ALKERMES INC Form S-1/A October 03, 2003

Table of Contents

As filed with the Securities and Exchange Commission on October 3, 2003

Registration No. 333-108483

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Pre-Effective Amendment No. 1 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

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: x

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: o

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: o

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; o

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

CALCULATION OF REGISTRATION FEE

Title of each class of Securities to be registered			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 September 24, 2003 the last sale price of our common stock, as reported on the Nasdaq National Market, was \$13.30 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 3, 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

SELLING SECURITYHOLDERS

PLAN OF DISTRIBUTION FOR THE RESALE OF THE SECURITIES

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS

OF OPERATIONS

OUANTITATIVE AND OUALITATIVE 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-5.1 OPINION OF BALLARD SPAHR ANDREWS & ...

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

i

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 ConstaTM is a trademark, of Janssen Pharmaceutica Products, LP.

1

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 $2\frac{1}{2}$ % Convertible Subordinated Notes, or, if the $2\frac{1}{2}$ % Convertible Subordinated Notes are not converted, and we exercise our right to repurchase the $2\frac{1}{2}$ % 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 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 If an automatic conversion occurs on or prior to September 1, 2006, we will pay additional during first three years upon auto-conversion 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

2

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 June 30, 2003, we had approximately \$6.825 million 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.
	3

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

J&J PRD received a non-approvable letter for Risperdal Consta from the FDA.

In June 2002, J&J PRD, an affiliate of our collaborative partner Janssen Pharmaceutica (Janssen), received a non-approvable letter for Risperdal Consta from the FDA. In April 2003, J&J PRD made a filing with the FDA of additional data and analyses as a response to the issues raised in the non-approvable letter. The issues raised in the letter and covered in the April filing may not be resolved on a timely basis, if at all, and Risperdal Consta may not be approved for commercial use in the United States. The FDA is response to and issues with the NDA submitted with respect to Risperdal Consta may impact the response of regulatory agencies in other countries where applications have not yet been approved. Even if Risperdal Consta is approved in the United States or elsewhere, the timing of the approvals is uncertain and there may be significant delays. It is uncertain whether the FDA is issues with the NDA will impact the labeling of Risperdal Consta in the United States or in other countries, if it is approved at all. The NDA was filed by an affiliate of J&J PRD and Janssen, and they are responsible for obtaining regulatory approvals. We cannot control the activity of any of our collaborative partners, and we are dependent upon Janssen is efforts to resolve the FDA is issues with the NDA for Risperdal Consta. Janssen may terminate our collaboration, including the license and manufacturing agreements, based on its right to do so on short notice under such agreements. If any of the foregoing events were to occur, it would have a material adverse effect on our business, results of operations and financial position.

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;

4

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.

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.

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 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 pricing and discounting, the reliance on third-party marketing partners outside the United States, the ability to obtain

5

Table of Contents

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

An NDA for Risperdal Consta was submitted to the FDA in August 2001 by J&J PRD, an affiliate of Janssen. A number of similar filings have been submitted with drug regulatory authorities worldwide by Janssen. In June 2002, J&J PRD received a non-approvable letter for Risperdal Consta from the FDA and, in April 2003, J&J PRD submitted additional data and analyses to the FDA in response to such non-approvable letter. Although approved for sale in 42 countries outside the United States, there can be no assurance that the NDA or other foreign regulatory filings will be approved in a timely fashion, if at all. If there is a significant delay in resolving the issues raised by the FDA, we may incur significant expenses without receipt of the corresponding royalty and manufacturing revenues. The revenues received from the sale of Risperdal Consta may not be significant and may 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.

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

6

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

7

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

8

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

9

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;

10

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

11

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.

12

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.

13

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.

14

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

15

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.

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 June 30, 2003, we had approximately \$6.825 million of senior indebtedness. 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.

16

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 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:

17

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.

18

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, proforma, 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) whether additional regulatory approvals will be received for Risperdal Consta, particularly in the United States after Johnson & Johnson Pharmaceutical Research and Development, LLC (J&J PRD) received a non-approvable letter for Risperdal Consta from the United States Food and Drug Administration (FDA); (ii) whether additional 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), 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; (iv) 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; (v) 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; (vi) our delivery technologies or product development efforts may not produce safe, efficacious or commercially viable products; (vii) 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; (viii) 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; (ix) 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; (x) 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; (xi) clinical trials are a time-consuming and expensive process; (xii) our product candidates could be ineffective or unsafe during preclinical studies and clinical trials and we and our collaborators may not be permitted by regulatory authorities to undertake new or additional clinical trials for product candidates incorporating our technologies, or clinical trials could be delayed; (xiii) we may not recoup any of our \$100 million investment in Reliant Pharmaceuticals, LLC (Reliant); (xiv) even if our product candidates appear promising at an early stage of development, product candidates could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace; (xv) technological change in the biotechnology or pharmaceutical industries could render our product candidates obsolete or noncompetitive; (xvi) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xvii) we may need to spend substantial funds to become profitable and will, therefore, continue to incur losses for the foreseeable future; and (xviii) we will need to raise substantial additional funding to continue research and development programs and clinical trials and could incur difficulties or setbacks in raising such funds.

19

Table of Contents

WHERE YOU CAN FIND MORE INFORMATION

Alkermes, Inc. is a reporting company and files annual, quarterly and current reports, proxy statements, and other information with the Securities and Exchange Commission. You may read and copy these reports, proxy statements, and other information at the Securities and Exchange Commission is public reference room located at 450 Fifth Street, N.W., Washington, DC 20549. You can request copies of these documents by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for more information about the operation of the public reference rooms. Our Securities and Exchange Commission filings are also available at the Securities and Exchange Commission is web site at http://www.sec.gov. In addition, you can read and copy our filings at the office of the National Association of Securities Dealers, Inc. at 1735 K Street, Washington, DC 20006.

Upon written or oral request, we will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered a copy of any or all of such documents which are filed with the Securities and Exchange Commission (other than exhibits to such documents). Written or oral requests for copies should be directed to Investor Relations, 88 Sidney Street, Cambridge, Massachusetts 02139 or (617) 494-0171.

20

Table of Contents

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the securities covered by this prospectus.

PRICE RANGE OF COMMON STOCK

Our common stock is traded on the Nasdaq National Market under the symbol ALKS. The following table sets forth, for the calendar periods indicated, the high and low sale prices per share of the common stock as reported on the Nasdaq National Market:

	High	Low
Fiscal year ended March 31, 2002		
First Quarter	\$37.75	\$20.38
Second Quarter	\$35.36	\$17.39
Third Quarter	\$28.90	\$18.22
Fourth Quarter	\$31.39	\$23.67
Fiscal year ended March 31, 2003		
First Quarter	\$26.65	\$14.65
Second Quarter	\$10.68	\$ 3.55
Third Quarter	\$11.31	\$ 6.00
Fourth Quarter	\$ 9.15	\$ 6.30
Fiscal year ended March 31, 2004		
First Quarter	\$14.50	\$ 8.74
Second Quarter (through September 24, 2003)	\$14.67	\$10.25

DIVIDEND POLICY

We have not paid any dividends on our common stock since our inception and do not anticipate paying any dividends on our common stock in the foreseeable future.

RATIO OF EARNINGS TO FIXED CHARGES

Our ratio of earnings to fixed charges for each of the periods indicated as follows:

	Fiscal Yo	Three Months Ended			
2003	2002	2001	2000	1999	June 30, 2003

Ratio of earnings to fixed charges⁽¹⁾

21

⁽¹⁾ For the fiscal years ended March 31, 2003, 2002, 2001, 2000 and 1999 and for the three months ended June 30, 2003, earnings were insufficient to cover fixed charges by \$106,898,000, \$61,355,000, \$24,137,000, \$77,436,000, \$48,511,000 and \$30,572,000, respectively. For this reason, no ratios are provided.

Table of Contents

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2003:

On a historical basis;

On an as adjusted basis to reflect the pro forma transactions which consisted of the exchange and conversion of our 6.52% Convertible Senior Subordinated Notes; and

On an as further adjusted basis to give effect to the receipt of the estimated net proceeds of \$121.3 million from the August and September 2003 offerings.

The interest make-whole provisions contained in the notes will be separately accounted for as derivative financial instruments in accordance with Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities. Of the aggregate principal amount of notes issued in August and September 2003, \$3,900,000 will be allocated to these instruments based on their estimated fair market values. This derivative liability will be adjusted quarterly for changes in fair value through either the date the interest make-whole provisions expire, at which time the liability will be zero, or the date at which an interest make-whole provision is triggered, with the corresponding charge or credit to other expense or income. This allocation of value to the interest make-whole provisions will be recorded as a discount on the notes and the notes will be accreted to par value through quarterly interest charges over the initial five-year term of the notes. The capitalization table which follows reflects the allocation of \$3,900,000 to the interest make-whole provisions of the notes based on the final terms of the notes and an aggregate of \$125,000,000 million principal amount of the notes.

22

Table of Contents

This table should be read in conjunction with Selected Historical Financial Data , our consolidated financial statements and notes included in this prospectus.

	June 30, 2003				
	Historical	As Adjusted for Pro Forma Transactions ⁽¹⁾	As Further Adjusted for the Offering of 2½% Convertible Subordinated Notes (1)		
		(dollars, in thousands)			
Cash and cash equivalents including short-term investments	\$ 104,679	\$ 102,354	\$ 223,604		
Current portion of long-term debt	6,825	6,825	6,825		
Long-term debt, excluding current portion:					
2½% convertible subordinated notes (net of \$3.9 million discount)			121,100		
6.52% convertible senior subordinated notes (net of \$8.4 million discount) ⁽¹⁾	166,131		121,100		
3.75% convertible subordinated notes	676	676	676		
Total long-term debt	166,807	676	121,776		
Convertible preferred stock, par value \$.01 per share:					
authorized and issued, 3,000 shares (at liquidation preference)	30,000	30,000	30,000		
Shareholders (deficit) equity:					
Capital stock, par value \$.01 per share:					
authorized 4,550,000 shares; none issued; includes 2,997,000 shares of preferred stock					
Common stock, par value \$.01 per share:					
authorized 160,000,000; issued and outstanding 64,776,830 shares ⁽¹⁾⁽²⁾	648	888	888		
Non-voting common stock, par value \$.01 per share:					
authorized, 450,000; issued and outstanding 382,632 shares	4	4	4		
Additional paid-in capital ⁽¹⁾	447,663	624,110	624,110		
Deferred compensation	(1,304)	(1,304)	(1,304)		
Accumulated other comprehensive income	580	580	580		
Accumulated deficit	(481,335)	(481,335)	(481,335)		
Total shareholders (deficit) equity	(33,744)	142,943	142,943		
Total capitalization	\$ 169,888	\$ 180,444	\$ 301,544		
r	,	/			

As adjusted and as further adjusted capitalization amounts include the July 2003 exchange and conversion of all the outstanding 6.52% Convertible Senior Subordinated Notes for and into 24,029,531 shares of common stock (including payment of the two-year interest make-whole payment), resulting in an increase in common stock and additional paid-in capital and the retirement of all the outstanding 6.52% Convertible Senior Subordinated Notes. On September 24, 2003, there were 88,915,880 shares of common stock outstanding.

Outstanding shares exclude the shares reserved for issuance upon conversion of the newly issued notes, 14,618,925 shares issuable under our stock option and award plans, 2,824,859 shares issuable upon conversion of the Convertible Preferred Stock and 9,978 shares issuable upon conversion of our 3.75% Convertible Subordinated Notes.

23

Table of Contents

SELECTED HISTORICAL FINANCIAL DATA

The following table presents our selected historical consolidated financial data for each of the years ended March 31, 2003, 2002, 2001, 2000 and 1999, which have been derived from our audited consolidated financial statements. The selected historical consolidated financial data for each of the three month periods ended June 30, 2003 and 2002, which have been derived from our unaudited consolidated financial statements, reflect in the opinion of management, all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of the results for such periods. The results for the three month period ended June 30, 2003 are not necessarily indicative of results for the full year. The selected historical consolidated financial data should be read in conjunction with our consolidated financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations herein.

24

Table of Contents

Alkermes, Inc. and Subsidiaries

(In thousands, except per share data)

	Year Ended March 31,					Three Months Ended June 30,	
	2003	2002	2001	2000	1999	2003	2002
Consolidated Statement of							
Operations Data:							
Revenues:							
Manufacturing and royalty							
revenues	\$ 15,482	\$	\$	\$	\$	\$ 1,545	\$
Research and development							
revenue under collaborative							
arrangements	31,784	54,102	56,030	22,920	33,892	2,757	10,291
Total revenues	47,266	54,102	56,030	22,920	33,892	4,302	10,291
Expenses:							
Cost of goods manufactured	10,910					2,560	
Research and development	85,388	92,092	68,774	54,483	48,457	21,673	24,599
General and administrative	26,694	24,387	19,611	14,878	14,556	5,781	6,016
Restructuring costs (1)	6,497	ŕ	ŕ	,	·	·	· ·
Noncash compensation							
(income) expense attributed							
to research and development			(2,448)	29,493	16,239		
Purchase of in-process			, ,	,	·		
research and development (2)					3,221		
•							
Total expenses	129,489	116,479	85,937	98,854	82,473	30,014	30,615
Net operating loss	(82,223)	(62,377)	(29,907)	(75,934)	(48,581)	(25,712)	(20,324)
Other income (expense):							
Interest income	3,776	15,302	22,437	11,539	9,823	975	1,366
Gain on exchange of notes (3)	80,849	,	,	,	,		,
Other income, net (4)	00,049					1,409	
Derivative loss related to						1,409	
convertible senior							
subordinated notes (5)	(4,300)					(3,764)	
Interest expense	(10,403)	(8,876)	(9,399)	(3,652)	(2,298)	(3,480)	(2,081)
interest expense	(10,103)	(0,070)	(5,555)	(5,032)		(2,100)	(2,001)
T-4-1 -4b:							
Total other income	60.022	6.406	12.020	7 007	7.505	(4.960)	(715)
(expense)	69,922	6,426	13,038	7,887	7,525	(4,860)	(715)
Equity in losses of Reliant							
Pharmaceuticals, LLC (6)	(94,597)	(5,404)					(24,213)
Net loss	(106,898)	(61,355)	(16,869)	(68,047)	(41,056)	(30,572)	(45,252)
Preferred stock dividends			(7,268)	(9,389)	(7,455)		
Net loss attributable to common							
shareholders	\$(106,898)	\$ (61,355)	\$(24,137)	\$(77,436)	\$(48,511)	\$(30,572)	\$(45,252)
	. , , ,	. , ,		. , ,		. , ,	. , ,

Basic and diluted loss per common share	\$ (1.66)	\$ (0.96)	\$ (0.43)	\$ (1.52)	\$ (0.99)	\$ (0.47)	\$ (0.70)
Weighted average number of common shares outstanding	64,368	63,669	55,746	51,015	49,115	64,736	64,261
		_	25	_	_	_	_

Table of Contents

March 31,

	2003	2002	2001	2000	1999	June 30, 2003
Consolidated Balance Sheet Data:						
Cash and cash equivalents and						
short-term investments	\$136,094	\$152,347	\$254,928	\$337,367	\$163,419	\$104,679
Total assets	255,699	350,350	391,297	413,961	213,452	226,313
Long-term obligations		7,800	11,825	22,792	28,417	
Convertible subordinated notes	166,586	200,000	200,000	200,000		166,807
Convertible preferred stock	30,000			22,990	23,000	30,000
Shareholders (deficit) equity	(5,046)	99,664	148,410	167,967	156,206	(33,744)

- (1) Represents charges taken in connection with our August 2002 restructuring of operations. We substantially completed our restructuring program during fiscal 2003.
- (2) Represents a \$3,221 nonrecurring charge in fiscal 1999 for RingCap® and DST technologies licensed from ALZA Corporation.
- (3) Represents an \$80,849 nonrecurring gain related to the exchange of our 3.75% Convertible Subordinated Notes for our 6.52% Convertible Senior Subordinated Notes.
- (4) Represents income recognized on the changes in the fair value of warrants held in connection with licensing arrangements, which are recorded under the caption other assets in our consolidated balance sheet. The recorded value of such warrants can change significantly based on fluctuations in the market value of the underlying securities of the issuer of the warrants.
- (5) Represents noncash charges in connection with a derivative liability associated with the Two-Year Interest Make-Whole payment provision of our 6.52% Convertible Senior Subordinated Notes. The derivative liability is recorded at fair value and on July 18, 2003, upon conversion of the then outstanding 6.52% Convertible Senior Subordinated Notes and payment of the Two-Year Interest Make-Whole, the embedded derivative was settled in full and balance was reduced to zero.
- (6) Represents our share of Reliant s losses recorded under the equity method of accounting. Since we have no further funding commitments to Reliant, we will not record any further share of the losses of Reliant in our consolidated statements of operations and comprehensive loss.

26

Table of Contents

BUSINESS

The following Business section contains forward-looking statements which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors. See Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations Forward-Looking Statements.

General

Alkermes, Inc. (together with its subsidiaries, referred to as we, us, our or the Registrant), a Pennsylvania corporation organized in 1987, is a 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 worlds 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 Strategy

We are building a pharmaceutical company leveraging our unique drug delivery capabilities and technologies as the means to develop our first commercial products initially with partners, then on our own. The key elements to our strategy are to:

Develop and acquire broadly applicable drug delivery systems. We develop and acquire drug delivery systems that have the potential to be applied to multiple proteins, peptides and small molecule pharmaceutical compounds to create new product opportunities.

Collaborate with pharmaceutical and biotechnology companies to develop and finance product candidates. We have entered into multiple collaborations with pharmaceutical and biotechnology companies to develop product candidates incorporating our technologies, to provide us with funding for product development independent of capital markets and to share development risk.

Apply drug delivery systems to both approved drugs and drugs in development. We are applying our drug delivery technologies to novel applications and formulations of pharmaceutical products that have already been approved by the U.S. Food and Drug Administration (the FDA) or other regulatory authorities. In such cases, we and our partners may develop a novel dosage form or application with the knowledge of a drug s safety and efficacy profile and a body of clinical experience from which to draw information for the design of clinical trials and for regulatory submissions. We also apply our technologies to pharmaceuticals in development that could benefit from one of our delivery systems.

Establish independent product development capabilities and infrastructure. Based upon the knowledge we have learned and the best practices we have adopted from our pharmaceutical company collaborators, our experienced scientists have built an in-house product development organization that enables us to develop product candidates for our collaborators and for ourselves. Our product development experience and infrastructure give us flexibility in structuring development programs and

27

Table of Contents

the ability to conduct both feasibility studies and clinical development programs for our collaborators and for ourselves.

Expand our pipeline with additional product candidates for our own account. We are now developing product candidates for our own account by applying our drug delivery technologies to certain off-patent pharmaceuticals. For example, we are developing Vivitrex, a Medisorb formulation of naltrexone, for the treatment of alcoholism and opiate dependence. We are also developing inhaled epinephrine based on our AIR pulmonary drug delivery system for the treatment of anaphylaxis. In addition, we may in-license or acquire certain compounds to develop on our own.

Product Candidates in Development

The following table summarizes the primary indications, technology, development stage and collaborative partner, if any, for our key product candidates. This table is qualified in its entirety by reference to the more detailed descriptions appearing elsewhere in this registration statement. The results from preclinical testing and early clinical trials may not be predictive of results obtained in subsequent clinical trials and there can be no assurance that our or our collaborators clinical trials will demonstrate the safety and efficacy of any product candidates necessary to obtain regulatory approval.

Product Candidate	Indication	Technology	Stage (1)	Collaborative Partner
Risperdal Consta	Schizophrenia	Medisorb	Marketed ⁽²⁾	Janssen
Nutropin Depot (hGH)	Growth Hormone Deficiency Pediatric	ProLease	Marketed	Genentech
Vivitrex	Alcohol Dependence	Medisorb	Phase III	Alkermes ⁽³⁾
Vivitrex	Opioid Dependence	Medisorb	Phase II	Alkermes ⁽³⁾
Nutropin Depot (hGH)	Growth Hormone Deficiency Adults	ProLease	Phase III	Genentech
Insulin	Diabetes	AIR	Phase II	Lilly
Exenatide LAR	Diabetes	Medisorb	Phase II	Amylin / Lilly
Epinephrine	Anaphylaxis	AIR	Phase I	Alkermes
r-hFSH (recombinant human follicle stimulating hormone)	Infertility	ProLease	Phase Ib	Serono
hGH	Growth Hormone Deficiency	AIR	Phase I	Lilly
Others	Various	AIR, Medisorb and ProLease	Preclinical	Undisclosed

⁽¹⁾ See Government Regulation for definitions of Phase I, Phase II and Phase III clinical trials. Preclinical indicates that we or our partner are conducting formulation, efficacy, pharmacology and/or toxicology testing of a compound in animal models or biochemical assays.

28

Table of Contents

Key Products under Development

Risperdal Consta. We have developed a Medisorb long-acting formulation of Janssen Pharmaceutica s (Janssen) anti-psychotic drug Risperdal known as Risperdal Consta. Janssen is an affiliate of Johnson & Johnson. Risperdal is the most commonly prescribed drug for the treatment of schizophrenia and had sales of over \$1.8 billion worldwide in 2002. In August 2001, Janssen Pharmaceutica Products, LP submitted an NDA for Risperdal Consta with the FDA. Similar regulatory filings have been submitted in more than 60 countries around the world. In June 2002, Johnson & Johnson Pharmaceutical Research and Development, LLC (J&J PRD), an affiliate of Janssen, received a non-approvable letter from the FDA and, in April 2003, J&J PRD submitted additional data and analyses to the FDA in a complete response to such non-approvable letter. It is anticipated, based on criteria set forth in the Prescription Drug Use Fee Act (PDUFA), that the FDA will issue a formal response to this most recent submission in the fourth quarter of calendar year 2003. Since August 2002, Risperdal Consta has been approved in 42 countries around the world and launched in Australia, Austria, the Czech Republic, Denmark, Finland, Germany, Iceland, Ireland, Israel, Korea, Latvia, Mexico, The Netherlands, New Zealand, Norway, Spain, Switzerland and the United Kingdom. Risperdal tablets are currently used for relief of symptoms associated with schizophrenia. Schizophrenia is a brain disorder the symptoms of which include disorganized thinking, delusions and hallucinations. We are the exclusive manufacturer of Risperdal Consta for Janssen.

We earn both manufacturing fees and royalties from Janssen. Manufacturing revenues are earned when product is shipped to Janssen. Royalty revenues are earned on product sales made by Janssen and are recorded in the period the product is sold by Janssen. Manufacturing revenues represented a significant portion of the manufacturing and royalty revenues earned during fiscal 2003 and in the quarter ended June 30, 2003.

Under a manufacture and supply agreement with Janssen, manufacturing revenues relating to our sales of Risperdal Consta to Janssen under that agreement are to be paid by Janssen to us in minimum annual amounts for up to ten years beginning in calendar 2003. The actual amount of such minimum manufacturing revenues will be determined by a formula and are currently estimated to aggregate approximately \$150 million. In December 2002, Janssen paid us approximately \$24 million as a prepayment of the first two years of these minimum manufacturing revenues.

There can be no assurance that the issues raised in the non-approvable letter from the FDA will be resolved on a timely basis or that further foreign regulatory filings will be approved. See Risk Factors J&J PRD received a non-approvable letter for Risperdal Consta from the FDA. Even if Risperdal Consta is approved by the FDA or other regulatory agencies, the anti-psychotic market is highly competitive and the revenues received from the sale of Risperdal Consta may not be significant and will depend on numerous factors outside of our control. Additionally, we cannot assure you that we will be able to manufacture Risperdal Consta on a commercial scale or economically. Any failure to obtain (or significant delay in obtaining) U.S. regulatory approval, pricing approvals, market share or significant revenues or manufacture at commercial scale or economically would have a material adverse effect on our business and financial position. See Risk Factors Our manufacturing experience is limited.

Nutropin Depot. We have developed and are manufacturing a ProLease formulation of Genentech, Inc. s (Genentech) recombinant human growth hormone (rhGH) Nutropin, known as Nutropin Depot, in collaboration with Genentech. rhGH is approved for use in the treatment of children with growth hormone deficiency, or GHD, which results in short stature and potentially other developmental deficits, Turner s syndrome, chronic renal insufficiency and other indications. Our extended-release formulation, approved by the FDA in December 1999 for use in children with GHD and commercially launched by Genentech in June 2000, requires only one or two doses a month (which may

29

Table of Contents

require more than one injection per dose) compared to current growth hormone therapies that require multiple doses per week.

We and Genentech have also agreed to continue the clinical development for Nutropin Depot in adults with growth hormone deficiency. This decision followed completion of a Phase I trial of Nutropin Depot in growth hormone deficient adults. We have initiated a Phase III clinical trial, funded by Genentech, which commenced in December 2001. Enrollment in this Phase III trial has been completed and initial results are expected in late fiscal 2004.

The GHD market is highly competitive and we cannot assure you that the marketing and sales of Nutropin Depot will be successful or that it will gain significant market share. Additionally, we cannot assure you that we will be able to continue to manufacture Nutropin Depot on a commercial scale or economically, or that we will ultimately be able to derive significant revenues from sales of Nutropin Depot. If we cannot continue to manufacture Nutropin Depot on a commercial scale, if we cannot manufacture Nutropin Depot economically or if we ultimately do not derive significant revenues from Nutropin Depot, a material adverse effect on our business and financial position could occur.

Vivitrex. We are developing a Medisorb formulation of naltrexone, an FDA-approved drug used for the treatment of alcohol and opioid dependence, which is currently available in daily oral dosage form. It is estimated that there are currently 2.3 million people in the U.S. who are receiving treatment for alcoholism. We believe there is a significant need for a product that will help improve compliance in this patient population. Vivitrex, which is our most advanced proprietary product, is based on our Medisorb injectable extended-release technology and is designed to provide once-a-month dosing to enhance patient adherence by removing the need for daily dosing. In September 2001, we completed a second trial, which was a multi-center clinical trial, of Vivitrex, the data from which was presented at the Annual Meeting of the American College of Neuropsychopharmacology. This trial tested the safety, tolerability and pharmacokinetics of repeat doses of Vivitrex administered monthly to alcohol-dependent patients. In March 2003, we announced the completion of enrollment in a Phase III clinical trial in alcohol-dependent patients testing the safety and efficacy of repeat doses of Vivitrex. We plan to manufacture Vivitrex for both clinical trials and commercial sales, if any. We plan to commercialize Vivitrex using a specialty sales force to call on addiction specialists and substance abuse centers. We may develop or commercialize Vivitrex alone or with a collaborative partner.

Inhaled epinephrine. We are developing an AIR formulation of epinephrine for the treatment of anaphylaxis, which is a sudden, often severe, systemic allergic reaction. Inhaled epinephrine is a proprietary product based on our AIR pulmonary delivery technology. Currently, patients self-administer epinephrine by intramuscular injection. We believe that an inhaled dosage form of epinephrine may offer patients significant advantages over injections, such as ease of use and direct topical treatment of airway obstruction. In August 2002, we completed our second Phase I study of inhaled epinephrine.

r-hFSH (*recombinant human follicle stimulating hormone*). We are developing a ProLease formulation of r-hFSH with Serono S.A. (Serono) for the treatment of infertility. This long-acting formulation is designed to provide patients with an alternative to multiple daily injections. A Phase I clinical trial for this product candidate has been completed. Serono recently conducted a Phase Ib study of r-hFSH and an analysis of the data is underway. Serono is responsible for clinical studies for this program. We will manufacture the long-acting formulation of r-hFSH for clinical trials and commercial sales, if any.

Exenatide LAR (formerly AC2993 LAR). We are developing a Medisorb formulation of Amylin Pharmaceutical, Inc. s (Amylin) exenatide LAR, formerly referred to as AC2993 LAR, a drug being

30

Table of Contents

developed for use in the treatment of diabetes. Amylin has entered into a collaboration agreement with Eli Lilly and Company (Lilly) for the development and commercialization of exenatide, including exenatide LAR. Phase I clinical trials have been completed for our Medisorb formulation of exenatide LAR and Phase II clinical trials have commenced. In March 2003, we, Amylin and Lilly released preliminary pharmacokinetic results from the first Phase II trial that verify sustained levels of exenatide are possible and support the continuation of the Phase II trial program. Additional activities are underway to optimize the formulation and manufacturing process. An additional Phase II clinical trial is currently being planned. Amylin is responsible for clinical trials and we will manufacture the Medisorb formulation of exenatide LAR for both clinical trials and commercial sales, if any.

Inhaled insulin. We are working with Lilly to develop inhaled formulations of insulin including short- and long-acting insulin and other potential products for the treatment of diabetes based on our AIR pulmonary drug delivery technology. Multiple early stage clinical trials have been completed for a short-acting formulation, which is currently in Phase II clinical development. Lilly is responsible for clinical trials and we will manufacture the formulations of insulin for clinical trials. We will manufacture any such products for clinical trials and both we and Lilly will manufacture such products for commercial sales, if any.

In December 2002, we expanded our collaboration with Lilly following the achievement of development milestones relating to clinical progress, and scale-up and manufacturing activities for our insulin dry powder aerosols and inhalers. In connection with the expansion, Lilly purchased \$30 million of our newly issued convertible preferred stock. We are using the significant portion of the proceeds from the sale of the preferred stock to fund the joint development program, including certain clinical trials, during calendar year 2003 and into calendar year 2004. In addition the royalty rate payable to us based on revenues of potential inhaled insulin products has been increased. Lilly has the right to exchange the preferred shares for a reduction in the royalty rate payable to us. The preferred stock is convertible into our common stock at market price at our option and automatically upon filing of an NDA with the FDA for a pulmonary insulin product. The collaboration cannot terminate without cause until January 2005.

Inhaled human growth hormone. We are working with Lilly to develop an inhaled formulation of human growth hormone based on our AIR pulmonary drug delivery technology. In January 2002, we announced the decision to move forward with multiple-dose Phase I clinical studies for inhaled human growth hormone following the successful completion of a single dose Phase I trial. In connection with the December 2002 preferred stock transaction, we agreed to use a portion of the proceeds to fund the hGH development program, including certain clinical trials, during calendar year 2003 and into 2004. Lilly is responsible for clinical trials and we will manufacture the formulation of human growth hormone for both clinical trials and commercial sales, if any.

Collaborative Arrangements

Our business strategy includes forming collaborations to provide technological, financial, marketing, manufacturing and other resources. We have entered into several corporate collaborations.

Janssen

Pursuant to a development agreement, we collaborated with Janssen, an affiliate of Johnson & Johnson, for the development of Risperdal Consta, an extended-release formulation of Risperdal utilizing our Medisorb technology. Under the development agreement, Janssen provided development funding to us for the development of Risperdal Consta and is responsible for securing all necessary regulatory approvals. Since August 2001, Janssen and its affiliates have submitted an NDA to the FDA and similar

31

Table of Contents

filings to other drug regulatory agencies in over 60 countries around the world. Risperdal Consta has been approved in 42 countries and launched in 18. However, in June 2002, a Janssen affiliate received a non-approvable letter for Risperdal Consta from the FDA and, in April 2003, submitted additional data and analyses to the FDA in a complete response to such non-approvable letter. See Risk Factors J&J PRD received a non-approvable letter for Risperdal Consta from the FDA. We manufacture Risperdal Consta for commercial sale, if, when and where it is approved. We receive manufacturing revenues when product is shipped and royalties upon the sale of product.

Under related license agreements, Janssen and an affiliate have exclusive worldwide licenses from us to use and sell Risperdal Consta. Under the license agreements, Janssen is required to pay us certain royalties with respect to all Risperdal Consta sold to customers. Janssen can terminate the license agreements upon 30 days prior written notice.

Pursuant to a manufacture and supply agreement, Janssen has appointed us as the exclusive supplier of Risperdal Consta for commercial sales. The agreement terminates on expiration of the license agreements. In addition, either party may terminate the agreement upon a material breach by the other party which is not resolved within 60 days—written notice or upon written notice in the event of the other party—s insolvency or bankruptcy. Janssen may terminate the agreement upon six-months—written notice after such event; provided, however, Janssen cannot terminate the agreement without good cause during the two-year period following commencement of commercial manufacturing unless it also terminates the license agreements. In August 2002, we announced the regulatory approval and expected commercial launch of Risperdal Consta in Germany and the United Kingdom. Under our agreement with Janssen and based on the foregoing, manufacturing revenues relating to our sales of Risperdal Consta under a manufacturing and supply agreement are to be paid by Janssen to us in minimum annual amounts for up to ten years beginning in calendar 2003. The actual amount of such minimum revenues will be determined by a formula and are currently estimated to aggregate approximately \$150 million. The minimum revenue obligation will be satisfied upon receipt by us of revenues relating to our sales of Risperdal Consta equaling such aggregate amount of minimum revenues. In December 2002, Janssen paid us approximately \$24 million as a prepayment of the first two years of these minimum revenues.

Genentech

In April 1999, we and Genentech amended and restated the November 1996 license agreement to expand our collaboration for Nutropin Depot, an injectable long-acting formulation of Genentech s recombinant human growth hormone based upon our ProLease drug delivery system. Nutropin Depot for pediatric use was launched in the U.S. in June 2000 by Genentech. Under the agreement, we and Genentech have been conducting expanded development activities, including clinical trials in an additional indication (adult growth hormone deficiency), process development and manufacturing. We will be responsible for conducting additional clinical trials (for which Genentech will reimburse the cost) and for manufacturing Nutropin Depot for the adult indication and are to receive manufacturing revenues and royalties on product sales in this indication, if any.

Genentech has the right to terminate the agreement for any reason upon six months—written notice. In addition, either party may terminate the agreement upon the other party—s material default, which is not cured within 90 days of written notice, or upon the other party—s insolvency or bankruptcy.

We executed a Manufacture and Supply Agreement with Genentech in April 2001 for the manufacture and supply of Nutropin Depot to Genentech for commercial sales. Pursuant to the terms of the agreement we are the sole supplier and manufacturer of Nutropin Depot. The Manufacture and Supply Agreement terminates on expiration of the license agreement. In addition, either party may terminate the agreement upon a material breach by the other party which is not cured within 90 days

32

Table of Contents

written notice, upon 60 days written notice in the event of the other party s insolvency or bankruptcy or upon 90 days written notice in the event a force majeure event occurs and continues for more than six months.

Serono

Pursuant to a development agreement dated December 1999, we are collaborating with Serono for the development of a ProLease formulation of r-hFSH (recombinant human follicle stimulating hormone) for the treatment of infertility. Serono provides us with research and development funding and milestone payments. We are responsible for formulation and preclinical testing and Serono will be responsible for conducting clinical trials and securing regulatory approvals and, together with its affiliates, for the marketing of any products that result from the collaboration. We will manufacture any such products for clinical trials and commercial sale and will receive manufacturing revenues and royalties on sales, if any.

Serono may terminate the development agreement for any reason, upon 90 days written notice if such termination notice occurs prior to the first commercial launch of a product under the development agreement, or upon six months written notice if such notice occurs subsequent to such event. In addition, either party may terminate the development agreement upon a material breach by the other party of such agreement which is not cured within 60 days written notice.

Lilly

Insulin

We entered into a development and license agreement with Lilly in April 2001 for the development of inhaled formulations of insulin, including short- and long-acting insulin and other potential products for the treatment of diabetes, based on our AIR pulmonary drug delivery technology. Pursuant to the agreement, we are responsible for formulation and preclinical testing as well as development of a device to use in connection with any products. Lilly has paid or will pay to us certain initial fees, research funding and milestone payments upon achieving certain development and commercialization goals. Lilly has exclusive worldwide rights to make, use and sell products resulting from such development. Lilly will be responsible for clinical trials, obtaining all regulatory approvals and marketing any insulin products. We manufacture such product candidates for clinical trials and both we and Lilly will manufacture such products for commercial sales, if any. We will receive certain royalties based upon such product sales, if any.

Lilly has the right to terminate the agreement upon 90 days written notice at any time prior to the first commercial launch of a product, or upon six months written notice at any time after such first commercial launch. In addition, either party may terminate the agreement upon a material breach or default by the other party which is not cured within 90 days written notice.

We entered into an agreement with Lilly in February 2002 that provided for an investment by Lilly in our commercial-scale production facility for inhaled pharmaceutical products based on our AIR pulmonary drug delivery technology. This new facility in Chelsea, Massachusetts is designed to accommodate the manufacturing of multiple products. Construction of the facility is complete and validation and scale-up is underway. Lilly s investment was used to fund pulmonary insulin production and packaging capabilities. This funding is secured by Lilly s ownership of specific equipment located and used in the facility. We have the right to purchase the equipment from Lilly, at any time, at the then-current net book value.

33

Table of Contents

In December 2002, we expanded our collaboration with Lilly following the achievement of development milestones relating to clinical progress, and scale-up and manufacturing activities for our insulin dry powder aerosols and inhalers. In connection with the expansion, Lilly purchased \$30 million of our newly issued convertible preferred stock. We are using the significant portion of the proceeds from the sale of the preferred stock to fund the joint development program during calendar year 2003 and into calendar year 2004. In addition the royalty rate payable to us based on revenues of potential inhaled insulin products has been increased. Lilly has the right to exchange the preferred shares for a reduction in the royalty rate payable to us. The preferred stock is convertible into our common stock at market price at our option and automatically upon filing of a new drug application with the FDA for a pulmonary insulin product. The collaboration cannot terminate without cause until January 2005.

hGH

We entered into a development and license agreement with Lilly in February 2000 for the development of an inhaled formulation of human growth hormone based on our AIR pulmonary drug delivery technology. Pursuant to the agreement, we are responsible for formulation and preclinical testing as well as development of a device to use in connection with any products. Lilly has paid or will pay to us certain initial fees, research funding and milestone payments upon achieving certain development and commercialization goals and we will also receive royalty payments based on product sales, if any. In connection with the December 2002 preferred stock transaction, we agreed to use a portion of the proceeds to fund the hGH development program during calendar year 2003 and into 2004. Lilly has exclusive worldwide rights to make, use and sell products resulting from such development. Lilly will be responsible for clinical trials, obtaining all regulatory approvals and marketing any products. We will manufacture any such products for clinical trials and commercial sales and receive manufacturing revenues and royalties on product sales, if any.

Lilly has the right to terminate the agreement upon 90 days written notice at any time prior to the first commercial launch of a product, or upon six months written notice at any time after such first commercial launch. In addition, either party may terminate the agreement upon a material breach or default by the other party which is not cured within 90 days written notice.

Amylin

We entered into a development and license agreement with Amylin in May 2000 for the development of a Medisorb formulation of exenatide LAR (formerly AC2993) for the treatment of type 2 diabetes.

Pursuant to the development agreement, Amylin has an exclusive, worldwide license to the Medisorb technology for the development and commercialization of injectable extended-release formulations of exendins and other related compounds that Amylin may develop. Amylin has entered into a collaboration agreement with Lilly for the development and commercialization of exenatide, including exenatide LAR. We receive funding for research and development and milestone payments comprised of cash and warrants for Amylin common stock upon achieving certain development and commercialization goals and will also receive a combination of royalty payments and manufacturing fees based on any future product sales. We are initially responsible for developing and testing several formulations, manufacturing for clinical trials and for commercial sales of any products that may be developed pursuant to the agreement. Amylin is responsible for conducting clinical trials, securing regulatory approvals and marketing any products resulting from the collaboration on a worldwide basis.

Amylin may terminate the development agreement for any reason on 90 days written notice if such termination occurs before filing an NDA with the FDA or six months written notice after such

34

Table of Contents

event. In addition, either party may terminate the development agreement upon a material default or breach by the other party that is not cured within 60 days written notice.

Clinical Partners

In 1992, Alkermes Clinical Partners, L.P. (Clinical Partners) was formed as a vehicle to raise money to fund the further development of Cereport. Cereport is a synthetic analog of bradykinin developed to increase transiently the permeability of the blood-brain barrier so that drug molecules in the bloodstream can diffuse into the brain in greater concentrations. In connection with that transaction, we transferred substantially all of our rights to Cereport to Clinical Partners, entered into a product development agreement and interim license with Clinical Partners and acquired the right to purchase all of the limited partnership interests in Clinical Partners. In total, Clinical Partners raised \$46.0 million from a private placement, which was substantially expended by June 1996. If Cereport were ever approved by the FDA, we would have to pay certain milestone and royalty payments to the limited partners whether or not we exercise our purchase option. We entered into an agreement with ALZA Corporation in October 1997 relating to the development and commercialization of Cereport which was mutually terminated in December 2002. As a result of the difficulties encountered in the development of Cereport, including clinical trial results and the termination of the agreement with ALZA, we determined that development of Cereport is not economically feasible and, therefore, we would not commit additional funds to the development of Cereport. We also abandoned patent rights relating to Cereport and receptor mediated permeabilizers (RMPs) outside the U.S. and Canada. As a consequence of the decision to discontinue funding, the development program and obligations will cease, the purchase option will terminate and Cereport and the RMP technology will revert to Clinical Partners in the U.S. and Canada.

Drug Delivery Technology

Our current focus is on the development of broadly applicable, proprietary drug delivery technologies addressing several important drug delivery opportunities, including injectable extended-release of proteins, peptides and small molecule pharmaceutical compounds and the pulmonary delivery of both small molecules and proteins and peptides. 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.

ProLease: injectable extended-release of fragile proteins and peptides

ProLease is our proprietary technology for the stabilization and encapsulation of fragile proteins and peptides in microspheres made of common medical polymers. Our proprietary expertise in this field lies in our ability to preserve the biological activity of fragile drugs over an extended period of time and to manufacture these formulations using components and processes believed to be suitable for human pharmaceutical use. ProLease is designed to enable novel formulations of proteins and peptides by replacing frequent injections with controlled, extended-release over time. We believe ProLease formulations have the potential to improve patient compliance and ease of use by reducing the need for frequent self-injection, to lower costs by reducing the need for frequent office visits and to improve safety and efficacy by reducing both the variability in drug levels inherent in frequent injections and the aggregate amount of drug given over the course of therapy. In addition, ProLease may provide access to important new markets currently inaccessible to drugs that require frequent injections or are administered orally.

The ProLease formulation process has been designed to assure stability of fragile compounds during the manufacturing process, during storage and throughout the release phase in the body. The formulation and manufacturing process consists of two basic steps. First, the drug is formulated with

35

Table of Contents

stabilizing agents and dried to create a fine powder. Second, the powder is microencapsulated in the polymer at very low temperatures. Incorporation of the drug substance as a stabilized solid under very low temperatures is critical to protecting fragile molecules from degradation during the manufacturing process and is a key element of the ProLease technology. The microspheres are suspended in a small volume of liquid prior to administration to a patient by injection under the skin or into a muscle. We believe drug release from the ProLease drug delivery system can be controlled to last from a few days to several months.

Drug release from the microsphere is controlled by diffusion of the drug through the microsphere and by biodegradation of the polymer. These processes can be modulated through a number of formulation and fabrication variables, including drug substance and microsphere particle sizing and choice of polymers and excipients.

Our experience with the application of ProLease to a wide range of proteins and peptides has shown that high incorporation efficiencies and high drug loads can be achieved. Proteins and peptides incorporated into ProLease microspheres have maintained their integrity, stability and biological activity when tested for up to 30 days in *in vitro* experiments conducted on formulations manufactured at the preclinical, clinical and commercial scale.

Medisorb: injectable extended-release of traditional small molecule pharmaceuticals

Medisorb is our proprietary technology for encapsulating traditional small molecule pharmaceuticals in microspheres made of common medical polymers. Like ProLease, Medisorb is designed to enable novel formulations of pharmaceuticals by providing controlled, extended-release over time. We believe Medisorb is suitable for encapsulating stable, small molecule pharmaceuticals and certain peptides at a large scale. We believe that Medisorb formulations may have superior features of safety, efficacy, compliance and ease of use for drugs currently administered by frequent injection or administered orally. Drug release from the microsphere is controlled by diffusion of the pharmaceutical through the microsphere and by biodegradation of the polymer. These processes can be modulated through a number of formulation and fabrication variables, including drug substance and microsphere particle sizing and choice of polymers and excipients.

The Medisorb drug delivery system uses manufacturing processes different from the ProLease manufacturing process. The formulation and manufacturing process consists of three basic steps. First, the drug is combined with a polymer solution. Second, the drug/polymer solution is mixed in water to form liquid microspheres (an emulsion). Third, the liquid microspheres are dried to produce finished product. The microspheres are suspended in a small volume of liquid prior to administration to a patient by injection under the skin or into a muscle. We believe drug release from the Medisorb system can be controlled to last from a few days to several months.

AIR: pulmonary drug delivery

The AIR technology is our proprietary pulmonary delivery system that enables the delivery of both small molecules and macromolecules to the lungs. Our proprietary technology allows us to formulate drugs into dry powders made up of highly porous particles with low mass density. These particles can be efficiently delivered to the deep lung by a small, simple inhaler. The AIR technology is useful for small molecules, proteins or peptides and allows for both local delivery to the lungs and systemic delivery via the lungs.

AIR particles can be aerosolized and inhaled efficiently with simple inhaler devices because low forces of cohesion allow the particles to deaggregate easily. AIR is developing a family of relatively

36

Table of Contents

inexpensive, compact, easy to use inhalers. The AIR devices are breath activated and made from injection molded plastic. The powders are designed to quickly discharge from the device over a range of inhalation flow rates, which may lead to low patient-to-patient variability and high lung deposition of the inhaled dose. By varying the ratio and type of excipients used in the formulation, we believe we can deliver a range of drugs from the device that may provide both immediate and extended release.

Manufacturing

We currently have manufacturing facilities in Cambridge and Chelsea, Massachusetts and Wilmington, Ohio. The manufacture of our product candidates for clinical trials and commercial purposes is subject to current good manufacturing practices (cGMP) and other agency regulations. We have limited experience operating an FDA-approved commercial manufacturing facility. There can be no assurance that we will maintain the necessary approvals for commercial manufacturing or obtain approvals for any additional facilities.

If we are not able to develop and maintain manufacturing capacity and experience, or to continue to contract for manufacturing capabilities on acceptable terms, our ability to supply product for commercial sales, clinical trials and preclinical testing will be compromised. In addition, delays in obtaining regulatory approvals might result, as well as delays of commercial sales if approvals are not obtained on a timely basis. Such delays could materially adversely affect our competitive position and our business, financial condition and results of operations.

ProLease

ProLease manufacturing involves microencapsulation of drug substances provided to us by our collaborators in small polymeric microspheres using extremely cold processing conditions suitable for fragile molecules. The ProLease manufacturing process consists of two basic steps. First, the drug is formulated with stabilizing agents and dried to create a fine powder. Second, the powder is microencapsulated in polymer at very low temperatures. Pursuant to agreements with certain of our collaborators, we have the right to manufacture ProLease products for commercial sale.

We have a commercial scale ProLease manufacturing facility of approximately 32,000 square feet in Cambridge, Massachusetts. The facility includes two manufacturing suites, one of which is dedicated to the production of Nutropin Depot at commercial scale. The facility has had successful pre-approval and one post-approval inspection by the FDA for the manufacture of Nutropin Depot and we are currently manufacturing Nutropin Depot to supply product to Genentech for commercial sale.

We had a clinical production facility that we validated for manufacturing in accordance with current good manufacturing practices (cGMP). The production facility is being moved into and validated in our principal location for clinical manufacturing. The facility was and will be used to manufacture product candidates incorporating our ProLease extended-release delivery system for use in clinical trials.

Medisorb

The Medisorb manufacturing process is significantly different from the ProLease process and is based on a method of encapsulating small molecule drugs in polymers using a large-scale emulsification. The Medisorb manufacturing process consists of three basic steps. First, the drug is combined with a polymer solution. Second, the drug/polymer solution is mixed in water to form liquid microspheres (an emulsion). Third, the liquid microspheres are dried to produce finished product.

37

Table of Contents

We operate a 50,000 square foot current good manufacturing practices (cGMP) manufacturing facility for commercial scale Medisorb manufacturing in Wilmington, Ohio. We manufacture Risperdal Consta for Janssen at this facility. The facility has been inspected by regulatory authorities and is producing product for commercial sales outside of the U.S. At this site, we recently completed construction of a 50,000 square foot manufacturing expansion which is being validated in preparation for additional commercial manufacture capacity.

AIR

The AIR manufacturing process uses spray drying. We take drugs provided by our partners or purchased from generic manufacturers, combine the drugs with certain excipients commonly used in other aerosol formulations and spray dry the solution in commercial spray dryers. During the manufacturing process, solutions of drugs and excipients are spray dried to form a free flowing powder and the powder is filled and packaged into final dosage units. AIR has a clinical manufacturing facility, where powders and final dosage units are prepared under current good manufacturing practices (cGMP) for use in clinical trials. Our current clinical manufacturing facility and equipment are at a scale equivalent to commercial manufacturing. This clinical production facility is being moved into and validated in our principle location for clinical manufacturing. In February 2002, we entered into an agreement with Lilly that provided for an investment by Lilly in our large-scale production facility for inhaled pharmaceutical products based on our AIR pulmonary drug delivery technology. This new 90,000 square foot facility is designed to accommodate the manufacturing of multiple products. Construction of this facility in Chelsea, Massachusetts was recently completed and validation is underway. AIR s inhalation devices are produced under current good manufacturing practices (cGMP) at two contract manufacturers in the U.S.

Marketing

We intend to market the majority of our ProLease, Medisorb and AIR products through corporate partners. We have entered into development agreements, which include sales and marketing arrangements, for ProLease product candidates with Genentech and Serono, for Medisorb product candidates with Janssen and Amylin and for AIR product candidates with Lilly. For our proprietary products, we will determine whether to market the products ourselves or to find a marketing partner. We plan to commercialize Vivitrex using a specialty sales force to call on addiction specialists and substance abuse centers. We may develop or commercialize Vivitrex alone or with a collaborative partner.

Alkermes is building the infrastructure necessary for commercialization of our proprietary products. We have increased our manufacturing capacity, we are expanding our product portfolio and we are beginning to develop the capabilities for marketing and selling our own products.

We currently have no experience in marketing or selling pharmaceutical products. In order to achieve commercial success for any product candidate approved by the FDA or other regulatory authorities, we must either develop a marketing and sales force or enter into arrangements with third parties to market and sell our products. There can be no assurance that we will successfully develop such experience or that we will be able to enter into marketing and sales agreements with others on acceptable terms, if at all. If we develop our own marketing and sales capability, we will compete with other companies that currently have experienced and well-funded marketing and sales operations. To the extent we enter into co-promotion or other sales and marketing arrangements with other companies, any revenues received by us will be dependent on the efforts of others, and there can be no assurance that such efforts will be successful.

38

Table of Contents

Competition

The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. We face, and will continue to face, intense competition in the development, manufacturing, marketing and commercialization of our product candidates from academic institutions, government agencies, research institutions, biotechnology and pharmaceutical companies, including our collaborators, and drug delivery companies. There can be no assurance that developments by others will not render our product candidates or technologies obsolete or noncompetitive, or that our collaborators will not choose to use competing drug delivery methods. At the present time, we have no sales force or marketing experience and we have only limited commercial manufacturing experience. In addition, many of our competitors and potential competitors have substantially greater capital resources, manufacturing and marketing experience, research and development resources and production facilities than we do. Many of these competitors also have significantly greater experience than we do in undertaking preclinical testing and clinical trials of new pharmaceutical products and obtaining FDA and other regulatory approvals.

With respect to ProLease and Medisorb, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. With respect to AIR, we are aware that there are other companies marketing or developing pulmonary delivery systems for pharmaceutical products. In many cases, there are products on the market or in development that may be in direct competition with our product candidates. In addition, other companies are developing new chemical entities or improved formulations of existing products which, if developed successfully, could compete against our formulations of any products we develop or those of our collaborators. These chemical entities are being designed to have different mechanisms of action or improved safety and efficacy. In addition, our collaborators may develop, either alone or with others, products that compete with the development and marketing of our product candidates.

There can be no assurance that we will be able to compete successfully with such companies. The existence of products developed by our competitors, or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed by us.

Patents and Proprietary Rights

Our success will be dependent, in part, on our ability to obtain patent protection for our product candidates and those of our collaborators, maintaining trade secret protection and operating without infringing upon the proprietary rights of others.

We have a proprietary portfolio of patent rights and exclusive licenses to patents and patent applications. We have filed numerous U.S. and international patent applications directed to composition of matter as well as processes of preparation and methods of use, including applications relating to each of our delivery technologies. We own approximately 90 issued U.S. patents. No U.S. patent issued to us that is currently material to our business will expire prior to 2009. In the future, we plan to file further U.S. and foreign patent applications directed to new or improved products and processes. We intend to file additional patent applications when appropriate and defend our patent position aggressively. We have determined that development of Cereport and RMPs is economically infeasible and, therefore, abandoned related patent rights outside the U.S. and Canada.

We have exclusive rights through licensing agreements with third parties to approximately 34 issued U.S. patents, a number of U.S. patent applications and corresponding foreign patents and patent applications in many countries, subject in certain instances to the rights of the U.S. government to use the

39

Table of Contents

technology covered by such patents and patent applications. No issued U.S. patent to which we have exclusive licensed rights and which is currently material to our business will expire prior to 2016. Under certain licensing agreements, we currently pay annual license fees and/or minimum annual royalties. During the fiscal year ended March 31, 2003, these fees totaled \$143,000. In addition, under all licensing agreements, we are obligated to pay royalties on future sales of products, if any, covered by the licensed patents.

We know of several U.S. patents issued to other parties that relate to our product candidates. One of those parties has asked us to compare our Medisorb technology to that party s patented technology. Another such party has asked a collaborative partner to substantiate how our ProLease microspheres are different from that party s patented technology. The manufacture, use, offer for sale, sale or importing of these product candidates might be found to infringe on the claims of these patents. A 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 U.S. and various foreign countries that may relate to some of our product candidates if 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 U.S. 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 biopharmaceutical 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, those we may file in the future, or those we may license from third parties, may not result in patents being issued. And, if issued, they may not provide us with 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 U.S.

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 corporate partners, collaborators, 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, results of operations and financial condition could be adversely affected.

Government Regulation

The manufacture and marketing of pharmaceutical products in the U.S. require the approval of the FDA under the Federal Food, Drug and Cosmetic Act. Similar approvals by comparable agencies are required in most foreign countries. The FDA has established mandatory procedures and safety standards which apply to the preclinical testing and clinical trials, manufacture and marketing of pharmaceutical products. Pharmaceutical manufacturing facilities are also regulated by state, local and other authorities.

40

Table of Contents

As an initial step in the FDA regulatory approval process, preclinical studies are typically conducted in animal models to assess the drug s efficacy and to identify potential safety problems. The results of these studies must be submitted to the FDA as part of an Investigational New Drug application (IND), which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. Phase I trials are conducted with a small number of subjects and are designed to provide information about both product safety and the expected dose of the drug. Phase II trials are designed to provide additional information on dosing and preliminary evidence of product efficacy. Phase III trials are large-scale studies designed to provide statistical evidence of efficacy and safety in humans. The results of the preclinical testing and clinical trials of a pharmaceutical product are then submitted to the FDA in the form of an NDA, or for a biological product in the form of a Product License Application (PLA), for approval to commence commercial sales. Preparing such applications involves considerable data collection, verification, analysis and expense. In responding to an NDA or PLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria.

Prior to marketing, any product developed by us or our collaborators must undergo an extensive regulatory approval process, which includes preclinical testing and clinical trials of such product candidate to demonstrate safety and efficacy. This regulatory process can require many years and the expenditure of substantial resources. Data obtained from preclinical testing and clinical trials are subject to varying interpretations, which can delay, limit or prevent FDA approval. In addition, changes in FDA approval policies or requirements may occur or new regulations may be promulgated which may result in delay or failure to receive FDA approval. Similar delays or failures may be encountered in foreign countries. Delays, increased costs and failures in obtaining regulatory approvals would have a material adverse effect on our business, financial condition and results of operations.

Among the conditions for NDA or PLA approval is the requirement that the prospective manufacturer s quality control and manufacturing procedures conform on an ongoing basis with GMP. Before approval of an NDA or PLA, the FDA will perform a pre-approval inspection of the facility to determine its compliance with GMP and other rules and regulations. In complying with GMP, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. After the establishment is licensed, it is subject to periodic inspections by the FDA.

The requirements which we must satisfy to obtain regulatory approval by governmental agencies in other countries prior to commercialization of our products in such countries can be as rigorous and costly as those described above.

We are also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, experimental use of animals and use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. Compliance with laws and regulations relating to the protection of the environment has not had a material effect on capital expenditures, earnings or our competitive position. However, the extent of government regulation which might result from any legislative or administrative action cannot be accurately predicted.

Employees

As of September 24, 2003, we had approximately 447 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel; however, competition for such

41

Table of Contents

personnel is intense. None of our employees are covered by a collective bargaining agreement. We consider our relations with employees to be good.

Properties

We lease approximately 295,000 square feet of laboratory, manufacturing and office space in Cambridge, Massachusetts under several leases expiring in the years 2004 to 2012. Approximately 81,000 square feet of laboratory and office space in Cambridge, Massachusetts is not utilized or is being sublet. A portion of the space was exited in connection with the move into our new corporate headquarters and the balance was exited as a part of the Company s restructuring of operations undertaken in August 2002. We are in the process of moving and validating our GMP clinical manufacturing suites for the manufacture of product candidates incorporating the ProLease delivery system and the AIR technology in the Company s principal location for clinical manufacturing. The lease for the Company s headquarters and principal location for clinical manufacturing and laboratory space commenced in June 2002 and will terminate in 2012. Several of the leases contain provisions permitting us to extend the term of such leases for up to two ten-year periods. We also have a 32,000 square foot commercial scale ProLease manufacturing facility in Cambridge, Massachusetts.

During fiscal 2001, we entered into a new lease for a 90,000 square foot building which we are developing as a commercial scale AIR manufacturing facility in Chelsea, Massachusetts. The lease term is for fifteen years with an option to extend the term of such lease for up to two five-year periods. Construction of this facility is substantially complete and the validation process is underway.

We own and occupy approximately 100,000 square feet of manufacturing, office and laboratory space in Wilmington, Ohio. The facility contains a GMP production facility designed for the production of Medisorb microspheres on a commercial scale. We recently completed construction of 50,000 square feet of this manufacturing facility and validation is currently underway. We also lease and occupy approximately 30,000 square feet of laboratory and office space in Blue Ash, Ohio under a lease expiring in 2004.

We believe that our current and planned facilities in Massachusetts and Ohio are adequate for our current and near-term preclinical, clinical and commercial operations.

Legal Proceedings

None.

Available Information

Our internet address is www.alkermes.com, at which you can find, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q and all other reports filed with the SEC. All such filings are available on the website as soon as reasonably practicable after filing.

42

Table of Contents

DESCRIPTION OF NOTES

Alkermes, Inc. issued the notes under an indenture dated August 22, 2003 between Alkermes, Inc. and U.S. Bank National Association, as notes trustee. The following summarizes the material provisions of the notes and the notes indenture. This summary is subject to and is qualified by reference to all the provisions of the notes and the notes indenture. As used in this description, the words we, us or our do not include any current or future subsidiary of Alkermes, Inc.

General

We issued \$125,000,000 aggregate principal amount of notes.

The notes are subordinated obligations of Alkermes, Inc. that are subordinate in right of payment as described under Subordination below. The notes are convertible into common stock as described under Conversion by Holders and Automatic Conversion below. The notes were issued in denominations of \$1,000 and multiples of \$1,000. The notes mature on September 1, 2023 unless earlier converted, redeemed or repurchased.

The notes bear interest at the rate of 2½% per year. Interest will be paid on March 1 and September 1 of each year, commencing on March 1, 2004, subject to limited exceptions if the notes are converted, redeemed or repurchased prior to the applicable interest payment date. The record dates for payment of interest are February 15 and August 15 of each year.

Interest will be payable in cash. Interest will be computed on the basis of a 360-day year comprised of twelve 30-day months.

We will pay principal and interest on the notes at the corporate trust office of the notes trustee or at the office or agency we maintain for such purpose in the Borough of Manhattan, The City of New York, which shall initially be the office or agency of the notes trustee. At our option, however, we may pay interest by check mailed to your address as it appears in the notes register. However, holders of \$2,000,000 or more in principal amount of notes may elect in writing to be paid by wire transfer; provided that any payment to DTC or its nominee will be made by wire transfer of immediately available funds to the account of DTC or its nominee.

We will not be restricted from paying dividends or repurchasing securities or incurring indebtedness under the notes indenture. The notes indenture has no financial covenants. Holders of the notes are not protected in the event of a highly leveraged transaction or a change in control of Alkermes except as described under Repurchase at Option of Holders upon a Repurchase Event below.

You are not required to pay a service charge for registration or transfer of notes. We may, however, require you to pay any tax or other governmental charge in connection with the transfer. We are not required to exchange or register the transfer of:

any note for a period of 15 days before selection for redemption;

any note or portion selected for redemption;

any note or portion surrendered for conversion;

43

Table of Contents

any note or portion surrendered for repurchase but not withdrawn in connection with a repurchase event; or

any note or portion tendered for repurchase on September 1, 2008, September 1, 2013 or September 1, 2018, each a repurchase date. The notes will be issued:

in fully-registered form; and

in denominations of \$1,000 and multiples of \$1,000.

Book-Entry System

Global Security

The notes were issued in the form of a global security held in book-entry form. Except as noted below under Certificated Notes, DTC or its nominee is the sole registered holder of the notes for all purposes under the notes indenture. Owners of beneficial interests in the notes represented by the global security hold these interests pursuant to the procedures and practices of DTC. Owners of beneficial interests must exercise any rights in respect of their interests, including any right to convert or require repurchase of their interests, in accordance with DTC s procedures and practices. Beneficial owners are not holders, and are not entitled to any rights under the global security or the notes indenture with respect to the global security. We and the trustee may treat DTC as the sole holder and owner of the global security. See Book-Entry System The Depository Trust Company.

Certificated Notes

Certificated notes may be issued in exchange for notes represented by the global security if DTC no longer serves as the depositary and no successor depositary is appointed by us.

Conversion by Holders

You may, at your option, convert some or all of your notes at any time prior to maturity into shares of our common stock at a conversion price of \$13.85 per share, subject to adjustment upon certain events, which amounts to a conversion ratio of 72.2022 shares of common stock per \$1,000 of notes. You may convert notes in denominations of \$1,000 and multiples of \$1,000; we will not, however, issue fractional shares upon conversion of the notes but will instead make a cash adjustment for any fractional share interest. The conversion price is subject to adjustment as described below. If the notes are called for redemption, the conversion rights on the notes called for redemption will expire at the close of business of the last business day before the redemption date, unless we default in payment of the redemption price. If you have submitted your notes for repurchase after a repurchase event or in connection with a repurchase date, you may only convert your notes if you deliver a withdrawal notice before the close of business on the last business day before the repurchase date.

If you convert your notes after a record date and prior to the next interest payment date, you will have to pay us interest, unless the notes have been called for redemption or we have issued a notice of an automatic conversion where such redemption or automatic conversion occurs prior to the interest payment date, under the notes indenture. We will pay a cash adjustment for any fractional shares based on the market price of our common stock on the last business day before the conversion date.

44

Table of Contents

You can convert your notes by delivering the notes to an office or agency of the notes trustee in the Borough of Manhattan, The City of New York, along with a duly signed and completed notice of conversion, a form of which may be obtained from the notes trustee. In the case of a global security, DTC will effect the conversion upon notice from the holder of a beneficial interest in the global security in accordance with DTC s rules and procedures. The conversion date will be the date on which the notes and the duly signed and completed notice of conversion are delivered. As promptly as practicable on or after the conversion date, but no later than three business days after the conversion date, we will issue and deliver to the conversion agent certificates for the number of full shares of common stock issuable upon conversion, together with any cash payment for fractional shares. In the event we fail to convert any tendered notes into common stock in accordance with the terms of the notes indenture, the holder may bring an action to enforce its right to convert.

You will not be required to pay any stamp, transfer, documentary or similar taxes or duties upon conversion but will be required to pay any stamp or transfer tax or duty if the common stock issued upon conversion of the notes is in a name other than your name. Certificates representing shares of common stock will not be issued or delivered unless all stamp or transfer taxes and duties, if any, payable by the holder have been paid.

Adjustment to the conversion price

The conversion price will be adjusted if:

- (1) we dividend or distribute shares of our common stock to our common shareholders;
- (2) we split, subdivide or combine our common stock;
- (3) we issue rights or warrants to all holders of our common stock to purchase common stock at less than the current market price;
- (4) we dividend or distribute to all holders of our common stock capital stock or evidences of indebtedness or assets, but excluding:
 - dividends, distributions and rights or warrants referred to in (3) above or to be exercised in connection with certain trigger events:
 - dividends and distributions paid exclusively in cash or paid in connection with our liquidation, dissolution or winding up; or capital stock, evidence of indebtedness, cash or assets distributed in a merger or consolidation;
- (5) we make a dividend or distribution consisting exclusively of cash to all holders of common stock. In the event of such a dividend or distribution, we will reduce the conversion price to a price to be determined by multiplying the then current conversion price by the fraction obtained by (i) subtracting the full amount of the dividend or distribution payable to the holder of one share of our common stock from the average closing price of our common stock for the three trading days immediately preceding the ex-dividend date for such dividend or distribution and (ii) dividing the difference obtained in (i) by the average closing price of our common stock for the three trading days immediately preceding the ex-dividend date for such dividend or distribution;

45

Table of Contents

- (6) the purchase of common stock pursuant to a tender offer made by us or any of our subsidiaries involves an aggregate consideration that, together with any cash and the fair market value of any other consideration payable in any other tender offer by us or any of our subsidiaries for common stock expiring within the 12 months preceding such tender offer, exceeds 10% of our market capitalization on the expiration of such tender offer; or
- (7) payment on tender offers or exchange offers by a third party other than Alkermes, Inc. or our subsidiaries if, as of the closing date of the offer, our board of directors does not recommend rejection of the offer. We will only make this adjustment if a tender offer increases the person s ownership to more than 25% of our outstanding common stock and the payment per share is greater than the current market price of the common stock. We will not make this adjustment if the tender offer is a merger or transaction described below under Consolidation, Merger or Transfer of Assets.

The conversion adjustment provisions apply to the conversion price for both voluntary conversions and automatic conversions.

Pursuant to our shareholders rights plan, the holders of notes will receive the rights upon conversion of the notes, whether or not these rights were separated from the common stock prior to conversion.

If we reclassify our common stock, consolidate, merge or combine with another person or sell or convey our property and assets as an entirety or substantially as an entirety, each note then outstanding will, without the consent of the holder of any note, become convertible only into the kind and amount of securities, cash and other property receivable upon such reclassification, consolidation, merger, combination, sale or conveyance by a holder of the number of shares of common stock into which the note was convertible immediately prior to the reclassification, consolidation, merger, combination, sale or conveyance. This calculation will be made based on the assumption that the holder of common stock failed to exercise any rights of election that the holder may have to select a particular type of consideration. The adjustment will not be made for a consolidation, merger or combination that does not result in any reclassification, conversion, exchange or cancellation of our common stock.

We are permitted to reduce the conversion price of the notes for limited periods of time, if our board of directors deems it advisable. Any such reduction shall be effective for not less than 20 days. We are required to give at least 15 days prior notice of any such reduction. We may also reduce the conversion price to avoid or diminish income tax to holders of our common stock in connection with a dividend or distribution of stock or similar event.

No adjustment in the conversion price of the notes will be required unless it would result in a change in the conversion price of at least one percent. Any adjustment not made will be taken into account in subsequent adjustments.

Automatic Conversion

We may elect to automatically convert the notes if our stock price hits specific targets.

We may elect to automatically convert some or all of the notes at any time 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 consecutive 30-day trading period ending within five trading days prior to the notice of automatic conversion. We refer to this as an automatic conversion. The notice of automatic

46

Table of Contents

conversion must be given not more than 30 and not less than 20 days prior to the date of automatic 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 shares of our common stock to holders of notes being converted. This additional interest shall be equal to three years worth of interest less any interest actually paid or provided for prior to the date of automatic conversion. We will specify in the automatic conversion notice whether we will pay the additional interest in cash or common stock. If we elect to pay the additional interest in shares of our common stock, the shares of common stock will be valued at 97.5% of the average of the closing price of our common stock for each of the five trading days immediately preceding the second trading day preceding the conversion date. We will not issue fractional shares for any additional interest upon conversion but will instead make a cash adjustment for any fractional share interest.

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.

You will not be required to pay any stamp, transfer, documentary or similar taxes or duties upon conversion but will be required to pay any stamp or transfer tax or duty if the common stock issued upon conversion of the notes is in a name other than your name. Certificates representing shares of common stock will not be issued or delivered unless all stamp or transfer taxes and duties, if any, payable by the holder have been paid.

Optional Redemption

At any time on or after September 6, 2006, we may redeem some or all of the notes, at our option, upon not less than 20 nor more than 60 days prior written notice sent via first class mail, at the redemption prices specified below. The redemption price, expressed as a percentage of the principal amount, is as follows for the periods beginning September 6, 2006:

Period	Redemption Price
September 6, 2006 to August 31, 2007	101.00%
September 1, 2007 to August 31, 2008	100.50%
September 1, 2008 to September 1, 2023	100.00%

In each case we will also pay accrued and unpaid interest to, but excluding, the redemption date. If the redemption date is an interest payment date, we will pay interest to the record holders as of the relevant record date.

No sinking fund will be provided for the notes, which means that the notes indenture will not require us to redeem or retire the notes periodically. We may not redeem the notes if there is a default under the notes indenture. See Events of Default and Remedies below.

Repurchase at Option of the Holder

You have the right to require us to repurchase the notes for cash on September 1, 2008, September 1, 2013 and September 1, 2018. We will be required to repurchase any outstanding note for

47

Table of Contents

which you deliver a written repurchase notice to the paying agent. This notice must be delivered during the period beginning at any time from the opening of business on the date that is 20 business days prior to the repurchase date until the close of business on the repurchase date. If a repurchase notice is given and withdrawn during that period, we will not be obligated to repurchase the notes listed in the notice. Our repurchase obligation will be subject to certain additional conditions.

The repurchase price payable for a note will be equal to 100% of the principal amount, plus accrued and unpaid interest to, but excluding, the repurchase date. Your right to require us to repurchase notes is exercisable by delivering a written repurchase notice to the paying agent within 20 business days of the repurchase date. The paying agent initially will be U.S. Bank National Association, the notes trustee.

The repurchase notice must state:

if certificated notes have been issued, the note certificate numbers (or, if your notes are not certificated, your repurchase notice must comply with appropriate DTC procedures);

the portion of the principal amount of notes to be repurchased, which must be in \$1,000 multiples; and

that the notes are to be repurchased by us pursuant to the applicable provisions of the notes and the notes indenture. You may withdraw any written repurchase notice by delivering a written notice of withdrawal to the paying agent prior to the close of business of the repurchase date. The withdrawal notice must state:

the principal amount of the withdrawn notes;

if certificated notes have been issued, the certificate numbers of the withdrawn notes (or, if your notes are not certificated, your withdrawal notice must comply with appropriate DTC procedures); and

the principal amount, if any, which remains subject to the repurchase notice.

We must give notice of an upcoming repurchase date to all note holders not less than 20 business days prior to the repurchase date at their addresses shown in the register of the registrar. We will also give notice to beneficial owners as required by applicable law. This notice will state, among other things, the procedures that holders must follow to require us to repurchase their notes.

Payment of the repurchase price for a note for which a repurchase notice has been delivered and not withdrawn is conditioned upon book-entry transfer or delivery of the note, together with necessary endorsements, to the paying agent at its office, or any other office of the paying agent, prior to, on or at any time after delivery of the repurchase notice. Payment of the repurchase price for the note will be made promptly following the later of the repurchase date and the time of book-entry transfer or delivery of the note. If the paying agent holds money sufficient to pay the repurchase price of the note, then, on and after the later of the repurchase date or the date such cash is first held the note will cease to be outstanding and all other rights of the note holder will terminate, other than the right to receive the repurchase price upon delivery of the note. This will be the case whether or not book-entry transfer of the note has been made or the note has been delivered to the paying agent.

48

Table of Contents

No notes may be repurchased by us at the option of the holders if the principal amount of the notes has been accelerated, and such acceleration has not been rescinded, on or prior to such date. We may be unable to repurchase the notes if you elect to require us to repurchase the notes pursuant to this provision. If you elect to require us to repurchase the notes we may not have enough funds to pay the repurchase price for all tendered notes. Any future credit agreements or other agreements relating to our indebtedness may contain provisions prohibiting repurchase of the notes under certain circumstances. If you elect to require us to repurchase the notes at a time when we are prohibited from repurchasing notes, we could seek the consent of our lenders to repurchase the notes or attempt to refinance this debt. If we do not obtain consent to repurchase, or successfully refinance the notes, we would not be permitted to repurchase the notes. Our failure to repurchase tendered notes would constitute an event of default under the notes indenture, which might constitute a default under the terms of our other indebtedness. Our ability to repurchase notes with cash may be limited by the terms of our then-existing borrowing agreements. Even though we become obligated to repurchase any outstanding note on a repurchase date, we may not have sufficient funds to pay the repurchase price on that repurchase date.

We will comply with the provisions of Rule 13e-4 and any other rules under the Securities Exchange Act of 1934 that may be applicable. We will file a Schedule TO or any other schedule required in connection with any offer by us to repurchase the notes.

Repurchase at Option of Holders upon a Repurchase Event

If a repurchase event occurs after issuance of the notes, you will have the right, at your option, to require us to repurchase all or any portion of your notes 40 days after we mail holders a notice of the repurchase event. The repurchase price we are required to pay will be equal to 105% of the principal amount of the notes submitted for repurchase, plus accrued and unpaid interest to, but excluding, the repurchase date. If a repurchase date is an interest payment date, we will pay the interest that is due and payable on such date to the record holder on the applicable record date.

We may pay the repurchase price, at our option, in cash or common stock. If we elect to pay the repurchase price in common stock, the number of shares we deliver will be valued at 95% of the average of the closing price for each of the five trading days immediately preceding the second trading day prior to the repurchase date. We may only pay the repurchase price in common stock if we satisfy conditions provided in the notes indenture.

A repurchase event will be considered to have occurred if:

our common stock or other common stock into which the notes are convertible is neither listed for trading on a United States national securities exchange nor approved for trading on an established automated over-the-counter trading market in the United States; or

one of the following change in control events occurs:

- 1. any person or group becomes the beneficial owner of more than 50% of the voting power of our outstanding securities entitled to generally vote for directors;
- 2. our shareholders approve any plan or proposal for our liquidation, dissolution or winding up;
- 3. we consolidate with or merge into, or participate in a share exchange with any other corporation, partnership, limited liability company or other entity or any other corporation, partnership, limited liability company or other entity merges into

40

Table of Contents

us, and, in the case of any such merger, consolidation or share exchange, our outstanding common stock is changed or exchanged into other assets or securities as a result;

- 4. we convey, transfer or lease all or substantially all of our assets to any person; or
- 5. the continuing directors do not constitute a majority of our board of directors at any time.

However, a change in control will not be deemed to have occurred if:

the last sale price of our common stock for any five trading days during the ten trading days immediately before the change in control is equal to at least 105% of the conversion price;

in the event of a transaction specified in (1), (3) or (4) above, if our shareholders immediately before such transaction constituting the change in control own, directly or indirectly, immediately following such transaction, at least 51% of the combined voting power of the outstanding voting securities resulting from such change in control in substantially the same proportion as their ownership of the voting stock immediately before such transaction; or

in the event of a transaction specified in (3) or (4) above, all of the consideration, excluding cash payments for fractional shares in the transaction constituting the change in control, consists of common stock traded on a United States national securities exchange or quoted on the NASDAQ National Market, and as a result of the transaction the notes become convertible solely into that common stock.

The term continuing director means at any date a member of our board of directors:

who was a member of our board of directors on August 15, 2003; or

who was nominated or elected by at least a majority of the directors who were continuing directors at the time of the nomination or election or whose election to our board of directors was recommended by at least a majority of the directors who were continuing directors at the time of the nomination or election or by the nominating committee comprised of our independent directors.

Under the above definition of continuing director, if the current board of directors approved a new director or directors and then resigned, no change in control would occur. The interpretation of the phrase all or substantially all used in the definition of change in control would likely depend on the facts and circumstances existing at such time. As a result, there may be uncertainty as to whether or not a sale or transfer of all or substantially all of our assets has occurred.

We will be required to mail holders of notes a notice within 15 days after the occurrence of a repurchase event. The notice must describe, among other things, the repurchase event, the holder s right to elect repurchase of the notes and the repurchase date. We must deliver a copy of the notice to the notes trustee and cause a copy, or a summary of the notice, to be published in a newspaper of general circulation in New York, New York. You may exercise your repurchase rights by delivering written notice to us and the notes trustee. The notice must be accompanied by the notes duly endorsed for

50

Table of Contents

transfer to us. You must deliver the exercise notice on or before the close of business on the thirty-fifth calendar day after the mailing date of the repurchase notice.

You may require us to repurchase all or any portion of your notes upon a repurchase event. We may not have sufficient cash funds to repurchase the notes upon a repurchase event. We may elect, subject to certain conditions, to pay the repurchase price in common stock. Certain of our existing debt agreements, as well as future debt agreements, may prohibit us from paying the repurchase price in either cash or common stock. If we are proh