AKORN INC
Form POS AM
June 14, 2005

As filed with the Securities and Exchange Commission on June 14, 2005.

Registration No. 333-119168

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Post-Effective Amendment No. 2 to
Form S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Akorn, Inc.
(Exact name of Registrant as specified in its charter)

Louisiana	**2834**	**72-0717400**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

2500 Millbrook Drive, Buffalo Grove, Illinois 60089
(Address, including zip code, of Registrant s principal executive offices)

Arthur S. Przybyl
President and Chief Executive Officer
Akorn, Inc.
2500 Millbrook Drive
Buffalo Grove, Illinois 60089
(847) 279-6100
(Name, Address and Telephone Number of Agent for Service)

Copies to:
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Approximate date of commencement of proposed sale to public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. R

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. £

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act of 1933 registration statement number of the earlier effective registration statement for the same offering. £

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. £

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Prospectus dated June 14, 2005, subject to completion

PROSPECTUS

The information contained in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities pursuant to this prospectus until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

61,329,087 Shares
Akorn, Inc.
Common Stock

This prospectus relates to the resale of 61,329,087 shares of our common stock by the selling stockholders identified in this prospectus, which have been issued or reserved for issuance upon the conversion or exercise of presently outstanding shares of Series A 6.0% Participating Convertible Preferred Stock, shares of Series B 6.0% Participating Convertible Preferred Stock, warrants and convertible notes, including shares estimated to be issuable in satisfaction of accrued and unpaid dividends and interest on shares of preferred stock and convertible notes, respectively.

We are registering 61,329,087 shares of our common stock for resale by the selling stockholders identified in this prospectus on pages 19 through 25. The selling stockholders may sell the shares of common stock described in this prospectus in public or private transactions, at prevailing market prices, or at privately negotiated prices. The selling stockholders may sell shares directly to purchasers or through brokers or dealers. Brokers or dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders. We will not receive any of the proceeds from the sale of the shares by the selling stockholders. The selling stockholders will receive all of the proceeds from the sale of the shares and will pay all underwriting discounts and selling commissions, if any, applicable to the sale of the shares. We will, in the ordinary course of business, receive proceeds from the issuance of shares upon exercise of the warrants described in this prospectus. We will pay the expenses of registration of the sale of the shares. It is not possible at the present time to determine the price to the public in any sale of the shares by the selling stockholders and each selling stockholder reserves the right to accept or reject, in whole or in part, any proposed purchase of shares. Accordingly, the public offering price, the amount of any applicable underwriting discounts and commissions and the net proceeds to the selling stockholders will be determined at the time of such sale by the selling stockholders.

Our common stock is traded on the American Stock Exchange under the symbol AKN. On June 9, 2005, the last reported sales price of our common stock was $2.58 per share.

Investing in our common stock involves risks.
See Risk Factors beginning on page 9.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 14, 2005

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are not offering to sell or seeking offers to buy shares of our common stock in jurisdictions where offers and sales are prohibited. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before buying shares in this offering. You should read this entire prospectus carefully, including Risk Factors and our financial statements before making an investment decision. References in this prospectus to Akorn, us, we, our, or the Company refer to Akorn, Inc. and its subsidiary, Akorn (New Jersey), Inc., as the context requires.

Akorn, Inc.

Business Overview

We manufacture and market diagnostic and therapeutic pharmaceuticals in specialty areas such as ophthalmology, rheumatology, anesthesia and antidotes, among others. Our customers include physicians, optometrists, wholesalers, group purchasing organizations and other pharmaceutical companies. We are a Louisiana corporation founded in 1971 in Abita Springs, Louisiana. In 1997, we relocated our headquarters and certain operations to Illinois. We have a wholly owned subsidiary named Akorn (New Jersey), Inc. which has operations in New Jersey and is involved in manufacturing, research and development, and administrative activities related to our ophthalmic and injectable segments. We also have a number of strategic alliances discussed elsewhere in this prospectus for the development and marketing of products.

We classify our operations into three identifiable business segments: ophthalmic, injectable and contract services.

Ophthalmic Segment. We market a 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 and other national account customers, include antibiotics, anti-infectives, steroids, steroid combinations, glaucoma medications, decongestants/antihistamines and anti-edema medications. Non-pharmaceutical products include various artificial tear solutions, preservative-free lubricating ointments, eyelid cleansers, vitamin supplements and contact lens accessories.

Injectable Segment. We market a line of specialty injectable pharmaceutical products, including antidotes, anesthesia, and products used in the treatment of rheumatoid arthritis and pain management. These products are marketed to hospitals through wholesalers and other national account customers, as well as directly to medical specialists.

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

Government Regulation. Pharmaceutical manufacturers and distributors are subject to extensive regulation by government agencies, including the Food and Drug Administration, or FDA, the Drug Enforcement Administration, or DEA, the Federal Trade Commission, or FTC and other federal, state and local agencies. The federal Food, Drug and Cosmetic Act, or 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, or cGMP regulations, non-compliance with which can result in fines, recall and seizure of products, total or partial suspension of production, refusal to approve new drug applications, or NDAs, and criminal prosecution. The FDA also has the authority to revoke approval of drug products.

FDA approval is required before any drug can be manufactured and marketed. New drugs require the 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 filing of an abbreviated new drug application, or 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 provide data demonstrating the equivalency and stability of the generic formulation that is comparable with the product originator. The time required by the FDA to review and approve NDAs and ANDAs is variable and beyond our control.

Business Trends

As described more fully in this prospectus, in recent years we have experienced significant regulatory and financial challenges. In response to these challenges, we have recruited new senior management, addressed our regulatory issues, improved our financial structure and raised additional capital. These improvements have positioned us for future growth and improved operating results.

In March 2002, we received a letter from the regional office of the Securities and Exchange Commission, or SEC, informing us that it would recommend enforcement action against us and that we had misstated our income for fiscal years 2000 and 2001. We continued to address these matters with the SEC into 2003. Also, during late 2002 and until October 2003, we were not in compliance with the covenants of our senior debt and from time to time negotiated forbearances. We had substantial operating losses during these periods, as well.

In September 2002, we appointed Mr. Arthur S. Przybyl, an experienced executive officer, as our president, and in February 2003 named him our chief executive officer. In March 2003, Mr. Ronald M. Johnson, a former FDA compliance and enforcement official, was appointed to our board of directors. We added Messrs. Arjun C. Waney and Jerry I. Treppel, both experienced investment managers, to our board of directors following our October 2003 Exchange Transaction (as defined below). Mr. Waney was one of the investors in that transaction, and Mr. Treppel has specific expertise in managing investments in health care and related industries. Mr. Jeffrey A. Whitnell, an experienced senior manager in the pharmaceutical business, became our chief financial officer in June 2004. Mr. Waney did not stand for election to our board of directors and ceased to serve on our board of directors effective May 27, 2005.

In 2002, 2003 and 2004, we continued to work to correct deviations from FDA regulatory requirements at our Decatur manufacturing facility, some of which were first identified by the FDA in October 2000. Resolution of deviations identified by the FDA has taken longer than expected although we believe that substantial progress has been made. The FDA inspections in 2000, 2002 and 2003 identified several significant deviations. In response, we have invested approximately $2,000,000 in improved cleaning validation and enhanced process controls and have developed a comprehensive corrective action plan. We have been in regular communication with the FDA and have provided periodic reports of our progress. In 2004, the FDA conducted two additional inspections of our Decatur manufacturing facility. The first, concluded on April 7, 2004, identified several deviations for which we provided the FDA with proposed corrective actions. The FDA initiated no enforcement action. Rather, the FDA notified us that another confirmatory inspection would be made to determine whether the deviations identified have been corrected. The confirmatory inspection concluded November 19, 2004. It identified deviations and we have responded to the FDA with corrective actions. We have since met with the FDA and provided the status of our corrective actions. The FDA has advised us that the findings of the latest inspection are under review and a final agency decision on our regulatory status has not been made. The FDA may conclude that the findings of the latest inspection do not represent significant deviations and our voluntary corrective actions are sufficient, in which case, we can expect the FDA to remove the sanctions of its warning letter. If, however, the FDA concludes that the deviations are significant and our voluntary actions have not been adequate, it may initiate enforcement action including the following: (1) maintain its warning letter sanctions or issue a new warning letter with sanctions; (2) seek a court-ordered injunction which may include suspension of some or all operations at the Decatur manufacturing facility until compliance is achieved, recall of certain products, potential monetary penalties or other sanctions; or (3) seize our products produced at the Decatur manufacturing facility. Any of these actions could significantly impair our ability to continue to manufacture and distribute products, generate cash from our operations and may result in a covenant violation under our senior debt.

According to the March 27, 2002 letter from the SEC, we had misstated our income in 2000 and 2001 by allegedly failing to reserve for doubtful accounts receivable and overstating our accounts receivable balance as of December 31, 2000. We determined the need to restate our financial statements for 2000 and 2001, resulting in the recording of a $7,500,000 increase to the allowance for doubtful accounts as of December 31, 2000, which we had originally recorded as of March 31, 2001. On September 25, 2003, we consented to the entry of an administrative cease and desist order with respect to these matters. The consent order also required that we commit to do the

following: (A) appoint a special committee comprised entirely of outside directors, (B) within 30 days after entry of the order, have the special committee retain a qualified independent consultant acceptable to the staff to perform a test of our material internal controls, practices, and policies related to accounts receivable, and (C) within 180 days, have the consultant present his or her findings to the commission for review to provide assurance that we are keeping accurate books and records and have devised and maintained a system of adequate internal accounting controls with respect to our accounts receivable. On October 27, 2003, we engaged Jefferson Wells International, Inc. to serve as consultant in this capacity. On February 6, 2004, Jefferson Wells reported its findings to the special committee, such findings being that we have made the necessary personnel changes and procedural improvements required to maintain control over the accounts receivable process and establish the necessary reserves. Jefferson Wells report was delivered to the SEC on February 13, 2004. We believe we have complied with all of the terms of the consent order.

In 1997, we entered into a $15,000,000 revolving credit arrangement with The Northern Trust Company, which was increased to $25,000,000 in 1998, and subsequently increased to $45,000,000 in 1999, subject to certain financial covenants and secured by substantially all of our assets. We were notified of default for failure to make payment in September 2002. Under various forbearance agreements, this facility was modified and extended through most of 2003 as we explored ways to restructure our debt. As a condition of our lenders continuing to forbear from exercising remedies against us as a result of certain defaults under our credit agreement, we engaged AEG Partners LLC to assist us in restructuring our credit arrangement. As required by the lenders, on May 9, 2003, we engaged Leerink Swann & Company, an investment banking firm, to assist in raising additional financing and explore other strategic alternatives for repaying the debt.

On October 7, 2003, a group of investors, including entities controlled by Dr. John N. Kapoor, Ph.D. and Mr. Arjun C. Waney, purchased all of our then outstanding senior bank debt from The Northern Trust Company, a balance of $37,731,000, at a discount. The investors then exchanged that debt with us for Series A 6.0% Participating Convertible Preferred Stock, or Series A Preferred Stock, approximately $2,767,000 in promissory notes, warrants to purchase our common stock, and $5,473,862 in cash from the proceeds of a new term loan (described in the next paragraph). We recorded a $3,102,000 loss from this transaction and we also paid a portion of the legal fees of the investors. We refer to this transaction as the Exchange Transaction.

Simultaneously with the consummation of the Exchange Transaction, we entered into a credit agreement with LaSalle Bank National Association providing us with $7,000,000 in term loans and a revolving line of credit of up to $5,000,000 (the New Credit Facility) to provide for working capital needs, secured by substantially all of our assets.

On August 23, 2004, we completed a private placement to certain investors of 141,000 shares of our Series B 6.0% Participating Convertible Preferred Stock, or Series B Preferred Stock, at a price of $100.00 per share, convertible into common stock at a price of $2.70 per share, with warrants to purchase 1,566,668 additional shares of our common stock exercisable until August 23, 2009, with an exercise price of $3.50 per share (the Series B Warrants). The net proceeds to us after payment of investment banker fees and expenses to Leerink Swann & Company and other transaction costs of approximately $1,056,000, were approximately $13,044,000. Under the terms of the private placement, we are required to file the registration statement of which this prospectus is a part to enable the investors to resell the shares of our common stock into which the Series B Preferred Stock is convertible and which may be purchased upon exercise of the Series B Warrants.

A portion of the net proceeds of the private placement paid off the term loans from LaSalle Bank. The remainder of the net proceeds is being used for working capital and general corporate purposes. Among other things, we are in the process of completing an expansion of our Decatur, Illinois manufacturing facility to add capacity to provide lyophilization manufacturing services, a manufacturing capability we currently do not have. Subject to among other things, our ability to generate operating cash flow or to obtain new financing for future operations, validation and approval of the lyophilization facility by the FDA is anticipated in late 2005. Manufacturing capabilities for

lyophilized products are projected to be in place by mid-2006.

On August 26, 2004, in connection with the pay off of our outstanding debt under the New Credit Facility, we and LaSalle Bank amended the New Credit Facility to release the guaranty of Dr. John N. Kapoor and The John N. Kapoor Trust dated September 20, 1989 (the Kapoor Trust) effective as of such date provided that if prior to

November 24, 2004 there is then pending a petition in bankruptcy court against us or our subsidiary and there is then existing a claim that all or any portion of the payoff amount is a fraudulent transfer or a preferential payment, or should otherwise be set aside, then the guaranty shall be reinstated.

The Exchange Transaction, coupled with the private placement, substantially reduced our overall debt from $45,755,000 as of September 30, 2003 to $10,452,000 as of March 31, 2005, and positioned us to improve our operating results. Although we continued to suffer operating losses for the year ended December 31, 2004, we generated positive earnings before interest, taxes, depreciation and amortization (EBITDA). Even without resolution of the remaining issues with the FDA, we believe that our ability to sustain historical revenue levels and positive EBITDA is achievable. If we can resolve the remaining issues with the FDA, we believe we will be able to manufacture new or revised products at our Decatur facility and enhance our revenue.

Partially because of our improving financial condition, we have been able to structure new strategic business alliances in an effort to enhance our growth opportunities. On April 21, 2004, we announced the signing of a memo of understanding with Strides Arcolab Limited, a major pharmaceutical manufacturer based in India. As a result of negotiations following the execution of the memo of understanding, on September 22, 2004, we entered into agreements with Strides for the development, manufacturing and marketing of grandfathered products, patent-challenging products and ANDA products for the United States hospital and retail markets under a joint venture. Strides will be responsible for developing, manufacturing and supplying products. We will be responsible for sales and marketing of the products. We and Strides each own 50% of the joint venture company, Akorn-Strides, LLC, and we each appointed one of its two managers. Under the terms of our agreement, each of us were to contribute $1,250,000 in capital to be used to finance the preparation of ANDAs by Strides. As of December 31, 2004, we had funded our $1,250,000 capital contribution to the joint venture company. An additional contribution of $250,000 for ANDA preparation by Strides was advanced in January 2005. In February 2005, we loaned an additional $1,250,000 to the joint venture company that was advanced to Strides to finance its capital contribution. Under the OEM agreement entered into between Strides and us, the respective contributions were advanced to Strides to finance the preparation, development and filing with the FDA of ANDAs for generic drugs based on a mutually agreed development schedule. The joint venture company will have exclusive rights to FDA approved generic drugs within the United States hospital, medical clinic, physician group and other wholesale drug markets. If within a mutually agreed time period, Strides manufacturing facilities in India have not received a satisfactory cGMP inspection by the FDA, which remains current, and twelve ANDAs for products developed by Strides at its manufacturing facilities in India have not been submitted to the FDA, among other things, we will become the sole owner of the joint venture company and the joint venture company will be entitled to draw on a $1,250,000 letter of credit put up by Strides from an Indian bank that is confirmed by a United States bank. On the other hand, if these conditions are met, and if both managers agree, we and Strides may make additional equivalent capital contributions to finance subsequent ANDA preparation costs under a similar arrangement to our initial capital contributions, including an additional loan by us to the joint venture company to finance Strides capital contribution.

In January 2003, the Financial Accounting Standards Board issued Interpretation No. 46, Consolidation of Variable Interest Entities, or FIN 46, with the objective of improving financial reporting by companies involved with variable interest entities. FIN 46 was revised in December 2003 by Interpretation No. 46, Consolidation of Variable Interest Entities, or FIN 46(R), which requires that a company consolidate the variable interest entity if the company is subject to a majority of the gain or loss from a variable interest entity s activities. Pursuant to the requirements of FIN 46(R), because we funded Strides capital contribution (even though that funding is supported by a letter of credit ultimately in our favor), we are required to consolidate the joint venture company until such time as our loan is collected. Those collections are expected to occur when the joint venture company begins to sell the products that Strides is currently contracted to develop into ANDAs. Accordingly, in our consolidated financial statements, our contributions to the joint venture company are eliminated. The total advance of $2,750,000 from the joint venture company to Strides is reflected as an other long-term asset and is being amortized over the mutually agreed upon development schedule

period. Amortization expense (reflected in Research & Development expense) in 2004 was $375,000. The first quarter 2005 amortization expense was $688,000. We have not and will not record a minority interest receivable to recognize Strides 50% portion of the joint venture company losses until such time as Strides has contributed capital at risk. Because of this, we recorded 100% of the joint venture company losses in our results of operations.

On July 21, 2004, we and FDC Limited, India s second largest manufacturer and marketer of ophthalmic pharmaceutical products, announced the signing of a purchase and supply agreement, which would provide us with an ophthalmic finished dosage form product pipeline for exclusive use in the United States and Canada. The ophthalmic products will be developed and manufactured for us by FDC. Under the agreement, we will be responsible for FDA regulatory submissions and marketing of the products directly in the United States. Innova, our Canadian distributor for ophthalmic products, will be responsible for the direct marketing of these products in Canada. FDC exports active pharmaceutical ingredients to over 45 countries, including the United States and Canada, and holds drug master files and registration in both countries. Products will be manufactured in India, and FDC intends to submit approximately four to six ANDAs in the first year of the agreement.

On October 15, 2004, we entered into an agreement with Serum Institute of India, the world s fifth largest vaccine manufacturer, in an exclusive drug development and distribution agreement for oncology and other injectable drug products for the United States and Canada. Under the terms of the five-year agreement, Serum will develop and manufacture certain ANDAs and we will be responsible for all regulatory submissions. We will also own the ANDAs and will buy the products from Serum under a negotiated transfer price arrangement, under which we must make a minimum purchase of $1,000,000 per product in the first year in order to maintain exclusivity. Additionally, we will market and sell the products in the United States and Canada under our label.

On November 16, 2004, we entered into an Exclusive License and Supply Agreement with Hameln Pharmaceuticals for two Orphan Drug NDAs: Calcium-DTPA and Zinc-DTPA. The two drugs were approved on August 11, 2004, by the FDA, and are indicated as antidotes for the treatment of radioactive poisoning specifically internal contamination with plutonium, americium, or curium. We received a shipment of these drugs from Hameln in December 2004 and recognized approximately $975,000 in revenue from selling the drugs in December 2004. Under the terms of the License and Supply Agreement, we paid a one-time license fee of 1,550,000 Euros ($2,095,000) for an exclusive license for five years, which may be extended by the parties for successive two-year periods. Orphan drug exclusivity status is granted by the FDA for a period of seven years from the date of approval of the NDA. We will be responsible for marketing and distributing both drugs in the United States and Canada and the two companies will share revenues 50:50, subject to adjustments. Hameln will be responsible for the manufacturing of both drugs for us. We will be responsible for the payment of any annual FDA establishment fees and for the cost of any post-approval studies.

On January 10, 2005, we and Apotex Corporation, the largest Canadian-owned pharmaceutical manufacturer, entered into an agreement for the purchase, supply, and marketing of select ophthalmic pharmaceutical products in the United States health care market. Under the terms of the agreement, Apotex will manufacture ophthalmic products in finished dosage forms for us, and we will market these products under our label. The agreement includes ophthalmic products currently available from Apotex, as well as select products in Apotex s ophthalmic research and development pipeline.

On February 17, 2005, we announced that we entered into an agreement to license a patent entitled M-EDTA Pharmaceutical Preparations of Uses Thereof and related technology rights invented by Issam I. Raad and Robert Sheretz. The license grants us the exclusive rights to develop and market the patent. Previously, on August 24, 2004 we announced that we had entered into an option agreement to license the patent with The University of Texas M.D. Anderson Cancer Center. The patent is targeted at the prevention of intravascular catheter-related infections and occlusions. We paid a license fee of $100,000 to M.D. Anderson and will fund all expenses necessary to commercialize the product. We are obligated to pay a milestone license fee upon FDA approval and royalties for the life of the patent.

On April 13, 2005, we announced the signing of a purchase and supply agreement with a company that will provide 17 anti-infective pharmaceutical products. Under the terms of the agreement, we will market these products

under our label.

The Offering

Issuer	Akorn, Inc.
Address and Phone Number	2500 Millbrook Drive Buffalo Grove, Illinois 60089 (847) 279-6100
American Stock Exchange Trading Symbol	AKN
Website	www.akorn.com (information found on our website is not part of this prospectus)
Securities Offered	Up to 61,329,087[(1)] shares of our common stock, no par value by the selling stockholders.
Use of Proceeds	We will not receive any proceeds from the sale of shares of our common stock covered by this prospectus. We will receive proceeds from the exercise of the warrants described in this prospectus.
Risk Factors	In analyzing an investment in our common stock offered by this prospectus, you should carefully consider the information set forth under Risk Factors.

(1) We are registering the following number of shares of common stock:

Issuable upon conversion of our Series B Preferred Stock	4,813,303
Issuable upon exercise of Series B Warrants	1,566,668
Issuable upon conversion of our Series A Preferred Stock	35,801,141
Issuable upon exercise of warrants issued to holders of our Series A Preferred Stock (the Series A Warrants)	5,986,400
Issuable upon conversion of the Convertible Tranche A Promissory Note in the aggregate principal amount of $3,000,000 (the Tranche A Note)	1,792,439
Issuable upon conversion of the Convertible Tranche B Promissory Note in the aggregate principal amount of $2,000,000 (the Tranche B Note)	1,499,957
Issuable upon exercise of the Tranche A Common Stock Purchase Warrants issued to the holders of the Tranche A Note (the Tranche A Warrants)	1,000,000
Issuable upon exercise of the Tranche B Common Stock Purchase Warrants issued to the holders of the Tranche B Note (the Tranche B Warrants)	667,000
Issuable upon exercise of warrants held by AEG Partners LLC pursuant to a Stock Purchase Warrant dated August 31, 2004 (the AEG Warrants)	1,200,000
Issuable upon exercise of warrants issued on October 7, 2003 as compensation for personal guarantees of our senior bank debt (the Guaranty Warrants)	960,000
Issuable upon exercise of warrants issued on October 7, 2003 in conjunction with the issuance of subordinated notes in the aggregate principal amount of $2,767,139 (the Note Warrants)	276,714
Previously issued upon exercise of Series A Warrants	2,135,578
Previously issued upon conversion of our Series A Preferred Stock	2,057,742
Previously issued upon conversion of our Series B Preferred Stock	670,345
Previously issued upon exercise of AEG Warrants	50,000
Issued upon exercise of warrants issued to The John N. Kapoor Trust dated September 20, 1989	851,800

TOTAL	61,329,087

Our Series A Preferred Stock and our Series B Preferred Stock each accrue dividends, which if not paid in cash as scheduled, increase the number of shares of common stock into which such preferred stock is convertible. Included in the shares listed above are 3,750,770 shares of common stock that are or could become issuable in respect of dividends on our Series A Preferred Stock and Series B Preferred Stock through June 30, 2005. Similarly, earned and unpaid interest on the Tranche A Note and Tranche B Note increases the number of shares of common stock into which such notes are convertible. Included in the shares listed above are 865,496 shares of common stock that are or could become issuable in respect of earned and unpaid interest on the Tranche A Note and Tranche B

Note through August 31, 2005. The number of shares of common stock set forth above is subject to adjustment to prevent dilution resulting from stock splits, stock dividends, the issuance of common stock or securities convertible into or exercisable for common stock at prices below certain thresholds or similar events. Therefore, pursuant to Rule 416, we are also registering such indeterminate number of shares as may be issuable in connection with stock splits, stock dividends or similar events. Other than holders of the Series B Preferred Stock and Series B Warrants, who have direct registration rights for this offering, each of the holders of each of the other securities listed above have piggy back registration rights for this offering.

We have reserved for issuance the shares of our common stock identified in this prospectus. Each of the above listed securities which are being sold by the selling stockholders were restricted securities under the Securities Act of 1933, or the Securities Act, prior to this registration. The selling stockholders will determine if and when they will sell their shares and if they will sell their shares at the current market price or at negotiated prices at the time of the sale. Although we have agreed to pay the expenses related to the registration of the shares being offered, we will not receive any proceeds from the sale of the shares by the selling stockholders.

Summary Selected Consolidated Financial Data

Summary Financial Data
(In thousands, except per share data)

The following summary financial data is derived from and qualified in its entirety by our financial statements. You should read this summary financial data together with Management s Discussion and Analysis of Financial Condition and Results of Operations and the audited consolidated financial statements, unaudited financial information and related notes beginning at page F-1 of this prospectus.

	Three Months Ended March 31,		Year Ended December 31,		
	2005	2004	2004	2003	2002
OPERATIONS DATA (000 s)					
Revenues	$ 10,181	$ 11,660	$ 50,708	$ 45,491	$ 51,419
Gross profit	3,343	4,018	18,202	12,148	20,537
Operating income (loss)[1]	(1,746)	110	(368)	(6,276)	(3,565)
Interest and other expense[2]	(526)	(1,327)	(2,650)	(6,220)	(3,148)
Pretax loss	(2,272)	(1,217)	(3,018)	(12,496)	(6,713)
Income tax provision (benefit)[3]	15		8	(171)	6,239
Net loss	(2,287)	(1,217)	(3,026)	(12,325)	(12,952)
Preferred stock dividends and adjustments[4]	(1,061)		(34,436)		
Net loss available to common stockholders	$ (3,348)	$ (1,217)	$ (37,462)	$ (12,325)	$ (12,952)
PER SHARE DATA					
Net Loss:					
Basic	$ (0.13)	$ (0.06)	$ (1.80)	$ (0.62)	$ (0.66)
Diluted	$ (0.13)	$ (0.06)	$ (1.80)	$ (0.62)	$ (0.66)
BALANCE SHEET (000 s)					
Current assets	$ 19,961	$ 13,455	$ 22,393	$ 10,595	$ 13,239
Net property plant & equipment	31,317	33,455	31,893	33,907	35,314
Total assets	62,710	60,789	66,922	59,415	63,538
Current liabilities including debt in default[5]	8,458	14,171	11,160	11,959	43,803
Long-term obligations, less current installments[6]	8,691	36,265	8,436	36,065	8,383
Shareholders equity	45,561	10,353	47,326	11,391	11,352

(1) Operating income (loss) includes the following (in thousands): (a) long-lived asset impairment charges of (i) $325 in the three months ended March 31, 2004, (ii) $2,037 in 2004, (iii) $2,362 in 2002.

(2) Interest and other expense includes the following (in thousands): (a) loss on Exchange Transaction of $3,102 in 2003 and (b) dividends and discount accretion related to our Series A Preferred Stock of $486 in the three months ended March 31, 2004, $1,064 in 2004 and $589 in 2003. After the July 2004 shareholder approval relating to our Series A Preferred Stock, such dividends and accretion do not impact net income (loss) but will continue to impact earnings (loss) per share.

(3) Income tax provision (benefit) includes (in thousands) a $9,216 charge in 2002 to establish a full valuation allowance against our net deferred income tax assets. Such net assets continued to be fully offset by a valuation allowance.

(4) Pursuant to the July 2004 shareholder approval that resulted in our Series A Preferred Stock being recharacterized as equity rather than debt, dividends and adjustments related to our preferred stock, while not impacting net loss, do result in increased losses available to common stockholders when computing

basic and diluted loss per share. A significant portion of these adjustments for 2004 relate to accreting the carrying value of the preferred stock up to its stated value. See Note H to our annual audited consolidated financial statements.

(5) Current liabilities include debt in default (in thousands) of $3,250 as of March 31, 2005 and December 31, 2004, and $35,565 and $44,800 as of December 31, 2002 and 2001, respectively. The $3,250 of debt in default was paid on May 16, 2005. The 2002 and 2001 debt was refinanced in 2003 as part of the Exchange Transaction.

(6) Long-term obligations include (in thousands) $21,618 and $21,132 of Series A Preferred Stock as of March 31, 2004 and December 31, 2003, respectively. Pursuant to the July 2004 shareholder approval relating to our Series A Preferred Stock, these securities were reclassified into shareholders equity.

RISK FACTORS

You should carefully consider the following risk factors and all other information contained in this prospectus before investing. Investing in our common stock involves a high degree of risk. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial also may impair our business. If any of the events described in the following risks occur, our business, results of operations and financial condition could be materially adversely affected. In addition, the trading price of our common stock could decline due to any of the events described in these risks, and you may lose all or part of your investment.

Risks Related to Us

Our Decatur, Illinois manufacturing facility is the subject of an FDA warning letter.

The FDA issued a warning letter to us in October 2000 following a routine inspection of our Decatur manufacturing facility. An FDA warning letter is intended to provide notice to a company of violations of the laws administered by the FDA and to elicit voluntary corrective action. Until the violations identified in the warning letter are corrected, the FDA frequently will withhold approval of any marketing applications (ANDAs, NDAs) submitted by the company and will share contents of the warning letter with other government agencies (for example, the Veterans Administration or Department of Defense) that may contract to purchase products from the company. Failure to take effective corrective actions can result in the FDA enforcement action such as monetary fines, seizure of products, or injunction that could suspend manufacturing and compel recall of product.

The warning letter addressed several deviations from regulatory requirements identified during the inspection and requested that we take corrective actions. Since then, additional FDA inspections in 2002 and 2003 found that certain deviations continued unresolved and identified additional deviations. We have invested approximately $2,000,000 in improved cleaning validation and enhanced process controls and have developed a comprehensive corrective action plan. We have been in regular communications with the FDA and have provided periodic reports of our progress in making corrections. In 2004, the FDA conducted two additional inspections of our Decatur manufacturing facility. The first, concluded on April 7, 2004, identified several deviations for which we provided the FDA with proposed corrective actions. The FDA initiated no enforcement action. Rather, the FDA notified us that another confirmatory inspection would be made to determine whether the deviations identified have been corrected. The confirmatory inspection concluded November 19, 2004. It identified deviations and we have responded to the FDA with corrective actions. We have met with the FDA and provided the status of our corrective actions. The FDA has advised us that the findings of the latest inspection are under review and a final agency decision on our regulatory status has not been made. The FDA may conclude that the findings of the latest inspection do not represent significant deviations and our voluntary corrective actions are sufficient, in which case, we can expect the FDA to remove the sanctions of the warning letter. If, however, the FDA concludes that the deviations are significant and our voluntary actions have not

been adequate, it may initiate enforcement action including the following: (1) maintain the warning letter sanctions or issue a new warning letter with sanctions; (2) seek a court-ordered injunction which may include suspension of some or all operations at the Decatur manufacturing facility until compliance is achieved, recall of certain products, potential monetary penalties or other sanctions; or (3) seize our products produced at the Decatur manufacturing facility. Any of these actions could

significantly impair our ability to continue to manufacture and distribute products, generate cash from our operations and may result in a covenant violation under our senior debt.

To date, the noncompliance of our Decatur manufacturing facility has prevented us from developing additional products at Decatur, some of which cannot be developed at our other facility. The inability to fully use our Decatur manufacturing facility has had a material adverse effect on our business, financial condition and results of operations.

Unless and until we correct the FDA deviations at our Decatur manufacturing facility, it is doubtful that the FDA will approve any applications that may be submitted by us for products to be manufactured in Decatur. This has adversely impacted, and is likely to continue to adversely impact our ability to grow sales. See Business Legal Proceedings.

We have experienced recent operating losses, working capital deficiencies and negative cash flows from operations, and these losses and deficiencies may continue in the future.

Our recent operating losses and negative cash flows from operations may continue in the future and there can be no assurance that our financial outlook will improve. For the three months ended March 31, 2005 and 2004, we experienced an operating loss of $1,746,000 and operating income of $110,000, respectively, and for the years ended December 31, 2004 and 2003, our operating losses were $368,000 and $6,276,000, respectively. We experienced negative cash flows from operations for the three months ended March 31, 2005 and 2004 of $1,075,000 and $837,000, respectively, and for the years ended December 31, 2004 and 2003 of $3,461,000 and $1,932,000, respectively. There can be no assurance that our results of operations will improve in the future. If our results of operations do not improve in the future, your investment in our common stock could be negatively affected.

We have invested significant resources in the development of lyophilization manufacturing capability, and we may not realize the benefit of these efforts and expenditures.

We are in the process of completing an expansion of our Decatur, Illinois manufacturing facility to add capacity to provide lyophilization manufacturing services, a manufacturing capability we currently do not have. Subject to among other things, our ability to generate operating cash flow or to obtain new financing for future operations, validation and approval of the lyophilization facility by the FDA is anticipated in late 2005. Manufacturing capabilities for lyophilized products are projected to be in place by mid-2006.

As of March 31, 2005, we had spent approximately $18,564,000 on the lyophilization expansion and anticipate the need to spend approximately $2,000,000 of additional funds (excluding capitalized interest) to complete the expansion. The majority of the additional spending will be focused on validation testing of the lyophilization facility as the major capital equipment items are currently in place. To this end, we expect to use a portion of the proceeds we obtained from the recent sale of our Series B Preferred Stock to help fund validation efforts for the lyophilization facility and to fund the development of an internal ANDA lyophilized product pipeline. However, there is no guarantee that we will be successful in completing development of lyophilization capability, or that other intervening events will not occur that reduce or eliminate the anticipated benefits from such capability. For instance, the market for lyophilized products could significantly diminish or be eliminated, or new technological advances could render the lyophilization process obsolete, prior to our entry into the market. There can be no assurance that we will realize the anticipated benefits from our significant investment into lyophilization capability at our Decatur manufacturing facility, and our failure to do so could significantly limit our ability to grow our business in the future.

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 large portion of our gross sales, revenues and accounts receivable. The following three distributors, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Drug Company, accounted for approximately 54% of total gross sales and 40% of total revenues for

the three months ended March 31, 2005, and 58% of gross trade receivables as of March 31, 2005. AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Drug Company accounted for approximately 57% of total gross sales and 46% of total revenues in 2004, and 74% of gross trade receivables as of December 31, 2004. In addition to acting as distributors of our products, these three companies also distribute a broad range of health care products for many other companies. 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 and results of operations and lead to a violation of debt covenants. A change in purchasing patterns or inventory levels, increases in returns of our products, delays in purchasing products and delays in payment for products by one or more distributors also could have a material negative impact on our revenue and results of operations. See Business Suppliers and Customers.

Our chairman and a significant shareholder who was formerly a director are subject to conflicts of interest.

Dr. John N. Kapoor, Ph.D., our current chairman of our board of directors and our chief executive officer from March 2001 to December 2002, and a principal shareholder, is affiliated with EJ Financial Enterprises, Inc., 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 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. In addition, one of these companies, NeoPharm, Inc., of which Dr. Kapoor is a director and major stockholder, entered into a loan agreement with us and issued to us a promissory note in the original principal amount of $3,250,000 (the NeoPharm Note). On May 16, 2005, we paid all principal and interest due under the NeoPharm Note with a one-time cash payment of $2,500,000. We also owe EJ Financial $11,000, $18,000, $18,000 and $18,000 in consulting fees for each of 2004, 2003, 2002 and 2001, respectively, as well as expense reimbursements of approximately $2,000, $2,000, $2,000 and $79,000 for 2004, 2003, 2002 and 2001, respectively. Further, the Kapoor Trust has loaned us $5,000,000 resulting in Dr. Kapoor effectively becoming a major creditor of ours as well as a major shareholder. See Management s Discussion and Analysis of Financial Condition and Results of Operations Financial Condition and Liquidity, and Certain Relationships and Related Transactions. As a result of the relationships described above, Dr. Kapoor s interests may be different from yours. Potential conflicts of interest could have a material adverse effect on our business, financial condition and results of operations.

In addition, the Kapoor Trust, Mr. Arjun C. Waney and Argent Fund Management collectively hold subordinated promissory notes issued by us in the aggregate principal amount of approximately $2,767,000 (the 2003 Subordinated Notes). Mr. Waney, one of our former directors and a continuing owner of 4.90% of our outstanding shares of common stock (see Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, below), serves as chairman and managing director of Argent, 52% of which is owned by Mr. Waney. The 2003 Subordinated Notes mature on April 7, 2006 and bear interest at prime plus 1.75%, but interest payments are currently prohibited under the terms of subordination arrangements with LaSalle Bank. See Management s Discussion and Analysis of Financial Condition and Results of Operations Financial Condition and Liquidity, and Certain Relationships and Related Transactions. Potential conflicts of interest could have a material adverse effect on our business, financial condition and results of operations.

We may require additional capital to grow our business and such funds may not be available to us.

We may require additional funds to grow our business. 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 when needed or on terms favorable to us due to our recent financial history. Without

sufficient additional funding, we may be unable to pursue growth opportunities that we view as essential to the expansion of our business, including the development of lyophilization manufacturing capability at our Decatur manufacturing facility. Further, the terms of such additional financing, if obtained, likely will require the granting of rights, preferences or privileges senior to those of our common stock and result in substantial dilution of the existing ownership interests of our 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 growth depends on our ability to timely develop additional pharmaceutical products and manufacturing capabilities.

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 not 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 infrastructure. There can be no assurance that 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 adversely affect the marketing and sale of our products. Unless and until our issues pending before the FDA are resolved, it is doubtful that the FDA will approve any NDAs or ANDAs we submit for products to be manufactured at our Decatur manufacturing facility. Our failure to develop new products, to successfully resolve the compliance issues at our Decatur manufacturing facility or to receive FDA approval of ANDAs or NDAs, could have a material adverse effect on our business, financial condition and results of operations. See Our Decatur, Illinois manufacturing facility is the subject of an FDA warning letter.

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

We have entered several strategic business alliances that have been formed to supply us with low cost finished dosage form products. In 2004, we entered into certain purchase and supply agreements, license agreements, and a joint venture that are all designed to provide finished dosage form products that can be marketed through our distribution pipeline. However, there can be no assurance that any of these agreements will result in FDA-approved ANDAs or NDAs, or that we will be able to market any such finished dosage form products at a profit. In addition, any clinical trial expenses that we incur may result in adverse financial consequences to our business.

Our success depends on the development of generic and off-patent pharmaceutical products which are particularly susceptible to competition, substitution policies and reimbursement policies.

Our success depends, in part, on our ability to anticipate which branded pharmaceuticals are about to come off patent and thus permit us to develop, manufacture and market equivalent generic pharmaceutical products. 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 that of branded pharmaceuticals. Generic substitution is regulated by 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 that third parties develop may render our generic products noncompetitive or obsolete. 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 are subject to legal proceedings against us, which may prove costly and time-consuming even if meritless.

We are currently involved in several pending or threatened legal actions with both private parties and certain government agencies. To the extent that our personnel must spend time and we must expend resources to

pursue or contest these various matters, or any additional matters that may be asserted from the time to time in the future, this represents time and money that is not available for other actions that we might otherwise pursue which could be beneficial to our future. In addition, to the extent that we are unsuccessful in any legal proceedings, the consequences could have a negative impact on our business, financial condition and results of operations. See Business Legal Proceedings.

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

We derive a significant portion of our revenues from the sale of products manufactured by third parties, including our competitors in some instances. There can be no assurance that our dependence on third parties for the manufacture of such products will not adversely affect our profit margins or our ability to develop and deliver our products on a timely and competitive basis. If for any reason we are unable to obtain or retain third-party manufacturers on commercially acceptable terms, we may not be able to distribute certain of our products as planned. No assurance can be made that the third-party manufacturers we use will be able to provide us with sufficient quantities of our products 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.

Dependence on key executive officers.

Our success will depend, in part, on our ability to attract and retain key executive officers. We are particularly dependent upon Dr. John N. Kapoor, Ph.D., chairman of our board of directors, and Mr. Arthur S. Przybyl, our chief executive officer. The inability to attract and retain key executive officers, or 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.

We must continue to attract and retain key personnel to be able to compete successfully.

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, operating results and financial condition.

Risks Related to Our Industry

We are subject to extensive government regulations that increase our costs and could subject us to fines and liabilities, 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 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, the recall, replacement or discontinuation of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes or new legislation could have a material adverse effect on our business, financial condition and results of operations. See Business Government Regulation.

FDA regulations. 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 powers over the activities of pharmaceutical manufacturers to ensure compliance with FDA regulations. Those powers include, but are not limited to, the authority to initiate court 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, and to seek civil monetary and criminal penalties. Other enforcement activities include refusal to approve product applications or the withdrawal of previously approved applications. Any such enforcement activities, including 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, product recalls may be issued at our discretion, or at the request of the FDA or other government agencies having regulatory authority for pharmaceutical products. Recalls may occur due to disputed labeling claims, manufacturing issues, quality defects or other reasons. No assurance can be given that restriction or prohibition on sales, halting of manufacturing operations or recalls of our pharmaceutical products will not occur in the future. Any such actions could have a material adverse effect on our business, financial condition and results of operations. Further, such actions, in certain circumstances, could constitute an event of default under our New Credit Facility.

We must obtain approval from the FDA for each pharmaceutical product that we market. The FDA approval process is typically lengthy and expensive, 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.

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 sterile pharmaceutical products. The FDA imposes stringent mandatory requirements on the manufacture and distribution of sterile pharmaceutical products to ensure their sterility. 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 indefinitely, our manufacturing, distribution or sales of certain products. While we believe that all of our current pharmaceuticals are lawfully marketed in the United States under current FDA enforcement policies or have received the requisite agency approvals for manufacture and sale, such marketing authority is subject to withdrawal by the FDA. 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.

A number of products we market are grandfathered drugs that are permitted to be manufactured and marketed without FDA-issued ANDAs or NDAs on the basis of their having been marketed prior to enactment of relevant sections of the FDC Act. The regulatory status of these products is subject to change and/or challenge by the FDA, which could establish new standards and limitations for manufacturing and marketing such products, or challenge the evidence of prior manufacturing and marketing upon which grandfathering status is based. We are not aware of any current efforts by the FDA to change the status of any of our grandfathered products, but there can be no assurance that such initiatives will not occur in the future. Any such change in the status of our grandfathered 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 established, 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. On March 6, 2002, we received a letter from the United States Attorney s Office, Central District of Illinois, Springfield, Illinois, advising us that the DEA had referred a matter to that office for a possible civil legal action for alleged violations of the Comprehensive Drug Abuse Prevention Control Act of 1970, 21 U.S.C. § 801 et. seq., and regulations promulgated thereunder. The alleged violations relate to record keeping and controls surrounding the storage and distribution of controlled substances. On November 6, 2002, we entered into a Civil Consent Decree with the DEA. Under the terms of the Civil Consent Decree, without admitting any of the allegations in the complaint from the DEA, we agreed to pay a fine of $100,000, upgrade our security system and to remain in substantial compliance with the Comprehensive Drug Abuse Prevention Control Act of 1970. If we failed to remain in substantial compliance during the two-year period following the entry of the Civil Consent Decree, we, in addition to other possible sanctions, might have been held in contempt of court and ordered to pay an additional $300,000 fine. We completed the upgrades to our security system in 2003 and have received no further notice from the DEA in connection with the Civil Consent Decree. The two-year compliance period lapsed on November 6, 2004. We were inspected by the DEA in February 2005 and the DEA has not informed us of any further violations. See Business Legal Proceedings.

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 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. There were no product recalls in 2004. In February 2003, we recalled two products, Fluress and Fluoracaine, due to container/closure integrity problems resulting in leaking containers. The recall was classified by the FDA as a Class II Recall, which means that the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or that the probability of serious health consequences as a result of such use or exposure is remote. We had not received any notification or complaints from end users of the recalled products. Because we had curtailed the production of these products due to the above container/closure integrity issues, the financial impact to us of this recall was not material as our customers did not hold significant inventories of these products. We began production of Fluress and re-started distribution in September 2004. We have discontinued production of Fluoracaine.

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 $5,000,000 for aggregate annual claims with a $50,000 deductible per incident and a $250,000 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.

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 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 our products. We believe that competition in sales of our products is based primarily on price, service and technical capabilities. There can be no assurance that: (1) we will be able to develop or acquire commercially attractive pharmaceutical products; (2) additional competitors will not enter the market; or (3) competition from other pharmaceutical companies will not 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 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.

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: (1) successfully challenge our patents or proprietary rights; (2) obtain patents or proprietary rights that may have an adverse effect on our ability to conduct business; or (3) 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 obsoleting 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.

Risks Related to an Investment in Our Common Stock

There is a limited market for our common stock.

The price at which you may be able to sell shares of our common stock is very unpredictable because there are very few trades in our common stock. Because our common stock is so thinly traded, a large block of shares traded can lead to a dramatic fluctuation in the share price.