

Edgar Filing: THORATEC CORP - Form 10-K/A

THORATEC CORP
Form 10-K/A
January 24, 2002

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

AMENDMENT NO. 1
TO
FORM 10-K

(MARK ONE)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 30, 2000

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____ .

COMMISSION FILE NUMBER: 1-8145

THORATEC CORPORATION
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

CALIFORNIA
(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)

94-2340464
(I.R.S. EMPLOYER
IDENTIFICATION NO.)

6035 STONERIDGE DRIVE, PLEASANTON, CALIFORNIA
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

94588
(ZIP CODE)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (925) 847-8600

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE EXCHANGE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE EXCHANGE ACT: COMMON
STOCK

Indicate by a 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 a check mark if disclosure of delinquent filers pursuant to
Item 405 of Regulation S-K 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.

Edgar Filing: THORATEC CORP - Form 10-K/A

The aggregate market value of the voting stock held by non-affiliates was \$247,230,000 computed by reference to the last sale reported of such stock on March 26, 2001 as listed on The Nasdaq National Stock Market (R). (1)

As of March 26, 2001, registrant had 54,727,616 shares of common stock outstanding.

(1) Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to cause the direction of the management or policies of the issuer, or that such person is controlled by or under common control with the issuer.

PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the documents incorporated by reference in this annual report, includes forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, those relating to:

- our ability to obtain and maintain regulatory approval of our products in the United States and internationally;
- the other competing therapies that may in the future be available to heart failure patients;
- our plans to develop and market new products;
- our ability to improve our financial performance; and
- effects of the merger with Thermo Cardiosystems.

Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the "Risk Factors" section and elsewhere in this annual report. We are not obligated to update or revise these forward-looking statements to reflect new events or circumstances.

You should assume that the information appearing in this annual report is accurate as of the date on the front cover of this annual report only. Our business, financial condition, results of operations and prospects may have changed since that date.

Thoratec, the Thoratec logo, Thoralon, and TLC-II are registered trademarks, and Vectra and Aria are trademarks of Thoratec Corporation.

HeartMate and HeartPak are registered trademarks of Thoratec Cardiosystems, Inc. (formerly Thermo Cardiosystems, Inc.) our wholly-owned subsidiary.

Edgar Filing: THORATEC CORP - Form 10-K/A

HEMOCHRON, ProTime, Surgicutt, Tenderlett and Tenderfoot are registered trademarks of International Technidyne Corporation, a wholly-owned subsidiary of Nimbus, Inc. Nimbus, Inc. is a wholly-owned subsidiary of Thoratec Cardiosystems.

ITEM 1. BUSINESS

GENERAL

We began our business in March 1976 and are incorporated in the State of California. Our initial public offering of common stock occurred in 1981.

We develop, manufacture and market proprietary medical devices used for circulatory support, vascular graft, blood coagulation and skin incision applications. We currently market the Thoratec Ventricular Assist Device System (which we call the Thoratec VAD System or the VAD System) and the HeartMate Left Ventricular Assist System (which we call the HeartMate LVAS) in the United States and internationally for use as a bridge to heart transplant. Additionally the Thoratec VAD System is marketed for use in the recovery of the heart after open-heart surgery and the HeartMate LVAS is marketed internationally as an alternative to medical therapy. We have also developed small diameter vascular grafts for use in hemodialysis access and coronary artery bypass surgery. All of these products that come into contact with human tissue or blood incorporate Thoralon, our proprietary biomaterial. Thoralon is a unique biomaterial that provides strength and

2

flexibility to our products with surface properties designed to minimize patient blood clotting and inflammatory response.

Our VAD System is currently the only device approved by the U.S. Food and Drug Administration (FDA) that can provide left, right or biventricular support for both bridge to heart transplant and for recovery of the heart after open-heart surgery. We are also pursuing additional indications for the VAD System and developing other circulatory support products for patients suffering from heart failure. At March 27, 2001, our VAD System had been used in more than 1,500 patients worldwide ranging in age from six to 77 years and in weight from 37 to 317 pounds (17 to 144 kg).

Our hemodialysis access graft product, which we call the Vectra, was approved for sale in the United States in December of 2000 and is currently marketed in Japan through Goodman Co., Ltd. and through Guidant Corporation in the United States and the rest of the world. We believe this graft offers significant advantages over currently available prosthetic grafts used in hemodialysis. Unlike current grafts, which require up to several weeks of patient recovery prior to use, the Vectra's self-sealing design allows for patient use as soon as 24 hours after surgical implantation. We are applying the same technological expertise used in the Vectra for use in coronary artery bypass surgery through our development of our Aria CABG (coronary artery bypass graft). This small diameter graft is designed for use by patients who have no or too few suitable blood vessels of their own. Clinical trials are underway in the United States for the Aria.

On February 14, 2001 we completed a merger with Thermo Cardiosystems Inc., which we call Cardiosystems, a Massachusetts-based manufacturer of cardiac assist, blood coagulation testing, and skin incision devices. As a consequence of the merger, Cardiosystems became our wholly-owned subsidiary, and Thermo Electron Corporation, Cardiosystems' sixty-percent owned parent acquired approximately 36% of our outstanding stock on a proforma basis.

Edgar Filing: THORATEC CORP - Form 10-K/A

At the time of the merger we changed our name from Thoratec Laboratories Corporation to Thoratec Corporation and Thermo Cardiosystems, Inc. was renamed Thoratec Cardiosystems, Inc. (Cardiosystems). Thermo Cardiosystems was originally incorporated in Massachusetts in 1988.

Cardiosystems develops, manufactures, and markets products in two segments: Left Ventricular Assist Systems (LVAS) also called the HeartMate, and blood coagulation testing, and skin incision products through International Technidyne. The Cardiosystems' LVAS is an implantable heart-assist device that is designed to perform substantially all or part of the pumping function of the left ventricle of the natural heart for patients suffering from cardiovascular disease. Cardiosystems has commercialized two systems for patients requiring cardiac support: an implantable pneumatic LVAS that is powered by an external electrically driven air-pump, and an electric LVAS that is driven by an implanted electric motor and powered by a lightweight battery pack worn by the patient.

In 1994, the U.S. Food and Drug Administration (FDA) granted approval for the commercial sale of the air-driven Cardiosystems' LVAS for use as a bridge to transplant. The electric Cardiosystems' LVAS was granted the same approval by the FDA in September 1998. With these approvals, the air-driven and electric systems became available for sale to cardiac centers throughout the United States. In August 1998, the HeartMate LVAS received Canadian approval, permitting the sale of both the air-driven and electric versions throughout Canada. Cardiosystems' air-driven LVAS received the European Conformity Mark (CE Mark) in April 1994, and received the same marking for the electric system in August 1995. In late 1995, the FDA approved the protocol for conducting clinical trials of the electric LVAS as an alternative to medical therapy, and in April 1996, the first patient was implanted with an electric LVAS under this trial. The electric LVAS is being used in Europe as both a bridge to transplant and as an alternative to medical therapy.

In addition, Cardiosystems is developing two advanced HeartMate systems, HeartMate II and HeartMate III, that meet the needs of a wider range of patients, offer extended durability and longevity, and further improve patients' quality of life. HeartMate II is a next-generation LVAS that features a miniature rotary blood pump with axial bearings. Nimbus, Inc. has been involved in artificial heart technology for over 20 years and has carried out research in two primary fields: ventricular assist devices and total artificial hearts. Nimbus was instrumental in developing the basic technology for high-speed rotary blood pumps. Because of

3

their smaller size, rotary blood pumps may potentially be used to provide cardiac support in small adults and in children.

In 2000, Cardiosystems initiated a clinical trial for HeartMate II, with a team of cardiac surgeons in Israel performing the first human implant. Clinical trials are about to commence in Europe, and data are being collected to support our intended Investigational Device Exemption (IDE) submission to the FDA, which, if approved, would allow us to begin conducting a human clinical trial in the U.S. HeartMate III is an advanced heart-assist system featuring a miniature centrifugal pump and state-of-the-art magnetic technology. This system is currently being evaluated under an ongoing animal trial.

International Technidyne Corporation, is a leading manufacturer of near-patient, whole-blood coagulation testing equipment and related disposables, and also manufactures premium-quality, single-use, skin incision devices.

OUR STRATEGY

Edgar Filing: THORATEC CORP - Form 10-K/A

Our goal is to be a leading developer and manufacturer of medical devices to the congestive heart failure, cardiac surgery and vascular graft markets. Our key strategies to achieve this goal are:

Increase Ventricular Assist Device Market Penetration. The Thoratec VAD System is the only ventricular assist device with approvals for both bridge-to-transplant and recovery after open-heart surgery indications and can be used to treat both ventricles for patients of all sizes, and in a less invasive manner than fully implanted systems. The HeartMate LVAS is implantable and is offered both as a pneumatic (air-driven) system and as an electric system driven by an internal electric motor mounted in the blood pump housing. It is approved as a bridge-to-transplant and is undergoing clinical trials in the U.S. as an alternative to medical therapy. We intend to utilize our existing sales channels throughout the world to continue to gain acceptance and adoption by both transplant and non-transplant open heart centers, and to treat a greater number and variety of patients within our current customer base. In addition, in order to further expand the clinical utility of all VAD products, we intend to pursue:

- the U.S. launch of the TLC-II Portable VAD Driver, which weighs approximately 20 pounds and operates interchangeably with current products. The TLC-II improves patient mobility, and is designed to allow patients to be discharged from the hospital while still using the VAD System;
- the completion of the REMATCH (Randomized Evaluation of Mechanical Assistance in Congestive Heart Failure) clinical trial for the HeartMate electric LVAS for use as an alternative to medical therapy;
- the initiation of clinical trials for the HeartMate II LVAS for use as an alternative to transplant;
- the initiation of clinical trials for our implantable ventricular assist device, which we call the IVAD, for use in longer term bridge-to-transplant patients;
- the education of cardiac surgeons and heart failure cardiologists as to the benefits of Thoratec's ventricular assist device products; and
- the regulatory approval of a therapeutic recovery indication.

Significant market expansion opportunities could exist for us in treating the end-stage heart failure patients:

- We estimate that there are as many as 160,000 late stage CHF patients in the United States whose cardiac recovery may potentially be facilitated by the use of the Thoratec VAD System in treating specific types of end-stage heart failure.
- The HeartMate electric LVAS may offer an alternative to current medical therapies in treating late stage CHF patients.

Support the European and the U.S. Market Launch of Vectra. We believe the clinical use of synthetic grafts for dialysis access is an established clinical practice. However, existing commercial graft technologies

have significant shortcomings that are widely recognized. We believe the Vectra device will address some of the most significant of those shortcomings. We

Edgar Filing: THORATEC CORP - Form 10-K/A

received FDA clearance to market and sell the Vectra in the United States in December 2000. We have established distribution partnerships for the Vectra product line, the most significant of which is Guidant. We will continue to identify and pursue opportunities for product line extensions that enhance the Vectra product offering.

Attain Global Approval to Commercialize the Aria Coronary Artery Bypass Graft. We intend to complete Aria coronary artery bypass clinical trials and seek approvals in all major medical device markets. Through clinical trials, we expect to demonstrate the efficacy of the Aria as an option for completing the revascularization of coronary artery bypass patients. These patients' only other option may be very poor quality veins, or even no available veins at all. Therefore, our objective in these clinical trials is to show that the Aria has similar or superior patency rates as compared to poor quality veins. We believe that in as many as 20% of the 900,000 bypass surgeries performed worldwide, the unavailability of any or enough suitable vessels creates a treatment problem.

Explore the Use of Thoralon for Additional Medical Products. Thoralon was developed for safe and effective use in long-term cardiovascular implants, with properties designed to provide:

- excellent blood and tissue compatibility;
- thromboresistance, which means resistance to blood clotting;
- durability; and
- stability.

These properties allow Thoralon biomaterials to be configured and applied in a variety of ways and may allow its use for other medical device applications as a coating or stand-alone material. We intend to apply our biomaterials technologies to those applications where our high-value, critical care implantable medical devices are desired.

Complete the Integration of Thoratec and Cardiosystems. We believe that the merger will result in a combined medical device company with:

- substantially greater resources than Thoratec as a stand-alone company;
- a more diversified product base than that of Thoratec as a stand-alone company;
- an enhanced research and development and manufacturing capability;
- a broader international presence; and
- a larger sales force able to reach more hospitals and doctors.

Continue to Explore the Acquisition of, or Partnership with, Companies that Possess Complementary Products or Technologies. We expect to leverage our expertise and technologies with other products and technologies being developed by other firms or research centers. We have established a strong direct sales presence with some of the world's largest heart centers. We believe other companies, product lines or technologies may benefit from this sales and distribution capability. We intend to pursue opportunities to acquire products or technologies that complement our products and allow us to leverage our competencies in selling and marketing, regulatory affairs and manufacturing.

CIRCULATORY SUPPORT MARKET

Cardiac failure is the leading cause of death in the United States,

Edgar Filing: THORATEC CORP - Form 10-K/A

accounting for more deaths than all forms of cancer combined. Deaths associated with cardiac failure fall into two broad categories:

- congestive heart failure, which is a chronic disorder that occurs when a weakening of the heart muscle reduces the pumping power of the heart; and
- acute cardiac failure resulting from heart attacks and various infections of the heart muscle.

5

CONGESTIVE HEART FAILURE

CHF is a slow, degenerative process leading to cardiac insufficiency resulting in a decreased supply of oxygen and nutrient rich blood to various vital organs such as the lungs, brain and kidneys. CHF tends to be progressive and is associated with profound symptoms that limit daily activities. Long-term survival rates are low. We estimate that more than 85% of patients die within eight to twelve years of diagnosis. CHF is the most common cause of hospitalization in patients over 65 years of age. According to the American Heart Association, there are currently four million to five million CHF patients in the United States, and approximately 550,000 newly diagnosed patients each year. While most patients suffering from CHF are initially treated with medication, which may delay the progression of CHF, conventional drug therapy cannot cure the disease. The only available method of treating end-stage CHF is a heart transplant.

Although heart transplants have been very successful, there are too few donor hearts available to adequately address the problem of cardiac failure. The United Network for Organ Sharing reported that there were only approximately 2,400 hearts available for transplant in the United States in 1998, a level that has remained relatively unchanged for the last several years. However, published government sources estimate that the number of patients suffering from CHF who could benefit from some form of permanent cardiac assist is 30,000 to 50,000 per year. The median wait for a donor heart by patients on a heart transplant waiting list is approximately seven months, and many patients have to wait as long as one to two years before receiving one of the few donor hearts available each year. In 1998, approximately 19% of such patients died while waiting for a donor heart.

When other therapies are unsuccessful, ventricular assist devices can be used to support one or both sides of the patient's heart until a donor heart can be found. Ventricular assist devices are mechanical systems used to assist the heart's function. In patients awaiting heart transplants, physicians decide to use a ventricular assist device when the death of the patient appears imminent.

ACUTE CARDIAC FAILURE

In addition to providing a bridge to heart transplant, ventricular assist devices have other potential applications. It is estimated that out of approximately 800,000 open-heart surgeries performed annually in the United States, some 15,000 to 20,000 patients die following such procedures, resulting in a total VAD market potential of over \$300 million. We believe that only approximately ten percent of the potential market is currently being treated with VAD devices. Many of these deaths are caused by heart failure when the heart, weakened by disease and the additional trauma of surgery, fails to maintain adequate blood circulation. The use of a ventricular assist device after surgery can support the circulation to the heart until it recovers. In addition, ventricular assist devices may also be useful in assisting the recovery of the heart in a small portion of patients suffering from acute cardiac failure that may result from heart attack and various infections of the

Edgar Filing: THORATEC CORP - Form 10-K/A

heart muscle. There is significant demand for effective ventricular assist devices serving a broad spectrum of patient profiles.

THORATEC CIRCULATORY SUPPORT PRODUCTS

We received FDA approval in December 1995 to market the Thoratec VAD System as a bridge to heart transplant in patients suffering from heart failure, and began marketing the VAD System in the United States in January 1996. The VAD System has received regulatory clearance and is currently being marketed in major European countries, Canada and certain other major international markets. As of February 2001, our VAD System had been used in more than 1,500 patients worldwide ranging in age from six to 77 years and in weight from 37 to 317 pounds (17 to 144 kg). The VAD System has also been approved for use after heart surgery to rest the heart and allow it to recover.

6

OVERVIEW OF THE THORATEC VAD SYSTEM

The VAD System consists of three major components:

- the single-use blood pump, a type of artificial ventricle;
- the single-use cannulae, which connect the blood pump to the heart and vessels; and
- the Thoratec Dual Drive Console, a multi-use device that pneumatically activates the blood pump.

Also available in international markets is the TLC-II Portable VAD Driver, a small lightweight unit that can be used interchangeably with the Dual Drive Console and is designed to allow the patient to move around the hospital or return home. A PMA Supplement was submitted to the FDA in September 2000 for market approval for the TLC-II in the United States.

The VAD System provides partial or total circulatory assistance when the natural heart is unable to maintain adequate circulation to perfuse vital organs and permits left, right, or biventricular support.

ADVANTAGES OF THE THORATEC VAD SYSTEM

Compared to other ventricular assist devices, we believe that the VAD System has the following principal advantages:

- Biventricular Support. Most long-term systems available today provide only left ventricular support. While many patients do well with only a LVAS, we estimate that at least 20 - 30% of these patients also have or can develop right ventricular failure and require a right ventricular assist device (RVAD). Death and morbidity rates are extremely high for this patient group if not adequately supported. Since there are no risk factors that allow a surgeon to predict reliably which patients will require biventricular support, the decision for univentricular or biventricular support is simplified with the Thoratec VAD System, as RVAD support may be added at the time of LVAS placement if needed. Isolated RVAD support may also be suitable for patients with right heart failure only.
- Paracorporeal Placement. With the Thoratec VAD System, the blood pump is worn outside the body. This placement facilitates patient movement and allows patients to walk, exercise and move around the hospital. This paracorporeal placement allows the system to support patients of varying

Edgar Filing: THORATEC CORP - Form 10-K/A

sizes, including very small patients such as small women, adolescents and children. To date, our VAD System has been used in patients as small as 37 pounds and as young as six years old. In contrast, other commercially available ventricular assist devices for bridge to heart transplant must be implanted and can only be used in patients large enough to accommodate the device within their abdomen. In addition, unlike implantable VAD's, paracorporeal attachment does not require two invasive abdominal surgeries, one for implant and one for extraction. This makes the VAD System more suitable for critically ill patients who may potentially recover normal function of the heart without this additional surgical trauma.

- Multiple Indications. Our VAD System is the only device approved in the United States to provide circulatory support for both post open-heart surgery recovery and bridge to transplant indications. To date, the VAD System has been used to support patients for periods ranging from a few hours to well over one year. This unique flexibility to treat multiple patient groups allows hospitals to invest in a single product line and, therefore, make a smaller investment in inventory as one product line can be used with two patient groups. In addition, the surgical training required for our device can apply to a broader patient population. Also, for those post open heart surgery patients who become transplant candidates, use of our VAD System can eliminate the need for a second surgery to remove a device designed or approved for recovery only.
- Thoratec Biomaterials. Our proprietary biomaterials are used in most surfaces of the VAD System that contact blood or are implanted in the body, providing biocompatibility, resistance to blood clotting, flex life and strength. These materials have been used in cardiovascular products for over 15 years. We have also licensed these biomaterials to health care manufacturers Gambro, Inc. and COBE Cardiovascular for use in non-competing applications.

7

- Multiple Cannulation Options. Cannulae for the VAD System come in a number of shapes and sizes, allowing the surgeon to fit the size of the cannulae to the size of the patient and to place the cannulae in different parts of the heart. Other commercially available systems have only limited cannula shape and size. The small size of our cannulae, compared to other systems, could make it easier for the heart to recover when the cannulae are removed. Variations of our cannulae also allow the surgeon to place the cannulae in places other than the apex of the heart (the only place used by the currently available left ventricular-only systems).

CURRENT AND POTENTIAL INDICATIONS

We have identified the following three basic clinical needs for the Thoratec VAD System:

- Bridge to Heart Transplant. We commenced marketing the Thoratec VAD System in the United States in January 1996 for use as a bridge to heart transplant in patients suffering from heart failure following receipt of pre-market approval from the FDA in December 1995. In 2000, we sold 689 VAD pumps to heart centers worldwide. We maintain a record of all patients reported treated with the VAD System, which we call the Voluntary Registry. Since FDA approval, this registry has relied upon strictly voluntary input from our customers. As of February 2001, our Voluntary Registry included 931 patients treated with the VAD System for bridge to transplant. At any given time, there are approximately 4,000 to

Edgar Filing: THORATEC CORP - Form 10-K/A

5,000 patients on the waiting list for a heart transplant in the United States, and we believe a comparable number are waiting in Europe. We believe that the percentage of these patients bridged to transplant will continue to increase, as surgeons' level of comfort with the technology increases, particularly for longer-term support cases.

- Recovery of the Natural Heart. Approximately two percent of patients who undergo open-heart surgery have difficulty recovering normal cardiac function, which makes it difficult to wean the patient from the heart/lung machine. Patients can only stay on the heart/lung machine after surgery for a limited period of time (generally less than six hours), and if they are unable to regain normal heart function, they will not survive without ventricular support. The use of a ventricular assist device after surgery can provide support to the heart until the heart can recover. We received FDA approval for this indication in May 1998.

As of February 2001, our voluntary registry reported that the VAD System had been used in 274 patients who were unable to regain normal heart function following surgery requiring cardiopulmonary bypass and were, therefore, unable to be removed from the heart/lung machine following surgery. Normally, patients who cannot be weaned from the heart/lung machine die. Of the 274 patients who have been placed on the VAD System, 34% (94 patients) survived following removal from the heart/lung machine. Of those patients, 59% were discharged from the hospital. Duration of patient cardiac support ranged from one to 118 days. Although most patients were supported less than ten days, several required support for between one and three months before they successfully recovered cardiac function.

- Therapeutic Recovery as an Alternative to Heart Transplant. We believe that for most patients, recovery of his or her own heart is a better alternative than either heart transplantation or permanent implantation of a blood-pumping device. Based on recently reported cases of recovery in heart failure patients, we believe that the VAD System is a potential therapy to reverse the complications of late-stage heart failure in certain patients. In December 2000, we filed a PMA Supplement with the FDA seeking approval to market the Thoratec VAD System for bridge to recovery in the therapeutic treatment and reversal of late stage heart failure in certain types of patients. While this therapeutic recovery indication is not yet approved for the device, we continue to actively investigate the worldwide experience with the Thoratec VAD System for this indication. It is estimated that as many as five million Americans experience congestive heart failure each year, and it is believed the use of the VAD System for therapeutic recovery could represent a significant opportunity for these patients, their doctors and Thoratec. We are working with physicians to track the experience of all patients who

8

recover while being treated with the VAD System while we continue to implement our regulatory and clinical strategy both in the U.S. and abroad.

We have noted that approximately two dozen patients have experienced recovery of their natural heart while being supported by the Thoratec VAD System. These patients have ranged in age from 12 to 46 years old and have been supported by the VAD System from ten to 190 days. Our PMA Supplement submission to the FDA included retrospective chart analysis of patients who have recovered compared with a control group of patients that were part of the primary cohort presented in our bridge to transplant PMA.

Edgar Filing: THORATEC CORP - Form 10-K/A

CIRCULATORY SUPPORT PRODUCTS UNDER DEVELOPMENT

In addition to our commercially available VAD System, we currently have under development or in the final stages of U.S. regulatory approval the circulatory support products described below. We may be unable to successfully develop any of these products, or if successfully developed, these products may not obtain regulatory approval or market acceptance or be manufactured and sold on commercially acceptable terms.

- TLC-II Portable VAD Driver. Although patients supported with the Dual Drive Console can walk throughout the hospital and transfer from critical care units to general wards, they usually cannot leave the hospital because of the size of the console. We have developed the TLC-II, a compact and lightweight (approximately 20 pounds), battery or line-operated biventricular pneumatic drive unit designed to promote greater mobility and self-care. It is designed to allow the patient to exercise more easily and move freely around the hospital grounds and eventually leave the medical facility. This device provides several portability options, either by hand-carrying the driver or by using a shoulder strap or mobility cart. This portable device connects with a docking station, which houses a battery charger and the external monitoring computer.

We received authority to CE Mark (an international symbol of quality required for products to be distributed in the European Community) this product in March 1998 and introduced the TLC-II in Europe in the middle of 1998. We received approval for an IDE from the FDA in November 1998 to begin a clinical trial of this device in the United States for use in conjunction with the approved VAD System and submitted a PMA supplement to the FDA in September 2000. We hope to receive FDA clearance of the TLC-II device in the first half of 2001.

In November 2000, we received approval from the FDA of an IDE supplement allowing for an additional 20 patients to be enrolled in an existing clinical trial using the TLC-II and we filed an additional original IDE for a new clinical trial involving home discharge of patients being supported by the TLC-II. In December 2000, we received conditional approval from the FDA of the home discharge IDE. The new trial will involve up to 35 patients at up to 15 hospitals. Once the total data added from all patients reaches 365 days of at-home VAD system support, that data will be submitted to the FDA in a separate PMA supplement. In February 2001, the first U.S. patient was discharged from the hospital supported by the TLC-II.

- Implantable VAD (IVAD). While the placement of the current VAD System outside the body of the patient has the advantages described above, we are developing an implantable version of our existing VAD blood pump and cannulae to provide additional options for surgeons. The Thoratec IVAD is designed for patients who require long-term VAD support. It is also significantly smaller than the other commercially available implantable LVAS devices, weighing approximately one pound. Because of its small size, the IVAD can be used in smaller patients, and through the use of two IVADs, in some biventricular patients, a capability unique to any commercially available implanted VAD device. In January 2001 we filed an IDE for the IVAD with the FDA to start clinical trials in the United States. The study is expected to treat up to 30 patients at up to ten hospitals. In February 2001, we received conditional approval of the IDE from the FDA.
- MVAD. MVAD is being developed as a muscle-powered, implantable VAD system that is expected to free patients from the battery powered console. MVAD

Edgar Filing: THORATEC CORP - Form 10-K/A

uses the patient's own muscle system to

9

hydraulically power a VAD pump. New technologies being developed for the MVAD product include tendon attachment methodology, a hydraulic transmission line between energy converter and blood pump, a modified IVAD for specific application for skeletal muscle applications, a compliance chamber, optimized pacing protocols, new surgical implantation techniques and control algorithms.

CARDIOSYSTEMS' CIRCULATORY SUPPORT PRODUCTS

Cardiosystems has commercialized two versions of its implantable LVAS and is developing two advanced systems, the HeartMate II and HeartMate III. Either a bedside or portable console can control the implantable pneumatic, or air-driven, system. The electric system features an internal electric motor powered by an external battery pack worn by the patient. All of Cardiosystems' Left Ventricular Assist Systems employ the HeartMate blood pump, and are designed for long-term use. This pump is implanted just below the diaphragm in a position that minimizes interference with normal circulation and other bodily functions. An inlet tube is inserted into the apex of the left ventricle to drain blood into the pump chamber. Blood is then forced out of the pump through an animal tissue valve and back into the aorta. The HeartMate blood pump works with the biological control mechanism of the natural heart to increase pumping capability when required for activities such as climbing stairs. Cardiosystems' LVAS devices are at various stages of regulatory approval.

AIR-DRIVEN LVAS. In October 1994, the FDA approved the air-driven system as a bridge to transplant for patients awaiting heart transplantation. This approval allows the air-driven LVAS to be sold to any of the nearly 900 cardiac surgery centers in the United States. In April 1994, Cardiosystems received the CE Mark for commercial sale of the air-driven LVAS in all European Community countries. In August 1998, the Medical Devices Bureau of Health Canada issued a Notice of Compliance for the air-driven HeartMate LVAS, permitting its sale throughout Canada. In the air-driven LVAS, the HeartMate blood pump is coupled to an external console connected to the body by a tube. Cardiosystems has also developed the HeartPak, a lightweight portable console that can be carried over the shoulder. The portable console received the CE Mark for commercial sale in European Community countries in February 1995. In July 1995, the FDA approved the beginning of clinical trials of the HeartPak portable pneumatic driver, and Cardiosystems began evaluating the safety of the system in the hospital. In June 1999, the FDA approved Cardiosystems' request to begin evaluating the HeartPak in the home environment. With this approval, patients in the trial may be discharged routinely.

ELECTRIC LVAS. Cardiosystems has also developed an electric LVAS that uses the HeartMate blood pump driven by an internal electric motor mounted in the blood pump housing. The system is connected to its external battery pack by wires that exit the body. Since the power source and control elements are worn on a battery belt, the system allows the patient complete mobility. In August 1995, the electric LVAS received the CE Mark, allowing commercial sale of this system in all European Community countries. The electric system is used as a bridge to transplant in the United States, Europe, and other regions, and is also implanted as an alternative to heart transplant in Europe and other regions. In August 1998, the Canadian Health approved the electric HeartMate LVAS, for sale throughout Canada. In September 1998, the FDA approved the electric system for commercial sale as a bridge to transplant for patients awaiting heart transplantation.

Edgar Filing: THORATEC CORP - Form 10-K/A

In December 1995, the FDA approved the protocol for conducting clinical trials of the electric LVAS as an alternative to medical therapy. The trial is called the REMATCH study and is expected to compare the results of approved patients using the device to a similar number using drug therapy. In December 1997, the FDA approved Cardiosystems' proposal to broaden the entrance criteria and increased the number of participating sites under this trial. We estimate that we will complete patient enrollment into this trial in 2001.

HEARTMATE II. HeartMate II is a next-generation LVAS that features a miniature rotary blood pump with axial bearings. In 2000, Cardiosystems initiated a clinical trial for HeartMate II, with a team of cardiac surgeons in Israel performing the first human implant. Data are being collected to support the intended IDE submission to the FDA, which, if approved, would allow Cardiosystems to begin

10

conducting a human clinical trial in the U.S. Because of its smaller size, HeartMate II may potentially be used to provide cardiac support in small adults and in children.

HEARTMATE III. HeartMate III is an advanced heart assist system featuring a miniature centrifugal pump and state-of-the-art magnetic technology. This system is currently being evaluated under an ongoing animal trial. We believe the HeartMate III will have a significantly longer life than any such device requiring traditional bearings because its moving components do not contact each other.

VASCULAR GRAFT MARKET

VASCULAR ACCESS FOR HEMODIALYSIS

The principal use of vascular access grafts is for hemodialysis for patients with end stage renal disease ("ESRD"), a debilitating disorder characterized by gradual erosion of kidney function. ESRD is irreversible, and the majority of all patients suffering from this disease worldwide are maintained by hemodialysis. According to the U.S. Renal Data System's 1999 Annual Data Report, hemodialysis is the primary treatment for approximately 87% of all end stage renal disease patients in the United States, an estimated 195,000 patients at the end of 1997. Market estimates suggest that approximately 200,000 prosthetic vascular access grafts used for hemodialysis were implanted worldwide in 1999, representing an annual market approaching \$120 million. We estimate that the United States represents less than one-half of the worldwide hemodialysis patient population.

Hemodialysis removes toxins and excess fluid from a patient's blood by circulating the blood through a dialyzer, or so-called "artificial kidney." This procedure is generally performed three times per week and lasts three to four hours. Patients undergoing hemodialysis require easy, routine access to the blood stream at a high flow rate. This access to the patient's blood stream is achieved using one of three methods: creation of an arterio-venous (A/V) shunt from the patient's blood vessels, inserting a central venous catheter, or implanting an artificial vascular access graft (VAG). The majority of hemodialysis patients in the United States depends on the use of a VAG that is surgically connected between the patient's artery and vein. The vast majority of available VAGs are made from expanded polytetrafluorethylene (ePTFE). The graft is accessed using needles connected to tubing that carries the patient's blood to the dialyzer and returns it back cleansed to the patient.

Vascular access methods currently available for hemodialysis applications

Edgar Filing: THORATEC CORP - Form 10-K/A

have certain limitations. Both A/V shunts and ePTFE grafts must mature for two to six weeks before use and therefore require the use of a temporary central venous catheter until the graft is ready for use. Such catheters entail additional cost, including those associated with catheter insertion, maintenance and treatment for complications, and risk to the patient such as infection, thrombosis and venous stenosis. Additionally, ePTFE VAGs are usually accompanied by profuse and prolonged bleeding, often up to 20 minutes, when the needles used for hemodialysis are removed, increasing patient treatment time at the dialysis center.

CORONARY ARTERY BYPASS SURGERY

Currently, obstructed coronary arteries are either partially cleared through the use of angioplasty or related procedures or treated surgically through coronary artery bypass surgery. Coronary artery bypass surgery involves connecting one or more new vessels from the aorta to the heart to re-route blood around blockages in the coronary arteries. Grafts using saphenous veins (from the leg) or the internal mammary artery of the patient have been successfully used in bypass procedures for a number of years and have shown a relatively high patency with no risk of tissue rejection. We estimate that in 1998 there were approximately 600,000 coronary artery bypass surgery procedures performed in the United States and approximately 300,000 performed outside the United States. We estimate that on average three bypasses are performed in each surgical procedure.

While the use of natural vessels is the standard of care in coronary artery bypass surgery, the harvesting of vessels from the patient for grafts involves significant trauma and expense. Use of these vessels requires additional time in surgery and results in patient morbidity associated with removal of the blood vessel. In addition, a significant number of patients requiring coronary artery bypass surgery have insufficient vessels as a result of previous bypass surgeries, or their vessels are of inferior quality due to trauma or disease. We estimate

11

that these patients may represent as much as 20% of the total patients undergoing bypass surgery. No artificial graft currently has full market approval or is being marketed in the United States for coronary artery bypass surgery, but we believe a significant market opportunity for such grafts exists. The major reason for the unavailability of a synthetic graft for this indication has been that synthetic grafts configured in small diameters (less than five millimeters) necessary for this indication generally do not remain patent.

THORATEC VASCULAR GRAFT PRODUCTS

We are developing small diameter vascular graft products intended initially to address the vascular access and coronary artery bypass surgery markets. Both products utilize our proprietary Thoralon biomaterial, and are protected by several patents covering Thoralon as well as the graft design and manufacturing processes. We believe that our vascular grafts are highly compliant, have excellent handling and suturing properties and have the "feel" of a natural blood vessel. Our manufacturing process creates a structure in which the three different layers in the graft wall have different properties, which make the graft closely resemble natural blood vessels. The inner textured layer is designed for contact with blood and provides improved resistance to blood clots. The solid middle layer gives the graft its strength and self-sealing properties. The outer textured layer is designed to promote tissue ingrowth to promote graft stability.

VECTRA VASCULAR ACCESS GRAFT

Edgar Filing: THORATEC CORP - Form 10-K/A

Other currently available vascular access grafts are commonly made out of ePTFE, which can lose integrity after repeated punctures and render the patient susceptible to bleeding and infection. The Vectra is designed for use as a shunt between an artery and a vein, primarily to provide access to the bloodstream for renal hemodialysis patients requiring frequent needle punctures during treatment. We believe that the Vectra may provide significant advantages over existing synthetic vascular access grafts that may encourage its use by surgeons who are currently using natural vessels for vascular access. The Vectra received marketing approval from the Canadian Ministry of Health in March 1996, from the Japanese Ministry of Health in May 1997, and authority to CE Mark the product in January 1998. In the second quarter of 2000, we submitted a 510(k) premarket notification to the FDA and we received FDA clearance to market and sell the Vectra in the United States in December 2000.

Based upon data obtained in clinical trials we believe that the Vectra offers the following advantages:

- reduced inflammatory response after implantation;
- the ability to begin hemodialysis as soon as 24 hours after implantation, as opposed to several weeks for ePTFE grafts;
- reduced bleeding complications during routine use because of the Vectra's self-sealing properties; and
- improved handling and suturability.

The Vectra vascular access graft was approved for distribution in the United States in December 2000. Clinical trial data involving 142 patients submitted to the FDA showed that the Vectra grafts were allowed cannulation for dialysis as early as 24-hours, with a significantly shorter time to hemostasis as compared to ePTFE grafts. The Vectra grafts also had comparable patency rates to the ePTFE control. These results were presented for the first time at the Southern Association for Vascular Surgery in January 2001 and the manuscript is being reviewed for publication in the prestigious Journal of Vascular Surgery.

In January 1999, we entered into a distribution agreement with Guidant Corporation. Under the terms of this agreement, Guidant receives exclusive worldwide marketing and distribution rights to the Thoratec Vectra product line, except in Japan. In exchange for these rights, Guidant paid us \$1.5 million at the time the agreement was signed and paid us an additional \$2.0 million when the Vectra product line received FDA approval for use in the United States in December 2000.

12

ARIA CORONARY ARTERY BYPASS GRAFT

We have developed from our proprietary Thoralon biomaterials a small diameter graft for use in coronary artery bypass surgery patients who have no suitable vessels of their own. A total of 27 patients in Canada and Germany received our Aria coronary artery bypass grafts, ranging in internal size from 2.0 to 3.5 millimeters. All patients were extremely ill at the time of surgery, and the grafts were implanted on a compassionate use basis (i.e., the patients were found to have no other viable therapeutic options). All 22 surviving patients were asymptomatic at follow-up points ranging from 2.5 to 5 years after surgery. Of the five patients who did not survive, none is known to have died from causes related to the graft. We need long-term test results from a controlled clinical trial on a much larger patient population before we can demonstrate the capabilities of this graft.

Edgar Filing: THORATEC CORP - Form 10-K/A

The potential for improved long-term patency in small diameter grafts is the most unique aspect of the Aria. We believe that to date no other suitable small diameter graft has been developed which will remain patent over long periods of time when used in this critical application.

Thoratec received the FDA approval for a Phase I IDE study of the Aria graft in May 2000. This study is designed to evaluate the Aria graft in patients with inadequate autologous vessels to complete revascularization. Phase I study will enroll up to 30 patients at six institutions. The first patient was enrolled in July 2000 and as of February 2001, 14 patients have received the Aria graft. After at least 20 patients have reached the two month follow-up period, Thoratec will submit a summary of the clinical findings to the FDA and request approval to begin the pivotal Phase II study involving an additional 120 patients and nine institutions. This submission is expected to occur sometime in the middle of 2001.

OTHER POTENTIAL APPLICATIONS OF OUR TECHNOLOGIES

In addition to the Vectra and Aria, our graft products and biomaterial technologies may potentially be used in other applications such as peripheral vascular grafts for patients who require restoration of circulation to their arms or legs due to blockages caused by certain disease processes. They may also be used as a patch material in cardiovascular or peripheral vascular repair procedures. While we are not currently pursuing development of these applications, we have completed sufficient early stage preclinical work in the graft area to believe our graft products could be developed for these applications. Guidant has a right to negotiate for these applications for a short period if we decide to develop them during the term of the Vectra distribution agreement.

THORATEC BIOMATERIALS -- THORALON

We have developed a proprietary biomaterials technology that is used in the Thoratec VAD System and graft products and licensed to other health care manufacturers.

Our Thoralon biomaterials technology is critical to the successful performance of the Thoratec VAD system and graft products that come into contact with human blood or tissue. These products and some of those under development incorporate these proprietary biomaterials, which are designed to minimize blood clotting and inflammatory response. In addition, these products must maintain their strength and flexibility. A VAD System blood pump, for instance, must contract and expand approximately 40 million times per year without a decrease in performance or failure. The two major components of Thoralon are surface modifying additives ("SMAs") and BPS-215 polyurethaneurea ("BPS-215"), a high flex-life elastomer.

SMAs are proprietary multipolymers designed to enhance the biocompatibility of the surface of a device that comes into contact with blood or other tissues. SMAs are added to the base polymer component of the biomaterial in the bulk fabrication stage. A unique property of SMAs is their ability to concentrate at the surface of any finished part, thus determining its surface properties independent of the base polymer. This SMA-based surface layer is not a coating but a fully integrated part of the polymer, which is not soluble in water or blood. The result is a biocompatible, thromboresistant surface. BPS-215 is the base component that provides the bulk properties of strength and flexibility to Thoralon. The combination of bulk and surface

Edgar Filing: THORATEC CORP - Form 10-K/A

properties provided by SMAs and BPS-215 provides Thoralon with the critical properties necessary for implantable cardiovascular and other medical devices.

In 1992, we granted COBE a royalty-bearing license and sublicense to use Thoratec's SMAs in certain COBE medical devices. In 1999, this license was divided into two separate licenses. One is retained by COBE Laboratories, now called Gambro, Inc., one of our major shareholders, and the other was granted to Sorin COBE Cardiovascular when that division of Gambro was sold to Sorin.

CARDIOSYSTEMS' OTHER MEDICAL EQUIPMENT

Cardiosystems, through its subsidiary International Technidyne, manufactures and supplies whole-blood coagulation testing equipment and related disposables, as well as premium-quality, single use, skin incision devices.

WHOLE-BLOOD COAGULATION TESTING EQUIPMENT. The HEMOCHRON and HEMOCHRON Jr. Signature product lines offer whole-blood coagulation systems for bedside anticoagulation management, coagulation screening, and transfusion management. Each analyzes small blood samples, then processes and quickly displays comprehensive patient homeostasis information. Blood management of this type is essential for cardiopulmonary bypass surgery and angioplasty. HEMOCHRON models are designed for use in a clinical setting at the patient's bedside. They are lightweight, battery-operated, portable, and some provide data-management features.

THE PROTINE MICROCOAGULATION SYSTEM. This system is designed to allow testing for patients who take the blood-thinning drug Warfarin (Coumadin). The system consists of a hand-held instrument, a five-channel cuvette, and a finger incision device. These tests are performed in a doctor's office, clinic, or by the patients themselves. This instrument was the first such device approved by the Federal government for home use.

SKIN INCISION DEVICES. International Technidyne manufactures a family of single-use skin incision devices for drawing blood from adults, children, and infants. Each employs a patented skin incision technology to provide a standardized surgical incision. International Technidyne's line of Surgicutt products are used to perform bleeding time tests on adults, children, and newborns. The Tenderlett finger incision products for blood sampling are available in models suitable for adults, children, and infants and toddlers. Tenderfoot is a heel incision device that is designed specifically for toddlers, infants, and premature infants. These devices feature a permanently retractable blade to ensure safety for the patient and healthcare worker.

14

SUMMARY OF EXISTING PRODUCTS AND PRODUCTS UNDER DEVELOPMENT

The table below summarizes our existing products and products under development.

| CIRCULATORY SUPPORT PRODUCTS | INDICATIONS | MARKETING STATUS |
|--|--|--|
| Thoratec VAD System, which consists of a single-use blood pump and cannulae, and a multi-use drive console which | <ul style="list-style-type: none"> - Bridge to transplant - Recovery after heart surgery | - Currently marketed in the United States and internationally for bridge to transplant recovery of the heart aft |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | |
|--|--|--|
| pneumatically activates the blood pump | - Therapeutic recovery as an alternative to heart transplantation | heart surgery. - PMA Supplement filed with FDA in December 2000; Comments have been received from t and are being evaluated. |
| TLC-II Portable VAD Driver, which is a battery or line operated pneumatic mobile drive unit weighing approximately 20 pounds | - Designed to improve patient mobility and facilitate hospital discharge. | - Currently marketed internationally; PMA Supplement submitted September 2000 hospital use; IDE approved use outside hospital. |
| IVAD, an implantable VAD weighing less than one pound | - Designed to support longer term bridge to transplant and recovery patients. | - Conditional approval of I received from FDA in February 2001. |
| MVAD, implantable Muscle Driven Support Device | - Alternative to heart transplant | - Very early stages of laboratory testing |
| Air-Driven HeartMate LVAS | - Bridge to transplant | - Currently marketed in the United States and in European countries for bridge to transplant. |
| Electric Driven HeartMate LVAS | - Bridge to transplant - Discharge from hospital - Alternative to medical therapy - Alternative to transplant | - Currently marketed in the and Europe. - REMATCH clinical study in for use as an alternative to medical therapy; expected to complete enrollment in mid- |
| HeartMate II | - Designed to be the smallest of the VAD family of products for longer-term bridge to transplants patients. | - Clinical trials to start Europe in first half of 200 |
| HeartMate III | - Designed to be longer-term product for all uses incorporating state-of-the-art magnetic technology. | - Currently being evaluated ongoing animal trials. |

| VASCULAR GRAFT PRODUCTS | INDICATIONS | MARKETING STATUS |
|--|--------------------------------------|---|
| Vectra, small diameter graft for patients needing hemodialysis | - ESRD patients needing hemodialysis | - Currently marketed through distributors in the United States and internationally. 510(k) approval received December 2000. |
| Aria, small diameter graft for | - CABG patients needing vessels | - U.S. clinical trials unde |

Edgar Filing: THORATEC CORP - Form 10-K/A

patients with blocked arteries and inadequate vessels of their own

for revascularization

IDE for Phase I approved March 2000. Expanded to six sites July 2000.

OTHER MEDICAL EQUIPMENT

INDICATIONS/DESCRIPTION

MARKETING STATUS

HEMOCHRON (R)
coagulation testing equipment

- Assessment of coagulation (hemostasis) status in cardio-pulmonary bypass surgery
- Catheterization procedures
- Critical care
- Intensive care
- Step-down units
- Dialysis

- All instruments approved available worldwide.

ProTime microcoagulation

- Prothrombin time assessment for patients on Coumadin (warfarin) therapy for home and clinic use

- Available worldwide.

Skin Incision Devices

- Surgicutt
- Tenderlett
- Tenderfoot

- Bleeding time assessment
- Finger stick incision for blood collection
- Heel stick incision for infants and toddlers blood collection

- All instruments approved available worldwide.

SALES AND MARKETING

Following the merger with Cardiosystems we will operate in two business segments with different products. One segment contains circulatory support and graft products with the other segment containing coagulation, testing, and skin incision products.

CIRCULATORY SUPPORT PRODUCTS

The potential customers for our circulatory support products are hospitals that perform open heart surgery procedures and heart transplants. Based upon published sources, we estimate that 140 of the approximately 900 hospitals in the United States that perform open-heart surgery also perform heart transplants. We are initially targeting these 140 heart transplant hospitals and the largest of the remaining 900 hospitals plus an additional 110 heart transplant hospitals in Europe.

We have recruited and trained a direct sales force that, as of March 2001, was comprised of 20 experienced cardiovascular sales specialists to sell the Thoratec VAD System and HeartMate LVAS products in the United States, Canada, France, Germany, Spain, United Kingdom, Austria, Switzerland, Netherlands, Portugal and South Africa.

The sales effort is complemented by eleven direct clinical specialists that conduct clinical educational seminars, assist with a new open heart center's first VAD implant and resolve clinical questions or issues. We also partner with universities, experienced clinicians and opinion leaders to assist with expanding clinical educational needs. The sales team focuses on cardiac surgeons that perform heart transplantation and transplant cardiologists, perfusionists and the transplant nursing staff. In addition to our direct selling effort,

Edgar Filing: THORATEC CORP - Form 10-K/A

we have established a network of international distributors that cover those markets that represent the majority of ventricular assist device potential. We employ sales and marketing tactics commonly found within the cardiovascular capital equipment device market such as direct mail, clinical education seminars, symposia, equipment purchase and lease programs, and journal advertisement. We have also assembled a Medical Advisory Board consisting of opinion leaders who provide clinical input and direction on product development, marketing and market issues.

Hospitals or other medical institutions that acquire the VAD System or the HeartMate LVAS generally purchase VAD pumps, related disposables and training and purchase or rent two of the associated pump drivers (to ensure that a backup driver is available). The time from the initial contact with the cardiac surgeon until purchase is generally between nine and eighteen months, due to the expense of the product and common hospital capital equipment acquisition procedures. Upon receipt of a purchase order, we will usually ship the products within thirty days.

The introduction of a new system requires training of the appropriate personnel. We provide initial training for the surgical and clinical support teams when a center purchases and takes delivery of one of our VAD products. As a follow-up to the initial training, we provide clinical support at the first implant whenever possible. We also provide 24-hour access to clinically trained personnel. Our sales force also assists customers with obtaining reimbursement from third-party payors.

VASCULAR GRAFT PRODUCTS

We intend to market the Vectra through our distributor in Japan and through Guidant in the rest of the world, and to market the Aria CABG device through a direct sales force in the United States and Europe and potentially through distributors in other international markets.

We envision the market positioning of the Vectra as one that replaces an existing product used in an accepted procedure, and at a comparable or premium price. We plan to commission additional studies comparing our products to ePTFE grafts. We believe the Vectra will have significant advantages over these existing products and will therefore offer significant benefits to users and patients, without the need for additional clinical training. We also believe the demand for prosthetic VAGs will continue to grow. The worldwide hemodialysis patient population continues to grow and is older and living longer, increasing the requirement for multiple access procedures over many years. Additionally, this population is increasingly made up of sicker patients, such as diabetics, who have exhausted the number of sites available for A/V fistula creation, thereby necessitating the need for a prosthetic VAG.

We intend to initially position the Aria CABG device as a preferable clinical option for patients who lack suitable native vessels. We believe that more clinician education will be required for the Aria CABG device in terms of patient indications, product use, and product capabilities. We may accomplish this education by sponsoring educational programs, video educational tools, and scientific lecture programs. We also anticipate that we will need a larger domestic sales force structure to effectively market the Aria CABG device.

BLOOD COAGULATION, TESTING, AND SKIN INCISION DEVICES

International Technidyne maintains a direct sales staff of 31 in the United States, selling to hospitals as well as to third party dealers/distributors. Outside of the United States, International Technidyne has two sales people selling principally to third party dealers.

Edgar Filing: THORATEC CORP - Form 10-K/A

MANUFACTURING

We manufacture our Thoratec VAD System and graft products at our 62,000 square foot leased facility in Pleasanton, California. This facility was inspected by the FDA under cGMP regulation prior to entering into production and has received the International Standards Organization (ISO) 9001 certification.

Our manufacturing processes for the VAD System consist of the assembly of standard and custom component parts, including blood-contacting components fabricated from our proprietary biomaterials, and the testing of completed products. We rely on single sources of supply for several components of the

17

VAD System. We are aware of alternative suppliers for all single-sourced items other than the mechanical valves. In October 1997, we executed a four-year supply agreement with Arrow International Inc. for the mechanical valves for the VAD System.

Cardiosystems' products are manufactured at facilities that we believe are in good condition and are adequate for present operations. We also believe that suitable alternative space is readily available if any leases are not extended. The Cardiosystems' properties by industry segment as of December 30, 2000, are as follows:

- HeartMate devices are manufactured at a 34,000 square foot sub-leased facility in Woburn, Massachusetts.
- Blood coagulation, testing, and skin incision devices are manufactured at a 66,000 square feet owned facility and a 24,000 square foot leased facility in Edison, New Jersey.

PATENTS AND PROPRIETARY RIGHTS

We seek to patent certain aspects of our technology. We hold, or have exclusive rights to, several U.S. patents. Except for the biomaterials patents mentioned below, which are utilized in the Thoratec VAD blood pump and cannulae, the VAD System is not protected by any patents other than one patent pertaining to the TLC-II. We do not believe that this lack of patent protection will have a material adverse effect on our ability to sell the VAD System because of the lengthy regulatory period required to obtain approval of a ventricular assist device. We are not aware of any ventricular assist devices that are based on our product design currently approved by the FDA or undergoing clinical trials. Several patents cover our proprietary biomaterials technology, some of these were sold to The Goldschmidt AG ("Goldschmidt"), a German chemical manufacturer, in 1989, but we have retained worldwide, royalty-free, exclusive rights to these patents for most medical applications. Our vascular graft products are covered by manufacturing process patents.

We and our subsidiaries hold, or have exclusive rights to, several international patents, including several biomaterial patents licensed from Goldschmidt. Thermedics has granted Cardiosystems a royalty-free license to use the Dermaport(R) access device and Tecoflex(R) biomaterial in its LVAS.

The validity of any of our patents may be challenged by others, and we could encounter legal and financial difficulties in enforcing our patent rights against alleged infringers. In addition, others could develop technologies or obtain patents which would render our patents obsolete. Although we do not believe patents are the sole determinant in the commercial success of our products, the loss of a significant percentage of our patents or the patents

Edgar Filing: THORATEC CORP - Form 10-K/A

relating to our graft products could have a material adverse effect on our business.

We have developed technical knowledge, which although non-patentable, we consider to be significant in enabling us to compete. However, the proprietary nature of such knowledge may be difficult to protect. We have entered into an agreement with each key employee prohibiting such employee from disclosing any confidential information or trade secrets. In addition, these agreements provide that any inventions or discoveries relating to our business by these individuals will be assigned to us and become our sole property.

Claims by competitors and other third parties that our products allegedly infringe the patent rights of others could have a material adverse effect on our business. The medical device industry is characterized by frequent and substantial intellectual property litigation. The cardiovascular device market is characterized by extensive patent and other intellectual property claims. Intellectual property litigation is complex and expensive and the outcome of this litigation is difficult to predict. Any future litigation, regardless of outcome, could result in substantial expense and significant diversion of the efforts of our technical and management personnel. An adverse determination in any such proceeding could subject us to significant liabilities or require us to seek licenses from third parties or pay royalties that may be substantial. Furthermore, we cannot assure you that necessary licenses would be available on satisfactory terms, or at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing or selling certain of our products, any of which could have a material adverse effect on our business.

18

Cardiosystems has received correspondence from a third party alleging that the textured surface of the HeartMate LVAS housing infringes certain patent rights of such third party. In general, an owner of intellectual property can prevent others from using such property without a license and is entitled to damages for unauthorized usage. We have investigated the bases of the allegation and, based upon an evaluation of all of the facts and circumstances, we believe that if sued on these bases, we would have meritorious defenses. Given the inherent uncertainties in dispute resolution, however, if we were sued and the outcome was unfavorable, our results of operations or financial condition could be materially adversely affected in amounts that cannot be reasonably estimated.

In August 1998, Cardiosystems obtained an exclusive license to incorporate technology developed by Sulzer Electronics Ltd. into an advanced version of the HeartMate LVAS, HeartMate III. HeartMate III is a miniature centrifugal pump featuring a magnetically controlled system that has been developed by Levitronix. In December 2000, Cardiosystems was informed by Sulzer Electronics that Sulzer had sold all of their business in the bearingless motor and magnetic bearing fields to Levitronix and had assigned the agreements between Sulzer and Cardiosystems to Levitronix.

COMPETITION

Principal competitors of the VAD System and the HeartMate LVAS include:

- World Heart, which manufactures and markets the Novacor implantable left ventricular assist device approved only for bridge to heart transplant in the United States; and
- ABIOMED, Inc., which manufactures and markets an FDA-cleared biventricular assist device for temporary circulatory support of patients in post heart surgery shock and other recovery indications.

Edgar Filing: THORATEC CORP - Form 10-K/A

We believe that the principal competitive factors in the ventricular assist device market (circulatory support) are patient outcomes, product performance, size and portability, quality, cost-effectiveness, and customer service. We believe that our principal competitive advantages are:

- we can provide left, right or biventricular support;
- we can provide short-term or long-term circulatory support;
- we can provide implantable or paracorporeal VAD placement;
- we can provide support in the hospital or in the home;
- we can provide support to a greater range of patients because the smaller size and placement of the paracorporeal system outside the body;
- the greater range of cannulation options available; and
- the quality of our biomaterials.

Although we believe that these attributes of the VAD System and/or the HeartMate LVAS offer certain advantages over existing ventricular assist devices, we expect our current competitors to defend their market positions vigorously.

Our principal competitors in the vascular access graft market are W.L. Gore, Inc., C.R. Bard, Boston Scientific/Vascular, and Baxter Corporation, who manufacture and market ePTFE grafts worldwide. Smaller competitors include CardioTech International, Inc., which manufactures and markets a polyurethane graft that is available for sale outside of the United States. Finally, Possis Medical, Inc. manufactures a self-sealing silicone rubber graft marketed with limited indications in the U.S. through Horizon Medical Products, Inc.

International Technidyne's principal competitor for the HEMOCHRON coagulation monitoring instruments, used in the operating room and in cardiac catheterization, is the HemoTec division of Medtronic. The Roche Group competes with the ProTime with a blood coagulation monitor that is marketed to clinics and also is used for patient self-testing. There are also several new competitors that have recently entered the blood

19

coagulation monitoring market. International Technidyne's products compete primarily on the basis of reputation, utility, and price.

International Technidyne's skin incision devices compete with products offered by a number of companies, including Organon Teknika; Becton, Dickinson and Company; and Owen-Mumford. The skin incision devices compete primarily on the basis of safety, quality, and reputation.

There are many companies focusing on the development of circulatory support devices, vascular grafts, coagulation monitoring equipment or skin incision equipment that have substantially greater financial resources, have substantially larger and more experienced sales and marketing organizations and engage in substantially greater research and development efforts than we do. One or more of these or other companies could design and develop products that compete directly with our products, in which case we would face intense competition. Moreover, certain academic institutions, government agencies and other research organizations are conducting research in areas in which we are working. These institutions are becoming increasingly aware of the commercial

Edgar Filing: THORATEC CORP - Form 10-K/A

value of their findings and are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. These institutions may also market competitive commercial products on their own or through joint ventures and will compete with us in recruiting highly qualified scientific personnel.

GOVERNMENT REGULATION

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the manufacture and marketing of our current and future products and in our ongoing product research and development activities. All of our proposed products will require regulatory approval prior to commercialization. In particular, medical devices are subject to rigorous preclinical testing as a condition of approval by the FDA and by similar authorities in foreign countries.

U.S. REGULATIONS

In the United States, the FDA regulates the manufacture, distribution and promotion of medical devices pursuant to the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder (the "FDC Act and Regulations"). The VAD System, TLC-II, IVAD, HeartMate II, HeartMate VE, and Aria and Vectra graft products are, or will be regulated as medical devices. To obtain FDA approval to market medical devices similar to those under development, the FDA requires proof of safety and efficacy in human clinical trials performed under an IDE. An IDE application must contain pre-clinical test data demonstrating the safety of the product for human investigational use, information on manufacturing processes and procedures, and proposed clinical protocols. If the IDE application is accepted, human clinical trials may begin. The trials must be conducted in compliance with FDA regulations. The results obtained from these trials, if satisfactory, are accumulated and submitted to the FDA in support of either a PMA application or a 510(k) premarket notification. Premarket approval from the FDA is required before commercial distribution of devices similar to those under development by the Company is permitted in the United States.

The PMA application must be supported by extensive data, including preclinical and human clinical data, to prove the safety and efficacy of the device. By regulation, the FDA has 180 days to review a PMA application and during that time an advisory committee may evaluate the application and provide recommendations to the FDA. While the FDA has approved PMA applications within the allotted time period, reviews more often occur over a significantly protracted period, usually 18 to 36 months, and a number of devices have never been cleared for marketing. This is a lengthy and expensive process and there can be no assurance that such FDA approval will be obtained.

Under the FDA's requirements, if a manufacturer can establish that a newly developed device is "substantially equivalent" to a legally marketed predicate device, the manufacturer may seek marketing clearance from the FDA to market the device by filing a 510(k) premarket notification with the FDA. This is the process that is used to gain FDA market clearance for most of the International Technidyne products including HEMOCHRON and ProTime. The 510(k) premarket notification must be supported by data establishing the claim of substantial equivalence to the satisfaction of the FDA. The process of obtaining a

20

510(k) clearance typically can take several months to a year or longer. If substantial equivalence cannot be established, or if the FDA determines that the device requires a more rigorous review, the FDA will require that the manufacturer submit a PMA application that must be approved by the FDA prior to marketing the device in the United States.

Edgar Filing: THORATEC CORP - Form 10-K/A

Both a 510(k) and a PMA, if approved, may include significant limitations on the indicated uses for which a product may be marketed. FDA enforcement policy prohibits the promotion of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial marketing.

The approval process for each of our products is expensive and time consuming and we cannot assure you that any regulatory agency will grant its approval. Our inability to obtain, or delays in obtaining, such approval would adversely affect our ability to commence marketing therapeutic applications of our products. We cannot assure you that we will have sufficient resources to complete the required testing and regulatory review processes. Furthermore, we are unable to predict the extent of adverse governmental regulation which might arise from future U.S. or foreign legislative or administrative action.

In addition, any products distributed pursuant to the above authorizations are subject to pervasive and continuing regulation by the FDA. Products must be manufactured in registered establishments and must be manufactured in accordance with cGMP regulations and adverse events must be reported to the FDA. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The failure to comply with the FDA's regulations can result in enforcement action, including seizure, injunction, prosecution, civil penalties, recall and suspension of FDA approval. The export of devices is also subject to regulation in certain instances.

INTERNATIONAL REGULATIONS

We are also subject to regulation in each of the foreign countries in which we sell products with regard to product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to our products in such countries are similar to those of the FDA. The national health or social security organizations of certain countries require our products to be qualified before they can be marketed in those countries.

In order to be positioned for access to European and other international markets, we sought and obtained certification under the ISO 9000 Series of Standards. ISO 9000 is a set of integrated requirements, which when implemented, form the foundation and framework for an effective quality management system. These standards were developed and published by the ISO, a worldwide federation of national bodies, founded in Geneva, Switzerland in 1946. ISO has over 92 member countries. ISO certification is widely regarded as essential to enter Western European markets. We obtained certification and were registered as an ISO 9002 compliant company in January 1995. Commencing in mid-1998, all companies are required to obtain CE Marks for medical devices sold or distributed in the European Community. The CE Mark is an international symbol of quality. With it, medical devices can be distributed within the European Community, which is comprised of 15 European countries representing a population of over 360 million people. A prerequisite for obtaining authority to CE Mark products is to achieve full quality system certification in accordance with ISO 9001 and EN 46001. These are quality standards that cover design, production, installation and servicing of medical devices. We have our ISO 9001 and EN 46001 certification and authority to CE Mark the VAD System, the TLC-II and the Vectra. We are also certified to be in compliance with the requirements of the European Medical Device Directive, another prerequisite for applying the CE Mark.

OTHER REGULATIONS

We are also subject to various federal, state and local laws and

Edgar Filing: THORATEC CORP - Form 10-K/A

regulations relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development work. Specifically, the manufacture of our biomaterials is subject to compliance with federal environmental regulations and by various state and local agencies. Although we believe we are in compliance with these laws and regulations in

21

all material respects, we cannot assure you that we will not be required to incur significant costs to comply with environmental laws or regulations in the future.

THIRD PARTY REIMBURSEMENT AND COST CONTAINMENT

Our products are purchased primarily by hospitals and other users, which then bill various third party payors for the services provided to the patients. These payors, which include Medicare, Medicaid, private health insurance companies and managed care organizations, reimburse part or all of the costs and fees associated with the procedures performed with these devices.

Third party payors are increasingly challenging the prices charged for medical products and services and may deny reimbursement if they determine that a device was not used in accordance with cost-effective treatment methods as determined by the payor, was experimental or was used for an unapproved application. To date, some private insurers and Medicare and Medicaid have determined to reimburse the costs of the Thoratec VAD System and the Cardiosystems' LVAS system. Changes in reimbursement, policies and practices of third party payors could have a material adverse impact on sales of our products.

EMPLOYEES

As of December 30, 2000 Thoratec had 183 full-time employees and Thoratec Cardiosystems had 494 employees. As of February 24, 2001, Thoratec Corporation and Thoratec Cardiosystems combined had 654 full-time employees, 321 of whom worked in manufacturing, 92 in engineering, 50 in quality control and regulatory affairs, 116 in marketing and sales support, 34 in administration and finance, and 41 in other support functions, including personnel, management information, purchasing and facilities. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

RESEARCH AND DEVELOPMENT

Thoratec's research and development expenses in 1998, 1999 and 2000 were \$5.1 million, \$5.8 million and \$7.2 million, respectively.

Cardiosystems' research and development expenses in 1998, 1999 and 2000 were \$12.3 million, \$16.0 million and \$16.2 million, respectively.

FACILITIES

Thoratec occupies leased facilities in Pleasanton, California totaling approximately 62,000 square feet. The manufacturing areas have been inspected, approved, and licensed by the FDA and the State of California Department of Health Services, Food and Drug Section for the manufacture of medical devices. We also have small leased facilities in the United Kingdom. We believe our facilities will be sufficient to meet our needs for the next two years and that additional space will be available at a reasonable price to satisfy space needs thereafter.

Edgar Filing: THORATEC CORP - Form 10-K/A

Cardiosystems believes that its facilities are in good condition and are adequate for its present operations and that suitable alternative space is readily available if any leases are not extended. The location and general character of Cardiosystems' properties by industry segment as of December 30, 2000, are as follows:

- Left Ventricular Assist Devices -- Cardiosystems subleases approximately 34,000 square feet of space from Thermo Electron Corporation in Electron in Woburn, Massachusetts, pursuant to a sublease expiring in 2004. It also leases approximately 12,000 square feet of office and research facilities in Chelmsford, Massachusetts, under a lease expiring in 2001. In addition, Cardiosystems occupies approximately 11,000 square feet of office and research facilities in Rancho Cordova, California, pursuant to a lease expiring in 2002.

22

- Blood Coagulation, Testing, and Skin Incision Devices -- Cardiosystems also owns approximately 66,000 square feet and leases approximately 24,000 square feet of office, manufacturing, and research facilities in Edison, New Jersey, under a lease expiring in 2002.

LITIGATION

We are not party to any material legal proceedings.

23

RISK FACTORS

We make statements in this Annual Report on Form 10-K and other statements from time to time that relate to future plans, events or performance that are forward-looking statements which involve risks and uncertainties. Actual results, events or performance may differ materially from those anticipated in any forward-looking statements as a result of a variety of factors, including those set forth below and elsewhere in this Annual Report on Form 10-K. You should consider each of the risks and uncertainties described in this section and all of the other information in this Annual Report on Form 10-K in evaluating our company and our business before deciding to invest in our common stock.

WE HAVE A HISTORY OF NET LOSSES, AND WE MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY.

We were founded in 1976 and have incurred a loss from operations in all but one of the years of our existence. At the end of fiscal year 2000, our accumulated deficit was approximately \$56.9 million. Cardiosystems had also accumulated a significant deficit at that time. While the combined company is expected to be cash flow positive, we anticipate that our expenses will increase as a result of increased preclinical and clinical testing, research and development and selling, general and administrative expenses. Additionally, we will incur significant costs in connection with the merger.

PHYSICIANS MAY NOT ACCEPT OR CONTINUE TO ACCEPT OUR PRODUCTS AND PRODUCTS UNDER DEVELOPMENT.

A limited number of cardiovascular and vascular surgeons and interventional cardiologists influence medical device selection and purchase decisions for a large portion of the target cardiac patient population. In addition, physicians'

Edgar Filing: THORATEC CORP - Form 10-K/A

acceptance of our whole-blood coagulation monitoring systems and Coumadin monitors is important to the success of those products. Accordingly, the success of our current and future products will require acceptance or continued acceptance by cardiovascular and vascular surgeons and interventional cardiologists. Such acceptance will depend on clinical results and the conclusion by these physicians that our products are safe, cost-effective and acceptable alternative methods of treatment. Our products may not provide benefits considered adequate by providers of cardiovascular and vascular treatments or a sufficient number of such providers may not use our products. Even if the safety and efficacy of our products are established, physicians may elect not to use them for a number of reasons. These reasons could include the high cost of equipment and training associated with their use or unfavorable reimbursement from health care payors.

We have developed working relationships with cardiac surgeons and cardiologists at a number of leading medical centers in connection with developing our products. In addition, surgical teams at these medical institutions have performed clinical trials to support our applications to be filed with the FDA. A continuing working relationship with these and other physicians and medical centers will be important to the commercial acceptance of present and any future products. We may fail to maintain existing relationships and arrangements and we may fail to establish new relationships in support of our circulatory support and graft technology. Also, economic, psychological, ethical and other concerns may limit general acceptance of ventricular assist and graft devices.

WE RELY ON SPECIALIZED SUPPLIERS.

We depend on a number of custom-designed components and materials supplied by other companies including, in some cases, single source suppliers. If we need alternative sources for key raw materials or component parts for any reason, such materials or component parts may not be available. For example, Arrow International, Inc. is currently the single source of supply for valves used in the blood pump portion of our VAD System. Sales of the VAD System accounted for substantially all of our revenue in 1998, 1999, and 2000. Cessation or interruption of sales of ventricular assist products would have a material adverse effect on our business, financial condition and results of operations.

Alternative suppliers may not agree to supply us. In addition, we may need to obtain FDA approval before using new suppliers. The cost to evaluate and test alternative materials and components and the time necessary to obtain FDA approval for these materials and components are inherently difficult to determine

24

because both time and cost are dependent on at least two factors, the similarity of the alternative material or component to the original material or component, and the amount of third-party testing that may have already been completed on alternative materials or components. If alternative suppliers are not available, we may not have the expertise or resources necessary to produce such materials or component parts internally. Any interruption in supply of raw materials or component parts could have a material adverse effect on our ability to manufacture products until a new source of supply is located.

WE MAY ENCOUNTER PROBLEMS MANUFACTURING OUR PRODUCTS.

We may encounter difficulties manufacturing our products for the following reasons:

- we do not have experience in manufacturing our products in the commercial

Edgar Filing: THORATEC CORP - Form 10-K/A

quantities that might be required if we receive FDA approval of several or all of the products currently under development;

- the manufacture of our products is complex and costly, involving a number of separate processes and components; and
- certain manufacturing processes for our products are labor intensive, and achieving significant cost reductions will depend in part upon reducing the time required to complete these processes.

In addition, manufacturers often encounter difficulties in scaling up manufacturing of new products. These difficulties include, for example:

- problems involving product yields, quality control and assurance;
- component and service availability;
- adequacy of control policies and procedures; and
- lack of qualified personnel.

We will continue to consider whether we should internally manufacture components that are currently provided by third parties. We will also continue to consider the implementation of new production processes, some of which may require prior FDA approval. We may not be able to obtain or manufacture such products in a timely fashion at acceptable quality and prices. In addition, we may not be able to comply with the FDA's current good manufacturing practices, also called cGMP. Our suppliers and we may not be able to manufacture an adequate supply of products.

INTENSE COMPETITION COULD HARM OUR FINANCIAL PERFORMANCE.

Competition from medical device companies and medical device subsidiaries of health care and pharmaceutical companies is intense and expected to increase. Many of our competitors have substantially greater financial, technical, distribution and marketing resources than we do. In addition, many of these competitors have significantly greater experience than we do in obtaining regulatory approvals for medical devices. Accordingly, our competitors may succeed in obtaining regulatory approval for products more rapidly than we can. Furthermore, many of these competitors have superior manufacturing capabilities, and such competitors may be able to manufacture products more efficiently and at a lower cost than we can. Our competitors may therefore offer competitive products at a lower cost than our products. Any product we develop that gains regulatory approval will have to compete for market acceptance and market share. An important factor in such competition may be the timing of market introduction of competitive products. Accordingly, we expect that competitive factors will include the relative speeds with which we can:

- develop products;
- complete clinical testing;
- receive regulatory approval; and
- manufacture and sell commercial quantities of products.

OUR COMPETITORS MAY DEVELOP MORE EFFECTIVE PRODUCTS AND RENDER OUR PRODUCTS OBSOLETE.

Edgar Filing: THORATEC CORP - Form 10-K/A

Our competitors may succeed in developing and marketing technologies and products that are more effective than ours. Any such products may render our technology and products obsolete or noncompetitive. In addition, new surgical procedures and medications could be developed that replace or reduce the importance of current procedures that use our products. Accordingly, our success will depend in part on our ability to respond quickly to medical and technological changes by developing and introducing new products, or modifying existing products.

IF WE FAIL TO OBTAIN APPROVAL FROM THE FDA AND FROM FOREIGN REGULATORY AUTHORITIES, WE CANNOT MARKET AND SELL OUR PRODUCTS UNDER DEVELOPMENT IN THE UNITED STATES AND IN OTHER COUNTRIES.

Before we can market new products in the United States we must obtain clearance from the FDA. This process is lengthy and uncertain. In the United States, one must obtain clearance from the FDA of a 510(k) premarket notification or approval of a more extensive submission known as a premarket approval (PMA) application. If the FDA concludes that any of our products do not meet the requirements to obtain clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, then we would be required to file a PMA application. The process for a PMA application is lengthy, expensive and typically requires extensive preclinical and clinical trial data. Preclinical data may need to comply with FDA good laboratory practices.

We may not obtain clearance of a 510(k) notification or approval of a PMA application with respect to any of our products on a timely basis, if at all. If we fail to obtain timely clearance or approval for our products, we will not be able to market and sell our products. That will limit our ability to generate revenue. We may also be required to obtain clearance of a 510(k) notification or PMA application from the FDA before we can market products that have been cleared that we have now modified or for which we wish to make new claims.

The FDA also requires us to adhere to cGMP regulations, which include production design controls, testing, quality control, storage and documentation procedures. The FDA may at any time inspect our facilities to determine whether we have adequately complied. Compliance with cGMP regulations for medical devices is difficult and costly. In addition, we may not be found to be compliant as a result of future changes in, or interpretations of, regulations by the FDA or other regulatory agencies. If we do not achieve compliance, the FDA may withdraw marketing clearance, require product recall or take other enforcement action. Any change or modification in a device is required to be made in compliance with cGMP regulations, which may cause interruptions or delays in the marketing and sale of our products.

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer or shorter than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements.

The federal, state and foreign laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties.

OUR INABILITY TO PROTECT OUR PROPRIETARY TECHNOLOGIES COULD HARM OUR COMPETITIVE POSITION.

Our success will depend, in part, on our ability to maintain the

Edgar Filing: THORATEC CORP - Form 10-K/A

proprietary nature of our technology, products and manufacturing processes. We rely on trade secrets, know-how and patents to maintain our competitive position. We have been issued or have licensed a number of U.S. and foreign patents covering our core biomaterials technology and our graft technologies. In addition, we have filed many other U.S. and non-U.S. patent applications. Aside from the biomaterials patents mentioned above, which are utilized in Thoratec's VAD System blood pump and cannulae, and one TLC-II patent, our VAD System is not protected by any patents. Cardiosystems relies principally on trade secret protection and, to a lesser extent, patents to

26

protect its rights with respect to LVAS and its reagents. It does, however, rely principally on patents to protect its coagulation equipment and skin-incision products.

Any existing or future patent applications may not result in issued patents. In addition, current or future trade secrets, know-how or issued or licensed patents may not sufficiently protect us from competitors with similar technologies or processes. Others may independently develop proprietary technologies and processes that are the same as or substantially equivalent to ours. Any patents issued may be infringed upon or designed around by others.

Our products may be found to infringe prior or future patents owned by others. We may need to acquire licenses under patents belonging to others for technology potentially useful or necessary, and such licenses may not be available to us. We could incur substantial costs in defending suits brought against us on such patents or in bringing suits to protect our patents or patents licensed by us against infringement.

Cardiosystems has received correspondence from another company alleging that Cardiosystems LVAS infringes certain patent rights of that company. Cardiosystems believes it has meritorious defense to that claim but cannot assure that it would be successful were the matter litigated.

SINCE WE DEPEND UPON DISTRIBUTORS, IF WE LOSE A DISTRIBUTOR OR A DISTRIBUTOR FAILS TO PERFORM, OUR OPERATION WOULD BE HARMED.

With the exception of Canada and Europe, Thoratec sells its VAD System in foreign markets through distributors. In addition, we sell our vascular access graft products through Goodman Co. Ltd., our distributor in Japan, and through Guidant Corporation in the rest of the world. Cardiosystems sells its LVAS System in foreign markets through distributors, and relies on distributors in all markets. Allied Healthcare is International Technidyne's U.S. distributor. Allied Healthcare's sales represented approximately 20% of Cardiosystems' consolidated revenues during the first nine months of 2000. To the extent we rely on distributors, our success will depend upon the efforts of others, over which we may have little control. If we lose a distributor or a distributor fails to perform, our revenues will be adversely affected.

SINCE WE DEPEND ON THIRD PARTY REIMBURSEMENT TO OUR CUSTOMERS, IF THIRD PARTY PAYORS FAIL TO PROVIDE APPROPRIATE LEVELS OF REIMBURSEMENT FOR OUR PRODUCTS, OUR OPERATION WOULD BE HARMED.

Significant uncertainty exists as to the reimbursement status of newly-approved health care products such as Thoratec's VAD System and its vascular grafts and Cardiosystems' LVAS system. Government and other third party payors are increasingly attempting to contain health care costs. Payors are attempting to contain costs by, for example, limiting coverage and the level of reimbursement of new therapeutic products. Payors are also attempting to contain costs by refusing in some cases to provide any coverage of uses of approved

Edgar Filing: THORATEC CORP - Form 10-K/A

products for disease indications other than those for which the FDA has granted marketing approval.

To date, some private insurers, Medicare and Medicaid have determined to reimburse the costs of Thoratec VAD System and Cardiosystems' LVAS systems. These Systems may not continue to be approved for reimbursement. In addition, changes in the health care system may affect the reimbursability of future products. If we fail to obtain such reimbursement or if the reimbursement levels are reduced, our revenues would be reduced.

PRODUCT LIABILITY CLAIMS COULD DAMAGE OUR REPUTATION AND HURT OUR FINANCIAL RESULTS.

Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing and sale of human medical devices. We maintain only a limited amount of product liability insurance. We also maintain general commercial and property insurance. Our insurance policies generally must be renewed on an annual basis. We may not be able to maintain or increase such insurance on acceptable terms or at reasonable costs, and such insurance may not provide us with adequate coverage against potential liabilities. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our financial condition and results of operations. Claims against us,

27

regardless of their merit or potential outcome, may also reduce our ability to obtain physician endorsement of our products or expand our business.

OUR NON-U.S. SALES PRESENT SPECIAL RISKS.

During 2000, sales originating outside the United States and U.S. export sales accounted for approximately 18% of Thoratec's total revenues and 16% of Cardiosystems' total revenues. Cardiosystems and Thoratec anticipate that sales outside the United States and U.S. export sales will continue to account for a significant percentage of their revenues. Both companies hope to continue to expand their presence in international markets. Non-U.S. sales are subject to a number of special risks. For example, agreements may be difficult to enforce and receivables difficult to collect through a foreign country's legal system, foreign customers may have longer payment cycles, foreign countries may impose additional withholding taxes or otherwise tax Thoratec's or Cardiosystems' foreign income, impose tariffs or adopt other restrictions on foreign trade, U.S. export licenses may be difficult to obtain, intellectual property may be more difficult to enforce in foreign countries, and fluctuations in exchange rates may affect product demand and adversely affect the profitability, in U.S. dollars, of products sold in foreign markets where payments are made in local currencies.

ANY CLAIMS RELATING TO IMPROPER HANDLING, STORAGE OR DISPOSAL OF HAZARDOUS CHEMICALS AND BIOMATERIALS COULD BE TIME CONSUMING AND COSTLY.

Producing our proprietary biomaterial, Thoralon, requires the use of hazardous materials, including chemicals and biomaterials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials.

We could be subject to civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed

Edgar Filing: THORATEC CORP - Form 10-K/A

our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

OUR STOCK PRICE HAS BEEN VOLATILE, IS LIKELY TO CONTINUE TO BE VOLATILE, AND COULD DECLINE SUBSTANTIALLY.

The price of our common stock has been, and is likely to continue to be, highly volatile. The price of our common stock could fluctuate significantly for the following reasons:

- future announcements concerning us or our competitors;
- quarterly variations in operating results;
- introduction of new products or changes in product pricing policies by us or our competitors;
- acquisition or loss of significant customers, distributors and suppliers;
- changes in earnings estimates by analysts;
- changes in third party reimbursement practices;
- regulatory developments; or
- fluctuations in the economy or general market conditions.

In addition, stock markets in general, and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years which have frequently been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our stock may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

In the past, shareholders have often instituted securities class action litigation after periods of volatility in the market price of a company's securities. If a shareholder files a securities class action suit against us, we

28

would incur substantial legal fees and our management's attention and resources would be diverted from operating our business in order to respond to the litigation.

FUTURE SALES OF OUR COMMON STOCK COULD ADVERSELY AFFECT OUR STOCK PRICE.

Future sales of substantial amounts of Thoratec's stock in the public market, or the perception that such sales could occur, could adversely affect the market price of Thoratec's stock. For example, Thermo Electron owns approximately 19 million shares and twenty-five percent of those shares will be eligible for sale starting in June 2001.

THE OCCURRENCE OF A CATASTROPHIC DISASTER COULD CAUSE DAMAGE TO OUR FACILITIES AND EQUIPMENT, WHICH WOULD REQUIRE US TO CEASE OR CURTAIL OPERATIONS.

We are vulnerable to damage from various types of disasters, including earthquake, fire, flood, power loss, communications failures and similar events. For example, in October 1989 a major earthquake that caused significant property

Edgar Filing: THORATEC CORP - Form 10-K/A

damage and a number of fatalities struck near the area in which our Pleasanton facility is located. If any disaster were to occur, we may not be able to operate our business at our facilities. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions.

WE DO NOT ANTICIPATE PAYING DIVIDENDS.

We intend to retain all of our earnings for the future operation and expansion of our business. We do not anticipate paying cash dividends on our common stock at any time in the foreseeable future.

WE WILL FACE SIGNIFICANT CHALLENGES IN INTEGRATING CARDIOSYSTEMS AND, AS A RESULT, MAY NOT REALIZE THE EXPECTED BENEFITS OF THE MERGER.

Thoratec and Cardiosystems have different technologies, products and business operations that have operated independently. The combination of these businesses is complex and difficult. We are uncertain that the integration will be completed in a timely manner. If we fail to integrate the businesses successfully, the operating results of the combined company could be adversely affected and the combined company may not achieve the benefits or operating efficiencies that we hope to obtain from the merger. The uncertainty of whether Thoratec and Cardiosystems employees will remain with the combined company during the integration process may also affect the business operations of each company. Thoratec may not be able to retain enough key employees for the combined company to operate its business effectively during the period after the merger. We do not yet know that the products, systems and personnel of the two companies will be fully compatible.

THE COSTS OF COMPLETING INTEGRATION ARE SUBSTANTIAL, AND WILL AFFECT OUR OPERATIONS.

Integrating Thoratec and Cardiosystems will result in substantial costs. These, primarily, are costs associated with combining the businesses of the two companies and the fees of financial advisors, attorneys, consultants and accountants. Unanticipated events could increase the costs of combining the two companies. In any event, the costs associated with the merger will negatively affect our results of operations for at least a year after the merger is completed.

IF THORATEC DOES NOT SUCCESSFULLY INTEGRATE CARDIOSYSTEMS OR THE MERGER'S BENEFITS DO NOT MEET THE EXPECTATIONS OF INVESTORS OR FINANCIAL OR INDUSTRY ANALYSTS, THE MARKET PRICE OF THORATEC STOCK MAY DECLINE.

The market price of our stock may decline as a result of the merger for any of the following reasons, among others:

- the integration of Thoratec and Cardiosystems is not completed in a timely and efficient manner
- Thoratec does not achieve the benefits of the merger as rapidly as, or to the extent, anticipated by financial or industry analysts
- significant numbers of our shareholders may dispose of their shares after the merger.

29

UNCERTAINTIES ASSOCIATED WITH THE MERGER MAY CAUSE US TO LOSE KEY PERSONNEL.

Current and prospective employees may experience uncertainty about their

Edgar Filing: THORATEC CORP - Form 10-K/A

future roles with us after the merger. This uncertainty may adversely affect our ability to retain key management, sales, marketing and technical personnel. In addition, our ability to successfully integrate the two companies may be adversely affected if a significant number of key personnel depart after the merger.

THE MERGER WILL HAVE A NEGATIVE IMPACT ON PROFITABILITY.

As a result of the merger, Thoratec expects to incur a noncash "in process research and development" expense of approximately \$77 million in the first quarter of 2001 and will also incur transaction related expenses. In addition, as a result of the merger, Thoratec will recognize goodwill (currently estimated to be approximately \$100 million) that will be amortized over 20 years pending adoption of new rules related to business combinations by the Financial Accounting Standards Board. Additional noncash intangible assets (currently estimated to be approximately \$210 million) will be amortized over periods ranging from 6 to 20 years. This amortization will result in a non-cash expense that will reduce any reported operating profit during the amortization period.

ITEM 2. PROPERTY

We occupy leased facilities in Pleasanton, California totaling approximately 62,000 square feet where we manufacture the Thoratec VAD system and graft products. The manufacturing areas have been inspected, approved, and licensed by the FDA and the State of California Department of Health Services, Food and Drug Section for the manufacture of medical devices. The Pleasanton facility also houses the research and development, sales and marketing, and administrative and support personnel. We also have small leased facilities in the United Kingdom. We believe our facilities will be sufficient to meet our needs for the next two years and that additional space will be available at a reasonable price to satisfy space needs thereafter.

We believe Cardiosystems' facilities are in good condition and are adequate for present operations and that suitable alternative space is readily available if any leases are not extended. The location and general character of the Cardiosystems' properties by industry segment as of December 30, 2000, are as follows:

- LVAS -- Cardiosystems subleases approximately 34,000 square feet of space from Thermo Electron Corporation in Woburn, Massachusetts, pursuant to a sublease expiring in 2004. It also leases approximately 12,000 square feet of office and research facilities in Chelmsford, Massachusetts, under a lease expiring in 2001. In addition, Cardiosystems occupies approximately 11,000 square feet of office and research facilities in Rancho Cordova, California, pursuant to a lease expiring in 2002.
- Blood Coagulation, Testing, and Skin Incision Devices -- Cardiosystems also owns approximately 66,000 square feet and leases approximately 24,000 square feet of office, manufacturing, and research facilities in Edison, New Jersey, under a lease expiring in 2002.

ITEM 3. LEGAL PROCEEDINGS

We are not party to any material legal proceedings.

ITEM 4. SUBMISSIONS OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

Edgar Filing: THORATEC CORP - Form 10-K/A

OFFICERS OF THE REGISTRANT

D. KEITH GROSSMAN*, PRESIDENT, CHIEF EXECUTIVE OFFICER AND DIRECTOR, AGE 40, joined our company as President and Chief Executive Officer in January 1996. He was elected to the Board of Directors in February 1996. Prior to joining us, Mr. Grossman was a Division President of Major Pharmaceuticals, Inc., from June 1992 to September 1995, at which time it was sold. From July 1988 to June 1992, Mr. Grossman served as the Vice President of Sales and Marketing for Calcitek, Inc., a manufacturer of implantable medical devices, and division of Sulzermedica (formerly Intermedics, Inc.). Prior to 1988, Mr. Grossman held various other sales and marketing management positions within the McGaw Laboratories Division of American Hospital Supply Corporation.

THOMAS E. BURNETT, JR.*, SENIOR VICE PRESIDENT AND CHIEF OPERATING OFFICER, AGE 37, joined our company as Vice President -- Sales and Marketing in August 1996 and was promoted to his current position in December 1999. Prior to joining us, Mr. Burnett was Vice President of Sales and Marketing at Sulzer Calcitek, Inc. from June 1992 to August 1996, where he was responsible for global sales and marketing which included a direct domestic sales force and an international network encompassing 30 countries as well as new business development, strategic and operational planning.

CHERYL D. HESS*, VICE PRESIDENT, CHIEF FINANCIAL OFFICER AND SECRETARY, AGE 54, joined our company as Vice President and Chief Financial Officer in December 1983 and became Secretary in 1994. Prior to joining us, Ms. Hess was a manager with the public accounting firm of Deloitte & Touche LLP, where she specialized in audit and financial advisory services for entrepreneurial, rapidly-growing, high technology companies. Ms. Hess is responsible for the direction of all financial management, control and reporting activities and a portion of administrative and operational activities. Ms. Hess is a Certified Public Accountant.

DAVID J. FARRAR, PH.D., VICE PRESIDENT -- RESEARCH AND DEVELOPMENT, AGE 53, joined our company as Program Manager of the VAD System in January 1980 and became Vice President -- Circulatory Support Products in 1988, and Vice President -- Research and Development in 1996. In addition, Dr. Farrar has a research appointment in the Department of Cardiac Surgery at the California Pacific Medical Center of San Francisco. Dr. Farrar has over 20 years of research experience in the cardiovascular and medical device industry.

DONALD A. MIDDLEBROOK, VICE PRESIDENT -- REGULATORY AFFAIRS/QUALITY ASSURANCE, AGE 50, joined our company as Vice President -- Regulatory Affairs/Quality Assurance in September 1996. Before joining our company, he held the position of Senior Director, Global Regulatory Affairs and Assurance for Chiron Vision Corporation, a manufacturer of implantable ophthalmic devices and surgical equipment. Prior to that, Mr. Middlebrook spent fifteen years with Baxter International in a number of positions, including Vice President of Regulatory Affairs and Quality Assurance for the Cardiovascular Group, a producer of a wide range of cardiopulmonary, critical care, vascular and cardiovascular products.

JOSEPH G. SHARPE, VICE PRESIDENT -- OPERATIONS, AGE 41, joined our company as Vice President -- Operations in September 1997. Prior to joining us, Mr. Sharpe was Director of Operations for the IV Systems Division of Baxter International, Inc. from 1992 to September 1997. Prior thereto, Mr. Sharpe held a number of other positions at Baxter International, Inc. including Director of Engineering of the Pharmaseal Division, and Honeywell Information Systems.

JEFFREY C. MACK, VICE PRESIDENT -- FINANCE AND CORPORATE CONTROLLER, AGE 38, joined our company as Controller in 1996. He was promoted to Director of Finance and Corporate Controller in September 1999 and to Vice President of Finance in September 2000. Prior to joining Thoratec, he served as Director of

Edgar Filing: THORATEC CORP - Form 10-K/A

Finance and Corporate Controller for The North Face, a designer and manufacturer of world-class high-tech outdoor apparel and equipment. He has also held various other financial and operational positions with Kenetech Corporation, a vertically integrated manufacturer and operator of utility grade wind turbines, and Deloitte & Touche, LLP. Mr. Mack is a CPA.

*Denotes executive officer as of the date of this report.

31

BETH A. TAYLOR, VICE PRESIDENT -- HUMAN RESOURCES, AGE 39, joined our company as Director of Human Resources in November 1999 and was promoted to Vice President of Human Resources in February 2001. Prior to joining Thoratec, Ms. Taylor served as Director of Human Resources for CCI/Triad and was responsible for a division of 1,100 employees. She has also held various other human resource positions such as Corporate Employee Development Manager with Valent U.S.A. Corporation, and as Director of Human Resources with ADP where she was responsible for 1,500 employees.

BRADLEY D. GOSKOWICZ, VICE PRESIDENT -- SALES AND MARKETING, AGE 45, joined our company as Vice President, Sales and Marketing in January 2001. Prior to joining Thoratec, Mr. Goskowitz was Director of Marketing in the Cardiac Surgery Division of Medtronic where he was responsible for directing, developing and implementing marketing strategies for a broad line of cardiovascular surgery products worldwide. He joined Medtronic in March of 1999, as part of Medtronic's acquisition of Avecor Cardiovascular, and was one of the original Directors when Avecor Cardiovascular was formed in 1991. Before assuming the role of Director of Marketing, he held the position of Director of Sales. Prior to 1991 Mr. Goskowitz held various sales and marketing positions with Bio-Medicus, Medtronic and Johnson & Johnson.

32

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on The NASDAQ National Market under the symbol "THOR." The following table sets forth, for the periods indicated, the high and low closing sales prices per share of our common stock, as reported by The NASDAQ National Market. At March 9, 2001 there were approximately 700 holders of record of our common stock, including multiple beneficial holders at depositories, banks and brokers listed as a single holder in the "street" name of each respective depository, bank or broker.

| | HIGH ----- | LOW ----- |
|---------------------|---------------|--------------|
| Fiscal Year 1999 | | |
| First Quarter..... | \$ 8.63 | \$ 6.25 |
| Second Quarter..... | 11.00 | 6.50 |
| Third Quarter..... | 11.63 | 6.38 |
| Fourth Quarter..... | 9.75 | 5.50 |
| Fiscal Year 2000 | | |
| First Quarter..... | \$19.88 | \$ 8.50 |
| Second Quarter..... | 18.63 | 8.50 |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | |
|---------------------|-------|-------|
| Third Quarter..... | 24.75 | 15.13 |
| Fourth Quarter..... | 20.56 | 7.75 |

We have not declared any dividends on our common stock.

33

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data presented below for the five fiscal years ended December 30, 2000 is derived from the Thoratec audited financial statements. We have a 52 or 53 week fiscal year that ends on the Saturday closest to December 31. Our consolidated financial statements at the fiscal years ended December 30, 2000 and January 1, 2000 and for each of the years in the three-year period ended December 30, 2000, and the independent auditors' report thereon, are included elsewhere in this annual report. Our selected consolidated financial data for fiscal 1998, 1997 and 1996 are derived from audited consolidated financial statements not included in this annual report. You should read the data set forth below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes thereto appearing elsewhere in this annual report. The selected data in this section is not intended to replace our financial statements.

| | FISCAL YEAR | | | | |
|---|---------------------------------------|------------|------------|------------|------------|
| | 2000 | 1999 | 1998 | 1997 | 1996 |
| | (IN THOUSANDS, EXCEPT PER SHARE DATA) | | | | |
| INCOME STATEMENT DATA: | | | | | |
| Product sales..... | \$ 30,429 | \$ 22,508 | \$ 16,320 | \$ 9,441 | \$ 7,503 |
| Cost of product sales..... | 10,919 | 9,739 | 6,504 | 4,005 | 3,254 |
| Research and development..... | 7,245 | 5,793 | 5,096 | 4,583 | 3,724 |
| Selling, general and administrative..... | 10,969 | 9,361 | 7,656 | 6,027 | 3,998 |
| Merger related expenses..... | 4,169 | -- | -- | -- | -- |
| Other operating income..... | 614 | 285 | -- | -- | -- |
| Loss from operations..... | (2,259) | (2,100) | (2,936) | (5,174) | (3,473) |
| Interest and other income (expense), net..... | 713 | 324 | 660 | 772 | 210 |
| Income tax expense..... | (183) | (13) | (45) | -- | -- |
| Net loss..... | \$ (1,729) | \$ (1,789) | \$ (2,321) | \$ (4,402) | \$ (3,263) |
| Basic and diluted loss per share.... | \$ (0.08) | \$ (0.09) | \$ (0.11) | \$ (0.24) | \$ (0.20) |
| Weighted average shares used in computing basic and diluted loss per share..... | 21,831 | 20,446 | 20,340 | 18,360 | 16,694 |
| BALANCE SHEET DATA: | | | | | |
| Cash and cash equivalents..... | \$ 3,406 | \$ 1,697 | \$ 2,713 | \$ 9,469 | \$ 5,348 |
| Working capital..... | 26,945 | 10,533 | 11,251 | 15,885 | 17,266 |
| Total assets..... | 44,721 | 25,060 | 25,208 | 28,477 | 21,847 |
| Deferred revenue..... | 2,064 | 854 | -- | -- | -- |
| Accumulated deficit..... | (56,920) | (55,191) | (53,402) | (51,082) | (46,679) |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | | | | |
|---------------------------------|--------|--------|--------|--------|--------|
| Total shareholders' equity..... | 35,358 | 20,276 | 21,877 | 24,027 | 19,330 |
|---------------------------------|--------|--------|--------|--------|--------|

34

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

The statements in "Management's Discussion and Analysis of Financial Condition and Results of Operations" that relate to future plans, events or performance are forward-looking statements which involve risks and uncertainties. Actual results, events or performance may differ materially from those anticipated in these forward-looking statements as a result of a variety of factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We undertake no obligation to publicly release the result of any revisions to these forward-looking statements that may be needed to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

OVERVIEW

We develop, manufacture and market medical devices for circulatory support and vascular applications. We market our first product, the Thoratec VAD System, in the United States and internationally for use as a bridge to heart transplant and for recovery of the heart after heart surgery. We are pursuing additional indications for the VAD System and developing other circulatory support products for patients suffering from heart disease. We are also developing vascular grafts for hemodialysis and coronary artery bypass surgery. All of our products utilize our proprietary biomaterial, Thoralon, with surface properties designed to minimize patient blood clotting and inflammatory response.

We have experienced operating losses in all but one year since inception in 1976. We incurred net losses of \$1.7 million in 2000, \$1.8 million in 1999, and \$2.3 million in 1998. At December 30, 2000, we had an accumulated deficit of \$56.9 million. We operate in a single business segment with different products in circulatory support and vascular grafts. We conduct business both domestically and internationally. Our domestic business comprises the United States, and our international operations comprise Europe and the rest of the world.

Because we acquired Cardiosystems after the end of fiscal year 2000, the information in this Item 7 does not include any information about Cardiosystems.

LIQUIDITY AND CAPITAL RESOURCES

We had cash, cash equivalents and short-term investments at the end of 2000 of \$16.1 million compared with \$2.0 million at the end of 1999. The increase in cash was due principally to the net proceeds from the April 2000 public offering of \$15.7 million partially offset by the loss from continuing operations of \$1.7 million and capital expenditures of \$1.2 million. Gross accounts receivable increased \$3.4 million in 2000 principally due to the \$2.0 million Guidant milestone payment, in addition to strong fourth quarter sales. The \$2.0 million Guidant milestone payment was recorded in December 2000 upon approval of the FDA to sell the Vectra graft product in the US, and was received in first quarter 2001. Inventory increased \$2.1 million in 2000 in preparation for planned increases in sales activity and the introduction of a new product, in addition to higher driver rental inventory. Accounts payable and accrued liabilities increased principally due to merger related expenses and the short-term portion of deferred distributor revenue associated with the Guidant agreement discussed below.

Edgar Filing: THORATEC CORP - Form 10-K/A

In 1999, we entered into a distribution agreement with Guidant Corporation. Under the terms of the agreement, Guidant receives exclusive worldwide marketing and distribution rights to the Vectra product line, except in Japan. In exchange for these rights, Guidant paid us \$1.5 million and an additional \$2.0 million payment when the Vectra product line received FDA approval. We received FDA approval for the Vectra graft in December 2000 and received the \$2 million payment in January 2001. The \$3.5 million in milestone payments will be recognized into income ratably over the estimated life of the contract with Guidant. Deferred distributor income of \$282,000 was recognized in 2000 and \$285,000 was recognized in 1999. \$2.8 million remains to be recognized in the four years of the remaining life of the Guidant agreement.

35

In 1996, we entered into a lease agreement on a new manufacturing facility in Pleasanton, California, which accommodates all of our manufacturing, and engineering and administrative activities. The administrative and engineering portion of the building was completed and occupied in late 1997. The manufacturing portion was completed in 1998 and occupied in April 1999. We invested approximately \$9.0 million in equipment and leasehold improvements to the building. Annual payments under the lease are \$781,000 for a lease term of 15 years beginning August 1997. The lease includes provisions, among others, for annual cost of living adjustments to the lease payments, two five-year renewal options, a purchase option, and a security deposit of \$885,600. We can reduce or eliminate a significant portion (\$750,000) of the remaining security deposit before the end of the initial lease term if we meet the criteria specified in the lease.

In April 2000, we sold, through an underwritten public offering, 2,000,000 shares of common stock at \$10.00 per share. Included in the 2,000,000 shares were 500,000 shares offered by Gambro Inc., a major shareholder, for which we received no proceeds. In addition, the underwriters exercised a 30-day option to purchase from us and Gambro 300,000 shares of common stock to cover any over-allotments of which the proceeds from 225,000 shares were received by us. After deducting underwriting discounts of \$983,000, we received a total of \$16,267,000, from which \$574,000 in offering-related costs have been paid. Underwriting discounts and the other estimated offering-related costs were recorded as an offset to common stock at the closing of the offering.

We believe that the current cash and short-term investments together with expected cash flow from operations and cash and short-term investments obtained in conjunction with our recent merger with Cardiosystems will be sufficient to fund our operations for at least the next twelve months.

RESULTS OF OPERATIONS

PRODUCT SALES

Product sales in 2000 were \$30.4 million compared to \$22.5 million in 1999, an increase of \$7.9 million, or 35%. This increase is attributable to sales of the VAD System disposable blood pump, which increased to \$23.1 million in 2000 from \$16.2 million in 1999, an increase of \$6.9 million, or 43%. The growth of sales in VAD pumps was primarily attributable to an increase of 29% in the quantity of VAD pumps sold, which resulted from the growth in the number of new centers using our VAD System. An increase in the average selling price of the VAD pumps also contributed to the increase in revenue.

Product sales in 1999 were \$22.5 million compared to \$16.3 million in 1998, an increase of \$6.2 million, or 38%. This increase is attributable to sales of the VAD System disposable blood pump, which increased to \$16.2 million in 1999

Edgar Filing: THORATEC CORP - Form 10-K/A

from \$11.0 million in 1998, an increase of \$5.2 million, or 47%. The growth of sales in VAD pumps was primarily attributable to an increase of 33% in the quantity of VAD pumps sold, which resulted from the growth in the number of new centers using our VAD System. An increase in the average selling price of the VAD pumps also contributed to the increase in revenue.

GROSS PROFIT

Gross profit was \$19.5 million, representing 64% of product sales in 2000 compared to a gross profit of \$12.8 million, representing 57% of product sales in 1999. The increase in the gross profit percentage in 2000 as compared to 1999 was due to proportionally higher domestic versus international sales, and improved average prices on domestic VAD pumps. We expect gross profit to increase as a percentage of product sales as we increase the number of devices manufactured and improve the efficiency with which we manufacture.

Gross profit was \$12.8 million, representing 57% of product sales in 1999 compared to a gross profit of \$9.8 million, representing 60% of product sales in 1998. The decrease in the gross profit percentage in 1999 as compared to 1998 was due to approximately \$400,000 of higher inventory scrap and rework costs associated with a component part used in the TLC-II portable driver, \$400,000 associated with higher overall manufacturing and service overhead costs associated with the new Pleasanton facility, and \$200,000 of costs associated with the move to the Pleasanton facility.

36

RESEARCH AND DEVELOPMENT

Research and development expenses increased to \$7.2 million in 2000, representing 24% of sales, from \$5.8 million in 1999, representing 26% of sales, an increase of \$1.4 million, or approximately 25%. Of the total increase in research and development expenses, \$375,000 was associated with the TLC-II, \$164,000 was associated with the IVAD, \$100,000 for grafts, and \$71,000 for support of the existing dual driver product. In addition to the above increases was an increase of \$748,000 in manufacturing support overhead applied to research and development activities. Expenses for the graft products increased primarily from the clinical trials for development of the Vectra. Expenses for the TLC-II included costs to upgrade a component part. Expenses for the IVAD included product prototype, development, and testing costs. We expect research and development expenses to increase in 2001 principally as a result of clinical trial costs for our graft products and our TLC-II portable driver, however, we expect these expenses to decrease in 2001 as a percentage of product sales.

Research and development expenses increased to \$5.8 million in 1999, representing 26% of sales, from \$5.1 million in 1998, representing 31% of sales, an increase of \$697,000, or 14%. Of the total increase in research and development expenses, \$372,000 was associated with the IVAD, \$251,000 was associated with graft products, and \$210,000 was associated with the TLC-II. Partially offsetting the above increases was a decrease of approximately \$216,000 in manufacturing support overhead applied to research and development activities. Expenses for the graft products increased primarily from the clinical trials for the Vectra. Expenses for the TLC-II included costs to upgrade a component part. Expenses for the IVAD included product prototype, design, development, and testing costs.

SELLING, GENERAL AND ADMINISTRATIVE

Selling, general and administrative expenses increased to \$11.0 million in 2000, representing 36% of sales, from \$9.4 million in 1999, representing 42% of sales, an increase of \$1.6 million, or 17%. Of the total increase in selling,

Edgar Filing: THORATEC CORP - Form 10-K/A

general and administrative expenses, \$900,000 is associated with higher payroll and related costs associated with the continued development and expansion of our domestic sales and marketing organization, and \$400,000 is associated with higher personnel-related administrative costs. We expect selling, general and administrative expenses to increase in 2001 as we continue to build our sales and marketing organization and as salaries for all personnel increase, however we expect these expenses to decrease in 2001 as a percentage of product sales.

Selling, general and administrative expenses increased to \$9.4 million in 1999, representing 42% of sales, from \$7.7 million in 1998, representing 47% of sales, an increase of \$1.7 million, or 22%. Of the total increase in selling, general and administrative expenses, \$1.3 million is associated with higher payroll and related costs associated with the continued development and expansion of our domestic sales and marketing organization.

MERGER RELATED EXPENSES

Merger related expenses in 2000 are comprised principally of external costs directly associated with the merger transaction previously discussed in the Liquidity and Capital Resources section. Included in the \$4.2 million merger related expenses are approximately \$1.7 million in accounting and legal costs (financing due diligence, statutory filings, and regulatory legal efforts), \$2.3 million in consulting costs (consulting and advisory services related to human capital, information technology, and risk management), and \$200,000 in other expenses.

OTHER OPERATING INCOME

Other operating income includes amortization of deferred revenue from the 1999 Guidant agreement and was approximately \$282,000 in 2000 and \$285,000 in 1999. Also included in other operating income in 2000 is a one-time payment of \$332,000 in conjunction with an amendment to a license granted to Gambro, Inc., formerly known as COBE Laboratories.

37

We expect other operating income to increase in 2001 with the amortization of the 2000 year end \$2,757,000 deferred distributor revenue balance over the remaining four year term of the distributor agreement.

INTEREST AND OTHER INCOME

Interest and other income includes interest earned on cash and marketable securities, foreign translation gains and losses, and income from government research grants. Interest and other income increased to \$713,000 in 2000 representing 2% of sales, from \$323,000 in 1999 representing 1% of sales, an increase of \$390,000, or approximately 121%. The increase in interest and other income was primarily attributable to higher interest income earned on higher cash balances due to cash proceeds from our stock offering partially offset by lower grant revenue.

Interest and other income decreased to \$323,000 in 1999 representing 1% of sales, from \$660,000 in 1998 representing 4% of sales, a decrease of \$337,000, or approximately 51%. The decrease in interest and other income was primarily attributable to lower interest income earned on lower cash balances.

NET LOSS

Our net loss decreased \$60,000 to \$1.7 million in 2000 from \$1.8 million in 1999, a decrease of 3%, as a result of the factors discussed above. Absent the effects of the \$4.2 million merger related expenses discussed above, net income

Edgar Filing: THORATEC CORP - Form 10-K/A

after taxes for the 2000 year would have been over \$2.4 million.

Our net loss decreased \$531,000 to \$1.8 million in 1999 from \$2.3 million in 1998, a decrease of 23%, as a result of the factors discussed above.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not use derivative financial instruments in our operations or investment portfolio. We do not have material exposure to market risk associated with changes in interest rates, as we have no long-term debt obligations or long-term investments outstanding. Our investment portfolio consists of short-term money market funds and municipal government auction bonds that are classified as available-for-sale. The weighted average maturity of our investment portfolio was less than 90 days in both 1999 and 2000. Accordingly, we do not expect to be subject to material interest rate risk with respect to our short-term investments. We do not believe we have any other material exposure to market risk associated with interest rates.

Although we conduct business in foreign countries, our international operations consist primarily of sales and service personnel for our VAD System. These employees report into our U.S. sales and marketing group and are internally reported as part of that group. Additionally, foreign currency transaction gains and losses were not material to our results of operations for 2000. Accordingly, we do not expect to be subject to material foreign currency risk with respect to future costs or cash flows from our foreign operations. To date, we have not entered into any significant foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements of the Company are set forth at pages F-1 to F-18 of this Report on Form 10-K.

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

Not applicable.

38

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE THORATEC CORPORATION

(a) Executive Officers -- See the section titled "Officers of the Registrant" in Part I, Item 4 hereof.

(b) As of March 9, 2001 there are eight directors on the company's Board of Directors. The term of office for each person elected as a director will continue until the next Annual Meeting of Shareholders or until his successor has been elected and qualified. There are no family relationships among any of the directors or officers of the company.

The name of and certain other information regarding the directors is set forth in the table below.

| NAME OF DIRECTOR | AGE | POSITION WITH THE COMPANY |
|------------------|-----|---------------------------|
|------------------|-----|---------------------------|

DI
S

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | |
|---------------------------------|----|---|
| J. Donald Hill(1)..... | 64 | Director and Chairman of the Board |
| D. Keith Grossman..... | 40 | Director, President and Chief Executive Officer |
| Howard E. Chase(2)..... | 64 | Director |
| J. Daniel Cole(2)..... | 54 | Director |
| William M. Hitchcock(2)..... | 61 | Director |
| George W. Holbrook, Jr.(1)..... | 69 | Director |
| Daniel M. Mulvena(1)..... | 52 | Director |
| Theo Melas-Kyriazi(3)..... | 41 | Director |

(1) Member of Compensation and Option Committee

(2) Member of Audit Committee

(3) Appointed as part of merger with Cardiosystems

D. KEITH GROSSMAN, PRESIDENT, CHIEF EXECUTIVE OFFICER AND DIRECTOR, joined our company as President and Chief Executive Officer in January 1996. He was elected to the Board of Directors in February 1996. Prior to joining us, Mr. Grossman was a Division President of Major Pharmaceuticals, Inc., from June 1992 to September 1995, at which time it was sold. From July 1988 to June 1992, Mr. Grossman served as the Vice President of Sales and Marketing for Calcitek, Inc., a manufacturer of implantable medical devices, and division of Sulzermedica (formerly Intermedics, Inc.). Prior to 1988, Mr. Grossman held various other sales and marketing management positions within the McGaw Laboratories Division of American Hospital Supply Corporation.

HOWARD E. CHASE became a director of our company in November 1986. Mr. Chase has been President and CEO of Carret Holdings, Inc. (formerly Matrix Global Investments, Inc.) since June 1999. Mr. Chase served as President and CEO of Trident Rowan Group, Inc. ("TRGI") from September 1995 to March 1998 and Chairman of the Board of TRGI from March 1998 to December 1999. From 1984 to August 1995, Mr. Chase was a partner in the law firm of Morrison Cohen Singer & Weinstein, LLP in New York City. He acted as an advisor and as a special counsel to our Company from 1979 to 1995. Mr. Chase also serves as a member of the board of directors of Trident Rowan Group, Inc. and Centerpoint Corporation (formerly Moto Guzzi Corporation).

J. DANIEL COLE became a director of our company in June 1997. Mr. Cole has been a general partner of the Spray Venture Fund of Boston since March 1997. Mr. Cole was President and Chief Operating Officer of SciMed Life Systems Corporation from March 1993 to March 1995, and Senior Vice President and Group President of Boston Scientific Corporation's vascular business from March 1995 to March 1997. He has also held a number of senior executive positions at Baxter Healthcare Corporation, including President of its Edwards Less Invasive Surgery Division and its Critical Care Division. Mr. Cole also serves as a member of the board of directors of numerous private companies.

J. DONALD HILL, M.D. has been a director of our company since its inception and is one of our significant shareholders. In January 1995, Dr. Hill became Chairman of the Board of Directors. Dr. Hill is the director of

the heart transplant program at California Pacific Medical Center in San Francisco where he has been a practicing cardiovascular surgeon since 1966.

Edgar Filing: THORATEC CORP - Form 10-K/A

WILLIAM M. HITCHCOCK became a director of our company in September 1996. Mr. Hitchcock serves as a member of the board of directors of Plains Resources Inc., Maxx Petroleum, Ltd and Luna Imaging, Inc. In 1996, Mr. Hitchcock became President of Avalon Financial, Inc. And in 1999, Mr. Hitchcock became President of Camelot Oil and Gas, LLC. He is a managing partner of Pembroke Financial Partners, LLC., a NASD Firm.

GEORGE W. HOLBROOK, JR. became a director of our company in June 1995. Since 1984 Mr. Holbrook has been the Managing Partner of Bradley Resources Company, a private investment partnership. Mr. Holbrook is also a director and trustee of Merrill Lynch Institutional Fund, Inc., and several associated funds, in addition to being a director of Autogenics, Ltd., Radiomed Corporation, Soilzone, and Radius Medical Technologies, Inc.

DANIEL M. MULVENA became a director of our company in May 1997. Mr. Mulvena is the founder and owner of Commodore Associates, a consulting company. Mr. Mulvena was Group Vice President of the Cardiac/Cardiology Division and a member of the operating committee for Boston Scientific Corporation from February 1992 to May 1995. Prior to that, he was the President and Chief Executive Officer and Chairman of Lithox Systems, Inc. Prior to that, Mr. Mulvena held a number of executive positions, including President of the Implants Division and President of the Cardiosurgery Division, at C.R. Bard, Inc. Mr. Mulvena also serves as a member of the board of directors of Echocath, Inc., Magna-Lab Inc., Zoll Medical Corporation and Cambridge Heart, Inc.

THEO MELAS-KYRIAZI became a director of our company in February 2001. He was appointed Chief Financial Officer of Thermo Electron Corporation on January 1, 1999. He joined Thermo Electron in 1986 as Assistant Treasurer, and became Treasurer in 1988. He was named President and Chief Executive Officer of ThermoSpectra in 1994, a position he held until becoming Vice President of Corporate Strategy of Thermo Electron in 1998.

BOARD MEETINGS AND COMMITTEES

The Board held a total of seven meetings during 2000. No director attended fewer than 75 percent of the aggregate of all meetings of the Board and of the committees upon which such director served.

The Audit Committee consists of Messrs. Chase, Cole, and Hitchcock, with Mr. Chase serving as Chairman. The principal functions of the Audit Committee are to recommend engagement of our Company's independent auditors, to consult with our Company's auditors concerning the scope of the audit and to review with them the results of their audit, to review and approve any material accounting policy changes affecting our Company's operating results and to review our Company's financial control procedures and personnel. The Audit Committee held four meetings during 2000.

The Compensation and Option Committee currently consists of Messrs. Holbrook and Mulvena, and Dr. Hill, with Mr. Mulvena serving as Chairman. The Compensation and Option Committee reviews and recommends to the Board compensation and benefits for our executive officers and management. The Compensation and Option Committee held four meetings during 2000.

The Board does not have a nominating committee.

BOARD COMPENSATION

Until February 2001, Directors received reimbursement for travel and other expenses directly related to their activities as directors. Outside directors were paid \$2,500 per meeting held in person and \$500 per quarter for committee meetings. In addition, with prior approval of the Chairman, consulting fees of \$1,500 per day for the first full day and \$1,000 per day thereafter may have

Edgar Filing: THORATEC CORP - Form 10-K/A

been paid.

After February 2001, all Directors will receive a \$15,000 retainer that will be paid annually on a calendar basis. They will also receive \$1,000 for each quarter where there is a board meeting attended by the Director,

40

and \$500 for each quarter where a committee meeting is attended by the Committee member. If the committee meeting exceeds four hours, the Chairman may also grant an additional fee. The Chairman of the Board will receive \$1,000 per quarter in which there is a board meeting that he attends, and each committee chairman will receive \$500 per quarter in which there is a committee meeting that he attends. Outside directors are eligible to participate in our 1996 Nonemployee Directors Stock Option Plan.

A total of 350,000 shares of our common stock have been reserved for issuance under the Directors Option Plan. The Directors Option Plan provides for the automatic granting of nonqualified stock options to directors of our company who are not employees of our company or any parent or subsidiary of our company and who have not been an employee of our company or any parent or subsidiary of our company in the previous 12 months ("Eligible Outside Directors"). Each person who is newly elected or appointed as an Eligible Outside Director on or after the meeting of shareholders in 1999 will be granted an option to purchase 15,000 shares of common stock, at fair market value, in quarterly installments on the effective date of such initial election or appointment (the "Initial Grant"). Each eligible Outside Director (including the existing outside directors) generally will be granted an option to purchase 7,500 shares of common stock, at fair market value, in quarterly installments beginning on the date of the first meeting of the Board of Directors following the annual shareholders meeting (the "Annual Grant"). In any event, both the Initial Grant and the Annual Grant will be made no later than August 31, November 30, February 28, or May 31 of the relevant year. As of March 9, 2001 options to purchase 182,915 shares, at fair market value, have been granted, of which 15,625 have been exercised. We currently have six nonemployee directors who are eligible to participate in the Directors Option Plan. The exercise price of the options in all cases is equal to the fair market value of common stock on the grant date. Each option granted after May 1999 pursuant to the Directors Option Plan expires five years after the date of grant or earlier in the event of the termination of the director's service on the Board. Each option granted after May 1999 under the Directors Option Plan is exercisable immediately after the date of grant with our company retaining the right to repurchase any stock acquired upon exercise. Such right of repurchase shall expire at the rate determined by us. In the event of acquisition of our company by a merger, consolidation, sale of all or substantially all our company's assets or acquisition of our company's shares, such right of repurchase shall lapse with respect to twice the number of shares still subject to the right of repurchase. The Board may waive the directors' fees in any given year and have the exercise price of options granted under the Directors Option Plan reduced by the amount of the fees so waived.

For 2000 Dr. Hill and Messrs. Chase, Cole, Hitchcock, Holbrook and Mulvena received compensation of \$11,000, \$12,000, \$11,000, \$12,000, \$11,500, and \$12,000 respectively. Each nonemployee director was granted options pursuant to the 1996 Directors Stock Option Plan to purchase 1,875 shares of common stock each on March 3, 2000, May 12, 2000, August 25, 2000, and November 17, 2000 with an exercise price of \$19.88 per share, \$11.63 per share, \$16.50 and \$13.13 per share respectively. Mr. Bell received compensation of \$3,000 and 1,875 shares of common stock on March 3, 2000, and retired shortly thereafter.

COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

Edgar Filing: THORATEC CORP - Form 10-K/A

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership on Form 3 and changes in ownership on Form 4 or 5 with the Securities and Exchange Commission and the National Association of Securities Dealers. Such officers, directors and ten percent shareholders are also required by Securities and Exchange Commission rules to furnish our company with copies of all Section 16(a) forms that they file.

Based solely on our review of copies of such reports received or written representations from certain reporting persons, we believe that, during 2000, there has been no failure by any of our officers, directors or ten percent shareholders to file on a timely basis any reports required by Section 16(a).

41

ITEM 11. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION

The following table sets forth certain summary information concerning the compensation received for services rendered to our company during 1998, 1999 and 2000 by the Chief Executive Officer of our company and each of the four additional most highly compensated executive officers (the "Named Executive Officers"):

SUMMARY COMPENSATION TABLE

| NAME AND PRINCIPAL POSITION | YEAR | ANNUAL COMPENSATION | | | LONG-TERM COMPENSATION | --- |
|----------------------------------|------|---------------------|-----------|-----------|---|---------------------------|
| | | SALARY | BONUS | OTHER (1) | SECURITIES UNDERLYING OPTIONS (#) | LIFE PR PAID COM |
| D. Keith Grossman(2)..... | 2000 | \$239,904 | \$224,798 | \$-- | 90,000 | |
| Chief Executive Officer, | 1999 | 214,362 | 107,569 | -- | 120,000 | |
| President and Director | 1998 | 192,750 | 131,070 | -- | 100,000 | |
| Thomas E. Burnett, Jr.(2)..... | 2000 | 188,750 | 141,528 | -- | 60,000 | |
| Senior Vice President, | 1999 | 158,318 | 57,614 | -- | 70,000 | |
| Chief Operating Officer | 1998 | 139,778 | 83,167 | -- | 52,500 | |
| David J. Farrar(2)(4)..... | 2000 | 168,300 | 98,649 | -- | 47,000 | |
| Vice President -- Research | 1999 | 152,598 | 58,674 | -- | 60,000 | |
| and Development | 1998 | 136,856 | 73,287 | -- | 52,500 | |
| Cheryl D. Hess(2)..... | 2000 | 170,250 | 106,299 | -- | 46,500 | |
| Chief Financial Officer and | 1999 | 156,588 | 57,108 | -- | 60,000 | |
| Secretary | 1998 | 139,778 | 76,930 | -- | 52,500 | |
| Donald A. Middlebrook(2)(4)..... | 2000 | 165,445 | 89,694 | -- | 45,000 | |
| Vice President -- Regulatory | 1999 | 152,473 | 43,437 | -- | 60,000 | |
| Affairs/Quality Assurance | 1998 | 137,808 | 66,417 | -- | 52,500 | |

(1) In accordance with the rules of the Securities and Exchange Commission, other annual compensation in the form of perquisites and other personal benefits has been omitted where the aggregate amount of such perquisites and other personal benefits constituted less than the lesser of \$50,000 or 10%

Edgar Filing: THORATEC CORP - Form 10-K/A

of the total annual salary and bonus for the Named Executive Officer for the fiscal year.

- (2) Other compensation in 1998, 1999, and 2000 represents employer contributions to a 401(k) retirement plan.
- (3) Amount represents premiums we paid for term life insurance for the benefit of the Named Executive Officer.
- (4) In accordance with the rules of the Securities and Exchange Commission, although this person was not an executive officer at the end of fiscal year 2000, this person is included as one of the Named Executive Officers because he would have been one of the Named Executive Officers but for the fact that he was not an executive officer at the end of fiscal year 2000.

42

OPTION GRANTS

The following table provides information concerning grants of options to purchase our stock made to each of the Named Executive Officers during 2000. No stock appreciation rights were granted to these individuals during 2000.

OPTION GRANTS IN 2000

| NAME | INDIVIDUAL GRANTS | | | | P AN PRI --- |
|--------------------------------|---|---|------------------------------|--------------------|-----------------------|
| | NUMBER OF SECURITIES UNDERLYING OPTIONS GRANTED | PERCENT OF TOTAL OPTIONS GRANTED TO EMPLOYEES IN 2000 | EXERCISE PRICE (\$/SH) | EXPIRATION DATE | |
| D. Keith Grossman..... | 90,000 | 9.8% | \$10.563 | 04/24/10 | \$59 |
| Thomas E. Burnett, Jr. | 60,000 | 6.5 | 10.563 | 04/24/10 | 39 |
| David J. Farrar..... | 45,000 | 4.9 | 10.563 | 04/24/10 | 29 |
| | 2,000 | .2 | 15.125 | 07/31/10 | 1 |
| Cheryl D. Hess..... | 45,000 | 4.9 | 10.563 | 04/24/10 | 29 |
| | 1,500 | .2 | 15.125 | 07/31/10 | 1 |
| Donald A. Middlebrook..... | 45,000 | 4.9 | 10.563 | 04/24/10 | 29 |

-
- (1) Amounts represent hypothetical gains that could be achieved for the respective options if exercised at the end of the option term. The assumed 5% and 10% rates of stock price appreciation are mandated by rules of the Securities and Exchange Commission and do not represent our estimate or projection of the future common stock price of our stock.

OPTION EXERCISES AND HOLDINGS

The following table sets forth the certain information regarding the value of exercised options and unexercised stock options held by each of the Named Executive Officers as of December 30, 2000.

2000 OPTION EXERCISES AND YEAR-END OPTION VALUES

Edgar Filing: THORATEC CORP - Form 10-K/A

| NAME | SHARES ACQUIRED ON EXERCISE (#) | VALUE REALIZED (\$) (1) | NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FISCAL YEAR END (2) | | VAL IN- AT |
|-------------------------------|------------------------------------|----------------------------|---|---------------|------------------|
| | | | EXERCISABLE | UNEXERCISABLE | |
| D. Keith Grossman..... | -- | -- | 373,333 | 270,000 | \$1,957 |
| Thomas E. Burnett, Jr..... | 19,000 | 158,385 | 129,750 | 133,750 | 309 |
| David J. Farrar..... | -- | -- | 120,333 | 115,000 | 630 |
| Cheryl D. Hess..... | 15,417 | 157,321 | 58,583 | 115,000 | 205 |
| Donald A. Middlebrook... | -- | -- | 142,500 | 115,000 | 403 |

(1) Value realized is based on the fair market value of our stock on the date of exercise (the closing sales price reported on The NASDAQ National Market, minus the exercise price, and does not necessarily indicate that the optionee sold such stock).

(2) Options vest over periods of two to four years from the date of the grant.

(3) Represents the difference between the option exercise price and the closing price of our stock as reported on The NASDAQ National Market at December 30, 2000.

REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS

During 2000, management compensation issues were reviewed by the Compensation and Option Committee, which consisted of Messrs. Holbrook, Mulvena and Dr. Hill. The function of the Compensation and Option Committee is to review and recommend management compensation to the Board. The Compensation and Option Committee met four times in 2000.

We believe that our ability to achieve the objectives of obtaining regulatory approval for and commercializing our circulatory support and graft products, and becoming profitable, is dependent largely upon our ability to recruit and retain qualified executives with substantive experience in the development, regulatory approval, manufacture, marketing and sale of new medical devices. We are competing for experienced executives within the San Francisco Bay Area, where over 100 biotechnology/biomedical/pharmaceutical companies are located.

We have a policy designed to control the base salaries of our executives while providing sufficient incentives to attract and retain qualified personnel. In accordance with this policy, we strive to set executive base salaries by considering relative contribution of the position to achievement of our goals and objectives, "market value" as defined by salaries of executives within the Bay Area with comparable experience in similar positions, and job-related responsibilities with respect to size of budget, number of subordinates and scope of activities. In general, we strive to set base salaries of new executives at market, which is defined as the average base salary of incumbents in comparable positions, and use our 1993, 1996 and 1997 Stock Option Plans to facilitate recruiting and to retain qualified executives by providing long-term

Edgar Filing: THORATEC CORP - Form 10-K/A

incentives. Typically, new executives are granted stock options as part of their initial employment package.

During 1993, the Internal Revenue Code of 1986 was amended to include a provision that denies a deduction to publicly held corporations for compensation paid to "covered employees" (defined as the chief executive officer and the next four most highly compensated officers as of the end of the taxable year) to the extent that compensation paid to any "covered employee" exceeds \$1 million in any taxable year of the corporation beginning after 1993. Certain "performance-based" compensation qualified for an exemption from the limits on deductions. It is our policy to attempt to qualify compensation paid to our top executives for deductibility in order to maximize our income tax deductions, to the extent that so qualifying the compensation is consistent with our fundamental compensation policies. Based upon the Internal Revenue Service's proposed regulations and compensation paid to our "covered employees" for the 2000 tax year, all compensation paid by our Company in 2000 to such covered employees was deductible to us.

Stock Options. We have determined that stock options are an important incentive for attracting and retaining qualified personnel, including executive-level personnel.

Corporate Performance Criteria. Management presents to us a set of corporate goals for a succeeding period, generally ranging from 12 to 18 months, as part of the annual plan and budget process. These goals establish benchmarks for assessing overall corporate performance. Given the dynamic nature of the new medical device development process, progress toward the achievement of corporate goals is reviewed with us periodically together with a description of any change in circumstances that management believes may warrant an update to or revisions of these goals. The principal corporate goals for 2000 were to achieve revenue and net income targets, successfully re-launch a product in Europe, and complete several clinical trials and regulatory submissions.

Periodic Salary Adjustments. Generally, executive salaries are reviewed annually, and salary adjustments may be awarded on the basis of increased responsibilities of individual executives over a period of time or the outstanding performance of individual executives as exhibited by consistently high standards in the execution of established duties, as described by the Chief Executive Officer to the Board. Company performance as a whole is a major consideration in our decision to award any salary increases and, to a lesser extent, we also consider general economic conditions and trends. The base salaries of our Company executives were increased by between three and four percent effective the first day of July 2000, based on performance and execution of duties.

44

Chief Executive Officer. Generally, the nonemployee members of the Board meet with the Chief Executive Officer to discuss the performance of the other executive officers and of our Company as a whole. The nonemployee members of the Board then meet in the absence of the Chief Executive Officer to discuss the performance of the Chief Executive Officer. Based on his leadership and achievements of key strategic and regulatory objectives for the year, Mr. Grossman's base salary was increased four percent effective the first day of July 2000. In addition, based on achievement of certain bonus-related objectives such as the corporate goals mentioned above, Mr. Grossman was awarded a bonus of \$224,798 for the 2000 fiscal year.

Summary. We believe that we have established a program for compensation of our executives which is fair and which aligns the financial incentives for executives with the interests of our shareholders.

Edgar Filing: THORATEC CORP - Form 10-K/A

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

During 2000, none of our executive officers served on the board of directors or compensation committee of another company that had an executive officer serve on our Board of Directors or our Compensation and Option Committee.

45

STOCK PRICE PERFORMANCE GRAPH

The Securities and Exchange Commission requires that we include a line-graph representation comparing five-year, cumulative shareholder returns for our common stock with a broad-based market index and either a nationally recognized industry standard or an index of peer companies selected by us.

The following line graph illustrates a five-year comparison of the cumulative total shareholder return on our common stock against the cumulative total return of The Nasdaq Stock Market (U.S.) Index and the Peer Group Index, assuming \$100 invested in our common stock and the two indexes on December 31, 1995.

In this report we compare the return on our common stock to the Nasdaq Stock Market Index (U.S. Companies only) and the Peer Group Index. Our company is included in the Nasdaq Stock Market Index (U.S. Companies only) and is similar in size and stage of commercialization as the other companies in the Peer Group.

The Peer Group Index consists of the following 14 Nasdaq companies: Abiomed, Inc., Advanced Neuromodulation Systems, Inc. (formerly Quest Medical, Inc.), Angeion Corporation, Arrow International, Inc., Atrion Corporation, Bio-Vascular, Inc., Cardiotech International, Inc., Datascope Corp., Eclipse Surgical Technologies, Inc., Fusion Medical Technologies, Inc., Gish Biomedical, Inc., Heartport, Inc., Possis Medical, Inc., and Thermo Cardiosystems Inc. Innerdyne was acquired by Tyco International Limited and has been removed from the peer group as their successor company is not of a similar size with our company.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
AMONG THORATEC CORPORATION,
THE NASDAQ STOCK MARKET (U.S.) INDEX AND A PEER GROUP

[PERFORMANCE GRAPH]

* \$100 INVESTED ON 12/31/95 IN STOCK OR INDEX --
INCLUDING REINVESTMENT OF DIVIDENDS.
FISCAL YEAR ENDING DECEMBER 31.

| | 12/95 | 12/96 | 12/97 | 12/98 | 12/99 | 12/00 |
|----------------------------|--------|--------|--------|--------|--------|--------|
| Thoratec Corporation | 100.00 | 63.33 | 44.17 | 47.50 | 65.00 | 73.33 |
| PEER GROUP | 100.00 | 68.98 | 66.91 | 41.35 | 47.60 | 47.33 |
| NASDAQ STOCK MARKET (U.S.) | 100.00 | 123.04 | 150.69 | 212.51 | 394.94 | 237.68 |

Edgar Filing: THORATEC CORP - Form 10-K/A

46

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of our common stock as of March 9, 2001 (i) by each of our directors, (ii) by each Named Executive Officer, (iii) by all directors and executive officers as a group, and (iv) by each person who is known by us to own beneficially more than 5% of our common stock.

| NAME AND ADDRESS(1) ----- | NUMBER OF SHARES BENEFICIALLY OWNED(2) ----- | PERCENT OF SH BENEFICIALLY OW ----- |
|--|--|---|
| Thermo Electron Corporation..... | 19,418,344 | 35.5% |
| Gambro (formerly COBE Laboratories, Inc.)..... | 3,133,077 | 5.7 |
| J. Donald Hill(3)..... | 1,416,120 | 2.6 |
| D. Keith Grossman(4)..... | 652,333 | 1.2 |
| George W. Holbrook, Jr.(5)..... | 468,892 | * |
| Bradley Resources Company(5)..... | 433,059 | * |
| James R. McGoogan(5)..... | 433,059 | * |
| William M. Hitchcock(6)..... | 389,573 | * |
| Thomas E. Burnett, Jr.(7)..... | 272,500 | * |
| Don A. Middlebrook(8)..... | 258,500 | * |
| David J. Farrar(9)..... | 242,189 | * |
| Cheryl D. Hess(10)..... | 230,381 | * |
| J. Daniel Cole(11)..... | 77,500 | * |
| Howard E. Chase(12)..... | 64,152 | * |
| Daniel M. Mulvena(13)..... | 37,500 | * |
| Theo-Melas Kyriazi(14)..... | 16,700 | * |
| Directors and Executive Officers as a Group (12 persons)(15)..... | 4,126,340 | 7.3 |

* Less than one percent

(1) The address of the persons set forth above is the address of our company appearing elsewhere in this 10-K.

(2) Applicable percentage ownership for each shareholder is based on 54,727,616 shares of common stock outstanding as of March 9, 2001, together with applicable options for such shareholder. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, and includes voting and investment power with respect to the shares. Beneficial ownership also includes shares of stock subject to options and warrants exercisable or convertible within 60 days of March 9, 2001. Shares of common stock subject to outstanding options are deemed outstanding for computing the percentage of ownership of the person holding such options, but are not deemed outstanding for computing the percentage ownership of any other person. Except pursuant to applicable community property laws or as indicated in the footnotes to this table, to our knowledge, each shareholder identified in the table possesses sole voting and investment power with respect to all shares of common stock shown as beneficially owned by such shareholder.

(3) Includes 104,722 shares issuable upon exercise of options exercisable

Edgar Filing: THORATEC CORP - Form 10-K/A

within 60 days of March 9, 2001.

- (4) Includes 643,333 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (5) Bradley Resources Company is an investment partnership which owns 433,059 shares. George W. Holbrook, Jr., a director of our company, is a general partner of Bradley Resources Company and is deemed to share beneficial ownership of such shares with Mr. James R. McGoogan, a general partner of Bradley Resources Company. Includes, in Mr. Holbrook's number only, 35,833 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (6) Includes 35,833 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (7) Includes 263,500 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (8) Includes 257,500 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.

47

- (9) Includes 217,833 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (10) Includes 173,583 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (11) Includes 37,500 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (12) Includes 64,152 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (13) Includes 37,500 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (14) Includes 16,700 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.
- (15) Includes 1,908,789 shares issuable upon exercise of options exercisable within 60 days of March 9, 2001.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In 1992 we entered into an agreement to sell common stock, representing 26% of the Company, to COBE Laboratories, Inc., or COBE, which included several provisions including a standstill agreement. We also finalized a licensing, manufacturing, and distribution agreement which provides for a royalty-bearing license to our biomaterial technology for use in certain of COBE's products, among other items. The licensing agreement was amended in 1999 to split the license into two separate agreements at the time of the sale of a portion of COBE's cardiovascular business. One is retained by COBE Laboratories, now called Gambro, Inc., a major shareholder of the company, and the other was granted to Sorin COBE Cardiovascular when that division of Gambro was sold to Sorin. In 1997, our obligation to manufacture biomaterials and distribute products through COBE terminated.

In the first quarter of 2000, we amended the license granted to Gambro,

Edgar Filing: THORATEC CORP - Form 10-K/A

Inc. to be a fully paid-up, world-wide, irrevocable field-of-use license and sublicense, with the right to sublicense others. The original license was for use in renal dialysis devices, blood component devices and blood tubing sets and accessories used in direct connection with any of these. We received a one-time payment of approximately \$330,000 in the first quarter of 2000 in conjunction with this amendment, which is included in other operating income in the first quarter of 2000. No additional consideration was granted in connection with this amendment. We have no continuing obligation to Gambro under this license agreement.

On February 14, 2001 we completed a merger with Thermo Cardiosystems, a Massachusetts-based manufacturer of cardiac assist, blood coagulation and skin incision devices. A merger agreement, a shareholder agreement and a registration rights agreement were entered into between Thoratec and Thermo Electron pursuant to the merger transaction. The transaction was a stock-for-stock transaction, accounted for as a reverse acquisition purchase in which Thermo Cardiosystems is treated as the acquirer of Thoratec for financial reporting purposes, and will be treated as a tax-free exchange. Under the terms of the merger agreement, each outstanding share of Thermo Cardiosystems stock was exchanged for 0.835 shares of newly issued Thoratec stock. Former Thoratec shareholders own approximately 43 percent of the shares outstanding. Thermo Electron Corporation, the parent company of Thermo Cardiosystems, received shares representing approximately 36 percent of the shares outstanding, which is subject to certain contractual lock-up provisions. In addition, we agreed to appoint a nominee of Thermo Electron to fill one of the seats on our Board of Directors until such time that Thermo Electron ceases to beneficially own at least 10% of the voting power of Thoratec.

We currently lease approximately 34,000 square feet of space from Thermo Electron, who is the beneficial holder of more than 5% of our voting securities, in Woburn, Massachusetts. This space is utilized for manufacturing, regulatory, research and development and administrative activities primarily associated with the Company's HeartMate products. The monthly rental is approximately \$15,000 per month.

Thermo Cardiosystems had subordinated convertible debentures outstanding prior to the merger with Thoratec, which were guaranteed by Thermo Electron. In connection with the merger, we obtained a letter of credit to guarantee Thermo Electron's obligations on the debentures. We also entered into a collateral and security agreement with the bank that issued the letter of credit for the pledge of cash and short term instruments of \$45.0 million to support the letter of credit. After the merger, the debentures became convertible into shares of Thoratec common stock, at a conversion price of \$37.62. Thermo Electron continues to guarantee the debentures.

48

PART IV

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

(a) LIST OF DOCUMENTS FILED AS PART OF THIS REPORT:

1. Financial Statements and Independent Auditors Report

Reference is made to the Index to Financial Statements under Item 8 of Part II of this report, where these documents are included.

2. Financial Statement Schedules

Financial Statement Schedules are not included because they are not

Edgar Filing: THORATEC CORP - Form 10-K/A

required or the information is otherwise shown in the financial statements or notes thereto.

3. Exhibits filed with this Report on Form 10-K (numbered in accordance with Item 601 of Regulation S-K)

| EXHIBIT NUMBER ----- | EXHIBIT ----- |
|----------------------------|--|
| 1.1 | Thoratec Corporation's Certificate of Incorporation, as amended.(1) |
| 1.2 | Thoratec Corporation's By-Laws, as amended.(1) |
| 4.1 | Form of Convertible Secured Promissory Note.(2) |
| 10.1 | Our amended 1984 Incentive Stock Option Plan.(3) |
| 10.2 | Our 1993 Stock Option Plan.(4) |
| 10.3 | Agreement for the acquisition of Th. Goldschmidt AG of Certain of the Assets of Thoratec Laboratories Corporation dated March 29, 1989.(5) |
| 10.4 | Common Stock Purchase Agreement between COBE Laboratories, Inc. dated November 23, 1992.(6) |
| 10.5 | License Agreement between COBE Laboratories, Inc. and us dated November 23, 1992.(6) |
| 10.6 | Lease Agreement dated July 25, 1996, between Main Street Associates and us, as amended.(7) |
| 10.7 | Our 1996 Stock Option Plan.(8) |
| 10.8 | Our amended 1996 Nonemployee Directors Stock Option Plan.(9) |
| 10.9 | First Amendment to Lease Agreement originally between Mainstream Associates and us dated July 25, 1996.(10) |
| 10.10 | Our 1997 Stock Option Plan.(9) |
| 10.11 | Second Amendment to Lease Agreement originally between Mainstreet Associates and us dated July 25, 1996.(11) |
| 10.12 | Distribution Agreement between Guidant Corporation and us dated January 13, 1999.(12) |
| 10.13 | Credit Agreement between us as Borrower, and Guidant Corporation as Lender dated January 13, 1999.(12) |
| 10.14 | Agreement and plan of merger by and among Thoratec Laboratories Corporation (since renamed Thoratec Corporation), Lightning Acquisition Corporation, Thermo Cardiosystems, Inc, and Thermo Electron Corporation dated October 3, 2000.(13) |
| 10.15 | Registration Rights Agreement by and between Thoratec Laboratories Corporation (since renamed to Thoratec Corporation) and Thermo Electron Corporation dated October 3, 2000.(13) |
| 10.16 | Shareholder Agreement by and between Thoratec Laboratories Corporation (since renamed to Thoratec Corporation) and Thermo Electron Corporation dated October 3, 2000.(13) |
| 21 | Subsidiaries of the Thoratec Corporation. |

| EXHIBIT NUMBER ----- | EXHIBIT ----- |
|----------------------------|------------------|
|----------------------------|------------------|

Edgar Filing: THORATEC CORP - Form 10-K/A

- 23.1 Independent Auditors' Consent -- Deloitte & Touche LLP.
24 Power of Attorney -- Reference is made to page 55 hereof.
The following exhibits filed by Thermo Cardiosystems (now Thoratec Cardiosystems) are incorporated herein by reference:
- 4.2 Form of Guarantee Agreement between the Thoratec Cardiosystems and Thermo Electron (filed as Exhibit 4(b) to the Thoratec Cardiosystems Registration Statement on Form S-1 [Reg. No. 33-25144] and incorporated herein by reference).
 - 4.3 Form of Amendment Number 1 to Guarantee Agreement between Thoratec Cardiosystems and Thermo Electron (filed as Exhibit 4(e) to the Thoratec Cardiosystems Registration Statement on Form S-1 [Reg. No. 33-34737] and incorporated herein by reference).
 - 4.4 Fiscal Agency Agreement dated January 5, 1993, among Thermo Electron, the Thoratec Cardiosystems, and Chemical Bank (filed as Exhibit 4.11 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the fiscal year ended January 1, 1994 [File No. 1-10114] and incorporated herein by reference).
 - 4.5 Guarantee Reimbursement Agreement dated February 7, 1994, among Thermo Cardiosystems, Thermo Voltek Corp., Thermedics, and Thermo Electron (filed as Exhibit 4.4 to Thermedics' Annual Report on Form 10-K for the fiscal year ended January 1, 1994 [File No. 1-9567] and incorporated herein by reference).
 - 4.6 Fiscal Agency Agreement dated as of May 14, 1997, among Thoratec Cardiosystems, Thermo Electron Corporation, and Bankers Trust Company as fiscal agent relating to \$70 million principal amount of 4 3/4% Convertible Subordinated Debentures due 2004 (filed as Exhibit 4 to Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended June 28, 1997 [File No. 1-10114] and incorporated herein by reference).
 - 10.17 Amended and Restated Corporate Services Agreement dated January 3, 1993, between Thermo Electron and Thoratec Cardiosystems (filed as Exhibit 10(b) to the Thoratec Cardiosystems' Annual Report on Form 10-K for the year ended January 2, 1993 [File No. 1-10114] and incorporated herein by reference).
 - 10.18 Sublease dated August 19, 1988, between the Thoratec Cardiosystems and Thermedics, as amended by Amendment No. 1 dated January 1, 1990 (filed as Exhibit 10(c) to the Thoratec Cardiosystems' Annual Report on Form 10-K for the fiscal year ended December 30, 1989 [File No. 1-10114] and incorporated herein by reference).
 - 10.19 Form of Indemnification Agreement between the Thoratec Cardiosystems and its officers and directors (filed as Exhibit 10(d) to the Thoratec Cardiosystems' Registration Statement on Form S-1 [Reg. No. 33-25144] and incorporated herein by reference).
 - 10.20 Intellectual Property Cross-license Agreement between Thermedics and the Thoratec Cardiosystems dated August 19, 1988 (filed as Exhibit 10(i) to the Thoratec Cardiosystems' Registration Statement on Form S-1 [Reg. No. 33-25144] and incorporated herein by reference).
 - 10.21 Agreement dated May 26, 1993, between The Polymer Technology Group Incorporated and the Thoratec Cardiosystems (filed as Exhibit 10(cc) to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended July 3, 1993 [File No. 1-10114] and incorporated herein by reference).
 - 10.22 Amended and Restated Master Repurchase Agreement dated July

Edgar Filing: THORATEC CORP - Form 10-K/A

2, 1996, between the Thoratec Cardiosystems and Thermo Electron (filed as Exhibit 10.7 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the fiscal year ended December 28, 1996 [File No. 1-10114] and incorporated herein by reference).

50

| EXHIBIT NUMBER ----- | EXHIBIT ----- |
|----------------------------|---|
| 10.23 | Incentive Stock Option Plan of the Thoratec Cardiosystems (filed as Exhibit 10(f) to the Thoratec Cardiosystems' Registration Statement on Form S-1 [Reg. No. 33-25144] and incorporated herein by reference). |
| 10.24 | Restated Stock Holdings Assistance Plan and Form of Promissory Note (filed as Exhibit 10.23 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the year ended January 3, 1998 [File No. 1-10114] and incorporated herein by reference). |
| 10.25 | Amended and Restated Master Guarantee Reimbursement and Loan Agreement dated as of December 18, 1997, between Thermo Electron and the Thoratec Cardiosystems (filed as Exhibit 10.24 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the year ended January 3, 1998 [File No. 1-10114] and incorporated herein by reference). |
| 10.26 | Amended and Restated Master Guarantee Reimbursement and Loan Agreement dated as of December 18, 1997, between Thermedics and the Thoratec Cardiosystems (filed as Exhibit 10.25 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the year ended January 3, 1998 [File No. 1-10114] and incorporated herein by reference). |
| 10.27 | Master Cash Management, Guarantee Reimbursement, and Loan Agreement dated as of June 1, 1999, between the Thoratec Cardiosystems and Thermo Electron Corporation (filed as Exhibit 10.1 to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended July 3, 1999 [File No. 1-10114] and incorporated herein by reference). |
| 10.28 | Amended and Restated Directors Stock Option Plan of the Company (filed as Exhibit 10.2 to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended July 3, 1999 [File No. 1-10114] and incorporated herein by reference). |
| 10.29 | Amended and Restated Deferred Compensation Plan for Directors of the Company (filed as Exhibit 10.3 to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended July 3, 1999 [File No. 1-10114] and incorporated herein by reference). |
| 10.30 | Amended and Restated Equity Incentive Plan of the Company (filed as Exhibit 10.4 to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended July 3, 1999 [File No. 1-10114] and incorporated herein by reference). |
| 10.31 | Amended and Restated Nonqualified Stock Option Plan of the Company (filed as Exhibit 10.5 to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended July 3, 1999 [File No. 1-10114] and incorporated |

Edgar Filing: THORATEC CORP - Form 10-K/A

- herein by reference).
- 10.32 Transition Agreement dated February 18, 2000, between R. Michael Kleine and Thermo Electron Corporation relating to the proposed sale of the Thoratec Cardiosystems (filed as Exhibit 10.27 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the year ended January 1, 2000 [File No. 1-10114] and incorporated herein by reference).
- 10.33 Transition Agreement dated February 18, 2000, between Victor L. Poirier and Thermo Electron Corporation relating to the proposed sale of the Thoratec Cardiosystems (filed as Exhibit 10.28 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the year ended January 1, 2000 [File No. 1-10114] and incorporated herein by reference).
- 10.34 Retention Agreement dated February 16, 2000, between Timothy Krauskopf and Thermo Electron Corporation relating to the Thoratec Cardiosystems (filed as Exhibit 10.29 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the year ended January 1, 2000 [File No. 1-10114] and incorporated herein by reference).
- 10.35 Retention Agreement dated February 16, 2000, between Jay Caplan and Thermo Electron Corporation relating to the Thoratec Cardiosystems (filed as Exhibit 10.30 to the Thoratec Cardiosystems' Annual Report on Form 10-K for the year ended January 1, 2000 [File No. 1-10114] and incorporated herein by reference).

51

EXHIBIT
NUMBER

EXHIBIT

- 10.36 Addendum to Transition Agreement dated February 18, 2000, between R. Michael Kleine and Thermo Electron Corporation (filed as Exhibit 10.1 to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 [File No. 1-10114] and incorporated herein by reference).
- 10.37 Addendum to Transition Agreement dated February 18, 2000, between Victor L. Poirier and Thermo Electron Corporation (filed as Exhibit 10.2 to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 [File No. 1-10114] and incorporated herein by reference).

-
- (1) Filed as an Exhibit with corresponding exhibit number to Thoratec's Registration Statement on Form S-1 (Registration No. 2-87293) and incorporated herein by reference. Amendment filed with the SEC on February 28, 2001 as Exhibit 3.1 to the Company's current report filed on Form 8-K (File No. 033-72502) and incorporated herein by reference.
- (2) Filed as an Exhibit to our Annual Report on Form 10-K for the fiscal year ended December 31, 1994 filed with the SEC on April 13, 1995, and incorporated herein by reference.
- (3) Filed as an Exhibit to our Annual Report on Form 10-K for the fiscal year

Edgar Filing: THORATEC CORP - Form 10-K/A

ended December 29, 1990 filed with the SEC on March 28, 1991, and incorporated herein by reference.

- (4) Filed as an Exhibit to our Annual Report on Form 10-K for the fiscal year ended January 1, 1994 filed with the SEC on March 22, 1994, and incorporated herein by reference.
- (5) Filed as an Exhibit to our Annual Report on Form 10-K for the fiscal year ended December 30, 1989 filed with the SEC on March 30, 1990, and incorporated herein by reference.
- (6) Filed as an Exhibit to our Annual Report on Form 10-K for the fiscal year ended January 2, 1993 filed with the SEC on March 22, 1993, and incorporated herein by reference.
- (7) Filed as an Exhibit to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 29, 1996, filed with the SEC on August 13, 1996, and incorporated herein by reference.
- (8) Filed as an Exhibit to our Registration Statement on Form S-8 filed with the SEC on September 12, 1996, (Registration No. 333-11883) and incorporated herein by reference.
- (9) Filed as an Exhibit to our Registration Statement on Form S-8 filed with the SEC on February 26, 2001 (Registration No. 333-56212), and incorporated herein by reference.
- (10) Filed as an Exhibit to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 28, 1997, filed with the SEC on July 30, 1997, and incorporated herein by reference.
- (11) Filed as an Exhibit to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 27, 1997 filed with the SEC on November 12, 1997, and incorporated herein by reference.
- (12) Filed as an Exhibit to our Annual Report on Form 10-K, for the fiscal year ended January 2, 1999, filed with the SEC on March 24, 1999, and incorporated herein by reference.
- (13) Filed as an Annex to our Registration on form S-4 filed with the SEC on December 29, 2000 (Registration No. 333-49120).

(b) REPORTS ON FORM 8-K

- (1) The following items were filed with the SEC on February 28, 2001 as exhibits to the current report on Form 8-K (File No. 033-72502) and are incorporated by reference:
 - Exhibit 3.1: certificate of Amended Restated Articles of Incorporation filed with the State of California on or about February 14, 2001
 - Exhibit 99.1: press release dated February 14, 2001 announcing closing of merger with Thermo Cardiosystems.

- (2) Thermo Cardiosystems press release dated January 31, 2000 announcing that its parent plans to seek a buyer for the Company (filed as Exhibit 99 to Thermo Cardiosystems, Inc. Current Report on Form 8-K dated February 1, 2000 (File No. 001-10114) and incorporated herein by reference.)

Edgar Filing: THORATEC CORP - Form 10-K/A

(3) Thermo Cardiosystems press release dated February 6, 2001 announcing 2000 year-end financial results (filed as Exhibit 99 to Thermo Cardiosystems, Inc. Current Report on Form 8-K dated February 6, 2001 (File No. 001-10114) and incorporated herein by reference.)

53

SIGNATURES

In accordance with Section 13 or Section 15(d) of the Exchange Act, the Thoratec Corporation caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

THORATEC LABORATORIES CORPORATION

By: /s/ D. KEITH GROSSMAN

D. Keith Grossman
Chief Executive Officer

Date: January 23, 2002

POWER OF ATTORNEY

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Thoratec Corporation and in the capacities and on the dates indicated.

| SIGNATURE ----- | TITLE ----- | DATE ----- |
|---|--|---------------|
| /s/ D. KEITH GROSSMAN ----- D. Keith Grossman | Chief Executive Officer, President and Director | January 23 |
| /s/ HOWARD E. CHASE ----- Howard E. Chase | Director | January 23 |
| /s/ J. DANIEL COLE ----- J. Daniel Cole | Director | January 23 |
| /s/ J. DONALD HILL ----- J. Donald Hill | Director and Chairman of the Board of Directors | January 23 |
| /s/ WILLIAM M. HITCHCOCK ----- William M. Hitchcock | Director | January 23 |
| /s/ GEORGE W. HOLBROOK, JR. ----- George W. Holbrook, Jr. | Director | January 23 |
| /s/ DANIEL M. MULVENA ----- Daniel M. Mulvena | Director | January 23 |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | |
|--|--|-------------------|
| <p>/s/ M. WAYNE BOYLSTON</p> <p>-----</p> <p>M. Wayne Boylston</p> | <p>Senior Vice President, Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)</p> | <p>January 23</p> |
| <p>/s/ THEO MELAS-KYRIAZI</p> <p>-----</p> <p>Theo Melas-Kyriazi</p> | <p>Director</p> | <p>January 23</p> |
| <p>/s/ D. KEITH GROSSMAN</p> <p>-----</p> <p>D. Keith Grossman *(Attorney-in-fact)</p> | <p>Chief Executive Officer, President and Director</p> | <p>January 23</p> |

54

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

| | PAGE |
|--|------|
| | ---- |
| Independent Auditor's Report..... | F-2 |
| Consolidated Balance Sheets..... | F-3 |
| Consolidated Statements of Operations..... | F-4 |
| Consolidated Statements of Comprehensive Loss..... | F-5 |
| Consolidated Statements of Shareholders' Equity..... | F-6 |
| Consolidated Statements of Cash Flows..... | F-7 |
| Notes to Consolidated Financial Statements..... | F-8 |

F-1

INDEPENDENT AUDITORS' REPORT

To the Shareholders and Board of Directors of
Thoratec Corporation:

We have audited the accompanying consolidated balance sheets of Thoratec Corporation and Subsidiary as of December 30, 2000 and January 1, 2000, and the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for the fiscal years ended December 30, 2000, January 1, 2000, and January 2, 1999. 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 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

Edgar Filing: THORATEC CORP - Form 10-K/A

all material respects, the financial position of Thoratec Corporation and Subsidiary as of December 30, 2000 and January 1, 2000 and the results of their operations and their cash flows for the fiscal years ended December 30, 2000, January 1, 2000, and January 2, 1999 in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California
February 14, 2001

F-2

THORATEC CORPORATION AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

ASSETS

| | FISCAL YEAR END | |
|--|-----------------|---------------|
| | 2000 | 1999 |
| Current Assets: | | |
| Cash and cash equivalents..... | \$ 3,405,733 | \$ 1,696,522 |
| Short-term investments available-for-sale (Note 2)..... | 12,650,233 | 276,464 |
| Receivables, net of allowance for doubtful accounts of \$6,108 in 2000 and \$32,795 in 1999 (Note 9)..... | 8,915,265 | 5,453,187 |
| Inventories (Note 3)..... | 8,710,005 | 6,611,487 |
| Prepaid expenses and other..... | 563,617 | 425,317 |
| Total current assets..... | 34,244,853 | 14,462,977 |
| Equipment and Improvements -- Net (Notes 4 and 5)..... | 9,309,294 | 9,560,814 |
| Other Assets (Note 5)..... | 1,167,224 | 1,036,647 |
| Total Assets..... | \$ 44,721,371 | \$ 25,060,438 |

LIABILITIES AND SHAREHOLDERS' EQUITY

| | | |
|--|--------------|--------------|
| Current liabilities: | | |
| Accounts payable..... | \$ 3,069,774 | \$ 1,703,089 |
| Accrued compensation..... | 2,894,076 | 1,466,147 |
| Deferred distributor revenue (Note 6)..... | 692,761 | 284,765 |
| Other..... | 642,755 | 475,870 |
| Total current liabilities..... | 7,299,366 | 3,929,871 |
| Long-term deferred distributor revenue (Note 6)..... | 2,063,968 | 854,294 |
| Total liabilities..... | 9,363,334 | 4,784,165 |
| Commitments (Notes 5, 8, 9, 13 and 15) | | |
| Shareholders' Equity: (Notes 7, 8, and 9) | | |
| Preferred shares -- none issued and outstanding..... | -- | -- |
| Common shares, 100,000,000 authorized; issued and outstanding: 22,421,375 in 2000; and 20,466,326 in 1999..... | 89,799,261 | 72,911,638 |
| Additional capital..... | 2,541,223 | 2,541,223 |
| Accumulated deficit..... | (56,919,784) | (55,191,216) |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | |
|--|---------------|---------------|
| Accumulated other comprehensive income (loss): | | |
| Cumulative translation adjustment..... | (62,663) | 14,628 |
| | ----- | ----- |
| Total accumulated other comprehensive income (loss)..... | (62,663) | 14,628 |
| | ----- | ----- |
| Total shareholders' equity..... | 35,358,037 | 20,276,273 |
| | ----- | ----- |
| Total Liabilities and Shareholders' Equity..... | \$ 44,721,371 | \$ 25,060,438 |
| | ===== | ===== |

See notes to consolidated financial statements.

F-3

THORATEC CORPORATION AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE FISCAL YEARS ENDED

| | 2000 | 1999 | 1998 |
|---|----------------|----------------|----------------|
| | ----- | ----- | ----- |
| Product sales (Notes 9 and 11)..... | \$30,429,424 | \$22,507,884 | \$16,319,531 |
| Cost of product sales..... | 10,918,980 | 9,738,946 | 6,503,986 |
| | ----- | ----- | ----- |
| Gross profit..... | 19,510,444 | 12,768,938 | 9,815,545 |
| | ----- | ----- | ----- |
| Operating Expenses: | | | |
| Research and development..... | 7,244,885 | 5,792,635 | 5,096,110 |
| Selling, general and administrative..... | 10,969,070 | 9,360,587 | 7,655,819 |
| Merger related expenses (Note 15)..... | 4,169,560 | -- | -- |
| | ----- | ----- | ----- |
| Total operating expenses..... | 22,383,515 | 15,153,222 | 12,751,929 |
| Other operating income (Notes 1 and 6)..... | 613,933 | 284,764 | -- |
| | ----- | ----- | ----- |
| Loss from operations..... | (2,259,138) | (2,099,520) | (2,936,384) |
| Interest and other income, net..... | 713,416 | 323,485 | 660,269 |
| | ----- | ----- | ----- |
| Loss before taxes..... | (1,545,722) | (1,776,035) | (2,276,115) |
| Income tax expense (note 10)..... | (182,846) | (13,075) | (44,437) |
| | ----- | ----- | ----- |
| Net loss..... | \$ (1,728,568) | \$ (1,789,110) | \$ (2,320,552) |
| | ===== | ===== | ===== |
| Basic and diluted loss per share (Note 1)..... | \$ (0.08) | \$ (0.09) | \$ (0.11) |
| | ===== | ===== | ===== |
| Shares used to compute basic and diluted loss per share..... | 21,830,723 | 20,445,837 | 20,339,816 |

See notes to consolidated financial statements.

F-4

THORATEC CORPORATION AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Edgar Filing: THORATEC CORP - Form 10-K/A

| | FOR THE FISCAL YEARS ENDED | | |
|---|----------------------------|----------------|----------------|
| | 2000 | 1999 | 1998 |
| Net Loss..... | \$ (1,728,568) | \$ (1,789,110) | \$ (2,320,552) |
| Other comprehensive income (loss): | | | |
| Unrealized gain (loss) on investments..... | -- | (8) | 7,547 |
| Foreign currency translation adjustments..... | (77,291) | 27,852 | 16,742 |
| Comprehensive Loss..... | \$ (1,805,859) | \$ (1,761,266) | \$ (2,296,263) |

See notes to consolidated financial statements.

F-5

THORATEC CORPORATION AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

| | COMMON STOCK | ADDITIONAL CAPITAL | ACCUMULATED DEFICIT | ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS) | TOTAL SHAREHOLDERS' EQUITY |
|---|--------------|--------------------|---------------------|---|----------------------------|
| BALANCE, FISCAL YEAR ENDED 1997..... | \$72,664,107 | \$2,482,229 | \$ (51,081,554) | \$ (37,505) | \$24,000,000 |
| Exercise of 292,535 common stock options for cash and exchange for 42,028 shares of common stock which were canceled..... | 146,343 | | | | 146,343 |
| Other comprehensive income: | | | | | |
| Unrealized gain on investments..... | | | | 7,547 | 7,547 |
| Foreign currency translation adjustments..... | | | | 16,742 | 16,742 |
| Net Loss..... | | | (2,320,552) | | (2,320,552) |
| BALANCE, FISCAL YEAR ENDED 1998..... | 72,810,450 | 2,482,229 | (53,402,106) | (13,216) | 21,679,567 |
| Exercise of 49,116 common stock options for cash and exchange for 5,742 shares of common stock which were canceled.... | 101,188 | | | | 101,188 |
| Issuance of common stock options for nonemployee services..... | | 58,994 | | | 58,994 |
| Other comprehensive income: | | | | | |
| Unrealized loss on investments..... | | | | (8) | (8) |
| Foreign currency translation | | | | | |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | | | | |
|---|--------------|-------------|----------------|------------|--------------|
| adjustments..... | | | | 27,852 | |
| Net Loss..... | | | (1,789,110) | | (1,789,110) |
| ----- | | | | | |
| BALANCE, FISCAL YEAR ENDED | | | | | |
| 1999..... | 72,911,638 | 2,541,223 | (55,191,216) | 14,628 | 20,273,285 |
| Exercise of 243,277 common stock options for cash and exchange for 13,228 shares of common stock which were canceled..... | 1,194,493 | | | | 1,194,493 |
| Issuance of 1,725,000 common shares, net of costs..... | 15,693,130 | | | | 15,693,130 |
| Other comprehensive income: Foreign currency translation adjustments..... | | | | (77,291) | (77,291) |
| Net Loss..... | | | (1,728,568) | | (1,728,568) |
| ----- | | | | | |
| BALANCE, FISCAL YEAR ENDED | | | | | |
| 2000..... | \$89,799,261 | \$2,541,223 | \$(56,919,784) | \$(62,663) | \$35,358,037 |
| | ===== | ===== | ===== | ===== | ===== |

See notes to consolidated financial statements.

F-6

THORATEC CORPORATION AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

| | FOR THE FISCAL YEARS ENDED | | |
|--|----------------------------|----------------|----------------|
| | 2000 | 1999 | 1998 |
| | ----- | ----- | ----- |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net loss..... | \$ (1,728,568) | \$ (1,789,110) | \$ (2,320,552) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Amortization of deferred distributor revenue..... | (282,330) | (284,764) | -- |
| Common stock options granted for services (Note 8)..... | -- | 58,994 | -- |
| Depreciation and amortization..... | 1,342,722 | 1,020,634 | 679,669 |
| Changes in assets and liabilities: | | | |
| Receivables..... | (3,588,239) | (1,344,479) | (2,827,077) |
| Prepaid expenses and other..... | (139,243) | (21,904) | (133,525) |
| Inventories..... | (2,171,476) | (1,349,296) | (1,380,538) |
| Other assets..... | (130,933) | (35,898) | 472,389 |
| Accounts payable and other liabilities..... | 3,153,216 | 462,939 | 36,469 |
| Deferred distributor revenue, net of fees... | 1,900,000 | 1,423,823 | -- |
| | ----- | ----- | ----- |
| Net cash used in operating activities.... | (1,644,851) | (1,859,061) | (5,473,165) |
| ----- | | | |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Purchases of short-term investments available-for-sale..... | (95,529,586) | (7,829,477) | (16,176,045) |
| Maturities of short-term investments available-for-sale..... | 82,871,602 | 6,354,000 | 18,620,000 |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | | |
|--|--------------|--------------|--------------|
| Sales of short-term investments available-for-sale..... | 284,215 | 3,231,112 | 922,148 |
| Capital expenditures..... | (1,153,263) | (988,860) | (4,800,285) |
| | ----- | ----- | ----- |
| Net cash provided by (used in) investing activities..... | (13,527,032) | 766,775 | (1,434,182) |
| | ----- | ----- | ----- |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Common stock issued in public placement -- net... | 15,711,057 | -- | -- |
| Common stock issued upon exercise of options..... | 1,194,493 | 101,188 | 146,343 |
| | ----- | ----- | ----- |
| Net cash provided by financing activities..... | 16,905,550 | 101,188 | 146,343 |
| | ----- | ----- | ----- |
| Effect of exchange rate changes on cash..... | (24,456) | (25,066) | 4,379 |
| | ----- | ----- | ----- |
| Net decrease in cash and cash equivalents..... | (1,709,211) | (1,016,164) | (6,756,625) |
| Cash and cash equivalents at beginning of year..... | 1,696,522 | 2,712,686 | 9,469,311 |
| | ----- | ----- | ----- |
| Cash and cash equivalents at end of year..... | \$ 3,405,733 | \$ 1,696,522 | \$ 2,712,686 |
| | ===== | ===== | ===== |
| NONCASH INVESTING TRANSACTIONS: | | | |
| Capital expenditures in accounts payable..... | \$ 34,082 | \$ 54,386 | \$ 71,828 |
| | ===== | ===== | ===== |
| Costs of financing in accounts payable..... | \$ 17,927 | | |
| | ===== | | |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION: | | | |
| Cash paid during the year for taxes..... | \$ 68,240 | \$ 13,075 | \$ 44,437 |
| | ===== | ===== | ===== |

See notes to consolidated financial statements.

F-7

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. OPERATIONS AND SIGNIFICANT ACCOUNTING POLICIES

Operations -- Thoratec Corporation and our subsidiary manufactures and markets medical devices utilizing specialty polymers and is engaged in ongoing research and development. Our products are marketed worldwide.

We report on a 52 - 53 week fiscal year, which ends on the Saturday closest to December 31. The fiscal years ended January 2, 1999 (fiscal 1998), January 1, 2000, (fiscal 1999), and December 30, 2000, (fiscal 2000) all include 52 weeks.

Principles of Consolidation -- The consolidated financial statements include Thoratec Corporation (a California corporation) and our subsidiary company, Thoratec Europe Limited (a corporation organized under the laws of the United Kingdom). All significant intercompany balances and transactions are eliminated in consolidation.

Use of Estimates -- The preparation of our consolidated financial statements in conformity with generally accepted accounting principles 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 consolidated balance sheet dates and the reported

Edgar Filing: THORATEC CORP - Form 10-K/A

amounts of revenues and expenses for the periods presented. Actual results could differ from these estimates.

Cash and Cash Equivalents -- Cash and cash equivalents include money market securities stated at cost, which approximates market value.

Investments -- Our short-term investments are classified as available-for-sale and reported at fair value. Net unrealized gains and losses are excluded from earnings and reported as a separate component of shareholders' equity. As of the end of 2000, short-term investments were comprised primarily of money market funds and municipal government auction bonds having maturity of 35 days or less from the date of investment.

Inventories -- Inventories are stated at the lower of first-in, first-out cost or market. We rent certain medical devices to customers on a month-to-month basis and include them in inventory, net of amortization when the devices are expected to be sold to customers within one year. Amortization expense of all rental equipment included in our rental program is recognized ratably over no longer than 36 months and is recorded in cost of product sales. The straight-line method is used for amortization.

Equipment and Improvements -- Equipment and improvements are stated at cost. Equipment is depreciated over estimated useful lives which range from two to eight years. Leasehold improvements are amortized over the term of the lease or over the estimated useful life of the improvements, whichever is shorter. Equipment and improvements includes certain medical devices rented to customers on a long-term basis. Amortization expense of all rental equipment included in our rental program is recognized ratably over no longer than 36 months and is recorded in cost of product sales. The straight-line method is used for depreciation and amortization.

We review for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of that asset may not be recoverable. An impairment loss would be recognized when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposal is less than carrying amount.

Income Taxes -- We follow an asset and liability approach for financial accounting and reporting of income taxes. Under this approach, we compute our tax liability at each consolidated financial statement date by applying provisions of current tax laws to temporary differences between consolidated financial statement and income tax bases. Changes in tax law may result in an adjustment to deferred tax assets.

F-8

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Fair Value of Financial Instruments -- Financial instruments include cash and cash equivalents, customer receivables, accounts payable, and certain other accrued liabilities. The carrying amounts of these items are a reasonable estimate of their fair values.

Foreign Currency Translation -- All assets and liabilities of our non-United States operations are translated into United States dollars at fiscal period-end exchange rates, and, except as follows, the resulting translation adjustments are included in comprehensive income. Income items are translated at actual or average monthly rates of exchange. Exchange rate fluctuations resulting from the period-end translation of the current portion of the intercompany obligation of our wholly-owned subsidiary into United States

Edgar Filing: THORATEC CORP - Form 10-K/A

dollars are recorded in the income statement as foreign currency translation gains or losses and are included in other non-operating expenses.

Revenue Recognition and Product Warranty -- We recognize product sales upon shipment of the related product. A provision for estimated future costs relating to warranty expense is recorded when products are shipped. We rent certain medical devices to customers on a month-to-month basis. Rental income is based on utilization and is included in income as earned. Included in product sales for 2000, 1999, and 1998 are approximately \$1,311,000, \$1,082,000, and \$1,064,000 respectively, for income earned from the rental of these medical devices. Sales related to training provided to customers are recognized as the services are provided.

We recognize distributor revenue ratably over the life of the related distributor agreement. Amortized distribution revenue is included in other operating income and was approximately \$282,000 in 2000 and 285,000 in 1999 (See Note 6). Also included in other operating income in 2000 is a one-time payment of approximately \$330,000 in conjunction with an amendment to a license granted to Gambro, Inc., formerly known as COBE Laboratories. (See Note 9).

Accounting for Stock-Based Compensation -- We account for stock-based awards to employees using the intrinsic value method in accordance with Accounting Principals Board Opinion No. 25, "Accounting for Stock Issued to Employees." Proforma disclosures of net earnings and earnings per share consistent with the method of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" are included in Note 8.

Loss Per Share -- Basic earnings per share are computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per share reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Diluted earnings per share for 2000, 1999, and 1998 exclude any effect from such securities as their inclusion would be antidilutive, therefore, diluted earnings per share is the same as basic earnings per share for all periods presented.

Comprehensive Loss -- Comprehensive loss includes net loss and is defined as the change in net assets during the period from non-owner sources, unrealized gains and losses on investments and foreign currency translation adjustments.

Operating Segments -- We are organized as a single operating segment, whereby our chief operating decision maker assesses the performance of and allocates resources to the business as a whole. (See Note 11).

Other Assets -- Other assets principally include deposits on our building lease and interest earned on those deposits.

Recently Issued Accounting Standard -- During June 1998, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities", which defines derivatives, requires that all derivatives be carried at fair value, and provides for hedging accounting when certain conditions are met. Such Statement is effective for all fiscal quarters of fiscal years beginning after June 15, 2000. We have completed our analysis of this standard and believe that it will not have a material impact on our financial statements.

F-9

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Edgar Filing: THORATEC CORP - Form 10-K/A

Presentation -- Certain 1999 and 1998 amounts have been reclassified to conform to the presentation in the 2000 financial statements.

2. SHORT-TERM INVESTMENTS

Short-term investments available-for-sale are summarized as follows:

| | AMORTIZED COST | GROSS UNREALIZED GAINS | GROSS UNREALIZED LOSSES | FAIR VALUE |
|---|-------------------|------------------------------|-------------------------------|--------------|
| | ----- | ----- | ----- | ----- |
| Fiscal 1999 | | | | |
| Corporate debt instruments..... | \$ 276,464 | \$-- | \$-- | \$ 276,464 |
| | ===== | == | == | ===== |
| Fiscal 2000 | | | | |
| Municipal government agency bonds..... | \$12,650,233 | \$-- | \$-- | \$12,650,233 |
| | ===== | == | == | ===== |

The Company classifies those investments which mature in less than one year as short-term investments.

3. INVENTORIES

Inventories consist of the following:

| | FISCAL YEAR | |
|----------------------|-------------|-------------|
| | 2000 | 1999 |
| | ----- | ----- |
| Finished goods..... | \$3,536,822 | \$2,172,493 |
| Rental drivers..... | 1,590,913 | 990,562 |
| Work-in-process..... | 1,740,536 | 2,033,194 |
| Raw materials..... | 1,841,734 | 1,415,238 |
| | ----- | ----- |
| Total..... | \$8,710,005 | \$6,611,487 |
| | ===== | ===== |

Rental drivers in the inventory are those rental units that we expect may be subject to purchase by customers.

4. EQUIPMENT AND IMPROVEMENTS

Equipment and improvements consist of the following:

| | FISCAL YEAR | |
|-----------------------------|--------------|--------------|
| | 2000 | 1999 |
| | ----- | ----- |
| Equipment..... | \$ 5,584,308 | \$ 4,568,466 |
| Leasehold Improvements..... | 7,587,197 | 7,540,866 |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | |
|--|--------------|--------------|
| Construction in Progress..... | 110,843 | 119,473 |
| | ----- | ----- |
| Total..... | 13,282,348 | 12,228,805 |
| Accumulated depreciation and amortization..... | (3,973,054) | (2,667,991) |
| | ----- | ----- |
| | \$ 9,309,294 | \$ 9,560,814 |
| | ===== | ===== |

Included in equipment for 2000 and 1999 is product used in our rental program of approximately \$1,062,000 and \$647,000 of cost, respectively, and \$456,000 and \$261,000 of accumulated amortization, respectively.

5. LEASES

We lease offices, laboratory and manufacturing space under noncancelable operating leases. In 1996 we entered into a lease agreement for a new facility located in Pleasanton, California, which accommodates all of

F-10

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

our manufacturing, engineering and administrative activities. The administrative and engineering portion of the building was completed and occupied in late 1997. The manufacturing portion was completed in 1998 and occupied in 1999 after receiving clearance from the FDA. We have invested approximately \$9 million in equipment and leasehold improvements to the building. Annual payments under the lease are approximately \$781,000 for a lease term of 15 years and commenced in August 1997. The lease includes provisions, among others, for annual cost of living adjustments to the lease payments, two five-year renewal options, a purchase option, and a security deposit of \$1,058,324 which is included in other assets. A significant portion (\$750,000) of the remaining security deposit can be reduced or eliminated before the end of the initial lease term if we meet certain criteria as specified by the contract. Future minimum lease payments as of the end of fiscal year 2000 are noted below:

FISCAL YEAR:

| | |
|-----------------|-------------|
| 2001..... | \$ 803,399 |
| 2002..... | 803,399 |
| 2003..... | 803,399 |
| 2004..... | 803,399 |
| 2005..... | 803,399 |
| Thereafter..... | 5,217,344 |
| | ----- |
| Total..... | \$9,234,339 |
| | ===== |

Rent expense for all operating leases was \$790,859 in 2000, \$871,162 in 1999, \$911,609 in 1998.

6. DEFERRED DISTRIBUTOR REVENUE

During the first quarter of 1999, we entered into a distribution agreement with Guidant Corporation. Under the terms of the agreement, Guidant receives

Edgar Filing: THORATEC CORP - Form 10-K/A

exclusive worldwide marketing and distribution rights to the Company's Vectra vascular access graft product line, except in Japan. In exchange for these rights, Guidant has made \$3.5 million in non-refundable payments which we have been recognizing as revenue over the estimated life of the agreement. \$1.5 million was recognized as deferred distributor revenue at the time the agreement was signed and \$2.0 million was recognized as deferred distributor revenue in December 2000 upon receiving FDA approval to market Vectra in the U.S.

Other operating income in 2000 and 1999 includes approximately \$282,000 and \$285,000, respectively, of the amortization of deferred distributor revenue. The remaining deferred distributor revenue of \$2,757,000 at the end of 2000 will be recognized into income ratably over the remaining four year term of the agreement.

7. COMMON AND PREFERRED STOCK AND WARRANTS

The Company has authorized 100,000,000 no par common shares, and 2,500,000 shares of preferred stock, of which 540,541 shares have been designated Series A and 500,000 shares designated Series B.

The Series A preferred stock is entitled to cumulative annual dividends of \$1.30 per share and has a liquidation preference of \$9.25 plus cumulative unpaid dividends. The Company may redeem the Series A preferred stock at any time for its liquidation preference. Each share of preferred stock is convertible into one-third of a share of common stock, after adjusting for earned but unpaid dividends. At December 30, 2000, no shares of Series A preferred stock were outstanding.

Series B preferred stock is senior to Series A in all preferences. Series B is entitled to cumulative annual dividends of \$.96 per share and has a liquidation preference of \$8.00 plus cumulative unpaid dividends. The Series B preferred stock is redeemable by the Company five years after issuance for \$8.00 per share plus cumulative unpaid dividends. Each share of Series B preferred stock is convertible at any time into three and

F-11

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

one-third shares of common stock and has certain anti-dilution provisions. Series B preferred votes on an as-converted basis. At December 30, 2000, no shares of the Series B preferred stock were outstanding.

In April 2000, we sold, through an underwritten public offering, 2,000,000 shares of common stock at \$10.00 per share. Included in the 2,000,000 shares were 500,000 shares offered by Gambro Inc., a major shareholder of our company, for which we received no proceeds. In addition, the underwriters exercised a 30-day option to purchase from us and Gambro 300,000 shares of common stock to cover any over-allotments, of which the proceeds from 225,000 shares were received by us. After deducting underwriting discounts of approximately \$983,000, we received a total of \$16,267,000, from which approximately \$574,000 in offering-related costs have been paid. Underwriting discounts and the other estimated offering-related costs were recorded as an offset to common stock at the closing of the offering. We intend to use the net proceeds for clinical trials of products under development, expansion of our sales and marketing capabilities, research and development, potential acquisitions of complementary technology, working capital and other general corporate purposes.

In November 1997, the Company sold through a public offering 2,000,000 shares of common stock at \$5.00 per share. Net cash proceeds received by the

Edgar Filing: THORATEC CORP - Form 10-K/A

Company related to this offering were approximately \$8,809,000 after placement agents' fees and approximately \$491,000 of other costs.

In July 1996, the Company sold, through an underwritten public offering, 1,644,000 shares of common stock at \$12.00 per share. In connection with the public offering the underwriters were issued five-year warrants to purchase 164,400 shares of the Company's common stock at \$14.40 per share. The warrants are currently exercisable and include a net exercise provision. Net cash proceeds received by the Company related to this offering were approximately \$17,591,000. Underwriters' commissions, the fair value of warrants issued to the underwriters, and approximately \$1,050,000 of other estimated costs have been recorded as a deduction to the proceeds received from the sale of the common stock. In February 2001, subsequent to the end of 2000, the warrants were cancelled as a result of the merger with Thermo Cardiosystems pursuant to the original terms of the warrants.

For other common stock information, see Note 8.

8. OPTIONS

In 1993, the Directors approved the 1993 Stock Option Plan ("1993 SOP"), which permits us to grant options to purchase up to 666,667 shares of common stock. During 2000 and 1998, 24,347 and 52,500 options, respectively, were granted under this plan. No options were granted under this plan in 1999.

In 1996, the Directors adopted the 1996 Stock Option Plan ("1996 SOP") and the 1996 Nonemployee Directors Stock Option Plan ("Directors Option Plan"). The 1996 SOP consists of two parts. Part One permits the Company to grant options to purchase up to 500,000 shares of common stock. During 2000, 1999, and 1998, 69,552, 6,000, and 132,500 options, respectively, were granted at fair market value under this Part of the Plan. Part Two related to the Chief Executive Officer (CEO) and permits the Company to grant non-qualified options to the CEO to purchase up to 333,333 shares of common stock. During 1996, 333,333 options were granted at fair market value under this Part of the Plan. In November 1997, these options were repriced to the then fair market value of \$5.00 per share. All other options of the CEO were canceled in conjunction with the repricing. The Directors Option Plan was amended by approval by a vote of the Company's shareholders in May 1999 for all option grants going forward. The amendments include increasing the number of shares granted to the Board of Directors in the initial grants from 10,000 to 15,000 shares (granted in four equal installments, once when elected to the Board then quarterly thereafter), and the annual grants from 5,000 to 7,500 shares (granted in four equal installments after re-election). Provisions were also made for immediate vesting of both initial and annual grants, and for changing the term of the options from ten to five years. In addition, the number of shares reserved for issuance under The Director's Option Plan was increased

F-12

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

from 150,000 to 350,000 and the plan administrator has been provided with the discretion to impose any repurchase rights in favor of the Company on any optionee. The Company currently has six non-employee directors who are eligible to participate in the Directors Option Plan. During 2000, 1999, and 1998, 46,875, 39,375, and 35,000 options, respectively, were granted at fair market value under this plan.

In 1997, the Directors adopted the 1997 Stock Option Plan ("1997 SOP"). The 1997 SOP was amended by approval of a vote of our Company's shareholders in

Edgar Filing: THORATEC CORP - Form 10-K/A

February 2001. During 2000, 1999, and 1998, 777,389, 1,038,276, and 718,960 options, respectively, were granted at fair market value under this plan. As of December 30, 2000, prior to the February amendment, 365,091 options remained available for grant under this plan. The amendment increased the number of shares of our common stock reserved for issuance for options granted under this plan by 6,400,000. This increase is to enable the company to assume the options to purchase shares of Thermo Cardiosystems common stock that were outstanding upon closure of the Thermo Cardiosystems merger and also to grant additional shares, over time after the merger, to an expanded employee base.

Including the 1993 SOP, the 1996 SOP, the Directors Option Plan, the 1997 SOP, and several older plans, we had eight common stock option plans. Options may be granted by the Board of Directors at fair market value at the date of grant. Options under closure plans generally become exercisable immediately to within five years of grant and expire between five and ten years from date of grant. At December 30, 2000, options to purchase 581,758 common shares remain available for grant under all the plans.

Agreements have been entered into with selected consultants whereby options to purchase our common stock were accepted by these consultants as full or partial payment for the services rendered to the Company. The fair market value of the consulting service is the basis for recording the fair market value of the transaction in the Company's financial records and is recognized as the related services are performed. Options issued under these agreements totaled 500 in 2000 and 17,341 in 1999, and are included in the grant activity previously discussed.

The Company applies APB Opinion 25 and related Interpretations in accounting for its employee stock-based compensation plans. Accordingly, no compensation cost has been recognized for its stock option plans. Had compensation cost for the Company's stock-based plans been determined based on the fair value at the grant dates for awards under those plans consistent with the method of FASB Statement 123, the Company's net loss and net loss per share would have been increased to the proforma amounts indicated in the following table. As 1996 was the initial phase-in period for applying this Statement, the proforma results indicated are not necessarily representative of the effects on proforma disclosures of net income for future periods as they exclude options that were granted prior to January 1, 1995, with vesting periods in 1995 and later.

| | FISCAL YEAR | | |
|----------------------------------|---------------|---------------|---------------|
| | 2000 | 1999 | 1998 |
| Net Loss | | | |
| As reported..... | \$(1,728,568) | \$(1,789,110) | \$(2,320,552) |
| Pro forma..... | (7,025,505) | (5,230,110) | (4,565,552) |
| Basic and diluted loss per share | | | |
| As reported..... | \$ (0.08) | \$ (0.09) | \$ (0.11) |
| Pro forma..... | (0.32) | (0.26) | (0.22) |

The fair value of each option grant is estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants made in 2000, 1999, and 1998: risk-free interest rates of 6.04% in 2000, 5.71% in 1999, and 5.09% in 1998; expected volatility of 86% in 2000, 77% for 1999, and 81% for 1998; expected lives of one year in 2000, and two years in 1999 and 1998 beyond each incremental vesting period (total life of one to six years), depending upon each grant's individual vesting

Edgar Filing: THORATEC CORP - Form 10-K/A

schedule. No dividends are assumed for any plan in any year.

F-13

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Option activity is summarized as follows:

| | NUMBER OF OPTIONS | WEIGHTED AVERAGE EXERCISE PRICE |
|--|----------------------|---------------------------------------|
| | ----- | ----- |
| Outstanding at fiscal year end 1997 (844,747 exercisable at \$3.56 weighted average exercise price per share)..... | 1,795,119 | \$ 4.98 |
| Granted (\$4.08 weighted average fair value per share)..... | 938,960 | 6.44 |
| Canceled and expired..... | (143,288) | 4.45 |
| Exercised(1)..... | (292,535) | 1.50 |
| | ----- | |
| Outstanding at fiscal year end 1998 (790,934 exercisable at \$5.60 weighted average exercise price per share)..... | 2,298,256 | \$ 6.05 |
| Granted (\$5.01 weighted average fair value per share)..... | 1,083,651 | 8.11 |
| Canceled and expired..... | (192,967) | 6.44 |
| Exercised(2)..... | (49,116) | 3.11 |
| | ----- | |
| Outstanding at fiscal year end 1999 (1,220,699 exercisable at \$6.09 weighted average exercise price per share)..... | 3,139,824 | \$ 6.78 |
| Granted (\$5.96 weighted average fair value per share)..... | 918,163 | 11.54 |
| Canceled and expired..... | (189,768) | 8.84 |
| Exercised(3)..... | (243,277) | 5.76 |
| | ----- | |
| Outstanding at fiscal year end 2000 (1,796,988 exercisable at \$7.18 weighted average exercise price per share)..... | 3,624,942 | \$ 7.94 |
| | ===== | |

-
- (1) Includes 68,893 options exercised for \$146,343 cash and 223,642 options exercised by exchange for 42,028 shares of common stock, which were canceled.
 - (2) Includes 36,402 options exercised for \$101,188 cash and 12,714 options exercised by exchange for 5,742 shares of common stock, which were canceled.
 - (3) Includes 211,193 options exercised for \$1,194,493 cash and 32,084 options exercised by exchange for 13,228 shares of common stock, which were canceled.

The status of options outstanding as of the end of fiscal 2000 is summarized as follows:

| PRICE CATEGORY | OPTIONS OUTSTANDING | | | OPTIONS EXERCISABLE | |
|----------------|-----------------------|---|---------------------------------------|-----------------------|---------------------------------------|
| | NUMBER OUTSTANDING | WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE | WEIGHTED AVERAGE EXERCISE PRICE | NUMBER OUTSTANDING | WEIGHTED AVERAGE EXERCISE PRICE |
| | ----- | ----- | ----- | ----- | ----- |
| | | | | | |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | | | | |
|--------------------|-----------|------------|---------|-----------|---------|
| \$ 0.75 | 38,870 | .26 years | \$ 0.75 | 37,499 | \$ 0.75 |
| \$ 1.14 to \$ 2.25 | 173,011 | 2.56 years | 2.18 | 173,011 | 2.18 |
| \$ 4.38 to \$ 6.00 | 888,360 | 6.82 years | 5.43 | 585,702 | 5.35 |
| \$ 6.06 to \$ 7.13 | 517,124 | 7.11 years | 6.44 | 275,511 | 6.45 |
| \$ 7.16 to \$ 8.25 | 709,591 | 8.33 years | 8.20 | 177,513 | 8.18 |
| \$ 8.44 to \$10.25 | 363,849 | 7.15 years | 8.99 | 212,954 | 9.09 |
| \$10.50 to \$13.13 | 746,885 | 8.91 years | 10.65 | 238,024 | 10.64 |
| \$13.13 to \$15.88 | 101,758 | 7.75 years | 14.99 | 64,275 | 14.99 |
| \$16.00 to \$21.00 | 75,495 | 7.95 years | 17.97 | 22,500 | 18.19 |
| \$30.00 | 9,999 | 5.43 years | 30.00 | 9,999 | 30.00 |
| | ----- | | | ----- | |
| \$ 0.75 to \$30.00 | 3,624,942 | 7.39 years | 7.94 | 1,796,988 | 7.18 |
| | ===== | | | ===== | |

In conjunction with the merger between Thoratec and Thermo Cardiosystems, options to purchase 887,621 shares of Thoratec stock became fully vested at the close of the merger transaction on February 14,

F-14

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

2001. This acceleration of vesting was provided in the terms of the original grants. Of the 887,621 options that accelerated, waiver and retention agreements involving options to purchase 868,750 shares were entered into whereby the option holders agreed not to sell or transfer any of their shares for a period of up to 18 months in exchange for a retention bonus if the option holder continues in the employ of Thoratec during the period ending 12 months after the effective date of the merger transaction. See note 14.

9. RELATED PARTIES

In 1992 we entered into an agreement to sell common stock, representing 26% of the Company, to COBE Laboratories, Inc., "COBE", which included several provisions including a standstill agreement. The Company and COBE also finalized a licensing, manufacturing, and distribution agreement which provides for a royalty-bearing license to our biomaterial technology for use in certain of COBE's products, among other items. The licensing agreement was amended in 1999 to split the license into two separate agreements at the time of the sale of a portion of COBE's cardiovascular business. One is retained by COBE Laboratories, now called Gambro, Inc., a major shareholder of the Company, and the other was granted to Sorin COBE Cardiovascular when that division of Gambro was sold to Sorin. In 1997, the Company's obligation to manufacture biomaterials and distribute products through COBE terminated.

In the first quarter of 2000, we amended the license granted to Gambro, Inc., to be a fully paid-up, world-wide, irrevocable field-of-use license and sublicense. The original license was for use in renal dialysis devices, blood component devices and blood tubing sets and accessories used in direct connection with any of these. We received a one-time payment of approximately \$330,000 in the first quarter of 2000 in conjunction with this amendment, which is included in other operating income in the first quarter of 2000. We have no continuing obligation to Gambro under this license agreement.

Sales to COBE and its affiliates for 2000, 1999, and 1998 were nil, \$167,000, and \$145,000, respectively. Receivables from COBE and its affiliates were nil at the end of fiscal year 2000 and \$17,100 at the end of fiscal year

Edgar Filing: THORATEC CORP - Form 10-K/A

1999.

For other related party transactions, see Notes 12 and 15.

10. TAXES ON INCOME

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating loss and tax credit carryforwards.

Significant components of the Company's net deferred taxes are as follows:

| | FISCAL YEAR | |
|--|--------------|--------------|
| | 2000 | 1999 |
| Deferred tax assets: | | |
| Federal tax loss carryforward (as adjusted for the limitation on change in ownership)..... | \$ 5,751,000 | \$ 6,920,000 |
| State tax loss carryforward..... | 49,000 | 375,000 |
| Deferred revenue..... | 295,000 | 450,000 |
| Foreign..... | 1,093,000 | 750,000 |
| Credits (research and manufacturing)..... | 1,192,000 | 970,000 |
| Other, net..... | 992,000 | 685,000 |
| | ----- | ----- |
| Total..... | 9,372,000 | 10,150,000 |
| Less: Valuation allowance..... | (9,372,000) | (10,150,000) |
| | ----- | ----- |
| | \$ -- | \$ -- |
| | ===== | ===== |

F-15

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

At the end of fiscal 2000, the Company had net operating loss ("NOL") carryforwards of approximately \$18.5 million. The majority of such carryforwards expire from 2003 through 2018. Use of the \$7.4 million NOL which arose prior to the greater than 50% change in ownership which occurred in 1992 is limited to approximately \$440,000 per year due to such change.

Due to these limitations and due to the fact that the Company has sustained cumulative losses, the potential future benefit from these deferred assets are fully reserved by means of a valuation allowance and will therefore produce a financial statement benefit if and when utilized.

A reconciliation between the effective tax rate and the statutory federal rate follows:

| | FISCAL YEAR | | |
|--|-------------|-------|-------|
| | 2000 | 1999 | 1998 |
| | ----- | ----- | ----- |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | | | | | |
|---|--------------|---------|--------------|---------|--------------|---------|
| Income tax benefit at statutory rate..... | \$ (526,000) | 34.0% | \$ (608,000) | (34.0)% | \$ (789,000) | (34.0)% |
| State taxes..... | 280,000 | (18.1) | (85,000) | (4.8) | (26,000) | (1.1) |
| Increase in tax credit carryforwards..... | (100,000) | 6.5 | (115,000) | (6.4) | (96,000) | (4.1) |
| Increase in valuation allowance... | (778,000) | 50.3 | 725,000 | 40.5 | 975,000 | 42.0 |
| Nondeductible merger expenses..... | 1,418,000 | (91.7) | -- | -- | -- | -- |
| Other, net..... | (112,000) | 7.2 | 96,000 | 5.4 | (20,000) | (.9) |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| | \$ 182,000 | (11.8)% | \$ 13,000 | (.7)% | \$ 44,000 | (1.9)% |
| | ===== | ===== | ===== | ===== | ===== | ===== |

11. ENTERPRISE AND RELATED GEOGRAPHIC INFORMATION

We manage our business on the basis of one reportable operating segment. (See Note 1 for a brief description of the Company's business.) Net sales by geographic area are presented by attributing revenues from external customers or distributors on the basis of where the products are sold. Long-lived assets by geographic area and information about products and services are included as enterprise-wide disclosures.

Receivables in 2000 include a \$2 million receivable due from Guidant related to the milestone payment generated by the FDA approval of the Vectra graft. No other customer accounted for greater than 10% of trade receivables in 2000 or 1999. No customer accounted for greater than 10% of product sales in 2000, 1999 or 1998. Export product sales accounted for 18%, 23%, and 26% of our total product sales in 2000, 1999, and 1998 respectively.

GEOGRAPHIC AREAS

| | FISCAL YEAR | | |
|------------------------------|--------------|--------------|--------------|
| | 2000 | 1999 | 1998 |
| Product Sales: | | | |
| International Europe..... | \$ 3,413,921 | \$ 3,597,973 | \$ 2,718,794 |
| All Other International..... | 2,081,501 | 1,606,447 | 1,497,584 |
| | ----- | ----- | ----- |
| Subtotal International..... | 5,495,422 | 5,204,420 | 4,216,378 |
| Domestic..... | 24,934,002 | 17,303,464 | 12,103,153 |
| | ----- | ----- | ----- |
| Total..... | \$30,429,424 | \$22,507,884 | \$16,319,531 |
| | ===== | ===== | ===== |

F-16

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

| FISCAL YEAR | |
|-------------|-------|
| 2000 | 1999 |
| ----- | ----- |

Edgar Filing: THORATEC CORP - Form 10-K/A

| | | |
|------------------------------|-------------|-------------|
| Long-lived assets: | | |
| International -- Europe..... | \$ 489,009 | \$ 377,958 |
| Domestic..... | 8,820,285 | 9,182,856 |
| | ----- | ----- |
| Total..... | \$9,309,294 | \$9,560,814 |
| | ===== | ===== |

CLASSES OF SIMILAR PRODUCTS

| | FISCAL YEAR | | |
|--------------------------|--------------|--------------|--------------|
| | 2000 | 1999 | 1998 |
| | ----- | ----- | ----- |
| Product Sales: | | | |
| Circulatory Support..... | \$29,374,316 | \$21,768,089 | \$15,637,756 |
| Vascular Graft..... | 1,055,108 | 739,795 | 681,775 |
| | ----- | ----- | ----- |
| Total..... | \$30,429,424 | \$22,507,884 | \$16,319,531 |
| | ===== | ===== | ===== |

12. UNAUDITED QUARTERLY INFORMATION FOR FISCAL YEAR 2000 AND 1999

| | FIRST | SECOND | THIRD | FOURTH |
|---|---------|---------|----------|---------|
| | ----- | ----- | ----- | ----- |
| FISCAL YEAR 2000 | | | | |
| Revenues..... | \$7,606 | \$7,261 | \$ 6,194 | \$9,368 |
| Gross profit..... | 4,674 | 4,700 | 3,973 | 6,163 |
| Net income (loss)..... | 648 | 354 | (1,869) | (862) |
| Basic earnings per share..... | .03 | .05 | (.13) | (.08) |
| Diluted earnings per share..... | .03 | .04 | (.13) | (.08) |
| FISCAL YEAR 1999 | | | | |
| Revenues..... | \$5,375 | \$4,892 | \$ 5,076 | \$7,165 |
| Gross profit..... | 3,027 | 3,231 | 2,751 | 3,760 |
| Net loss..... | (336) | (53) | (902) | (498) |
| Basic and diluted earnings per share..... | (.02) | (.00) | (.04) | (.02) |

13. COMMITMENTS

In October 1997, we executed a four-year agreement with Arrow International, Inc. ("Arrow") to supply the mechanical valves for the disposable blood pump used in the Company's VAD System. As of December 30, 2000, the remaining long-term purchase commitment associated with this agreement was approximately \$1.2 million.

In July 1998, we established an Executive Officer Severance Benefits Plan and an Employee Severance Benefits Plan as part of the employee benefits package. The plans provide severance benefits to certain employees whose employment is terminated, other than for cause. An Executive Officer's standard severance pay benefit is equal to one times annualized base salary. An employee's severance pay benefit is equal to an amount based on job level and length of service.

Edgar Filing: THORATEC CORP - Form 10-K/A

In January 2000, we entered into a four-year employment agreement with a key executive officer. This employment agreement provides for, among other provisions, a minimum base salary, an annual bonus based on performance, and a severance package. In September 2000, we entered into a three-year employment agreement with another key executive officer. This employment agreement provides for, among other provisions, a minimum base salary, an annual bonus based on performance, and a severance package.

F-17

THORATEC CORPORATION AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

We are not party to any legal proceedings other than ordinary routine litigation incidental to our business. We believe that the ultimate resolution of these matters will not have a material adverse effect on our consolidated financial statements taken as a whole.

See Notes 6, 8, 9, and 14 for additional commitments.

14. RETIREMENT SAVINGS PLAN

Effective January 1997, we implemented a 401(k) Plan, or the Plan, covering all employees who have met certain eligibility requirements. Under the Plan, employees may elect to contribute up to 18% of their eligible compensation to the Plan, subject to certain limitations. In 1998 and 1999 we matched employee contributions at 25% up to the first 6% of employees' compensation. In 2000 the Company match was changed to 50% up to the first 6% of employee contributions. Employees vest at the rate of 25% per year, with full vesting after four years of service with the Company. For fiscal years 2000, 1999, and 1998 we made contributions to the Plan of approximately \$251,000, \$91,000, and \$54,000, respectively.

15. SUBSEQUENT EVENT

On February 14, 2001 the Company completed a merger with Thermo Cardiosystems, a Massachusetts-based manufacturer of cardiac assist, blood coagulation and skin incision devices. A merger agreement, a shareholder agreement and a registration rights agreement were entered into between Thoratec and Thermo Electron Corporation, the parent company of Thermo Cardiosystems, pursuant to the merger transaction. The transaction was a stock-for-stock transaction, accounted for as a reverse acquisition purchase in which Thermo Cardiosystems is treated as the acquirer of Thoratec for financial reporting purposes. The transaction will be treated as a tax-free exchange. Under the terms of the agreement, each outstanding share of Thermo Cardiosystems stock was exchanged for 0.835 shares of newly issued Thoratec stock. The estimated purchase price of \$348 million has been assigned to the tangible and intangible assets acquired and liabilities assumed of Thoratec. Current Thoratec shareholders own approximately 43 percent of the shares outstanding. Thermo Electron received shares representing approximately 36 percent of the proforma shares outstanding, which is subject to certain contractual lock-up provisions. In addition, Thoratec agreed to appoint a nominee of Thermo Electron to fill one seat on Thoratec's Board until such time that Thermo Electron ceases to beneficially own at least 10% of the voting power of Thoratec. A nominee of Thermo Electron was appointed to Thoratec's Board in February 2001.

As part of the merger with Thermo Cardiosystems, subordinated debentures (4 3/4%) with a face value of approximately \$54 million at December 30, 2000, became convertible into shares of Thoratec common stock. The debentures are due May 15, 2004, and continue to be guaranteed by Thermo Electron, the former

Edgar Filing: THORATEC CORP - Form 10-K/A

parent of Thermo Cardiosystems. We have issued a standby letter of credit for \$45 million as surety for the debentures with securities received in the merger pledged in an amount equal to the face value of the letter of credit.

F-18