

Edgar Filing: ALKERMES INC - Form 10-K405

ALKERMES INC  
Form 10-K405  
June 29, 2001

1

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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934

For the fiscal year ended March 31, 2001

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-19267

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.)

64 Sidney Street, Cambridge, MA

02139-4234

-----  
(Address of principal executive offices)

-----  
(Zip Code)

Registrant's telephone number, including area code: (617) 494-0171  
-----

Securities registered pursuant to Section 12(b) of the Act: None  
-----

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$.01 per share ("Common Stock")  
3 3/4% Convertible Subordinated Notes Due 2007  
-----

(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports  
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of  
1934 during the preceding 12 months (or for such shorter period that the  
Registrant was required to file such reports), and (2) has been subject to such  
filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item  
405 of Regulation S-K (ss. 229.405 of this chapter) is not contained herein, and  
will not be contained, to the best of Registrant's knowledge, in definitive  
proxy or information statements incorporated by reference in Part III of this

## Edgar Filing: ALKERMES INC - Form 10-K405

Form 10-K or any amendment to this Form 10-K. [X]

Based upon the last sale price of the Registrant's Common Stock on June 6, 2001, the aggregate market value of the 59,967,618 outstanding shares of voting and non-voting common equity held by non-affiliates of the Registrant was \$2,056,889,297.

As of June 6, 2001, 63,303,238 shares of the Registrant's Common Stock were issued and outstanding, and 382,632 shares of the Registrant's Non-Voting Common Stock were issued and outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the following documents are incorporated by reference in this Report on Form 10-K:

- 1) Definitive Proxy Statement to be filed within 120 days after March 31, 2001 for the Registrant's Annual Shareholders' Meeting to be held on July 26, 2001 (Part III).

2

### PART I

#### ITEM 1. 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" or the "Registrant"), a Pennsylvania corporation organized in 1987, is a leader in the development of products based on sophisticated drug delivery technologies. We have several areas of focus, including: (i) controlled, sustained-release of injectable drugs lasting several days to several weeks, utilizing our ProLease(R) and Medisorb(R) technologies and (ii) the development of pharmaceutical products based on our proprietary Advanced Inhalation Research ("AIR(TM)") pulmonary technology. Our first product, Nutropin Depot(TM) was launched in the United States by our partner, Genentech, Inc. ("Genentech"), in June 2000. Nutropin Depot is a long-acting form of Genentech's recombinant human growth hormone using our ProLease technology. Our other technologies and product candidates are in various stages of preclinical and clinical development.

#### OVERVIEW OF DRUG DELIVERY

Drug delivery technologies can improve the way a therapeutic drug is administered to a patient. Products utilizing drug delivery technologies are generally novel, cost-effective dosage forms that provide any of several benefits, including control of drug concentration in the blood, improved safety and efficacy, improved patient compliance and ease of use and expanded indications. Drug delivery technologies can provide pharmaceutical companies with a means of developing new products, as well as expanding existing drug franchises. In addition, companies with patented drug delivery systems can apply their technologies to off-patent or proprietary products to develop drugs for their own account.

## Edgar Filing: ALKERMES INC - Form 10-K405

The drug delivery industry emerged to address the opportunities for improved delivery of traditional pharmaceutical compounds. These compounds are generally stable, small molecules manufactured by conventional synthetic methods, for which oral or transdermal (through the skin) delivery could be enabled or enhanced by drug delivery technologies. Technologies such as passive transdermal systems (patches) and improved tablets and capsules have been developed and successfully applied to a range of pharmaceutical products. In addition, certain traditional small molecule pharmaceuticals are delivered by means of encapsulation in polymeric microspheres.

With the advent of biotechnology, new opportunities in drug delivery have arisen. Advances in biotechnology have facilitated the development of a new generation of biopharmaceutical products based on proteins, peptides and nucleic acids. At the same time, the scientific tools of biotechnology have enabled new approaches to drug delivery based on exploiting particular biological phenomena, for example, utilizing the lung for systemic delivery of proteins and peptides.

Proteins and peptides present drug delivery challenges because they are often large molecules which degrade rapidly in the bloodstream, have limited ability to cross cell membranes and generally cannot be delivered orally. As a result, many biopharmaceuticals must be administered by injection, often multiple times per day or per week. Consequently, the methods of administration of biopharmaceuticals

2

3

can limit their clinical applications to certain disease states that warrant the expense and inconvenience of frequent injection.

Delivery of drugs via the lungs also presents challenges. The effectiveness of pulmonary dosage forms is often limited by the poor efficiency of pulmonary devices and the difficulty of administering high doses of certain drugs. Additionally, drugs that act systemically require deposition in the deep lung, which can lead to the use of complicated and expensive devices.

### BUSINESS STRATEGY

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

Develop and Acquire Broadly Applicable Drug Delivery Systems and Apply Them to Multiple Pharmaceutical Products. We develop or 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 funding for product development independent of capital markets and to share development risk. Currently, we are collaborating with major pharmaceutical and biotechnology companies, including Amylin Pharmaceuticals, Inc. ("Amylin"), Eli Lilly and Company ("Lilly"), Genentech, GlaxoSmithKline, Janssen Pharmaceutica International ("Janssen"), MedImmune, Inc. ("MedImmune") and Serono S.A. ("Serono").

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 United States Food and Drug Administration ("FDA") or other

## Edgar Filing: ALKERMES INC - Form 10-K405

regulatory authorities. In such cases, we and our partners can 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 are also applying our technologies to pharmaceuticals in development that could benefit from one of our delivery systems.

**Establish Independent Product Development Capabilities and Infrastructure.** Based on the knowledge we assembled from our pharmaceutical partners, our experienced scientists have built our in-house product development organization that enables us to develop product candidates for our collaborators and for ourselves. Our product development experience and infrastructure gives us flexibility in structuring development programs and 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 a Medisorb formulation of naltrexone for the treatment of alcoholism and opiate abuse and a long-acting formulation of albuterol for the treatment of asthma using our AIR technology. In addition, we may in-license or acquire certain compounds to develop on our own.

3

4

### DRUG DELIVERY TECHNOLOGY

Our current focus is on the development of broadly applicable drug delivery technologies addressing several important drug delivery opportunities, including injectable sustained-release of proteins, peptides and small molecule pharmaceutical compounds, the pulmonary delivery of both small molecules and proteins and peptides and drug delivery to the brain across the blood-brain barrier. We are applying delivery technologies to develop product candidates for our collaborators and for our own account.

**ProLease:** injectable sustained-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, sustained-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 stabilizing agents and dried to create a fine powder. Second, the powder is

## Edgar Filing: ALKERMES INC - Form 10-K405

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 for up to 30 days in in vitro experiments conducted on formulations manufactured at the preclinical, clinical trial and commercial scale.

Medisorb: injectable sustained-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, sustained-release over

4

5

time. We believe Medisorb is suitable for encapsulating stable, small molecule pharmaceuticals 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

## Edgar Filing: ALKERMES INC - Form 10-K405

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 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 sustained release.

Cereport (R): drug delivery across the blood-brain barrier

Cereport is a nine amino acid peptide based on bradykinin, a compound occurring naturally in the body and known to affect vascular permeability. Cereport is a proprietary, synthetic analog of bradykinin developed by us to increase transiently the permeability of the blood-brain barrier. Following injection, Cereport increases permeability by triggering a brief relaxation of the tight cellular junctions of the blood-brain barrier. During the time the tight junctions are relaxed, permeability is increased and drug molecules in the bloodstream can diffuse into the brain in concentrations greater than can usually be achieved without Cereport. Preclinical and clinical data also suggest that Cereport increases the uptake of pharmaceuticals in the region of brain tumor and other pathology.

Cereport exerts a pharmacologic effect on the vasculature of the brain and does not itself bind to or serve as a carrier for the drug of which it is facilitating delivery. Cereport is intended to be marketed as an independent agent to increase the utility of other therapeutic and diagnostic compounds given with it. In the clinical setting, Cereport is administered in conjunction with the therapeutic or diagnostic agent. Timing of Cereport administration relative to that of the therapeutic or diagnostic agent is determined on a drug-by-drug basis to optimize barrier permeability during the time of peak drug plasma concentrations.

5

6

### PRODUCT CANDIDATES IN DEVELOPMENT

The following table summarizes the primary indications, technology, development stage and collaborative partner for our product candidates. This table is qualified in its entirety by reference to the more detailed descriptions appearing elsewhere in this Form 10-K. 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) -----	COLLABO -----
Nutropin Depot (hGH)	Growth Hormone Deficiency - Pediatric	ProLease	Marketed	Genent

# Edgar Filing: ALKERMES INC - Form 10-K405

RISPERDAL (R)	Schizophrenia	Medisorb	Phase III completed	Jansse
Nutropin Depot (hGH)	Growth Hormone Deficiency - Adults	ProLease	Phase II/III	Genent
Albuterol	Asthma	AIR	Phase II	Alkerm
Cereport and Carboplatin	Metastatic Brain Tumor	Cereport	Phase II completed	Alkerm Partne ("Clin Partne
Cereport and Carboplatin	Recurrent Malignant Glioma	Cereport	Phase II completed	Clinic
Medisorb Naltrexone	Alcoholism and Opiate Abuse	Medisorb	Phase I/II	Alkerm
Cereport and Carboplatin	Pediatric Brain Tumor	Cereport	Phase I/II(4)	Clinic
r-hFSH (recombinant human follicle stimulating hormone)	Infertility	ProLease	Phase I completed	Serono
Exendin-4 (AC2993)	Diabetes	Medisorb	Phase I	Amylin
Insulin	Diabetes	AIR	Clinical phase undisclosed	Lilly
Multiple small molecule products	Respiratory Disease	AIR	Preclinical	GlaxoS
hGH	Growth Hormone Deficiency	AIR	Preclinical	Lilly
Monoclonal antibody	RSV	AIR	Preclinical	MedImm
Others	Various	AIR, Medisorb and ProLease	Preclinical	Undisc

- 
- (1) See "Government Regulation" for definitions of "Phase I," "Phase II" and "Phase III" clinical trials. "Phase I/II" 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/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) ALZA Corporation ("ALZA") has an option to obtain co-development and worldwide marketing rights to Cereport pursuant to an agreement entered into as of September 1997.
  - (3) This program has been funded in part with federal funds from the National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health.
  - (4) This clinical trial is being sponsored and conducted by the Pediatric Branch of the National Cancer Institute.

## PROLEASE

Product Development Strategy. Our strategy is to generate multiple partnered and proprietary product opportunities by applying ProLease technology to the development of superior formulations of proteins and peptides that we believe address significant market opportunities. We believe these formulations have the potential to expand the utilization of these products and improve the competitive advantage to us and our collaborators in major markets.

The product development plan for individual ProLease formulations is expected to proceed in several stages. First, we, either on our own or pursuant to a collaboration, conduct initial feasibility work to test various ProLease formulations for a particular drug in vitro and in vivo. Second, following the successful completion of the feasibility stage, preclinical development and manufacturing scale-up activities directed toward the initiation of clinical trials of the ProLease formulation are conducted in collaboration with a partner or on our own. See "Collaborative Arrangements."

ProLease Recombinant Human Growth Hormone. We have developed a ProLease formulation of Genentech's rhGH, known as Nutropin Depot, in collaboration with Genentech. In December 1999, the FDA approved Nutropin Depot for use in growth hormone deficient children and, in June 2000, Nutropin Depot was commercially launched. This new formulation 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. For instance, rhGH is currently administered frequently, often daily, by subcutaneous injection. Growth hormone deficiency ("GHD") results in short stature and potentially other developmental defects. Genentech is the leading supplier of rhGH in the United States. rhGH is approved for use in the treatment of children with growth hormone deficiency, Turner's syndrome, chronic renal insufficiency and other indications and is being tested in an additional indication in adults.

Genentech is marketing Nutropin Depot in the United States and has announced its commitment to seek a partner for marketing Nutropin Depot outside the United States. We are conducting the manufacturing operations that convert Genentech's Nutropin bulk product into the long-acting dosage form.

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 be able to derive significant revenues from sales of Nutropin Depot. If we cannot continue to manufacture Nutropin Depot on a commercial scale or economically or if we do not derive significant revenues from Nutropin Depot, a material adverse effect on our business and financial position could occur.

We and Genentech have also agreed to continue the clinical development for Nutropin Depot in adults with growth hormone deficiency. This decision follows completion of a Phase I trial of Nutropin Depot in growth hormone deficient adults. We will conduct a Phase II/III clinical trial, funded by Genentech, which we anticipate will commence in calendar year 2001.

r-hFSH (Recombinant Human Follicle Stimulating Hormone). We are developing a ProLease formulation of r-hFSH with Serono. The product development program for this product candidate was announced in January 2000 after the completion of a feasibility study. This product candidate has successfully completed a Phase I trial. Serono has decided to move forward with the development of the product



## Edgar Filing: ALKERMES INC - Form 10-K405

candidate. Serono is responsible for clinical studies for this program and will be responsible for further clinical development, if any.

7

8

Additional ProLease Formulations. We continue to develop ProLease formulations of other undisclosed compounds pursuant to feasibility agreements with several pharmaceutical and biotechnology companies and for our own account.

### MEDISORB

Product Development Strategy. Our strategy is to generate multiple product opportunities by applying our Medisorb technology to the development of superior formulations of small molecule pharmaceutical products. We believe these formulations have the potential to expand the utilization of these products and improve the competitive advantage of our collaborators in major markets.

The product development plan for individual Medisorb formulations is expected to proceed in several stages. First, we, either on our own or pursuant to a collaboration, conduct initial feasibility work to test various Medisorb formulations for a particular drug in vitro and in vivo. Following the successful completion of the feasibility stage, preclinical development and manufacturing scale-up activities directed toward the initiation of clinical trials of the Medisorb formulation are conducted in collaboration with a partner or on our own. See "Collaborative Arrangements."

RISPERDAL. We are developing and manufacturing a Medisorb sustained-release formulation of Janssen's anti-psychotic drug RISPERDAL. Janssen is an affiliate of Johnson & Johnson. In February 2001, Janssen notified us of the positive results of two multi-center Phase III clinical trials of an intra-muscular ("IM") injectable sustained-release formulation of RISPERDAL. With the completion of the Phase III clinical trials, we and Janssen are preparing for the expected submissions to regulatory agencies, including the FDA. We will manufacture the Medisorb formulation of RISPERDAL for any future clinical trials and commercial sales, if any. Janssen will continue to provide funding to us as we continue the development of Medisorb RISPERDAL and as we prepare to be the commercial manufacturer.

Naltrexone. We are developing and manufacturing a Medisorb formulation of naltrexone, an FDA-approved drug used for the treatment of alcoholism and opiate abuse and currently available in daily oral dosage form. In April 2001, we announced the initiation of enrollment in the second, multi-center clinical trial of Medisorb Naltrexone. The trial will test the safety, tolerability and pharmacokinetics of repeated doses of Medisorb Naltrexone administered monthly to alcohol-dependent patients. The clinical trial follows the successful completion of a single-dose safety and pharmacokinetic clinical assessment of the drug in normal volunteers conducted in the second half of calendar year 2000. We will manufacture Medisorb Naltrexone for both clinical trials and commercial sales, if any.

AC2993 (synthetic Exendin-4). In May 2000, we signed a development and license agreement with Amylin for the development of a Medisorb formulation of AC2993, a drug being developed for use in the treatment of type 2 diabetes. Our Medisorb formulation of AC2993 is currently in Phase I clinical trials. We will manufacture the Medisorb formulation of AC2993 for both clinical trials and commercial sales, if any.

Additional Medisorb formulations. We continue to develop Medisorb formulations of other undisclosed compounds pursuant to feasibility agreements

## Edgar Filing: ALKERMES INC - Form 10-K405

with pharmaceutical and biotechnology companies and for our own account.

AIR

Product Development Strategy. Our strategy is to generate multiple product opportunities by applying the AIR technology to the development of superior pulmonary formulations of small molecules

8

9

and proteins and peptides. We believe these formulations have the potential to expand the utilization of these products and improve the competitive advantage of our collaborators in major markets.

The product development plan for individual AIR formulations is expected to proceed in several stages. First, we, either on our own or pursuant to a collaboration, conduct initial feasibility work to test various AIR formulations for a particular drug in vitro and in vivo. Following the successful completion of the feasibility stage, preclinical development and manufacturing scale-up activities directed toward the initiation of clinical trials of the AIR formulation would be conducted in collaboration with a partner or on our own.

Albuterol. We have formulated and are currently conducting a Phase II clinical trial for our proprietary AIR formulation of albuterol sulfate, which is designed to provide both immediate and long-term relief from asthma symptoms. We will manufacture the AIR formulation of albuterol for both clinical trials and commercial sales, if any.

Lilly. In April 2001, we signed a development and license agreement 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. A short-acting formulation is currently in clinical development. We will manufacture the formulations of insulin for clinical trials and Lilly will manufacture such products for commercial sales, if any.

GlaxoSmithKline. In May 2000, we signed a development and license agreement with GlaxoSmithKline to develop certain product candidates for the treatment of four designated fields of respiratory diseases based on our AIR pulmonary drug delivery technology. This agreement followed the completion of a twelve-month feasibility program with GlaxoSmithKline. We are currently in the preclinical stage of development. We and GlaxoSmithKline each have certain rights and obligations with regard to manufacturing any formulations for commercial sales, if any.

Lilly. In February 2000, we signed a development and license agreement with Lilly to develop an inhaled formulation of human growth hormone based on our AIR pulmonary drug delivery technology. The agreement followed the completion of a nine-month feasibility program conducted by the two companies. The formulation is currently in the preclinical stage of development. We will manufacture the formulation of human growth hormone for both clinical trials and commercial sales, if any.

MedImmune. In June 2000, we signed a development and license agreement with MedImmune to develop an AIR formulation of a monoclonal antibody for the treatment of respiratory syncytial virus ("RSV"). The formulation is currently in the preclinical stage of development. We will manufacture the formulation of the monoclonal antibody for both clinical trials and commercial sales, if any.

## Edgar Filing: ALKERMES INC - Form 10-K405

Additional AIR Formulations. We continue to develop AIR formulations of other undisclosed compounds pursuant to feasibility agreements with undisclosed partners and for our own account.

### CEREPORT

Product Development Strategy. Our strategy to date has been to advance Cereport through clinical trials while establishing its safety, permeability effects in humans and efficacy when used in combination with other drugs. To support the clinical development of Cereport, we formed and transferred substantially all of our rights to the Cereport technology to Clinical Partners, which completed a \$46.0 million unit offering in April 1992. We have the option to purchase all of the limited partnership interests in Clinical Partners. As of September 30, 1997, we entered into an agreement with ALZA pursuant to which ALZA has an option to obtain exclusive worldwide commercialization rights to Cereport, subject

9

10

to the rights of Clinical Partners. See "Collaborative Arrangements -- Clinical Partners" and "Collaborative Arrangements -- ALZA."

Clinical Trials. We have completed Phase II clinical trials of Cereport and carboplatin in patients with recurrent malignant glioma and metastatic brain tumors. The Pediatric Branch of the National Cancer Institute ("NCI") has completed one study and is conducting two other studies of Cereport in pediatric patients. The first study began in August 1996 and enrolled 25 patients. The study was a non-controlled, open label Phase I/II clinical trial of intravenous Cereport and carboplatin in pediatric brain tumor patients who have failed other therapies. The study was completed in August 1999. The second study began in June 1998 and is a Phase II multi-center study in pediatric brain tumor patients. Ten centers are enrolling up to a total of 146 children over a two- to four-year period. The third study began in April 2001 and is a Phase I/II multi-center study in pediatric patients with brainstem glioma. Ten centers are enrolling up to a total of 60 children over a two- to four-year period.

### COLLABORATIVE ARRANGEMENTS

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

### GENENTECH

In November 1996, Genentech exercised its option to obtain from us a license for a ProLease formulation of rhGH. In April 1999, Alkermes and Genentech amended and restated the 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 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 and manufacturing for 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

## Edgar Filing: ALKERMES INC - Form 10-K405

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.

In April 2001, we executed a Manufacture and Supply Agreement with Genentech 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' 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.

In connection with the expanded collaboration in April 1999, Genentech purchased 3,500 shares of our 1999 redeemable convertible exchangeable preferred stock for an aggregate purchase price of \$35 million. The proceeds from the sale of our 1999 preferred stock were used to fund our expanded rhGH program for calendar years 1999 and 2000. In February 2000, Genentech exercised its option to convert the 1999 convertible preferred stock together with accrued and unpaid dividends into 322,376 shares of our common stock and 382,632 shares of our non-voting common stock.

10

11

### JANSSEN

Pursuant to a development agreement, we are collaborating with Janssen, an affiliate of Johnson & Johnson, in the development of a sustained-release formulation of RISPERDAL utilizing the Medisorb technology. In October 1996, we announced the expansion of the development agreement. Under the development agreement, we are responsible for production of Medisorb RISPERDAL for clinical trials. Janssen is responsible for conducting clinical trials of Medisorb RISPERDAL and securing all necessary regulatory approvals. Janssen has provided development funding to us for the continued clinical development of Medisorb RISPERDAL. Based upon positive results of two Phase III clinical trials, we are working with Janssen towards filing a New Drug Application ("NDA") with the FDA and other regulatory agencies. We will manufacture any such products for commercial sale and will receive manufacturing revenues and royalties on sales, if any.

Under related license agreements, Janssen and an affiliate have exclusive worldwide licenses from us to manufacture, use and sell Medisorb RISPERDAL. Under the license agreements, Janssen is required to pay us certain royalties with respect to all Medisorb RISPERDAL sold to customers. Janssen can terminate the development agreement or 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 Medisorb RISPERDAL for commercial sales, if any. 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 cured 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 30 days' written notice prior to commencement of commercial manufacturing and 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.

SERONO

Pursuant to a development agreement entered into in January 2000, we are collaborating with Serono for the development of a ProLease formulation of r-hFSH (recombinant human follicle stimulating hormone). Serono is to provide 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

hGH

In February 2000, we entered into a development and license agreement with Lilly 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

11

12

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. Lilly has exclusive worldwide rights to make, use and sell products resulting from such development. Lilly will be responsible for 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.

Insulin

In April 2001, we entered into a development and license agreement with Lilly 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

## Edgar Filing: ALKERMES INC - Form 10-K405

exclusive worldwide rights to make, use and sell products resulting from such development. Lilly will be responsible for obtaining all regulatory approvals and marketing any insulin products. We will manufacture any such products for clinical trials and Lilly will manufacture any such products for commercial sales. 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.

### GLAXOSMITHKLINE

In May 2000, following a twelve-month feasibility study, we entered into a license agreement with GlaxoSmithKline for the use of our AIR technology in the development of multiple product candidates for four respiratory disease categories. Under the agreement, GlaxoSmithKline has exclusive worldwide rights to products resulting from the collaboration in exchange for development funding, milestones and royalties. GlaxoSmithKline is responsible for conducting clinical trials, if any, obtaining regulatory approvals and marketing any resulting products on a worldwide basis. We each have manufacturing rights for commercial sales and we will receive certain manufacturing revenues and royalties on product sales, if any.

GlaxoSmithKline has the right to terminate the agreement at any time with 60-days' written notice. 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.

12

13

### AMYLIN

In May 2000, we entered into a development and license agreement with Amylin for the development of a Medisorb formulation of AC2993 (synthetic Exendin-4) 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 sustained-release formulations of exendins and other related compounds that Amylin may develop. We will 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, if any, and for commercial sales of any products that may be developed pursuant to the agreement. Amylin is responsible for conducting clinical trials, if any, 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 a NDA with the FDA or six months' written notice after such 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 90 days' written notice.

### MEDIMMUNE

## Edgar Filing: ALKERMES INC - Form 10-K405

In June 2000, we entered into a development, license and supply agreement with MedImmune for the development of an AIR formulation of a monoclonal antibody for the treatment of RSV.

Pursuant to the agreement, MedImmune has an exclusive license to any products produced under the agreement. We will receive certain fees, development funding and milestone payments upon achieving certain development and commercialization goals and will also receive manufacturing fees and royalties on product sales, if any. We will be responsible for product formulation, pulmonary delivery device development and manufacturing. MedImmune will be responsible for clinical trials, if any, regulatory approvals and worldwide marketing of any products resulting from the collaboration.

MedImmune may terminate the development agreement for any reason upon 90 days' written notice if such termination occurs prior to the filing of a Biologics License Application ("BLA") or NDA with the FDA or six months' written notice after such event. In addition, either party may terminate the development agreement upon a material default or breach by the other party which is not cured within a certain cure period ranging from 30 to 120 days.

### CLINICAL PARTNERS

In April 1992, units consisting of limited partnership interests in Clinical Partners and warrants to purchase our common stock were sold to investors in a private placement. The proceeds of the \$46.0 million private placement were used to fund the further development and clinical testing of Cereport for human pharmaceutical use in the United States, Canada and Europe. Such funding was not sufficient to complete clinical trials and seek regulatory approval of Cereport. Since the completion of funding from Clinical Partners, which ended during the quarter ended June 30, 1996, we have used, and intend to continue to use, our own resources to develop Cereport, but may seek alternative sources of funding, including additional collaborators.

13

14

Pursuant to a product development agreement, dated March 6, 1992, we transferred substantially all of our rights related to Cereport to Clinical Partners. We have an option to purchase all of the limited partnership interests in Clinical Partners and thereby reacquire the transferred technology. We are required to fund the development of Cereport to maintain our purchase option.

Clinical Partners may terminate the research program for any or all products upon the affirmative vote of 75% of the directors of the general partner of Clinical Partners, Alkermes Development Corporation II ("ADC II"), one of our wholly owned subsidiaries, that such research is not feasible or is not economical. Clinical Partners may terminate the marketing program for any or all products upon the affirmative vote of 75% of the directors of ADC II based on the directors' good faith business judgment. Clinical Partners may also terminate the research or marketing program if we have materially breached the agreement and not cured such breach within 30 days' written notice. Both parties may terminate the research or marketing program upon mutual consent or upon the insolvency or bankruptcy of the other party.

Clinical Partners has granted us an exclusive interim license to manufacture and market Cereport for human pharmaceutical use in the United States and Canada. Upon the first marketing approval of Cereport by the FDA, we are obligated to make a payment to Clinical Partners equal to 20% of the aggregate capital contributions of all limited partners. Additionally, we will

## Edgar Filing: ALKERMES INC - Form 10-K405

pay to Clinical Partners a 12% royalty on revenues from any sales of Cereport in the United States and Canada and, in certain circumstances, a 10% royalty on revenues from any sales of Cereport in Europe. The interim license will terminate if we do not exercise the purchase option. We can exercise our purchase option by making a payment to Clinical Partners equal to 80% of the aggregate capital contributions of all limited partners in addition to paying certain royalty payments.

The general partner of Clinical Partners is ADC II. One of the three current members of the board of directors of ADC II is a person not affiliated with us. The non-affiliated person was nominated by the sales agent for the private placement. The sales agent has the right and will continue to have the right to nominate at least half of the members of ADC II's board of directors until ADC II or some other affiliate of Alkermes ceases to be the general partner of Clinical Partners, Clinical Partners is terminated in accordance with the terms of the limited partnership agreement or the sales agent's venture capital investment partnership ceases to be a limited partner of Clinical Partners.

### ALZA

In October 1997, we, along with ALZA, announced that we had entered into an agreement relating to the development and commercialization of Cereport. Under the terms of the agreement, ALZA has the option to acquire exclusive, worldwide, commercialization rights to Cereport, subject to the rights and obligations of Clinical Partners. If ALZA chooses to exercise its option, ALZA will make additional payments to cover costs associated with advanced clinical development. If Cereport is commercialized successfully by ALZA, they will pay us certain milestone payments. We would be responsible for the manufacturing of Cereport and we would share approximately equally in profits from sales of the product, if any.

### MANUFACTURING

We currently have manufacturing facilities in Cambridge, Massachusetts and Wilmington, Ohio. The manufacture of our product candidates for clinical trials and commercial purposes is subject to current good manufacturing practices ("GMP") and other federal regulations. Prior to our manufacture of Nutropin Depot, we had never operated an FDA-approved commercial manufacturing facility. There can

14

15

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



## Edgar Filing: ALKERMES INC - Form 10-K405

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 a successful pre-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 also have a clinical production facility that we have validated for manufacturing in accordance with current GMP. The facility is being used to manufacture product candidates incorporating our ProLease sustained-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.

We operate a 50,000 square foot GMP manufacturing facility for commercial scale Medisorb manufacturing in Wilmington, Ohio. We manufacture the Medisorb formulation of RISPERDAL for Janssen at this facility. The facility has not been inspected by the FDA or other foreign regulatory agencies. We are currently expanding in Wilmington, Ohio for additional Medisorb manufacturing 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 manufacturing facility which is part of our 46,000 square foot facility which AIR leases in Cambridge, Massachusetts, where powders and final dosage units

15

16

are prepared under current GMP for use in clinical trials. Our current manufacturing facility and equipment have the capacity to produce commercial scale quantities of certain product candidates. In addition, we have plans to build an AIR manufacturing facility in Chelsea, Massachusetts. AIR's inhalation devices are produced under current GMP at a contract manufacturer in the United States.

### CEREPORT

Cereport is a small peptide manufactured using standard synthetic techniques. We rely on an independent European pharmaceutical company for the

## Edgar Filing: ALKERMES INC - Form 10-K405

manufacture and supply of Cereport. Scale-up of the Cereport manufacturing process to support international clinical trials and commercial launch, if any, has been completed. Other companies have been identified which could manufacture and supply our requirements for Cereport.

### 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, GlaxoSmithKline and MedImmune. For our proprietary products, we will determine whether to market the products ourselves or to find a marketing partner.

In October 1997, we entered into an agreement with ALZA pursuant to which ALZA has an option to enter into a worldwide exclusive commercialization agreement for Cereport. If Cereport is successfully commercialized by ALZA, they will pay us certain milestone payments. Under the terms of the agreement, we are responsible for the manufacture of Cereport, and we will share approximately equally in profits from the sale of the product, if any.

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, 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.

### 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 sustained-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.

With respect to Cereport, we believe that there are currently no products approved by the FDA for increasing the permeability of the blood-brain barrier. There are, however, many novel experimental therapies for the treatment of brain tumors and central nervous system infections being tested in the United States and Europe.

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 United States and international patent applications directed to composition of matter as well as processes of preparation and methods of use, including applications relating to permeabilizers, certain rights to which have been licensed to Clinical Partners and to each of our delivery technologies. We own approximately 55 issued United States patents. No United States patent issued to us that is currently material to our business will expire prior to 2009. In the future, we plan to file further United States 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 exclusive rights through licensing agreements with third parties to approximately 26 issued United States patents, a number of United States patent applications and corresponding foreign patents and patent applications in many countries, subject in certain instances to the rights of the United States government to use the technology covered by such patents and patent applications. No issued United States 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, 2001, these fees totaled \$124,000. In addition, under all licensing agreements, we are obligated to pay royalties on future sales of products, if any, covered by the licensed patents.

## Edgar Filing: ALKERMES INC - Form 10-K405

We know of several United States 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 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 United States 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 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 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 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 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 United States 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.

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.

## Edgar Filing: ALKERMES INC - Form 10-K405

Typically, clinical testing involves a three-phase process. Phase I trials are conducted with a small number of

18

19

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 June 6, 2001, we had approximately 415 employees. A significant

## Edgar Filing: ALKERMES INC - Form 10-K405

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 personnel; however, competition for such personnel is intense. None of our employees are covered by a collective bargaining agreement. We consider our relations with employees to be good.

19

20

### MANAGEMENT

The following sets forth certain information with respect to the executive officers of Alkermes:

#### EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, who are elected to serve at the pleasure of the Board of Directors, are as follows:

NAME ----	AGE ---	POSITION -----
Richard F. Pops	39	Chief Executive Officer and Director
Robert A. Breyer	57	President and Director
David A. Broecker	40	Chief Operating Officer
Raymond T. Bartus	54	Senior Vice President, Preclinical Research and Development
J. Duncan Higgons	46	Senior Vice President, Proprietary Product Development
James L. Wright	53	Senior Vice President, Research and Development
James M. Frates	33	Vice President, Chief Financial Officer and Treasurer
Michael J. Landine	47	Vice President, Corporate Development

Mr. Pops has been Chief Executive Officer and a Director since February 1991. Mr. Pops currently serves on the Board of Directors of Neurocrine Biosciences, Inc., the Biotechnology Industry Organization (BIO), the Massachusetts Biotechnology Council (MBC) and The Brain Tumor Society (a non-profit organization).

Mr. Breyer has been President and a Director since July 1994 and served as Chief Operating Officer from July 1994 to February 2001. From August 1991 to December 1993, Mr. Breyer was President and General Manager of Eli Lilly Italy, a subsidiary of Eli Lilly and Company.

Mr. Broecker has been Chief Operating Officer since February 2001. From August 1985 to January 2001, he was employed at Eli Lilly and Company. During his tenure at Eli Lilly, Mr. Broecker managed Eli Lilly's largest pharmaceutical manufacturing facility outside of the United States, located in Kinsale, Ireland, where as General Manager he led manufacturing operations for products accounting for 50% of worldwide Eli Lilly sales. He also worked as a General Manager in Eli Lilly's packaging and distribution operations in Germany, and Director of Marketing for Advanced Cardiovascular Systems, now a part of Guidant. Mr. Broecker holds a B.A. in Chemistry from Wabash College, an M.S. in Chemical Engineering from M.I.T. and an M.B.A. in Marketing and Finance from

## Edgar Filing: ALKERMES INC - Form 10-K405

the University of Chicago.

Dr. Bartus has been Senior Vice President, Preclinical Research and Development since December 1996. From November 1992 to December 1996, Dr. Bartus served as our Senior Vice President, Neurobiology. He holds an M.S. in Experimental Psychology and a Ph.D. in Physiological Psychology from North Carolina State University.

Mr. Higgons has been Senior Vice President, Proprietary Products since February 2001. From December 1994 to February 2001, Mr. Higgons served as Vice President, Business Development of Alkermes.

Dr. Wright became Senior Vice President, Research and Development of Alkermes in June 2001 and has been a Senior Vice President of AIR since September 1999. From December 1994 to September 1999, Dr. Wright was Vice President, Pharmaceutical Development of Alkermes. Dr. Wright received a B.A. in Chemistry and Biology from the University of California, Santa Barbara and a Ph.D. in Pharmacy from the University of Wisconsin.

20

21

Mr. Frates has been Vice President, Chief Financial Officer and Treasurer since July 1998. From June 1996 to July 1998, he was employed at Robertson, Stephens & Company, most recently as a Vice President in Investment Banking. Prior to that time he was employed at Robertson, Stephens & Company and at Morgan Stanley & Co. In June 1996, he obtained his M.B.A. from Harvard University.

Mr. Landine has been Vice President, Corporate Development since March 1999. From March 1988 until June 1998, he was Chief Financial Officer and Treasurer of Alkermes. Mr. Landine is currently an advisor to Walker Magnetics Group, an international manufacturer of industrial equipment.

21

22

### RISK FACTORS

OUR DELIVERY TECHNOLOGIES MAY NOT PRODUCE SAFE, EFFICACIOUS OR COMMERCIALY VIABLE PRODUCTS

Each of our product candidates, except Nutropin Depot needs significant additional research and development and requires FDA approval before it can be marketed. Nutropin Depot has received FDA approval and was commercially launched in June 2000. 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 to be approved and we may not be successful in bringing additional product candidates to the market. A new drug 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 drug 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;

## Edgar Filing: ALKERMES INC - Form 10-K405

- be difficult to manufacture on a large scale;
- be uneconomical;
- 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 technologies fail to generate product candidates that lead to the successful development and commercialization of products, or if our partners decide not to pursue our product candidates, our business and financial condition will be materially adversely affected.

### NUTROPIN DEPOT MAY NOT PRODUCE SIGNIFICANT REVENUES

Our first product, Nutropin Depot, was approved by the FDA in December 1999 and was commercially launched in June 2000. Genentech is responsible for marketing the product, which faces significant competition from the currently approved products that treat growth hormone deficiency. In addition, Genentech has a number of daily injection formulations on the market, which may affect its efforts related to Nutropin Depot. The revenues we receive from the sale of Nutropin Depot may not be significant and depend on numerous factors outside of our control, including Genentech's decisions on pricing and discounting, Genentech's reliance on third-party marketing partners outside the United States, the ability to obtain reimbursement from third-party payors, the market size for the product and the reaction of companies that market competitive products, as well as general market conditions. In addition, our costs to manufacture Nutropin Depot may be higher than we anticipate if certain volume levels are not achieved. If Nutropin Depot does not produce significant revenues or if our manufacturing costs are higher than we anticipate, our business and financial condition could be materially adversely affected.

22

23

### OUR MANUFACTURING EXPERIENCE IS LIMITED

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

In October 1998, we completed construction of a new commercial manufacturing plant for Nutropin Depot and future ProLease product candidates. In 2000, we completed an expansion of our existing Medisorb manufacturing facility. The only manufacturing facility that the FDA has inspected and approved is for the manufacture of Nutropin Depot. We cannot guarantee that the FDA or foreign regulatory agencies will approve any of our other facilities or, once they are approved, that we will remain in compliance with current GMP.

We rely on an unrelated party to manufacture Cereport for use in clinical trials. We expect to rely on the same party to manufacture Cereport for



## Edgar Filing: ALKERMES INC - Form 10-K405

commercial sale, if any. If we are unable to do so, or the manufacturer fails to perform as required, we may be unable to secure an alternative manufacturer on reasonable terms or in a timely manner.

If more of our product candidates progress to late stage development, we will incur significant expenses in the expansion 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 will be able to develop this manufacturing infrastructure in a timely or economical manner, or at all.

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 GMP, 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.

AS NUTROPIN DEPOT IS USED COMMERCIALY, UNINTENDED SIDE EFFECTS, ADVERSE REACTIONS OR INCIDENTS OF MISUSE MAY APPEAR

Until last year, the use of Nutropin Depot had been limited to clinical trial patients under controlled conditions and under the care of physicians. We cannot predict whether the commercial use of Nutropin Depot will produce undesirable or unintended side effects that have not been evident in our clinical trials to date. Additionally, incidents of product misuse may occur. These events, among others, could result in additional regulatory controls.

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

23

24

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. 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 collaborators 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

## Edgar Filing: ALKERMES INC - Form 10-K405

technology and a drug, either as a single formulation or, as in the case of Cereport, as two products administered in conjunction with each other. This makes testing more complex because the outcome of the trials depends on the performance of our technology in combination with a drug.

We have other product candidates in preclinical development. We have not submitted investigational new drug applications or begun clinical trials for these product candidates. Our preclinical and clinical development efforts may not be successfully completed. We may not file further investigational new drug applications. We or our collaborators 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 inability to recruit patients at the expected rate;
- the failure of clinical trials to demonstrate a product candidate's efficacy;
- the inability to follow patients adequately after treatment;
- the inability to predict unforeseen safety issues;
- our inability to manufacture sufficient quantities of materials used for clinical trials; and
- the potential for 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 collaborators 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.

### 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 GMP. 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 can be interpreted by FDA or foreign regulatory officials in different ways than we interpret it;

## Edgar Filing: ALKERMES INC - Form 10-K405

- 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; and
- a product candidate may not be approved for all the indications we requested.

Most of our product candidates are drug delivery systems combined with a drug in a single formulation to treat a specific condition. In most cases, the FDA has already approved the drug used in these product candidates for treating the condition targeted by the product candidate. In some cases, the drug used in our product candidates has not been approved at all or has not been approved for every indication we are targeting. Any delay in the approval process for any of our product candidates will result in increased costs that could materially and 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.

### WE ANTICIPATE WE WILL INCUR CONTINUED LOSSES FOR THE FORESEEABLE FUTURE

We have had net operating losses since being founded in 1987. At March 31, 2001, our accumulated deficit was \$282.5 million. These losses principally consist of the costs of research and development, the costs of acquiring rights to research and development performed by others and general and administrative expenses. The majority of revenues that we have received have come from collaboration and development agreements and interest income. We expect to incur substantial additional expenses over the next several years as our research and development activities, including clinical trials, accelerate and as we continue to manufacture Nutropin Depot or other future products for commercial sale. In addition, we expect these costs to increase over prior years as we expand development of our proprietary product candidates. Because we do not expect to generate significant revenues from the sale of products, if any, for several years, we anticipate that additional expenses will result in losses.

Our future profitability depends, in part, on:

- obtaining regulatory approval for additional product candidates;
- obtaining regulatory approval in foreign countries;
- entering into agreements to develop and commercialize products;

- developing the capacity to manufacture and market products or entering into agreements with others to do so;
- market acceptance of our products;
- the ability to obtain additional research and development funding from collaborative partners; and

- the ability to achieve certain product development milestones.

We may not achieve any or all of these goals and, thus, cannot provide assurances that we will ever achieve significant revenues or profits. Even if we do receive regulatory approval for additional products, we may not achieve significant commercial success.

Our manufacturing facilities in Cambridge, Massachusetts and Wilmington, Ohio require specialized personnel and are expensive to operate and maintain. Any delay in the approval or market launch of future product candidates to be manufactured in these facilities will require us to continue to operate these expensive facilities and retain the specialized personnel, which may increase our expected losses.

#### WE NEED TO SPEND SUBSTANTIAL FUNDS TO BECOME PROFITABLE

We believe that our liquid assets, anticipated funding from our collaborators, and interest income will satisfy our capital and operating requirements for the foreseeable future, but we cannot guarantee that this will be the case. We will need to spend substantial amounts of money before we can be profitable, if ever. The amount we will spend, and when we will spend it, will depend, in part, on:

- how our research and development programs for proprietary and collaborative product candidates, including clinical trials, progress;
- how much time and expense will be required to receive FDA and foreign regulatory approvals for our product candidates;
- the cost of building, operating and maintaining manufacturing facilities;
- how many product candidates we pursue, especially proprietary product candidates;
- how much time and money we need to prosecute and enforce patent rights;
- how competing technological and market developments affect our product candidates;
- the cost of possible acquisitions of drug delivery technologies, compounds or companies;
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise; and
- whether and how we choose to exercise our option to purchase the limited partnership interests in Clinical Partners.

If we require additional funds to complete any of our programs, we may seek funds through arrangements with collaborators, by issuing securities or through debt financing. 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 programs, give up some of our rights to our

## Edgar Filing: ALKERMES INC - Form 10-K405

technologies or product candidates or agree to reduced royalty rates from collaborators.

### WE RELY HEAVILY ON COLLABORATORS

Our arrangements with collaborators and licensors are critical to our success in bringing our product candidates to the market. In some cases, we depend on these parties to conduct preclinical testing and clinical trials and to provide funding for our development programs. Most of our collaborators 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 collaborator's performance may materially adversely affect our business and financial condition.

We cannot control our collaborators' performance or the resources they devote to our programs. If a collaborator fails to perform, the research, development or commercialization program on which it is working will be delayed. If this happens, we may have to use funds, personnel, laboratories and other resources that we have not budgeted, and consequently, we may not be able to continue the program. The failure of a collaborator to perform or a loss of a collaborator may materially adversely affect our business and financial condition.

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

A collaborator 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 collaborators 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 often must obtain the drug from another party. We cannot assure you that we will be able to obtain any such drugs on reasonable terms, if at all.

### WE MAY NOT BE SUCCESSFUL IN THE DEVELOPMENT OF PRODUCTS FOR OUR OWN ACCOUNT

In addition to our development work with collaborators, we are developing proprietary product candidates for our own account and applying our drug delivery technologies to off-patent drugs. Because we are 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 more resources than our programs with collaborators. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those with our programs with collaborators.

WE ARE SUBJECT TO EXTENSIVE GOVERNMENT REGULATIONS AND WE MAY NOT BE ABLE TO

OBTAIN REGULATORY APPROVALS

Our product candidates are subject to extensive and rigorous domestic government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our products are marketed abroad, they will also be subject to extensive regulation by foreign governments. Certain material changes to an approved product, such as manufacturing changes or additional labeling claims, are subject to further FDA review and approval. Any required approvals, once obtained, may be withdrawn. Further, if we fail to comply with FDA and other regulatory requirements at any stage during the regulatory process, we may be subject to sanctions, including:

- delays, warning letters and fines;
- product recalls or seizures and injunctions on sales;
- refusal of the FDA to review pending market approval applications or supplements to approval applications;
- total or partial suspension of production;
- withdrawals of previously approved marketing applications; and
- civil penalties and criminal prosecutions.

We are also subject to federal, state and local government regulation in the conduct of our business, including regulations on employee safety and our handling and disposal of hazardous and radioactive materials. Any new regulation or change to an existing regulation could require us to implement costly capital or operating improvements for which we have not budgeted. We cannot assure you that these regulations will remain the same or that we will maintain compliance with these regulations.

We and our contract manufacturer of Cereport also are required to comply with the FDA current GMP regulations. GMP regulations include requirements relating to quality control, quality assurance and maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA and other foreign regulatory agencies and must be approved before we can use them in commercial manufacturing of our products. We or our contract manufacturer may be unable to comply with current GMP requirements and other FDA or foreign regulatory requirements. If we or our contract manufacturer fail to comply, our business and financial condition will be materially adversely affected.

WE ARE EXPOSED TO PRODUCT LIABILITY CLAIMS

We may be exposed to liability claims arising from the use of our product candidates in clinical trials and the commercial sale of our product, Nutropin Depot. These claims may be brought by consumers, our collaborators or parties selling the products. We currently carry liability insurance for claims arising from the use of our product candidates during clinical trials and the commercial sale of our products in the amount of up to \$10 million per occurrence and \$10 million in the aggregate. 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; and we may be unable to get 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. Even if we are able to continue to carry insurance that we believe is adequate, our financial condition may be materially adversely affected by a product liability claim.

#### COMPETITION IN THE BIOTECHNOLOGY INDUSTRY

We can provide no assurance that we will be able to compete successfully against the competitive forces discussed below in developing, marketing or selling our products.

We face intense competition

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 collaborators. These competitors are working to develop and market other drug delivery systems, 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 sustained-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 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 collaborators 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 and marketing experience, 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 approvals. In addition, they may succeed in obtaining patents that would make it difficult or impossible for us to compete with their products.

Rapid technological change could render our drug delivery systems obsolete or noncompetitive

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.

The competitive nature of our industry could adversely affect market acceptance of our products

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 clinical efficacy and safety;
- their cost-effectiveness;

- their potential advantage over alternative treatment methods;

29

30

- the marketing and distribution support they receive; and
- reimbursement policies of government and third-party payors.

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

#### PATENT PROTECTION FOR OUR PRODUCTS IS IMPORTANT AND UNCERTAIN

The following factors are important to our success:

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

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 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 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 United States 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 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 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

30

31

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 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 and financial condition could be materially adversely affected.

#### WE HAVE ONLY LIMITED RIGHTS TO CEREPORIT

We transferred to Clinical Partners substantially all of our rights to certain technology that includes Cereport and then entered into an agreement with Clinical Partners under which we perform research and development of Cereport. Clinical Partners issued securities and used the proceeds from the sale of those securities to fund our research and development of Cereport. Funding provided by Clinical Partners was insufficient to complete clinical trials and apply for FDA approval. Since June 1996, we have used our or ALZA's funds to develop Cereport. So long as we continue this funding, we have an option to purchase the limited partnership interests in Clinical Partners for cash or our common stock. If this purchase option terminates, we will have no rights to Cereport or the related technology in the United States or Canada.

If we exercise this purchase option, we must make a substantial cash payment or issue a large number of shares of common stock. The exercise of the option may require us to record significant charges to earnings for the purchase of in-process research and development. If we acquire rights to the Cereport technology under the option, we will still be obligated to pay royalties to the limited partners.

#### WE HAVE NO MARKETING OR SALES EXPERIENCE

We currently have no experience in marketing or selling pharmaceutical products. To achieve commercial success for any product that may be approved by the FDA or foreign regulatory authorities, particularly products developed for our own account, we must either develop a marketing and sales force or contract with another party (including collaborators) to perform these services for us. In either case, we will be competing with companies that have experienced and well-funded marketing and sales operations. We may not be successful in developing a marketing and sales force or in contracting with a third party on acceptable terms to sell our products.

#### EFFORTS TO KEEP DOWN THE COST OF HEALTHCARE MAY THREATEN OUR PROFITABILITY

Third-party payors, which include governments and private health insurers, are increasingly challenging the prices charged for medical products and services. In their attempts to reduce healthcare costs, they have also been limiting their coverage and reimbursement levels for new drugs. In some cases, they are refusing to cover the costs of drugs that are not new but are being used for newly approved purposes. Patients who use a product that we may develop might not be reimbursed for its cost. If third-party payors do not provide adequate coverage and reimbursement for our products, if and when they reach the market, doctors may not prescribe them or patients may not use them.

The federal government and various state governments have considered proposals to regulate the prices of prescription drugs, as is done in certain foreign countries. We expect that there will be more

31

32

proposals like these. If any of these proposals are enacted, we may receive a lower price for our products, if and when they reach the market, than we currently estimate. Lack of adequate reimbursement or the enactment of price controls would have a material adverse effect on our business and financial condition.

WE MAY NOT BE ABLE TO RETAIN OUR KEY EXECUTIVES AND RESEARCH AND DEVELOPMENT PERSONNEL

Our success depends on the services of key employees in executive and research and development positions. The loss of the services of one or more of these employees could have a material adverse effect on our business.

WE MAY ENCOUNTER DIFFICULTIES INTEGRATING FUTURE ACQUISITIONS

We may acquire novel technologies or compounds through acquisitions. We cannot assure you that any such future acquisition will be 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, 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.

WE DO NOT ANTICIPATE PAYING DIVIDENDS ON OUR COMMON STOCK

We have not paid cash dividends on our common stock and do not expect to do so in the foreseeable future.

WE MAY ISSUE MORE COMMON STOCK

As discussed above under "We need to spend substantial funds to become profitable," we may issue additional 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 must issue common stock to certain security holders and other parties under the circumstances described below. Any of these parties could sell all or a large number of its shares, which could adversely affect the market price of our common stock. Even if none of these sales happen, the perception by investors that sales might occur could adversely affect the market price of our common

stock.

### 3 3/4% Convertible Subordinated Notes due 2007

In February 2000, we issued and sold \$200 million aggregate principal amount of 3 3/4% convertible subordinated notes due 2007 (the "3 3/4% notes"). The 3 3/4% notes carry certain redemption provisions and each holder may convert its 3 3/4% notes into shares of common stock at any time prior to maturity. We have already registered for resale shares of our common stock issuable on conversion under the Securities Act of 1933. The 3 3/4% notes are convertible into our common stock, at the option of the holder, at a price of \$67.75 per share, subject to adjustment upon certain events.

### Convertible note held by Schering

In October 1998, we issued a promissory note in the principal amount of approximately \$6.0 million to Schering Corporation. We have the option to pay in cash or convert the amount due on this note into our common stock. If we convert the amount due into common stock, we may need to register the common stock under the Securities Act of 1933. This note is due in October 2001.

32

33

### Stock options and awards

At March 31, 2001, we were obligated to issue 9,674,703 shares of common stock upon the exercise of stock options and vesting of stock awards.

### 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:

- announcements of technological innovations or new therapeutic products by us or others;
- public concern as to the safety of drugs developed by us or others;
- general market conditions;
- success of our research and development programs;
- changes in government regulations or patent decisions; and
- developments of our corporate partners.

### ANTI-TAKEOVER PROVISIONS MAY NOT BENEFIT SHAREHOLDERS

We are a Pennsylvania corporation. Anti-takeover provisions of Pennsylvania law could make it more difficult for a person or group 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

## Edgar Filing: ALKERMES INC - Form 10-K405

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.

### ITEM 2. PROPERTIES

We lease and occupy approximately 153,000 square feet of laboratory, manufacturing and office space in Cambridge, Massachusetts under several leases expiring in the years 2002 to 2012. Additionally, we have entered into a new lease in October 2000, for a new facility to be constructed adjacent to our current headquarters for approximately 145,000 square feet of laboratory, clinical manufacturing and office space. The term of this lease is scheduled to commence in May 2002 and terminate in April 2012. Several of the leases contain provisions permitting us to extend the term of such leases for up to two ten-year periods. We have a GMP clinical suite at one of our Massachusetts facilities, which is for the manufacture of product candidates incorporating the ProLease delivery system. We operate a GMP manufacturing facility for our AIR technology at another of our Massachusetts facilities. We also have a 32,000 square foot commercial scale ProLease manufacturing facility in Cambridge, Massachusetts.

33

34

During fiscal 2001, we entered into a new lease for a 91,000 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.

We own and occupy approximately 50,000 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. During 2000, we completed an expansion of our Medisorb commercial manufacturing facility in Wilmington, Ohio, to prepare for commercial scale manufacture of Medisorb RISPERDAL. Additionally, we are currently planning to construct a second facility in Wilmington, Ohio for commercial manufacturing. We also lease and occupy approximately 30,000 square feet of laboratory and office space in Blue Ash, Ohio under a lease expiring in 2003.

Alkermes Europe, Ltd., one of our wholly owned subsidiaries, leases and occupies approximately 4,600 square feet of office space in Cambridge, England under a lease expiring in the year 2002.

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.

ITEM 3. LEGAL PROCEEDINGS      NOT APPLICABLE.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS      NOT APPLICABLE.

34

35

PART II

## Edgar Filing: ALKERMES INC - Form 10-K405

### ITEM 5. MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the Nasdaq National Market under the symbol ALKS. We have 382,632 shares of our non-voting common stock issued and outstanding. There is no established public trading market for our non-voting common stock. Set forth below for the indicated periods are the high and low sale prices for our common stock.

	FISCAL 2001		FISCAL 2000	
	HIGH	LOW	HIGH	LOW
1st Quarter	\$55.00	\$21.56	\$15.06	\$10.81
2nd Quarter	49.38	29.00	19.94	11.38
3rd Quarter	43.50	25.69	28.75	14.19
4th Quarter	33.50	18.75	98.50	23.75

There were 496 shareholders of record for our common stock and one shareholder of record for our non-voting common stock on June 6, 2001. No dividends have been paid on the common stock to date and we do not expect to pay cash dividends thereon in the foreseeable future.

#### 3 3/4% Convertible Subordinated Notes due 2007

In February 2000, we issued and sold \$200 million aggregate principal amount of 3 3/4% Convertible Subordinated Notes due 2007 (the "3 3/4% Notes") to Robertson Stephens, Adams, Harkness & Hill, Inc., ING Barings, J.P. Morgan & Co., PaineWebber Incorporated, SG Cowen and U.S. Bancorp Piper Jaffray (the "3 3/4% Notes Initial Purchasers"). The underwriting commissions and discounts totaled \$6 million. The maturity date of the 3 3/4% Notes is February 15, 2007. We are obligated to pay interest at a rate of 3 3/4% per year on each of February 15 and August 15, which began on August 15, 2000.

The 3 3/4% Notes were issued and sold in transactions exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), to persons reasonably believed by the 3 3/4% Notes Initial Purchasers to be "qualified institutional buyers" ("QIBs") as defined in Rule 144A under the Securities Act or institutional accredited investors or sophisticated investors.

The 3 3/4% Notes are convertible into our common stock, at the option of the holder, at a price of \$67.75 per share, subject to adjustment upon certain events.

The 3 3/4% Notes are redeemable by us in cash at any time prior to February 19, 2003 if our stock price exceeds \$135.50 per share for at least 20 of the 30 trading days immediately prior to our delivery of the redemption notice. The 3 3/4% Notes are redeemable at any time on or after February 19, 2003 at redemption prices of 102.14%, 101.61%, 101.07% and 100.54% for each of the years 2003, 2004, 2005 and 2006, respectively.

In certain circumstances, at the option of the holders, we may be required to repurchase the 3 3/4% Notes. The required repurchase may be in cash or, at our option, in common stock at 105% of the principal amount of the 3 3/4% Notes, plus accrued and unpaid interest.

On February 29, 2000, we filed a registration statement on Form S-3 to register the 3 3/4% Notes and the shares of common stock issuable upon

conversion thereof, which was declared effective on March 6, 2000.

35

36

#### 1999 Preferred Stock

On April 14, 1999, we issued and sold 3,500 shares of 1999 Redeemable Convertible Exchangeable Preferred Stock, par value \$.01 per share (the "1999 Preferred Stock"), to Genentech, Inc. for an aggregate purchase price of \$35,000,000.

The 1999 Preferred Stock was issued and sold in a transaction exempt from the registration requirements of the Securities Act pursuant to Rule 506 of Regulation D promulgated under the Securities Act. We reasonably believed that Genentech, Inc. was and is an accredited investor, based on representations made to us by Genentech and by our review of Genentech's filings with the SEC under the Securities Exchange Act of 1934, as amended.

The 1999 Preferred Stock was convertible at Genentech's option. In February 2000, Genentech exercised its option to convert the 1999 Preferred Stock together with accrued and unpaid dividends into 322,376 shares of common stock and 382,632 shares of non-voting common stock.

On April 13, 2000, we filed a registration statement on Form S-3 to register for resale the 705,008 shares of common stock issued upon conversion of the 1999 Preferred Stock or issuable upon conversion of the non-voting common stock, which was declared effective on April 25, 2000.

#### AIR Transaction

As of February 1, 1999, we issued 7,361,016 shares of our common stock (the "AIR Shares") to the stockholders of Advanced Inhalation Research, Inc. ("AIR") in connection with the merger of one of our wholly owned subsidiaries with and into AIR. Each share of the common stock of AIR was converted into 2.3659508 shares of our common stock on the effective date of the merger. As of March 31, 2001, approximately 265,000 of the AIR Shares remain restricted under various restricted stock purchase agreements and cannot be resold until such shares vest over a four year period at different amounts for each shareholder.

The AIR Shares were issued in a transaction exempt from the registration requirements of the Securities Act pursuant to Rule 506 of Regulation D promulgated under the Securities Act to persons reasonably believed to be accredited investors or investors who, alone or with their purchaser representatives had such knowledge and experience in financial and business matters that he or she was capable of evaluating the merits and risks of the investment. The AIR Shares were issued to 34 purchasers.

On April 2, 1999, we filed a registration statement on Form S-3 to register for resale the AIR Shares, which was declared effective on May 13, 1999.

Also in February 1999 and in connection with the merger, we assumed stock options previously granted to certain persons by AIR. On April 2, 1999, we filed a registration statement on Form S-3 to register 238,908 shares of our common stock issuable upon exercise of such stock options, which was also declared effective on May 13, 1999.

36

37

# Edgar Filing: ALKERMES INC - Form 10-K405

## ITEM 6. SELECTED FINANCIAL DATA

ALKERMES, INC. AND SUBSIDIARIES  
(In thousands, except per share data)

	YEAR ENDED MARCH 31,		
	2001	2000	1999
CONSOLIDATED STATEMENT OF OPERATIONS DATA:			
Total revenues (1)	\$ 78,467	\$ 34,459	\$ 43,716
Research and development expenses	68,774	54,483	48,457
Total expenses (2) (3)	95,336	102,506	84,772
Net loss (2) (3)	\$ (16,869)	\$ (68,047)	\$ (41,056)
Basic and diluted loss per common share	\$ (0.43)	\$ (1.52)	\$ (0.99)
Weighted average number of common shares outstanding	55,746	51,015	49,115

	MARCH 31,		
	2001	2000	1999
CONSOLIDATED BALANCE SHEET DATA:			
Cash and cash equivalents and short-term investments	\$ 254,928	\$ 337,367	\$ 163,419
Total assets	391,297	413,961	213,452
Long-term obligations	211,825	222,792	28,417
Shareholders' equity	148,410	167,967	156,206

- (1) Total revenues include research and development revenue under collaborative arrangements and interest and other income.
- (2) Includes noncash compensation (income) expense of (\$2,488), \$29,493, \$16,239, \$2,183 and \$173, respectively.
- (3) Includes a \$3,221 nonrecurring charge in fiscal 1999 for RingCap(TM) and DST technologies licensed from ALZA Corporation.

37

38

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### INTRODUCTION

Alkermes, Inc. (together with our subsidiaries, "we" or "us") is a leader in the development of products based on sophisticated drug delivery technologies. We have several areas of focus, including: (i) controlled, sustained-release of injectable drugs lasting several days to several weeks, utilizing our ProLease(R) and Medisorb(R) technologies and (ii) the development of pharmaceutical products based on our proprietary Advanced Inhalation Research, Inc. ("AIR(TM)") pulmonary technology. Our first product, Nutropin Depot(TM), was launched in the United States by our partner, Genentech, Inc. ("Genentech"), in June 2000. Nutropin Depot is a long-acting form of Genentech's recombinant human growth hormone using our ProLease technology. Since our inception in 1987, we have devoted substantially all of our resources to research and development programs. We expect to incur substantial additional operating losses over the next few years. At March 31, 2001, we had an accumulated deficit of \$282.5 million.

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 generally develop our product candidates in collaboration with others on whom we rely for funding, development, manufacturing and/or marketing.

### FORWARD-LOOKING STATEMENTS

Any statements herein or otherwise made in writing or orally by us with regard to our expectations as to financial results and other aspects of our business 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 words like "believe," "expect," "may," "will," "should," "seek," 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) we may be unable to continue to manufacture our first product, Nutropin Depot, or to manufacture future products on a commercial scale or economically;



(ii) Nutropin Depot may not produce significant revenues and, in commercial use, may have unintended side effects, adverse reactions or incidents of misuse; (iii) our collaborators could elect to terminate or delay programs at any time; (iv) even if clinical trials are completed and the data is submitted to the United States Food and Drug Administration ("FDA") as a New Drug Application ("NDA") for marketing approval and to other health authorities as a marketing authorization application, the NDA or marketing authorization application could fail to be accepted, or could fail to receive approval on a timely basis, if at all; (v) 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; (vi) our product candidates could be ineffective or unsafe during clinical trials; (vii) disputes with collaborators or failure to negotiate acceptable new collaborative arrangements for our technologies could occur; (viii) 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; (ix) technological change in the biotechnology or pharmaceutical industries could render our product candidates obsolete or noncompetitive; (x) difficulties

38

39

or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xi) we could incur difficulties or set-backs in obtaining the substantial additional funding required to continue research and development programs and clinical trials; and (xii) disputes with Alkermes Clinical Partners, L.P. ("Clinical Partners") over rights to Cereport(R) and related technology could occur.

#### RESULTS OF OPERATIONS

Our research and development revenue under collaborative arrangements was \$56.0 million, \$22.9 million and \$33.9 million for the fiscal years ended in 2001, 2000 and 1999, respectively. The increase in such revenue for fiscal 2001 as compared to fiscal 2000 was mainly the result of non-recurring milestone revenues earned as a result of the launch of Nutropin Depot by our collaborative partner, Genentech, in June 2000. Nutropin Depot is an injectable long-acting formulation of Genentech's recombinant human growth hormone based on our ProLease drug delivery system. In addition, there was an increase in funding earned under other collaborative agreements. The decrease in such revenue for fiscal 2000 as compared to fiscal 1999 was mainly a result of the decreased funding earned under collaborative agreements related to our ProLease and Medisorb technologies. Furthermore, the research and development funding from Genentech decreased in connection with the expanded license agreement and the sale of our convertible exchangeable preferred stock (the "1999 Preferred Stock") to Genentech in April 1999 at a purchase price of \$35 million (see Note 4 to the consolidated financial statements). We used the proceeds from the issuance of the 1999 Preferred Stock to conduct expanded development activities for Nutropin Depot.

Total operating expenses were \$85.9 million for the fiscal year ended in 2001 compared to \$98.9 million and \$82.5 million for the fiscal years ended in 2000 and 1999, respectively. The decrease for fiscal 2001 as compared to fiscal 2000 was primarily related to a decrease in noncash compensation charges partially offset by an increase in research and development expenses and general and administrative expenses, which are discussed below. The increase for fiscal 2000 as compared to fiscal 1999 was primarily related to an increase in noncash

## Edgar Filing: ALKERMES INC - Form 10-K405

compensation charges, as well as an increase in research and development expenses, which are discussed below. In addition, we incurred a \$3.2 million nonrecurring charge during fiscal 1999 for RingCap(TM) and dose sipping technologies licensed from ALZA Corporation which are not yet commercially viable.

Research and development expenses were \$68.8 million for the fiscal year ended in 2001 compared to \$54.5 million and \$48.5 million for the fiscal years ended in 2000 and 1999, respectively. The increases for fiscal 2001 as compared to fiscal 2000 and for fiscal 2000 as compared to fiscal 1999 were primarily the result of an increase in salary and related benefits and other costs associated with an increase in personnel as we advance our own and our collaborators' product candidates through development, clinical trials and commercialization. In addition, we had an increase in depreciation expense as a result of the acquisition of fixed assets. There was also an increase in occupancy costs as we expand our facilities in both Massachusetts and Ohio. The increase in research and development expenses in fiscal 2000 as compared to fiscal 1999 was partially offset by a decrease in clinical trial costs as we completed the Phase III clinical trial for Nutropin Depot during fiscal 1999 and discontinued the Phase III clinical trial of Cereport in April 1999.

General and administrative expenses were \$19.6 million, \$14.9 million and \$14.6 million for the fiscal years ended in 2001, 2000 and 1999, respectively. The increase for fiscal 2001 as compared to fiscal 2000 was a result of increased professional fees, consulting costs and an increase in amortization of expenses associated with the sale of \$200 million principal amount of our 3 3/4% Subordinated Convertible Notes due 2007 (the "3 3/4% Notes"). There was also an increase in occupancy costs as we expand our facilities in both Massachusetts and Ohio. The increase for fiscal 2000 as compared to fiscal 1999 was the result of increased salary, benefits and other costs relating primarily to an increase in personnel. In

39

40

addition, in fiscal 1999 we recorded one-time merger costs of \$1.3 million in connection with the acquisition of our subsidiary, AIR, which was accounted for as a pooling of interests.

Noncash compensation (income) expense was (\$2.4) million, \$29.5 million and \$16.2 million for fiscal years ended 2001, 2000 and 1999, respectively. Noncash compensation charges primarily relate to common stock issued and stock options granted to certain employees, consultants and other individuals associated with our subsidiary, AIR. Fluctuations in noncash compensation charges are primarily a result of changes in the market value of our common stock, partially offset by a reduction in the number of shares of common stock subject to future vesting. As a result of fluctuations in our common stock price during fiscal 2001, we recognized noncash compensation income for the year based on the calculation of noncash compensation for consultants, as prescribed under the fair value method of accounting.

Interest income was \$22.4 million, \$11.5 million and \$9.8 million for the fiscal years ended in 2001, 2000 and 1999, respectively. The increase for fiscal 2001 as compared to fiscal 2000 was primarily the result of the interest income earned on the increase in average cash and investment balances mainly resulting from the investment of the net proceeds from the sale of the 3 3/4% Notes. Interest income also increased as a result of an increase in interest rates as compared to the prior year. The increase for fiscal 2000 as compared to fiscal 1999 was the result of the interest income earned on the net proceeds from the sale of the 1999 Preferred Stock to Genentech, as discussed above.

# Edgar Filing: ALKERMES INC - Form 10-K405

Interest expense was \$9.4 million for the fiscal year ended in 2001 compared to \$3.7 million and \$2.3 million for the fiscal years ended in 2000 and 1999, respectively. The increase for fiscal 2001 as compared to fiscal 2000 was primarily the result of interest costs related to the 3 3/4% Notes. The increase for fiscal 2000 as compared to fiscal 1999 was primarily the result of an increase in interest costs related to an increase in indebtedness.

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

40

41

## QUARTERLY FINANCIAL DATA

(In thousands, except per share data)

	June 30, 2000	September 2000
Revenues:		
Research and development revenue under collaborative arrangements	\$ 28,967	\$ 7,51
Expenses:		
Research and development	14,440	16,49
General and administrative	4,817	4,94
Noncash compensation expense (income)	3,149	(2,29
Total Expenses	22,406	19,15
Net Operating Income (Loss)	6,561	(11,63
Other Income (Expense):		
Interest income	5,599	5,66
Interest expense	(2,395)	(2,30
Total Other Income	3,204	3,35
Net Income (Loss)	9,765	(8,28
Preferred Stock Dividends	1,868	1,86
Net Income (Loss) Attributable to Common Shareholders	\$ 7,897	\$ (10,15
Earnings (Loss) Per Common Share:		
Basic	\$ 0.15	\$ (0.1
Diluted	\$ 0.13	\$ (0.1
Weighted Average Common Shares Used to Compute Earnings (Loss) Per Common Share:		
Basic	53,957	54,65
Diluted	59,856	54,65

	June 30, 1999	September 1999
Revenues:		
Research and development revenue under collaborative arrangements	\$ 5,763	\$ 4,36
Expenses:		
Research and development	12,270	13,56
General and administrative	3,436	3,34
Noncash compensation expense	62	3,63
Total Expenses	15,768	20,55
Net Operating Loss	(10,005)	(16,19
Other Income (Expense):		
Interest income	2,460	2,48
Interest expense	(743)	(72
Total Other Income	1,717	1,76
Net Loss	(8,288)	(14,42
Preferred Stock Dividends	2,099	2,33
Net Loss Attributable to Common Shareholders	\$ (10,387)	\$ (16,76
Basic and Diluted Loss Per Common Share	\$ (0.21)	\$ (0.3
Weighted Average Number of Common Shares Outstanding	50,079	50,41

41

42

## LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents and short-term investments were approximately \$254.9 million at March 31, 2001 as compared to \$337.4 million at March 31, 2000. The decrease in cash and cash equivalents and short-term investments was primarily the result of cash used to fund our operations, to make interest and principal payments on our indebtedness, to acquire fixed assets and to pay preferred stock dividends. In addition, in an effort to obtain higher interest rates during the upcoming year, we have a larger amount of our total investment portfolio invested for a period in excess of one year, therefore, long-term investments total \$73.4 million at March 31, 2001 compared to \$20.1 million at March 31, 2000. Notwithstanding the decrease in total cash and investments there was an increase in interest income earned on the net proceeds from the sale of the 3 3/4% Notes. There was also an increase in total cash and investments due to the receipt of the net proceeds from the exercise of stock options, \$5.0 million received from the sale of our common stock to our collaborative partner, GlaxoSmithKline, in August 2000 and the non-recurring milestone payment received as a result of the launch of Nutropin Depot.

In order to provide more flexibility with our investment portfolio, we have begun to treat a portion of our short-term investments as "available-for-sale" and have provided guidance to two of our three portfolio managers accordingly. All of our short-term investments had previously been accounted for as "held-to-maturity" as those were the instructions we had given to our portfolio managers. During fiscal 2001, short-term investments with an amortized cost of \$119.4 million (which approximated fair market value) were designated as "available-for-sale" securities. We invest in cash equivalents, U.S. Government obligations, high-grade corporate notes and commercial paper. Our investment objectives for all of our investments taken as a whole are, first, to assure conservation of capital and liquidity, and second, to obtain investment income. Investments classified as "held-to-maturity" include \$67.6 million principal amount of high-grade corporate notes and U.S. Government obligations with maturities ranging from 13 months to 6 years.

#### CORPORATE AND COLLABORATIVE DEVELOPMENTS

The following are important corporate and collaborative developments since December 2000. Because of our ongoing and expected research and development activities on these projects, we expect to incur substantial additional research and development expenses over the next few years.

- In January 2001, Genentech and Alkermes announced that they will continue clinical development of Nutropin Depot in adults with growth hormone deficiency. Genentech's decision to proceed to a Phase II/III clinical trial follows the completion of a Phase I trial of Nutropin Depot in growth hormone deficient adults. The clinical trial will be funded by Genentech and conducted by us. It is expected to begin during calendar year 2001.
- In February 2001, we announced that our partner, Janssen Pharmaceutica, had completed two multi-center Phase III clinical trials of an intra-muscular ("IM") injectable sustained-release formulation of the anti-psychotic drug RISPERDAL(R) (risperidone). The formulation is based on our Medisorb injectable sustained-release drug delivery system and is designed to provide patients with prolonged therapeutic benefit from a single administration. With the completion of the Phase III clinical trials, Alkermes and Janssen are preparing for the expected submissions to regulatory health authorities including the FDA. Janssen will continue to provide funding to us as we continue the development of Medisorb RISPERDAL.

- In April 2001, we announced the initiation of enrollment in the second clinical trial of Medisorb Naltrexone, our proprietary injectable sustained-release formulation of naltrexone. The trial will test the safety, tolerability and pharmacokinetics of repeated doses of Medisorb Naltrexone administered monthly to alcohol-dependent patients. The clinical trial follows the successful completion of a single-dose safety and pharmacokinetic clinical assessment of the drug in normal volunteers conducted in the second half of calendar year 2000. Naltrexone is an FDA-approved drug used for the treatment of alcohol dependence and opiate abuse, and is currently available in a daily oral dosage form. Medisorb Naltrexone is a formulation of naltrexone based on our Medisorb injectable sustained-release drug delivery technology and is designed to enhance patient compliance by removing the need for daily dosing and providing therapeutic drug

## Edgar Filing: ALKERMES INC - Form 10-K405

levels consistently over a one-month period. We are funding the development of Medisorb Naltrexone.

- In April 2001, we announced that we signed a broad, mutually exclusive agreement with Eli Lilly and Company 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 system. The companies' decision to enter into this agreement follows the analysis of data generated in ongoing human clinical trials we conducted of inhaled insulin formulations and the completion of a series of tests evaluating the performance of our AIR(TM) inhaler. Under the terms of the agreement, we will receive funding for product and process development activities, milestone payments and royalties based on product sales. In exchange, Lilly will receive exclusive worldwide rights to products resulting from the collaboration. Lilly will be responsible for conducting clinical trials, securing regulatory approvals, large-scale manufacturing and marketing on a worldwide basis.
- In May 2001, Serono S.A. announced their intention to proceed with the clinical development of a novel, long-acting formulation of recombinant human follicle stimulating hormone (r-hFSH) for the treatment of infertility. The new formulation is based on our ProLease injectable sustained-release drug delivery technology and is designed to provide patients with a single injection alternative to multiple daily injections. The decision follows the successful completion and analysis of data from a Phase I trial and triggered an undisclosed milestone payment to us.

At March 31, 2001, we have approximately \$209.0 million of net operating loss ("NOL") carryforwards for United States federal income tax purposes and approximately \$14.3 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 years 2008 through 2027. 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, 2001 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. Therefore, we expect that our costs, including research and development costs for our product candidates,

will exceed revenues significantly for the next few years, which will result in continuing losses from operations.

Capital expenditures were approximately \$10.0 million for the year ended March 31, 2001, principally reflecting equipment purchases and building improvements. We expect our capital expenditures to increase significantly during fiscal year 2002 as we expand our facilities in both Massachusetts and Ohio. Our capital expenditures for equipment, facilities and building

## Edgar Filing: ALKERMES INC - Form 10-K405

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 has a security interest in certain of our assets which secure the outstanding obligations under the loans.

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, lease arrangements relating to fixed assets or other financing methods. 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 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.

We believe that our current cash and cash equivalents and short-term investments, combined with anticipated interest income and research and development revenues under collaborative arrangements, will be sufficient to meet our anticipated capital requirements through at least March 31, 2003.

We may need to raise substantial additional funds for longer-term product development, including development of our proprietary product candidates, regulatory approvals and manufacturing or 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.

### ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS No. 133"). The standard was amended in June 2000 by SFAS No. 138, "Accounting for Certain Derivative Instruments and Certain Hedging Activities—an amendment of FASB Statement No. 133." The standards are collectively referred to as SFAS No. 133. We adopted SFAS No. 133 on April 1, 2001 and the adoption did not have a material impact on our financial position and results of operations.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We own financial instruments that are sensitive to market risks as part of our investment portfolio. The investment portfolio 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. In order to provide more flexibility with our investment portfolio, we have begun to treat a portion of our short-term investments as "available-for-sale" and have provided guidance to two of our three portfolio managers accordingly. All

## Edgar Filing: ALKERMES INC - Form 10-K405

of our short-term investments had previously been accounted for as "held-to-maturity" as those were the instructions we had given to our portfolio managers. During fiscal 2001 short-term investments with an amortized cost of \$119.4 million (which approximated fair market value) were designated as "available-for-sale" securities. The amount of the short-term investment portfolio that is "held-to-maturity" is comprised of investments that mature within one year, are not callable by the issuer and have fixed interest rates. Our investments 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 we do not believe that we have a material exposure to interest rate risk. Although our investments 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% decrease in year-end market interest rates would result in no material impact on the net fair value of such interest-sensitive financial instruments.

The interest rates on our 3 3/4% Notes are fixed and, therefore, are not subject to interest rate risk.

45

46

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

#### ALKERMES, INC. AND SUBSIDIARIES

##### CONSOLIDATED FINANCIAL STATEMENTS AS OF MARCH 31, 2001 AND 2000 AND FOR EACH OF THE THREE YEARS IN THE PERIOD ENDED MARCH 31, 2001 AND INDEPENDENT AUDITORS' REPORT

46

47

#### INDEPENDENT AUDITORS' REPORT

Board of Directors  
Alkermes, Inc.  
Cambridge, Massachusetts

The Board of Directors of Alkermes, Inc.:

We have audited the accompanying consolidated balance sheets of Alkermes, Inc. and subsidiaries as of March 31, 2001 and 2000, and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for each of the three years in the period ended March 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and



## Edgar Filing: ALKERMES INC - Form 10-K405

perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Alkermes, Inc. and subsidiaries as of March 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Boston, Massachusetts  
May 23, 2001

-47-

48

### ALKERMES, INC. AND SUBSIDIARIES

#### CONSOLIDATED BALANCE SHEETS MARCH 31, 2001 AND 2000

ASSETS	2001
CURRENT ASSETS:	
Cash and cash equivalents	\$ 5,923,282
Short-term investments	249,004,850
Prepaid expenses and other current assets	16,678,373
	-----
Total current assets	271,606,505
	-----
PROPERTY, PLANT AND EQUIPMENT:	
Land	235,000
Building	4,888,469
Furniture, fixtures and equipment	43,432,360
Leasehold improvements	14,401,828
Construction in progress	562,331
	-----
	63,519,988
Less accumulated depreciation and amortization	(27,200,590)
	-----
	36,319,398
	-----
INVESTMENTS	73,416,252

Edgar Filing: ALKERMES INC - Form 10-K405

OTHER ASSETS	9,955,060
TOTAL ASSETS	\$ 391,297,215

LIABILITIES AND SHAREHOLDERS' EQUITY	2001
CURRENT LIABILITIES:	
Accounts payable and accrued expenses	\$ 9,414,327
Accrued interest	2,158,087
Deferred revenue	8,523,326
Long-term obligations - current portion	10,966,626
Total current liabilities	31,062,366
LONG-TERM OBLIGATIONS	11,825,000
CONVERTIBLE SUBORDINATED NOTES	200,000,000
OTHER LONG-TERM LIABILITIES	--
COMMITMENTS (Note 10)	
SHAREHOLDERS' EQUITY:	
Capital stock, par value \$.01 per share:	
authorized, 4,550,000 shares; none issued	
Convertible exchangeable preferred stock, par value \$.01 per share: authorized, 0 and 2,300,000 shares at March 31, 2001 and 2000, respectively; outstanding, 0 and 2,299,000 shares at March 31, 2001 and 2000, respectively	--
Common stock, par value \$.01 per share:	
authorized, 160,000,000 shares; issued, 63,124,248 and 53,953,996 shares at March 31, 2001 and 2000, respectively	631,243
Non-voting common stock, par value \$.01 per share:	
authorized, 450,000 shares; issued, 382,632 shares at March 31, 2001 and 2000	3,826
Additional paid-in capital	427,129,226
Deferred compensation	(1,024,303)
Accumulated other comprehensive income	4,179,938
Accumulated deficit	(282,510,081)
Total shareholders' equity	148,409,849
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 391,297,215

# Edgar Filing: ALKERMES INC - Form 10-K405

See notes to consolidated financial statements.

-48-

49

## ALKERMES, INC. AND SUBSIDIARIES

### CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS YEARS ENDED MARCH 31, 2001, 2000 AND 1999

CONSOLIDATED STATEMENTS OF OPERATIONS	2001	2000
REVENUES:		
Research and development revenue under collaborative arrangements	\$ 56,029,865	\$ 22,920,357
EXPENSES:		
Research and development	68,773,691	54,482,672
General and administrative	19,611,284	14,878,753
Noncash compensation (income) expense - attributed to research and development	(2,447,663)	29,492,656
Purchase of in-process research and development	--	--
Total expenses	85,937,312	98,854,081
NET OPERATING LOSS	(29,907,447)	(75,933,724)
OTHER INCOME (EXPENSE):		
Interest and other income	22,436,856	11,538,884
Interest expense	(9,398,724)	(3,652,498)
Total other income	13,038,132	7,886,386
NET LOSS	(16,869,315)	(68,047,338)
PREFERRED STOCK DIVIDENDS	7,267,331	9,388,803
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$ (24,136,646)	\$ (77,436,141)
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.43)	\$ (1.52)
WEIGHTED AVERAGE NUMBER OF		

# Edgar Filing: ALKERMES INC - Form 10-K405

COMMON SHARES OUTSTANDING	55,746,462 =====	51,014,956 =====
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS		
NET LOSS	\$ (16,869,315)	\$ (68,047,338)
Foreign currency translation adjustments	(72,876)	(17,813)
Unrealized (loss) gain on marketable securities	(2,489,250)	6,806,750
Carrying value adjustments	--	--
	-----	-----
COMPREHENSIVE LOSS	\$ (19,431,441) =====	\$ (61,258,401) =====

See notes to consolidated financial statements.

-49-

50

## ALKERMES, INC. AND SUBSIDIARIES

### CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY YEARS ENDED MARCH 31, 2001, 2000 AND 1999

	\$3.25 CONVERTIBLE EXCHANGEABLE PREFERRED STOCK		1999 CONVERTIBLE EXCHANGEABLE PREFERRED STOCK	
	SHARES	AMOUNT	SHARES	AMOUNT
BALANCE, APRIL 1, 1998	2,300,000	\$23,000	--	\$ --
Issuance of common stock	--	--	--	--
Noncash compensation	--	--	--	--
Amortization of noncash compensation	--	--	--	--
Cumulative foreign currency translation adjustments	--	--	--	--
Carrying value adjustments	--	--	--	--
Net loss for year	--	--	--	--
Preferred stock dividends	--	--	--	--
	-----	-----	-----	-----
BALANCE, MARCH 31, 1999	2,300,000	23,000	--	--
Issuance of common stock, net	--	--	--	--
Issuance of common stock in connection with warrants exercised	--	--	--	--

Edgar Filing: ALKERMES INC - Form 10-K405

Issuance of 1999 convertible exchangeable preferred stock	--	--	3,500	3
Conversion of \$3.25 convertible exchangeable preferred stock	(1,000)	(10)	--	--
Conversion of 1999 convertible exchangeable preferred stock	--	--	(3,500)	(3)
Conversion of note payable to corporate partner	--	--	--	--
Options and restricted awards canceled	--	--	--	--
Noncash compensation	--	--	--	--
Amortization of noncash compensation	--	--	--	--
Cumulative foreign currency translation adjustments	--	--	--	--
Unrealized gain on marketable securities	--	--	--	--
Net loss for year	--	--	--	--
Preferred stock dividends	--	--	--	--
	-----	-----	-----	-----
BALANCE, MARCH 31, 2000	2,299,000	22,990	--	--
	-----	-----	-----	-----

	NON-VOTING COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	
	SHARES	AMOUNT		
BALANCE, APRIL 1, 1998	--	\$ --	\$316,352,629	\$
Issuance of common stock	--	--	7,001,953	
Noncash compensation	--	--	23,245,026	
Amortization of noncash compensation	--	--	--	
Cumulative foreign currency translation adjustments	--	--	--	
Carrying value adjustments	--	--	--	
Net loss for year	--	--	--	
Preferred stock dividends	--	--	--	
	-----	-----	-----	

Edgar Filing: ALKERMES INC - Form 10-K405

BALANCE, MARCH 31, 1999	--	--	346,599,608
Issuance of common stock, net	--	--	6,249,901
Issuance of common stock in connection with warrants exercised	--	--	6,217,628
Issuance of 1999 convertible exchangeable preferred stock	--	--	34,999,965
Conversion of \$3.25 convertible exchangeable preferred stock	--	--	(24)
Conversion of 1999 convertible exchangeable preferred stock	382,632	3,826	157,445
Conversion of note payable to corporate partner	--	--	5,247,030
Options and restricted awards canceled	--	--	(754,849)
Noncash compensation	--	--	28,861,232
Amortization of noncash compensation	--	--	--
Cumulative foreign currency translation adjustments	--	--	--
Unrealized gain on marketable securities	--	--	--
Net loss for year	--	--	--
Preferred stock dividends	--	--	--
	-----	-----	-----
BALANCE, MARCH 31, 2000	382,632	3,826	427,577,936
	-----	-----	-----

	OTHER COMPREHENSIVE INCOME (LOSS)	
	-----	
	UNREALIZED GAIN (LOSS) ON MARKETABLE SECURITIES	ACCUMULATED DEFICIT
BALANCE, APRIL 1, 1998	\$ (37,500)	\$ (132,426,624)
Issuance of common stock	--	--
Noncash compensation	--	--
Amortization of noncash compensation	--	--
Cumulative foreign currency translation adjustments	--	--

# Edgar Filing: ALKERMES INC - Form 10-K405

Carrying value adjustments	37,500	--
Net loss for year	--	(41,056,370)
Preferred stock dividends	--	(7,454,300)
	-----	-----
BALANCE, MARCH 31, 1999	--	(180,937,294)
Issuance of common stock, net	--	--
Issuance of common stock in connection with warrants exercised	--	--
Issuance of 1999 convertible exchangeable preferred stock	--	--
Conversion of \$3.25 convertible exchangeable preferred stock	--	--
Conversion of 1999 convertible exchangeable preferred stock	--	--
Conversion of note payable to corporate partner	--	--
Options and restricted awards canceled	--	--
Noncash compensation	--	--
Amortization of noncash compensation	--	--
Cumulative foreign currency translation adjustments	--	--
Unrealized gain on marketable securities	6,806,750	--
Net loss for year	--	(68,047,338)
Preferred stock dividends	--	(9,388,803)
	-----	-----
BALANCE, MARCH 31, 2000	6,806,750	(258,373,435)
	-----	-----

(Continued)

51

## ALKERMES, INC. AND SUBSIDIARIES

### CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY YEARS ENDED MARCH 31, 2001, 2000 AND 1999

-----

	\$3.25 CONVERTIBLE EXCHANGEABLE PREFERRED STOCK		1999 CONVERTIBLE EXCHANGEABLE PREFERRED STOCK	
	SHARES	AMOUNT	SHARES	AMOUNT

Edgar Filing: ALKERMES INC - Form 10-K405

BALANCE, MARCH 31, 2000 (CARRIED FORWARD)	2,299,000	22,990	--	--
Issuance of common stock	--	--	--	--
Issuance of common stock to collaborative partner	--	--	--	--
Conversion and redemption of \$3.25 convertible exchangeable preferred stock	(2,299,000)	(22,990)	--	--
Noncash compensation	--	--	--	--
Amortization of noncash compensation	--	--		--
Cumulative foreign currency translation adjustments	--	--	--	--
Unrealized loss on marketable securities	--	--	--	--
Net loss for year	--	--	--	--
Preferred stock dividends	--	--	--	--
	-----	-----	----	----
BALANCE, MARCH 31, 2001	-- =====	\$ -- =====	-- =====	\$ -- =====

	NON-VOTING COMMON STOCK SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL
BALANCE, MARCH 31, 2000 (CARRIED FORWARD)	382,632	3,826	427,577,936
Issuance of common stock	--	--	4,601,681
Issuance of common stock to collaborative partner	--	--	4,998,378
Conversion and redemption of \$3.25 convertible exchangeable preferred stock	--	--	(79,483)
Noncash compensation	--	--	(9,969,286)
Amortization of noncash compensation	--	--	--
Cumulative foreign currency translation adjustments	--	--	--
Unrealized loss on marketable securities	--	--	--



Edgar Filing: ALKERMES INC - Form 10-K405

Net loss for year	--	--	--
Preferred stock dividends	--	--	--
	-----	-----	-----
BALANCE, MARCH 31, 2001	382,632	\$3,826	\$427,129,226
	=====	=====	=====

	OTHER COMPREHENSIVE INCOME (LOSS)	
	-----	
	UNREALIZED GAIN (LOSS) ON MARKETABLE SECURITIES	ACCUMULATED DEFICIT
BALANCE, MARCH 31, 2000 (CARRIED FORWARD)	6,806,750	(258,373,435)
Issuance of common stock	--	--
Issuance of common stock to collaborative partner	--	--
Conversion and redemption of \$3.25 convertible exchangeable preferred stock	--	--
Noncash compensation	--	--
Amortization of noncash compensation	--	--
Cumulative foreign currency translation adjustments	--	--
Unrealized loss on marketable securities	(2,489,250)	--
Net loss for year	--	(16,869,315)
Preferred stock dividends	--	(7,267,331)
	-----	-----
BALANCE, MARCH 31, 2001	\$ 4,317,500	\$ (282,510,081)
	=====	=====

See notes to consolidated financial statements.

(Concluded)

# Edgar Filing: ALKERMES INC - Form 10-K405

CONSOLIDATED STATEMENTS OF CASH FLOWS  
YEARS ENDED MARCH 31, 2001, 2000 AND 1999

	2001
CASH FLOWS FROM OPERATING ACTIVITIES:	
Net loss	\$ (16,869,315)
Adjustments to reconcile net loss to net cash used by operating activities:	
Depreciation and amortization	7,697,662
Noncash interest expense	509,229
Compensation relating to issuance of common stock and grant of stock options and awards made	(2,447,663)
Adjustments to other assets	270,064
Gain on sale of equipment	--
Changes in assets and liabilities:	
Prepaid expenses and other current assets	(9,135,796)
Accounts payable and accrued expenses	3,343,574
Deferred revenue	(131,736)
Other long-term liabilities	(1,224,258)
Net cash used by operating activities	(17,988,239)
CASH FLOWS FROM INVESTING ACTIVITIES:	
Additions to property, plant and equipment	(10,019,024)
Purchases of available-for-sale short-term investments	(158,203,910)
Sales of available-for-sale short-term investments	103,348,135
Maturities (purchases) of held-to-maturity short-term investments, net	139,909,645
Purchases of held-to-maturity long-term investments, net	(53,321,814)
Increase in other assets	(521,456)
Disposal of equipment	--
Net cash provided by (used by) investing activities	21,191,576
CASH FLOWS FROM FINANCING ACTIVITIES:	
Proceeds from issuance of common stock, net	4,614,194
Proceeds from issuance of common stock to collaborative partner	4,999,978
Proceeds from issuance of 1999 convertible exchangeable preferred stock	--
Proceeds from issuance of convertible subordinated notes	--
Proceeds from issuance of long-term debt	--
Payment of preferred stock dividends	(7,267,331)
Payment of long-term obligations	(5,625,000)
Payment for redemption of \$3.25 convertible exchangeable preferred stock	(24,883)
Payment of financing costs in connection with convertible subordinated notes	--
Net cash (used by) provided by financing activities	(3,303,042)
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(77,656)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(177,361)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	6,100,643
CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 5,923,282
SUPPLEMENTARY INFORMATION:	
Cash paid for interest	\$ 8,396,088
Noncash activities:	
Conversion of \$3.25 convertible exchangeable preferred stock to common stock	\$ 110,459,074

# Edgar Filing: ALKERMES INC - Form 10-K405

Note payable and accrued interest converted to common stock	\$	--
1999 preferred stock dividends exchanged for common stock	\$	--
Deferred revenue and accrued interest converted to long-term obligations	\$	--

See notes to consolidated financial statements.

-52-

53

## ALKERMES, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS YEARS ENDED MARCH 31, 2001, 2000 AND 1999

#### 1. FORMATION OF THE COMPANY

Alkermes, Inc. (the "Company") is a leader in the development of products based on sophisticated drug delivery technologies. The Company has several areas of focus, including: (i) controlled, sustained-release of injectable drugs lasting several days to several weeks, utilizing its ProLease(R) and Medisorb(R) technologies and (ii) the development of pharmaceutical products based on its proprietary Advanced Inhalation Research, Inc. ("AIR(TM)") pulmonary technology. The Company's first product, Nutropin Depot(TM), was launched in the United States by its partner, Genentech, Inc. ("Genentech"), in June 2000. Nutropin Depot is a long-acting form of Genentech's recombinant human growth hormone using the Company's ProLease technology.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**PRINCIPLES OF CONSOLIDATION** - The consolidated financial statements include the accounts of Alkermes, Inc. and its wholly owned subsidiaries, Alkermes Controlled Therapeutics, Inc. ("ACTI"), Alkermes Controlled Therapeutics Inc. II ("ACT II"), Alkermes Investments, Inc., Alkermes Development Corporation II ("ADC II"), Alkermes Europe, Ltd. and AIR. ADC II serves as the one percent general partner of Alkermes Clinical Partners, L.P. ("Clinical Partners"), a limited partnership engaged in a research and development project with the Company (see Note 8). ADC II's investment in Clinical Partners is accounted for under the equity method of accounting, for which the carrying value was zero at March 31, 2001 and 2000 (see Note 8). All significant intercompany balances and transactions have been eliminated.

**USE OF ESTIMATES** - The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States of America necessarily requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**FAIR VALUE OF FINANCIAL INSTRUMENTS** - Statement of Financial Accounting

Standards ("SFAS") No. 107, "Disclosures About Fair Value of Financial Instruments," requires disclosure of the fair value of certain financial instruments. The carrying amounts of cash, cash equivalents, accounts payable and accrued expenses approximate fair value because of their short-term nature. Marketable equity securities have been designated as "available-for-sale" and are recorded as other assets in the consolidated financial statements at fair value with any unrealized holding gains or losses included as a component of shareholders' equity. The carrying amounts of the Company's debt instruments with its bank and corporate partner approximate fair value. The carrying amount of the Company's 3 3/4% Convertible Subordinated Notes due 2007 (the "3 3/4% Notes") was \$200,000,000. The fair value of the 3 3/4% Notes was \$171,159,000 at March 31, 2001. The fair value of the 3 3/4% Notes was determined from a quoted market source.

-53-

54

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

NET LOSS PER SHARE - Basic and diluted net loss per share are computed using the weighted average number of common shares outstanding during the period. The Company accounts for earnings per share in accordance with the provisions of SFAS No. 128, "Earnings per Share." Basic earnings per share exclude any dilutive effect from stock options, warrants, convertible exchangeable preferred stock and convertible subordinated notes. The Company continues to be in a net loss position and, therefore, diluted earnings per share is the same amount as basic earnings per share. Certain securities were not included in the computation of diluted earnings per share for the years ended March 31, 2001, 2000 and 1999 because they would have an antidilutive effect due to net losses for such periods. These securities include (i) options and awards to purchase 9,674,703, 7,706,790 and 6,684,432 shares of common stock in fiscal 2001, 2000 and 1999, respectively; (ii) warrants to purchase zero, 1,800 and 911,844 shares of common stock in fiscal 2001, 2000 and 1999, respectively; (iii) zero, 7,760,504 and 7,763,880 shares of common stock for conversion of the \$3.25 convertible exchangeable preferred stock in fiscal 2001, 2000 and 1999, respectively; and (iv) 2,952,030 shares of common stock for issuance upon conversion of the 3 3/4% Notes in fiscal 2001 and 2000.

REVENUE RECOGNITION - Research and development contract revenues consist of non-refundable research and development funding under collaborative agreements with various corporate partners. Research and development funding generally compensates the Company 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 product 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.

## Edgar Filing: ALKERMES INC - Form 10-K405

RESEARCH AND DEVELOPMENT EXPENSES - Research and development expenses are charged to operations as incurred.

NONCASH COMPENSATION (INCOME) EXPENSE - Noncash compensation (income) expense primarily relates to equity transactions at the Company's subsidiary, AIR. Noncash compensation expense has been recorded in accordance with the intrinsic-value method prescribed by Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," for common stock issued and stock options and awards granted to employees. Stock or other equity-based compensation for nonemployees must be accounted for under the fair value-based method as required by SFAS No. 123, "Accounting for Stock-Based Compensation," and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Under this method, the equity-based instrument is measured at the fair value of the equity instrument on the date of vesting. The measurement date is generally the issuance date for employees and others and the vesting date for consultants. The resulting noncash (income) expense has been recorded in the statements of operations upon issuance or over the vesting period of the common stock, stock option or award.

-54-

55

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

INCOME TAXES - The Company accounts for income taxes under SFAS No. 109, "Accounting for Income Taxes." SFAS No. 109 requires the recognition of deferred tax assets and liabilities relating to the expected future tax consequences of events that have been recognized in the consolidated financial statements and tax returns (see Note 7).

CASH EQUIVALENTS - Cash equivalents, with purchased maturities of three months or less, consist of money market accounts, mutual funds and an overnight repurchase agreement. The repurchase agreement is fully collateralized by U.S. Government securities.

INVESTMENTS - Debt securities that the Company has the positive intent and ability to hold to maturity are reported at amortized cost and are classified as "held-to-maturity." All other debt securities are classified as "available-for-sale" and are recorded at fair value. Fair value was determined based on quoted market prices. In order to provide more flexibility with the Company's investment portfolio, during fiscal 2001, the Company began to treat a portion of its short-term investments, amounting to approximately \$119,400,000 (which approximated fair market value) as "available-for-sale."

All short-term investments and investments consist of U.S. Treasury and other government securities, commercial paper and corporate notes. Short-term investments classified as "held-to-maturity" have maturity dates within one year from March 31, 2001. Investments classified as long-term have maturity dates up to 69 months from March 31, 2001 and include securities totaling \$5,861,000 held as collateral under certain letters of credit, lease and loan agreements.

Short-term investments and investments consist of the following:

# Edgar Filing: ALKERMES INC - Form 10-K405

	AMORTIZED COST			
	DUE	DUE	AMORTIZED	GROSS
	UNDER 1 YEAR	AFTER 1 YEAR	COST	GAINS
March 31, 2001				
Held-to-maturity securities:				
U.S. Government obligations	\$ 14,866,529	\$ 49,177,530	\$ 64,044,059	\$ 420,18
Corporate debt securities	114,875,685	18,377,987	133,253,672	2,308,98
	-----	-----	-----	-----
	129,742,214	67,555,517	197,297,731	2,729,17
	-----	-----	-----	-----
Available-for-sale securities:				
U.S. Government obligations	10,708,654	33,554,543	44,263,197	2,354,97
Corporate debt securities	54,709,256	23,359,160	78,068,416	467,20
	-----	-----	-----	-----
	65,417,910	56,913,703	122,331,613	2,822,18
	-----	-----	-----	-----
Total	\$ 195,160,124	\$ 124,469,220	\$ 319,629,344	\$ 5,551,36
	=====	=====	=====	=====
March 31, 2000				
Held-to-maturity securities:				
U.S. Government obligations	\$ 108,127,995	\$ 7,759,114	\$ 115,887,109	\$ 270,72
Corporate debt securities	223,138,725	12,335,324	235,474,049	1,407,86
	-----	-----	-----	-----
Total	\$ 331,266,720	\$ 20,094,438	\$ 351,361,158	\$ 1,678,59
	=====	=====	=====	=====

-55-

56

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

INVESTMENTS (CONTINUED) - The Company also has investments in marketable equity securities (approximately \$3,574,000 and \$7,669,000 at March 31, 2001 and 2000, respectively) that are currently classified as "available-for-sale" securities under the caption "other assets." Unrealized gains (losses) are included in accumulated other comprehensive income in shareholders' equity. This caption also includes nonmarketable warrants to purchase securities. The warrants are recorded at the lower of cost or market.

PROPERTY, PLANT AND EQUIPMENT - Property, plant and equipment are recorded at cost. Depreciation and amortization are recorded using the straight-line method over the following estimated useful lives of the assets: building - 25 years; furniture, fixtures and equipment - 3 to 7 years; or, in the case of leasehold improvements, over the lease terms - 1 to 15 years.

## Edgar Filing: ALKERMES INC - Form 10-K405

OTHER ASSETS - Other assets consist primarily of unamortized debt offering costs and purchased patents, which are being amortized over seven and five years, respectively, and certain equity securities (see discussion in "Investments" above).

DEFERRED REVENUE - SHORT-TERM - During fiscal 1998, the Company received a \$10,000,000 upfront payment from ALZA Corporation ("ALZA") to fund clinical development of Cereport. This amount has been recorded as deferred revenue and is being amortized based on actual costs incurred for the clinical development of Cereport. In addition, the Company received prepayments for research and development costs under collaborative research projects with other corporate partners that are being amortized over the estimated term of the agreements using the straight-line method. The Company has received cash milestone payments that are creditable against future royalty payments which are being recognized upon product sales of Nutropin Depot.

DEFERRED COMPENSATION - Deferred compensation is related to awards under the Company's 1991 Restricted Common Stock Award Plan, compensatory stock options and common stock and is amortized over vesting periods ranging from one to five years.

401(k) PLAN - The Company's 401(k) Retirement Savings Plan (the "401(k) Plan") covers substantially all of its employees. Eligible employees may contribute up to 20% of their eligible compensation, subject to certain Internal Revenue Service limitations. The Company matches a portion of employee contributions. The match is equal to 50% of the first 6% of deferrals and is fully vested when made. During fiscal 2001, 2000 and 1999, the Company contributed approximately \$632,000, \$505,000 and \$307,000, respectively, to match employee deferrals under the 401(k) Plan.

RECLASSIFICATIONS - Certain reclassifications have been made in fiscal 2000 and 1999 to conform to the presentation used in fiscal 2001.

COMPREHENSIVE INCOME - Comprehensive income is composed of net income and other comprehensive income. Other comprehensive income includes certain changes in equity of the Company that are excluded from the net loss. Specifically, other comprehensive income includes unrealized holding gains and losses on the Company's "available-for-sale" securities and changes in the cumulative foreign currency translation adjustments.

SEGMENTS - The Company's operations are treated as one operating segment reporting to the chief operating decision-makers of the Company. Accordingly, the segment disclosures contemplated by SFAS No. 131, "Disclosures About Segments of an Enterprise and Related Information," are not applicable.

-56-

57

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

NEW ACCOUNTING PRONOUNCEMENTS - In June 1998, the Financial Accounting Standards Board ("FASB") issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The standard was amended in June 2000 by SFAS No. 138, "Accounting for Certain Derivative Instruments and Certain Hedging Activities - an Amendment of SFAS No. 133." The standards are collectively referred to as SFAS No. 133. The Company adopted SFAS No. 133 on April 1, 2001 and the adoption did not have a material impact on its financial position and results of operations.

## Edgar Filing: ALKERMES INC - Form 10-K405

### 3. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following at March 31:

	2001	2000
Accounts payable	\$5,831,589	\$2,896,018
Accrued compensation	1,821,644	1,263,926
Accrued other	1,761,094	3,067,953
	-----	-----
	\$9,414,327	\$7,227,897
	=====	=====

### 4. SHAREHOLDERS' EQUITY

RESTRICTED STOCK PURCHASE AGREEMENTS/Common Stock - During fiscal 1999, the Company issued 7,361,016 shares of its common stock in conjunction with its acquisition of AIR. Of these shares, 4,802,230 shares of common stock were issued to key employees and consultants of AIR and are subject to restricted stock purchase agreements. The Company assumed these restricted stock purchase agreements entered into by AIR. The restricted stock vests quarterly over a four-year period at different amounts for each shareholder. At March 31, 2001 and 2000, approximately 4,537,000 and 3,332,000 shares of restricted stock, respectively, had vested. The agreements state that if the consulting or employment relationship terminates within four years of issuance, the Company shall have the right, but not the obligation, to repurchase the nonvested shares from the shareholder at the share price initially paid by the shareholder. During fiscal 2000, the Company exercised its right to repurchase 83,602 shares of non-vested restricted stock.

\$3.25 Preferred Stock - In March 1998, the Company completed a private placement of 2,300,000 shares of its convertible exchangeable preferred stock (the "\$3.25 Preferred Stock") at \$50.00 per share. Net proceeds to the Company were approximately \$110,500,000. The \$3.25 Preferred Stock was convertible at the option of the holder at any time, unless previously redeemed or exchanged, into the Company's common stock at a conversion rate of 3.3756 shares of common stock for each share of \$3.25 Preferred Stock.

In February 2001, the Company called, without penalty, for redemption of the then outstanding 1,768,200 shares of the \$3.25 Preferred Stock. In March 2001, the holders of 1,767,724 shares of the \$3.25 Preferred Stock converted their shares into 5,967,124 shares of the Company's common stock prior to the redemption of the unconverted shares. The Company redeemed the remaining shares that did not convert at a redemption price of \$52.275 per share plus accrued and unpaid dividends, or approximately \$25,000. Prior to February 2001, holders of 530,800 shares of \$3.25 Preferred Stock converted their shares into 1,791,764 shares of the Company's common stock. During fiscal 2000, holders of the \$3.25 Preferred Stock converted 1,000 shares into 3,374 shares of common stock.



# Edgar Filing: ALKERMES INC - Form 10-K405

## 4. SHAREHOLDERS' EQUITY (CONTINUED)

\$3.25 PREFERRED STOCK (CONTINUED) - Dividends on the \$3.25 Preferred Stock were cumulative from the date of original issue and were paid quarterly, commenced on June 1, 1998, and were paid each September 1, December 1, March 1 and June 1 thereafter, at the annual rate of \$3.25 per share. The final dividend payment was made on March 1, 2001.

1999 PREFERRED STOCK - In April 1999, the Company amended its license agreement with Genentech to expand its collaboration for Nutropin Depot, an injectable long-acting formulation of Genentech's recombinant human growth hormone based on the Company's ProLease drug delivery system. Under the agreement, the companies have been conducting expanded development activities, including clinical trials in an additional indication, process and formulation development and manufacturing. The agreement included milestone payments to reimburse the Company for its past research expenditures incurred from January 1, 1999 through December 31, 2000 plus an additional \$5 million. The milestone payment for past research expenditures was earned in June 2000 when Genentech launched Nutropin Depot for sale in the United States.

The terms of the collaboration included the purchase by Genentech of \$35 million (3,500 shares) of newly issued redeemable convertible exchangeable preferred stock of the Company (the "1999 Preferred Stock"). The 1999 Preferred Stock was convertible at Genentech's option into shares of common stock and non-voting common stock during any period after September 1, 1999 that the closing price of the Company's common stock was above \$22.50 per share for at least 10 consecutive trading days. In February 2000, Genentech exercised its option to convert the 1999 Preferred Stock together with accrued and unpaid dividends into 322,376 shares of voting and 382,632 shares of non-voting common stock.

Dividends on the 1999 Preferred Stock were paid quarterly through March 2000 at a floating three-month LIBOR rate.

## 5. LONG-TERM OBLIGATIONS

Long-term obligations at March 31 consist of the following:

	2001	
Notes payable to a bank, bearing interest at fixed rates (6.97%-8.58%), payable in monthly or quarterly installments, maturing in fiscal 2002 through 2004	\$16,808,334	\$22,
Note payable to a corporate partner, bearing interest (8.50% at March 31, 2001) at 2.5% above the one-year LIBOR, maturing in fiscal 2002	5,983,292	5,
	-----	----
	22,791,626	28,
Less current portion	10,966,626	5,
	-----	----
	\$11,825,000	\$22,
	=====	=====

5. LONG-TERM OBLIGATIONS (CONTINUED)

The bank notes listed above are secured by a building and real property pursuant to a mortgage and certain of the Company's equipment pursuant to security agreements. The loan is also secured by cash collateral (included in long-term investments at March 31, 2001) having a minimum market value of the lesser of \$1,000,000 or the outstanding principal amount of the loan. Under the terms of the loan agreement, the Company is required to maintain a minimum unencumbered balance of cash and permitted investments and a minimum ratio of unencumbered cash and net quick assets to total liabilities as well as a minimum consolidated capital base.

In October 1998, the Company converted a prepayment of royalties from a former corporate partner, plus accrued interest, to a promissory note in the principal amount of \$5,983,292 as a result of the discontinuation of a collaboration. The principal amount of the note, together with interest, is due in October 2001 and is payable in the Company's common stock or cash, at the Company's option.

At March 31, 2001, the maturities of the long-term obligations are as follows:

2002	\$10,966,626
2003	4,025,000
2004	7,800,000
	-----
	\$22,791,626
	=====

6. 3 3/4% CONVERTIBLE SUBORDINATED NOTES

In February 2000, the Company issued \$200 million principal amount of its 3 3/4% Notes which are due in 2007. The 3 3/4% Notes are convertible into the Company's common stock, at the option of the holder, at a price of \$67.75 per share, subject to adjustment upon certain events. The 3 3/4% Notes bear interest at 3 3/4% payable semi-annually, which commenced on August 15, 2000. The 3 3/4% Notes are redeemable by the Company in cash at any time prior to February 19, 2003 if the Company's stock price exceeds \$135.50 per share for at least 20 of the 30 trading days immediately prior to the Company's delivery of the redemption notice. The 3 3/4% Notes are also redeemable at any time on or after February 19, 2003 at certain declining redemption prices. In certain circumstances, at the option of the holders, the Company may be required to repurchase the 3 3/4% Notes. The required repurchase may be in cash or, at the option of the Company, in common stock, at 105% of the principal amount of the 3 3/4% Notes, plus accrued and unpaid interest. As a part of the sale of the 3 3/4% Notes, during fiscal 2000, the Company incurred approximately \$6,530,000 of offering costs which were recorded as other assets and are being amortized over seven years, the term of the 3 3/4% Notes. The net proceeds to the Company after offering costs were approximately \$193,470,000. The Company has reserved 2,952,030 shares of its common stock for issuance upon conversion of the 3 3/4% Notes.

## Edgar Filing: ALKERMES INC - Form 10-K405

### 7. INCOME TAXES

At March 31, 2001, the Company has approximately \$208,954,000 of net operating loss ("NOL") carryforwards for United States federal income tax purposes and approximately \$14,250,000 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 2008 through 2027.

The components of the net deferred income tax assets at March 31 are as follows:

	2001	2000
NOL carryforwards, federal and state	\$ 54,190,000	\$ 46,049,000
Tax benefit from stock options	27,350,000	17,721,000
Tax credit carryforwards	19,130,000	14,670,000
Capitalized research and development expenses, net of amortization	9,010,000	10,310,000
Alkermes Europe NOL carryforward	6,140,000	5,040,000
Other	2,410,000	1,952,000
Less valuation allowance	(118,230,000)	(95,742,000)
	-----	-----
	\$ --	\$ --
	=====	=====

Tax benefits from stock options will be credited to additional paid-in capital when realized.

The valuation allowance has been provided because of the uncertainty of realizing the future benefits of the net deferred income tax assets. The valuation allowance increased by \$33,378,000 from March 31, 1999 to March 31, 2000.

### 8. RELATED-PARTY TRANSACTIONS

On April 10, 1992, the Company and Clinical Partners, a limited partnership of which ADC II is the general partner, sold in a private placement (i) 920 Class A units, each unit consisting of one Class A limited partnership interest in Clinical Partners and warrants to purchase shares of the Company's common stock; and (ii) one Class B unit, consisting of one Class B limited partnership interest in Clinical Partners and warrants to purchase shares of the Company's common stock. At March 31, 2001, all warrants were either exercised or expired.

The net proceeds of the offering were used primarily to fund the further development and clinical testing of a family of molecules designated by the Company as Receptor-Mediated Permeabilizers(TM) ("RMPs(TM)"), including Cereport, for human pharmaceutical use in the United States and Canada. Pursuant to the Product Development Agreement entered into in March 1992, the Company licensed to Clinical Partners certain of its technology relating to RMPs. Research and development of RMPs is being conducted by the Company for Clinical Partners pursuant to the Product Development Agreement. Since the funding was not sufficient to complete clinical trials and seek regulatory approval of Cereport, Alkermes has used its own

resources, and intends to continue to use its own resources, to develop Cereport. Alkermes has obtained and intends to continue to obtain such resources through equity offerings, bank borrowings and collaborative arrangements. The Company is required to fund the development of Cereport to maintain its Purchase Option, as defined below, with the limited partners.

-60-

61

8. RELATED-PARTY TRANSACTIONS (CONTINUED)

Clinical Partners has granted the Company an exclusive interim license to manufacture and market RMPs for human pharmaceutical use in the United States and Canada. Upon the first marketing approval of an RMP product by the United States Food and Drug Administration, the Company is obligated to make a payment (approximately \$8,300,000) to Clinical Partners equal to 20% of the aggregate capital contributions of all partners. Additionally, the Company will make royalty payments to Clinical Partners equal to 12% of United States and Canadian revenues and 10% of European revenues, in certain circumstances, from any sales of RMPs by the Company. The interim license will terminate if the Company does not exercise the Purchase Option.

The warrants were issued by the Company in consideration of the grant by each limited partner to the Company of an option to purchase (the "Purchase Option"), under certain circumstances, the limited partnership interests in Clinical Partners held by such limited partner. Upon exercise of such Purchase Option, each Class A limited partner will be entitled to receive an initial payment, at the Company's option, of \$40,000 in cash or approximately \$42,100 in the Company's common stock, as well as certain additional royalty payments ranging from 4% to 12% of the Company's net revenues (subject to certain limitations).

9. RESEARCH AND DEVELOPMENT ARRANGEMENTS

The Company has entered into several collaborative agreements with corporate partners (the "Partners") to provide research and development activities relating to the Partners' products. In connection with these agreements, the Company has granted certain licenses or the right to obtain certain licenses to technology developed by the Company. In return for such grants, the Company will receive certain payments upon the achievement of certain milestones and will receive royalties on sales of products developed under the terms of the agreements. Additionally, the Company has, or may obtain, the right to manufacture and supply products developed under certain of these agreements.

During fiscal 2001, 2000 and 1999, research and development revenue under collaborative arrangements from Genentech amounted to 51%, 18% and 42% and from Johnson & Johnson amounted to 21%, 41% and 37%, respectively, of research and development revenues.

10. COMMITMENTS

LEASE COMMITMENTS - The Company leases certain of its offices, research laboratories and manufacturing facilities under operating leases with initial terms of one to fifteen years, expiring between 2002 and 2015. Several of the leases contain provisions for extensions for up to ten years. These lease commitments include a commitment for a building for new corporate headquarters, which is expected to be completed during fiscal

## Edgar Filing: ALKERMES INC - Form 10-K405

2003. Total annual future minimum lease payments are as follows:

2002	\$ 5,764,000
2003	12,220,000
2004	12,305,000
2005	11,867,000
2006	10,446,000
Thereafter	38,846,000

Rent expense charged to operations was approximately \$6,213,000, \$5,223,000 and \$4,237,000 for the years ended March 31, 2001, 2000 and 1999, respectively.

-61-

62

### 10. COMMITMENTS (CONTINUED)

**LICENSE AND ROYALTY COMMITMENTS** - The Company has entered into license agreements with certain corporations and universities that require the Company to pay annual license fees and royalties based on a percentage of revenues from sales of certain products and royalties from sublicenses granted by the Company. Amounts paid under these agreements were approximately \$124,000, \$165,000 and \$127,000 for the years ended March 31, 2001, 2000 and 1999, respectively, and are included in research and development expenses.

### 11. STOCK OPTIONS AND AWARDS

The Company's Stock Option Plans (the "Plans") include the Amended and Restated 1989 Non-Qualified Stock Option Plan (the "1989 Plan"), the Amended and Restated 1990 Omnibus Stock Option Plan, as amended (the "1990 Plan"), the 1992 Non-Qualified Stock Option Plan (the "1992 Plan"), the 1998 Equity Incentive Plan (the "1998 Plan") and the 1999 Stock Option Plan (the "1999 Plan"), which provide for the granting of stock options to employees, officers and directors of, and consultants to, the Company. In addition, the Stock Option Plan for Non-Employee Directors (the "Director Plan") provides for the granting of stock options to non-employee directors of the Company. Non-qualified options to purchase up to 450,000 shares of the Company's common stock may be granted under the 1989 Plan, non-qualified and incentive options to purchase up to 6,500,000 shares of the Company's common stock may be granted under the 1990 Plan, non-qualified options to purchase up to 2,000,000 shares of the Company's common stock may be granted under the 1992 Plan, non-qualified and incentive stock options and restricted stock to purchase up to 1,156,262 shares may be granted under the 1998 Plan, non-qualified and incentive options to purchase up to 7,400,000 shares may be granted under the 1999 Plan and non-qualified options to purchase up to 500,000 shares of the Company's common stock may be granted under the Director Plan. The 1989 Plan terminated on July 18, 1999 and the 1990 Plan terminated on September 19, 2000. Unless sooner terminated, the 1992 Plan will terminate on November 11, 2002, the 1998 Plan will terminate on April 1, 2008, the 1999 Plan will terminate on June 2, 2009 and the Director Plan will terminate on March 18, 2006. The Company has reserved a total of 12,916,353 shares of common stock for issuance upon exercise of options that have been or may be granted under the Plans.

The Compensation Committee of the Board of Directors administers the Plans and determines who is to receive options and the exercise price and terms of such options. The Compensation Committee has delegated its authority to

the Compensation Sub-Committee to make grants and awards under the Plans to "officers." The Board of Directors administers the Director Plan. The option exercise price of stock options granted under the 1989 Plan, the 1990 Plan, the 1998 Plan, the 1999 Plan and the Director Plan may not be less than 100% of the fair market value of the common stock on the date of grant. Under the terms of the 1992 Plan, the option exercise price may be below the fair market value, but not below par value, of the underlying stock at the time the option is granted.

The 1989 Plan, the 1990 Plan and the 1992 Plan also provide that the Compensation Committee may grant Limited Stock Appreciation Rights ("LSARs") with respect to all or any portion of the shares covered by stock options granted to directors and executive officers. LSARs may be granted with the grant of a non-qualified stock option or at any time during the term of such option but may only be granted with the grant of an incentive stock option. The grant of LSARs will not be effective until six months after their date of grant. Upon the occurrence of certain triggering events, including a change of control, the options with respect to which LSARs have been granted shall become immediately exercisable and the persons who have received LSARs will automatically receive a cash payment in lieu of shares. At March 31, 2001, there are 117,000 LSARs outstanding which have been granted under the 1990 Plan. No LSARs were granted during fiscal 2001, 2000 or 1999.

-62-

63

#### 11. STOCK OPTIONS AND AWARDS (CONTINUED)

The Company has also adopted the 1991 Restricted Common Stock Award Plan (the "Award Plan"). The Award Plan provides for the award to certain eligible employees, officers and directors of, and consultants to, the Company of up to a maximum of 500,000 shares of common stock. The Award Plan is administered by the Compensation Committee. Awards generally vest over five years. During fiscal 2001, 2000 and 1999, 2,500, 7,000 and zero shares of common stock, respectively, were awarded under the Award Plan and zero, 8,200 and 5,700 shares, respectively, ceased to be subject to forfeiture and were issued. In addition, zero, zero and 4,000 shares were canceled during the years ended March 31, 2001, 2000 and 1999, respectively. At March 31, 2001, 2000 and 1999 there were awards for 62,100, 59,600 and 60,800 shares outstanding under the Award Plan, respectively. The Award Plan will terminate on November 15, 2001, unless sooner terminated by the Board of Directors.

The Company has elected to continue to follow APB No. 25 for accounting for its employee stock options. Under APB No. 25, no compensation expense is recognized with respect to the grant of any stock options to employees if the exercise price of the Company's employee stock options equals the fair market price of the underlying stock on the date the option is granted.

Pro forma information regarding net loss and basic and diluted loss per common share in fiscal 2001, 2000 and 1999 has been determined as if the Company had accounted for its employee stock options under the fair value method prescribed by SFAS No. 123. The resulting effect on pro forma net loss and basic and diluted loss per common share is not necessarily likely to be representative of the effects on net loss and basic and diluted loss per common share on a pro forma basis in future years, due to (i) grants made prior to fiscal 1996 being excluded from the calculation and (ii) the uncertainty regarding the magnitude of future grants. The fair value of options was estimated at the date of grant using the Black-Scholes option

# Edgar Filing: ALKERMES INC - Form 10-K405

pricing model with the following weighted average assumptions: risk-free interest rates ranging from 4.64% - 6.30% in fiscal 2001, 5.81% - 6.50% in fiscal 2000 and 4.79% - 5.68% in fiscal 1999; dividend yields of 0% in fiscal 2001, 2000 and 1999; volatility factors of the expected market price of the Company's common stock of 70% in fiscal year 2001 and 67% in fiscal years 2000 and 1999; and a weighted average expected life of 4 years in fiscal years 2001, 2000 and 1999. Using the Black-Scholes option pricing model, the weighted average fair value of options granted in fiscal 2001, 2000 and 1999 was \$16.99, \$9.38 and \$3.95, respectively. For purposes of pro forma disclosures, the estimated fair value of options is amortized to pro forma expense over the vesting period of the option. Pro forma information for the years ended March 31 is as follows:

	2001	2000
Net loss - as reported	\$ (24,136,646)	\$ (77,436,141)
Net loss - pro forma	(49,346,718)	(87,469,415)
Basic and diluted loss per common share - as reported	(0.43)	(1.52)
Basic and diluted loss per common share - pro forma	(0.89)	(1.71)

-63-

64

## 11. STOCK OPTIONS AND AWARDS (CONTINUED)

A summary of option activity under the 1989, 1990, 1992, 1998, 1999 and Director Plans is as follows:

	NUMBER OF SHARES	EXERCISE PRICE PER SHARE	WEIGHTED AVERAGE EXERCISE PRICE
Balance, April 1, 1998	4,245,896	\$ 0.28 - \$14.38	\$ 4.17
Granted	2,663,934	0.30 - 15.92	7.42
Exercised	(136,816)	0.28 - 11.50	2.13
Canceled	(149,382)	0.30 - 12.63	9.11
	-----	-----	-----
Balance, March 31, 1999	6,623,632	0.28 - 15.92	5.41
Granted	3,214,700	11.61 - 96.88	17.29
Exercised	(1,768,252)	0.28 - 5.50	3.56
Canceled	(422,890)	1.66 - 17.27	8.79
	-----	-----	-----
Balance, March 31, 2000	7,647,190	0.30 - 96.88	10.60
Granted	3,478,450	23.19 - 48.03	30.67
Exercised	(1,250,434)	0.30 - 22.13	3.69

# Edgar Filing: ALKERMES INC - Form 10-K405

Canceled	(262,603)	5.00 - 94.10	18.19
	-----	-----	-----
Balance, March 31, 2001	9,612,603	\$ 0.30 - \$96.88	\$ 18.43
	=====	=====	=====

Options granted generally vest over four years, except options granted under the Director Plan which vest after six months.

The following table summarizes information concerning outstanding and exercisable options at March 31, 2001:

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
	NUMBER OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE	WEIGHTED AVERAGE EXERCISE PRICE
\$ 0.30 - \$ 5.94	1,740,738	6.46	\$ 4.52	958,300	\$ 3.89
5.96 - 12.75	1,588,766	6.67	8.79	1,029,116	8.25
12.82 - 16.69	2,584,124	8.56	16.63	667,977	16.58
16.94 - 23.19	199,500	8.71	20.12	100,500	20.14
23.22 - 29.31	2,590,250	9.63	29.16	2,750	26.25
29.34 - 96.88	909,225	9.53	36.02	110,875	40.98
-----	-----	----	-----	-----	-----
\$ 0.30 - \$96.88	9,612,603	8.25	\$18.43	2,869,518	\$10.43
=====	=====	=====	=====	=====	=====

\* \* \* \* \*

-64-

65

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

NOT APPLICABLE.

## PART III

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

(a) DIRECTORS. The information with respect to directors required by this item is incorporated herein by reference to pages 2, 3 and 21 of our Proxy Statement for our annual shareholders' meeting to be held on July 26, 2001 (the "2001 Proxy Statement").

(b) EXECUTIVE OFFICERS. The information with respect to executive officers required by this item is set forth in Part I of this Report.



## Edgar Filing: ALKERMES INC - Form 10-K405

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to pages 8 through 17 of the 2001 Proxy Statement.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated herein by reference to pages 18 and 19 of the 2001 Proxy Statement.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated herein by reference to page 20 of the 2001 Proxy Statement.

## PART IV

### ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

#### (a) Documents filed as part of the Report:

- (1) Consolidated Financial Statements of the Registrant and Independent Auditors' Report thereon:

Consolidated Balance Sheets, March 31, 2001 and 2000.

Consolidated Statements of Operations and Comprehensive Loss for the Years Ended March 31, 2001, 2000 and 1999.

Consolidated Statements of Shareholders' Equity for the Years Ended March 31, 2001, 2000 and 1999.

Consolidated Statements of Cash Flows for the Years Ended March 31, 2001, 2000 and 1999.

65

66

Notes to Consolidated Financial Statements.

- (2) Financial Statement Schedules:

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or the notes thereto.

- (3) Exhibits

Exhibit No.  
-----

- |     |   |
|-----|---|
| 3.1 | Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on June 7, 2001. |
| 3.2 | Amended and Restated By-Laws of Alkermes, Inc., effective as of February 11, 2001.                                      |

## Edgar Filing: ALKERMES INC - Form 10-K405

- 4.1 Specimen of Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 33-40250).)
- 4.2 Specimen of Non-Voting Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4.4 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999.)
- 4.3 Indenture, dated as of February 18, 2000, between Alkermes, Inc. and State Street Bank and Trust Company, as Trustee. (Incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-3, as amended (File No. 333-31354).)
- 10.1 Amended and Restated 1989 Non-Qualified Stock Option Plan, as amended. (Incorporated by reference to Exhibit 4.2(c) to the Registrant's Registration Statement on Form S-8 (File No. 33-44752).)+
- 10.2 Amended and Restated 1990 Omnibus Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1998.)+
- 10.3 1991 Restricted Common Stock Award Plan. (Incorporated by reference to Exhibit 4.2(a) to the Registrant's Registration Statement on Form S-8 (File No. 33-58330).)
- 10.4 1992 Non-Qualified Stock Option Plan. (Incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-4, as amended (File No. 33-54932).)+
- 10.5 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1996.)+
- 10.6 Alkermes, Inc. 1998 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999.)
- 10.7 1999 Stock Option Plan.+

66

67

- 10.8 Lease, dated as of October 26, 2000, between FC88 Sidney, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-K for the quarter ended December 31, 2000.)
- 10.9 Lease, dated as of October 26, 2000, between Forest City 64 Sidney Street, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2000.)
- 10.10 Lease, dated July 26, 1993, between the Massachusetts Institute of Technology and Alkermes, Inc. (Incorporated by reference to Exhibit 10.8 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1997.)
- 10.10(a) First Amendment of Lease, dated June 9, 1997, between the Massachusetts Institute of Technology and Alkermes, Inc. (Incorporated by reference to Exhibit 10.8(a) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1997.)
- 10.11 Product Development Agreement, dated as of March 6, 1992, between Alkermes Clinical Partners, L.P. and the Registrant. (Incorporated by reference to Exhibit 10.11 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999.)

## Edgar Filing: ALKERMES INC - Form 10-K405

to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1992.

- 10.12 Purchase Agreement, dated as of March 6, 1992, by and among the Registrant and each of the Limited Partners, from time to time, of the Partnership. (Incorporate reference to Exhibit 10.22 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1992.)
- 10.13 Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of February 7, 1992. (Incorporated by reference to Exhibit 10.23 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1992.)
- 10.13(a) Amendment No. 1 to Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of September 29, 1992. (Incorporated by reference to Exhibit 10.22(a) to the Registrant's Registration Statement on Form S-4, as amended (File 33-54932).)
- 10.13(b) Amendment No. 2 to Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of March 30, 1993. (Incorporated by reference to Exhibit 10.22(b) to the Registrant's Registration Statement on Form S-3, as amended (File 33-64964).)
- 10.14 Class A Note of Alkermes Development Corporation II, dated April 10, 1992, to PaineWebber Development Corporation in the amount of \$100.00. (Incorporated by reference to Exhibit 10.24 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1992.)
- 10.15 License Agreement, dated as of April 14, 1999, by and between Genentech, Inc. and Alkermes Controlled Therapeutics, Inc. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999.)\*
- 10.16 Manufacture and Supply Agreement, entered into April 5, 2001, by and between Alkermes, Inc. and Genentech, Inc.\*\*

67

68

- 10.17 Patent License Agreement, dated as of August 11, 1997, between Massachusetts Institute of Technology and Advanced Inhalation Research, Inc., as amended. (Incorporated by reference to Exhibit 10.25 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999.)\*
- 10.18 Letter Agreement, dated September 27, 1996, by and among Fleet National Bank, Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutic Inc. II and the Registrant. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.18(a) Loan Supplement and Modification Agreement, dated as of June 2, 1997, by and among Fleet National Bank, Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutics Inc. II and the Registrant. (Incorporated by reference to Exhibit 10.27(a) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1997.)
- 10.18(b) Second Loan Supplement and Modification Agreement, dated as of March 19, 1998, by and among Fleet National Bank, Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutics Inc. II and the Registrant. (Incorporated by reference to Exhibit 10.29(b) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1998.)

## Edgar Filing: ALKERMES INC - Form 10-K405

- 10.18(c) Third Loan Supplement and Modification Agreement, dated as of September 24, 1998, by and among Fleet National Bank, Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutics Inc. II and the Registrant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1998.)
- 10.19 Security Agreement, dated as of September 27, 1996, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutic Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.20 Pledge Agreement, dated as of September 27, 1996, from the Registrant to Fleet National Bank. (Incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.21 Mortgage and Security Agreement, dated as of September 27, 1996, from Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.6 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.22 Environmental Indemnity Agreement, dated as of September 27, 1996, from the Registrant and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.7 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.23 Promissory Note, dated September 27, 1996, from the Registrant and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.8 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1996.)

68

69

- 10.24 Promissory Note, dated June 2, 1997, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.35 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1997.)
- 10.25 Promissory Note, dated March 19, 1998, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.38 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1998.)
- 10.26 Promissory Note, dated September 24, 1998, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank (\$11,000,000). (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1998.)
- 10.27 Promissory Note, dated September 24, 1998, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank (\$9,000,000). (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1998.)
- 10.28 Employment Agreement, entered into as of February 7, 1991, between Richard F. Pops and the Registrant. (Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 33-40250).)

## Edgar Filing: ALKERMES INC - Form 10-K405

- 10.29      Employment Agreement, entered into as of June 13, 1994, by and between Robert A. Breyer and the Registrant. (Incorporated by reference to Exhibit 10.28 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1994.)+
- 10.30      Change in Control Employment Agreement, dated as of December 19, 2000, between Alkermes, Inc. and Richard F. Pops. (Incorporated by reference to Exhibit 10.1 to Registrant's Report on Form 10-Q for the quarter ended December 31, 2000.)+
- 10.31      Change in Control Employment Agreement, dated as of December 19, 2000, between Alkermes, Inc. and each of Robert A. Breyer, Raymond T. Bartus, J. Duncan Higgons, James L. Wright, James M. Frates and Michael J. Landine. (Form of agreement incorporated by reference to Exhibit 10.2 to the Registrant's report on Form 10-Q for the quarter ended December 31, 2000.)+
- 10.32      Employment Agreement, dated December 22, 2000 by and between David A. Broecker and the Registrant.+
- 10.33      Change in Control Employment Agreement, dated as of June 27, 2001, between Alkermes, Inc. and David A. Broecker. (Form of agreement incorporated by reference to Exhibit 10.2 to the Registrant's report on Form 10-Q for the quarter ended December 31, 2000.)+
- 21          Subsidiaries of the Registrant.
- 23          Consent of Deloitte & Touche LLP.

69

70

- \*      Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted August 19, 1999. Such provisions have been filed separately with the Commission.
- \*\*      Confidential status has been requested for certain portions thereof pursuant to a Confidential Treatment Request filed June 29, 2001. Such provisions have been filed separately with the Commission.
- +      Constitutes a management contract or compensatory plan required to be filed as an Exhibit to this Report pursuant to Item 14(c) of Form 10-K.
- (b)      Since the beginning of the quarter ended March 31, 2001, the Registrant filed no reports on Form 8-K. After March 31, 2001, the Registrant filed no reports on Form 8-K.

70

71

### UNDERTAKING

For the purposes of complying with the amendments to the rules governing Form S-8 (effective July 13, 1990) under the Securities Act of 1933, the undersigned Registrant hereby undertakes as follows, which undertaking shall be incorporated by reference into Registrant's Registration Statements on Form S-8, Nos. 33-44752, 33-58330, 33-97468, 333-13283, 333-50357, 333-71011, 333-89573, 333-89575, 333-48768 and 333-48772 and on Form S-3, Nos. 333-31354, 333-34702, 333-75645, 333-75649 and 333-50157.

## Edgar Filing: ALKERMES INC - Form 10-K405

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

71

72

### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALKERMES, INC.

June 29, 2001

By: /s/ Richard F. Pops

-----  
Richard F. Pops  
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature

Title

-----

-----

/s/ Michael A. Wall

Director and Chairman of the  
Board

-----  
Michael A. Wall

/s/ Richard F. Pops

Director and Chief Executive Officer  
(Principal Executive Officer)

-----  
Richard F. Pops

/s/ James M. Frates

Vice President, Chief  
Financial Officer and  
Treasurer (Principal  
Financial and Accounting  
Officer)

-----  
James M. Frates

/s/ Floyd E. Bloom

Director

-----  
Floyd E. Bloom

# Edgar Filing: ALKERMES INC - Form 10-K405

/s/ Robert A. Breyer	President and Director
-----	
Robert A. Breyer	
/s/ John K. Clarke	Director
-----	
John K. Clarke	
/s/ Alexander Rich	Director
-----	
Alexander Rich	
/s/ Paul Schimmel	Director
-----	
Paul Schimmel	

72

73

## EXHIBIT INDEX

- |      |   |
|------|---|
| 3.1  | Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on June 7, 2001.   |
| 3.2  | Amended and Restated By-Laws of Alkermes, Inc., effective as of February 11, 2001.  |
| 4.1  | Specimen of Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 33-40250).)   |
| 4.2  | Specimen of Non-Voting Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4.4 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999.)  |
| 4.3  | Indenture, dated as of February 18, 2000, between Alkermes, Inc. and State Street Bank and Trust Company, as Trustee. (Incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-3, as amended (File No. 333-31354).) |
| 10.1 | Amended and Restated 1989 Non-Qualified Stock Option Plan, as amended. (Incorporated by reference to Exhibit 4.2(c) to the Registrant's Registration Statement on Form S-8 (File No. 33-44752).)+   |
| 10.2 | Amended and Restated 1990 Omnibus Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1998.)+   |
| 10.3 | 1991 Restricted Common Stock Award Plan. (Incorporated by reference to Exhibit 4.2(a) to the Registrant's Registration Statement on Form S-8 (File No. 33-58330).)  |
| 10.4 | 1992 Non-Qualified Stock Option Plan. (Incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-4, as amended (File No. 33-54932).)+   |
| 10.5 | Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 10-K for the fiscal year ended March 31,  |

## Edgar Filing: ALKERMES INC - Form 10-K405

1996.)+

- 10.6 Alkermes, Inc. 1998 Equity Incentive Plan. (Incorporated by reference to Exhibit 1 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999.)
- 10.7 1999 Stock Option Plan.+
- 10.8 Lease, dated as of October 26, 2000, between FC88 Sidney, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2000.)
- 10.9 Lease, dated as of October 26, 2000, between Forest City 64 Sidney Street, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2000.)

74

- 10.10 Lease, dated July 26, 1993, between the Massachusetts Institute of Technology and Alkermes, Inc. (Incorporated by reference to Exhibit 10.8 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1997.)
- 10.10(a) First Amendment of Lease, dated June 9, 1997, between the Massachusetts Institute of Technology and Alkermes, Inc. (Incorporated by reference to Exhibit 10.8(a) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1997.)
- 10.11 Product Development Agreement, dated as of March 6, 1992, between Alkermes Clinical Partners, L.P. and the Registrant. (Incorporated by reference to Exhibit 10.21 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1992.)
- 10.12 Purchase Agreement, dated as of March 6, 1992, by and among the Registrant and each of the Limited Partners, from time to time, of the Partnership. (Incorporated by reference to Exhibit 10.22 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1992.)
- 10.13 Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of February 7, 1992. (Incorporated by reference to Exhibit 10.23 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1992.)
- 10.13(a) Amendment No. 1 to Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of September 29, 1992. (Incorporated by reference to Exhibit 10.22(a) to the Registrant's Registration Statement on Form S-4, as amended (File No. 33-54932).)
- 10.13(b) Amendment No. 2 to Alkermes Clinical Partners, L.P. Agreement of Limited Partnership, dated as of March 30, 1993. (Incorporated by reference to Exhibit 10.22(b) to the Registrant's Registration Statement on Form S-3, as amended (File No. 33-64964).)
- 10.14 Class A Note of Alkermes Development Corporation II, dated April 10, 1992, to PaineWebber Development Corporation in the amount of \$100.00. (Incorporated by reference to Exhibit 10.24 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1992.)
- 10.15 License Agreement, dated as of April 14, 1999, by and between Genentech, Inc. and Alkermes Controlled Therapeutics, Inc. (Incorporated by reference to Exhibit 10.15 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999.)\*



## Edgar Filing: ALKERMES INC - Form 10-K405

- 10.16      Manufacture and Supply Agreement, entered into April 5, 2001, by and between Alkermes, Inc. and Genentech, Inc.\*\*
- 10.17      Patent License Agreement, dated as of August 11, 1997, between Massachusetts Institute of Technology and Advanced Inhalation Research, Inc., as amended. (Incorporated by reference to Exhibit 10.25 to the Registrant's Report on Form 10 for the fiscal year ended March 31, 1999.)\*
- 10.18      Letter Agreement, dated September 27, 1996, by and among Fleet National Bank, Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutic Inc. II a
- 75
- the Registrant. (Incorporated by reference to Exhibit 10.3 to the Registrant's Rep on Form 10-Q for the quarter ended September 30, 1996.)
- 10.18(a)      Loan Supplement and Modification Agreement, dated as of June 2, 1997, by and among Fleet National Bank, Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutics Inc. II and the Registrant. (Incorporated by reference to Exhibit 10.27(a) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1997.)
- 10.18(b)      Second Loan Supplement and Modification Agreement, dated as of March 19, 1998, by and among Fleet National Bank, Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutics Inc. II and the Registrant. (Incorporated by reference to Exhibit 10.29(b) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1998.)
- 10.18(c)      Third Loan Supplement and Modification Agreement, dated as of September 24, 1998, by and among Fleet National Bank, Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutics Inc. II and the Registrant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the quarter ended Septemb 30, 1998.)
- 10.19      Security Agreement, dated as of September 27, 1996, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutic Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.4 to the Registrant's Repo on Form 10-Q for the quarter ended September 30, 1996.)
- 10.20      Pledge Agreement, dated as of September 27, 1996, from the Registrant to Fleet National Bank. (Incorporated by reference to Exhibit 10.5 to the Registrant's Repo on Form 10-Q for the quarter ended September 30, 1996.)
- 10.21      Mortgage and Security Agreement, dated as of September 27, 1996, from Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference Exhibit 10.6 to the Registrant's Report on Form 10-Q for the quarter ended Septemb 30, 1996.)
- 10.22      Environmental Indemnity Agreement, dated as of September 27, 1996, from the Registrant and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.7 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.23      Promissory Note, dated September 27, 1996, from the Registrant and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference Exhibit 10.8 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1996.)

## Edgar Filing: ALKERMES INC - Form 10-K405

10.24 Promissory Note, dated June 2, 1997, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.35 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1997.)

76

10.25 Promissory Note, dated March 19, 1998, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank. (Incorporated by reference to Exhibit 10.38 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1998.)

10.26 Promissory Note, dated September 24, 1998, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank (\$11,000,000). (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1998.)

10.27 Promissory Note, dated September 24, 1998, from the Registrant, Alkermes Controlled Therapeutics, Inc. and Alkermes Controlled Therapeutics Inc. II to Fleet National Bank (\$9,000,000). (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended September 30, 1998.)

10.28 Employment Agreement, entered into as of February 7, 1991, between Richard F. Pops and the Registrant. (Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 33-40250).)

10.29 Employment Agreement, entered into as of June 13, 1994, by and between Robert A. Breyer and the Registrant. (Incorporated by reference to Exhibit 10.28 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1994.)+

10.30 Change in Control Employment Agreement, dated as of December 19, 2000, between Alkermes, Inc. and Richard F. Pops. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2000.)+

10.31 Change in Control Employment Agreement, dated as of December 19, 2000, between Alkermes, Inc. and each of Robert A. Breyer, Raymond T. Bartus, J. Duncan Higgons, James L. Wright, James M. Frates and Michael J. Landine. (Form of agreement incorporated by reference to Exhibit 10.2 to the Registrant's report on Form 10-Q for the quarter ended December 31, 2000.)+

10.32 Employment Agreement, dated December 22, 2000 by and between David A. Broecker and the Registrant.+

10.33 Change in Control Employment Agreement, dated as of June 27, 2001, between Alkermes, Inc. and David A. Broecker. (Form of agreement incorporated by reference to Exhibit 10.2 to the Registrant's report on Form 10-Q for the quarter ended December 31, 2000.)+

21 Subsidiaries of the Registrant.

23 Consent of Deloitte & Touche LLP.

\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted August 19, 1999. Such provisions have been

## Edgar Filing: ALKERMES INC - Form 10-K405

filed separately with the Commission.

77

- \*\* Confidential status has been requested for certain portions thereof pursuant to a Confidential Treatment Request filed June 29, 2001. Such provisions have been filed separately with the Commission.
- + Constitutes a management contract or compensatory plan required to be filed as an Exhibit to this Report pursuant to Item 14(c) of Form 10-K.