ALKERMES INC
Form S-1
September 03, 2003

Table of Contents

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

Registration No. 333-_____

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ALKERMES, INC.

(Exact name of registrant as specified in its charter)

Pennsylvania	23-2472830
(State or other jurisdiction of incorporation or organization)	(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	Amount to be registered	Proposed maximum offering price per unit	Proposed maximum aggregate offering price	Amount of registration fee
2½% Convertible Subordinated Notes due 2023	$125,000,000	100%(1)(2)	$125,000,000	$10,113
Common Stock, par value $.01 per share	11,133,603 shares(3)	(4)	(4)	(4)

(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) 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.

(4) 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 August 29, 2003 the last sale price of our common stock, as reported on the Nasdaq National Market, was $11.65 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 September 3, 2003

TABLE OF CONTENTS

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

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.

Table of Contents

Securities to be Offered

We issued and sold $100 million aggregate principal amount of the notes in August 2003 to the initial purchaser in a transaction that was exempt from the registration requirements imposed by the Securities Act of 1933. The initial purchaser has an option to purchase an additional $25 million principal amount of the notes. 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	$100,000,000 principal amount of 2½% Convertible Subordinated Notes due 2023, which may increase up to $125,000,000 principal amount of the notes if the initial purchaser exercises its option to purchase additional notes. 9,025,275 shares of common stock, issuable upon conversion of the 2½% Convertible Subordinated Notes, or, if the 2½% Convertible Subordinated Notes are not converted, and we exercise our right to repurchase the 2½% Convertible Subordinated Notes for stock, 10,627,530 shares of common stock, which may be issuable upon a repurchase event, assuming a market value of the common stock of $13.00 per share, and 506,073 shares of common stock which may be issuable to satisfy the three-year interest make-whole payment, assuming a market value of the common stock of $19.00 per share.
Interest	Interest is payable at the rate of 2½% per year on each March 1 and September 1 beginning on March 1, 2004.
Maturity date	September 1, 2023
Conversion	The notes are convertible at the option of the holder at any time prior to maturity into common stock at a conversion price of $13.85 per share, subject to adjustment upon certain events.
Auto-conversion	We may elect to automatically convert some or all of the notes on or prior to maturity if the closing price of our common stock has exceeded 150% of the conversion price for at least 20 trading days during any 30-day trading period, ending within five trading days prior to the notice of automatic conversion. During the two-year period after the issue date of the notes, we may automatically convert the notes only if a registration statement has been declared effective prior to the date of the notice of automatic conversion and such registration statement remains effective on the date of automatic conversion.
Interest make-whole provisions during first three years upon auto-conversion	If an automatic conversion occurs on or prior to September 1, 2006, we will pay additional interest in cash or, at our option, in common stock, equal to three full years of interest on the converted notes, less any interest actually paid or provided for on the notes prior to automatic conversion. If we elect to pay the additional interest in common stock, the shares of common stock will be valued at 97.5% of the average closing price of our common stock for the five trading days immediately preceding the second trading day prior to the

Table of Contents

	conversion date.
Optional redemption	We may redeem some or all of the notes on or after September 6, 2006 at the declining redemption prices listed in this offering memorandum, plus accrued and unpaid interest.
Repurchase at the option of the holder	You may require us to repurchase the notes for cash on September 1, 2008, September 1, 2013 and September 1, 2018 at a repurchase price equal to 100% of the principal amount, plus accrued and unpaid interest.
Repurchase at the option of the holder upon a repurchase event	You may require us to repurchase your notes upon a repurchase event in cash, or, at our option, in common stock, at 105% of the principal amount of the notes, plus accrued and unpaid interest.
Ranking	The notes are subordinated to our senior indebtedness. As of 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.

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 s 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 s 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 s efforts to resolve the FDA s 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;

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

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 38 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

Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

We will need to spend substantial funds to become profitable.

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

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

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

Table of Contents

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

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

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

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

- obtain and maintain regulatory approval for our products in the United States and in foreign countries;
- enter into agreements to develop and commercialize products;
- develop and expand our capacity to manufacture and market products or enter into agreements with others to do so;
- obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third party payors;
- obtain additional research and development funding from collaborative partners or funding for our proprietary product candidates; and
- achieve certain product development milestones.

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

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

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

- a product candidate may not be safe or effective;
- data from preclinical testing and clinical trials may be interpreted by the FDA or foreign regulatory agencies in different ways than we or our partners interpret it;

Table of Contents

- the FDA or foreign regulatory agencies might not approve our manufacturing processes or facilities;
- the FDA or foreign regulatory agencies may change their approval policies or adopt new regulations;
- a product candidate may not be approved for all the indications we or our partners request; and
- the FDA may not agree with our or our partners regulatory approval strategies or components of our or our partners filings, such as clinical trial designs.

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

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

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

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

Patent protection for our products is important and uncertain.

The following factors are important to our success:

- receiving and maintaining patent protection for our products and product candidates and for those of our collaborative partners;
- maintaining our trade secrets;
- not infringing the proprietary rights of others; and
- preventing others from infringing our proprietary rights.

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

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

Table of Contents

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

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

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

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

We are exposed to product liability claims and recalls.

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

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

Table of Contents

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

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

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

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

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

develop new products in a cost effective manner.

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

develop their products more rapidly than we can;

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

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

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

Foreign currency exchange rates may affect revenue.

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

We face competition in the biotechnology and pharmaceutical industries.

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

Table of Contents

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

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

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

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

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

- demonstration of their safety and clinical efficacy;
- their cost-effectiveness;
- their potential advantage over alternative treatment methods;
- the marketing and distribution support they receive; and
- reimbursement policies of government and third-party payors.

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

Table of Contents

We may not be able to retain our key personnel.

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

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

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

Our common stock price is highly volatile.

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

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

We may encounter difficulties integrating future acquisitions.

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

Table of Contents

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

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

Anti-takeover provisions may not benefit shareholders.

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

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.

Table of Contents

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

We may not have sufficient funds to repurchase the notes.

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

We have substantially increased our indebtedness.

As a result of the sale of the notes, we incurred $100 million of additional indebtedness and will further increase it by up to $25 million of additional indebtedness if the initial purchaser exercises its option. Our other indebtedness is principally comprised of bank financing. We may incur substantial additional indebtedness in the future. The level of our indebtedness among other things, could:

- make it difficult for us to make payments on the notes;
- make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements or other purposes;
- limit our flexibility in planning for, or reacting to changes in, our business; and
- make us more vulnerable in the event of a downturn in our business.

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

There may be no active market for the notes.

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

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

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

Table of Contents

the factors described under Risks Related to Alkermes Our common stock price is highly volatile;

our operating results;

announcement by us or our competitors of technological innovations or new products; and

general economic and market conditions.

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

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

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

Table of Contents

Special Note Regarding Forward-Looking Statements

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

Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our development and manufacturing activities and our results of operations will not differ materially from our expectations. Factors which could cause actual results to differ from expectations include, among others: (i) 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.

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 s 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 s 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.

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 August 29, 2003)	$13.52	$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 Year Ended March 31,					Three Months Ended
	2003	2002	2001	2000	1999	June 30, 2003
Ratio of earnings to fixed charges[1]						

(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 $97 million from the August 2003 offering (assuming the option granted to the initial purchaser is not exercised).

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 the August 2003 offering, $3,000,000 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 $3,000,000 to the interest make-whole provisions of the notes based on the final terms of the notes and an aggregate of $100,000,000 million principal amount of the notes. The amount allocated to the derivative liability will increase if the initial purchaser exercises its option to purchase an additional $25,000,000 principal amount of the notes.

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 August 2003 Offering [1]
	(dollars, in thousands)		
Cash and cash equivalents including short-term investments	$ 104,679	$ 102,354	$ 199,354
Current portion of long-term debt	6,825	6,825	6,825
Long-term debt, excluding current portion:			
2½% convertible subordinated notes (net of $3.0 million discount)			97,000
6.52% convertible senior subordinated notes (net of $8.4 million discount)[1]	166,131		
3.75% convertible subordinated notes	676	676	676
Total long-term debt	166,807	676	97,676
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	$ 277,444

(1) 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 August 29, 2003, there were 88,886,394 shares of common stock outstanding.

(2) 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 20, 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.

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						
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)						1,409	
Derivative loss related to 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)
Total other income (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

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.

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 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 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

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
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
Insulin	Diabetes	AIR	Clinical phase undisclosed	Lilly
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 partne are conducting formulation, efficacy, pharmacology and/or toxicology testing of a compound in animal models or biochemical assays.

(2) Approved for marketing in 38 countries outside of U.S. Marketed in 18 of such countries. An affiliate of our collaborative partner received a non-approvable letter from the U.S. FDA. See Risk Factors.

(3) This program has been funded in part with federal funds from the National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health.

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 50 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 38 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

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

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 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

Table of Contents

filings to other drug regulatory agencies in over 50 countries around the world. Risperdal Consta has been approved in 38 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

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.

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

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

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

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.

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.

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 33 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

Table of Contents

technology covered by such patents and patent applications. No issued U.S. patent to which we have 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.

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 August 29, 2003, we had approximately 443 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

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 principle 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.

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 $100,000,000 aggregate principal amount of notes, which may increase up to $125,000,000 principal amount of the notes if the initial purchaser exercises its option to purchase additional 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;

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.

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;

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

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

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.

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

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

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 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 or refinance, we would be prohibited from repurchasing the notes. If we were unable to repurchase the notes upon a repurchase event, it would result in an event of default under the notes indenture. An event of default under the notes indenture could result in a further event of default under our 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 notes indenture.

The change in control feature may not necessarily afford you with protection in the event of a highly leveraged transaction, a change in control or similar transactions involving us. We could, in the future, enter into transactions, including recapitalizations, that would not constitute a change in control but that would increase the amount of our senior indebtedness or other debt. We are not prohibited from incurring senior indebtedness or debt under the notes indenture. If we incur significant amounts of additional debt, this could have an adverse effect on our ability to make payments on the notes.

In addition, our management could undertake leveraged transactions that could constitute a change in control. The Board of Directors will not have the right under the notes indenture to limit or waive the repurchase right in the event of these types of leveraged transactions. Our requirement to repurchase notes upon a repurchase event could delay, defer or prevent a change of control. As a result, the repurchase right may discourage:

a merger, consolidation or tender offer;

the assumption of control by a holder of a large block of our shares; and

the removal of incumbent management.

The repurchase feature is not the result of any specific effort to accumulate shares of common stock or to obtain control of us by means of a merger, tender offer or solicitation, or part of a plan by us to adopt a series of anti-takeover provisions. We have no present intention to engage in a transaction involving a change of control, although it is possible that we would decide to do so in the future.

The Securities Exchange Act of 1934 and the Securities and Exchange Commission rules thereunder require the distribution of specific types of information to security holders in the event of issuer tender offers. These rules may apply in the event of a repurchase. We will comply with these rules to the extent applicable.

Subordination

The notes are unsecured and subordinated to the prior payment in full of all existing and future senior indebtedness as provided in the notes indenture. The notes are pari passu in right of payment with our 3.75% Convertible Subordinated Notes due 2007. Upon any distribution of our assets upon our dissolution, winding up, liquidation or reorganization, payments on the notes will be subordinated to the

Table of Contents

prior payment in full of all senior indebtedness. If the notes are accelerated following an event of default under the notes indenture, the holders of any senior indebtedness will be entitled to payment in full before the holders of the notes are entitled to receive any payment on the notes.

We may not make any payments on the notes if:

- we default in the payment on senior indebtedness beyond any grace period; or
- any other default occurs and is continuing under any designated senior indebtedness that permits holders of the designated senior indebtedness to accelerate its maturity, and we and the trustee receive a notice, known as a payment blockage notice, from a person permitted to give this notice under the notes indenture.

We may resume making payments on the notes:

- in the case of a payment default, when the default is cured or waived or ceases to exist; and
- in the case of a nonpayment default, the earlier of when the default is cured or waived or ceases to exist or 179 days after receipt of the payment blockage notice.

No new period of payment blockage may be commenced unless:

- 365 days have elapsed since our receipt of the prior payment blockage notice; and
- all scheduled payments on the notes have been paid in full, or the notes trustee or the holders of notes shall not have begun proceedings to enforce the right of the holders to receive payments.

No default that existed on any senior indebtedness on the date of delivery of any payment blockage notice may be the basis for a subsequent payment blockage notice.

The term senior indebtedness means the principal, premium, if any, and interest on, including bankruptcy interest, and any other payment on the following current or future incurred:

- indebtedness for money borrowed or evidenced by notes, debentures, bonds or other securities;
- reimbursement obligations under letters of credit, bank guarantees or bankers acceptances;
- indebtedness under interest rate and currency swap agreements, cap, floor and collar agreements, currency spot and forward contracts and other similar agreements and arrangements;
- indebtedness consisting of commitment or standby fees under our credit facilities or letters of credit;
- obligations under leases required or permitted to be capitalized under generally accepted accounting principles;

Table of Contents

obligations of the type listed above that have been assumed or guaranteed by us or in effect guaranteed, directly or indirectly, by us through an agreement to purchase; and

any amendment, modification, renewal, extension, refunding or deferral of any indebtedness or obligation of the type listed in the bullet points above.

Senior indebtedness will not include:

any indebtedness or amendment or modification that expressly provides that it is subordinate to or is not senior to or is on the same basis as the notes;

any indebtedness to any subsidiary;

indebtedness for trade payables or the deferred purchase price of assets or services incurred in the ordinary course of business; or

the notes.

If the trustee or any holder of the notes receives any payment or distribution of our assets of any kind on the notes in contravention of any of the terms of the notes indenture, then such payment or distribution will be held by the recipient in trust for the benefit of the holders of senior indebtedness, and will be immediately paid or delivered to the holders of senior indebtedness or their representative or representatives.

In the event of our insolvency, liquidation, reorganization or payment default on senior indebtedness, 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 notes indenture. If we incur additional debt, our ability to pay amounts due on the notes could be adversely affected. At June 30, 2003, we had approximately $6.825 million of senior indebtedness. We may also incur additional debt in the future. The subordination provisions will not prevent the occurrence of any default or event of default or limit the rights of any holder of notes to pursue any other rights or remedies with respect to the notes.

As a result of the subordination provisions, in the event of the liquidation, bankruptcy, reorganization, insolvency, receivership or similar proceedings, holders of the notes may receive less than other creditors on a ratable basis.

Events of Default and Remedies

The following events constitute events of default under the notes indenture:

we fail to pay the principal or premium, if any, on any of the notes when due, whether or not prohibited by the subordination provisions of the notes indenture;

we fail to pay interest or additional interest or liquidated damages, if any, on the notes when due if such failure continues for 30 days, whether or not prohibited by the subordination provisions of the notes indenture;

we fail to perform any covenant in the notes indenture if such failure continues for 45 days after notice is given in accordance with the notes indenture;

Table of Contents

we fail to repurchase any notes after a repurchase event or on a repurchase date;

we fail to provide timely notice of a repurchase event;

we fail or any of our significant subsidiaries fail to make any payment at maturity on any indebtedness, including any applicable grace periods, in an amount in excess of $7,500,000, and such amount has not been paid or discharged within 30 days after notice is given in accordance with the notes indenture;

a default by us or any significant subsidiary on any indebtedness that results in the acceleration of indebtedness in an amount in excess of $7,500,000, without this indebtedness being discharged or the acceleration being rescinded or annulled for 30 days after notice is given in accordance with the notes indenture; or

certain events involving bankruptcy, insolvency or reorganization of us or any significant subsidiary.

The notes trustee is generally required under the notes indenture, within 90 days after its becoming aware of a default, to provide holders written notice of all incurred default. However, the notes trustee may, except in the case of a payment default on the notes, withhold this notice of default if it determines that withholding the notice is in the best interest of the holders.

If an event of default has occurred and is continuing, the notes trustee or the holders of not less than 25% in principal amount of outstanding notes, may declare the principal and premium, if any, on the notes to be immediately due and payable. After acceleration, but before a judgment or decree based on acceleration, the holders of a majority in aggregate principal amount of outstanding notes may, under circumstances set forth in the notes indenture, rescind the acceleration of the principal of and premium, if any, on the notes, other than the payment of principal of the notes that has become due other than because of the acceleration. If an event of default arising from events of bankruptcy, insolvency or reorganization occurs and is continuing with respect to us, all unpaid principal of and accrued interest on the outstanding notes would become due and payable immediately without any declaration or other act on the part of the notes trustee or holders of notes.

Holders of a majority in principal amount of outstanding notes may direct the time, method and place of conducting any proceeding for any remedy available to the notes trustee or exercising any trust or power conferred on the notes trustee, subject to specified limitations. Before exercising any right or power under the notes indenture at the direction of the holders, the notes trustee will be entitled to receive from such holders reasonable security or indemnity against any costs, expenses and liabilities that it might incur as a result.

Before the holder of a note may take any action to institute any proceeding relating to the notes indenture, or to appoint a receiver or a trustee, or for any other remedy, each of the following must occur:

the holder must have given the notes trustee written notice of a continuing event of default;

the holders of at least 25% of the aggregate principal amount of all outstanding notes must make a written request of the notes trustee to take action because of the default;

holders must have offered reasonable indemnification to the notes trustee against the cost, expenses and liabilities of taking action; and

Table of Contents

the notes trustee must not have taken action for 60 days after receipt of such notice and offer of indemnification.

These limitations do not apply to a suit for the enforcement of payment of the principal of or any premium or interest on a note or the right to convert the note in accordance with the notes indenture.

Generally, the holders of not less than a majority of the aggregate principal amount of outstanding notes may waive any default or event of default, except if:

we fail to pay the principal of, premium or interest on any note when due;

we fail to convert any note into common stock; or

we fail to comply with any of the provisions of the notes indenture that would require the consent of the holder of each outstanding note affected.

We will send the notes trustee annually a statement as to whether we are in default and the nature of any default under the notes indenture.

Consolidation, Merger or Transfer of Assets

We may not consolidate or merge into another person or sell, lease, convey or transfer all or substantially all of our assets to another person, whether in a single or series of related transactions, unless:

either (A) we are the surviving entity, or (B) the resulting entity is a United States corporation, limited liability company, partnership or trust and expressly assumes in writing all of our obligations under the notes and the notes indenture;

no default or event of default exists or would occur; and

other conditions specified in the notes indenture are satisfied.

Modification and Waiver

The consent of the holders of a majority in principal amount of the outstanding notes affected is required to make a modification or amendment to the notes indenture. However, a modification or amendment requires the consent of the holder of each outstanding note affected if it would:

extend the fixed maturity of any note;

reduce the interest rate or extend the time of payment of interest on any note;

reduce the principal amount or any premium of any note;

reduce any amount payable upon redemption or repurchase of any note;

adversely change our obligation to repurchase any note upon a repurchase event or a repurchase date;

adversely change the holder s right to institute suit for the payment of any note;

Table of Contents

change the currency in which any note is payable;

adversely modify the right to convert the notes;

adversely modify the subordination provisions of the notes; or

reduce the percentage required to consent to modifications and amendments.

Under the notes indenture, we may make certain modifications and amendments to the notes indenture without obtaining the prior consent of the holders of the notes.

Satisfaction and Discharge

We may discharge our obligations under the notes indenture while notes remain outstanding if:

all notes will become due in one year or are scheduled for redemption in one year; and

we deposit sufficient funds to pay all outstanding notes on their scheduled maturity or redemption date.

Registration Rights of Holders of the Notes

Under the registration rights agreement between us and the initial purchaser, we generally are required to:

file, within 60 days after August 22, 2003, a registration statement covering the resale of the notes and the common stock issuable upon conversion of the notes;

use our reasonable best efforts to cause the registration statement to be declared effective as promptly as practicable; and

use our reasonable best efforts to keep the registration statement effective until the earlier of the resale of all the transfer restricted securities or two years after the latest date of original issuance.

When we use the term transfer restricted securities in this section, we mean the notes and the common stock issued upon conversion of the notes until the earlier of the following events:

the date the note or common stock issued upon conversion has been effectively registered under the Securities Act of 1933 and sold or transferred pursuant to the registration statement; or

the date on which the note or common stock issued upon conversion is distributed to the public pursuant to Rule 144 under the Securities Act of 1933 or is saleable pursuant to Rule 144(k) under the Securities Act of 1933; or

the date the note or common stock issued upon conversion ceases to be outstanding.

We are required to pay predetermined liquidated damages if one of the following registration defaults occurs:

Table of Contents

we do not file the registration statement within 60 days after the closing date of this offering;

the Securities and Exchange Commission does not declare the registration statement effective within 150 days after the closing date of this offering; or

after it has been declared effective and during the period in which we are obligated to keep it effective, the registration statement ceases to be effective or available for more than 90 days in any period of 365 consecutive days.

If a registration default occurs, liquidated damages initially will accrue (a) for the notes that are transfer restricted securities, at the rate of $.05 per week per $1,000 principal amount of the notes and (b) for any common stock issued on conversion of the notes that are transfer restricted securities, at an equivalent rate based on the conversion price. If the registration default has not been cured within 90 days, the liquidated damages rate will increase by $.05 per week per $1,000 principal amount of the notes that are transfer restricted securities (and an equivalent amount for any common stock issued upon conversion of the notes that are transfer restricted securities) for each subsequent continuing 90-day non-compliance period, up to a maximum rate of $.25 per week per $1,000 principal amount of the notes that are transfer restricted securities (and an equivalent amount for any common stock issued upon conversion of the notes that are restricted securities). Liquidated damages generally will be payable at the same time as interest payments on the notes.

We may suspend the use of the prospectus, which is a part of the registration statement, in certain circumstances described in the registration rights agreement upon notice to the holders of the transfer restricted securities. We will provide copies of the prospectus and notify registered holders of notes and common stock issued upon conversion when the registration statement is filed and when it becomes effective.

Under the registration rights agreement, you will be required to deliver a prospectus to purchasers and will be bound by the provisions of the agreement.

Governing Law

The notes, the notes indenture and the registration rights agreement are governed by the laws of the State of New York.

Concerning the Trustee

We have appointed the notes trustee as the initial paying agent, conversion agent, registrar and custodian for the notes. We may maintain deposit accounts and conduct other banking transactions with the notes trustee or its affiliates in the ordinary course of business. In addition, the notes trustee and its affiliates may in the future provide banking and other services to us in the ordinary course of their business.

If the notes trustee becomes one of our creditors, the notes indenture and the Trust Indenture Act of 1939 may limit the right of the notes trustee to obtain payment on or realize on security for its claims. If the notes trustee develops any conflicting interest with the holders of notes or us, it must eliminate the conflict or resign.

Table of Contents

BOOK-ENTRY SYSTEM - THE DEPOSITORY TRUST COMPANY

The Depositary Trust Company (DTC) acts as depositary for the notes. The certificates representing the notes are in fully registered, global form without interest coupons registered in the name of Cede & Co. (DTC s partnership nominee) or such other name as may be requested by an authorized representative of DTC. Ownership of beneficial interests in a global note will be limited to persons who have accounts with DTC (participants) or persons who hold interests through participants. Ownership of beneficial interests in a global note will be shown on, and the transfer of that ownership will be effected only through, records maintained by DTC or its nominee (with respect to interests of participants) and the records of participants (with respect to interests of persons other than participants).

So long as DTC or its nominee is the registered owner or holder of the global notes, DTC or such nominee, as the case may be, will be considered the sole record owner or holder of the notes represented by such global notes for all purposes under the notes indenture. No beneficial owner of an interest in the global notes will be able to transfer that interest except in accordance with DTC s applicable procedures, in addition to those provided for under the notes indenture.

DTC has advised us as follows: DTC is a limited-purpose trust company organized under the New York Banking Law, a banking organization within the meaning of the New York Banking Law, a member of the Federal Reserve System, a clearing corporation within the meaning of the New York Uniform Commercial Code, and a clearing agency registered pursuant to the provisions of Section 17A of the Exchange Act. DTC holds the notes that its participants deposit with DTC. DTC also facilitates the settlement among participants of notes transactions, such as transfers and pledges, in deposited notes through electronic computerized book-entry changes in participants accounts, thereby eliminating the need for physical movement of notes certificates. Participants include securities brokers and dealers, banks, trust companies, clearing corporations, and certain other organizations. DTC is owned by a number of its participants and by the New York Stock Exchange, Inc., the American Stock Exchange LLC, and the National Association of Securities Dealers, Inc. Access to the DTC system is also available to others such as securities brokers and dealers, banks, and trust companies that clear through or maintain a custodial relationship with a participant, either directly or indirectly. The rules applicable to DTC and its participants are on file with the SEC.

Purchases of notes under the DTC system must be made by or through participants, which will receive a credit for the notes on DTC s records. The beneficial ownership interest of each actual purchaser of each new note is in turn to be recorded on the participants records. Beneficial owners will not receive written confirmation from DTC of their purchase, but they are expected to receive written confirmations providing details of the transaction, as well as periodic statements of their holdings, from the participant through which the beneficial owner entered into the transaction. Transfers of ownership interests in the notes are to be accomplished by entries made on the books of participants acting on behalf of beneficial owners. Beneficial owners will not receive certificates representing their ownership interests in notes, except in the event that use of the book-entry system for the notes is discontinued.

To facilitate subsequent transfers, all notes deposited by participants with DTC are registered in the name of DTC s partnership nominee, Cede & Co. or such other name as may be requested by an authorized representative of DTC. The deposit of notes with DTC and their registration in the name of Cede & Co. or such other nominee do not effect any change in beneficial ownership. DTC has no knowledge of the actual beneficial owners of the notes; DTC s records reflect only the identity of the participants to whose accounts such notes are credited, which may or may not be the beneficial owners. The participants will remain responsible for keeping account of their holdings on behalf of their customers.

Table of Contents

Conveyance of notices and other communications by DTC to participants and by participants to beneficial owners will be governed by arrangements among them, subject to any statutory or regulatory requirements as may be in effect from time to time. Beneficial owners of notes may wish to take certain steps to augment transmission to them of notices of significant events with respect to the notes, such as redemptions, tenders, defaults, and proposed amendments to the notes documents. Beneficial owners of notes may wish to ascertain that the nominee holding the notes for their benefit has agreed to obtain and transmit notices to beneficial owners, or in the alternative, beneficial owners may wish to provide their names and addresses to the registrar and request that copies of the notices be provided directly to them.

Payments of the principal of and interest on the global notes will be made to DTC or its nominee, as the case may be, as the registered owner thereof. We understand that DTC s practice is to credit participants accounts, upon DTC s receipt of funds and corresponding detail information from us or the notes trustee on payable date in accordance with their respective holdings shown on DTC s records. Payments by participants to beneficial owners will be governed by standing instructions and customary practices, as is the case with securities held for the accounts of customers in bearer form or registered in street name, and will be the responsibility of such participant and not of DTC, the notes trustee, or us, subject to any statutory or regulatory requirements as may be in effect from time to time. Payment of redemption proceeds, distributions, and dividends to Cede & Co. (or such other nominee as may be requested by an authorized representative of DTC) is our responsibility or the responsibly of the notes trustee, disbursement of such payments to participants shall be the responsibility of DTC, and disbursement of such payments to the beneficial owners shall be the responsibility of participants.

We will send any redemption notices to Cede & Co. We understand that if less than all of the notes are being redeemed, DTC s practice is to determine by lot the amount of the holdings of each participant to be redeemed. We also understand that neither DTC nor Cede & Co. will consent or vote with respect to the notes. We have been advised that under its usual procedures, DTC will mail an omnibus proxy to us as soon as possible after the record date. The omnibus proxy assigns Cede & Co. s consenting or voting rights to those participants to whose accounts the notes are credited on the record date identified in a listing attached to the omnibus proxy.

A beneficial owner shall give notice to elect to have its notes purchased or tendered, through its participant, to the notes trustee, and shall effect delivery of such notes by causing the participant to transfer the participant s interest in the notes, on DTC s records, to the notes trustee. The requirement for physical delivery of notes in connection with an optional tender or a mandatory purchase will be deemed satisfied when the ownership rights in the notes are transferred by participants on DTC s records and followed by a book-entry credit of tendered notes to the notes trustee DTC account.

DTC may discontinue providing its services as notes depositary with respect to the notes at any time by giving reasonable notice to us or the notes trustee. If DTC is at any time unwilling or unable to continue as a depositary for the global notes and a successor depositary is not appointed within 90 days, we will issue definitive, certificated original notes in exchange for the global notes.

The information in this section concerning DTC and DTC s book-entry system has been obtained from sources that we believe to be reliable, but we take no responsibility for the accuracy thereof.

Table of Contents

DESCRIPTION OF CAPITAL STOCK

General

Alkermes, Inc. is authorized to issue 165,000,000 shares of capital stock, $0.01 par share, of which 160,000,000 shares have been designated as common stock par value $.01 par share, 88,886,394 of which are issued and outstanding as of August 29, 2003; 3,000,000 shares have been designated as preferred stock, par value $0.01 per share, 3,000 of which are designated as 2002 redeemable convertible preferred stock (the 2002 preferred stock) and are issued and outstanding and 110,000 of which are designated as Series A Junior participating preferred stock (the junior preferred) none of which are issued or outstanding; 450,000 shares have been designated as non-voting common stock, 382,632 of which are issued and outstanding as of August 29, 2003; and 1,550,000 shares are undesignated capital stock. As of August 29, 2003, there were 448 holders of record of our common stock and one holder of record of our non-voting common stock. The following description of Alkermes, Inc. s capital stock is subject to and qualified in its entirety by the provisions of Alkermes, Inc. s Third Amended and Restated Articles of Incorporation, as amended, and Bylaws, as amended, and by the provisions of applicable Pennsylvania law. As used in this section of the prospectus, the words, we, us or our do not include any current or future subsidiary of Alkermes, Inc.

Description of Common Stock

The majority of our authorized capital stock consists of common stock, par value $.01 per share. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders. Subject to preferences applicable to any series or class of capital stock with superior dividend rights that may be outstanding, holders of common stock are entitled to receive ratably such dividends as may be declared by the Board of Directors out of funds legally available therefor. We have paid no cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future.

In the event of liquidation, dissolution or winding up of Alkermes, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any series or class of capital stock with superior liquidation rights that may be outstanding. The outstanding shares of common stock are, and the common stock to be issued upon conversion of the notes will be, fully paid and nonassessable. No pre-emptive rights, conversion rights, redemption rights or sinking fund provisions are applicable to the common stock.

The 1988 Pennsylvania Business Corporation Law (1988 BCL), as amended, includes certain shareholder protection provisions, which apply to us. The following is a description of those provisions of the 1988 BCL that apply to us and that may have an anti-takeover effect. This description of the 1988 BCL is only a summary thereof, does not purport to be complete and is qualified in its entirety by reference to the full text of the 1988 BCL.

(i) Upon a control-share acquisition (acquiring person acquires or proposes to acquire 20%, 33.3% or 50% or more of the voting power of our common stock) the 1988 BCL operates to suspend the voting rights of the control shares (the newly acquired shares upon such an acquisition, plus any shares acquired within 180 days of exceeding a threshold) held by an acquiring person upon a control share acquisition. The acquiring person can regain his right to vote such control shares upon the approval of a majority of the outstanding disinterested shares and a majority of all common stock.

(ii) The disgorgement provisions require a controlling person (a person who acquired, offered to acquire or publicly disclosed the intention of acquiring at least 20% of the voting power

of Alkermes) to disgorge greenmail profits, or profits realized from the disposition of our securities within 18 months after becoming a controlling person and the security was acquired by the controlling person within 24 months before or 18 months after becoming a controlling person.

(iii) The control transaction provisions of the 1988 BCL allow holders of voting shares of a corporation to put their stock to an acquiror for fair value in the event of a control transaction (the acquisition of 20% of voting power over our common stock). Fair value is defined as not less than the highest price paid by the acquiror during a certain 90 day period.

(iv) An interested shareholder (the beneficial owner of 20% of the voting stock either of a corporation or of an affiliate of the corporation who was at any time within the five-year period immediately prior to the date in question the beneficial owner of 20% of the voting stock of the corporation) cannot engage in a business combination with the corporation for a period of five years unless: (a) the board approves the business combination prior to the interested shareholder becoming such or approves the acquisition of shares in advance, or (b) if the interested shareholder owns 80% of such stock, the business combination is approved by a majority of the disinterested shareholders and the transaction satisfies certain fair price provisions. After the five-year period, the same restrictions apply, unless the transaction either is approved (a) by a majority of the disinterested shareholders and satisfies the fair price provisions or (b) by all shareholders.

(v) Corporations may adopt shareholders rights plans with discriminatory provisions (sometimes referred to as poison pills) whereby options to acquire shares or corporate assets are created and issued which contain terms that limit persons owning or offering to acquire a specified percentage of outstanding shares from exercising, converting, transferring or receiving options and allows the exercise of options to be limited to shareholders or triggered based upon control transactions. Such poison pills take effect only in the event of a control transaction. Pursuant to the 1988 BCL, such poison pills may be adopted by the Board without shareholder approval.

(vi) Shareholders of a corporation do not have a statutory right to call special meetings of shareholders or to propose amendments to the articles under the provisions of the 1988 BCL.

(vii) In discharging the duties of their respective positions, the board of directors, committees of the board and individual directors may, in considering the best interests of the corporation, consider to the extent they deem appropriate, (i) the effects of any action upon shareholders, employees, suppliers, customers and creditors of the corporation and the community in which the corporation is located, (ii) the short-term and long-term interests of the corporation, including benefits that may accrue to the corporation from its long-term plans and the possibility that these interests may be best served by the continued independence of the corporation, (iii) the resources, intent and conduct (past, stated and potential) of any person seeking to acquire control of the corporation and (iv) all other pertinent factors. Further, the board of directors, committees of the board and individual directors are not required, in considering the best interests of the corporation or the effects of any action, to regard any corporate interest or the interests of any particular group affected by such action as a dominant or controlling interest or factor. The consideration of the foregoing factors shall not constitute a violation of the applicable standard of care.

Table of Contents

Description of Non-Voting Common Stock

We have designated 450,000 shares of our capital stock as non-voting common stock of which 382,632 are currently outstanding. The holder of non-voting common stock is not entitled to vote on any matters submitted to a vote of shareholders except for (a) such statutory voting rights provided under the 1988 BCL or (b) any matter submitted to a vote of the shareholders which would amend, alter or repeal any provisions of our Articles of Incorporation or the Bylaws so as to adversely affect the rights of the non-voting common stock.

The holders of non-voting common stock (a) shall be entitled to receive the same dividends or distributions, in cash, shares of stock of other property, as the holders of common stock receive; (b) shall be entitled to the same liquidation rights as, and on a parity with, the holders of common stock; and (c) shall be entitled to any other rights or privileges as, and on a parity with, the holders of the common stock.

The non-voting common stock is convertible, at the option of the holder, on a one-for-one basis into common stock. Additionally, each share of non-voting common stock shall automatically be converted into one share of common stock immediately upon the transfer of ownership by the initial holder or an affiliate of the initial holder to a third party which is not an affiliate of such holder.

Description of Preferred Stock

The Board of Directors has the authority, from time to time and without further action by the shareholders, to divide its unissued capital stock and its undesignated unissued preferred stock into one or more classes and one or more series within any class and to make determinations of the designation and number of shares of any class or series and determinations of the voting rights, preferences, limitations and special rights, if any, of the shares of any class or series. The rights, preferences, limitations and special rights of different classes of capital stock may differ with respect to dividend rates, amounts payable on liquidation, voting rights, conversion rights, redemption provisions, sinking fund provisions and other matters.

2002 preferred stock

We have designated 3,000 shares of 2002 redeemable convertible preferred stock all of which was sold to Eli Lilly and Company. This preferred stock is convertible into our common stock at market price at our option and upon filing of a new drug application with the U.S. Food and Drug Administration for a pulmonary insulin product. We must redeem this preferred stock in the event a development and license agreement between us and Lilly terminated for certain reasons. Lilly has the right to exchange the preferred stock for a reduction in the royalty rate payable to us under the development and license agreement for inhaled insulin products. This preferred stock ranks senior to the common stock and the non-voting common stock as to distribution of our assets upon liquidation, dissolution or winding up. This preferred stock has a liquidation preference of $10,000 per share and, in certain instances, accrued and unpaid dividends. This preferred stock has no voting rights other than required by law.

Junior preferred stock

The junior preferred stock was designated in connection with adoption by Alkermes of a Shareholder Rights Plan in February 2003. The holder of each share of common stock has a right to purchase from the Company one one-thousandth of a share of the Series A junior participating preferred stock at a purchase price of $80.00. This right is not excisable until the earlier of (i) 10 days following a public announcement that a person or group has acquired beneficial ownership of 15% or more of the

Table of Contents

outstanding shares of common stock or (ii) 10 days following the commencement of a tender offer or exchange offer that would result in a person or group beneficially owning 15% or more of the outstanding shares of common stock. This right will expire on February 19, 2013 unless earlier redeemed by the Company.

Transfer Agent and Registrar

The Transfer Agent and Registrar for the common stock, the non-voting common stock, the junior preferred and the 2002 preferred stock is EquiServe Trust Co., NA.

Table of Contents

SELLING SECURITYHOLDERS

We originally issued the notes in a transaction exempt from the registration requirements of the Securities Act to the initial purchaser. 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. As used in this prospectus, the term selling securityholders includes their transferees, pledgees, donees and their successors. The selling securityholders may from time to time offer and sell pursuant to this prospectus any or all of the notes and the shares of common stock initially issued or issuable under the notes indenture, if issued.

The following table sets forth information regarding (1) the beneficial ownership of the notes and the maximum principal amount of the notes that each selling securityholder may offer and (2) the number of shares of common stock that each selling securityholder may sell under this prospectus. Because the selling securityholders may offer all or a portion of the notes and the common stock, if issued, under this prospectus, we cannot estimate the amount of notes or the common stock that the selling securityholders will hold upon termination of any sale. The following table is based upon information furnished to us by the selling securityholders.

Name of Selling Securityholder	Principal Amounts of Notes Beneficially Owned and Offered	Percentage of Notes Outstanding	Number of Shares of Common Stock Issued Upon Conversion of the Notes that May be Offered	Percentage of Common Stock Outstanding(1)(2)
U.S. Bancorp Piper Jaffray Inc.	$ 6,500,000	6.5%	469,314	*
All other holders	93,500,000	93.5%	6,750,906	7.6%
Total	$ 100,000,000	100%	7,220,220	8.1%

* Less than 1%.

(1) Assumes conversion of all of the holders s notes at a conversion rate of approximately 72.2022 shares of our common stock for each $1,000 principal amount of notes. However, this conversion rate will be subject to adjustment as described under Description of Notes Conversion by Holders. As a result, the amount of common stock issuable upon conversion of notes may increase or decrease in the future.

(2) Assumes that the outstanding common stock is 88,886,394.

Table of Contents

PLAN OF DISTRIBUTION FOR THE RESALE OF THE SECURITIES

A selling securityholder may from time to time, in one or more transactions, sell all or a portion of the securities in negotiated transactions, in underwritten transactions or otherwise or, with respect to the common stock, on the Nasdaq National Market, at prices then prevailing or related to the then current market price or at negotiated prices. The offering price of the securities from time to time will be determined by a selling securityholder, and, with respect to the common stock, at the time of such determination, may be higher or lower than the market price of our common stock on the Nasdaq National Market. The securities may be sold directly or through broker-dealers acting as principal or agent. The methods by which the securities may be sold include:

a block trade in which the broker-dealer so engaged will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by such broker-dealer for its account pursuant to this prospectus;

ordinary brokerage transactions and transactions in which the broker solicits purchasers; and

privately negotiated transactions.

In effecting sales, brokers or dealers engaged by a selling securityholder may arrange for other brokers or dealers to participate. These brokers or dealers may receive commissions or discounts from a selling securityholder as applicable, in amounts to be negotiated immediately prior to the sale. A selling securityholder and any underwriters, dealers or agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act, and any profit on the sale of the securities by a selling securityholder and any commissions received by any broker-dealers may be deemed to be underwriting commissions under the Securities Act. In addition, any securities covered by this prospectus that qualify for sale pursuant to Rule 144 might be sold under Rule 144 rather than pursuant to this prospectus.

Additionally, in connection with the sale of the securities, a selling securityholder may enter into hedging transactions with broker-dealers and the broker-dealers may engage in short sales of the securities in the course of hedging the positions they assume with the selling securityholder. A selling securityholder may also enter into option or other transactions with broker-dealers that involve the delivery of the shares to the broker-dealers, who may then resell or otherwise transfer the shares. A selling securityholder may also loan or pledge the shares to a broker-dealer and the broker-dealer may sell the securities so loaned or upon a default may sell or otherwise transfer the pledged securities.

When a selling securityholder elects to make a particular offer of securities, we will distribute a prospectus supplement, if required, that will identify any underwriters, dealers or agents and any discounts, commissions and other terms constituting compensation from a selling securityholder, as applicable, and any other required information.

In order to comply with the securities laws of certain states, if applicable, the securities may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the securities may not be sold unless they have been registered or qualified for sale in such state or an exemption from such registration or qualification requirement is available and is complied with.

We also have agreed to indemnify the selling securityholders in certain circumstances, against certain liabilities arising under the Securities Act. Each selling securityholder has agreed to indemnify us

Table of Contents

and our directors and officers who sign the registration statement against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to pay all costs and expenses relating to the registration of the securities (other than fees and expenses, if any, of counsel or other advisors to the selling securityholders). Any commissions, discounts or other fees payable to broker-dealers in connection with any sale of the securities will be borne by the selling securityholder selling such shares.

All references to selling securityholders in this section of the prospectus shall also be deemed to include any transferees, assignees and pledgees of the selling securityholders.

Table of Contents

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

Introduction

Alkermes, Inc. (as used in this section, together with our subsidiaries, us , we or our), a Pennsylvania corporation organized in 1987, is an emerging pharmaceutical company developing products based on applying our proprietary drug delivery technologies to enhance therapeutic outcomes. 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 business strategy is two-fold. 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 pipeline of products in various stages of development and two marketed products, Risperdal Consta and Nutropin Depot. In addition to our Cambridge, Massachusetts corporate headquarters, research and manufacturing facilities, we operate research and manufacturing facilities in Ohio. Since our inception in 1987, we have devoted a significant portion of our resources to research and development programs and the purchase of property, plant and equipment. At June 30, 2003, we had an accumulated deficit of $481.3 million. We expect to incur substantial additional operating losses over the next few years.

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans and payments under research and development agreements with collaborators. We historically have developed our product candidates in collaboration with others on whom we rely for funding, development, manufacturing and/or marketing. While we continue to develop product candidates in collaboration with others, we also develop proprietary product candidates for our own account that we fund on our own.

Forward-Looking Statements

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

Table of Contents

(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.

Critical Accounting Policies

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements for the year ended March 31, 2003 included elsewhere in this registration statement, we believe the following accounting policies to be important to the portrayal of our financial condition and results of operations and can require estimates from time to time.

Revenue Recognition Manufacturing and royalty revenues consist of revenue earned under certain manufacturing and supply and license agreements for our two commercial products, Risperdal Consta and Nutropin Depot. Manufacturing revenues are earned when product is shipped to our collaborative partners. Royalty revenues are earned on product sales made by our collaborative partners and are recorded in the period the product is sold by our collaborative partners. Manufacturing revenues recognized by us are based on information supplied to us by our collaborative partners and may require estimates to be made.

Research and development revenue consists of nonrefundable research and development funding under collaborative arrangements with various collaborative partners. Research and development funding generally compensates us for formulation, preclinical and clinical testing related to the collaborative research programs, and is recognized as revenue at the time the research and development activities are

performed under the terms of the related agreements, when the corporate partner is obligated to pay and when no future performance obligations exist.

Fees for the licensing of technology or intellectual property rights on initiation of collaborative arrangements are recorded as deferred revenue upon receipt and recognized as income on a systematic basis (based upon the timing and level of work performed or on a straight-line basis if not otherwise determinable) over the period that the related products or services are delivered or obligations, as defined in the agreement, are performed. Revenue from milestone or other upfront payments is recognized as earned in accordance with the terms of the related agreements. These agreements may require deferral of revenue recognition to future periods.

Equity Method Investment in Reliant In December 2001, we purchased 63% of an offering by Reliant of its Series C Convertible Preferred Units, representing approximately 19% of the equity interest in Reliant, for a purchase price of $100 million. The investment has been accounted for under the equity method of accounting because Reliant is organized as a limited liability company, which is treated in a manner similar to a partnership. Because, at the time of our investment, Reliant had an accumulated deficit from operations and a deficit in members capital, under applicable accounting rules, our share of Reliant s losses from the date of our investment has been recognized in proportion to our percentage participation in the Series C financing, and not in proportion to our percentage ownership interest in Reliant. We recorded our equity in the income or losses of Reliant three months in arrears. For the fiscal years ended 2003 and 2002, this charge amounted to $94.6 million and $5.4 million, respectively, and for the three months ended June 30, 2003 and 2002, this charge amounted to $0 and $24.2 million, respectively, and is recorded in our consolidated statements of operations under the caption Equity in losses of Reliant Pharmaceuticals, LLC. Our $100 million investment was reduced to $0 during the fiscal year ended March 31, 2003. Since we have no further funding commitments to Reliant, we will not record any further share of losses in Reliant in our consolidated statement of operations. To the extent Reliant has net income in the future, we would record our proportional share of Reliant s net income. Reliant is a privately held company over which we do not exercise control and we have relied on the unaudited and audited financial statements prepared by Reliant s management and provided to us to calculate our share of Reliant s losses.

Embedded Derivative We exchanged our 3.75% Convertible Subordinated Notes due 2007 (the 3.75% Subordinated Notes) and offered for sale new 6.52% Convertible Senior Subordinated Notes due December 31, 2009 (the 6.52% Senior Notes) to existing holders in December 2002. The 6.52% Senior Notes are automatically convertible by us if the closing price of our common stock has exceeded $11.523 for at least 20 trading days during any 30-day trading period. If the automatic conversion occurs on or prior to December 30, 2004 or if the holders voluntarily convert prior to December 30, 2004, the Company will pay additional interest equal to two full years of interest on the 6.52% Senior Notes (the Two-Year Interest Make-Whole), less any interest paid or provided for on the 6.52% Senior Notes prior to conversion. The Two-Year Interest Make-Whole represents an embedded derivative which is required to be accounted for apart from the underlying 6.52% Senior Notes. At March 31, 2003, this embedded derivative had an estimated fair value of $13.3 million and is accounted for as a liability on the consolidated balance sheets. A $4.3 million noncash charge to Derivative loss related to convertible senior subordinated notes has been recorded in the year ended March 31, 2003 to account for the increase of this derivative liability. On June 18, 2003, we announced that we exercised our automatic conversion right for the 6.52% Senior Notes. The embedded derivative was adjusted to the value of the remaining balance of the Two-Year Interest Make-Whole payment, or approximately $17.1 million, at June 30, 2003 and is accounted for as a liability on the consolidated balance sheets. A $3.8 million noncash charge to Derivative loss related to convertible senior subordinated notes has been recorded in the consolidated statements of operations in the quarter ended June 30, 2003 to account for the increase of this derivative liability. On July 18, 2003, upon conversion of the then outstanding 6.52%

Table of Contents

Senior Notes and payment of the Two-Year Interest Make-Whole, the embedded derivative was settled in full and balance was reduced to reduced to zero.

Cost of Goods Manufactured Our cost of goods manufactured includes estimates made with respect to allocations of salaries and related benefits, occupancy costs, depreciation expense and other allocable costs directly related to our manufacturing activities. Costs of goods manufactured are incurred in connection with the manufacture of Risperdal Consta and Nutropin Depot.

Research and Development Expenses Our research and development expenses include salaries and related benefits, laboratory supplies, temporary help costs, external research costs, consulting costs, occupancy costs, depreciation expense and other allocable costs directly related to our research and development activities. Research and development expenses are incurred in conjunction with the development of our technologies, proprietary product candidates, collaborators product candidates and in-licensing arrangements. External research costs relate to toxicology studies, pharmacokinetic studies and clinical trials that are performed for us under contract by external companies, hospitals or medical centers. All such costs are charged to research and development expenses as incurred.

Restructuring of Operations In August 2002, we announced a restructuring program to reduce our cost structure as a result of our expectations regarding the financial impact of a delay in the U.S. launch of Risperdal Consta by our partner Janssen Pharmaceutica or Janssen (a wholly owned subsidiary of Johnson & Johnson). The restructuring program reduced our workforce by 122 employees, representing 23% of our total workforce and includes consolidation and closure of certain leased facilities in Cambridge, Massachusetts, closure of our medical affairs office in Cambridge, England, write-off of leasehold improvements at leased facilities being vacated and other expenses.

In connection with the restructuring program, we recorded charges of approximately $6.5 million in the consolidated statements of operations and comprehensive loss in the year ended March 31, 2003, which consisted of approximately $1.5 million in employee separation costs, including severance and related benefits, and approximately $5.0 million in facility consolidation and closure costs, including significant estimates relating to a lease cancellation fee, the length of time it will take to sublease certain of our facilities and the lease rates at which we may negotiate sublease agreements with third parties. As of June 30, 2003, we had paid an aggregate of approximately $1.5 million and $2.0 million in employee separation costs and facility closure costs, respectively.

Results of Operations

Three Months Ended June 30, 2003 and 2002

The net loss provided in accordance with accounting principles generally accepted in the U.S. (known as GAAP) for the three months ended June 30, 2003 was $30.6 million or $0.47 per share as compared to a net loss of $45.3 million or $0.70 per share in the same period of the prior year. Included in the net loss for the three months ended June 30, 2002 is a $24.2 million noncash charge related to the equity investment we made in Reliant in December 2001. Our investment in Reliant has been reduced to zero, and since no further funding commitments exist to Reliant, we have not recorded any share of Reliant s losses in the current quarter.

Total manufacturing and royalty revenues were $1.5 million for the three months ended June 30, 2003, including $1.1 million of manufacturing and royalty revenues for Risperdal Consta. During the quarter, we conducted our semi-annual shutdown of the Risperdal Consta facility in Ohio. In July 2003, we resumed manufacturing and began multi-shift operations at this facility in anticipation of approval of Risperdal Consta in the U.S. Alkermes developed the delivery technology for Risperdal Consta, which is

Table of Contents

an injectable, long-acting formulation of Risperdal, a Janssen Pharmaceutica, Inc. (Janssen) drug. Johnson & Johnson has filed for approval of Risperdal Consta around the world. As of August 2003, the product has been approved for sale in 38 countries. Janssen-Cilag, a wholly owned subsidiary of Johnson & Johnson, is currently marketing Risperdal Consta 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. The product is approved, but has not yet been launched in Argentina, Aruba, Bahrain, Belgium, Bulgaria, Colombia, Estonia, Guatemala, Hong Kong, Hungary, Jamaica, Kuwait, Lithuania, Philippines, Portugal, Singapore, Slovenia, Thailand, Trinidad/ Tobago and Uruguay.

Our research and development revenue under collaborative arrangements was $2.8 million and $10.3 million for the three months ended June 30, 2003 and 2002, respectively. The decrease in such revenue was primarily the result of the restructuring of our AIR insulin and AIR hGH programs with Eli Lilly and Company (Lilly), changes in our partners, as well as changes in the stage of several other collaborative programs. Beginning January 1, 2003, we no longer record research and development revenue for work performed on the Lilly programs but instead use the proceeds from Lilly s purchase of $30 million of our convertible preferred stock in December 2002 to pay for development costs into calendar year 2004. Also, in December 2002, the royalty payable to us based on revenues of potential inhaled insulin products was increased. Lilly has the right to return the convertible Preferred Stock to us in exchange for a reduction in this royalty rate.

For the three months ended June 30, 2003, the cost of goods manufactured was $2.6 million consisting of approximately $1.4 million for Risperdal Consta and approximately $1.2 million for Nutropin Depot.

Research and development expenses were $21.7 million for the three months ended June 30, 2003 compared to $24.6 million for the three months ended June 30, 2002. The decrease in research and development expenses for three months ended June 30, 2003 as compared to the three months ended June 30, 2002 is primarily because we now separately report the cost of goods manufactured for our commercial products, Risperdal Consta and Nutropin Depot. The decrease in research and development expenses for the three months ended June 30, 2003 as compared to the three months ended June 30, 2002 was partially offset by an increase in occupancy costs and depreciation expense related to the expansion of our facilities in both Massachusetts and Ohio. We expect an increase in research and development costs in fiscal 2004 resulting from the continuing development of our proprietary product candidates and our collaborators product candidates.

A significant portion of our research and development expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or our drug delivery technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative research and development activities are tracked by project and are reimbursed to us by our partners. We generally bill our partners under collaborative arrangements using a single full-time equivalent or hourly rate. This rate has been established by us annually based on our annual budget of salaries, employee benefits and the billable non-project-specific costs mentioned above and is often increased annually thereafter based on increases in the consumer price index. Each collaborative partner is billed using a full-time equivalent or hourly rate for the hours worked by our employees on a particular project, plus any direct external research costs. We account for our research and development expenses on a departmental and functional basis in accordance with our budget and management practices.

Below is a summary of our key proprietary and collaborators commercial products and product candidates and their respective stages of clinical development as of August 2003.

Table of Contents

Product Candidate	Indication	Phase of Clinical Development (1)
Risperdal Consta	Schizophrenia	Marketed (2)
Nutropin Depot	Pediatric growth hormone deficiency	Marketed
Vivitrex	Alcohol dependence	Phase III
Vivitrex	Opioid dependence	Phase II
Nutropin Depot	Adult growth hormone deficiency	Phase III
Exenatide LAR (AC2993)	Diabetes	Phase II
AIR Epinephrine	Anaphylaxis	Phase I
ProLease r-hFSH	Infertility	Phase Ib
AIR Insulin	Diabetes	Undisclosed
AIR hGH	Growth hormone deficiency	Phase I
Others	Various	Preclinical

(1) Phase I clinical trials indicates that the compound is being tested in humans for safety and preliminary indications of biological activity in a limited patient population. Phase II clinical trials indicates that the trial is being conducted in patients and is to provide information on dosing and is testing for safety and preliminary evidence of efficacy. Phase III clinical trials indicates that the trial is being conducted in patients and is testing the safety and efficacy of the compound. Preclinical indicates that we or our partners are conducting formulation, efficacy, pharmacology and/or toxicology testing of a compound in animal models or biochemical assays.

(2) Approved for sale in 38 countries. Marketed 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. Janssen has also received marketing approval, but has not yet launched in Argentina, Aruba, Bahrain, Belgium, Bulgaria, Colombia, Estonia, Guatemala, Hong Kong, Hungary, Jamaica, Kuwait, Lithuania, Philippines, Portugal, Singapore, Slovenia, Thailand, Trinidad/Tobago and Uruguay. Received a non-approvable letter from the U.S. FDA. See Results of Operations - Risperdal Consta.

General and administrative expenses were $5.8 million for the three months ended June 30, 2003 as compared to $6.0 million for the comparative period of the prior year. The decrease for the three months ended June 30, 2003 as compared to the three months ended June 30, 2002 was primarily the result of a decrease in consulting costs. The decrease in general and administrative expenses was partially offset by an increase in personnel costs and insurance costs.

In August 2002, we announced a restructuring program to reduce our cost structure as a result of our expectations regarding the financial impact of a delay in the U.S. launch of Risperdal Consta by our collaborative partner, Janssen. The restructuring program reduced our workforce by 122 employees, representing 23% of our total workforce and includes consolidation and closure of certain leased facilities in Cambridge, Massachusetts, closure of our medical affairs office in Cambridge, England, write-off of leasehold improvements at leased facilities being vacated and other expenses. The workforce reductions were made across all functions of the Company.

In connection with the restructuring program, we recorded charges of approximately $6.5 million in the consolidated statements of operations and comprehensive loss for the year ended March 31, 2003, which consisted of approximately $1.5 million in employee separation costs, including severance and related benefits, and approximately $5.0 million in facility consolidation and closure costs, including significant estimates relating to a lease cancellation fee, the length of time it will take to sublease certain

Table of Contents

of our facilities and the lease rates at which we may negotiate sublease agreements with third parties. As of June 30, 2003, we had paid an aggregate of approximately $1.5 million and $2.0 million in employee separation costs and facility closure costs, respectively.

The amounts in the accrual are expected to be paid through fiscal 2006. Pursuant to the restructuring plan, the following charges and payments have been recorded during the three months ended June 30, 2003:

Type of Liability	Balance, April 1, 2003	Charge for the Period	Payments for the Period	Balance, June 30, 2003
Employee separation costs	$ 16,547	$	$ (1,000)	$ 15,547
Facility closure costs	3,520,463		(534,669)	2,985,794
Total	$3,537,010	$	$(535,669)	$3,001,341

We substantially completed our restructuring program during fiscal 2003. However, the remaining restructuring accrual is an estimate of costs associated with leases or closed facilities and may require adjustment in the future.

Interest income was $1.0 million for the three months ended June 30, 2003 as compared to $1.4 million for the same period of the prior year. The decrease for the three months ended June 30, 2003 as compared to the three months ended June 30, 2002 was primarily the result of a decline in interest rates.

Other income, net was $1.4 million in the three months ended June 30, 2003 as compared to $0 for the three months ended June 30, 2002. Other income, net for the three months ended June 30, 2003 represents income recognized on the changes in the fair value of the warrants held in connection with licensing arrangements, which are recorded as derivatives under the caption other assets in the consolidated balance sheets. The recorded value of such warrants can fluctuate significantly based on fluctuations in the market value of the underlying securities of the issuer of the warrants.

Derivative loss related to convertible senior subordinated notes was $3.8 million in the three months ended June 30, 2003 as compared to $0 for the three months ended June 30, 2002. On June 18, 2003, we announced that we had exercised our right to automatically convert the 6.52% Senior Notes into our common stock on July 18, 2003. The 6.52% Senior Notes contained a provision that if the automatic conversion occurred on or prior to December 30, 2004 or if the holders voluntarily converted prior to December 30, 2004, we would pay additional interest equal to two full years of interest on the converted new notes or the Two-Year Interest Make-Whole, less any interest paid prior to conversion. The Two-Year Interest Make-Whole represented an embedded derivative. The value of the embedded derivative was increased by $3.8 million in the quarter to reflect the full value of amounts to be paid pursuant to the Two-Year Interest Make-Whole. The total value of the derivative was approximately $17.1 million at June 30, 2003 and is reflected as a liability in the consolidated balance sheets. On July 18, 2003, upon the conversion of the then outstanding 6.52% Senior Notes and payment of the Two-Year Interest Make-Whole, the embedded derivative was settled in full and the balance was reduced to zero.

Interest expense was $3.5 million for the three months ended June 30, 2003 as compared to $2.1 million for the three months ended June 30, 2002. The increase for the three months ended June 30, 2003 as compared to the prior year period was primarily the result of interest charges related to the 6.52% Senior Notes issued in December 2002.

We do not believe that inflation and changing prices have had a material impact on our results of operations.

Table of Contents

Reliant

For the three months ended June 30, 2003 and 2002, the noncash charge related to our equity in the losses of Reliant amounted to $0 and $24.2 million, respectively, and is recorded in our consolidated statements of operations and comprehensive loss under the caption Equity in losses of Reliant Pharmaceuticals, LLC. Our $100 million investment was reduced to zero during the year ended March 31, 2003. Since we have no further funding commitments to Reliant, we will not record any further share of losses of Reliant in our consolidated statements of operations and comprehensive loss. To the extent that Reliant has net income in the future, we would record our proportional share of Reliant s net income. There can be no assurance that Reliant will have net income in the near future, if ever. Reliant is a privately held company over which we do not exercise control and we relied on the unaudited and audited financial statements prepared by Reliant s management and provided to us to calculate our share of Reliant s losses.

Risperdal Consta

In August 2001, Janssen filed an NDA for Risperdal Consta with the FDA and similar regulatory filings have been submitted to other drug regulatory agencies worldwide. Risperdal Consta is a Medisorb long-acting formulation of Janssen s antipsychotic drug Risperdal. In June 2002, an affiliate of Janssen received a non-approvable letter for Risperdal Consta from the FDA. Johnson & Johnson has met with the FDA and, in April 2003, submitted additional data and analyses as a complete response to the agency s questions. There can be no assurance that the complete response will resolve the issues raised in the FDA s letter on a timely basis, if at all. Risperdal Consta has been approved in 38 countries and Risperdal Consta is in late-stage regulatory review in a number of other countries. Nevertheless, the impact of the FDA s non-approvable letter on other regulatory filings made worldwide is not known at this time. There can be no assurance that Risperdal Consta will be approved by the FDA or other regulatory agencies on a timely basis, if at all. See Risk Factors J&J PRD received a non-approvable letter for Risperdal Consta from the FDA.

Fiscal Years Ended March 31, 2003, 2002 and 2001

The net loss provided in accordance with GAAP for the fiscal year ended March 31, 2003 was $106.9 million or $1.66 per share as compared to a net loss of $61.4 million or $0.96 per share in the prior year. Included in the net loss for fiscal 2003 is a $94.6 million noncash charge related to the equity investment we made in Reliant in December 2001, as well as an $80.8 million noncash gain on the exchange of our convertible notes in December 2002.

Due to the amount of revenues earned as a result of the commercial launch of Risperdal Consta in certain countries outside of the U.S., we have, for the first time, separately reported manufacturing and royalty revenues. Total manufacturing and royalty revenues were $15.5 million for the fiscal year ended in 2003, including $13.4 million of manufacturing and royalty revenues for Risperdal Consta. The majority of the manufacturing and royalty revenues were earned from manufacturing fee revenues for Risperdal Consta as our partner, Janssen, purchased product to build inventory and support the commercial launch of the product.

Our research and development revenue under collaborative arrangements was $31.8 million, $54.1 million and $56.0 million for the fiscal years ended in 2003, 2002 and 2001, respectively. The decrease in such revenue was primarily the result of the change in the Risperdal Consta program from a development stage program to a commercial product, the restructuring of our AIR insulin and AIR hGH programs with Lilly and changes in our partners, as well as changes in the stage of several other collaborative programs. Beginning January 1, 2003, we no longer record research and development

Table of Contents

revenue for work performed on the Lilly programs but instead use the proceeds from Lilly s purchase of $30 million of our preferred stock in December 2002 to pay for development costs into calendar year 2004. The decrease in such revenue for fiscal 2002 as compared to fiscal 2001 was mainly the result of a significant non-recurring milestone earned in fiscal 2001 which was largely offset by a significant increase in funding earned under other collaborative agreements during fiscal 2002.

Due to the amount of revenues earned as a result of the commercial launch of Risperdal Consta in certain countries outside the U.S., we are reporting cost of goods manufactured separately from research and development expenses for the first time. For fiscal 2003, the cost of goods manufactured was $10.9 million consisting of approximately $5.5 million for Risperdal Consta and approximately $5.4 million for Nutropin Depot.

Research and development expenses were $85.4 million for the fiscal year ended in 2003 compared to $92.1 million and $68.8 million for the fiscal years ended in 2002 and 2001, respectively. The decrease in research and development expenses for fiscal 2003 as compared to fiscal 2002 is primarily because we are now separately reporting the cost of goods manufactured for our commercial products as Risperdal Consta moved from a development stage program to a commercial product. This decrease was partially offset by an increase in external research expenses as we advanced our proprietary product candidates and our collaborators product candidates through development and clinical trials. We currently have two products in Phase III clinical trials: Vivitrex, our proprietary product candidate for alcohol dependence, and Nutropin Depot for adult growth hormone deficiency in collaboration with Genentech, Inc. The increase in research and development expenses for fiscal 2002 as compared to fiscal 2001 was mainly the result of increases in personnel, external research expenses and lab supplies as we advance our proprietary product candidates and our collaborators product candidates through development and clinical trials and prepare for commercialization. For fiscal 2003 as compared to fiscal 2002 and fiscal 2002 as compared to fiscal 2001, there was also an increase in occupancy costs and depreciation expense related to the expansion of our facilities in both Massachusetts and Ohio. We expect an increase in research and development costs in fiscal 2004 resulting from the continuing development of our proprietary product candidates and our collaborators product candidates.

A significant portion of our research and development expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or our drug delivery technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative research and development activities are tracked by project and are reimbursed to us by our partners. We generally bill our partners under collaborative arrangements using a single full-time equivalent or hourly rate. This rate has been established by us annually based on our annual budget of salaries, employee benefits and the billable non-project-specific costs mentioned above and is often increased annually thereafter based on increases in the consumer price index. Each collaborative partner is billed using a full-time equivalent or hourly rate for the hours worked by our employees on a particular project, plus any direct external research costs. We account for our research and development expenses on a departmental and functional basis in accordance with our budget and management practices.

General and administrative expenses were $26.7 million, $24.4 million and $19.6 million for the fiscal years ended in 2003, 2002 and 2001, respectively. The increase for fiscal 2003 as compared to fiscal 2002 was primarily the result of $2.6 million of merger costs that were expensed as a result of the mutual termination of the merger agreement with Reliant in August 2002. General and administrative expenses also increased as a result of an increase in professional fees, insurance costs and consulting costs, partially offset by a decrease in personnel and related costs as a result of our restructuring in August 2002. The increase for fiscal 2002 as compared to fiscal 2001 was primarily a result of an increase in personnel, as well as increased professional fees, consulting costs and noncash compensation expense.

Table of Contents

For fiscal 2003 as compared to fiscal 2002 and fiscal 2002 as compared to fiscal 2001, there was also an increase in occupancy costs related to the expansion of our facilities in both Massachusetts and Ohio.

In August 2002, we announced a restructuring program to reduce our cost structure as a result of our expectations regarding the financial impact of a delay in the U.S. launch of Risperdal Consta by our collaborative partner, Janssen. The restructuring program reduced our workforce by 122 employees, representing 23% of our total workforce and includes consolidation and closure of certain leased facilities in Cambridge, Massachusetts, closure of our medical affairs office in Cambridge, England, write-off of leasehold improvements at leased facilities being vacated and other expenses. The workforce reductions were made across all functions of the Company.

In connection with the restructuring program, we recorded charges of approximately $6.5 million in the consolidated statements of operations and comprehensive loss for the year ended March 31, 2003, which consisted of approximately $1.5 million in employee separation costs, including severance and related benefits, and approximately $5.0 million in facility consolidation and closure costs, including significant estimates relating to a lease cancellation fee, the length of time it will take to sublease certain of our facilities and the lease rates at which we may negotiate sublease agreements with third parties. As of March 31, 2003, we had paid an aggregate of approximately $1.5 million and $1.5 million in employee separation costs and facility closure costs, respectively.

The amounts in the accrual are expected to be paid through fiscal 2006. Pursuant to the restructuring plan, the following charges and payments have been recorded during the year ended March 31, 2003:

Type of Liability	Balance, April 1, 2002	Charge for the Year	Payments for the Year	Balance, March 31, 2003
Employee separation costs	$	$1,480,025	$(1,463,478)	$ 16,547
Facility closure costs		5,016,599	(1,496,136)	3,520,463
Total	$	$6,496,624	$(2,959,614)	$3,537,010

We have substantially completed our restructuring program during fiscal 2003. However, the remaining restructuring accrual is an estimate of costs associated with leases or closed facilities and may require adjustment in the future.

Interest income was $3.8 million, $15.3 million and $22.4 million for the fiscal years ended in 2003, 2002 and 2001, respectively. The decrease for fiscal 2003 as compared to 2002 and fiscal 2002 as compared to fiscal 2001 was primarily the result of lower average cash and investment balances as compared to the prior year as well as a decline in market interest rates.

Interest expense was $10.4 million for the fiscal year ended in 2003 as compared to $8.9 million and $9.4 million for the fiscal years ended in 2002 and 2001, respectively. The increase for fiscal 2003 as compared to fiscal 2002 was primarily the result of interest charges related to the 6.52% Senior Notes issued in December 2002. The decrease for fiscal 2002 as compared to fiscal 2001 was primarily the result of a decrease in the average outstanding debt balance as compared to the prior year.

Gain on exchange of notes was $80.8 million for the fiscal year ended in 2003 and was a result of the gain on the exchange of $199.3 million principal of the 3.75% Subordinated Notes for $114.6 million principal of the 6.52% Senior Notes in December 2002.

Table of Contents

A $4.3 million noncash charge to Derivative loss related to convertible senior subordinated notes has been recorded in the year ended March 31, 2003 to account for the increase in the derivative liability associated with our 6.52% Senior Notes. The 6.52% Senior Notes are automatically convertible by us if the closing price of our common stock has exceeded $11.523 for at least 20 trading days during any 30-day trading period. If the automatic conversion occurs on or prior to December 30, 2004 or if the holders voluntarily convert prior to December 30, 2004, the Company will pay additional interest equal to two full years of interest on the converted new notes or the Two-Year Interest Make-Whole, less any interest paid or provided for on the 6.52% Senior Notes prior to conversion. The Two-Year Interest Make-Whole represents an embedded derivative which is required to be accounted for apart from the underlying 6.52% Senior Notes and at March 31, 2003 had an estimated fair value of $13.3 million and is accounted for as a liability in the consolidated balance sheets. This embedded derivative was adjusted for changes in its estimated fair value through the date of conversion of the 6.52% Senior Notes which occurred on July 18, 2003 based on our exercise of the automatic conversion right on June 18, 2003.

We do not believe that inflation and changing prices have had a material impact on our results of operations.

Reliant

In December 2001, we purchased approximately 63% of an offering by Reliant of its Series C Convertible Preferred Units, representing approximately 19% of the equity interest in Reliant, for a purchase price of $100 million. The investment is being accounted for under the equity method of accounting because Reliant is organized as a limited liability company, which is treated in a manner similar to a partnership. Because, at the time of our investment, Reliant had an accumulated deficit from operations and deficit in members capital, under applicable accounting rules, our share of Reliant s losses from the date of our investment is being recognized in proportion to our percentage participation in the Series C financing, and not in proportion to our 19% ownership interest in Reliant. We have been recording our equity in the losses of Reliant three months in arrears. For the fiscal year ended in 2003 and 2002, this noncash charge amounted to $94.6 million and $5.4 million, respectively, and is recorded in our consolidated statements of operations and comprehensive loss under the caption Equity in losses of Reliant Pharmaceuticals, LLC. Our $100 million investment was reduced to zero during the year ended March 31, 2003. Since we have no further funding commitments to Reliant, we will not record any further share of losses of Reliant in our consolidated statements of operations and comprehensive loss. To the extent that Reliant has net income in the future, we would record our proportional share of Reliant s net income. There can be no assurance that Reliant will have net income in the near future, if ever. Reliant is a privately held company over which we do not exercise control and we relied on the unaudited and audited financial statements prepared by Reliant s management and provided to us to calculate our share of Reliant s losses.

In connection with our $100 million equity investment in Reliant, we allocated our proportionate share of the assets acquired and liabilities assumed in accordance with the guidance set forth in SFAS No. 141, Business Combinations. In the quarter ended December 31, 2001, we recorded a $2.7 million noncash charge for in-process research and development through the consolidated statements of operations and comprehensive loss under the caption Equity in losses of Reliant Pharmaceuticals, LLC.

In March 2002, we entered into an Agreement and Plan of Merger (the Merger Agreement) with Reliant. In August 2002, we and Reliant announced the mutual termination of the Merger Agreement. The companies agreed to terminate due to general market conditions. There were no payments triggered by the mutual termination and each company was responsible for its own legal and transaction fees. As a result of the termination of the Merger Agreement, we expensed approximately

Table of Contents

$2.6 million in fiscal 2003 of deferred merger costs that are included in general and administrative expenses.

Risperdal Consta

In August 2001, Janssen filed an NDA for Risperdal Consta with the FDA and similar regulatory filings have been submitted to other drug regulatory agencies worldwide. Risperdal Consta is a Medisorb long-acting formulation of Janssen s antipyschotic drug Risperdal. In June 2002, an affiliate of Janssen received a non-approvable letter for Risperdal Consta from the FDA. Johnson & Johnson has met with the FDA and, in April 2003, submitted additional data and analyses as a complete response to the agency s questions. There can be no assurance that the complete response will resolve the issues raised in the FDA s letter on a timely basis, if at all. In August 2002, we announced that Risperdal Consta received approval to be marketed in Germany and the United Kingdom. Since then, Risperdal Consta has been approved in numerous other countries and Risperdal Consta is in late-stage regulatory review in a number of other countries. Nevertheless, the impact of the FDA s non-approvable letter on other regulatory filings made worldwide is not known at this time. There can be no assurance that Risperdal Consta will be approved by the FDA or other regulatory agencies on a timely basis, if at all. See Risk Factors J&J PRD received a non-approvable letter for Risperdal Consta from the FDA.

Table of Contents

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

	Three Months Ended				
	June 30, 2002	September 30, 2002	December 31, 2002	March 31, 2003	June 30, 2003
Revenues:					
Manufacturing and royalty revenues	$ 1,771	$ 1,655	$ 3,490	$ 8,566	$ 1,545
Research and development revenue under collaborative arrangements	8,520	7,816	11,705	3,743	2,757
Total Revenues	10,291	9,471	15,195	12,309	4,302
Expenses:					
Cost of goods manufactured	1,248	1,166	2,459	6,036	2,560
Research and development	23,351	27,020	18,707	16,311	21,673
General and administrative	6,016	9,196	5,367	6,115	5,781
Restructuring costs		3,682	2,274	541	
Total Expenses	30,615	41,064	28,807	29,003	30,014
Net Operating Loss	(20,324)	(31,593)	(13,612)	(16,694)	(25,712)
Other Income (Expense):					
Interest income	1,366	1,068	553	789	975
Gain on exchange of notes			80,849		
Other income, net					1,409
Derivative loss related to convertible senior subordinated notes				(4,300)	(3,764)
Interest expense	(2,081)	(2,067)	(2,058)	(4,197)	(3,480)
Total Other Income (Expense)	(715)	(999)	79,344	(7,708)	(4,860)
Equity in losses of Reliant Pharmaceuticals, LLC	(24,213)	(35,257)	(24,482)	(10,645)	
Net (Loss) Income	$(45,252)	$(67,849)	$ 41,250	$(35,047)	$(30,572)
Net (Loss) Income per Common Share:					
Basic	$ (0.70)	$ (1.05)	$ 0.64	$ (0.54)	$ (0.47)
Diluted	$ (0.70)	$ (1.05)	$ 0.62	$ (0.54)	$ (0.47)
Weighted Average Common Shares Used to Compute Net (Loss) Income per Common Share:					
Basic	64,261	64,318	64,409	64,552	64,736
Diluted	64,261	64,318	67,059	64,552	64,736

79

Table of Contents

	Three Months Ended			
	June 30, 2001	September 30, 2001	December 31, 2001	March 31, 2002
Revenues:				
Research and development revenue under collaborative arrangements	$ 15,527	$ 14,505	$ 11,451	$ 12,619
Expenses:				
Research and development	20,710	22,593	23,040	25,749
General and administrative	5,374	6,411	5,903	6,699
Total Expenses	26,084	29,004	28,943	32,448
Net Operating Loss	(10,557)	(14,499)	(17,492)	(19,829)
Other Income (Expense):				
Interest income	4,525	4,217	4,428	2,132
Interest expense	(2,310)	(2,331)	(2,136)	(2,099)
Total Other Income	2,215	1,886	2,292	33
Equity in losses of Reliant Pharmaceuticals, LLC			(2,700)	(2,704)
Net Loss	$ (8,342)	$ (12,613)	$ (17,900)	$ (22,500)
Basic and Diluted Loss per Common Share	$ (0.13)	$ (0.20)	$ (0.28)	$ (0.35)
Weighted Average Number of Common Shares Outstanding	63,237	63,399	63,896	64,148

Liquidity and Capital Resources

Cash and cash equivalents and short-term investments were approximately $104.7 million at June 30, 2003 as compared to $136.1 million at March 31, 2003. The decrease in cash and short-term investments during the three months ended June 30, 2003 was primarily a result of cash used to fund our operations, to acquire fixed assets and to make interest and principal payments on our indebtedness.

We invest in cash equivalents, U.S. Government obligations, high-grade corporate notes and commercial paper, with the exception of our $100 million investment in Reliant. Our investment objectives for our investments, other than our investment in Reliant, are, first, to assure liquidity and conservation of capital and, second, to obtain investment income. Investments classified as long-term at June 30, 2003 consist of U.S. Government obligations held as collateral under certain letters of credit, lease and loan agreements.

All of our investments in debt securities are classified as available-for-sale and are recorded at fair value. Fair value is determined based on quoted market prices.

In November 2002, we and General Electric Capital Corporation (GECC) entered into a Master Lease Agreement to provide us with sale-leaseback equipment financing under which we received $6 million in equipment financing from GECC under the Master Lease Agreement. Under the terms of the agreement, we will make lease payments to GECC over a 36-month period which began in December 2002. The sale-leaseback qualified for accounting as an operating lease which resulted in a loss of $1.3 million which has been deferred and will be recognized as an adjustment to rent expense over the term of the agreement.

On December 31, 2002, we consummated our exchange offer with, and cash offer to, the holders of our 3.75% Subordinated Notes. We issued $174.6 million aggregate principal amount of the 6.52% Senior Notes including $114.6 million of 6.52% Senior Notes issued in exchange for 3.75% Subordinated Notes tendered in the exchange offer and $60.0 million of 6.52% Senior Notes sold for cash to holders of 3.75% Subordinated Notes who participated in the exchange offer.

In December 2002, we and Lilly expanded the collaboration for the development of inhaled formulations of insulin and hGH based on our AIR pulmonary drug delivery technology and Lilly purchased $30 million of our newly issued Convertible Preferred Stock pursuant to a stock purchase agreement. We agreed to use the proceeds from the Convertible Preferred Stock to fund the development of inhaled insulin and hGH during calendar year 2003 and into 2004. We will not record any research and development revenue for these programs while the $30 million in proceeds from the Convertible Preferred Stock are used to fund this development. To the extent that the $30 million is not used for purposes specified in the agreement, Lilly will be entitled to credits for additional research services in the future. In addition, the royalty rate payable to us based on revenues of potential inhaled insulin products has been increased. Lilly has the right to return the Convertible Preferred Stock to us in exchange for a reduction in this royalty rate. The Convertible Preferred Stock is convertible into our common stock at the market price at the time of conversion at our option or automatically upon the filing of a new drug application with the FDA for a pulmonary insulin product. The collaboration cannot terminate without cause until January 2005. We will register for resale all of our shares of common stock issued upon conversion of the Convertible Preferred Stock.

In August 2002, we announced the regulatory approval and expected commercial launch of Risperdal Consta in Germany and the United Kingdom. Under our agreements with Janssen and based on the foregoing, manufacturing revenues relating to our sales of Risperdal Consta to Janssen 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 manufacturing revenues will be determined by a formula and is currently estimated to aggregate approximately $150 million. The minimum revenue obligation will be satisfied upon receipt by us of manufacturing revenues relating to our sales of Risperdal Consta equaling such aggregate amount of minimum manufacturing revenues. In December 2002, Janssen prepaid the first two years of minimum manufacturing revenues to us, totaling $23.9 million and these amounts were recorded as deferred revenue.

At March 31, 2003, we have approximately $364.0 million of net operating loss (NOL) carryforwards for U.S. federal income tax purposes available to offset future taxable income and approximately $21.0 million of research and development tax credits available to offset future federal income tax, subject to limitations for alternative minimum tax. The NOL and research and development credit carryforwards are subject to examination by the tax authorities and expire in various years from fiscal 2004 through 2024. Due to the uncertainty of realizing the future benefits of the net deferred income tax assets, a full valuation allowance has been established at March 31, 2003 and, therefore no benefit has been recognized in the financial statements.

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans and payments under research and development agreements with collaborators. We expect to incur significant additional research and development and other costs in connection with collaborative arrangements and as we expand the development of our proprietary product candidates, including costs related to preclinical studies, clinical trials and facilities expansion. We expect that our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any future products to be marketed by us, will exceed revenues significantly for the next few years, which will result in continuing losses from operations.

Table of Contents

Capital expenditures were approximately $5.5 million for the three months ended June 30, 2003, principally reflecting equipment purchases and building expansion and improvements. We expect our capital expenditures to total approximately $14 million during fiscal year 2004, primarily to complete the expansion of our facilities in both Massachusetts and Ohio and for general purposes. During the three months ended June 30, 2003, the expansion of our Ohio facility was substantially completed and validation is ongoing. Our capital expenditures for equipment, facilities and building improvements have been financed to date primarily with proceeds from bank loans and the sales of debt and equity securities. Under the provisions of the existing loans, Fleet National Bank and GECC have security interests in certain of our assets.

We have summarized below our material contractual cash obligations as of March 31, 2003:

Contractual Cash Obligations (in thousands)	Total	Less Than One Year (Fiscal 2004)	One to Three Years (Fiscal 2005-2007)	Four to Five Years (Fiscal 2008-2009)	After Five Years (After Fiscal 2009)
Convertible Subordinated Notes principal	$175,265	$	$ 676	$	$174,589
Convertible Subordinated Notes interest	77,094	11,409	34,223	22,766	8,696
Long-Term Debt	7,800	7,800			
Operating Leases	218,947	14,751	35,294	20,772	148,130
Capital Expansion Programs	7,000	7,000			
Total Contractual Cash Obligations	$486,106	$40,960	$70,193	$43,538	$331,415

On June 18, 2003, we announced that we had exercised our right to automatically convert all of our outstanding 6.52% Senior Notes into shares of our common stock on July 18, 2003. We had the right to elect to automatically convert the 6.52% Senior Notes because the closing price of our common stock exceeded 150% of the conversion price of the 6.52% Senior Notes ($7.682) for 20 trading days during the 30-day trading period that ended on June 18, 2003.

Prior to June 30, 2003, certain holders of the 6.52% Senior Notes elected to convert $106,000 principal amount of the 6.52% Senior Notes into 13,798 shares of our common stock at the ratio of 130.1744 shares of our common stock per $1,000 principal amount of the 6.52% Senior Notes. Pursuant to the terms of the 6.52% Senior Notes, we also made a cash payment of approximately $14,000 to satisfy the Two-Year Interest Make-Whole payment.

During July 2003, $150.7 million principal amount of 6.52% Senior Notes were exchanged for shares of our common stock. We issued an aggregate of 20.9 million shares of common stock in exchange for such 6.52% Senior Notes, reflecting the value of both principal and interest.

On July 18, 2003, upon conversion of the remaining $23.8 million principal amount of the 6.52% Senior Notes, we issued an aggregate of 3.1 million shares of common stock and paid an aggregate of approximately $2.3 million in cash to satisfy the Two-Year Interest Make-Whole payment. The Company converted each $1,000 principal amount of such 6.52% Senior Notes into 130.1744 shares of common stock and paid the holder thereof an interest payment of $97.80 in cash, representing the remaining 1.5 years of interest due on the 6.52% Senior Notes.

In August 2003, we issued $100 million principal amount of our 2½% Convertible Subordinated Notes due 2023 (the 2½% Subordinated Notes). We have granted the initial purchaser an option to purchase up to an additional $25 million principal amount of notes. The 2½% Subordinated Notes will be convertible into shares of our common stock at a conversion price of $13.85 per share. The 2½% Subordinated Notes will bear interest at 2½% per year, which will be paid on March 1 and September 1 each year beginning on March 1, 2004. The 2½% Subordinated Notes are subordinated to existing and future subordinated indebtedness of Alkermes. We may elect to automatically convert the 2½% Subordinated Notes anytime 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. We may redeem some or all of the notes on or after September 6, 2006. Holders of the 2½% Subordinated Notes will have the right to require us to repurchase some or all of their notes on September 1, 2008, 2013, and 2018 and upon certain events, including a change in control.

We will continue to pursue opportunities to obtain additional financing in the future. Such financing may be sought through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. 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 factors, including continued scientific progress in our research and development programs

(including our proprietary product candidates), the magnitude of these programs, progress with preclinical testing and clinical trials, the time

Table of Contents

and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing facilities and of commercialization activities and arrangements and the cost of product in-licensing and any possible acquisitions and, for any future proprietary products, the sales, marketing and promotion expenses associated with marketing products.

We may need to raise substantial additional funds for longer-term product development, including development of our proprietary product candidates, regulatory approvals and manufacturing and sales and marketing activities that we might undertake in the future. There can be no assurance that additional funds will be available on favorable terms, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our research and development programs and/or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or future products.

Recent Accounting Pronouncements

In July 2000, the Emerging Issues Task Force (EITF) released EITF Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, for comment which addresses revenue recognition for arrangements with multiple deliverables. EITF Issue No. 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. The adoption of EITF Issue No. 00-21 did not have a material impact on our financial position and results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of the Statement and still existing at the beginning of the interim period of adoption. Restatement is not permitted. The adoption of FASB 150 is not expected to have a material impact on our financial position and results of operations.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As part of our investment portfolio we own financial instruments that are sensitive to market risks. The investment portfolio, excluding our December 2001 $100 million investment in Reliant, is used to preserve our capital until it is required to fund operations, including our research and development activities. Our short-term investments and investments consist of U.S. Government obligations, high-grade corporate notes and commercial paper. All of our investments in debt securities are classified as available-for-sale and are recorded at fair value. Our investments, excluding our investment in Reliant, are subject to interest rate risk, and could decline in value if interest rates increase. Due to the conservative nature of our short-term investments and investments policy we do not believe that we have a material exposure to interest rate risk. Although our investments, excluding our investment in Reliant, are subject to credit risk, our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

Our available-for-sale marketable securities are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair value of these financial instruments due to the difference between the market interest rate and the rate at the date of purchase of the financial instrument. A 10%

Table of Contents

decrease in year-end market interest rates would result in no material impact on the net fair value of such interest-sensitive financial instruments.

A 10% increase or decrease in market interest rates on our 6.52% Senior Notes and 3.75% Subordinated Notes would result in no material impact on our notes.

Table of Contents

MANAGEMENT

Directors of the Registrant

Our directors are as follows:

Name	Age	Principal Occupation/Employer
Michael A. Wall	74	Chairman of the Board, Alkermes, Inc.
Floyd E. Bloom, M.D.	66	Chairman, Department of Neuropharmacology, The Scripps Research Institute
Robert A. Breyer	60	Former President and Chief Operating Officer, Alkermes, Inc.
John K. Clarke[1]		