

ALKERMES INC
Form POS AM
October 30, 2003

Table of Contents

As filed with the Securities and Exchange Commission on October 30, 2003

Registration No. 333-108483

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Post-Effective Amendment No. 2
FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ALKERMES, INC.

(Exact name of registrant as specified in its charter)

Pennsylvania
(State or other jurisdiction of
incorporation or organization)

23-2472830
(I.R.S. Employer
Identification No.)

88 Sidney Street
Cambridge, Massachusetts 02139
(617) 494-0171
(Address, including zip code, and telephone
number, including area code,
of registrant's principal executive offices)

Richard F. Pops, Chief Executive Officer
Alkermes, Inc.
88 Sidney Street, Cambridge, Massachusetts 02139
(617) 494-0171
(Name, address, including zip code, and telephone
number, including area code,
of agent for service)

Copies to:

Jennifer L. Miller, Esq.
Ballard Spahr Andrews & Ingersoll, LLP
1735 Market Street, 51st Floor
Philadelphia, Pennsylvania 19103
(215) 665-8500

Edgar Filing: ALKERMES INC - Form POS AM

Approximate date of commencement of proposed sale to the public:
From time to time after this Registration Statement becomes effective

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

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

Table of Contents

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act 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:

CALCULATION OF REGISTRATION FEE

Title of each class of Securities to be registered	Amount to be registered	Proposed maximum offering price per unit	Proposed maximum aggregate offering price	Amount of registration fee
2½% Convertible Subordinated Notes due 2023	\$ 125,000,000	100%(1)(2)	\$ 125,000,000	\$ 10,113(3)
Common Stock, par value \$.01 per share	11,133,603 shares(4)	(5)	(5)	(5)

(1) Estimated solely for the purposes of calculating the registration fee pursuant to Rule 457(i) of the Securities Act of 1933.

(2) Exclusive of accrued interest, if any.

(3) Previously paid.

(4) This number represents 9,025,275 shares of common stock, issuable upon conversion of the Notes, or, if the 2½% Convertible Subordinated Notes are not converted, and we exercise our right to repurchase the 2½% Convertible Subordinated Notes for stock, 10,627,530 shares of common stock, which may be issuable upon a repurchase event, and 506,073 shares of common stock which may be issuable to satisfy the three-year interest make-whole payment. For purposes of estimating the number of shares of common stock to be included upon conversion of the notes, Alkermes, Inc. calculated the number of shares issuable upon conversion of the notes based on a conversion price of \$13.85 per share (equivalent to 72.2022 shares of common stock for each \$1,000 principal amount of the notes), upon repurchase of the notes based on an estimated market value of \$13.00 and upon satisfaction of the three-year interest make-whole obligation at an estimated market value of \$19.00. In addition, the shares set forth in the table, pursuant to Rule 416 under the Securities Act of 1933, include an indeterminate number of shares of common stock issuable upon conversion or repurchase of the notes and satisfaction of the three-year interest make-whole payment, as this amount may be adjusted as a result of stock splits, stock dividends and antidilution provisions.

(5) No additional consideration will be received for the common stock and, therefore, no registration fee is required pursuant to Rule 457(i).

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 this Registration Statement shall become effective on such date as the SEC, acting pursuant to said Section 8(a), may determine.

Table of Contents

PROSPECTUS

Alkermes, Inc.

**\$125,000,000 2½% Convertible Subordinated Notes due 2023
11,133,603 Shares of Common Stock**

The selling securityholders named in this prospectus or in prospectus supplements may offer and sell the notes and the common stock issued upon conversion or repurchase of the notes or issued to satisfy the three-year interest make-whole obligation with this prospectus. We will not receive any of the proceeds from sales of these securities by the selling securityholders.

The notes are convertible at any time prior to maturity into common stock at a conversion price of \$13.85 per share, subject to adjustment upon certain events.

Interest is payable on each March 1 and September 1, beginning March 1, 2004. The notes mature on September 1, 2023. The notes are subordinated to our senior indebtedness and structurally subordinated to the indebtedness and other liabilities of our subsidiaries.

We may redeem some or all of the notes on or after September 6, 2006 at the declining redemption prices listed in this prospectus, plus accrued but unpaid interest. At any time prior to maturity, we may elect to automatically convert the notes if the closing price of our common stock has exceeded 150% of the conversion price for at least 20 trading days during any 30-day trading period, ending within five trading days prior to the notice of automatic conversion. If we elect to automatically convert your notes on or prior to September 1, 2006, we will pay additional interest in cash or, at our option, in common stock, equal to three full years of interest on the converted notes, less any interest actually paid or provided for on the notes prior to automatic conversion. You have the option to require us to repurchase any notes held by you in the event of a repurchase event at a repurchase price equal to 105% of the principal amount of the notes plus accrued and unpaid interest, which we may pay in cash or, at our option, in common stock. You also have the option to require us to repurchase for cash any note held by you on September 1, 2008, 2013 and 2018 at a price equal to 100% of the principal amount of the notes plus accrued and unpaid interest.

The notes, issued in denominations of \$1,000, are currently eligible for trading on the Portal Market of the Nasdaq Stock Market. Our common stock is traded on the Nasdaq National Market under the symbol ALKS. On October 28, 2003 the last sale price of our common stock, as reported on the Nasdaq National Market, was \$13.45 per share.

The selling securityholders may sell their securities from time to time on the Nasdaq National Market or otherwise. They may sell the securities at prevailing market prices or at prices negotiated with purchasers. The selling securityholders will be responsible for any commissions or discounts due to brokers or dealers. The amount of those commissions or discounts cannot be known now because they will be negotiated at the time of the sales. We will pay all registration expenses.

Investing in the securities offered by this prospectus involves a high degree of risk.

See Risk Factors beginning on page 4.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved 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 October 30, 2003

TABLE OF CONTENTS

SUMMARY

RISK FACTORS

WHERE YOU CAN FIND MORE INFORMATION

USE OF PROCEEDS

PRICE RANGE OF COMMON STOCK

DIVIDEND POLICY

RATIO OF EARNINGS TO FIXED CHARGES

CAPITALIZATION

SELECTED HISTORICAL FINANCIAL DATA

BUSINESS

DESCRIPTION OF NOTES

BOOK-ENTRY SYSTEM - THE DEPOSITORY TRUST COMPANY

DESCRIPTION OF CAPITAL STOCK

PLAN OF DISTRIBUTION FOR THE RESALE OF THE SECURITIES

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

MANAGEMENT

EXECUTIVE COMPENSATION AND OTHER INFORMATION

REPORT OF THE COMPENSATION COMMITTEE ON EXECUTIVE COMPENSATION

PERFORMANCE GRAPH

EQUITY COMPENSATION PLAN INFORMATION

MANAGEMENT AND PRINCIPAL SHAREHOLDERS

CERTAIN TRANSACTIONS

LEGAL MATTERS

EXPERTS

FINANCIAL STATEMENTS

FINANCIAL STATEMENTS OF RELIANT PHARMACEUTICALS, LLC

SIGNATURES

EXHIBIT INDEX

EX-23.1 CONSENT OF DELOITTE & TOUCHE LLP

EX-23.2 CONSENT OF ERNST & YOUNG LLP

Table of Contents

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information that is different from that contained in this prospectus. The selling securityholders are offering to sell, and seeking offers to buy, the securities only in jurisdictions where offers and sales are permitted. 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 any sale of the securities. References to we, us and our refer to Alkermes, Inc. and its subsidiaries in this prospectus unless otherwise specified.

TABLE OF CONTENTS

Table of Contents

	Page
SUMMARY	1
RISK FACTORS	4
WHERE YOU CAN FIND MORE INFORMATION	20
USE OF PROCEEDS	21
PRICE RANGE OF COMMON STOCK	21
DIVIDEND POLICY	21
RATIO OF EARNINGS TO FIXED CHARGES	21
CAPITALIZATION	22
SELECTED HISTORICAL FINANCIAL DATA	24
BUSINESS	27
DESCRIPTION OF NOTES	43
BOOK-ENTRY SYSTEM - THE DEPOSITORY TRUST COMPANY	58
DESCRIPTION OF CAPITAL STOCK	60
SELLING SECURITYHOLDERS	64
PLAN OF DISTRIBUTION FOR THE RESALE OF THE SECURITIES	65
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	67
QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	82
MANAGEMENT	84
EXECUTIVE COMPENSATION AND OTHER INFORMATION	88
REPORT OF THE COMPENSATION COMMITTEE ON EXECUTIVE COMPENSATION	93
PERFORMANCE GRAPH	97
EQUITY COMPENSATION PLAN INFORMATION	98
MANAGEMENT AND PRINCIPAL SHAREHOLDERS	99
CERTAIN TRANSACTIONS	101
LEGAL MATTERS	101
EXPERTS	101
INDEX TO FINANCIAL STATEMENTS OF ALKERMES AND OF RELIANT PHARMACEUTICALS, LLC	F-1

Table of Contents

SUMMARY

This summary does not contain all of the information you should consider before investing in our notes or any shares of common stock issuable upon conversion or repurchase of the notes or upon satisfaction of the three-year interest make-whole obligation. You should read this entire prospectus carefully. Unless otherwise indicated, we, us, our, Alkermes and similar terms refer to Alkermes, Inc. and its subsidiaries.

Our Business

Alkermes, Inc., a Pennsylvania corporation organized in 1987, is an emerging pharmaceutical company developing products based on applying its proprietary drug delivery technologies. Our areas of focus include: controlled, extended-release of injectable drugs using our ProLease® and Medisorb® delivery systems and the development of inhaled pharmaceuticals based on our proprietary Advanced Inhalation Research, Inc. (AIR®) pulmonary delivery system. Our product development strategy is twofold. We partner our proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies and we also develop novel, proprietary drug candidates for our own account. We have a broad pipeline of products and product candidates including two marketed products and several product candidates at various stages of clinical development. In addition to our Cambridge, Massachusetts headquarters, research and manufacturing facilities, we operate research and manufacturing facilities in Ohio.

Our principal executive offices are located at 88 Sidney Street, Cambridge, Massachusetts 02139 and our telephone number is (617) 494-0171.

Alkermes®, the Alkermes logo, ProLease®, Medisorb®, AIR® and Vivitrex® are registered trademarks of Alkermes, Inc. Nutropin Depot® is a registered trademark of Genentech, Inc. RISPERDAL® is a registered trademark, and Risperdal Consta™ is a trademark, of Janssen Pharmaceutica Products, LP.

Table of Contents

Securities to be Offered

We issued and sold \$100 million and \$25 million aggregate principal amount of the notes in August and September 2003, respectively, to the initial purchaser in a transaction that was exempt from the registration requirements imposed by the Securities Act of 1933. The initial purchaser reasonably believed that the persons to whom it resold the notes were qualified institutional buyers as defined in Rule 144A under the Securities Act.

Securities offered	\$125,000,000 principal amount of 2½% Convertible Subordinated Notes due 2023, 9,025,275 shares of common stock, issuable upon conversion of the 2½% Convertible Subordinated Notes, or, if the 2½% Convertible Subordinated Notes are not converted, and we exercise our right to repurchase the 2½% Convertible Subordinated Notes for stock, 10,627,530 shares of common stock, which may be issuable upon a repurchase event, assuming a market value of the common stock of \$13.00 per share, and 506,073 shares of common stock which may be issuable to satisfy the three-year interest make-whole payment, assuming a market value of the common stock of \$19.00 per share.
Interest	Interest is payable at the rate of 2½% per year on each March 1 and September 1 beginning on March 1, 2004.
Maturity date	September 1, 2023
Conversion	The notes are convertible at the option of the holder at any time prior to maturity into common stock at a conversion price of \$13.85 per share, subject to adjustment upon certain events.
Auto-conversion	We may elect to automatically convert some or all of the notes on or prior to maturity if the closing price of our common stock has exceeded 150% of the conversion price for at least 20 trading days during any 30-day trading period, ending within five trading days prior to the notice of automatic conversion. During the two-year period after the issue date of the notes, we may automatically convert the notes only if a registration statement has been declared effective prior to the date of the notice of automatic conversion and such registration statement remains effective on the date of automatic conversion.
Interest make-whole provisions during first three years upon auto-conversion	If an automatic conversion occurs on or prior to September 1, 2006, we will pay additional interest in cash or, at our option, in common stock, equal to three full years of interest on the converted notes, less any interest actually paid or provided for on the notes prior to automatic conversion. If we elect to pay the additional interest in common stock, the shares of common stock will be valued at 97.5% of the average closing price of our common stock for the five trading days immediately preceding the second trading day prior to the

Table of Contents

conversion date.

Optional redemption	We may redeem some or all of the notes on or after September 6, 2006 at the declining redemption prices listed in this offering memorandum, plus accrued and unpaid interest.
Repurchase at the option of the holder	You may require us to repurchase the notes for cash on September 1, 2008, September 1, 2013 and September 1, 2018 at a repurchase price equal to 100% of the principal amount, plus accrued and unpaid interest.
Repurchase at the option of the holder upon a repurchase event	You may require us to repurchase your notes upon a repurchase event in cash, or, at our option, in common stock, at 105% of the principal amount of the notes, plus accrued and unpaid interest.
Ranking	The notes are subordinated to our senior indebtedness. As of September 30, 2003, we had approximately \$460,000 of senior indebtedness outstanding. The indenture for the notes does not limit our ability to incur additional indebtedness, senior or otherwise.
Trading	The notes are eligible for trading in the PORTAL Market. Our common stock is traded on the NASDAQ National Market under the symbol ALKS.

Table of Contents

RISK FACTORS

You should carefully consider the risks described below before you decide to buy the notes or any shares of common stock issuable upon conversion or repurchase of the notes or upon satisfaction of the three-year interest make-whole obligation. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business operations.

If any of the following risks actually occur, they could materially adversely affect our business, financial condition or operating results. In that case, the trading price of our common stock and the notes could decline.

Risks Related to Alkermes

Our products or product candidates may not generate significant revenues.

Even if a product receives regulatory approval for commercial use, the revenues received or to be received from the sale of such products may not be significant and will depend on numerous factors outside of our control, including, in many instances, our collaborators' decisions on the timing of product launches, pricing and discounting, the reliance on third-party marketing partners outside the United States, the ability to obtain reimbursement from third-party payors, the market size for the product, the reaction of companies that market competitive products and general market conditions. In addition, if certain volume levels are not achieved, the costs to manufacture our products may be higher than anticipated.

Risperdal Consta

On October 29, 2003, J&J PRD received a letter from the FDA approving Risperdal Consta for sale in the U.S. for the treatment of schizophrenia. The success of launch in the U.S. is uncertain and the revenues received from the sale of Risperdal Consta may not be significant and each depend on numerous factors outside of our control, including those outlined above. In addition, the costs to manufacture Risperdal Consta may be higher than anticipated if certain volume levels are not achieved. If Risperdal Consta does not produce significant revenues or if the manufacturing costs are higher than anticipated, our business, results of operations and financial condition would be materially adversely affected.

Vivitrex

We are currently conducting a Phase III clinical trial in alcohol-dependent patients testing the safety and efficacy of repeat doses of Vivitrex, an injectable extended-release formulation of naltrexone. Our proprietary product candidate, Vivitrex, was tested in a small number of patients in early clinical trials and there can be no assurance that the Phase III clinical trial will produce results sufficient to obtain regulatory approvals. Even if the Phase III clinical trial is successful and we submit an NDA to the FDA for Vivitrex, there can be no assurance that the FDA will accept our data or that the NDA will be approved. We are relying on data from the original approval of oral naltrexone under Section 505(b)(2) of the U.S. Food, Drug and Cosmetic Act. While we believe only one Phase III efficacy study will be required for approval, the FDA will require that additional safety data be collected on Vivitrex's long-term use before approval. Even if an NDA is approved, we will have to market Vivitrex ourselves or enter into co-promotion or sales and marketing arrangements with other companies. We currently have no sales force or any marketing experience and arrangements with other companies will result in dependence on such other companies for revenues. In either event, a market for Vivitrex may not develop as expected. There are manufacturing risks that come with the manufacture of Vivitrex. See Our manufacturing experience is limited. In addition, naltrexone is made using controlled substances and, therefore, we may be unable to obtain commercial-quantity supplies of pharmaceutical grade naltrexone on commercially reasonable terms.

We rely heavily on collaborative partners.

Our arrangements with collaborative partners are critical to our success in bringing our products and product candidates to the market and promoting such marketed products profitably. We rely on these parties in various respects, including to conduct preclinical testing and clinical trials, to provide funding for product candidate development programs, raw materials, product forecasts, and sales and marketing services, or to participate actively in the regulatory approval process. Most of our collaborative partners can terminate their agreements with us for no reason and on limited notice. We cannot guarantee that any of these relationships will continue. Failure to make or maintain these arrangements or a delay in a collaborative partner's performance may materially adversely affect our business and financial condition.

Edgar Filing: ALKERMES INC - Form POS AM

We cannot control our collaborative partners' performance or the resources they devote to our programs. Consequently, programs may be delayed or terminated or we may have to use funds, personnel, laboratories and other resources that we have not budgeted. A program delay or termination or unbudgeted use of our resources may materially adversely affect our business and financial condition.

Disputes may arise between us and a collaborative partner and may involve the issue of which of us owns the technology that is developed during a collaboration or other issues arising out of the collaborative agreements. Such a dispute could delay the program on which the collaborative partner or we are working. It could also result in expensive arbitration or litigation, which may not be resolved in our favor.

A collaborative partner may choose to use its own or other technology to develop a way to deliver its drug and withdraw its support of our product candidate.

Our collaborative partners could merge with or be acquired by another company or experience financial or other setbacks unrelated to our collaboration that could, nevertheless, adversely affect us.

None of our drug delivery systems can be commercialized as stand-alone products but must be combined with a drug. To develop any new proprietary product candidate using one of these drug delivery systems, we must obtain the drug substance from another party. We cannot assure you that we will be able to obtain any such drug substance on reasonable terms, if at all.

Our delivery technologies or product development efforts may not produce safe, efficacious or commercially viable products.

Many of our product candidates require significant additional research and development, as well as regulatory approval. To be profitable, we must develop, manufacture and market our products, either alone or by collaborating with others. It can take several years for a product candidate to be approved and we may not be successful in bringing additional product candidates to the market. A product candidate may appear promising at an early stage of development or after clinical trials and never reach the market, or it may reach the market and not sell, for a variety of reasons. The product candidate may:

- be shown to be ineffective or to cause harmful side effects during preclinical testing or clinical trials;

- fail to receive regulatory approval on a timely basis or at all;

- be difficult to manufacture on a large scale;

- be uneconomical;

Table of Contents

not be prescribed by doctors or accepted by patients;

fail to receive a sufficient level of reimbursement from government or third-party payors; or

infringe on proprietary rights of another party.

If our delivery technologies or product development efforts fail to generate product candidates that lead to the successful development and commercialization of products, if our collaborative partners decide not to pursue our product candidates or if new products do not perform as anticipated, our business and financial condition will be materially adversely affected.

Table of Contents

Our manufacturing experience is limited.

We currently manufacture Risperdal Consta, Nutropin Depot and all of our product candidates. The manufacture of drugs for clinical trials and for commercial sale is subject to regulation by the FDA under current good manufacturing practices (cGMP) regulations and by other regulators under other laws and regulations. We have manufactured product candidates for use in clinical trials but have limited experience manufacturing products for commercial sale. We cannot assure you that we can successfully manufacture our products under current good manufacturing practices (cGMP) regulations or other laws and regulations in sufficient quantities for commercial sale, or in a timely or economical manner.

Our manufacturing facilities in Massachusetts and Ohio require specialized personnel and are expensive to operate and maintain. Any delay in the regulatory approval or market launch of product

Table of Contents

candidates to be manufactured in these facilities will require us to continue to operate these expensive facilities and retain specialized personnel, which may increase our expected losses.

We have a number of manufacturing facilities, including current good manufacturing practices (cGMP) facilities for Risperdal Consta, Nutropin Depot and facilities for future ProLease product candidates, Medisorb product candidates and AIR pulmonary drug delivery product candidates. We have recently completed expansion of our facility in Ohio for Risperdal Consta and our Medisorb technology product candidates (including Vivitrex) and construction of a facility in Chelsea, Massachusetts for our AIR technology product candidates and both facilities are currently being validated. Validation is a lengthy process that must be completed before we can manufacture under cGMP guidelines.

To date, the FDA has inspected and approved our manufacturing facility for Nutropin Depot and inspected our manufacturing facility for Risperdal Consta and issued an approvable letter. In addition, a European regulatory body has approved the Ohio facility for the commercial manufacture of Risperdal Consta. We cannot guarantee that the FDA or foreign regulatory agencies will approve any of the other facilities or, once they are approved, that such facilities will remain in compliance with current good manufacturing practices (cGMP) regulations.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time. We may not be able to resolve any such difficulties in a timely fashion, if at all. We are currently the sole manufacturer of Risperdal Consta and Nutropin Depot. If anything were to interfere with the continuing manufacturing operations in either of these facilities, it could materially adversely affect our business and financial condition.

If more of our product candidates progress to mid- to late-stage development, we will incur significant expenses in the expansion and/or construction of manufacturing facilities and increases in personnel in order to manufacture product candidates. The development of a commercial-scale manufacturing process is complex and expensive. We cannot assure you that we have the necessary funds or that we will be able to develop this manufacturing infrastructure in a timely or economical manner, or at all.

Currently, many of our product candidates, including Vivitrex, are manufactured in small quantities for use in clinical trials. We cannot assure you that we will be able to successfully scale-up the manufacture of each of our product candidates in a timely or economical manner, or at all. If any of these product candidates are approved by the FDA or other drug regulatory authorities for commercial sale, we will need to manufacture them in larger quantities. If we are unable to successfully scale-up our manufacturing capacity, the regulatory approval or commercial launch of such product candidate may be delayed or there may be a shortage in supply of such product candidate.

If we fail to develop manufacturing capacity and experience, fail to continue to contract for manufacturing on acceptable terms, or fail to manufacture our product candidates economically on a commercial scale or in accordance with current good manufacturing practices (cGMP) regulations, our development programs will be materially adversely affected. This may result in delays in receiving FDA or foreign regulatory approval for one or more of our product candidates or delays in the commercial production of a product that has already been approved. Any such delays could materially adversely affect our business and financial condition.

Clinical trials for our product candidates are expensive and their outcome is uncertain.

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we or our partners must demonstrate

Table of Contents

through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, preclinical testing and clinical trials.

Historically, the results from preclinical testing and early clinical trials have often not predicted results of later clinical trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Our proprietary product candidate, Vivitrex, was tested in a small number of patients in early clinical trials and there can be no assurance that our ongoing Phase III clinical trial for this product candidate will produce results sufficient to obtain regulatory approval. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

Clinical trials conducted by us, by our collaborative partners or by third parties on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our product candidates. Regulatory authorities may not permit us to undertake any additional clinical trials for our product candidates.

Clinical trials of each of our product candidates involve a drug delivery technology and a drug. This makes testing more complex because the outcome of the trials depends on the performance of technology in combination with a drug.

We have other product candidates in preclinical development. We or our collaborative partners have not submitted Investigational New Drug Applications, or INDs, or begun clinical trials for these product candidates. Preclinical and clinical development efforts performed by us may not be successfully completed. We may not file further INDs. We or our collaborative partners may not begin clinical trials as planned.

Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product candidate. The commencement and rate of completion of clinical trials may be delayed by many factors, including the:

- potential delay by a collaborative partner in beginning the clinical trial;
- inability to recruit clinical trial participants at the expected rate;
- failure of clinical trials to demonstrate a product candidate's safety or efficacy;
- inability to follow patients adequately after treatment;
- unforeseen safety issues;
- inability to manufacture sufficient quantities of materials used for clinical trials; and
- unforeseen governmental or regulatory delays.

If a product candidate fails to demonstrate safety and efficacy in clinical trials, this failure may delay development of other product candidates and hinder our ability to conduct related preclinical testing and clinical trials. As a result of these failures, we may also be unable to find additional collaborative

Table of Contents

partners or to obtain additional financing. Our business and financial condition may be materially adversely affected by any delays in, or termination of, our clinical trials.

We may not recoup any of our \$100 million investment in Reliant.

In December 2001, we made a \$100 million investment in Series C Preferred Units of Reliant in exchange for approximately a 19% interest in Reliant. Reliant is a privately held pharmaceutical company marketing branded, prescription pharmaceutical products to primary care physicians in the United States. Our investment in Reliant is illiquid and required us to take noncash charges based on Reliant's net losses from its operations. We recorded equity losses of \$100 million related to our Reliant investment from the date of our investment through March 31, 2003 and, as required under the equity method of accounting, our \$100 million dollar investment was reduced to zero in the same time period. Since we have no further funding commitments to Reliant, we will not record any further share of Reliant's losses in our consolidated statements of operations and comprehensive loss. We may not see any return on our \$100 million investment.

We will need to spend substantial funds to become profitable.

We will need to spend substantial amounts of money before we can be profitable, and there can be no assurance we will achieve profitability. The amount we will spend and when we will spend it depends, in part, on:

- the progress of our research and development programs for proprietary and collaborative product candidates, including clinical trials;
- the time and expense that will be required to pursue FDA or foreign regulatory approvals for our product candidates and whether such approvals are obtained;
- the cost of building, operating and maintaining manufacturing and research facilities;
- how many product candidates we pursue, particularly proprietary product candidates;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;
- how competing technological and market developments affect our product candidates;
- the cost of possible acquisitions of drug delivery technologies, compounds, product rights or companies; and
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise.

If we require additional funds to complete any of our programs, we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. We will continue to pursue opportunities to obtain additional financing in the future. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. Our future capital requirements will also depend on many of the factors listed above. If we are unable to raise additional funds on terms that are favorable to us, we may have to cut back significantly on one or more of our

Table of Contents

programs, give up some of our rights to our technologies, product candidates or licensed products or agree to reduced royalty rates from collaborative partners.

We anticipate that we will incur substantial losses in the foreseeable future.

We have had net operating losses since being founded in 1987. At June 30, 2003, our accumulated deficit was \$481.3 million. These losses principally consisted of the costs of research and development, capital expenditures and general and administrative expenses, as well as noncash compensation costs and noncash charges related to our share of Reliant's losses. We expect to incur substantial additional expenses over the next several years as our research and development activities, including clinical trials, increase and as we continue to manufacture products. In addition, we expect these costs to increase over prior years as we expand development of our collaborators' and our own product candidates.

Our future profitability depends, in part, on our ability to:

obtain and maintain regulatory approval for our products in the United States and in foreign countries;

enter into agreements to develop and commercialize products;

develop and expand our capacity to manufacture and market products or enter into agreements with others to do so;

obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third party payors;

obtain additional research and development funding from collaborative partners or funding for our proprietary product candidates; and
achieve certain product development milestones.

We may not achieve any or all of these goals and, thus, we cannot provide assurances that we will ever be profitable or achieve significant revenues. Even if we do achieve some or all of these goals, we may not achieve significant commercial success.

The FDA or foreign regulatory agencies may not approve our product candidates.

Approval from the FDA is required to manufacture and market pharmaceutical products in the United States. Regulatory agencies in foreign countries have similar requirements. The process that pharmaceutical products must undergo to obtain this approval is extensive and includes preclinical testing and clinical trials to demonstrate safety and efficacy and a review of the manufacturing process to ensure compliance with current good manufacturing practices (cGMP) regulations. This process can last many years and be very costly and still be unsuccessful. FDA or foreign regulatory approval can be delayed, limited or not granted at all for many reasons, including:

a product candidate may not be safe or effective;

data from preclinical testing and clinical trials may be interpreted by the FDA or foreign regulatory agencies in different ways than we or our partners interpret it;

Table of Contents

the FDA or foreign regulatory agencies might not approve our manufacturing processes or facilities;

the FDA or foreign regulatory agencies may change their approval policies or adopt new regulations;

a product candidate may not be approved for all the indications we or our partners request; and

the FDA may not agree with our or our partners' regulatory approval strategies or components of our or our partners' filings, such as clinical trial designs.

For some product candidates, the drug used has not been approved at all or has not been approved for every indication it is targeting. Any delay in the approval process for any of our product candidates will result in increased costs that could materially adversely affect our business and financial condition.

Regulatory approval of a product candidate is limited to specific therapeutic uses for which the product has demonstrated safety and efficacy in clinical testing. Approval of a product candidate could also be contingent on post-marketing studies. In addition, any marketed drug and its manufacturer continue to be subject to strict regulation after approval. Any unforeseen problems with an approved drug or any violation of regulations could result in restrictions on the drug, including its withdrawal from the market.

If and when approved, the commercial use of our products may cause unintended side effects or adverse reactions or incidence of misuse may appear.

We cannot predict whether the commercial use of products (or product candidates in development, if and when they are approved for commercial use) will produce undesirable or unintended side effects that have not been evident in the use of, or clinical trials conducted for, such products (and product candidates) to date. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls.

Patent protection for our products is important and uncertain.

The following factors are important to our success:

receiving and maintaining patent protection for our products and product candidates and for those of our collaborative partners;

maintaining our trade secrets;

not infringing the proprietary rights of others; and

preventing others from infringing our proprietary rights.

Patent protection only provides rights of exclusivity for the term of the patent. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We know of several United States patents issued to third parties that relate to our product candidates. One of those third parties has asked us to compare our Medisorb technology to that third

Table of Contents

party's patented technology. Another such third party has asked a collaborative partner to substantiate how our ProLease microspheres are different from that third party's patented technology. The manufacture, use, offer for sale, sale or importing of any of these product candidates might be found to infringe the claims of these third party patents. A third party might file an infringement action against us. Our cost of defending such an action is likely to be high and we might not receive a favorable ruling.

We also know of patent applications filed by other parties in the United States and various foreign countries that may relate to some of our product candidates if such patents are issued in their present form. If patents are issued to any of these applicants, we may not be able to manufacture, use, offer for sale or sell some of our product candidates without first getting a license from the patent holder. The patent holder may not grant us a license on reasonable terms or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing or selling those of our product candidates that would require the license.

We try to protect our proprietary position by filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Because the patent position of pharmaceutical and biotechnology companies involves complex legal and factual questions, enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, together with those we may file in the future, or those we may license from third parties, may not result in patents being issued. Even if issued, such patents may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our collaborative partners, licensors, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, our business and financial condition could be materially adversely affected.

We are exposed to product liability claims and recalls.

We may be exposed to liability claims arising from the commercial sale of our products, Nutropin Depot or Risperdal Consta, or the use of our product candidates in clinical trials and those awaiting regulatory approval. These claims may be brought by consumers, clinical trial participants, our collaborative partners or third parties selling the products. We currently carry product liability insurance coverage in such amounts as we believe are sufficient for our business. However, we cannot provide any assurance that this coverage will be sufficient to satisfy any liabilities that may arise. As our development activities progress and we continue to have commercial sales, this coverage may be inadequate; we may be unable to obtain adequate coverage at an acceptable cost or we may be unable to get adequate coverage at all. This could prevent or limit our commercialization of our product candidates or commercial sales of our products. Even if we are able to maintain insurance that we believe is adequate, our financial condition may be materially adversely affected by a product liability claim.

Additionally, product recalls may be issued at our discretion or at the direction of the FDA, other government agencies or other companies having regulatory control for pharmaceutical product sales. We cannot assure you that product recalls will not occur in the future or that, if such recalls occur, such recalls will not adversely affect our business, financial condition or reputation.

Table of Contents

We may not be successful in the development of products for our own account.

In addition to our development work with collaborative partners, we are developing proprietary product candidates for our own account by applying drug delivery technologies to off-patent drugs. Because we will be funding the development of such programs, there is a risk that we may not be able to continue to fund all such programs to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals or market any approved products on a worldwide basis. We expect the development of products for our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

If we are not able to develop new products, our business may suffer.

We compete with other pharmaceutical companies, including large pharmaceutical companies with financial resources and capabilities substantially greater than our resources and capabilities, in the development of new products. We cannot assure you that we will be able to:

develop or successfully commercialize new products on a timely basis or at all; or

develop new products in a cost effective manner.

Further, other companies may develop products or may acquire technology for the development of products that are the same as or similar to our platform technologies or the product candidates we have in development. Because there is rapid technological change in the industry and because other companies have more resources than we do, other companies may:

develop their products more rapidly than we can;

complete any applicable regulatory approval process sooner than we can; or

offer their newly developed products at prices lower than our prices.

Any of the foregoing may negatively impact our sales of newly developed products. Technological developments or the FDA's approval of new therapeutic indications for existing products may make our existing products or those product candidates we are developing obsolete or may make them more difficult to market successfully, any of which could have a material adverse effect on our business and financial condition.

Foreign currency exchange rates may affect revenue.

To the extent that significant revenues from Risperdal Consta are derived from foreign countries, such revenues may fluctuate when translated to United States dollars as a result of changes in foreign currency exchange rates.

We face competition in the biotechnology and pharmaceutical industries.

We can provide no assurance that we will be able to compete successfully against the competitive forces in developing our products and product candidates.

Table of Contents

We face intense competition from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including other drug delivery companies. Some of these competitors are also our collaborative partners. These competitors are working to develop and market other drug delivery systems, pharmaceutical products, vaccines and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs that can be used without a drug delivery system.

There are other companies developing extended-release drug delivery systems and pulmonary delivery systems. In many cases, there are products on the market or in development that may be in direct competition with our products or product candidates. In addition, we know of new chemical entities that are being developed that, if successful, could compete against our product candidates. These chemical entities are being designed to work differently than our product candidates and may turn out to be safer or to be more effective than our product candidates. Among the many experimental therapies being tested in the United States and Europe, there may be some that we do not now know of that may compete with our drug delivery systems or product candidates. Our collaborative partners could choose a competing drug delivery system to use with their drugs instead of one of our drug delivery systems.

Many of our competitors have much greater capital resources, manufacturing, research and development resources and production facilities than we do. Many of them also have much more experience than we do in preclinical testing and clinical trials of new drugs and in obtaining FDA and foreign regulatory approvals.

Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development by competitors of technologically improved or different products or drug delivery technologies may make our product candidates or platform technologies obsolete or noncompetitive.

Further, our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any product candidates that we develop will depend on a number of factors, including:

demonstration of their safety and clinical efficacy;

their cost-effectiveness;

their potential advantage over alternative treatment methods;

the marketing and distribution support they receive; and

reimbursement policies of government and third-party payors.

Our product candidates, if successfully developed and approved for commercial sale, will compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our product candidates may also compete with new products currently under development by others or with products which may cost less than our product candidates. Physicians, patients, third-party payors and the medical community may not accept or utilize any of our product candidates that may be approved. If our products do not achieve significant market acceptance, our business and financial condition will be materially adversely affected.

Table of Contents

We may not be able to retain our key personnel.

Our success depends on the services of key employees in executive, research and development, manufacturing and regulatory positions. The loss of the services of key employees could have a material adverse effect on our business.

If we issue additional common stock, you may suffer dilution of your investment and a decline in stock price.

As discussed above under "We will need to spend substantial funds to become profitable," we may issue additional equity securities or securities convertible into equity securities to raise funds, thus reducing the ownership share of the current holders of our common stock, which may adversely affect the market price of the common stock. In addition, we were obligated, at June 30, 2003, to issue 14,618,925 shares of common stock upon the vesting and exercise of stock options and vesting of stock awards, 9,978 shares of common stock issuable upon conversion of the 3.75% Subordinated Notes, 2,824,859 shares of common stock issuable upon conversion of the Convertible Preferred Stock and 22,713,226 shares of common stock issuable upon conversion of the 6.52% Convertible Senior Subordinated Notes. In July 2003, we issued 24,029,531 shares of our common stock in exchange for and upon conversion of all of the 6.52% Convertible Senior Subordinated Notes. Any of our shareholders could sell all or a large number of their shares, which could adversely affect the market price of our common stock.

Our common stock price is highly volatile.

The realization of any of the risks described in these "Risk Factors" or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. Additionally, market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that were unrelated to the operating performance of any one company. In particular and in addition to circumstances described elsewhere under "Risk Factors," the following factors can adversely affect the market price of our common stock:

- non-approval or set-backs in development of our product candidates and success of our research and development programs;
- public concern as to the safety of drugs developed by us or others;
- announcements of issuances of common stock or acquisitions by Alkermes;
- developments of our corporate partners;
- announcements of technological innovations or new therapeutic products or drug delivery methods by us or others;
- changes in government regulations or policies or patent decisions; and
- general market conditions.

We may encounter difficulties integrating future acquisitions.

We have in the past and may again acquire novel technologies, compounds or the rights to certain products through acquisitions of such technologies and intellectual property rights or through the

Table of Contents

acquisition of businesses or companies. We cannot assure you that any such future acquisition will be completed, successfully integrated with our current businesses, will achieve revenues or will be profitable. We may have difficulty assimilating the operations, technology and personnel of any acquired businesses.

If we make significant acquisitions for stock consideration, the current holders of our common stock may be significantly diluted. If we make significant acquisitions for cash consideration, we may be required to use a substantial portion of our available cash.

Anti-takeover provisions may not benefit shareholders.

We are a Pennsylvania corporation and Pennsylvania law contains strong anti-takeover provisions. In February 2003, our board of directors adopted a shareholder rights plan. The shareholder rights plan provides for a dividend of one preferred share purchase right on each outstanding share of our common stock. Each right entitles shareholders to buy 1/1000th of a share of our Series A Junior Participating Preferred Stock at an exercise price of \$80.00. Each right will become exercisable following the tenth day after a person or group announces an acquisition of or commences a tender offer to purchase 15% or more of our common stock. We will be entitled to redeem the rights at \$0.001 per right at any time on or before the close of business on the tenth day following acquisition by a person or group of 15% or more of our common stock. The shareholder rights plan and Pennsylvania law could make it more difficult for a person or group to, or discourage a person or group from attempting to, acquire control of us, even if the change in control would be beneficial to shareholders. Our articles of incorporation and bylaws also contain certain provisions that could have a similar effect. The articles provide that our board of directors may issue, without shareholder approval, preferred stock having such voting rights, preferences and special rights as the board of directors may determine. The issuance of such preferred stock could make it more difficult for a third party to acquire us.

Litigation may result in financial losses or harm our reputation and may divert management resources.

The Company has become aware of a complaint that was posted to a law firm website on October 29, 2003, naming the Company and certain of its directors and existing and former officers as defendants, alleging violations of the federal securities laws. This and any other litigation that may be brought against us may result in financial losses, harm our reputation and require the dedication of significant management resources.

Risks Related to the Notes

The notes are subordinated to our senior debt.

The notes are unsecured and subordinated to our existing and future senior indebtedness, including our existing bank loan and equipment lease financing. As a result of such subordination, in the event of our insolvency, liquidation, reorganization, payment default on senior indebtedness, covenant default on our designated senior indebtedness, or upon acceleration of the notes due to an event of default, we will not be able to make payments on the notes until we have paid in full all of our senior indebtedness. We may, therefore, not have sufficient assets to pay the amounts due on the notes. Neither we nor our subsidiaries are prohibited from incurring debt under the indenture for the notes, including debt senior to, on parity with or subordinate to the notes. If we incur additional debt, our ability to pay amounts due on the notes could be adversely affected. As of September 30, 2003, we had approximately \$460,000 of senior indebtedness outstanding. We may also incur additional debt in the future.

Our subsidiaries will not be prohibited from incurring debts in the future that would be senior to the notes.

The notes are effectively subordinate to all indebtedness and other liabilities of our subsidiaries. Substantially all of our operations are conducted through our subsidiaries. Because substantially all of our operations are conducted through subsidiaries, claims from holders of indebtedness of our subsidiaries, as well as claims of regulators and creditors of our subsidiaries, will have priority with respect to the assets and any earnings of such subsidiaries over the claims of creditors of Alkermes, Inc., including you.

Table of Contents

The notes are obligations exclusively of Alkermes, Inc. Our subsidiaries are separate and distinct legal entities. Our subsidiaries have no obligation to pay any amounts due on the notes or to provide us with funds for our payment obligations, whether by dividends, distributions, loans or other payments. In addition, any payment of dividends, distributions, loans or advances by our subsidiaries to us could be subject to statutory or contractual restrictions. Payments to us by our subsidiaries will also be contingent upon our subsidiaries' earnings and business considerations.

We may not have sufficient funds to repurchase the notes.

At maturity, the entire outstanding principal amount of the notes will become due and payable by us. We cannot assure you that we will have sufficient funds, or will be able to arrange for financing, to pay the principal amount due. You may require us to repurchase all or any portion of your notes on September 1, 2008, September 1, 2013 and September 1, 2018, each a repurchase date, or upon a repurchase event, including a change in control. We may not have sufficient cash funds to repurchase the notes on a repurchase date or upon a repurchase event. If the repurchase is in connection with a repurchase event, we may elect, subject to certain conditions, to pay the repurchase price in common stock. Any future credit agreements or debt agreements may prohibit us from repaying the repurchase price in either cash or common stock or expressly prohibit the repurchase of the notes upon a change in control or may provide that a change in control constitutes an event of default under that agreement. If we are prohibited from repurchasing the notes, we could seek consent from our lenders to repurchase the notes. If we are unable to obtain their consent, we could attempt to refinance the notes. If we were unable to obtain a consent to repurchase, or refinance the notes, we would be prohibited from repurchasing the notes. If we were unable to repurchase the notes upon a repurchase date or repurchase event, it would result in an event of default under the indenture. An event of default under the indenture could result in a further event of default under other then-existing debt. In addition, the occurrence of the repurchase event may be an event of default under our other debt. As a result, we would be prohibited from paying amounts due on the notes under the subordination provisions of the indenture.

We have substantially increased our indebtedness.

As a result of the sale of the notes, we incurred \$125 million of additional indebtedness. Our other indebtedness is principally comprised of bank financing. We may incur substantial additional indebtedness in the future. The level of our indebtedness among other things, could:

make it difficult for us to make payments on the notes;

make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes;

limit our flexibility in planning for, or reacting to changes in, our business; and

make us more vulnerable in the event of a downturn in our business.

We cannot assure you that we will be able to meet our debt service obligations, including our obligations under the notes.

There may be no active market for the notes.

There was no trading market for the notes prior to the closing of the notes on August 22, 2003. Since then, the notes were approved for trading on the Portal Market. Although the initial purchaser of the notes has advised us that it intends to make a market in the notes, it is not obligated to make a market in the notes. The initial purchaser could stop making a market at any time without notice. Accordingly, no market for the notes may develop, and any market that develops may not last or be active.

We expect the trading price of the notes and the underlying common stock to be highly volatile, which could adversely affect the market price of our notes and underlying common stock.

The trading price of the notes and the underlying common stock will fluctuate in response to variations in:

Table of Contents

the factors described under Risks Related to Alkermes Our common stock price is highly volatile;
our operating results;
announcement by us or our competitors of technological innovations or new products; and
general economic and market conditions.

In addition, stock markets have experienced extreme price volatility in recent years, particularly for biotechnology companies. In the past, our common stock has experienced volatility not necessarily related to announcements of our financial performance. Broad market fluctuations may also adversely affect the market price of our notes and underlying common stock.

If we automatically convert the notes, you should be aware that there is a substantial risk of fluctuation in the price of our common stock from the date we elect to automatically convert to the conversion date.

We may elect to automatically convert the notes on or prior to maturity if our common stock price has exceeded 150% of the conversion price for at least 20 trading days during a 30-day trading period ending within five trading days prior to the notice of automatic conversion. You should be aware that there is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the notes and the automatic conversion date. This time period may extend up to 30 calendar days from the time we elect to automatically convert the notes until the conversion date.

Table of Contents

Special Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements that involve risks and uncertainties. These statements may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to our future plans, objectives, expectations and intentions and may be identified by the use of words like believe, expect, may, will, should, seek, pro forma, or anticipate, and similar expressions.

Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our development and manufacturing activities and our results of operations will not differ materially from our expectations. Factors which could cause actual results to differ from expectations include, among others: (i) Nutropin Depot, Risperdal Consta and our product candidates (including our proprietary product candidate, Vivitrex), if approved for marketing, may not produce significant revenues and we rely on our partners to determine the regulatory and marketing strategies for Risperdal Consta and Nutropin Depot; (ii) whether additional regulatory approvals will be received or whether commercial launches of Risperdal Consta in countries where it has been or may be approved occur in a timely or successful manner; (iii) Nutropin Depot, Risperdal Consta and our product candidates (including our proprietary product candidate, Vivitrex), in commercial use, may have unintended side effects, adverse reactions or incidents of misuse; (iv) we may enter into a collaboration with a third party to market or fund a proprietary product candidate and the terms of such a collaboration may not meet our expectations; (v) our delivery technologies or product development efforts may not produce safe, efficacious or commercially viable products; (vi) our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable new collaborative arrangements for our technologies could occur; (vii) we may be unable to manufacture our products, Nutropin Depot and Risperdal Consta, or to manufacture or scale-up our future products, on a commercial scale or economically; (viii) unexpected events could interrupt manufacturing operations at our Risperdal Consta and Nutropin Depot facilities, which are, in each case, the sole source of supply for these products; (ix) after the completion of clinical trials and the submission to the FDA of a New Drug Application (NDA) for marketing approval and to other health authorities as a marketing authorization application, the FDA or other health authorities could refuse to accept such filings or could request additional preclinical or clinical studies be conducted, each of which could result in significant delays, or such authorities could refuse to approve the product at all; (x) clinical trials are a time-consuming and expensive process; (xi) our product candidates could be ineffective or unsafe during preclinical studies and clinical trials and we and our collaborators may not be permitted by reg