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THORATEC CORP

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 OR 15(d) of
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported):
April 26, 2005

THORATEC CORPORATION

(Exact name of registrant as specified in its charter)

California

*(State or other jurisdiction
of incorporation)*

1-8145

*(Commission
File Number)*

94-2340464

*(IRS Employer
Identification No.)*

**6035 Stoneridge Drive
Pleasanton, California 94588**
(Address of principal executive offices including zip code)

(925) 847-8600

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On April 26, 2005, Thoratec Corporation (the "Company") conducted an investment community conference call that was simultaneously webcast. The transcript from the conference call is attached hereto as Exhibit 99.1. In the conference call, the Company presented non-GAAP net income and non-GAAP net income per share, each a non-GAAP financial measure, for the first quarter of 2005 and the first quarter of 2004. A reconciliation of these non-GAAP financial measures to GAAP income before tax expense is included in the press release announcing the Company's fiscal 2005 first quarter results, the text of which was filed as Exhibit 99.1 to the Current Report on Form 8-K filed on April 26, 2005, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of April 26, 2005 conference call.
99.2	Press Release, dated April 26, 2005, regarding fiscal 2005 first quarter results.*

* Filed as an Exhibit to the Company's Form 8-K filed with the SEC on April 26, 2005, and incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated as of April 29, 2005

THORATEC CORPORATION

By: /s/ D. Keith Grossman
D. Keith Grossman
President and Chief Executive Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of April 26, 2005 conference call.



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Conference Call Transcript

THOR - Q1 2005 Thoratec Corporation Earnings Conference Call

Event Date/Time: Apr. 26, 2005 / 1:30PM PT

Event Duration: 51 min

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Apr. 26. 2005 / 1:30PM, THOR – Q1 2005 Thoratec Corporation Earnings Conference Call

CORPORATE PARTICIPANTS

David Lehman

Thoratec Corporation – VP and General Counsel

Keith Grossman

Thoratec Corporation – President and CEO

Jeff Nelson

Thoratec Corporation – President, Cardiovascular Division

CONFERENCE CALL PARTICIPANTS

Time Lee

Merrill Lynch & Co, Inc. – Analyst

Jason Mills

First Albany Corporation – Analyst

Mike Bailey

Bear Stearns – Analyst

Mike Weinstein

J.P. Morgan – Analyst

Kaey Nakae

C.E. Unterberg, Towbin – Analyst

Matt Scalo

Adams Harkness, Inc. – Analyst

David Zimbalist

Natexis Bleichroeder, Inc. – Analyst

PRESENTATION

Operator

Good day, everyone. Thank you for holding, and welcome to the Thoratec first quarter earnings release conference call. Today's call is being recorded. And at this time, for opening remarks, I would like to turn things over to David Lehman, General Counsel. Please go ahead, sir.

David Lehman - Thoratec Corporation – VP and General Counsel

Good afternoon and thank you for your participation today. Joining me are Keith Grossman, President and Chief Executive Officer; Jeff Nelson, President of our Cardiovascular Division; and Jeff McCormick, Thoratec's corporate Controller.

Before I turn the call over to Keith, I want to remind you that during the course of this conference call and the question and answer session that follows, we may make projections or other forward-looking statements that are subject to the Safe Harbor Provisions of the Securities Laws regarding future events or the financial performance of the Company.

These forward-looking statements can be identified by words such as; "believe," "expects," "appears," "hopes," "encouraged," "anticipates," "projects," "thinks," and other similar words or phrases that may relate to market size and future growth rates; new market adoption and penetration rates; clinical trial and regulatory approval time lines; changes in the mix of product sales and related growth margins; the effect of healthcare reimbursement and coverage policies; the effects of seasonality; and price competition in our sales; and financial guidance for future periods, among other matters. We caution you that these statements are only predictions, and that actual results may differ materially.

We also alert you to the risks contained in the documents we filed with the Securities and Exchange Commission, such as our annual and quarterly reports on forms 10-K and 10-Q. We do not undertake any obligation to update or correct any forward-looking statements: Keith?

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Apr. 26. 2005 / 1:30PM, THOR – Q1 2005 Thoratec Corporation Earnings Conference Call

Keith Grossman - Thoratec Corporation – President and CEO

Okay, thank you, David. Good afternoon, everyone. As indicated in today's press release, Thoratec had an excellent quarter, with record revenues of \$50.5 million, an 18% increase over revenues in the first quarter year ago, and up from revenues of \$48.3 million in the prior quarter. We experienced strong growth in both our businesses, as our cardiovascular division sales increased 21%, driven by a 21% increase in VAD product sales, and our ITC sales increased 13%, versus the first quarter of last year. I will discuss our results in more detail shortly.

Our VAD activity was strong across the board, including growth in both the bridge and destination therapy, or DT businesses. We believe a number of factors are contributing to growing market acceptance for VAD's. For example, a number of our smaller centers that were doing fewer implants a year ago, have meaningful levels of activity during this quarter. Also contributing to our growth were increased sales of our IVAD, or the implantable VAD. The IVAD is clearly having an impact in the marketplace, as it represents a way for implanted patients to experience a better quality of life, and also makes the care of these patients easier.

While there has been certainly some cannibalization of our Thoratec VAD, as we expected, it happens that it's at lower levels than we anticipated. In the meantime, we remind you that the IVAD commands a higher average selling price than the PVAD. We do expect that the IVAD growth will begin to level out over the next several quarters as, at least some of the recent activity reflects initial orders of this new device by our customers. In addition, we continue to record initial sales of our HeartMate II pump, as we begin enrolling patients in our Phase II pivotal trial in the U.S. Aside from our financial performance, the start of this trial and its early results, and our filings for European approval for the HeartMate II, were also key events of the quarter and I will touch on all of these in more detail in a few moments.

With respect to DT, we received voluntary notifications of 52 DT implants during the quarter. This compares with 42 in the first quarter a year ago, and 55 last quarter. It brings to approximately 220 reported DT implants over the past five quarters. Now, approximately 55% of those reported DT implants during the quarter took place at our Heart Hope Centers, of which there are now 28. On a cumulative basis, 60 centers have performed at least one implant, up from 57 at the end of last quarter, and up from 21 in the first quarter a year ago. 14 centers have now reported doing 5 or more DT procedures, while four centers have reported doing 10 or more. Currently, there are 69 CMS certified centers, meaning nearly 85% of all eligible centers have performed at least one implant. I should point out that we do continue to work with CMS regarding a more formalized accreditation process to expand the number of centers certified for DT, and we're hopeful the new guidelines will be in place by – maybe early next year.

An issue that seems to be gaining in importance surrounding DT, is a factor that we have actually touched on with you in prior calls, and that is the blurring of the line between bridge to transplantation and DT patients. While I will review some of the more recent DT patient experience shortly, I want to spend a couple of minutes discussing this important issue, which, by the way, was raised by presenting clinicians at both the recent American College of Cardiology and the International Society for Heart Lung Transplantation meetings, and is becoming a prevalent topic of discussion throughout our field. To help us achieve a better understanding of what is occurring in the market with respect to both bridge and DT activity. We recently surveyed both surgeons and other clinical personnel in our centers. This study was completed during the ISHLT and AATS meetings or Thoracic Surgery meetings, over the past few weeks. We spoke with surgeons and VAD coordinators at the top 30 CMS certified DT centers, and I thought it would be useful to highlight some of the key findings, as well as our sense of what they may mean, with you today.

First, let's start with what we consider the traditional bridge business. The consensus was that neither the number of heart transplants, nor the size of the waiting list for those donor organs is increasing. However, VAD penetration of the transplant waiting list seems to be increasing, due to several factors. One is that there is an increasing comfort level among cardiologist about the use of VAD's, just in general. Second, patients being referred to surgeons are sicker, having been treated previously with other therapy, such as drug therapy, biventricular pacers (ph) and ICD's. Being supported by VAD typically improves their health prior to and after transplantation, but they are requiring longer durations of support to improve their health, to the point where they can be transplanted. Third, an improving reimbursement environment is also facilitating adoption.

Now, let me discuss this issue of blending – or blurring between bridge and DT patients which appears to be a meaningful one to, at least many of our customers. These customers are indicating that maybe between 5% and 15% of their patients could be defined as either bridge or DT patients. And please keep in mind that our findings are really designed to demonstrate emerging trends to be directional in nature, and not precise in the numbers. This phenomenon seems to be driven by several factors, including increased awareness of DT therapy, the current and narrow patient definition criteria for DT, and the reimbursement environment. With the growing acceptance of long-term, VAD use, clinicians are becoming more comfortable listing high-risk patients for transplantation, with the option of permanent or sustained support, if the patient does not

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improve to an ideal or acceptable transplantation status. This may suggest that patients are being treated with the option of DT, but are now being listed, and showing up in our reporting as bridge.

Going forward, we'll continue to gauge whether the voluntary reporting of DT patients is providing an appropriate and/or meaningful metric to shareholders. In the meantime, we would encourage you to place, at least equal importance on the total number of VADs sold in any given period, given the lack of clarity around the voluntary DT number. In the first quarter, we sold 465 total pumps, and that compares to 394 in the first quarter a year ago, which is an 18% increase in units, and it compares to 429 in this past quarter.

As I mentioned a moment ago, there have been three major professional meetings over the past several weeks. The ACC, ISHLT, and the AATS. I wanted to briefly highlight at least a few of the events that took place at two of them. At the ACC, there was a panel discussion entitled "who is an appropriate candidate for DT?" There was a significant amount of discussion regarding this blurring issue between bridge and DT. Both Doctor Lynne Warner Stevenson of the Brigham Women's Hospital, and who is also, by the way, a lead REMATCH investigator, and Dr. Randle Starling of the Cleveland Clinic, cited examples of DT patients who became eligible for transplantation after being supported by VAD, as well as patients who are on the transplant list and put on VAD support with no reasonable or near-term expectation for transplantation. The panel also felt that the void in peer-reviewed, post-REMATCH data and the inability to cite improvements and survival rates and adverse events, were limiting cardiologist referrals, and of course, that's an issue we've discussed with you in the past. However, we're starting to see more post-REMATCH data being presented and just learned that a paper on data from four very active DT centers, that we have discussed with you in the past, has been accepted for publication in the issue of "Congestive Heart Failure," that will be distributed in early June.

Another point made during the ACC panel, was the belief that on-going improvements in the device technology and patient selection of management, would favorably impact the cost of the procedure. At ISHLT, we had a very successful HeartMate II investigators meeting that was attended by around 50 of our investigating clinicians. We focused on the design of our Phase II pivotal trial and patient management issues, and we witnessed a continued high level of enthusiasm about this device's potential among our clinicians.

Also at the ISHLT, a panel from LDS hospital in Salt Lake City provided their findings regarding advances in DT patient and economic outcomes, based on experience at their center. They reviewed data involving REMATCH and post-approval patients and found, among other things, that the length of stay in hospitals for post-approval patients was approximately 43% shorter than those in the REMATCH trial, and the cost of implantation for the post-approval group had declined by one-third. They also found that the frequency of rehospitalization and costs associated with rehospitalization were declining among the post-approval patient group. They also provided multi-center data from three active centers covering 9,000 days of cumulative patient support. They found that mean hospital costs have decreased dramatically, by roughly one-third since approval, and 15% in just the past year alone. And are now close to the current average Medicare reimbursement levels which have increased by more than 100% since the end of the REMATCH trial.

Their data suggested that improving outcomes and lower costs are a result of device improvements and sharing of best practices and improved patient selection and management. The panel also noted that these cost trends reflect the early experience with heart transplantation, as well. In general, we're seeing a significant level of post-REMATCH study activity and we anticipate that there will be a number of manuscripts submitted for publication over the course of the rest of this year, and we will update you on these as we can.

Our presentation on the HeartMate II phase 1 trial by a number of our leading clinicians included data that showed there were no debilitating embolic strokes, no pump failures resulting in loss of support, and very low ammolosis (ph) rates. And they concluded that the HeartMate II is providing excellent circulatory support over large range of body sizes, with low rates of complications.

We're seeing improved results with the new HeartMate XVE. The data in our registries shows that at 18 months, nearly 74% of the XVE's were free of any major malfunction, and that compares to 51% for the prior device, the VE. We believe this data reflects the impact of device improvements, and, of course, better patient management – better patient selection and the value of sharing best practices among our clinicians. We expect the data confirming this experience will be published at some point in the future. In the meantime, we continue to identify and implement further improvements of the XVE. These include enhance automode software that should be incorporated into the device later this year, and the introduction of new peripherals that will commence later this year and into '06. The important point about these new peripherals is that they represent a single platform for the XVE and the HeartMate II – and by the way a majority of them will be appropriate for the HeartMate III. We think our customers will view this as a real benefit.

In our last call, we mentioned the piloting of a small sales force that would be focusing specifically on the referring cardiologists to increase DT patient referrals to our centers in key geographies. We now have four of these five positions filled, and we expect to complete the hiring process within the next couple of weeks. We will be conducting training next month, and we expect to have the sales reps in the field by the

end of the quarter, with the expectation that we would conduct our initial evaluation of this pilot effort by the end of the year, or very early in '06.

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Certainly, a high point of the past several months has been our experience with the HeartMate II, including the significant level of activity that has occurred over just the past few weeks. As you may remember, we completed the Phase I trial at the end of last year, enrolling 25 patients in the U.S., and recording more than eight years of cumulative support. Patients were typically discharged to their homes, with many resuming normal activities. A brief update on those patients as of last week shows that ten are being supported by the device, all of whom have been discharged to their homes – including the first patient who has now been supported for nearly a year and a half. A second patient who has surpassed a year of support, and five who have been supported for between six months and one year. Nine patients have been transplanted and six have died for reasons unrelated to the device.

On February 22nd, we announced FDA approval of our IDE to begin the Phase II pivotal trial, with a number of unique elements, including the use of the device for both bridge and DT. It is the first time the FDA has approved a clinical trial for both indications in one protocol. And as a reminder, the DT arm also includes a separate cohort for small patients, as well as cross-over patients, who are currently being supported by the XVE that can't be – or rather, can be implanted with a HeartMate II on an elective basis, in the event of the need for device replacements.

Around three weeks following FDA approval of our IDE, we announced the initiation of enrollment in both arms of the trial. And because we're now in controlled pivotal trials, we'll be limited in the level of disclosure we can provide you versus the Phase I safety study. While we will continue to report on the pace of enrollment in the trial, we will be unable report on any of the outcomes of either the test or the control arms of the study, even on an anecdotal basis. I can tell you that we now have a total of seven patients enrolled in Phase II, including three in the DT arm and four in the bridge arm. These procedures have taken place at only the first five centers to get approval. And have – and that have been IRB approved rather internally and that have been screening patients. In all, we expect that more than 15 centers will have received IRB approval and be able to screen patients within the next several weeks.

The results of the trial to date are creating a high level of enthusiasm in the clinical community which was evident at the ISHLT among both our investigators and general attendees. Including patients implanted in Europe and those under compassionate or emergency use provisions for DT, 52 patients have been implanted to date with this device. Additionally, in the final days of March, we announced that we had filed for approval to CE-mark the HeartMate II, which would allow the commercial launch of this device in Europe. This process continues to be, we believe, on track and we hope to receive authority to CE-mark the device sometime later this year.

As you can tell, we have a great deal going on in our VAD business and we're excited about our emerging opportunities with DT and the HeartMate II. At the same time, the performance of ITC continues to be very solid. Overall sales increased 13% versus first quarter a year ago. International activity was particularly strong, with sales outside the U.S. growing 20% year over year. In the past, we have identified Europe as a growing market opportunity, and we are starting to see some good results there. We also recorded a good growth in Asia. In the U.S., sales were up 11%, versus the first quarter a year ago. From a product standpoint, our hospital point-of-care coagulation monitoring offering showed very strong growth, recording a 39% increase in sales year-over-year.

In addition to revenue growth, ITC also realized several other key milestones in the quarter, including approval of our 510-K for the HEMOCHRON Signature Elite product. This is the next generation device for the HEMOCHRON line of products, and provides for greater quality control and tracking features. We have two new HEMOCHRON tests, and a new IRMA test that we anticipate will be available in the second half of the year. In addition, ITC reached agreements with two large group purchasing organizations for HEMOCHRON products. Again, we've identified this as a market with great potential for ITC, and are pleased to be gaining a subtraction there. ITC also recently signed a new distribution agreement for ProTime that will cover Germany, Switzerland and Austria, which we expect will drive greater growth in Europe during the balance of this year. As a reminder, ITC has now completed its transition to a direct sales force for the U.S. point of care market.

Turning to our financial performance, as I said earlier, we had revenues of \$50.5 million, that represents a record quarter for the Company, and an 18% increase over the same quarter prior year. As I indicated at the outset of the call, we experienced growth in all key areas of our business. Cardiovascular division sales were \$32.1 million, a 21% increase over the first quarter of last year and a 5% increase over the fourth quarter of 2004, and remember, that our fourth quarter is historically our strongest, and in the past we have typically seen a sequential decline from fourth to first quarters. This included \$30.9 million for VADs and \$1.2 million for vascular grafts. Sales at ITC were \$18.4 million, and as I said earlier, that is a 13% increase over same quarter prior year.

You may have noticed that in today's press release we use the term non-GAAP net income, instead of tax cash earnings. This is a result of comments we received very recently from the SEC. The SEC apparently felt that the term "tax cash earnings" might be interpreted by investors as a cash flow or a liquidity measurement which of course it is not. Therefore, we have changed the name of this measure, but the change in nomenclature does not reflect a change in how we calculate the number, nor does it impact the prior result's quarter.

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Non-GAAP net income was \$5.1 million, or \$0.10 per diluted share, versus non-GAAP net income of \$3.2 million, or \$0.06 cents per diluted share a year ago. And if you are comparing our results for this quarter to prior quarter, meaning fourth quarter, keep in mind that our effective tax rate on non-GAAP net income in the first quarter of '05 was 34%, versus only 5% in prior quarter, as we were playing catch-up in the fourth quarter, to reflect a proper tax rate for the entire year, due to some changes in how the state of California R&D tax credits impacted the Company. At that time, we indicated that our tax rate would return to more traditional levels in 2005. As a comparison, using a 34% tax rate in the fourth quarter, our non-GAAP net income would have been \$4.1 million compared to the \$5.1 million performance in the first quarter of 2005.

As a reminder, non-GAAP net income excludes as applicable, amortization of intangibles in process R&D, impairment of intangibles, certain litigation restructuring and unusual and nonrecurring costs, and takes into account of course the tax effect of these adjustments. In addition, total diluted share counts were approximately 49 million shares for the first quarter of '05, 57.5 million for the first quarter of 2004, and 49.3 million for the fourth quarter of '04. Operating expenses were \$22.5 million versus \$20.4 million in the first quarter of last year, up roughly 7% over the fourth quarter. Approximately half of this increase reflects corporate G&A expenses, including audit and Sarbanes-Oxley related expenses. It should be largely back to normal levels beginning in this current quarter. A reconciliation of the quarter's non-GAAP net income to GAAP earnings is available in our press release furnished on form 8-K, and also on our website.

On a GAAP basis, the Company reported net income of \$3.1 million or \$0.06 a share, versus \$1.3 million or \$0.02 per diluted share in the first quarter of '04. Gross margin just exceeded 60%, which is at the top end of the range we provided in our guidance earlier in the year. Gross margin for the quarter versus that in the same period a year ago, reflects increased VAD sales and improved margins at ITC, resulting from our transition to a direct-selling organization.

We ended the quarter with cash and short-term investments available for sale of \$152 million, that compares to \$146 at the end of '04, or about a \$6 million dollar increase. We invested \$2.2 million to repurchase approximately 200,000 shares early in the first quarter, and we continue to have approximately \$5 million left in that share repurchase program which was authorized last July. As a reminder, we've repurchased approximately 8.5 million shares over the past five quarters. Before stock repurchase activity and capital expenditures, our net cash flow from operations was \$10.3 million in the first quarter.

In our previously issued guidance for fiscal '05, we indicated that we expected overall revenue growth of approximately 10% in 2005 over 2004 with revenues in our cardiovascular division growing 5% to 10%, and 10% to 15% at ITC. Based on the result reported today, however, we feel that the higher end of this range is certainly achievable, and finally it is important to remember that revenues in the second and third quarters are, at least historically, lower than the first and fourth quarters. Our guidance for the cardiovascular division business contemplates a very modest growth in the bridge market, and a measured pace of increased adoption in DT. With growth at ITC coming from both current and new products. Now clearly, if current trends continue, we may revisit this guidance, but we would like to get further into the year before doing so. We do expect a quarter-to-quarter seasonality in 2005, or the balance of 2005 revenues to be similar to those in 2004. We also expect non-GAAP net income to increase 35% to 40% over that in 2004, based on projected efficiencies and operating expense levels relative to revenue growth. Fully diluted shares outstanding of approximately \$49 to \$50 million and net income on a GAAP basis of approximately \$0.15 to \$0.16 a share. Our assumption at this point is that our tax rate for the balance of the year will be around 35%.

As we've indicated in the past, these results could be impacted by further litigation-related expenses that are not easy to predict at this point or any point in time. With respect to the expensing of stock options, we no longer expect to reflect those costs in our GAAP results until 2006, based on the latest guidance from the SEC. Of course, this had not been factored into our GAAP earnings guidance anyway, as we have not yet determined the evaluation methodology we will be using. But, you can get, at least, a sense for the potential impact by reviewing our FAS-123 disclosure in the foot notes to our financial statements and prior SEC filings. Of course, we will provide more detail on this later in the year.

Some of you have asked me about the status of the CFO search. That process is very active, and I hope to have somebody on board just as soon as possible. But, in the meantime, I want to assure you have in place a very strong, and very capable financial organization, as evidence by our ability to file our 10-K, and successfully complete our stocks for board certification in a timely manner.

For your information, our next conference appearance will be at the B -of-A health care conference on May 17, in Las Vegas. And as always, we appreciate your time and interest today, and we thank you for joining us. And, Operator, why don't we now open the call up for questions.

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QUESTION AND ANSWER

Operator

[OPERATOR INSTRUCTIONS] First up from Merrill Lynch, this is Tim Lee. Please go ahead, sir.

Time Lee - Merrill Lynch & Co, Inc. – Analyst

Keith, Good afternoon.

Keith Grossman - Thoratec Corporation – President and CEO

Hi, Tim.

Time Lee - Merrill Lynch & Co, Inc. – Analyst

Hey, just some questions on the strength of the VAD sales. Up 18% was clearly well ahead of what we're looking for. Was there any one-time words, or anything that skewed those numbers – was the growth across the board, in all geographies? Any more color you can provide on that would be greatly appreciated.

Keith Grossman - Thoratec Corporation – President and CEO

You know, generally I think we have given you what we can, Tim. It was strong across all products. It was strong across all geographies, and it was strong across all indications for use. We certainly are seeing strength in the IVAD. We are not only seeing a good reception to that product, but we are not seeing the level of cannibalization of the PVAD that we had planned and anticipated. IVAD also brings with it a higher ASP. And we're selling HeartMate IIs now, into our clinical trial sites. But we saw strength in all of our products, the PVAD, HeartMate XVE, HeartMate II and IVAD.

Time Lee - Merrill Lynch & Co, Inc. – Analyst

If I can just follow-up on that. Given your unchanged outlook for the full year for the cardiology group of 5% to 10%, that kind of assumes that you are expecting, at least conservatively, expecting a marked slow-down in VAD sales for the balance of the year. Is that how you are looking at it right now?

Keith Grossman - Thoratec Corporation – President and CEO

No, I think what it reflects is a reluctance to adjust guidance after one quarter. Just given the uncertainties and the volatility in the VAD business, what we're seeing is now for two quarters in a row, some pretty solid and encouraging strength across the board in the VAD business. But we're one quarter into the year, and I think we would look to get a little further in before we begin to reflect a change in guidance.

Time Lee - Merrill Lynch & Co, Inc. – Analyst

Fair enough. Thank you very much.

Operator

Next up is Jason Mills at First Albany.

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Jason Mills - First Albany Corporation – Analyst

Hey, Keith, congratulations on a good quarter.

Keith Grossman - Thoratec Corporation – President and CEO

Thanks, Jason.

Jason Mills - First Albany Corporation – Analyst

Back to your comment on blurring of the lines, it seems to me, if I think about it, in some ways, it certainly helps you with respect to DT barriers to entry, having two indications, destination therapy and bridge to transplant. Obviously, you being the only one out there with a DT approval, it helps you from a barrier-to-entry standpoint. But in some ways, I guess you could think about it as a hindrance to you, presuming that you receive HeartMate II bridge approval well ahead of DT approval. And other folks may not be able to get DT approval, and you can see where I'm going with that. But clearly, it is helping you now. Can you just speak about the DT indication and potentially expanding the bridge business, vis-à-vis increasing awareness a little bit more, and give us more color there? We are certainly hearing that as well. But is it something that – Wall Street pays more attention to DT indication than does clinicians? And is it that they are more willing to put sicker patients on the bridge to transplantation lists now? Give us a little bit more color there.

Keith Grossman - Thoratec Corporation – President and CEO

Let me answer the very last question first, and then I'll ask Jeff Nelson to comment on the balance of it. I think clearly, that we're at a point now where the Wall Street audience has probably placed more importance on that number. We're hearing time after time from our clinicians, that, not only are they not using the indication distinctions that have traditionally been used in the past like bridge and DT, but they're getting up on panels and podiums at different meetings, and encouraging others not to view patients this way for a variety of reasons and so, I think it remains an appropriate way to lump patients in a broad sense, but if you are looking at only the DT numbers, we said a few moments ago, it is not, I think, an accurate way to really assess the health of long-term VAD support, whether technically falls under the umbrella of DT or not. Jeff, maybe you want to expand a little on some of what we're hearing.

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

Yeah, I think the – maybe I'll start with the first part of your question, on our competitive situation and how that relates to HeartMate II. I still think that, unlike maybe some of our competitors, we feel we've got a destination therapy trial that will be able to enroll in and be able to move forward with. If you look at the very short experience we have so far in the trial, we have enrolled almost as many destination therapy patients in the trial as we have bridge to transplant, and we also have capability for small patients and cross-over XVE patients into the trial. So, I think this kind of blurring of the line or capability to treat sicker patients, or patients that may need to get healthier in order to get a transplant, will be helpful in the HeartMate II arm, as well.

I think the clinicians want to treat patients they feel can benefit from mechanical circulatory support. They certainly see the opportunity to treat those patients within our current indications, as a challenge but also an opportunity to see more patients than they saw in the past. I think they're trying to deal with that on a case-by-case basis, on a hospital-by-hospital basis, and if you talk to them there are different situations in every hospital. Certainly, the noise level on a longer-term support option without necessarily a prospective classification whether there is a bridge to transplant patient or DT patient, is getting louder.

Jason Mills - First Albany Corporation – Analyst

Just to clarify here, because we hear the term “sustained support” quite a bit as well. At the ACC symposium brown-bag lunch, it was mentioned maybe 50 times. So, quite a bit there. Does that mean that what we're seeing is clinicians that would love to give a patient a heart regardless of age, even though it seems like age limitations are – they would love to put someone on the bridge list under 65, but regardless of age, they are considering more patients for a heart, if, in fact, they can improve their condition. And if so, what does that mean for the potential expansion of

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the transplant list once HeartMate II is approved, and now you have a device that is approved for bridge of transplant, but not destination therapy and therefore you can't get the same device for both indications.

Keith Grossman - Thoratec Corporation – President and CEO

Well, I think what you're hearing is the same thing we're hearing; first of all, to the first part of your question; from clinicians, in terms of how they want to view these patients and how they are beginning to view these patients. In terms of the HeartMate II, bridge approval – it is a hypothetical. We honestly can't say – it will be a great problem to have, but clearly, there are patients who can be legitimately listed as bridge to transplant patients, who might otherwise, with a different technology, at a different time, might not have been. They clearly are being treated now, we believe, with what we think a smaller, better, longer-lasting, more durable, reliable product, as we believe HeartMate II will be. We think that whatever trend is happening with something like the XVE would continue. But we'll just have to wait and see. That's not today. That's after we get approval, and obviously, any expanded use of VADs is a good problem to have, regardless of how it happens.

Jason Mills - First Albany Corporation – Analyst

And last question, and I'll hop back in queue, an update, maybe, on the regulatory timeline as you see it now for HeartMate II for bridge indication. Can we still think about it potentially by the second half of '06?

Keith Grossman - Thoratec Corporation – President and CEO

You know, there is really no change in that. We're not far enough into the experience. I think another quarter from now, certainly two, we'll have a much clearer idea based on rate of enrollment, but if we still feel like the end of '06 is definitely a possibility for that product. It really will just come down to the rate of enrollment more than anything else.

Jason Mills - First Albany Corporation – Analyst

Great. Thanks, Keith, good quarter.

Operator

Moving on to Rick Weiss at Bear Stearns.

Mike Bailey - Bear Stearns – Analyst

This is Mike Bailey for Rick.

Keith Grossman - Thoratec Corporation – President and CEO

Hi, Mike.

Mike Bailey - Bear Stearns – Analyst

Hi, Good afternoon. Just a quick question on reimbursement, can you give us – it sounded like, in the physician survey that you did in a couple of conferences, that was certainly one of the reasons that there has been an increased demand or use of the DT and the bridge to transplant. Can you give us your sense – do you think that is one of the more important drivers or just sort of one of the drivers involved? And also, can you give us your sense of what do you expect for next year for reimbursement? Do you expect similar levels or an increase in reimbursement? Thanks.

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Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

This is Jeff. I think that the reimbursement, or the lack of reimbursement was a gate, as opposed to a driver. I think now that there is a favorable reimbursement environment, there is less push-back about treating patients that need the device. As far as prospectively, we view next year's reimbursement environment to be very similar to this year's.

Mike Bailey - Bear Stearns – Analyst

Great, thanks. And also, just looking ASPs, can you give us a sort of rough idea in the U.S. what the average prices were for pumps?

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

They were pretty consistent. The only difference, IVADs got higher ASP as it's gotten greater penetration and it increases that overall ASP.

Mike Bailey - Bear Stearns – Analyst

Is that roughly at \$78,000 level or where is that?

Keith Grossman - Thoratec Corporation – President and CEO

I don't think in the past we have really broken out detailed ASP by the device. We kind of track ASPs on a weighted basis. We have given ranges on a per-device basis. If you look at our average selling price for the entire VAD product line, at least over the pumps, it is higher than – a little higher than the same quarter last year, but it's roughly equivalent to fourth quarter of '04 and I think that's – with the exception of the IVAD you can probably say that is true for each of the devices.

Mike Bailey - Bear Stearns – Analyst

Great, thanks very much.

Operator

Next up is Mike Weinstein of J.P. Morgan.

Mike Weinstein - J.P. Morgan – Analyst

Thank you. Can you hear me, Keith? Yes, hi, Mike. How are you doing?

Keith Grossman - Thoratec Corporation – President and CEO

Good.

Mike Weinstein - J.P. Morgan – Analyst

Maybe provide us a little more color on the CFO search. I think it has been about four months since Wayne's departure, so I was hoping to get some insight into that search, and maybe when we could hear something?

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Keith Grossman - Thoratec Corporation – President and CEO

Well, as I indicated earlier, when we announced that change, sometimes they happen right away and sometimes they can take six to 12 months. I think the average is somewhere in between. We're about four months into the process. We said last quarter we would really hope to have somebody in the position by the end of the second quarter. I still hope that's true. Certainly, it is been an active process, and encouraging in terms of the interest in Thoratec. But we'll just let you know as soon as we find the right person, and we have somebody to announce. I have no reason to believe we won't be somewhere in that very broad timeline I just gave you.

Mike Weinstein - J.P. Morgan – Analyst

Okay. Now, let me ask you one financial question before I move to the fundamental business. You mentioned briefly in your remarks impact of FAS-123 which numbers are out to '06. The '04 impact increased pretty materially from 2003. I think it was like \$0.23 in '04, versus almost half of that in 2003. And your guidance, or your expectation is that it would hold at roughly that level? Or does it continue to roll over and actually increase as we look at '05 or '06?

Keith Grossman - Thoratec Corporation – President and CEO

You know, we really haven't given specific guidance in that area. What we've said is if you want a general idea of the ballpark, you can look at the FAS-123 footnote in our public filings. What we have to do between now and when we have to begin reporting those expenses, which will be first quarter of '06, is go through and look at the data as it exists then, which as you know, it is a fairly complex set of calculations. It looks at volatility of stock and the number of options outstanding and strike price, et cetera. And it could change. It could be higher, it could be lower. But it is likely to be somewhere in the neighborhood, however you would like to interpret that of what we have shown in the foot note in recent quarters.

Mike Weinstein - J.P. Morgan – Analyst

Is there in anything you are doing to alter the compensation structure that might lower that?

Keith Grossman - Thoratec Corporation – President and CEO

Yes, I think like most companies, our practices around stock options have changed in anticipation of this, over the last year or two. And the issuance of stock options have, in general, gone down, in both absolute numbers and as a percent of total shares outstanding. Certainly, I think that's a trend that will continue, and we have begun alternate forms of incentive compensation for some levels of the organization, and we continue to look at other ideas in the future. I think we're not unlike most companies, where this will have an impact on our practices going forward.

Mike Weinstein - J.P. Morgan – Analyst

But you mentioned alternate forms of that starting in '05, or were you working on that before that?

Keith Grossman - Thoratec Corporation – President and CEO

We were working on that before that and, I believe, most of it kicked in in '05. I am not talking about the management levels of the organization.

Mike Weinstein - J.P. Morgan – Analyst

Okay. And then, just moving more towards the fundamentals, I guess my question is the same as the first one that was asked, I think by Tim – relative to what we saw this quarter, which was clearly a good quarter in the bridge market, after what had been several difficult quarters for bridge. Anything else you could add that would give us comfort on the sustainability of what we saw here, other than just being one good quarter, the ability to make this more of a trend?

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Keith Grossman - Thoratec Corporation – President and CEO

Well, I think from our stand point, first of all, we feel like it is more than one good quarter. I mean, there's some health in the activity of the VAD business, that, obviously, we were seeing in Q4 as well. I think between our prepared remarks, and my answer to Tim a moment ago, that probably about covers it. We don't have a crystal ball, particularly in this business, maybe less so than most. We do know there is variability in the bridge business that we've had – peaks and troughs – that are difficult to explain. What we tried to communicate today is that there are some – aside from those that you see all the time, that there are some kind of fundamental changes in the kinds of bridge patients we're seeing, and the penetration of that waiting list and just the traditional bridge business growing for reasons that are explainable in this case, and therefore, very possibly sustainable. We are also seeing, as we tried to explain, some growth in the so-called bridge category, that may not be traditional bridge patients. There is no reason I think to believe that that is not also sustainable. I think, not surprisingly, I would like to get another quarter or two under my belt to give you more color.

Mike Weinstein - J.P. Morgan – Analyst

Understood. You understand why we're asking. Bridge units were down 10% last year. And this quarter just doing the math, bridge units were up 17%. So, that is a pretty good contract. And then, last question, I want to make sure we're clear on HeartMate II. The dialogue with the FDA, relative to the timeline on the bridge approval – how clear is that discussion at this point in time? I know, typically, when you have your sit downs with the FDA and you talk about the approval path, how clear is it to them, at this point, what they want to see relative to the existing data set you have on your devices to make it viewed as a equivalent or noninferior device?

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

I think we have a very clear pathway. This was a very collaborative process over the course of the end of the summer and early fall, and designing a trial design that the FDA can be – would be very happy with it. And they made a number of suggestions that we incorporated in how we can treat additional patient populations on the – on our destination therapy arm, especially. So, I think we have very good insight, that if we're able to complete our trial with the clinical end-points that we have defined, I think that we've got a very clear path.

Mike Weinstein - J.P. Morgan – Analyst

Thank you.

Operator

I have a question from Kaey Nakae at Unterberg.

Kaey Nakae - C.E. Unterberg, Towbin – Analyst

Yes, Keith, regarding the increase in BTT sales, and you mentioned the sicker patients on the transplant list, now, while that, perhaps, is facilitating increased use of VADs for BTT patients, at the same time, if you are getting the same class of patient as a potential candidate for DT, does that work against you? Is that patient, perhaps too sick to get the device as a permanent implant?

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

This is Jeff. I don't think so. I mean, that's certainly, as we look at trying to demonstrate improved outcomes, getting sicker patients doesn't help. But – but right now, in the destination therapy arm, those are the patients that our indication is set for. We're already seeing those patients. I think the difference is in the bridge arm, if in the past they could keep patients at home on drugs, and then transplant them without having to go through a second surgery to put a VAD in, they did that. And now they really don't have that luxury of bringing the patient in, and putting the VAD in, and discharging the home – once they get better sending him home. And the outcomes are actually just as good, from what we've been able to see.

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Keith Grossman - Thoratec Corporation – President and CEO

Let me add something. I mean, we typically are bridging the sickest patients on the waiting list, anyway. What we are seeing now, is the waiting list is comprised of more of those patients who are sick. So, we're treating more patients on this waiting list because there are more who are sick. That doesn't necessarily mean that every patient we're bridging is sicker than the patients we were bridging before. Does that make sense?

Kaey Nakae - C.E. Unterberg, Towbin – Analyst

Yes. But in terms of, you know, in terms of the development of DT side of the market, some of the previous suggestions were that the surgeon was getting the patient at a point where he was too sick. And so if the cardiologist is holding onto that patient, and he is not a candidate for transplant, and he had a CRT that has not helped him – is that going to hurt you when you think about them as a DT patient, because, obviously, as a bridge patient you have the fall back of – hopefully they are going to get a heart soon.

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

I think that's what we've seen with DT. If we're looking at why are the percentage of patients on the transplant list that get VADs, why is that increasing, it is because that sub-population that has always been there, is sicker than in the past. On the destination therapy side, our challenge is getting them further up stream, once they get into different patient populations. We believe getting some of these patients that aren't as further progressed. But, the bridge patients, in general, have been pretty sick patients.

Kaey Nakae - C.E. Unterberg, Towbin – Analyst

Okay. Two other quick questions. First, as far as the number of centers in the HeartMate II study, where do you expect that number to end up at? You said perhaps 15 by the end of this quarter, but what's the ultimate number centers?

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

On the bridge side, it will be 25 centers, and it will be up to 40 centers on the destination therapy side. We hope to have 27 centers up and going by the end of the summer. And maybe up to 30 by the end of the year.

Kaey Nakae - C.E. Unterberg, Towbin – Analyst

Okay. And then, with respect to the automode function in the HeartMate II, the protocol for the study, does that have to automatically be turned on or is that up to the physicians to decide to turn that on or not?

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

That's up to the physician.

Kaey Nakae - C.E. Unterberg, Towbin – Analyst

And with that being the case, is there any risks? You get down to the end of the line here and you get approval. If it hasn't been used in all patients is there any risks that the FDA has an issue with that?

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

I would have to ask my regulatory guys. I think that if it's not used in a large enough subset to demonstrate that it has enough sample size that we'd have an issue there. I don't know if that's a large risk or a small risk, to be honest with you.

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Kaey Nakae - C.E. Unterberg, Towbin – Analyst

I guess my concern is if it is up to the physician, how do you guarantee that you get a large enough subset?

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

I think it is a feature that if the physicians – I think it is a self-fulfilling prophesy. The physicians will want to use it because it is an enhanced feature. If they don't view it as an enhanced feature, it kind of – at the end of the day, why do we really need it? Certainly, the feedback we get from the clinical community is it would be a nice feature to have on the product, and so I sense they are going to use it in the trial.

Kaey Nakae - C.E. Unterberg, Towbin – Analyst

Okay. Thank you.

Operator

Jayson Bedford of Adams Harkness has the next question.

Matt Scalo - Adams Harkness, Inc. – Analyst

Hey, guys, actually it is Matt Scalo, calling here for Jayson. Good quarter. Congratulations.

Keith Grossman - Thoratec Corporation – President and CEO

Thank you.

Matt Scalo - Adams Harkness, Inc. – Analyst

Wanted to walk through, as far as the 465 pumps, if we take out the 52 for destination therapy, can you give me a rough estimate, as far as the range that were PVADs versus XVEs. Is it still around a 50-50 split?

Keith Grossman - Thoratec Corporation – President and CEO

It is just not something we have broken out in the past. The more detail you get into in these pump units, the more it moves around quarter to quarter, month to month. We just haven't broken it down beyond total pumps. Other than to say, in our comments, that we have seen growth across all products and all indications

Matt Scalo - Adams Harkness, Inc. – Analyst

Okay. Is it safe to say then, as far as the IVAD and maybe getting a bit more detail there, that it is not a material portion of that 413 pump number?

Keith Grossman - Thoratec Corporation – President and CEO

No, I don't think that is safe to say.

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Matt Scalo - Adams Harkness, Inc. – Analyst

More than 5%.

Keith Grossman - Thoratec Corporation – President and CEO

Yeah, no. I think it is safe to say the IVAD is certainly a material portion of the total pump count. And that we've seen some corresponding cannibalization in the PVAD number, though not as much as we planned. If you lump PVAD and IVAD kind of into one category, then together, they probably represent a greater percentage of the total pumps sold than the PVAD did all by itself in prior periods.

Matt Scalo - Adams Harkness, Inc. – Analyst

Okay. Okay, great. And as far as – just upcoming presentations in regards to the 25 patients from the Phase 1 trial, is there going to be anything in the near-term that be could probably get some feedback on as far as adverse events, just a follow-up type –

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

I think that 25 patient cohort was presented at the ISHLT.

Matt Scalo - Adams Harkness, Inc. – Analyst

Okay.

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

And there really aren't that many more meetings in the future, until you get to the fall cycle. There will probably be a presentation at the ASAIO, but it won't be anymore detailed than the presentation that was just presented.

Matt Scalo - Adams Harkness, Inc. – Analyst

Terrific, guys. Thank you.

Operator

Next up is David Zimbalist, Natexis.

David Zimbalist - Natexis Bleichroeder, Inc. – Analyst

A couple questions. First, if you just take the absolute VAD revenues by units, it looks like the average selling price all in, seems to have gotten a little bit lighter in the first quarter as compared to the second half of 2004, but it's up over last year. I know there are other products to go in there, but if you can talk about the mix of products that you have – are we seeing a maturing of the mix here with the IVAD now ramped up, to where you think the balance would be? For the mix of IVAD and PVAD and HeartMate products across the board?

Keith Grossman - Thoratec Corporation – President and CEO

What you are doing is dividing the number of pumps into total VAD system revenues. Of course, when we talk about ASP trends in a general sense, we are talking about dividing the number of pumps just into pump revenues. When you do it your way, I realize that's the information we're giving you. When you do it your way, your denominator includes service and training and other peripheral products, driver rentals, and all kinds of things. I don't know that that's a great metric. I think what we're telling you is that from a pump standpoint, which tracks actual pump



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ASPs, they were about flat with fourth quarter, and maybe up very, very slightly, and up over the same period prior year. So I think ASPs continue to trend up, though that trend up is slowing a little bit, and it's probably ASPs – absent the IVAD impact, we're probably relatively flat, to maybe up very slightly over prior year.

David Zimbalist - Natexis Bleichroeder, Inc. – Analyst

So, should we be looking for the mix of IVADs to be relatively stable now as a percentage of the total HeartMates, PVADs, in other words, the overall underling pump ASP should be tracking flat relative to where it has been the last couple quarters?

Keith Grossman - Thoratec Corporation – President and CEO

I think that's a fairly safe assumption. Over time, I would expect to see IVAD continue to cannibalize more and more of PVAD sales. But we've not given any guidance in terms of what that percentage is, or how long it would take. But I do think that it will trend up, and it will affect ASPs for the whole line.

David Zimbalist - Natexis Bleichroeder, Inc. – Analyst

And also, any new centers– did you sign up any new centers for the standard [inaudible] this quarter –

Keith Grossman - Thoratec Corporation – President and CEO

Sorry –

David Zimbalist - Natexis Bleichroeder, Inc. – Analyst

In other words, not destination therapy.

Keith Grossman - Thoratec Corporation – President and CEO

Just NSPs?

David Zimbalist - Natexis Bleichroeder, Inc. – Analyst

Yes.

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

Yes, we had two new centers.

David Zimbalist - Natexis Bleichroeder, Inc. – Analyst

Okay. Okay, great. And can you talk a little about the graft business –? I can't recall the number, it was \$1.2 million?

Keith Grossman - Thoratec Corporation – President and CEO

Yes, correct.

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David Zimbalist - Natexis Bleichroeder, Inc. – Analyst

So is that a number we should be taking as more sustainable at this point, or is this just to catch-up and now, your partner's revenues – or your partner's inventories are now where they need to be and –

Jeff Nelson - Thoratec Corporation – President, Cardiovascular Division

Yes, we think it will be flat for the remainder of the year.

David Zimbalist - Natexis Bleichroeder, Inc. – Analyst

Okay. Great. All right. Thank you.

Operator

Mr. Grossman, I'll turn things back over to you. That will conclude the question and answer portion of the program. But I will leave it to you for any additional closing comments.

Keith Grossman - Thoratec Corporation – President and CEO

Thank you again, everyone, for joining us. We are excited and pleased about the quarter, and about some of the trends we're seeing in the business, and we'll look forward to updating you on future quarters, as we get our results in.

Operator

Thank you again for joining us, everyone. That will conclude today's teleconference. Have a good day.

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