain additional funding from external sources at acceptable terms, we may not have sufficient funds to satisfy our interest payment obligations when those obligations are due which would place us in default under the Indenture (as defined below). If a fundamental change (as defined in the Indenture) occurs, holders of the Notes may require us to repurchase their Notes. If we fail to repurchase the Notes when required, we will be in default under the Indenture.

Availability under our Credit Agreement may be restricted if we fail to meet our covenant requirements.

We are party to a revolving Credit Agreement with Bank of America, N.A., (the “Agent”) and other financial institutions (collectively with the Agent, the “BoA Lenders”) through which we obtained a \$20.0 million revolving line of credit (the “BoA Credit Facility”), which includes a \$2.0 million letter of credit facility. We may request expansion of the BoA Credit Facility from time to time in increments of at least \$5.0 million up to a maximum commitment of \$35.0 million, so long as no default or event of default has occurred and is continuing. As of December 31, 2012, no amounts or letters of credit were outstanding under the BoA Credit Facility.

Availability under the BoA Credit Facility is equal to the lesser of (a) \$20.0 million reduced by outstanding letter of credit obligations or (b) the amount of a Borrowing Base (as defined in the BoA Credit Agreement) determined by reference to the value of the borrowers' eligible accounts receivable, eligible inventory and fixed assets as of the closing date and the end of each calendar month thereafter. The BoA Credit Agreement contains representations and warranties, and affirmative and negative covenants customary for financings of this type, including, but not limited to, limitations on: distributions; additional borrowings, liens and guarantees; additional investments and asset sales; and fundamental changes to corporate structure or organization documents. The financial covenants require the Borrowers to maintain a fixed charge coverage ratio of at least 1.1 to 1.0 during any period commencing on the date that an event of default occurs or availability under the BoA Credit Agreement is less than 15% of the aggregate BoA Lenders' commitments under the BoA Credit Agreement. In addition, we must periodically provide to the Agent financial statements, compliance certificates and budget projections. Should we fail to maintain compliance with these covenants, availability under the Credit Agreement could be restricted which would negatively impact our liquidity and may require us to seek additional sources of capital in order to maintain our continuing operations or to fund growth opportunities.

We may need to obtain additional capital to continue to grow our business.

We may require additional funds in order to materially grow our business. We require substantial liquidity to implement long-term cost savings and productivity improvement plans, continue capital spending to improve our manufacturing plants to increase capacity and support product development programs, meet scheduled term debt and lease maturities, and run our normal business operations. We may seek additional funds through public and private financing, including equity and debt offerings. However, adequate funds through the financial markets or from other sources may not be available to us when needed or on favorable terms. Without sufficient additional capital funding, we may be required to delay, scale back or abandon some or all of our product development, manufacturing, acquisition, licensing and marketing initiatives, or operations. Further, such additional financing, if obtained, may require the granting of rights, preferences or privileges senior to those of the common stock and result in substantial dilution of the existing ownership interests of the common stockholders and could include covenants and restrictions that limit our ability to operate or expand our business in a manner that we deem to be in our best interest.

Our industry is very competitive. Additionally, changes in technology could render our products obsolete.

We face significant competition from other pharmaceutical companies, including major pharmaceutical companies with financial resources substantially greater than ours, in developing, acquiring, manufacturing and marketing pharmaceutical products. The selling prices of pharmaceutical products typically decline as competition increases. Further, other products now in use, under development or acquired by other pharmaceutical companies, may be more effective or offered at lower prices than our current or future products. The industry is characterized by rapid technological change that may render our products obsolete, and competitors may develop their products more rapidly than we can. Competitors may also be able to complete the regulatory process sooner, and therefore, may begin to market their products in advance of ours. We believe that competition in sales of our products is based primarily on price, service and technical capabilities. There can be no assurance that: (i) we will be able to develop or acquire commercially attractive pharmaceutical products; (ii) additional competitors will not enter the market; (iii) our existing products will not be rendered obsolete by the introduction or switch to generic or competing products; or (iv) competition from other pharmaceutical companies will not have a material adverse effect on our business, financial condition and results of operations.

Unstable market and economic conditions may have serious adverse consequences on our business.

Our general business strategy may be adversely affected by general economic conditions, a volatile business environment and continued unpredictable and unstable market conditions. If equity and credit market conditions prove

unfavorable, we may have difficulty obtaining desired debt or equity financing, or obtaining such financing may be more difficult, more costly, and more dilutive. A prolonged or profound economic downturn could result in adverse changes to product reimbursement, pricing or sales levels, which would harm our operating results. There is a risk that one or more of our current service providers, manufacturers and other partners may not survive difficult economic times, which would directly affect our ability to attain our operating goals on schedule and on budget. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. Moreover, our stock price may decline due to the volatility of the stock market and general economic conditions.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, timely file our periodic reports, maintain our reporting status or prevent fraud.

In connection with the audit of our financial statements as of and for the year ended December 31, 2012, we concluded there is a material weakness in internal control over financial reporting related to deficiencies in the financial statement close process. Under standards established by the Public Company Oversight Board, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected or corrected on a timely basis.

We are working to remediate the material weakness. We have begun taking steps and plan to take additional measures to remediate the underlying causes of the material weakness, primarily through the continued development and implementation of formal policies, improved processes and documented procedures, as well as the hiring of additional finance personnel. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. Although we plan to complete this remediation as quickly as possible, we cannot at this time estimate how long it will take, and our initiatives may not prove to be successful in remediating this material weakness. If our remedial measures are insufficient to address the material weakness, or if additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results.

Our management or our independent registered public accounting firm may identify other material weaknesses in our internal control over financial reporting in the future. The existence of internal control material weaknesses may result in current and potential stockholders losing confidence in our financial reporting, which could harm our business, the market price of our common stock, and our ability to retain our current, or obtain new, alliance and collaboration agreements' partners.

In addition, the existence of material weaknesses in our internal control over financial reporting may affect our ability to timely file periodic reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The inability to timely file periodic reports could result in the SEC revoking the registration of our common stock, which would prohibit us from listing or having our stock quoted on any public market. This would have an adverse effect on our business and stock price by limiting the publicly available information regarding us and greatly reducing the ability of our stockholders to sell or trade our common stock.

We may become involved in legal proceedings from time to time which may result in losses, damage to our business and reputation and place a strain on our internal resources.

In the ordinary course of our business, we may be involved in legal proceedings with both private parties and certain government agencies, including FDA. Litigation may result in verdicts against us, which may include significant monetary awards, judgments that certain of our intellectual property rights are invalid or unenforceable and injunctions preventing the manufacture, marketing and sale of our products. If disputes are resolved unfavorably, our business, financial condition and results of operations may be adversely affected.

Any litigation, whether or not successful, may damage our reputation. Furthermore, we are likely to incur substantial expense in defending these lawsuits and the time demands of such lawsuits could divert management's attention from ongoing business concerns and interfere with our normal operations.

In the normal course of business, we periodically enter into employment agreements, legal settlements, and other agreements which incorporate indemnification provisions. We maintain insurance coverage which we believe will

effectively mitigate our obligations under these indemnification provisions. However, should our obligation under an indemnification provision exceed our coverage or should coverage be denied, it could have a material adverse effect on our business, financial position and results of operations.

Third parties may claim that we infringe their proprietary rights and may prevent or delay us from manufacturing and selling some of our new 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. Pharmaceutical companies with patented brand products frequently sue companies that file applications to produce generic equivalents of their patented brand products for alleged patent infringement or other violations of intellectual property rights, which may delay or prevent the entry of such generic products into the market. Generally, a generic drug may not be marketed until the applicable patent(s) on the brand name drug expire or are held to be not infringed, invalid, or unenforceable. When we or our development partners submit an ANDA to the FDA for approval of a generic drug, we and/or our development partners must certify either (1) that there is no patent listed by the FDA as covering the relevant brand product, (2) that any patent listed as covering the brand product has expired, (3) that the patent listed as covering the brand product will expire prior to the marketing of the generic product, in which case the ANDA will not be finally approved by the FDA until the expiration of such patent, or (4) that any patent listed as covering the brand drug is invalid or will not be infringed by the manufacture, sale or use of the generic product for which the ANDA is submitted.

Under any circumstance in which an act of infringement is alleged to occur, there is a risk that a brand pharmaceutical company may sue us for alleged patent infringement or other violations of intellectual property rights. Also, competing pharmaceutical companies may file lawsuits against us or our strategic partners alleging patent infringement or may file declaratory judgment actions of non-infringement, invalidity, or unenforceability against us relating to our own patents. We have been sued for patent infringement related to several of our current ANDA filings and we anticipate that we will be sued once we file ANDAs for other products in our pipeline. Such litigation is often costly and time-consuming and could result in a substantial delay in, or prevent, the introduction and/or marketing of our products, which could have a material adverse effect on our business, financial condition and results of operations.

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.

Our patents and proprietary rights may not adequately protect our products and processes.

The patent and proprietary rights position of competitors in the pharmaceutical industry generally is highly uncertain, involves complex legal and factual questions, and is the subject of much litigation. There can be no assurance that any patent applications or other proprietary rights, including licensed rights, relating to our potential products or processes will result in patents being issued or other proprietary rights secured, or that the resulting patents or proprietary rights, if any, will provide protection against competitors who: (i) successfully challenge our patents or proprietary rights; (ii) obtain patents or proprietary rights that may have an adverse effect on our ability to conduct business; or (iii) are able to circumvent our patent or proprietary rights position. It is possible that other parties have conducted or are conducting research and could make discoveries of pharmaceutical formulations or processes that would precede any discoveries made by us, which could prevent us from obtaining patent or other protection for these discoveries or marketing products developed therefrom. Consequently, there can be no assurance that others will not independently develop pharmaceutical products similar to or rendering obsolete those that we are planning to develop, or duplicate any of our products. Our inability to obtain patents for, or other proprietary rights in, our products and processes or the ability of competitors to circumvent or obsolete our patents or proprietary rights could have a material adverse effect on our business, financial condition and results of operations.

Further, virtually all the drug products that we market are generics, with essentially no patent or proprietary rights attached. While this fact allowed us the opportunity to develop or to purchase and obtain FDA approval to market our generic products, it also allows competing drug companies to do the same. Should multiple additional drug companies choose to develop and market the same generic products that we actively market, our profit margins could decline, which would have a material adverse effect on our business, financial condition and results of operations.

The Chairman of our Board of Directors is subject to conflicts of interest, and through his stock ownership and position as Chairman has substantial influence over our business strategies and policies.

John N. Kapoor, Ph.D., the Chairman of our Board of Directors and a principal shareholder, is the President of EJ Financial Enterprises, Inc. ("EJ Financial"), a health care consulting investment company. EJ Financial is involved in the management of health care companies in various fields, and Dr. Kapoor is involved in various capacities with the management and operation of these companies. The John N. Kapoor Trust dated 9/20/89 (the "Kapoor Trust"), the beneficiary and sole trustee of which is Dr. Kapoor, is a principal shareholder of each of these companies. As a result, Dr. Kapoor does not devote his full time to our business. Although such companies do not currently compete directly with us, certain companies with which EJ Financial is involved are in the pharmaceutical business. Discoveries made by one or more of these companies could render our products less competitive or obsolete. Potential conflicts of interest could have a material adverse effect on our business, financial condition and results of operations.

As of December 31, 2012, Dr. Kapoor beneficially owns approximately 31% of our common stock. As a result, Dr. Kapoor can strongly influence, and potentially control, the outcome of our corporate actions, including the election of our directors and transactions involving a change of control. This concentrated control limits other shareholders' ability to influence corporate matters and, as a result, the Company may take actions that other shareholders do not view as beneficial. Further, decisions made by Dr. Kapoor with respect to his and his related parties' ownership or trading of our common stock could have an adverse effect on the market value of our common stock and an adverse effect on our business.

We depend on key executive officers and must continue to attract and retain key personnel in order to compete successfully.

Our success will depend, in part, on our ability to attract and retain key executive officers. The loss of one or more of our key executive officers could have a material adverse effect on our business, financial condition and results of operations.

Further, our performance depends, to a large extent, on the continued service of our key research and development personnel, other technical employees, managers and sales personnel and our ability to continue to attract and retain such personnel. Competition for such personnel is intense, particularly for highly motivated and experienced research and development and other technical personnel. We are facing increasing competition from companies with greater financial resources for such personnel. There can be no assurance that we will be able to attract and retain sufficient numbers of highly skilled personnel in the future, and the inability to do so could have a material adverse effect on our business, and on our results of operations and financial condition.

We may implement product recalls and could be exposed to significant product liability claims; we may have to pay significant amounts to those harmed and may suffer from adverse publicity as a result.

The manufacturing and marketing of pharmaceuticals involves an inherent risk that our products, or items within our products, may prove to be defective and cause a health risk. In that event, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. We have recalled products in the past and, based on this experience, believe that the occurrence of a recall could result in significant costs to us, potential disruptions in the supply of our products to our customers and adverse publicity, all of which could harm our ability to market our products. For example, we were prompted to initiate one product recall of our Cyanide Antidote Kit during 2008 due to recall notification by Becton, Dickinson and Company of their 60ml syringe. Our recall of the Cyanide Antidote Kit was monitored by FDA and has resulted in no patient impact and no shortage of product supply to the marketplace. There were no product recalls during 2010, 2011 or 2012.

Although we are not currently subject to any material product liability proceedings, we may incur material liabilities relating to product liability claims in the future. Even meritless claims could subject us to adverse publicity, hinder us from securing insurance coverage in the future and require us to incur significant legal fees and divert the attention of the key employees from running our business. Successful product liability claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We currently have product liability insurance in the amount of \$10,000,000 for aggregate annual claims with a \$100,000 deductible per incident and a \$500,000 aggregate annual deductible. However, there can be no assurance that such insurance coverage will be sufficient to fully cover potential claims. Additionally, there can be no assurance that adequate insurance coverage will be available in the future at acceptable costs, if at all, or that a product liability claim would not have a material adverse effect on our business, financial condition and results of operations.

FDA may require us to stop marketing certain grandfathered drugs.

We market several generic prescription products which do not have formal FDA approvals because these products have been grandfathered. These products are non-application drugs that are manufactured and marketed without FDA-issued ANDAs or NDAs on the basis of their having been marketed by industry prior to the 1962 Amendment of the FDC Act. We marketed eight such products during 2012, generating net sales revenue of \$20.8 million. Following enactment of the FDC Act in 1938, drugs on the market prior to that time were exempted or “grandfathered” and manufacturers were not required to file an NDA. Recently, FDA has increased its efforts to force companies to file and seek FDA approval for grandfathered products. Efforts have included issuing notices to companies currently manufacturing these products to cease its distribution of said products.

On October 2, 2012, we received a warning letter from FDA citing that we were manufacturing Pilocarpine Hydrochloride Ophthalmic Solution (“PHOS”), a long grandfathered drug, without an approved NDA. We fully cooperated with the FDA and discontinued selling PHOS. No enforcement action was initiated and no fines were assessed by FDA against us and the loss of revenue associated with the discontinuation of PHOS is expected to be insignificant. Further, in the second quarter of 2012, we filed an ANDA for PHOS, which has been granted expedited

review.

If FDA issues additional warning letters with respect one or more of our grandfathered products, we may be forced to discontinue marketing the affected products, which could have an adverse effect on our revenues and results of operations.

The FDA may authorize sales of some prescription pharmaceuticals on a non-prescription basis, which would reduce the profitability of our prescription products.

From time to time, the FDA elects to permit sales of some pharmaceuticals currently sold on a prescription basis, without a prescription. FDA approval of the sale of our products without a prescription would reduce demand for our competing prescription products and, accordingly, reduce our profits.

Our revenues depend on sale of products manufactured by third parties, which we cannot control.

We rely on external third parties to manufacture certain of the products we sell. Currently, this risk is limited to several of our products. However, we expect this risk to become more significant as we receive approvals for new products to be manufactured through our strategic partnerships and as we seek additional growth opportunities beyond the capacity and capabilities of our current manufacturing facilities. If we are unable to obtain or retain third-party manufacturers for these products on commercially acceptable terms, we may not be able to distribute such products as planned. Further, no assurance can be given that the manufacturers we use will be able to provide us with sufficient quantities of our products to meet our needs or that the products supplied to us will meet our specifications. Any delays or difficulties with third-party manufacturers could adversely affect the marketing and distribution of certain of our products, which could have a material adverse effect on our business, financial condition and results of operations.

Many of the raw materials and components used in our products come from a single source.

We require a supply of quality raw materials and components to manufacture and package pharmaceutical products for ourselves and for third parties with which we have contracted. Many of the raw materials and components used in our products come from a single source and interruptions in the supply of these raw materials and components could disrupt our manufacturing of specific products and cause our sales and profitability to decline. Further, in the case of many of our ANDAs and NDAs, only one supplier of raw materials has been identified. Because FDA approval of drugs requires manufacturers to specify their proposed suppliers of active pharmaceutical ingredients and certain packaging materials in their applications, FDA approval of any new supplier would be required if active ingredients or such packaging materials were no longer available from the specified supplier. The qualification of a new supplier could delay our development and marketing efforts. If for any reason we are unable to obtain sufficient quantities of any of the raw materials or components required to produce and package our products, we may not be able to manufacture our products as planned, which could have a material adverse effect on our business, financial condition and results of operations.

We could experience business interruptions at our manufacturing facilities, which may have a material adverse effect on our business, financial position and results of operations.

We manufacture drug products at one international and two domestic manufacturing facilities. Any one or more of these facilities may be forced to shut down or may be unable to operate at full capacity as a result of hurricanes, tornadoes, earthquakes, storms and other extreme weather events as well as strikes, war, violent upheavals, terrorist acts and other force majeure events. For example, our manufacturing plant in Somerset, New Jersey was shut down for approximately two weeks in October/November 2012 as a result of power outages and related business disruptions caused by Superstorm Sandy. A significant disruption at any of these facilities, even on a short-term basis, could impair our ability to produce and ship drug products to the market on a timely basis, which may have a material adverse effect on our business, financial position and results of operations.

The testing required for the regulatory approval of our products is conducted by independent third parties. Any failure by any of these third parties to perform this testing properly and in a timely manner may have an adverse effect upon our ability to obtain regulatory approvals.

Our applications for the regulatory approval of our products incorporate the results of testing and other information that is conducted or gathered by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, contract research organizations or independent research facilities). Our ability to obtain regulatory approval of the products being tested is dependent upon the quality of the work performed by these third parties, the quality of the third parties' facilities, and the accuracy of the information provided by third parties. We have little or no control over any of these factors. If this testing is not performed properly, our ability to obtain regulatory approvals

could be restricted or delayed.

We may be subject to disruptions or failures in our information technology systems and network infrastructures that could have a material adverse effect on our business.

We rely on the efficient and uninterrupted operation of complex information technology systems and network infrastructures to operate our business. We also hold data in various data center facilities upon which our business depends. A disruption, infiltration or failure of our information technology systems or any of our data centers as a result of software or hardware malfunctions, system implementations or upgrades, computer viruses, third-party security breaches, employee error, theft or misuse, malfeasance, power disruptions, natural disasters or accidents could cause breaches of data security, loss of intellectual property and critical data and the release and misappropriation of sensitive competitive information. Any of these events could result in the loss of key information, impair our production and supply chain processes, harm our competitive position, cause us to incur significant costs to remedy any damages and ultimately materially and adversely affect our business, results of operations and financial condition. While we have implemented a number of protective measures, such measures may not be adequate or implemented properly to prevent or fully address the adverse effect of such events.

Failure to comply with the U.S. Foreign Corrupt Practices Act could subject us to, among other things, penalties and legal expenses that could harm our reputation and have a material adverse effect on our business, financial condition and operating results.

Our U.S. operations are currently subject to the FCPA. We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of “off books” slush funds from which such improper payments can be made. If our employees, third-party sales representatives or other agents are found to have engaged in such practices, we could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, including further changes or enhancements to our procedures, policies and controls, as well as potential personnel changes and disciplinary actions.

Any failure to comply with the complex reporting and payment obligations under Medicare, Medicaid and other government programs may result in litigation or sanctions.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, marketing and pricing laws. We are also subject to Medicaid and other government reporting and payment obligations that are highly complex and somewhat ambiguous. Violations of these laws and reporting obligations are punishable by criminal and/or civil sanctions and exclusion from participation in federal and state healthcare programs such as Medicare and Medicaid. The recent healthcare reform legislation made several changes to the federal anti-kickback statute, false claims laws, and health care fraud statute such as increasing penalties and making it easier for the government to bring sanctions against pharmaceutical companies. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and negatively impact our financial results. Further, if there is a change 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, financial position and results of operations.

The requirements of being a public company may strain our resources and distract management.

As a public company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”). These requirements are extensive. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight is required. This may divert management’s attention from other business concerns, which could have a material adverse effect on our business, financial condition and results of operations.

Exercise of warrants and options, or issuance of shares pursuant to our convertible debt, may have a substantial dilutive effect on our common stock.

If the price per share of our common stock at the time of exercise or conversion of any warrants or stock options is in excess of the various exercise or conversion prices of such convertible securities, exercise or conversion of such convertible securities would have a dilutive effect on our common stock. As of December 31, 2012, holders of our

outstanding warrants and options would receive 16,919,342 shares of our common stock at a weighted average exercise price of \$2.91 per share. Any additional financing that we secure likely will require the granting of rights, preferences or privileges senior to those of our common stock which may result in substantial dilution of the existing ownership interests of our common shareholders.

Our earnings per share will be diluted if the average closing price of our common stock exceeds the conversion price (currently \$8.76 per share) on our convertible Notes. In addition, the Notes become convertible if the closing trading price of our common stock exceeds 130% of the Conversion Price for 20 of the last 30 trading days of any calendar quarter through the remaining term of the Notes. If the Notes become convertible and are surrendered for conversion, we have the option of satisfying all or a portion of our obligation in shares of our common stock, which could result in substantial dilution of the existing ownership interests of our common shareholders.

We may issue preferred stock and the terms of such preferred stock may reduce the market value of our common stock.

We are authorized to issue up to a total of 5,000,000 shares of preferred stock in one or more series. Our board of directors may authorize issuance of additional shares of preferred stock and the terms of such preferred stock without further action by holders of our common stock. If we issue additional shares of preferred stock, it could affect the rights or reduce the market value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with or sell our assets to a third party. These terms may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, and sinking fund provisions. We continue to seek capital for the growth of our business, and this additional capital may be raised through the issuance of additional preferred stock.

We experience significant quarterly fluctuation of our results of operations, which may increase the volatility of our stock price.

Our results of operations may vary from quarter to quarter due to a variety of factors including, but not limited to, the timing of the development and marketing of new pharmaceutical products, the failure to develop such products, delays in obtaining government approvals, including FDA approval of NDAs or ANDAs for our products, expenditures to comply with governmental requirements for manufacturing facilities, expenditures incurred to acquire and promote pharmaceutical products, changes in our customer base, a customer's termination of a substantial account, the availability and cost of raw materials, interruptions in supply by third-party manufacturers, seasonal or cyclical fluctuations in the sales of certain of our products, the introduction of new products or technological innovations by our competitors, loss of key personnel, changes in the mix of products sold by us, changes in sales and marketing expenditures, competitive pricing pressures, expenditures incurred to pursue or contest pending or threatened legal action and our ability to meet our financial covenants. There can be no assurance that we will be successful in avoiding losses in any future period. Such fluctuations may result in volatility in the price of our common stock.

Further, concentrated ownership of our common stock creates a risk of sudden changes in our share price. As such, the sale by any of our large shareholders of a significant portion of that shareholder's holdings could have a material adverse effect on the market price of our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We have two company-owned facilities in Decatur, Illinois. The Wyckles Road facility, which consists of 76,000 square feet of building space located on 15 acres of land, is used for packaging, warehousing, distribution, and office space. The Grand Avenue facility is a 65,000 square-foot manufacturing facility. Our Decatur facilities support our ophthalmic, hospital drugs & injectables, and contract services segments.

Our wholly-owned subsidiary, Akorn (New Jersey) Inc. leases a 50,000 square-foot facility in Somerset, New Jersey pursuant to a seven-year lease agreement that commenced on August 1, 2010. This lease allows us the option to renew for up to four additional 5-year periods beyond the initial expiration date of July 31, 2017. The Somerset facility is used for drug manufacturing, research and development and administrative activities related to our ophthalmic and hospital drugs & injectables segments.

Our current space in Decatur is considered adequate to accommodate our current manufacturing needs, and at Somerset we have expanded our manufacturing space and continue to make capital improvements to accommodate both current demand and anticipated future growth opportunities.

Our corporate headquarters and administrative offices consist of 34,000 square feet of leased space in an office building in Lake Forest, Illinois. We maintain a leased space in Gurnee, Illinois, consisting of 74,000 square feet, to accommodate our product warehousing and distribution needs. Both the Lake Forest lease and the Gurnee lease extend through March 2018. We are in the process of relocating our R&D operations to a 19,000-square foot leased facility in Vernon Hills, Illinois pursuant to an 89-month lease expiring April 30, 2020. We anticipate moving into this new facility in March 2013 and vacating our previous R&D facility in Skokie, Illinois shortly thereafter. The lease on our Skokie, Illinois R&D facility has been shortened by two years and will now expire on January 31, 2014. Our subsidiary, AVR, maintains their corporate offices in a 3,200-square foot leased facility in Ann Arbor, Michigan.

Our wholly-owned subsidiary, AIPL, owns and operates approximately 245,000 square feet of pharmaceutical manufacturing, warehousing and distribution facilities situated on approximately 14 acres of land in Paonta Sahib, Himachal Pradesh, India. This facility manufactures drugs primarily for contract customers in India and for export to various unregulated world markets.

Item 3. Legal Proceedings.

On September 12, 2012, Fera Pharmaceuticals, LLC (“Fera”) filed a civil complaint against the Company and certain individual defendants (together, the “Defendants”) in the Supreme Court of New York (the “Fera lawsuit”). The complaint alleges, among other things, breach of manufacturing and confidentiality agreements and misappropriation of the plaintiff’s trade secrets. On October 15, 2012, the case was removed to the Federal District Court for the Southern District of New York. Fera filed an amended complaint on December 21, 2012. The Defendants filed a motion to dismiss portions of the amended complaint on January 25, 2013. The Company intends to vigorously defend these allegations. However, no assurance may be given regarding the ultimate outcome of this lawsuit.

In April 2012, Allergan Sales (“Allergan”) filed a lawsuit alleging patent infringement claims against the Company relating to the 0.4% ketorolac tromethamine formulation. Allergan seeks unspecified monetary damages in this case. The Company has asserted invalidity and non-infringement. The Company intends to vigorously defend these

allegations. However, no assurance may be given regarding the ultimate outcome of this lawsuit.

We are party to legal proceedings and potential claims arising in the ordinary course of our business. The amount, if any, of ultimate liability with respect to such matters cannot be determined. Despite the inherent uncertainties of litigation, we at this time do not believe that such proceedings will have a material adverse impact on our financial condition, results of operations, or cash flows.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The following table sets forth, for the fiscal periods indicated, the high and low sales prices for our common stock for the two most recent fiscal years and for the first quarter of our current fiscal year. On February 7, 2007, our common stock was listed on the NASDAQ Global Market under the symbol "AKRX" and continues to be listed there as of the date hereof. Previously, from November 24, 2004 until February 6, 2007, our common stock was listed on the American Stock Exchange under the symbol "AKN."

	High	Low
Year Ending December 31, 2013		
1st Quarter (through February 25, 2013)	\$ 14.70	\$ 12.44
Year Ended December 31, 2012		
4th Quarter	\$ 13.77	\$ 11.73
3rd Quarter	16.87	11.99
2nd Quarter	16.09	10.53
1st Quarter	13.09	10.52
Year Ended December 31, 2011		
4th Quarter	\$ 11.77	\$ 7.10
3rd Quarter	9.50	6.63
2nd Quarter	7.15	5.66
1st Quarter	6.20	4.87

As of February 25, 2013, there were 95,921,212 shares of our common stock outstanding, held by approximately 385 stockholders of record. This number does not include stockholders for which shares are held in a "nominee" or "street" name. The closing price of our common stock on February 25, 2013 was \$12.56 per share.

We did not pay cash dividends in 2012, 2011 or 2010 and do not expect to pay dividends on our common stock in the foreseeable future. Moreover, we may be restricted from making dividend payments pursuant to the terms of our \$20.0 million revolving Loan and Security Agreement with Bank of America, N.A., and other financial institutions (see Note 6, Financing Arrangements).

We did not repurchase any shares of our common stock during the fourth quarter of the fiscal year covered by this report.

PERFORMANCE GRAPH

The following Stock Performance Graph and related information shall not be deemed “soliciting material” or “filed” with the Securities and Exchange Commission, nor should such information be incorporated by reference into any future filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference in such filing.

The graph below compares the cumulative shareholder return on our common stock with the NASDAQ Stock Market (U.S.) Index, and the Nasdaq Health Care Index (ticker symbol: ^IXHC) over the last five years through December 31, 2012. The graph assumes \$100 was invested in our common stock, and also the two indices presented, at the end of December 2007 and that all dividends were reinvested during the subsequent five-year period.

Total Return Chart	2007	2008	2009	2010	2011	2012
NASDAQ Stock Market (U.S.) Index	100	59	86	100	98	114
NASDAQ Health Care Index (^IXHC)	100	83	97	107	112	142
Akorn, Inc. (AKRX)	100	31	24	83	151	182

Item 6. Selected Financial Data

The following table sets forth selected summary historical financial data. We have prepared this table using our consolidated financial statements for the five years ended December 31, 2012. Our consolidated financial statements during this period have been audited by Ernst & Young LLP, independent registered public accounting firm. This summary should be read in conjunction with our audited Consolidated Financial Statements and Notes thereto, and "Item 7 -- Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information included herein.

	Years Ended December 31,				
	2012	2011	2010	2009	2008
(In thousands, except per share data)					
Revenues	\$256,158	\$136,920	\$86,409	\$75,891	\$93,598
Gross profit	148,692	79,689	42,465	15,672	26,592
Operating income (loss)	68,756	33,266	11,272	(19,512)	(7,183)
Interest and other non-operating income (expense)	(11,256)	8,040	10,704	(5,792)	(752)
Pretax income (loss)	57,500	41,306	21,976	(25,304)	(7,935)
Income tax provision (benefit)	22,122	(1,707)	152	2	4
Net income (loss)	\$35,378	\$43,013	\$21,824	\$(25,306)	\$(7,939)
Weighted average shares outstanding:					
Basic	95,189	94,549	92,801	90,253	89,209
Diluted	110,510	103,912	99,250	90,253	89,209
PER SHARE:					
Equity, per diluted share	\$1.82	\$1.52	\$0.87	\$0.43	\$0.69
Net income (loss):					
Basic	0.37	0.45	0.24	(0.28)	(0.09)
Diluted	0.32	0.41	0.22	(0.28)	(0.09)
Share Price: High					
Low	16.87	11.77	6.50	2.69	8.19
	10.52	4.87	1.27	0.73	1.11
BALANCE SHEET DATA:					
Current assets	\$158,707	\$155,949	\$73,613	\$26,069	\$40,746
Net property, plant & equipment	80,679	44,389	32,731	31,473	34,223
Total assets	369,565	307,145	111,116	68,759	82,329
Current liabilities, including debt in default	43,291	28,289	21,940	21,666	18,103
Long-term obligations, less current installments	125,193	120,648	2,424	8,456	2,783
Shareholders' equity	201,081	158,208	86,752	38,637	61,443
CASH FLOW DATA:					
Cash provided by (used in) operating activities	\$26,244	\$19,657	\$12,282	\$(1,038)	\$(5,420)
Cash (used in) provided by investing activities	(75,501)	(95,034)	31,555	(1,397)	(3,787)
Cash provided by (used in) financing activities	6,366	117,716	(3,831)	2,989	2,322
(Decrease)/increase in cash and cash equivalents	(43,181)	42,339	40,006	554	(6,885)

The Company's consolidated statement of cash flows for the year ended December 31, 2011 has been restated to correct a classification error which resulted in overstatement of cash provided by operating activities in the amount of \$3,346,000 and overstatement of cash used by investing activities by that same amount. The error was related to capital expenditures that were accrued but unpaid.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

OVERVIEW

We manufacture and market a full line of diagnostic and therapeutic ophthalmic pharmaceuticals as well as niche hospital drugs and injectable pharmaceuticals. We manufacture and/or offer products in various specialty areas, including ophthalmology, antidotes, anti-infectives, controlled substances for pain management and anesthesia, and vaccines, among others. We also manufacture and market a line of over-the-counter dry eye and eye health products under the brand name TheraTears®.

We have three identified operating segments:

Active segments:

Ophthalmic – sales of diagnostic and therapeutic ophthalmic drugs and over-the-counter eye care products
Hospital Drugs & Injectables – sales of diagnostic and therapeutic injectables and other hospital drugs, as well as biologics and vaccines

Contract Services – sales of various drugs that we manufacture for others to be sold under their own brand names

Revenue:

The year 2012 was marked by continued growth in revenue and profitability, as we continued to execute on our strategic objectives. Revenue grew to \$256.2 million in 2012 compared to \$136.9 million in 2011, and we generated operating income of \$68.8 million compared to \$33.3 million in the prior year. This growth was the result of new product launches, the re-launch of dormant products and acquisitions.

New Product Development:

During 2012, we continued the expansion of our R&D efforts and began to reap the benefits of prior FDA filings by receiving a number of ANDA approvals. Among our product approvals in 2012 were vancomycin hydrochloride capsules and progesterone capsules. R&D expenses increased from \$11.6 million in 2011 to \$15.9 million in 2012, and we are in the process of relocating our R&D center to a new, larger facility to support future growth.

Re-launch of Dormant Products:

During 2011, we re-launched a number of dormant products in response to market shortages and/or changes in their overall market. During 2012, we sought to establish an ongoing market presence for these products, as well as filling any market shortage needs. New products and re-launched products launched since the start of 2011 combined to account for 37.8% of our sales growth in 2012 over the prior year.

Acquisitions:

On February 28, 2012, we completed the acquisition of the business assets and principal manufacturing plant of Kilitch Drugs (India) Limited which operated a pharmaceutical manufacturing plant in Paonta Sahib, India. This facility currently manufactures drugs for contract customers in India and for export to unregulated worldwide markets. Our goal is for this facility to gain FDA approval for the manufacture of various drugs for distribution to the United States, which will supplement our existing manufacturing capacity and provide opportunity for expansion of our product menu as well as provide additional capabilities.

The Kilitch Acquisition followed our acquisition of three branded, injectable drugs from Lundbeck in December 2011 and our acquisition of AVR, the makers of the TheraTears® line of over-the-counter eye care products, in May 2011. Business combinations and product acquisitions combined to account for 56.3% of our sales growth in 2012 over the prior year.

RESULTS OF OPERATIONS

For the years 2012, 2011 and 2010, we have identified and reported operating results for three distinct business segments: Ophthalmic; Hospital drugs & injectables; and Contract services. Our reported results by segment are based upon various internal financial reports that disaggregate certain operating information. Our chief operating decision maker, as defined in Accounting Standards Codification (“ASC”) Topic 280, Segment Reporting, is our CEO. Our CEO oversees operational assessments and resource allocations based upon the results of our reportable segments, all of which have available discrete financial information.

In prior years, we had reported a fourth segment, Biologics & vaccines, which consisted of our sale of Td vaccine and various influenza vaccines manufactured by others and marketed by us. We ceased the distribution of vaccines in early 2010, and restarted their distribution at the end of 2012. Due to the non-material nature of vaccine sales in 2010 and 2012, and the similarities in customers and distribution methods to our hospital drugs & injectables segment, we have included sales of biologics and vaccines in our Hospital drugs & injectables segment for all years presented below.

The following table sets forth amounts and percentages of total revenue for certain items from our Consolidated Statements of Operations and our segment reporting information for the years ended December 31, 2012, 2011 and 2010 (dollar amounts in thousands):

	2012			2011			2010		
	Amount	% of Revenue		Amount	% of Revenue		Amount	% of Revenue	
Revenues:									
Hospital drugs & injectables	\$ 129,723	50.6	%	\$ 55,077	40.2	%	\$ 34,053	39.4	%
Ophthalmic	103,765	40.5	%	68,591	50.1	%	32,750	37.9	%
Contract services	22,670	8.9	%	13,252	9.7	%	19,606	22.7	%
Total revenues	256,158	100.0	%	136,920	100.0	%	86,409	100.0	%
Gross profit and gross margin percentage:									
Hospital drugs & injectables	83,413	64.3	%	30,057	54.6	%	15,768	46.3	%
Ophthalmic	58,785	56.7	%	43,054	62.8	%	19,453	59.4	%
Contract services	6,494	28.6	%	6,578	49.6	%	7,244	36.9	%
Total gross profit	148,692	58.0	%	79,689	58.2	%	42,465	49.1	%
Operating expenses:									
Selling, general & administrative expenses	48,053	18.8	%	32,392	23.7	%	22,721	26.3	%
Research and development expenses	15,858	6.2	%	11,555	8.4	%	6,975	8.1	%
Amortization & write-down of intangibles	6,870	2.7	%	1,733	1.3	%	1,497	1.7	%
Acquisition-related costs	9,155	3.6	%	743	0.5	%	—	0.0	%
Operating income	\$ 68,756	26.8	%	\$ 33,266	24.3	%	\$ 11,272	13.0	%
Net income	\$ 35,378	13.8	%	\$ 43,013	31.4	%	\$ 21,824	25.3	%

COMPARISON OF TWELVE MONTHS ENDED DECEMBER 31, 2012 AND 2011

Our revenues were \$256.2 million in 2012, an increase of \$119.2 million, or 87.1%, compared to 2011. This increase in revenue was related to a number of factors, including acquisitions, sales of new and revived products and increased sales of existing products. Of the \$119.2 million increase in revenues, \$67.1 million was related to business combinations and product acquisitions completed since the start of 2011, \$45.1 million was from a combination of newly-approved products and re-launched products in response to more favorable market conditions, and \$9.3 million was related to sales volume increases for continuing products, partially offset by a \$2.3 million reduction attributable to price changes on continuing products.

In terms of reportable segments, 2012 revenues from our hospital drugs & injectables segment were \$129.7 million, an increase of \$74.6 million, or 135.5%, over the prior year. This increase was principally attributable to sales of products acquired through the Lundbeck acquisition, and sales of newly-approved and revived products. Ophthalmic segment revenues were \$103.8 million, an increase of \$35.2 million, or 51.3%, over the prior year. The three main factors contributing to this increase were sales from new and revived products, a full year's revenue from the AVR acquisition, and sales increases from existing ophthalmic products. Contract services revenue was \$22.7 million in 2012, an increase of \$9.4 million, or 71.1%, over the prior year. This increase was related to the \$16.7 million revenue generated from the Kilitch Acquisition, partially offset by a decline in U.S. contract business of \$7.3 million due to a shift in manufacturing toward Akorn products.

Our 2012 revenues of \$256.2 million was net of adjustments totaling \$130.8 million for chargebacks, rebates, administration fees, returns, discounts and allowances, and coupons and advertising. Chargeback and rebate expense for 2012 was \$112.2 million, or 29.0% of gross revenue, compared to \$68.1 million, or 31.5% of gross revenue, in 2011. The \$44.1 million increase in chargeback and rebate expense was due to higher gross sales volume in 2012. The slight decrease in chargeback and rebate expense as a percentage of gross sales was attributable to increases in sales outside the wholesale channel. Our products returns provision in 2012 was \$3.8 million, or 1.0% of gross sales, compared to \$2.7 million, or 1.3% of gross sales, in 2011. The slight decrease in percentage was due to favorable historical product return trends and a higher percentage of sales of non-returnable products.

Our consolidated gross profit for 2012 was \$148.7 million, or 58.0% of revenue, compared to \$79.7 million, or 58.2% of revenue, in 2011. This gross profit increase of \$69.0 million, or 86.6%, was principally due to our revenue growth from acquisitions, new product introductions and product revivals. The slight decrease in overall profit margin was due to lower margin business, such as the contract revenue of Akorn India, which offset higher-margin business, such as the sales of products acquired through the Lundbeck Acquisition. The gross profit margin on ophthalmic segment sales was 56.7% in 2012 compared to 62.8% in 2011, this decline being primarily attributable to increased sales of over-the-counter ophthalmic products by our subsidiary, AVR, which was acquired in May 2011. The gross profit margin on hospital drugs & injectables increased to 64.3% in 2012 from 54.6% in 2011 primarily due to the higher gross margin on the Lundbeck products. The gross profit margin on contract services decreased to 28.6% in 2012 from 49.6% in 2011 primarily due to lower margin business from our Indian subsidiary.

Selling, general and administrative (“SG&A”) expenses were \$48.1 million in 2012, an increase of \$15.7 million, or 48.3%, over the prior year SG&A expenses of \$32.4 million. This increase was due primarily to compensation-related costs resulting from higher headcount supporting our growth, operating expenses associated with our India operations that were acquired during the first quarter of 2012 and marketing costs associated with our AVR business. As a percentage of sales, SG&A expenses was 18.8% down from 23.7% in 2011.

Research and development (“R&D”) expenses were \$15.9 million in 2012 compared to \$11.6 million in 2011. This increase of \$4.3 million was the result of continued increases in R&D activities, both internally and through strategic partnerships and includes \$1.2 million of expenses associated with the FDA’s backlog and new filing fees that went into effect in the fourth quarter of 2012.

Amortization of intangibles consists of the amortization of NDA and ANDA drug acquisition costs over the anticipated market lives of the acquired products, as well as the amortization of other intangible assets acquired through business combinations. Amortization of intangibles was \$6.9 million in 2012 compared to \$1.7 million in 2011. This increase of \$5.2 million was primarily due to amortization of the product rights acquired through the Lundbeck Acquisition, and amortization of intangible assets acquired through the Kilitch Acquisition.

Amortization of deferred financing costs totaled \$0.8 million in 2012 compared to \$1.9 million in 2011. The 2012 expense was related to amortizing the financing costs on our Notes and our BoA credit facility. The 2011 expense included a \$1.2 million write-off of the unamortized deferred financing costs to our EJ Credit Facility, which we elected to early terminate in June 2011. Our 2011 expense also included \$0.4 million in amortization of deferred financing costs related to our Notes.

In 2012, we recorded non-cash interest expense of \$6.4 million compared to \$2.1 million in the prior year. Our non-cash interest expense was related to the debt discount on our Notes and to the change in fair value of our contingent consideration payable related to the acquisition of Lundbeck products.

Interest expense was \$4.0 million in 2012 compared to \$2.3 million in 2011. Our interest expense in each year was principally related to the Notes, which were issued effective June 1, 2011.

We are a 50% partner in the Joint Venture Company, which we account for using the equity method. During 2011, we recorded \$14.6 million of equity in income from this unconsolidated joint venture, of which \$13.4 million was related to our share of the gain from the Joint Venture Company's sale of its ANDAs to Pfizer on December 29, 2010, and the remaining \$1.2 million was from the Joint Venture Company's operations. The Joint Venture Company ceased operations in 2011 and no income was recorded in 2012.

In 2011, we recorded a non-operating expense of \$0.2 million related to an option agreement we entered into to protect ourselves from a negative movement in the foreign exchange rate between U.S. dollars and Indian rupees. We entered into this option agreement in October 2011 following our entry into an agreement to buy certain assets from Kilitch in India, as the purchase price for the Kilitch Acquisition was established in Indian rupees. We incurred no similar expense in 2012.

COMPARISON OF TWELVE MONTHS ENDED DECEMBER 31, 2011 AND 2010

Our revenues were \$136.9 million in 2011, an increase of \$50.5 million, or 58.5%, compared to 2010. This increase in revenue was related to a number of factors, including the acquisition of AVR, increased sales of existing products through sales efforts and share gains from market shortages, introduction of new products, and price increases for certain products. Of the \$50.5 million increase in revenues, \$18.0 million was related to new products and the re-launch of dormant products to capitalize on market opportunities, \$17.8 million was due to increased sales of existing products, \$5.0 million was related to selected price increases, and \$14.9 million was related to acquisitions, partially offset by a decline of \$5.2 million related to our strategic decision to cease the distribution of biologics & vaccines effective March 2010.

As it relates to our reportable segments, the increase in revenue for our ophthalmic segment was primarily due to the acquisition of AVR and sales volume increases for our existing products. The increase in revenue in our hospital drugs & injectables segment was primarily due to re-launches and new products, along with volume increases for existing products. The decline in contract segment revenues was due to refocusing our manufacturing plants on producing Akorn-branded products, along with the loss of AVR as a contract customer upon our acquisition of this business in May 2011.

The market shortages are related to a number of factors, including cGMP issues experienced by various competing drug companies and competitors' strategic decisions to cease manufacturing various products. We monitor market conditions and attempt to respond to market opportunities, such as those provided by market shortages. However, it is difficult to predict the duration and severity of market shortage for most drugs, and our revenues and gross profit margins may fluctuate accordingly.

Our 2011 revenues of \$136.9 million was net of adjustments totaling \$79.1 million for chargebacks, rebates, administration fees, returns, discounts and allowances, and coupons and advertising. Chargeback and rebate expense for 2011 was \$68.1 million or 31.5% of gross revenue, compared to 2010 expense of \$45.0 million, or 32.9% of gross revenue. The \$23.1 million increase in chargeback expense was due to higher gross sales volume in 2011. As a percentage of gross sales, the decrease in chargeback and rebate expenses is attributable to the AVR business, which is subject to minimal chargebacks. Our products returns provision was \$2.7 million in 2011 compared to \$1.5 million in 2010. This \$1.2 million increase was due to higher sales volume in 2011.

Our consolidated gross profit for 2011 was \$79.7 million, or 58.2% of revenue, compared to \$42.5 million, or 49.1% of revenue, in 2010. This gross profit increase of \$37.2 million, or 87.5%, was due to several factors, including revenue growth from our introduction of new products carrying higher profit margins, increased sales and selected price increases for existing products, improved plant utilization, and improved inventory management. The gross profit margin on ophthalmic segment sales increased to 62.8% in 2011 compared to 59.4% in 2010, and the gross profit margin on hospital drugs & injectables increased to 54.6% in 2011 compared to 46.3% in the prior year. These increases were primarily due to improved utilization of our manufacturing facilities, as well as a number of lesser factors, such as selected price increases for certain products. The gross profit margin on contract services increased to 49.6% in 2011 compared to 36.9% in the prior year, this increase being primarily attributable to improved plant utilization, price increases for certain products, and the elimination of lower margin contract revenue from AVR upon our acquisition of that business.

Selling, general and administrative ("SG&A") expenses were \$32.4 million in 2011, an increase of \$9.7 million, or 42.6%, from the prior year. This increase was due primarily to SG&A expenses for AVR, increases in wages and salaries for additional headcount to support our growth, and increases in non-cash stock compensation expense and management bonuses in accordance with our improved financial performance.

Research and development (“R&D”) expenses were \$11.6 million in 2011 compared to \$7.0 million in 2010. This increase of \$4.6 million was the result of our commitment to enhancing our internal R&D infrastructure, increased R&D activity at our dedicated facility in Skokie, Illinois, and the establishment of a \$1.7 million reserve against inventory of products pending FDA approval.

Amortization of intangibles consists of the amortization of NDA and ANDA drug acquisition costs over the anticipated market lives of the acquired products, as well as the amortization of other intangible assets acquired through business combinations. Amortization of intangibles was \$1.7 million in 2011 compared to \$1.5 million in 2010. This increase was due to amortization expense of products acquired in 2011, including the AVR TheraTears® trademark.

Write-off and amortization of deferred financing costs totaled \$1.9 million in 2011 compared to \$2.8 million in 2010. In each year, the majority of the expense was related to write-offs. In June 2011, we elected to early terminate our EJ Credit Facility and wrote off \$1.2 million in remaining unamortized deferred financing costs. In December 2010, we early paid the balance due under our Subordinated Note, writing off \$1.2 million of unamortized deferred financing costs and \$0.6 million of early payment fee. In 2011, we also recorded \$0.4 million in amortization of deferred financing costs related to our Notes.

In 2011, we recorded non-cash interest expense of \$2.1 million related to the debt discount of our Notes. We incurred no similar expense in 2010.

Interest expense was \$2.3 million in 2011 compared to \$0.9 million in the prior year. This increase was related to our Notes, which were issued effective June 1, 2011. Interest expense related to the Notes was \$2.5 million and was partially offset by interest earned on the proceeds from the offering. The lower interest expense in 2010 was related primarily to our Subordinated Note with EJ Funds.

We are a 50% partner in the Joint Venture Company, which we account for using the equity method. During 2011, we recorded \$14.6 million of equity in income from this unconsolidated joint venture, compared to \$23.4 million in the prior year. Of the \$14.6 million income in 2011, \$13.4 million was related to our share of the gain from the Joint Venture Company's sale of its ANDAs to Pfizer on December 29, 2010, and the remaining \$1.2 million was from the Joint Venture Company's operations. Of the \$23.4 million income in 2010, \$21.6 million was related to our share of the gain. The Joint Venture Company entered into an Asset Purchase Agreement to sell the rights to all of its ANDAs to Pfizer for \$63.2 million in cash. The Asset Purchase Agreement contained two closing dates, with some ANDAs having been transferred on the initial close date of December 29, 2010 and the rest transferred on the final closing date of May 1, 2011. The gains from this sale were allocated between the two closing dates based on the relative fair value of the ANDAs transferred to Pfizer on each date. The Joint Venture Company essentially ceased operations in the second quarter of 2011.

During 2010, we incurred non-cash expenses of \$8.9 million related to the change in fair value of warrants we granted at various dates in 2009 to companies controlled by our Chairman, Dr. John Kapoor (the "Kapoor Warrants"). We classified the Kapoor Warrants as current liabilities from their grant dates until June 28, 2010, and adjusted their book values quarterly to reflect changes in their fair values. As a result of an amendment entered into on June 28, 2010 to the registration rights agreement associated with these warrants, we reclassified the Kapoor Warrants from current liabilities to a component of shareholders' equity on June 28, 2010 and made no subsequent fair value adjustments beyond that date. Accordingly, there was no similar expense recorded in 2011.

In 2011, we recorded a non-operating expense of \$0.2 million related to an option agreement we entered into to protect ourselves from a negative movement in the foreign exchange rate between U.S. dollars and Indian rupees. We entered into this option agreement in October 2011 following our entry into an agreement to buy certain assets from Kilitch in India, as the purchase price for the Kilitch Acquisition was established in Indian rupees. We incurred no similar expenses in 2010.

FINANCIAL CONDITION AND LIQUIDITY

Cash Flow

As of December 31, 2012, we had cash and cash equivalents of \$40.8 million, which is \$43.2 million lower than our cash and cash equivalents balance of \$84.0 million as of December 31, 2011. This decrease in cash and cash equivalents was primarily due to the \$54.2 million we used to complete the Kilitch Acquisition on February 28, 2012 and \$20.5 million used to acquire property, plant and equipment, partially offset by \$26.2 million in positive cash flow

from operations. Our net working capital was \$115.4 million at December 31, 2012 compared to \$127.7 million at December 31, 2011. This decrease of \$12.3 million was primarily attributable to the decline in our cash and cash equivalents balance, partially offset by increases in accounts receivable and inventory, which grew in step with our overall business growth during 2012.

For the year 2012, we generated \$26.2 million in cash flow from operations. This positive operating cash flow was primarily the result of our net income of \$35.4 million and non-cash expenses of \$20.6 million, partially offset by a \$23.9 million increase in accounts receivable and a \$15.4 million increase in inventory. In the prior year of 2011, we generated \$19.7 million in positive cash flow from operations. This positive operating cash flow was primarily due to the combination of \$43.0 million of net income and \$14.5 million of non-cash expenses, partially offset by \$14.6 million equity in earnings of the Joint Venture Company and a combined increase of \$22.9 million in accounts receivable and inventory.

In 2012, we used \$75.5 million cash in investing activities. Of this total, \$54.2 million was used to complete the Kilitch Acquisition in February and \$20.5 million was used to acquire property, plant and equipment, principally as part of the expansion project at our Somerset, New Jersey manufacturing plant. In the prior year, we used \$95.0 million in investing activities, of which \$77.4 million was used for business and product acquisitions, \$11.5 million was used to purchase property, plant and equipment, and \$10.0 million was used to make an equity method investment in Aciex, offset by \$3.9 million generated from distributions from the Joint Venture Company.

Financing activities generated \$6.4 million in cash during 2012, all of which was related to stock option exercises and participation in the employee stock purchase plan. During 2011, we generated \$117.7 million in cash through financing activities, with the most significant source being the net \$115.3 million generated through our \$120.0 million offering of 3.5% Convertible Senior Notes due 2016, partially offset by \$5.1 million in financing fees related to the Notes and the BoA Credit Facility. Additional financing cash flow of \$1.7 million was generated from PIPE Warrant exercises in the first quarter of 2011, while stock option exercises and participation in the employee stock purchase plan generated a combined \$1.1 million during the year.

We believe that our cash reserves, operating cash flows and availability under our BoA Credit Facility will be sufficient to meet our cash needs for the foreseeable future.

Liquidity and Capital Needs

We require certain capital resources in order to maintain and expand our business. Specifically, we anticipate investing in the range of \$25.0 million in capital projects during 2013, which includes approximately \$15.0 million to continue the expansion and upgrade of our manufacturing facility in Paonta Sahib, India. As of December 31, 2012, we had \$40.8 million in cash and cash equivalents. We believe that our cash reserves, operating cash flows and availability under our Credit Facility will be sufficient to meet our cash needs for the foreseeable future.

We continue to evaluate opportunities to grow and expand our business through the acquisition of new businesses, manufacturing facilities, or pharmaceutical product rights. Such acquisitions may require us to obtain additional sources of capital. We cannot predict the amount of capital that may be required to complete such acquisitions, and there is no assurance that sufficient financing for these activities would be available on terms acceptable to us, if at all.

Convertible Notes

On June 1, 2011, we completed our offering of \$120.0 million aggregate principal amount of 3.50% Convertible Senior Notes due 2016 (the “Notes”), which includes \$20.0 million of Notes issued in connection with the full exercise by the initial purchasers of their over-allotment option. The Notes are governed by our indenture with Wells Fargo Bank, National Association, as trustee (the “Indenture”). The Notes were offered and sold only to qualified institutional buyers. The net proceeds from the sale of the Notes were approximately \$115.3 million, after deducting underwriting fees and other related expenses.

The Notes have a maturity date of June 1, 2016 and pay interest at an annual rate of 3.50% semiannually in arrears on June 1 and December 1 of each year, beginning on December 1, 2011. The Notes are convertible into our common stock, cash or a combination thereof at an initial conversion price of \$8.76 per share, which is equivalent to an initial conversion rate of approximately 114.1553 shares per \$1,000 principal amount of Notes. The conversion price is subject to adjustment for certain events described in the Indenture, including certain corporate transactions which will increase the conversion rate and decrease the conversion price for a holder that elects to convert its Notes in connection with such corporate transaction.

The Notes may be converted at any time prior to the close of business on the business day immediately preceding December 1, 2015 only under the following circumstances: (1) during any calendar quarter commencing after September 30, 2011, if the closing sale price of the our common stock, for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the calendar quarter immediately preceding the calendar quarter in which the conversion occurs, is more than 130% of the conversion price in effect on each applicable trading day; (2) during the five consecutive trading-day period following any five consecutive trading-day period in which the trading price for the Notes per \$1,000 principal amount of Notes for each such trading day was less than 98% of the closing sale price of our common stock on such date multiplied by the

then-current conversion rate; or (3) upon the occurrence of specified corporate events. On or after December 1, 2015 until the close of business on the business day immediately preceding the stated maturity date, holders may surrender all or any portion of their Notes for conversion at any time, regardless of the foregoing circumstances. Upon conversion, we will pay or deliver, at our option, cash, shares of our common stock, or a combination thereof. We may not redeem the Notes prior to the maturity date. If a fundamental change (as defined in the Indenture) occurs prior to the stated maturity date, holders may req