

CHAD THERAPEUTICS INC

Form 10-K

June 25, 2004

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO
SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 2004

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 1-12214

Chad Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

California
(State or other jurisdiction of
incorporation or organization)

95-3792700
(I.R.S. Employer
Identification No.)

21622 Plummer Street, Chatsworth, CA
(Address of principal executive offices)

91311
(Zip Code)

Registrant's telephone number, including area code: (818) 882-0883

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

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

Title of each class	Name of each exchange on which registered
Common Shares, \$.01 par value	American Stock Exchange

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

Edgar Filing: CHAD THERAPEUTICS INC - Form 10-K

Indicate by check mark if disclosures of delinquent filers pursuant to Item 405 of Regulation SK (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 Form 10-K or any amendment to this Form 10-K.

Table of Contents

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).
Yes [] No [x]

As of September 30, 2003, the last business day of the registrant's most recently completed second fiscal quarter, the approximate aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant was \$20,086,000 (based upon the last closing price for shares of the registrant's common stock as reported by the American Stock Exchange as of that date). Shares of common stock held by each officer, director, and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were approximately 10,096,000 shares of common stock outstanding as of June 14, 2004.

Certain information required in Part III hereto is incorporated by reference to the Proxy Statement (Proxy Statement) for the Registrant's 2004 Annual Meeting of Shareholders to be filed with the Securities Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K. Portions of the Registrant's Annual Report to Shareholders for the year ended March 31, 2004 (Annual Report) are incorporated into Part II as set forth herein and only such portions of the Annual Report as are specifically incorporated by reference are thereby made a part of this Annual Report on Form 10-K.

TABLE OF CONTENTS

PART I

Item 1. Business

Item 2. Properties

Item 3. Legal Proceedings

Item 4. Submission of Matters to a Vote of Security Holders

PART II

Item 5. Market for Registrant's Common Equity and Stockholder Matters

Item 6. Selected Financial Data

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 7a. Quantitative and Qualitative Disclosures about Market Risk

Item 8. Financial Statements and Supplementary Data

Item 9. Disagreements on Accounting and Financial Disclosure

Item 9A. Controls and Procedures

PART III

Item 10. Directors and Executive Officers of the Registrant

Item 11. Executive Compensation

Item 12. Security Ownership of Certain Beneficial Owners and Management

Item 13. Certain Relationships and Related Transactions

Item 14. Principal Accountant Fees and Services

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

SIGNATURES

EXHIBIT 13.1

EXHIBIT 23.1

EXHIBIT 28.13

Exhibit 31.1

Exhibit 31.2

Exhibit 32.1

Exhibit 32.2

Table of Contents

PART I

Item 1. Business

Chad Therapeutics, Inc. (CHAD or the Company) was organized in August, 1982, to develop, produce and market respiratory care devices designed to improve the efficiency of oxygen delivery systems for both home and hospital treatment of patients who require supplemental oxygen. The Company introduced its first respiratory care device in the market in June of 1983 and has introduced additional respiratory care devices in subsequent years.

Pulmonary Disease and Oxygen Therapy

The Company was organized to pursue the development and marketing of devices that improve the efficiency of systems used to administer oxygen to patients requiring supplemental oxygen. These are primarily patients suffering from chronic obstructive pulmonary diseases.

Chronic obstructive pulmonary diseases (COPD) are progressive, debilitating conditions that affect millions of Americans, severely limiting their activities and shortening their lives. Such conditions, which include chronic bronchitis, emphysema and severe asthma, decrease the capacity of the lungs to oxygenate the blood. To make up for this deficiency, it is common medical practice to administer supplemental oxygen, usually on a 24 hours per day basis in an amount sufficient to increase blood oxygenation to near normal levels.

According to the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH) between 1980 and 1990 the death rate from COPD increased by 22 % in the United States and by 1998 had increased another 27%.

More recently, the American Lung Association reported that in 2001 there were 14.1 million Americans suffering from COPD, which is the fourth leading cause of death in the United States and claimed the lives of over 115,000 people that year. This report also notes that in 2001 the annual cost to the nation for COPD in health care and indirect costs was estimated to be \$32.1 billion.

Although precise data are not available, various individual and institutional sources and reports estimate that there are more than 1 million home care patients receiving supplementary administration of oxygen. Total dealer revenues for home oxygen therapy were estimated at over \$2 billion for 1996. Medicare, which accounts for about 60% of home oxygen dealers' revenues, spent approximately \$1.8 billion in 2002 for home oxygen according to a report by the Centers for Medicare and Medicaid Services Office of Actuary. This represented a 13% increase over the previous year according to the report.

Chronic obstructive pulmonary diseases are also prevalent in other countries, particularly in some European nations and the Far East where the incidence is higher than in the United States. The potential international market for home oxygen is expected to grow to 150% of the U.S. market over the next five to ten years.

The primary oxygen supply for home patients are concentrators which concentrate oxygen from the ambient air (85-90%), reservoirs containing liquid oxygen (10-15%) and cylinders containing compressed gaseous oxygen (less than 1%).

Standard oxygen delivery systems are characteristically inefficient, permitting over 67% of the oxygen supply delivered to the patient to be wasted, primarily because the oxygen is administered steadily to the patient, even while he is exhaling. Since the normal breathing cycle consists of an exhalation period which is approximately twice as long

as the inhalation period, at least two-thirds of the

Table of Contents

oxygen from this continuous flow system is wasted. Furthermore, it is generally accepted that the oxygen breathed in during the first one-third of the inhalation period provides most of the oxygenation benefit to the patient.

Currently, Medicare provides a prospective flat fee monthly payment for home oxygen services based solely on the patient's prescribed oxygen requirement and disregards modality, the type of system in use. In the past, dealers were reimbursed on the basis of total oxygen delivered by the dealer with variances based on the modality used and other variables. The prior procedure tended to encourage waste and inefficiency. Consequently, with the incentive to operate efficiently, inexpensive concentrators have grown in popularity because of their low cost and less frequent servicing requirements. At the same time, interest in oxygen conserving devices which can extend the life of oxygen supplies and reduce service calls by dealers has heightened. There is also a separate fixed allowance from Medicare for patients who need to be mobile and therefore require portable oxygen systems.

In November 2003, Congress enacted the Medicare Improvement and Modernization Act, which will impact reimbursement for home oxygen over the next several years. The new legislation will result in continued pressure on homecare providers to reduce the cost of providing home oxygen services.

While these cost pressures have intensified, mobility has increased in importance as the treatment of pulmonary patients has moved away from hospitals and into home care. Also, leading authorities now state that maintenance and improvement of the patient's quality of life should be a major objective in the treatment of COPD. Maintaining quality of life and compliance with prescribed exercise programs require that the patient be as mobile as possible and thus increase the demand for portable oxygen equipment.

CHAD's Products

Recognizing the need for more efficient oxygen delivery systems, the Company has pursued, since its inception, the development and marketing of devices that are designed to conserve oxygen. The benefits of such improvements include substantial cost savings for the home care provider, as well as increased mobility for ambulatory patients who require portable oxygen supplies. These devices extend the life of oxygen supplies and make possible more compact and longer lasting portable systems, thereby improving the quality of life for home oxygen patients.

OXYMIZER® and OXYMIZER Pendant Oxygen-Conserving Devices. In June, 1983, the Company began marketing its first product, the OXYMIZER disposable oxygen-conserving device, a unique, patented, disposable device developed to provide up to 4 to 1 savings of oxygen when used with any oxygen supply source.

The OXYMIZER device contains a collapsible reservoir, which captures incoming oxygen delivered during expiration and prevents its waste. The oxygen captured in this reservoir is then inhaled by the patient during the first instant of his next inspiration. Thus the OXYMIZER device both conserves oxygen and provides the patient with an extra rich supply of oxygen at the beginning of the inhalation period when it can be most effectively utilized.

Extensive clinical testing and trials over the past nineteen years have repeatedly demonstrated that patients using the OXYMIZER device are able to achieve equivalent blood oxygenation levels while using significantly less oxygen. There have been more than 32 clinical evaluations from institutions worldwide that have confirmed the efficacy and oxygen savings of the OXYMIZER devices.

The greater efficiency provided by these devices over standard oxygen delivery systems also permits home health care patients to achieve greater mobility by enabling them to use smaller portable cylinders or by obtaining two to four times the life from standard sized portable cylinders.

Table of Contents

For home oxygen dealers, the disposable OXYMIZER devices afford the cost advantages of oxygen conservation without capital investment in expensive equipment.

In hospitals, the OXYMIZER devices are used for maintenance of certain patients requiring higher flow levels of oxygen without having to resort to uncomfortable oxygen masks.

The Company is pursuing a marketing strategy that emphasizes the cost savings, efficiencies and level of patient comfort associated with the use of the OXYMIZER devices. See Marketing and Competition .

The OXYMIZER Pendant device is similar to the OXYMIZER device, except that its reservoir is located in a pendant which hangs over the patient's chest rather than under the nose. The OXYMIZER Pendant has a more traditional appearance than the OXYMIZER. The Company began marketing the OXYMIZER Pendant in August, 1984.

OXYMATIC® Electronic Oxygen Conservers. The Company began marketing the OXYMATIC conserver in March, 1986. This product is a small electronic device, designed for use with portable oxygen systems. The OXYMATIC conserver electronically senses the optimal moment in the breathing cycle for delivery of oxygen and at that moment, releases a very brief pulse of oxygen to the patient. The OXYMATIC conserver concentrates the administration of oxygen during the first one-third of the inhalation phase, when oxygen is most efficiently utilized. Through its optimal efficiency, the OXYMATIC electronic conserver makes possible oxygen savings ratios of from 4 to 1 up to 12 to 1 depending on the user's breathing rate. In clinical experience, the average saving has been shown to be 7 to 1 about twice the efficiency of most competitive products. There have been at least twelve controlled clinical trials and studies of patient groups using the OXYMATIC conserver, all of which have confirmed its efficacy and efficiency.

In June, 1993, the Company introduced a different version of the OXYMATIC conserver, the OXYMATIC 2400. This model incorporates substantial improvements and additional features, including an alarm system, which are designed to allow it to be used 24 hours a day with both primary and portable oxygen sources. The OXYMATIC 2400 conserver affords the same oxygen savings ratios as the original OXYMATIC conserver.

In July, 2000, the Company introduced the first of the OXYMATIC 400 series of conservers. Additional models were added to this line in January and March of 2001. This new line of conservers was designed to capitalize on the proven reliability and efficiency of the Company's previous models. In addition, features and options were added to create state-of-the-art conservers that would give homecare providers a wide choice of products to service their patient's individual needs and preferences. These new conservers include a built-in regulator, expanded flow rates and provide average savings of 5 to 1 over continuous flow oxygen.

In November, 2001, the Company introduced the SEQUOIA OXYMATIC line of conservers. These conservers utilize the same electronic features as the OXYMATIC 400 series conservers but do not contain a built-in regulator.

CYPRESS OXYPneumatic® Conservers. In July, 2002, the Company began marketing the CYPRESS pneumatic conserver, which allows the Company to compete in the pneumatic segment of the conserver market for the first time. This device incorporates no electronic parts, thus eliminating the need for batteries. It is lightweight, small and allows the use of a standard single-lumen cannula, unlike many other pneumatic conservers that require special cannulas. The CYPRESS conserver provides flow rates from one to six liters per minute and oxygen savings greater than 3:1 over continuous flow oxygen.

Table of Contents

Sales of OXYMATIC electronic and CYPRESS OXYPneumatic conservers accounted for approximately 77% and 74% of the Company's sales in 2004 and 2003, respectively. Sales of OXYMATIC electronic conservers accounted for approximately 60% of the Company's sales in 2002.

The OXYMATIC electronic and CYPRESS pneumatic conservers extend the time the contents of the cylinders will last over continuous flow oxygen. They provide ambulatory patients with greater mobility and less weight. The Company believes these systems offer a superior alternative to commonly used liquid oxygen systems for mobile patients and are more cost effective for homecare dealers to supply.

SAGE Oxygen Therapeutic Device In May 2004 the Company received clearance from the FDA to market its new SAGE Oxygen Therapeutic Device. The SAGE device is the first in a planned family of oxygen therapeutic devices that use the Company's proprietary technologies to sense a patient's movements and automatically adjust the rate of oxygen delivery to reduce the risk of desaturation as activity increases. The SAGE device combines the industry's first truly dynamic, patented delivery technology with the proven oxygen sensor technology in the Company's OXYMATIC 400 series conserver. As a result, the device addresses the common problem of oxygen desaturation, which causes a patient to feel weak and out of breath when activity increases, yet it still maximizes patient ambulatory capability.

OXYCOIL® Coiled Oxygen Tubing. In January, 1986, the Company began marketing the OXYCOIL coiled oxygen tubing, a device which replaces the standard supply tubing for the OXYMIZER devices, the OXYMATIC conserver or conventional nasal cannulas. The OXYCOIL tubing is a convenience and safety device which can be used with any oxygen system to help keep the supply tubing out of the patient's way, thus minimizing the tripping and tangling problems associated with standard supply tubing.

TOTAL O₂® Delivery System. In January, 1998, the Company began marketing the TOTAL O₂ Delivery System. This system provides stationary oxygen for patients at home, portable oxygen including an oxygen conserving device for ambulation and a safe and efficient mechanism for filling portable oxygen cylinders. The TOTAL O₂ Delivery System was designed to provide home care dealers with a more cost effective means to provide home oxygen services while at the same time providing the patients with a higher quality of service. This can be accomplished as the home care dealer will no longer be required to make regular monthly service calls to deliver full portable cylinders and the patient will no longer be dependent on the dealer for those deliveries to obtain full cylinders.

Initial sales of the TOTAL O₂ system were adversely affected by several factors, including the overall home oxygen market climate, as well as start-up manufacturing and supplier issues. The Company believes it has resolved the manufacturing and supplier issues. Nonetheless, the Company has still not achieved the level of sales originally anticipated for this product and now believes its success will be dependent on the healthcare community's acceptance of the technology and willingness to substitute a higher capital acquisition cost for lower operating costs. No assurances can currently be given regarding the level of success the Company may achieve with the TOTAL O₂ system. See Outlook:Issues & Risks - New Product in the Company's Annual Report to Shareholders.

The technology for each of the devices described above has been licensed from the inventors thereof, with the exception of the CYPRESS OXYPneumatic conserver, which belongs to the Company. The Company has acquired exclusive licenses to manufacture and market the OXYMIZER devices, the OXYMATIC conservers, the OXYCOIL tubing and the TOTAL O₂ system. See Licensing and Related Agreements .

Other Products. The Company also offers a variety of ancillary products that support the principal oxygen conserving products. These include oxygen cylinders of various sizes and compositions,

Table of Contents

regulators, cannulas and connecting tubing and assorted carrying pouches. In addition, with a field sales force of manufacturer's representatives and direct sales representatives covering the entire United States (see Marketing) the Company will utilize this team as part of a strategy to market and sell additional products that are targeted for the Company's current customer base, the homecare provider.

Products Under Development

It is the Company's objective to continuously improve and add to its oxygen conserving and related products. During the fiscal years ended March 31, 2004 and 2003 the Company entered into contracts with outside vendors to develop products in the home oxygen market and sleep disorder market. No assurance can be given that any products developed pursuant to these contracts will be successfully marketed or that the Company will ever derive significant revenues or earnings from the sale of such products.

Research and Development

For the year ended March 31, 2004, the Company expended approximately \$1,292,000 on research and development and has expended approximately \$7,619,000 since its inception in August of 1982. The Company operates in an industry that is subject to rapid technological change, and its ability to compete successfully depends upon, among other things, its ability to stay abreast or ahead of new technological developments. Accordingly, the Company expects to expend increasing amounts for the development or acquisition of new products or the improvement of existing products. In the next fiscal year the Company expects to spend approximately \$1,570,000 on several projects. The Company conducts research and development internally and also utilizes the services of outside firms and consultants for its research and development activities.

Licensing and Related Agreements

The Company has entered into license agreements (the Inventors License Agreements) with Brian L. Tiep, M.D., Robert E. Phillips and Ben A. Otsap, the inventors of the OXYMIZER device (the Inventors), with respect to that device and each of the additional oxygen conserving devices developed by them. At the present time, the Company has licensed the OXYMATIC conserver, thereby acquiring exclusive rights to manufacture and market such product.

Pursuant to the Inventors License Agreements, the Inventors grant to the Company an exclusive license (with the right to grant sublicenses) to manufacture, use and sell such device. Through September 2003, the Inventors License Agreements provided that the Company pay royalties to the Inventors on the net proceeds of sales of the device covered by the agreement at the rate of 6% on amounts up to \$10 million and 3% on amounts of \$10 million or more. The Inventors License Agreements also provided that the Company pay minimum advance royalties for each license year in the amount of \$10,000 for each year. The advance payments are to be applied toward royalties payable for the corresponding license year. As of September 2003, no further royalty payments are due. The Company is obligated to prosecute and defend, at its own expense, any infringement suits related to manufacture or sale of each device covered by any such agreement.

Each Inventors License Agreement continues until the expiration of the last to expire of any patent covering the related device or, if no patent is issued, for 17 years. The Inventors may terminate the Inventors License Agreements at an earlier date if the Company is in arrears for 60 days on any royalty payment or if the Company defaults in performing any other term of the agreement and fails to cure such default within 60 days.

The Company has also entered into a license agreement (the Carleton License Agreement) with the Life Support Division of Carleton (formerly Litton Life Support) for the TOTAL O₂ Delivery

Table of Contents

System. Pursuant to the Carleton License Agreement, the Licensor grants to the Company an exclusive license (with the right to grant sublicenses) to manufacture, use and sell such device in the health care market. The Carleton License Agreement provides that the Company pay royalties to the Licensor on the net proceeds of sales of the device covered by the agreement at the rate of 4% and requires minimum annual royalties of \$100,000, \$300,000 and \$500,000 in 1999, 2000 and subsequent years, respectively. The Carleton License Agreement continues until the expiration of the last to expire of any patent covering the related device or until the Company ceases uses of the licensed technology. The Licensors may terminate the Carleton License Agreement at an earlier date if the Company is in arrears for 30 days on any royalty payment or if the Company defaults in performing any other material obligation of the agreement and fails to cure such default within 30 days.

The Company has also entered into a license agreement (the Phillips and Otsap License Agreement) with Robert E. Phillips and Ben A. Otsap for the SAGE Oxygen Therapeutic Device. Pursuant to the Phillips and Otsap Agreement, the Licensor grants to the Company an exclusive license (with the right to grant sublicenses) to manufacture, use and sell such devices in the health care market. The Phillips and Otsap License Agreement provides that the Company pay royalties to the Licensor on the net proceeds of sales of the device covered by the agreement at the rate of 3% for unit sales up to 1,499 units, 4% for unit sales from 1,500 to 1,999 units per month, 5% for unit sales from 2,000 to 2,499 units per month and 6% for unit sales of 2,500 or more per month. The agreement also requires minimum annual royalties of \$15,000 in the first year after FDA clearance is received to market the product and \$30,000 per annum thereafter. The Phillips and Otsap License Agreement continues until the expiration of the last to expire of any patent covering the related device or until the Company ceases uses of the licensed technology. The Licensors may terminate the Phillips and Otsap License Agreement at an earlier date if the Company is in arrears for six days on any royalty payment or if the Company defaults in performing any other material obligation of the agreement and fails to cure such default within 30 days.

Manufacturing and Sources of Supply

The Company tests and packages its products in its own facility. Some other manufacturing processes are conducted by other firms and the Company expects to continue using outside firms for certain manufacturing processes for the foreseeable future. All outside manufacturing is conducted under the supervision and control of the Company and with tooling provided by the Company.

Pursuant to an oral agreement, the Company purchases semi-finished units of the OXYMIZER Pendant device from a supplier in Southern California. Final assembly and packaging are completed at the Company's facilities. The Company does not contemplate entering into a formal written agreement for these units. This arrangement is terminable at will by either party. The Company believes that other injection molding facilities would be available in the event of a termination of this arrangement. Pursuant to a written agreement, the Company purchases finished units of the OXYMIZER device from a supplier in Hong Kong. The Company believes that other injection molding facilities would be available in the event of a termination of this arrangement.

Production of the OXYMATIC 300 series, 2400 and 400 series conservers, the CYPRESS pneumatic conservers, and the SAGE Oxygen Therapeutic Device are being handled internally with only a portion of the electronic assembly for electronic conservers being subcontracted outside the Company. The Company is currently subcontracting with two electronic assembly facilities and believes that other facilities would be available in the event of an interruption of supply from the existing facilities.

Pursuant to oral agreements, the Company purchases components for its OXYLITE systems (other than the OXYMATIC conserver) from several suppliers. These arrangements are terminable at will and the Company believes other suppliers would be available in the event of termination of these arrangements.

Table of Contents

Production of the TOTAL O₂ system is being handled internally with a number of subassemblies being subcontracted outside the Company. The Company believes that there are alternate sources of supply for these subassemblies, including internal manufacturing as production quantities increase.

The Company is not aware of any shortages of materials necessary for the manufacture of its products. The Company provides customers the right to return merchandise for credit and requires payment within a time frame consistent with industry standards. The Company provides warranties for certain of its products based on industry standards and accrues for the estimated expenses associated with those warranties based on the best information available, primarily historical claims experience.

Marketing

The Company's products are designed to reduce the cost of health care while maintaining or enhancing the therapeutic benefits to the patient, and improving the user's quality of life. The Company's marketing efforts have focused primarily on providing home oxygen suppliers with products that they can utilize to increase their revenues and provide a better quality of care at less cost.

Homecare dealers have reportedly increased their revenues by assembling small portable systems incorporating the Company's OXYMATIC electronic conserver or CYPRESS pneumatic conserver as a vehicle to attract new and additional patients to their business. The Company believes these lightweight, long-lasting portable systems have both high professional and patient acceptance which allows the supplier promoting these products to attract new and additional customers. The Company has been advised that medical professionals, who frequently refer patients to specific home oxygen suppliers, find that these systems assist patients in more easily complying with prescribed exercise programs and help them to achieve the therapeutic benefits of maintaining a lifestyle as normal as possible. Patients, most of whom are free to select their oxygen supplier, are reportedly receptive to changing suppliers in order to obtain equipment that will allow them to travel and maintain their quality of life.

A large portion of home oxygen patients are covered by Medicare or other government programs. Since June 1989, home oxygen suppliers have been reimbursed on a fixed monthly fee basis by Medicare. The monthly reimbursement amount does not vary, as in the past, with either the type of oxygen delivery equipment provided or the amount of oxygen supplied. Since monthly per patient revenues are fixed, home oxygen suppliers can only increase their per patient profitability by reducing costs. The Company's oxygen conserving products and TOTAL O₂ Delivery System allow these suppliers to decrease their costs while providing their patients with improved therapeutic benefits and quality of life.

While the home respiratory care dealer remains the primary focus of the Company's marketing efforts, this focus has been augmented by a major effort to increase professional awareness. Promotional programs target respiratory care physicians, nurses and therapists.

The Company markets its products directly to home oxygen suppliers throughout the U.S. The Company currently has a Vice President of Sales & Marketing, two Regional Vice Presidents of Sales, a manager of sales administration, an art and media manager, a marketing manager, a customer relations manager and five in-house sales and customer service representatives who are in regular and frequent proactive telephone sales contact with customers and potential customers. In addition, the Company has a field sales force of direct sales representatives and independent manufacturer's sales representatives to handle direct selling to customers. This field sales force is currently comprised of 4 direct sales representatives and 37 manufacturer's sales representatives with coverage throughout the United States. The Company also utilizes direct mail, trade show attendance, trade advertising and a web site to

Table of Contents

promote the benefits of its products to home care dealers. Additionally, the Company actively seeks to increase professional awareness of its products through professional advertising and participation in professional meetings.

Home oxygen therapy markets outside the United States are, in most cases, at a much earlier stage of development. In many countries, these patients are cared for in institutional settings. As the trend develops to move patients into home care, opportunities for the Company's products should increase. Sales of the OXYMATIC conserver in Canada and Japan have become an important part of the Company's business. Based on industry market research projections, the Company expects the international market to increase to 150% of the U.S. potential over the next five to ten years.

The Company has entered into exclusive distributorship agreements in Germany, Japan, Australia and several other countries. The Company's largest distributor in Germany covers portions of the European Community. The Company also has non-exclusive distributors in many other countries.

Sales outside of the United States subjects the Company to certain risks, including those involving political and economic factors, interruption of shipments of products, currency fluctuations and devaluations, and governmental restrictions and regulations.

Customers, Backlog and Orders

The Company presently has an active list of over 4,000 dealer and hospital customers. Based upon information developed from various lists the Company believes that there are approximately 7,000 to 8,000 home oxygen dealers and 3,000 general hospitals in the United States which are potential customers or customer sources for the Company. Of these 7,000 to 8,000 homecare providers, approximately 48% are represented by three major national chain accounts. One national chain customer accounted for 27%, 24% and 23% of net sales during 2004, 2003 and 2002, respectively, and one other chain accounted for 14% and 11% of sales in 2004 and 2003, respectively.

**Financial Information Relating to Foreign and
Domestic Operations and Export Sales**

	2004	2003	2002
	<hr/>	<hr/>	<hr/>
Sales (thousands):			
United States	\$20,498	18,639	17,904
Canada	303	307	265
Japan	238	207	240
Germany	44	46	289
All other countries	458	342	308
	<hr/>	<hr/>	<hr/>
Total	\$21,541	19,541	19,006
	<hr/>	<hr/>	<hr/>

All identifiable assets are located in the United States.

At March 31, 2004, the Company had no backlog of orders for any of its products. The Company presently endeavors to maintain sufficient inventory to ship all of its products immediately upon receipt of orders. The Company believes that maintaining such levels of inventory is necessary to meet the requirements of its customers.

Competition

The Company is aware of several demand valve, electronically controlled devices currently being marketed. Of these devices, those that have been the principal competitors of the OXYMATIC conserver

Table of Contents

in the past were targeted primarily to a specific segment of the market – liquid oxygen usage. Several companies, including Caire Inc. and Puritan Bennett market small (3.4 to 5.5 lbs.) portable liquid oxygen systems incorporating simple oxygen conserving devices which double the useful life of these systems. Some of these companies have substantially greater marketing and financial resources than the Company. However, these units are more expensive than systems utilizing the OXYMATIC conservers and still require the supplier to make frequent and costly oxygen deliveries. The Company does not know the levels of sales achieved by the companies marketing these systems.

Several of these competitors are now marketing conservers in direct competition with the Company's OXYMATIC electronic and CYPRESS pneumatic conservers. Some of these conservers only provide 2:1 to 3:1 savings ratios. As a result, these units while weighing about the same as the OXYMATIC conserver provide only 1/3 or 1/2 as much ambulation time. In addition, the Company is aware of two companies marketing oxygen conserving devices which claim similar oxygen savings ratios as the OXYMATIC conserver. The Company believes that some of these competitors have been able to offer their oxygen conservers as part of a bundle of products with perceived pricing advantages over the Company's products. In addition, some of these competitors had introduced conservers with features not found in the Company's products prior to the introduction of the OXYMATIC 400 series conservers. While the reliability and superior conservation of the OXYMATIC conservers partially offset these advantages, some of these companies have attained market share at the Company's expense. The Company does not know the level of sales achieved by these companies.

There are several other types of portable oxygen systems which compete with the Company's OXYMATIC conservers but do not utilize oxygen conserving devices. Aluminum and steel oxygen cylinders with continuous flow regulators are utilized by some oxygen suppliers as portable systems. Although they do provide users with some portability, their size and bulk limits their use by patients who need or want to be truly ambulatory. The most commonly used of these cylinders is approximately three feet high, weighs over 20 lbs., and provides an average patient with less than 5 hours of oxygen. These systems are enjoying some level of success due to their lower unit price advantage. The OXYMATIC electronic and CYPRESS pneumatic conservers allow the use of smaller, lighter cylinders and thus provides greater mobility.

Until the availability of OXYLITE systems and the previously cited changes in Medicare oxygen reimbursement, liquid oxygen was the modality of choice for truly mobile users. Portable liquid oxygen systems that weigh 3.4 to 10 lbs., provide an average patient with 6 to 8 hours of oxygen, compared to the smallest OXYLITE system which weighs 4.5 lbs. and provides an average patient with 7.3 hours of oxygen. These systems are more costly than OXYLITE systems and require frequent and expensive (often weekly) deliveries of bulk liquid oxygen to the patient's home. In addition, the patient must remain within range of the base unit for refilling, unlike with the OXYLITE systems with which a patient can take as many cylinders as needed to provide the amount of time necessary to be away from their base unit.

The Company is aware of one combination oxygen concentrator and refilling station being marketed by Invacare in competition with the TOTAL O₂ system. This system is larger and heavier and does not contain some of the integrated features found in the TOTAL O₂ system. The Company does not know the level of sales achieved by Invacare for this system.

Patents and Trademarks

The Company regards the products that it develops or licenses and its manufacturing processes as proprietary and relies on a combination of patents, trademarks, trade secret laws and confidentiality agreements to protect its rights in its products. U.S. patents have been issued covering the original

Table of Contents

OXYMATIC conserver, the CYPRESS OXYPneumatic conserver, the TOTAL O₂ Delivery System, and the SAGE Oxygen Therapeutic Device. A number of foreign patent applications pertaining to the Company's activities have also been issued.

The Company pursues a policy of obtaining patents for appropriate inventions related to products marketed or manufactured by the Company. The Company considers the patentability of products developed for it to be significant to the success of the Company. To the extent that the products to be marketed by the Company do not receive patent protection, competitors may be able to manufacture and market substantially similar products. Such competition could have an adverse impact upon the Company's business.

There can be no assurance that patents, domestic or foreign, will be obtained with respect to the Company's products, or that, if issued, they will provide substantial protection or be of commercial benefit to the Company. In addition, the patent laws of foreign countries may differ from those of the United States as to the patentability of the Company's products and processes and, accordingly, the degree of protection afforded by foreign patents may be more or less than in the United States.

In the United States, although a patent has a statutory presumption of validity, the issuance of a patent is not conclusive as to such validity or as to the enforceable scope of its claims therein. The validity and enforceability of a patent can be attacked by litigation after its issuance by the U.S. Patent and Trademark Office. If the outcome of such litigation is adverse to the owner of the patent in that the patent is held to be invalid, other parties may then use the invention covered by the patent. Accordingly, there can be no assurance that patents with respect to the Company's products, if issued, will afford protection against competitors with similar products, nor can there be any assurance that the patents will not be infringed upon or designed around by others.

Through patent searches, contacts in the industry and representations and indemnities received from licensors and development partners, the Company seeks to ensure that its products do not infringe on the intellectual property rights claimed by others. However, interpretation of the scope and validity of existing patent rights may differ, and no assurance can be given that the Company products will in all cases not infringe on the rights of others. Moreover, any dispute regarding potential infringement may require substantial management and financial resources to defend.

The Company has obtained U.S. registration for the trademarks OXYMIZER, OXYMATIC, OXYPneumatic, CHAD, OXYCOIL, and TOTAL O₂. A series of foreign applications to register the trademark OXYMIZER in a number of countries of commercial interest to the Company have been filed.

Governmental Regulation

The commercialization of the OXYMIZER, OXYMATIC, CYPRESS, TOTAL O₂, and SAGE devices is subject to the Federal Food, Drug and Cosmetic Act (the Food and Drug Act) and to regulations issued thereunder. The Company anticipates that commercialization of other devices that it intends to market will also be subject to the Food and Drug Act. The Food and Drug Act is administered by the FDA, which has authority to regulate the marketing, manufacturing, labeling, packaging and distribution of products subject to the Food and Drug Act. In addition, there are requirements under other federal laws and under state, local and foreign statutes that may apply to the manufacture and marketing of the Company's products. The Medical Device Amendments of 1976 to the Food and Drug Act (the Amendments) and the Safe Medical Device Act of 1990 significantly extended the authority of the FDA to regulate the commercialization of medical devices. The Amendments established three classifications of medical devices: Class I, Class II and Class III. With respect to all three classes, the general provisions of the Food and Drug Act prohibit adulteration and misbranding. A medical device may be adulterated if the device is or could be adversely affected by its methods of manufacture, storage

Table of Contents

or packaging. A medical device may be misbranded if its labeling is false or misleading or if its labeling does not contain specific information required by law applicable to such type of device. In addition, failure to register a medical device covered under the Food and Drug Act will render it misbranded under the Food and Drug Act.

All manufacturers of medical devices must register with the FDA and list all medical devices produced by them. This listing must be updated annually. In addition, prior to commercial distribution of additional devices, the manufacturer must file with the FDA and receive approval prior to the commencement of such commercial distribution, a notice setting forth certain information about the device, including the classification into which the manufacturer believes it falls.

Class I devices are subject only to the general controls concerning adulteration, misbranding, good manufacturing practices, record keeping and reporting requirements. Class II devices must, in addition, comply with performance standards as promulgated by the FDA.

The Company has registered with the Bureau of Medical Devices of the FDA as a Medical Device Establishment and with the Department of Health Services of the State of California as a Medical Device Manufacturer. In addition, the Company has developed procedures to comply with FDA standards concerning good manufacturing practices, record keeping and reporting and is ISO 9001 certified.

The Company has filed notification submissions pursuant to Section 510(k) of the Food and Drug Act of its intent to market the OXYMIZER, the OXYMIZER Pendant, the OXYMATIC conserver, the CYPRESS OXYPneumatic conserver, the OXYCOIL, the TOTAL O₂ Delivery System, and the SAGE Oxygen Therapeutic Device; it has been granted permission by the FDA to market the OXYMIZER and the OXYMIZER Pendant as Class I devices. Permission has been granted to market the OXYMATIC, the CYPRESS OXYPneumatic, the OXYCOIL, the TOTAL O₂ Delivery System, and the SAGE Oxygen Therapeutic Device as Class II devices.

Employees

As of June 25, 2004, CHAD had 117 full-time employees and 1 part-time employee. Sixty-two of the Company's employees are engaged in manufacturing and the remaining are engaged in marketing, sales, administration and management. None of the Company's employees are represented by unions; the Company believes its employee relations are satisfactory. The Company will employ additional personnel in all phases of its activities as required by the growth in its activities. The number of additional personnel will be dependent on sales levels of individual products.

Item 2. Properties.

The Company's offices and manufacturing facilities are situated in premises located in Chatsworth, California and consist of approximately 55,500 square feet, at a monthly rental fee of \$32,000 pursuant to a lease expiring in June, 2008. Management believes this facility should adequately handle the Company's needs for the foreseeable future. The Company does not own any real property and does not anticipate acquiring any in the foreseeable future.

Item 3. Legal Proceedings.

The Company becomes involved in legal proceedings in the ordinary course of business. The Company maintains product liability insurance in an amount it deems customary in the industry for protection of the Company against potential product liability claims. Although the Company believes its

Table of Contents

product liability insurance is sufficient and no pending legal proceeding poses a material threat, no assurance can be given that pending or future proceedings will not have a material impact on the Company's financial condition or results of operations.

Item 4. Submission of Matters to a Vote of Security Holders.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity and Stockholder Matters.

The information required herein is hereby incorporated by reference to the information contained under the caption Corporate Data in the Company's Annual Report.

Item 6. Selected Financial Data.

The information required herein is hereby incorporated by reference to the information contained under the caption Selected Financial Data in the Company's Annual Report.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The information required herein is hereby incorporated by reference to the information contained under the caption Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's Annual Report.

Item 7a. Quantitative and Qualitative Disclosures about Market Risk

The Company has no significant exposure to market risk sensitive instruments or contracts.

Item 8. Financial Statements and Supplementary Data.

The information required herein is hereby incorporated by reference to the Financial Statements and the Notes thereto contained in the Company's Annual Report.

Item 9. Disagreements on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures.* An evaluation as of the end of the period covered by this report was carried out under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective to ensure that we record, process, summarize, and report information required to be disclosed by us in our reports filed under the Securities Exchange Act within the time periods specified by the Securities and Exchange Commission's rules and forms.

Table of Contents

(b) *Changes in Internal Control Over Financial Reporting.* There have not been any changes in the Company's internal control over financial reporting during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The information required herein is hereby incorporated by reference to the information appearing under the captions Election of Directors and Executive Officers in the Company's definitive Proxy Statement to be filed with the Securities and Exchange Commission.

Item 11. Executive Compensation.

The information required herein is hereby incorporated by reference to the information appearing under the caption Compensation of Directors and Executive Officers in the Company's definitive Proxy Statement to be filed with the Securities and Exchange Commission.

Item 12. Security Ownership of Certain Beneficial Owners and Management.

The information required herein is hereby incorporated by reference to the information appearing under the caption Voting Securities and Principal Holders Thereof in the Company's definitive Proxy Statement to be filed with the Securities and Exchange Commission.

Item 13. Certain Relationships and Related Transactions.

None.

Item 14. Principal Accountant Fees and Services

The information required herein is hereby incorporated by reference to the information appearing under the caption Proposal 2: Ratification of Appointment of Independent Accountants in the Company's definitive Proxy Statement to be filed with the Securities and Exchange Commission.

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

(a) (1) Financial Statements.

Included in Part II of this Report:

Edgar Filing: CHAD THERAPEUTICS INC - Form 10-K

Report of Independent Registered Public Accounting Firm

Balance Sheets March 31, 2004 and 2003

Statements of Operations Years ended March 31, 2004, 2003 and 2002.

Statements of Shareholders Equity Years ended March 31, 2004, 2003 and 2002.

Statements of Cash Flows Years ended March 31, 2004, 2003 and 2002.

Notes to Financial Statements.

Table of Contents

(a) (2) Financial Statement Schedules.

See Notes to Financial Statements.

(3) Exhibits.

3.1 Articles of Incorporation of the Registrant, as amended*****

3.2 Bylaws of the Registrant, as amended*

10.5 Pulser System License Agreement, as amended, with Robert E. Phillips, Brian L. Tiep, M.D. and Ben A. Otsap. (The Pulser System is now called the OXYMATIC.)*

10.20 OXYCOIL tubing License Agreement with Mary Smart (licensed under the name Respi-Coil).***

10.23 Summary plan description for Chad Therapeutics, Inc. Employee Savings and Retirement Plan*****

10.24 1994 Stock Option Plan*****

10.25 Lease on real property at 21622 Plummer Street, Chatsworth, California*****

10.26 TOTAL O₂ Delivery System License Agreement, as amended, with the Life Support Division of Litton Industries, Inc.*****

13.1 Annual Report to Shareholders for the year ended March 31, 2004.

23.1 Consent of Independent Registered Public Accounting Firm

28.1 Letter from the FDA authorizing the Company to market the OXYMIZER oxygen conserving device as a Class 1 device.*

28.2 Letter from the FDA authorizing the Company to market the OXYMIZER Pendant oxygen conserving device as a Class 1 device.**

28.5 Letter from the FDA authorizing the Company to market the OXYMATIC electronic oxygen conserver as a Class 2 device.***

28.6 Letter from the FDA authorizing the Company to market the OXYCOIL coiled oxygen tubing as a Class 2 device.***

28.7 Letter from the FDA authorizing the Company to market the TOTAL O₂ Delivery System as a Class 2 device*****

28.9 Letter from the FDA authorizing the Company to market the OXYMATIC 411 conserver as a Class 2 device*****

28.10 Letter from the FDA authorizing the Company to market the OXYMATIC 401A and 411A conservers as a Class 2 devices*****

28.11 Letter from the FDA authorizing the Company to market the TOTAL 02 Post Valve

Table of Contents

Cylinders*****

28.12 Letter from the FDA authorizing the Company to market the CYPRESS OXYPneumatic
conserver*****

28.13 Letter from the FDA authorizing the Company to market the SAGE Oxygen Therapeutic Device

31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906
of the Sarbanes-Oxley Act of 2002

32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906
of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K None filed.

(c) Index to Exhibits.

(d) Financial Statement Schedules None

* Previously filed as an Exhibit to the Registrants Registration Statement on Form S-18, File No. 2-83926.

** Previously filed as an Exhibit to the Registrants Annual Report on Form 10-K for the year ended March 31, 1984.

*** Previously filed as an Exhibit to the Registrants Annual Report on Form 10-K for the year ended March 31, 1986.

**** Previously filed as an Exhibit to the Registrants Annual Report on Form 10-K for the year ended March 31,
1993.

***** Previously filed as an exhibit to the Registrant s Annual Report on Form 10-K for the year ended March 31,
1994.

***** Previously filed as an exhibit to the Registrant s Annual Report on Form 10-K for the year ended March 31,
1996.

***** Previously filed as an exhibit to the Registrant s Annual Report on Form 10-K for the year ended March 31,
1998.

***** Previously filed as an exhibit to the Registrant s Annual Report on Form 10-K for the year ended March 31,
2001.

***** Previously filed as an exhibit to the Registrant s Annual Report on Form 10-K for the year ended
March 31, 2002.

***** Previously filed as an exhibit to the Registrant s Annual Report on Form 10-K for the year ended
March 31, 2003.

Table of Contents

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, in the City of Los Angeles, State of California, on the 20th day of June, 2004.

CHAD THERAPEUTICS, INC.

By /s/ Earl L. Yager

Earl L. Yager, 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	Date
<u>/s/ Thomas E. Jones</u> Thomas E. Jones	Chairman, and Director (Principal Executive Officer)	June 25, 2004
<u>/s/ Earl L. Yager</u> Earl L. Yager	Chief Executive Officer, President, and Secretary and Director (Principal Financial and Accounting Officer)	June 25, 2004
<u>/s/ Tracy A. Kern</u> Tracy A. Kern	Chief Financial Officer	June 25, 2004
<u>/s/ Kathleen M. Fisher</u> Kathleen M. Fisher	Director	June 25, 2004
<u>/s/ John C. Boyd</u> John C. Boyd	Director	June 25, 2004
<u>/s/ Norman Cooper</u> Norman Cooper	Director	June 25, 2004
<u>/s/ Philip Wolfstein</u> Philip Wolfstein	Director	June 25, 2004
<u>/s/ James M. Brophy</u>	Director	June 25, 2004

James M. Brophy

Table of Contents

Exhibit Index

Exhibit No.	Exhibit Index Document
13.1	Annual Report to Shareholders for the year ended March 31, 2004.
23.1	Consent of Independent Accountant
28.13	Letter from the FDA authorizing the Company to market the SAGE Oxygen Therapeutic Device
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002