

Congestive heart failure currently affects nearly five million people. Only about 2,000 heart transplants are available per year. Thoratec devices offer an option for survival.

Thoratec Corporation  
2004 Annual Report



**Ella Penrice, age 50**  
**(HeartMate II LVAD patient)**

“The HeartMate made a difference in my life. The biggest thing is I can enjoy life. I clean, I cook, I built my own deck. Those were things I couldn’t do before, but now I can.”



**HeartMate II LVAD\***  
**(Left Ventricular Assist Device)**

This next-generation technology has the potential to benefit a broader patient population due to its small size. It has been designed to last five years or longer.



**HeartMate XVE LVAD**  
**(Left Ventricular Assist Device)**

The most widely used implantable LVAD and the only device approved in the U.S. for Destination Therapy—permanent support.





**Gary Morris, age 76**  
**(HeartMate XVE LVAD - Destination Therapy patient)**

"I'm enjoying my life. I have granddaughters that just love me. If there was one thing I'd like to do, it would be to watch them grow up a little more. With this device, I can do that."





**Brenda Locke, age 47**  
**(Thoratec IVAD patient, transplanted)**

“I survived six months with the device while I waited for my transplant. After I got the device, there were a number of things I could do that I never dreamt of, like getting on a treadmill. I was able to enjoy my life even while waiting for the transplant.”



**Thoratec IVAD  
(Implantable Ventricular Assist Device)**

The only implantable VAD for left, right, or biventricular support that allows patients to go home.



**Thoratec VAD**  
**(Ventricular Assist Device)**

With a decade in clinical use, a wide range of patients have benefited from this device—nearly 3,000 patients worldwide.





**Mark Yahiro, age 45**  
**(Thoratec VAD patient, transplanted)**

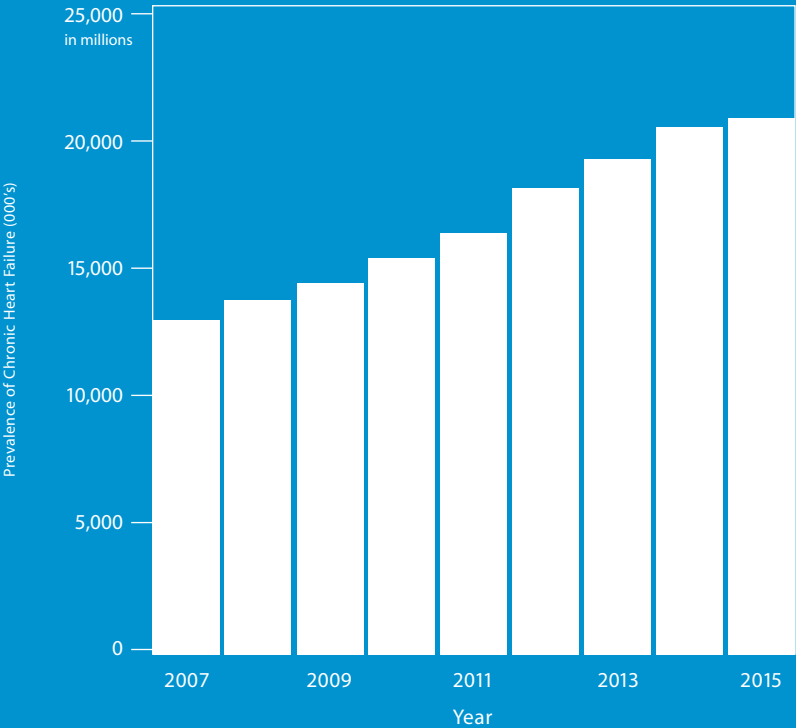
“The device sustained my life and allowed me to get a transplant. It also enabled me to see my loved ones. I’ve realized what’s most important in my life.”



As heart failure becomes more pervasive, solutions for patients become even more important. Our device technology has demonstrated compelling results in treating the disease and improving patients' quality of life.



# Projected Prevalence of Chronic Heart Failure



EpiVision Heart Failure - Epidemiology Forecasts to 2015; Datamonitor 2002

# Thoratec: Pioneering an Industry

## **Stage D** (*Refractory symptoms requiring special intervention*)

VAD, transplantation

Inotropes

Hospice

## **Stage C** (*Structural disease, previous or current symptoms*)

Standard medical therapy

Cardiac resynchronization therapy

Revascularization, mitral-valve surgery

Aldosterone antagonist, nesiritide

## **Stage B** (*Structural heart disease, no symptoms*)

ACE inhibitors or ARB's in all patients

Beta-blockers in selected patients

## **Stage A** (*High risk with no symptoms*)

Risk-factor reduction; patient education

Treat hypertension, diabetes, dyslipidemia, ACE inhibitors

The ACC/AHA heart failure guidelines define Stage D patients as those with marked symptoms of heart failure at rest despite maximal medical therapy. For these late-stage patients, there are very limited treatment options.



# Heart Failure

Heart failure is a progressive disease that affects an increasing number of people every year. This is attributable in great part to the “graying” of America—within the next 15 years, it is estimated that at least 53 million people living in the U.S. will be 65 years of age or older. Not only are people living longer, but due to advances in treatment, they are also surviving the earlier stages of heart disease.

Heart failure is a leading cause of death in America, and it remains Medicare’s greatest area of healthcare-related spending. Those who are afflicted with late-stage heart failure experience a poor quality of life, account for a high consumption of costly healthcare and experience high mortality rates. While heart transplantation is an option, there is an insufficient number of hearts available, and many patients do not qualify because of other health conditions. Nevertheless, the most widely used form of treatment—drug-based therapy—has limited effectiveness in treating these late-stage patients.

It is estimated that by later this decade, more than half a million Americans suffering from late-stage heart failure will have received some form of device-related therapy. As a result of continuously improving patient outcomes for those implanted with a device, clinicians are increasingly turning to cardiac assist devices, such as those developed by Thoratec.

# Destination Therapy

Destination Therapy, or permanent support with the use of our HeartMate XVE LVAS (Left Ventricular Assist System) is now an increasingly viable option for late-stage heart failure patients who do not qualify for a transplant. A landmark study demonstrated survival and quality-of-life benefits for patients implanted with our device. More current clinical data suggest these outcomes are getting even better, and we are hopeful that the level of adverse events will continue to decline.

Since becoming the only company with an approved device for Destination Therapy in the U.S., we have been developing the market in a measured and responsible fashion. With reimbursement more than doubling in the past two years and improving outcomes, we are seeing increasing receptivity to the procedure among clinicians.

Thoratec’s Heart Hope program continues to be an important element of our market development effort. Additionally, we are working closely with our centers to foster increased awareness among referring physicians and their patients of the full spectrum of treatment options that VADs offer to restore hemodynamics and improve survival and quality of life for late-stage heart failure patients.

# An Unmatched Track Record of Innovation

- First commercial, FDA-approved implantable LVAD in the U.S.
- Most widely used implantable LVAD
- Only LVAD that does not require systemic anticoagulation
- Landmark clinical trial comparing left ventricular assist device support to optimally medically managed patients
- Only FDA-approved LVAD for Destination Therapy or permanent support
- Only paracorporeal device approved to discharge patients home
- Only company with three approved ventricular assist devices, a fourth in clinical trial and fifth under development



# Product Development

With an unmatched track record of innovation and successful product development programs, we are creating an ever-increasing portfolio of solutions that can treat a wide range of heart failure patients.

Our most exciting near-term opportunity is the HeartMate II. With the potential to provide support for five years or longer, the device portends a seminal change in the treatment of those suffering from late-stage heart failure. Its approval could greatly expand the market for cardiac assist devices.

The Phase I clinical trial results for the HeartMate II, which concluded at the end of 2004, have created a high level of interest among clinicians. In the study, we collected approximately six years of cumulative patient support, and the device performed very well. Patients were typically discharged to their homes and resumed many normal activities. We understand from clinicians that the surgical process appears to be much simpler and faster with this device, with some reporting that they completed the procedure in half the time required for implant of the XVE.

We received conditional approval to begin a pivotal Phase II trial for the HeartMate II in February 2005. This study represents a breakthrough for clinical trials involving cardiac assist devices as it includes a number of unique elements.

Our HeartMate III, another next-generation rotary pump with a bearingless system, continues to perform well in the laboratory. Based on the results of additional testing during the year, we hope to initiate a clinical program for the device as early as 2006.

# Emerging Therapies

Potentially revolutionary advancements in the treatment of heart failure are emerging. They involve exploration of how novel biotherapeutics or pharmacologic agents can be used in combination with current or next-generation cardiac assist devices. As part of our vision to offer a broad range of solutions for the treatment of heart failure, we have taken steps during the past year to position Thoratec in the forefront of these efforts.

Among the possible approaches we are exploring are the use of pharmaceuticals, gene therapy and cell therapies, such as skeletal myoblasts and adult stem cells. A hypothesis with growing support is that a patient suffering from heart failure could be supported with a VAD, unloading the heart and allowing these therapies to improve the heart's function through the regeneration of heart cells. Ultimately, the patient would regain use of his native organ.

An important step in this strategy occurred with our equity investment in BioCardia, Inc., a privately-held company that is developing tools to enable the local delivery of biotherapeutics to the heart, including its Helical Infusion Catheter System. The device has performed well in preclinical studies and results from initial human safety studies have been positive.

We will continue to explore similar kinds of partnerships with organizations that will provide us access to emerging technologies. While the development of these therapies will be a long-term process, we expect to see significant progress later this decade.

# Continued Growth Through Product Diversity

- Most complete line of coagulation and critical care testing for point-of-care
- 45% sales growth in alternate site sector for 2004
- Emerging markets in several European countries where the growth rate exceeds that in the U.S.
- Next-generation ProTime and HEMOCHRON Signature Systems in product development



# International Technidyne Corporation (ITC)

Since introducing the first point-of-care coagulation test device nearly 40 years ago, ITC has played an important role in the delivery of cardiovascular care by providing critical data at the patient's bedside.

Point-of-care devices represent an alternative to the traditional method of utilizing a hospital's central lab to conduct blood analysis. Improving technology—much of which was pioneered by ITC—and growing demand by clinicians for time sensitive patient data are driving market growth for ITC's offerings.

Today, ITC augments its strong presence in the hospital point-of-care market with a growing line of products that can be used at alternate sites, such as a doctor's office, nursing home, clinic or a patient's home. ITC sales in this sector alone grew by 45 percent in 2004.

ITC's products include HEMOCHRON point-of-care systems that perform a variety of blood coagulation tests, and can also provide the surgeon important information about heparin and protamine dosing during an open heart procedure.

ITC's ProTime Microcoagulation System is an alternate site device used to manage dosing of blood-thinning drugs, while the Hgb Pro measures hemoglobin levels in blood within 30 seconds at the point of care. The latest addition to ITC's point-of-care product line, IRMA TRUpoint, tests for blood gas,

electrolytes and other chemistries. These offerings combine to give ITC the most complete line of coagulation and critical care testing products for point-of-care applications. The division also markets a leading line of skin incision products used to obtain small blood samples for analysis.

A key factor in ITC's growth has been its transition to a direct sales force, an initiative that was completed in the first quarter of 2005. As a result, ITC has been able to increase its share in the core U.S. hospital market and capitalize on new opportunities. These emerging markets include Europe—where the growth rate in several countries exceeds that in the U.S.—and group purchasing organizations that are becoming increasingly important to our business.

To handle the increased demand for ITC's current and future offerings, we have expanded cuvette manufacturing capacity by 50 percent through additional automation and staffing, and in 2005 will incorporate new facilities that offer room for additional growth.

ITC has several important product development initiatives underway, including the next generation of ProTime and HEMOCHRON Signature systems, a new platform combining HEMOCHRON and IRMA TRUpoint technology, and a new device for the alternate site market.

# VAD Product Portfolio

## 1. HeartMate XVE

Only mid- to long-term LVAD requiring no systemic anticoagulation

## 2. Thoratec IVAD

First and only implantable BiVAD for short- to mid-term support

## 3. Thoratec VAD

Proven technology for short- to mid-term RVAD, LVAD or BiVAD support

## 4. HeartMate II \*

Small LVAD with patented design for long-term support

## 5. HeartMate III \*\*

Magnetically levitated bearingless design for longer life



\* Caution: Investigational device limited by federal (U.S.A.) law to investigational use. Exclusively for clinical investigators.

\*\* Under development, not for sale in the U.S.

# ITC Product Portfolio

## 6. IRMA TRUpoint

Point-of-care blood gas, electrolyte and chemistry testing

## 7. HEMOCHRON Response

Hospital point-of-care whole blood coagulation testing

## 8. HEMOCHRON Jr. Signature+

Low-volume point-of-care whole blood coagulation testing

## 9. Hgb Pro

Point-of-care hemoglobin testing

## 10. ProTime

Prothrombin time testing for office, clinic and home



6.



8.



7.



9.



10.

“We continue our track record of getting new products to market, expanding what is already the broadest product portfolio in the industry.”



# To Our Shareholders



D. Keith Grossman  
President and Chief Executive Officer

This past year was marked by a number of significant accomplishments, as we successfully pursued our strategy of building a long-term leadership position in our industry and capitalizing on an ever-growing market opportunity.

Evidence of our success was reflected by solid revenue growth of 15 percent, increased market presence, significant advances in the third party reimbursement area, new product approvals and major progress in the development of our next-generation technologies. We also strengthened the Company's financial position with a \$144 million convertible debt offering. Despite investing more than \$100 million to repurchase approximately 8.5 million shares of stock, we ended 2004 with a strong cash and short-term investments position of \$146 million. Our progress in 2004 was exciting and a tribute to the efforts of Thoratec employees and our pioneering customers.

We are seeking to create enduring value for Thoratec by becoming a leading developer of technology to treat late-stage heart failure and other cardiovascular disorders. We recognize that achieving success will require a thoughtful, long-term strategy, but we have accomplished much over this past year.

## Progress in Destination Therapy

The Company realized major achievements in the development of the VAD market during 2004, the first full year in which we had Medicare reimbursement for the Destination Therapy indication. This is a significant opportunity for the Company and one where we believe our FDA approval has put us ahead of U.S. commercial competition for a number of years. Others developing devices for this market are entering lengthy and challenging clinical trials—typically with their first product—even as we ended 2004 with three approved ventricular assist devices and a fourth already in clinical trials.

Because of its importance in fostering the Destination Therapy market, customer reimbursement for this therapy has been a major focus. The fact that average Medicare payment for procedures completed by CMS VAD centers has increased from approximately \$54,000 to approximately \$136,000 in just two years speaks to the success of our efforts and the importance of the procedure in treating late-stage heart failure. The most significant portion of this increase occurred in late 2004, which we believe will have an enabling effect on our business going forward.

A second element of our strategy has been to achieve ever-improving patient outcomes through device enhancements, and the dissemination of best practices among clinicians and our centers. We have seen dramatic improvements in the patient experience as evidenced by meaningful declines in adverse events and improved survival rates in our most experienced centers.

We believe that the combination of higher reimbursement and these improving patient outcomes is resonating in the marketplace. An increasing number of centers are putting Destination Therapy programs in place and more clinicians are beginning to refer patients for treatment. We think the pace of adoption will continue to reflect that the market is beginning to recognize the advantages of this procedure.

A key element of our strategy is increasing the focus on the referring cardiologists who traditionally have treated these patients with other therapies, primarily drugs. Improving patient outcomes are aiding our cause, but we are also embarking on new educational and sales programs as part of an expanded marketing effort to create greater appreciation of the patient experience for those supported by our device. We recognize that we are attempting to overcome many years of

“One of the most exciting developments in 2004 was the initiation and completion of our promising HeartMate II Phase I clinical trial.”

“We launched an initiative to explore emerging therapies that represent new approaches to the treatment of heart failure.”

established treatment standards, but believe that our efforts are taking hold. Having more current and compelling clinical outcomes data published in peer review journals throughout 2005 will facilitate our efforts in this area.

#### **Milestones in Product Development**

During the year, we continued our track record of getting products to market with FDA approval of the Thoratec IVAD (Implantable VAD). This approval followed a very successful clinical trial that involved more than 2,400 patient days of cumulative support without any device failures.

We launched our U.S. sales effort for the IVAD in the fourth quarter. Initial market response to the device, along with the TLC-II Portable VAD Driver that was approved for use outside the hospital at the end of 2003, furthered our position as having the broadest product portfolio in the industry and contributed to incremental market expansion.

One of the most exciting developments in 2004 was the initiation and completion of our promising HeartMate II Phase I clinical trial. This device represents a major step forward in next-generation technology and is designed to support patients for five years or longer.

We were encouraged to learn of dramatic reductions in surgical and recovery times with this ground-breaking device, and we were pleased to hear from clinicians that many patients have been living comfortably at home. In fact, as of early 2005, our first patient in the trial had been supported by the device for more than 15 months and has resumed many normal activities.

In February 2005, the FDA gave approval for our Phase II pivotal study. This Phase II study for the HeartMate II will include a number of first-time elements, including both a Bridge-to-Transplantation and Destination Therapy arm—the first time both classes of patients have been included in a device trial. The innovative and unique elements of this trial signal the importance of this study, and were made possible by the Company’s significant historical data, experience and expertise.

While the first FDA approval of this device in the U.S. is not likely until at least late 2006, its performance to date offers the promise of a heart failure therapy that might be indicated for many more patients than our currently approved devices. In the meantime, we filed for European approval in March 2005 and hope to begin marketing the device there by the end of the year or in early 2006.

To ensure that we maintain our leadership position, we launched an initiative to explore emerging therapies that represent new approaches to the treatment of heart failure. Our first visible effort in this area was our equity investment in BioCardia, Inc., which is developing tools for the delivery of cellular and other biotherapeutic agents directly to the heart. We believe that there will be a meaningful opportunity to combine these and other pharmacologic agents with our VADs in treating a certain segment of the heart failure population in whom full recovery of their heart might be a realistic option.

#### **Growth at ITC**

Our ITC division continued its excellent performance in 2004 and is contributing increasing value to the Company. We are

“ITC’s revenue growth in 2004 was driven by increased market share for its ProTime and HEMOCHRON product lines.”

“No other company in this sector can equal our proven record of product development, regulatory approvals and market success.”

benefiting from underlying market growth for quick and accurate patient information at the point of care, such as the operating room and doctor’s office, or even at home. By having nearly instantaneous and accurate analysis, clinicians are able to act on a patient’s condition immediately, rather than waiting for results from a central laboratory.

ITC’s revenue growth in 2004 was driven by increased market share for its ProTime and HEMOCHRON product lines. This growing market presence also resulted from the successful transition to a direct sales force for the U.S. hospital market. In addition, ITC generated momentum with new products and a stronger presence in Europe, and by gaining a foothold in the potentially significant group purchasing market.

#### **Creating Value for Patients and Shareholders**

For nearly 30 years, Thoratec has pioneered the development of the most technologically advanced devices to address the growing need to treat late-stage heart failure, a disease that strikes a large and increasing number of people every year. Our ability to deliver continuously improving solutions is unmatched in our industry. No other company in this sector can equal our proven record of product development, regulatory approvals and market success.

Our vision will be realized as we further our already meaningful presence in emerging and new markets, and gain access to a greater number of patients by offering a broader range of more effective and durable solutions. Our strategy also encompasses the development of an ever-growing array of services and support for customers and patients that will further solidify our competitive position.

As we enter 2005, your Company has the critical assets—including technology, financial resources and people—to build upon our already strong position. As we leverage the market presence of our core product lines, we are also taking a leadership role in the development of emerging therapies and technologies, and determining how they can complement our devices.

We are always mindful that the primary beneficiary of what we do is the late-stage heart failure patient. As HeartMate II patient Everado Flores (age 20), said, “I owe my life to the HeartMate II. Now I can go out to the park, I can play baseball and I go bowling. I’m not in the hospital and I’ve gone back to my normal life.”

We continue to pursue excellence and implement strategies that will build long-term shareholder value. We appreciate your interest and support and look forward to reporting on our future success.



D. Keith Grossman  
President and Chief Executive Officer

## Forward-Looking Statements

This Annual Report includes forward-looking statements. These statements can be identified by the words “expects,” “projects,” “hopes,” “believes,” “intends,” “should,” “estimate,” “will,” “would,” “may,” “anticipates,” “plans,” “could,” and other similar words. Actual results could differ materially from these forward-looking statements based on a variety of factors—many of which are beyond our control. Therefore, readers are cautioned not to put undue reliance on these statements. Investors are cautioned that all such statements involve risks and uncertainties, including risks related to the development of new markets such as Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of our products, changes in the mix of our product sales and the related gross margin for such product sales, the results of clinical trials including the HeartMate II, the ability to improve financial performance, regulatory approval processes, the effect of healthcare reimbursement and coverage policies, the effects of seasonality in our product sales, the effects of price competition from any of our competitors and the effects of any merger and acquisition related activities.

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 “Factors That May Affect Future Results” section of our 10-K for the fiscal year ended January 1, 2005 and in other documents we file with the Securities and Exchange Commission. Actual results, events or performance may differ materially. These forward-looking statements speak only as of the date hereof. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.



## **Corporate Directory**

### **Executive Officers**

D. Keith Grossman  
*President, Chief Executive Officer, and Director*

Lawrence Cohen  
*President,*  
International Technidyne Corporation

Jeffrey W. Nelson  
*President,*  
Cardiovascular Division

### **Board of Directors**

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*Chairman of the Board,*  
Thoratec Corporation  
*Clinical Professor,*  
University of California at San Francisco  
San Francisco, California

Howard E. Chase  
*President,*  
The Hollandbrook Group, LLC  
Somerset, New Jersey

J. Daniel Cole  
*General Partner,*  
Spray Venture Fund  
Boston, Massachusetts

Neil Dimick  
*Executive Vice President and Chief Financial Officer,*  
AmerisourceBergen Corporation  
(Retired)  
Laguna Hills, California

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*Managing Partner,*  
Bradley Resources Company  
Southport, Connecticut

Daniel M. Mulvena  
*Founder and Owner,*  
Commodore Associates  
Marblehead, Massachusetts

### **General Counsel**

David A. Lehman  
*Vice President,*  
*General Counsel,*  
*and Secretary*

### **Independent Registered Public Accounting Firm**

Deloitte & Touche LLP  
San Francisco, California

### **Stock Transfer Agent**

Computershare Investor Services  
350 Indiana Street, Suite 800  
Golden, Colorado 80401

## **Additional Information**

For more information, please write to:  
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Thoratec Corporation  
6035 Stoneridge Drive  
Pleasanton, California 94588  
[www.thoratec.com](http://www.thoratec.com)

### **Annual Meeting**

The Company's annual meeting of shareholders will be held May 25, 2005 at 9:00 a.m.

### **Trademarks**

Thoratec, the Thoratec logo, Thoralon, TLC-II, HeartMate, and Vectra are registered trademarks, and Heart Hope and IVAD are trademarks of Thoratec Corporation.

HEMOCHRON, ProTime, Surgicutt, Tenderlett, tenderfoot and IRMA are registered trademarks, and TRUpoint and Hgb Pro are trademarks of International Technidyne Corporation.



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