## Edgar Filing: HeartWare International, Inc. - Form 425

HeartWare International, Inc. Form 425 February 17, 2009

> Filed by Thoratec Corporation Commission File No. 000-49798 Pursuant to Rule 425 Under the Securities Act of 1933 And Deemed Filed Pursuant to Rule 14a-12 Under the Securities Exchange Act of 1934 Subject Company: HeartWare International, Inc. Commission File No. 000-52595

This filing relates to the proposed acquisition of HeartWare International, Inc., a Delaware corporation (HeartWare), by Thoratec Corporation, a California corporation (Thoratec), and pursuant to the terms of that certain Agreement and Plan of Merger, dated as of February 12, 2009, by and among HeartWare, Thoratec, Thomas Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of Thoratec, and Thomas Merger Sub II, Inc., a Delaware corporation and a wholly owned subsidiary of Thoratec.

The following is a transcript of a conference call conducted by Thoratec and HeartWare regarding the proposed acquisition of HeartWare on February 13, 2009 at 5:30 a.m., Pacific Standard Time (8:30 a.m., Eastern Standard Time).

Thomson StreetEvents<sup>sm</sup>
THOR Thoratec Announces Definitive Agreement to Acquire HeartWare International For US\$282 Million
Event Date/Time: Feb. 13.2009 / 8:30AM ET

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## Feb. 13.2009 / 8:30AM, THOR Thoratec Announces Definitive Agreement to Acquire HeartWare

**International For US\$282 Million** 

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**PRESENTATION** 

## **Operator**

Good day, everyone, and welcome to the Thoratec conference call. Today s call is being recorded. Now at this time, I ll turn the conference over to Mr. David Smith.

## **David Smith** Thoratec Corp. CFO

Thank you, Operator. Good morning and thank you for joining us to discuss today s announcement regarding Thoratec s definitive agreement to acquire HeartWare International.

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With me are Gary Burbach, President and Chief Executive Officer of Thoratec; Doug Godshall, President and Chief Executive Officer of HeartWare; and David McIntyre, CFO and COO of HeartWare. Gary will begin the call with a review of the strategic drivers of this transaction, Doug will provide some perspectives from HeartWare on today s announcement, and then I will discuss the financial aspects of the transaction. We will then open the call to your questions.

Before turning the call over to Gary, during the course of today s 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. We caution you that these statements are only predictions and that the actual results may differ materially.

We ll (multiple speakers) also alert you to the risks contained in the documents we file with the Securities and Exchange Commission, such as our annual and quarterly reports on Forms 10-Kand 10-Q. Wedo not undertake any obligation to update or correct any forward-looking statements.

#### Gary Burbach Thoratec Corp. President, CEO

Good morning. We appreciate you being able to join us on short notice to discuss today s announcement. Needless to say, we re excited about the opportunity to partner with HeartWare in the future development and commercialization of a broad portfolio of devices that can dramatically improve the treatment of chronic heart failure patients, and in doing so, create the opportunity for significant ongoing growth for years to come.

As we will discuss over the next few minutes, there are a number of favorable and complementary aspects to this transaction, not only in terms of advancing therapies for the large and underserved heart failure patient population, but also in creating significant long-term value for the shareholders of both companies.

As a leader in the mechanical circulatory support arena, Thoratec brings a number of commercially-approved devices that serve a range of patient needs, along with a proven track record of innovation. The use of VADs is a growing trend and is experiencing increasing traction, particularly over the past year since the approval of Thoratec s HeartMate II for bridge to transplantation in the U.S. and the very positive patient outcomes and clinician enthusiasm it has experienced.

At the same time, HeartWare possesses a portfolio of innovative device technologies. This includes its HVAD, which has generated positive patient outcomes in its Australian and European trial, resulting in a recent CE approval. In addition, the HeartWare team has made meaningful progress in the development of their innovative next-generation technology, the MVAD, which provides the promise of a less invasive procedure.

Doug will provide additional color on HeartWare s current device and innovation program shortly. We believe that cardiac centers and clinicians will be highly supportive of the combination of our two companies, and enthusiastic about the benefits this transaction offers to their patients.

Second, Thoratec has in place a well-developed and proven infrastructure in critical areas such as manufacturing, clinical, regulatory, reimbursement, customer support and training, and sales and marketing. As a result, we believe we can accelerate the commercial launch of the HVAD in Europe as well as its clinical trial efforts in the U.S.. Additionally, we believe we can further the development and successful introduction of next-generation devices from both companies pipelines that will serve a wide spectrum of heart failure patients and continue to broaden our market opportunities.

Equally important, Thoratec possesses the financial resources to fund the needed future clinical, product development, and market expansion programs to realize this growth opportunity. This includes not only funding our existing and planned initiatives for the HeartMate II, such as center development, referral programs, enhanced peripherals, and securing destination therapy

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approval, but also the commercialization of the HVAD and the continued development of next-generation technologies to enable the long-term expansion of VAD therapy.

As David will discuss during his comments, it is important to understand that this transaction is not driven by expected cost savings in the near term, but rather the opportunity to dramatically expand the utilization of VADs to treat heart failure patients more effectively as a combined entity. This transaction creates a vehicle for realizing revenue growth more aggressively, and avoiding costs at both organizations going forward.

For Thoratec, it provides a vehicle for leveraging our existing infrastructure by providing a broader portfolio of products, both now and in the future, as well as complementary product development capabilities.

For HeartWare, it means it doesn thave to raise additional capital in order to fund its operations or create a larger infrastructure to support its market development efforts.

We believe that by joining forces that we can facilitate broader market penetration of mechanical circulatory support, while achieving meaningful operating synergies over the long term.

As I am sure you can appreciate, we will be finalizing the details of our integration plan over the next few months and we cannot begin any formal integration activities until this transaction closes. However, our current thinking is that for the foreseeable future, following the closing, we will maintain HeartWare s existing manufacturing facility in Miami Lakes, Florida, where there are currently nearly 100 employees, as well as moving the Boston-based employees overtime to our Burlington facility.

Finally, it s important to note that we don't expect the transaction to negatively impact any of the activities and objectives for 2009 which we outlined during our Q4 earnings call last week.

Before I turn the call over to Doug, I d like to congratulate the employees of both companies for all they have accomplished in advancing the treatment of patients with heart failure. This transaction provides an exciting opportunity for all of us to continue the pursuit of this mission in the years ahead.

I ll now asked Doug to provide some perspectives from HeartWare, and then David will outline the financial and timing aspects of the transaction.

#### **Doug Godshall** HeartWare International President, CEO

Good morning. First, I want to congratulate Gary and the Thoratec team for the great news they shared last week regarding the destination therapy submission, as described in their quarterly earnings call. This is an important development for those suffering from heart failure in America.

As you might expect, this is a very exciting day for all of us at HeartWare, and to echo Gary s comments we believe that this will be a seminal event for our customers, patients, and employees.

We re delighted at the prospect of joining forces with Thoratec. It has been a pioneer in the development of circulatory support devices, and the clinical and market performance of HeartMate II has truly fostered new hope for many patients who suffer from heart failure.

Thoratec has proven capabilities in many areas necessary to successfully grow this still-emerging market. At the same time, I want to acknowledge the efforts of the HeartWare team, which has done an exceptional job of bringing our technology to market in Europe and furthering innovation in mechanical circulatory support. They and our physician partners

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deserve a great deal of credit for getting HeartWare to where it is today, and I am confident that our merger with Thoratec will allow us to further accelerate our efforts to benefit our patients and achieve even more than we could by remaining independent.

For those of you who are not familiar with HeartWare, I ll provide just a quick overview of the Company. As Gary mentioned, our lead device is the HVAD, which is the only full-output centrifugal pump designed to be implanted in the chest.

Just two weeks ago, we received a CE Mark for bridge to transplantation, following a very successful European trial involving 50 patients. We received approval based on the data from the first 25 of those patients, 23 of which met the primary endpoint of survival to 180 days, or heart transplantation.

We recently provided an update on that trial, which showed that 90% of the first 41 patients had met the primary endpoint. We have had one patient support on the device for two years, and have total patient support of more than 37 years. At the same time, our adverse event rate has been well within the range of previous studies. All of this bodes well for the prospects of the HVAD in the future.

We have learned a tremendous amount about our technology and how best to manage patients who are supported by the device during this initial clinical experience. As Gary mentioned, we are just now initiating our European commercial launch, which will focus initially on those centers that served as trial sites, followed by a steady expansion throughout the course of 2009.

The positive initial experience from our international study and the information we have gained from that experience gives us a strong base on which to launch our U.S. trial.

In the U.S., we initiated enrollment in a bridge to transplant trial late last year and now have enrolled 11 patients in this 150-patient trial. Currently, three centers have implanted an HVAD. An additional six centers are expected to begin enrolling patients in the next few weeks. The trial design calls for participation by up to 28 centers and our expectation is that enrollment in that trial will be completed within a year.

We re delighted with the performance of our HVAD to date and are also encouraged by the potential of our next-generation offering, the MVAD, which is an axial flow VAD that is approximately one-third the size of the HVAD. It is based on the same proprietary impeller suspension technology that is used in the HVAD. And the MVAD is designed so it can be implanted using less invasive techniques than other pumps.

As an organization, our goal has been to expand patient access to circulatory support by decreasing the invasiveness of the implant procedure with and with the pericardial placement of the HVAD being the first step in this process. We currently have three MVAD designs, all of which have performed well in the lab and all of which can be implanted without the need for a sternotomy. Our current plan is to select a final MVAD design by the end of 2009 and dedicate a full development team to complete the work on that project.

On the corporate side, we recently shifted our headquarters to the United States and had announced an intention to list our shares of common stock on NASDAQ this month. We just recently received approval from NASDAQ to list our shares and will do so on February 24. Listing will enable our shareholders to move shares between the ASX in Australia and NASDAQ in the United States, which will give our shareholders an opportunity to avoid currency risk as well as giving our U.S. holders, who hold 80% of our outstanding shares at this time, a liquid trading market. Entering into this transaction with Thoratec, the Company that knows this arena better than anyone, is a flattering endorsement of what our team has achieved. Our entire organization is enthusiastic about this announcement today and what it means for our shared mission of bringing better treatment options for heart failure patients. I ll now turn the call back over to David Smith. Thank you very much.

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## **David Smith** Thoratec Corp. CFO

As we indicated in our press release, the value of the transaction is \$282 million, which will be funded with an equal combination of Thoratec stock and cash. The terms of the agreement include a 30% downside and a 30% upside collar on the stock portion of the consideration. In addition, we re providing HeartWare with a convertible loan facility of up to \$28 million, available over time to fund its ongoing activities.

The merger agreement also contains customary transaction protection provisions, including a termination fee if HeartWare terminates the agreement under certain circumstances. The transaction has been approved by both companies boards of directors and it will require approval by HeartWare shareholders.

In addition, of course, the transaction is subject to regulatory review and the satisfaction of other customary closing conditions. We hope to close the transaction sometime in the second half of 2009.

The deal structure is designed to leverage the strength of Thoratec s balance sheet, while also preserving capital for our future operational programs, such as those supporting the HeartMate II and other strategic opportunities.

We will be providing additional details on the financial impact of the transactions as the process moves forward, but as we indicated in the press release, we expect that it will be dilutive to earnings on both the GAAP and non-GAAP basis into 2011. We expect to record approximately \$15 million to \$20 million in nonrecurring charges related to the transaction through the balance of 2009, although they will be excluded from our non-GAAP earnings.

As a reminder, this transaction is driven by the opportunity to create long-term shareholder value by bringing innovative products to market faster and increasing the demand for new circulatory support therapies, rather than an opportunity to achieve near-term savings. However, we believe that this combination will create long-term synergies across all functional areas, which has been factored into our valuation analyses.

We will provide more details on the integration process in the future. Additional details of the transaction will also be available in the documents we file with the SEC over the coming days.

Again, thank you for joining us today. As a reminder, a replay of this call will be available beginning later today, the details of which may be found in our press release. We will now open the call to your questions, and ask that you confine your questions to the transaction and limit yourselves to one question and a follow-up. Operator?

## **QUESTIONS AND ANSWERS**

#### **Operator**

(Operator Instructions). Bob Hopkins, Bank of America.

### **Bob Hopkins** Bank of America Analyst

Thanks and congratulations to everybody involved. A couple quick things. One, David, do you guys plan on needing to raise any capital or ~ in association with this transaction?

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**David Smith** Thoratec Corp. CFO

No, we don t.

## **Bob Hopkins** Bank of America Analyst

I m sure that a lot of people that will be commenting on this transaction this afternoon, and next week, will be talking about how Thoratec is now essentially assured themselves to be without any meaningful competition for quite some time. I m just wondering, how confident are you that there will be no antitrust issues with this?

## Gary Burbach Thoratec Corp. President, CEO

I certainly wouldn t position it as no meaningful competition. As you know, there s a number of other players in the field. [intrial] is entering trials.

I think our perspective is that it puts bringing the two companies together creates an entity that is incredibly well-suited to pursue this very large opportunity to create LVAD as a real standard of care for heart failure patients versus the small niche therapy for bridge to transplant that it s been historically. So, given the landscape, we feel quite optimistic that we will be able to get positively through that regulatory process.

## **Bob Hopkins** Bank of America Analyst

Just one real quick one, you mentioned on the call that you had the potential, with this transaction, to accelerate some of HeartWare s timelines. I was wondering if you could be a little more specific on that, because I think I m pretty aware of HeartWare s timelines, and Doug just went through them. But where specifically are you thinking you might be able to accelerate some of the timelines?

## Gary Burbach Thoratec Corp. President, CEO

I think certainly, I wouldn t have set that expectation for the current U.S. bridge to transplant trial. There will be a time period here where we are going through the various processes to get to a close, so the core of that activity will be occurring as we are going through this process, and then, obviously, you get into the FDA regulatory review process, where, I think, our team can obviously be a very positive contributor to creating additional confidence in moving through that process expeditiously and successfully.

But I wouldn t, at this point, create an expectation that the timelines relative to that submission and approval process would be different than the expectations that Doug has set up until now.

I think as you look more broadly beyond that to destination therapy, where having HeartMate II in the same portfolio as the HVAD can provide some opportunities in terms of the path to get through the whole trial and approval process, the ramp-up in Europe, and leveraging our extensive commercial organization, post-bridge approval, the ramp-up in the U.S., and again, leveraging our established commercial organization. And then, also, in terms of development of next-generation technologies, so the MVAD, the greater resources that we can bring to bear to help drive that program forward, would be a few of the areas that I think we could see some real benefit.

## **Bob Hopkins** Bank of America Analyst

Thanks very much and congrats again.

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#### **Operator**

(Operator Instructions). Taylor Harris, JPMorgan.

### **Taylor Harris** JPMorgan Analyst

Thanks a lot and my congratulations as well. So, I guess, just following up on Bob s FTC question, were you able to prescreen this transaction with the FTC?

#### **Gary Burbach** Thoratec Corp. President, CEO

No. We did certainly consult with external counsel that specializes in this area to get their read and got, as I mentioned, an optimistic view in terms of our ability to be successful in that process.

#### Taylor Harris JPMorgan Analyst

Great. David, on the financial front, is there anything you can share with us that might help us be able to model out the combination ourselves? I guess, particularly, a couple things I would be interested in my last recollection was that HeartWare was burning about \$2.5 million a month. Is that a good rough estimate to work with?

And then, of course, things change once they start recognizing revenue this year. I have been thinking they could do \$15 million or so of revenue in 2009, just between the clinical trial in the U.S. and commercial implants in Europe. So, maybe can you just comment on some of those rough numbers?

## David Smith Thoratec Corp. CFO

Actually, what I ll do is let Doug do that. But what I will point out is they have been filing their financials, and I think that s a good reference point. But perhaps Doug has some commentary there.

#### **Doug Godshall** HeartWare International President, CEO

Thanks. Good talking to you, Taylor. You re correct in terms of our historic burn, sometimes higher, sometimes lower. Certainly going through things like redomiciliation process were fairly expensive and I m pretty sure we will have a nice fee from our lawyers for this transaction that will hit here shortly.

But the we don't provide forward-looking forecasts in terms of our revenue. Certainly having sold, I think it was, \$300,000 worth last year in total, it stough to map out exactly what we ll do this year.

Certainly, your number is one of in the range of sort of high and low that we could achieve this year. The higher we are on the revenue stream, obviously, the lower our burn would be. We certainly are expecting, by the end of this year, to be south of that \$2.5 million per month burn rate.

## Taylor Harris JPMorgan Analyst

Thanks a lot.

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#### **Operator**

Mimi Pham, JMP Securities.

### Mimi Pham JMP Securities Analyst

Congratulations. In terms of the transaction, I guess the data so far has been very promising, but why not wait until more patient data? And how confident are you in terms of you re not seeing any kind of surprises with the HVAD down the road as we get more clinical experience?

### Gary Burbach Thoratec Corp. President, CEO

I think in terms of the strategic rationale, just to step back for a second, obviously we re big believers in the VAD opportunity and the ability to address a much broader population of heart failure patients.

I think the thing that happened in 2008 that s critically important is we saw with HeartMate II for the first time that we really are at an inflection point where we re really starting to push forward in realizing that potential with the strong patient outcomes, the strong clinician enthusiasm. So I think we re at a very important juncture, in terms of the development of this market, to move forward aggressively and position Thoratec to be able to really optimally move that market opportunity forward.

And so, we looked at HeartWare as a great opportunity in that regard, with a number of exciting technologies that they have in development, the HVAD obviously in clinical trial, the MVAD in earlier development, and certainly, the clinical experience that we have seen so far is quite promising. As you mentioned, it s still relatively early, but all the indicators are quite positive and so, based on all our experience and what we ve seen there, we feel quite optimistic about what we re seeing in that device.

#### Mimi Pham JMP Securities Analyst

And then, also, just in terms of the purchase price, can you generally talk about your assumptions in terms of growth of the \$250 million VAD market and incremental market share gains you think that you can gain with HeartWare under Thoratec sumbrella?

#### Gary Burbach Thoratec Corp. President, CEO

I don t think it s so much a bout market share gain, I think it s more a bout market expansion and driving the growth of the market. So the expectation is clearly that, by bringing these portfolio of products together, that we re going to be able to more aggressively grow that market with this portfolio of products over the coming years, as soon as the transaction closes. So that s really the fundamental underpinning of this transaction.

## Mimi Pham JMP Securities Analyst

Thank you very much. Congratulations again.

## **Operator**

Jason Mills, Canaccord Adams.

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Jason Mills Canaccord Adams Analyst

Hello, everyone, congratulations. Can you hear me okay? Okay, great. Congratulations on the transaction. First one to start, Gary and Doug, in Europe. I know the transaction is not expected to close until the second half of the year, but I m sure you re confident that it will and will be working together in the first half of the year. So, perhaps you, Gary, could talk about how you will perhaps segment the market in terms of your marketing focus, if not before the transaction closes, certainly after the transaction closes, with from what we can tell a very successful HeartMate II uptake, especially since the approval last year in the U.S., and with what we can tell a very strong pent-up demand for the HVAD as Doug gets ready to launch that in Europe.

### Gary Burbach Thoratec Corp. President, CEO

One thing, we won t be working together prior to close, so prior to close, we will each be operating as totally independent companies.

Relative to post-close, it s a little early to really talk about specific market segmentation strategies. We re going to be doing a lot of work in the coming months, as we kind of move through integration planning and post-close. But I think the best way to think about it is that the market has responded quite positively when there has been multiple devices that are experiencing good outcomes. More clinicians get engaged. There is more enthusiasm about what they re seeing with these devices.

So again, I see it more as an additive element in terms of building the market, be that in Europe or in the United States, in both cases. As we ve talked about, we see a huge opportunity. We really think we ve only capped the tip of the iceberg in terms of the utilization of LVADs for heart failure patients. So I think that s kind of the fundamental thought at this point. And I ll turn it to Doug for any additional comments.

## **Doug Godshall** HeartWare International President, CEO

My focus is, obviously, very near term, and we will be operating as an independent company for the foreseeable future. All of our activities will be heading in that direction. So we re going to continue our rollout as planned, which we ve indicated would start at the end of this month, and focus initially on our first our five centers who participated in the trial, the three in Europe and two in Australia.

Once we solidify those sites as customers, we ll start to expand and bring on additional sites while ensuring that we balance the infrastructure build for Europe and utilization of devices in our U.S. trial. We ve made very nice strides in expanding our production capacity, but we want too make sure that we don't overcommit to somebody in Europe and then constrain our U.S. trial.

So, thus far, it has been no problem. We have plenty of supply and capacity and inventory and the like. Then, looking forward to the assuming the transaction closes, we will start contemplating, at a higher level, what a combined entity would look like in Europe, but for now, operationally, we have to assume that the transaction won t close and we just run our business the way we plan to run our business, and when it closes, we will have a plan in place for integrating the two groups in Europe as well as the U.S..

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Jason Mills Canaccord Adams Analyst

That s helpful. Let me ask that question another European question a little bit differently, then I have one question on the U.S. trials and I ll get back in queue.

With the however you want to phrase it unfortunate announcement last week from Ventracor, the recall there is clearly change in dynamics, at least a little bit in Europe. They were doing okay in Europe, as far as we could tell, so there is going to be, at least in our estimation, market share up for grabs. I am sure Doug, you mentioned you re going to be focused on your five centers, but I m sure both companies, operating independently and then as the merged company later, will be focused on that.

And I am wondering if you could comment about what you re seeing or hearing from clinicians in Europe, specifically as it relates to the announcement out of your competitor last week, and perhaps what opportunity does that provide you?

And then, asking the last question, as it relates to both the bridge to transplant and DT trials for HVAD, from a bridge to transplant side, while you re operating as independent companies, there is every expectation this merger goes through, from your perspective, I m sure. I m wondering if you could just help us understand, Gary, there s probably going to be, with that in mind, expectation for close, there s going to be sort of a hope or a desire to get the HVAD enrolled as quickly as possible? And wondered what your thoughts on how you may be able to augment that. And then, from a DT perspective, presumably it ll be randomized against HeartMate II. You ll have control over both sides of that. I m wondering if that helps expedite, whenever it starts, a DT trial for the HVAD. And thanks for putting up with all my questions.

## Gary Burbach Thoratec Corp. President, CEO

No problem. So in terms of the bridge trial, we ll obviously be focused up until close on continuing to drive HeartMate II expansion, and really will leave it up to Doug and his team to drive a successful ramp-up of the bridge trial. And I have every confidence that he has a very capable team and that they will be successful in doing that. But we obviously won t really have any role in that until after our close.

In terms of a DT trial, I know that Doug and his team have been working with the FDA on various possibilities in terms of what makes sense there. Certainly, the accelerated submission timeline for HeartMate II, and expected earlier approval for HeartMate II, makes that a more realistic possibility. So I m certain I m sure Doug and his team will evaluate that amongst the other options.

And once we close, we Il certainly be actively engaged in that process. So it certainly seems like that would be kind of a pretty reasonable path at this point, given just how strongly HeartMate II has been adopted by clinicians. Obviously, the good outcomes that we re seeing in the interim analysis, so in terms of, maybe we d certainly start a trial later, but you would presumably, potentially finish a trial quite a bit more quickly.

### **Doug Godshall** HeartWare International President, CEO

From the HeartWare perspective, within or outside of Thoratec, it has become increasingly evident that running a trial today prior to HeartMate II approval is almost unachievable, given what the kind of trial that a clinician can enroll and the kind of trial the FDA would find acceptable, at least based on all of our discussions with them. So I tend to agree with you, that, as we have analyzed probably seven or eight different trial designs with different control arms, the ones that the FDA, at least at this juncture, has indicated they would be willing to support are then shot down by our investigators pretty aggressively. They just don t think they can enroll the trial.

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So we are 98%, 99% of the way towards coming to the conclusion that we would be best fit running the trial that our doctors really want us to run, which is randomizing it against HeartMate II, and we would likely start slightly later than if we ran a different kind of trial, but we would probably enroll three times as fast because it would actually be a scientifically interesting and appropriate alternative to offer patients offering two different devices versus something more complex that the FDA has indicated a willingness to consider.

## Jason Mills Canaccord Adams Analyst

That s helpful. Gary and Doug, the European question, what s going on competitively with the dynamics sort of changing?

## Gary Burbach Thoratec Corp. President, CEO

I m not going to get deeply into Ventracor and what they re trying to tackle. Obviously, we feel very good about HeartMate II and the performance that we ve seen with that device clinically and in terms of adoption, and so, we re going to be continuing to push aggressively, both in Europe as well as the U.S. to continue to drive that into additional accounts.

We mentioned during our call an expectation of adding that to 25 additional accounts worldwide with 10 of those being in Europe. So certainly, we have significant continued expansion expectations in Europe this year.

#### **Jason Mills** Canaccord Adams Analyst

Clearly, Gary, just pushing, though what s Ventracor s share, as best you can guess, in Europe? Clearly, there is not asking you to say anything derogatory about them or what they re going through, just generally we will make that analysis. But generally, what have they been doing, roughly, in your estimation, and we ll make our own assumptions as to whether that is up for grabs.

#### **Gary Burbach** Thoratec Corp. President, CEO

I don t have an exact share estimate for you. They have done reasonably well in Europe. So I ll leave it at that.

## **Jason Mills** Canaccord Adams Analyst Thanks, guys.

## **Operator**

Tim Lee, Piper Jaffray.

## **Tim Lee** Piper Jaffray Analyst

Good morning, congratulations as well from my part. What happens to HeartMate III? Were there some development costs that were going that you guys can now can [curtail] and savings on that front?

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Gary Burbach Thoratec Corp. President, CEO

The way we view it, post-close, we have HeartMate II which is clearly the standard of care in terms of VADs; has kind of established itself very strongly in terms of its European experience, the bridge to transplant approval, and our expectation of a BTT approval in the first half of next year. We would have HVAD continuing to evolve, we expect in a positive way in the European market, driving through its bridge trial and hopefully entering into a DT trial. And then there would be a couple of platforms in the pipeline, the MVAD and HeartWare and the HeartMate III here at Thoratec. Our expectation currently would be to continue to drive both those prog rams forward. They re really taking some fairly different approaches to some of the additional needs that could be met versus the technologies that are currently in clinical usage.

So we continue to move those forward, and it s too early to say today whether both would wind up in clinical experience or both would wind up as commercial products. But certainly at this point, we re not expecting to kind of stop a program. We think they both have very exciting potential, and definitely merit continued investment for the foreseeable future.

## Tim Lee Piper Jaffray Analyst

In terms of the premium paid for HeartWare, clearly reflective of the technology, but was this a bidding process where you kind of outbid some folks for this asset?

#### **Gary Burbach** Thoratec Corp. President, CEO

We don t want to comment on those kinds of particulars. But certainly it was an extensive process in terms of due diligence and the typical kinds of activities that you would expect.

### Tim Lee Piper Jaffray Analyst

One last one here. In terms of the second half 09 at close, what are the key gain factors, and when should we see the FTC approval? I suspect those should be some of the key hurdles. What s the time line on the regulatory front?

## Gary Burbach Thoratec Corp. President, CEO

The FTC process is really the primary determinant of the time line here. They have various potential phases of review that they go through. And we would expect to keep you apprised as there are meaningful developments in that process.

### **Tim Lee** Piper Jaffray Analyst

Thank you very much.

### **Operator**

Suraj Kalia, Sanders Morris.

## Suraj Kalia Sanders Morris Analyst

Good morning gentlemen, congratulations. Gary, in terms of or Doug, for that matter in terms of patient stratification, what does the thought process let s assume we get FTC the green light from FTC, financials, everything works through, and once

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the companies are integrated, and assume I show up in end stage heart failure, what is the stratification for choosing either the HeartMate II or one of the HeartWare devices? At least what s the thought process right now? And what is the pricing difference?

## Gary Burbach Thoratec Corp. President, CEO

I think it s really still too early to get into a lot of detail there. The most meaningful difference at the point of close will be in the United States where you ll have the HeartMate II, which is a commercially approved bridge to transplant device, you ll have the HVAD, which is still in a clinical trial environment.

So HVAD will be in much more limited availability in terms of centers, in terms of inclusion, exclusion criteria in a trial environment. So there is a lot of learning that will go on over the course of the coming months to help inform those product strategies. But the expectation is that both devices are going to be applicable to a broad range of patients.

#### **Suraj Kalia** Sanders Morris Analyst

But, Gary, in Europe, you would need to make a decision before the end of the year how you re going to market it or should we expect it like the [taxes] promise thing?

#### **Gary Burbach** Thoratec Corp. President, CEO

As we mentioned, we re really just at the front end of those kinds of integration planning thoughts. So that s certainly something that as we move forward, you can expect to get more visibility to.

### Suraj Kalia Sanders Morris Analyst

Okay, one last question. Gary, our analysis tells us that given the announcement from this morning, the hurdle rate for anyone to acquire Ventracor, and essentially commercialize, just went through the roof.

Have you been solicited in light of what s going on in the Ventracor front, unfortunate as it is, have you all been solicited by hospitals to stand ready, willing and able to provide support in case things don t work out as Ventracor plans, and (inaudible) over 100 close to 100 BTT patients worldwide, and if something goes wrong with the pumps or drivelines or batteries, would you all be do you anticipate being called to help on that front?

## Gary Burbach Thoratec Corp. President, CEO

It s not our current expectation. Our current expectation is that Ventracor will find a path forward. We re not hearing those kinds of requests from hospitals. So I think that s currently their expectation. So we ll just have to see how that continues to play forward.

**Suraj Kalia** Sanders Morris Analyst Gentlemen, congratulations again.

#### **Operator**

Keay Nakae, Collin Stewart.

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Keay Nakae Collin Stewart Analyst

If you were to get a superior offer before this closes, what would be your breakup fee?

Gary Burbach Thoratec Corp. President, CEO

The breakup fee is \$11.3 million.

#### Keay Nakae Collin Stewart Analyst

Thanks. And for Gary, HeartWare does have a number of interesting MVAD devices. As Doug said, their strategy was take one of those forward.

Within Thoratec, with greater resources, would you guys be thinking of perhaps taking more than one of those forward? Obviously one of the three is quite innovative and possibly disruptive, but also much riskier. Could you give us your thoughts on that?

## Gary Burbach Thoratec Corp. President, CEO

Yes, I think that depends largely on their work as they go forward here over the coming months. They set an objective by the end of this year to get through that process of evaluating these three potential approaches.

So I think we d look to see what comes out of all that work, lab work, animal work, assess that. We will also be driving the HeartMateIII program forward simultaneously, and then make an assessment kind of as we move through the end of 2009 and into 2010 as to which of these farther reaching development programs make sense to continue to drive forward.

Keay Nakae Collin Stewart Analyst

Okay, thanks.

#### **Operator**

Spencer Nam, Summer Street.

#### **Spencer Nam** Summer Street Analyst

Thanks for taking my questions. Congratulations to all of you, it s a great deal. Just one question for Doug and one question for Gary.

Doug, I know you can t really complain about \$282 million deal, but you guys were ramping up very quickly on your trial enrollments, DT trial enrollment, and things were looking very positive in terms of feedback from the community. Why do the deal now? What kind of math went into your thoughts as you guys kind of evaluated this situation? I ll ask the second question after I get the answer.

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### **Doug Godshall** HeartWare International President, CEO

We certainly feel very optimistic and felt very optimistic about our prospects as a stand-alone enterprise and should for whatever reason this transaction not close, it is not as if we are entering into a distressed sale kind of environment. And I think the premium paid, it sort of clearly reflects that.

As we did our calculation as a board and contemplated this offer against the prospect of raising additional capital, diluting our current shareholders and obviously having some level of both execution and financial markets risk moving forward, it seemed like — it was quite clear to the board that this was, in our estimation, a very strong and appropriate price to take at this juncture, and provide our shareholders with meaningful upside still within the context of the transaction in the form of Thoratec shares.

It also provides our employees with a very an excellent Company, stable work environment with a better financial wherewithal. And ultimately we felt that in our mission of bringing our technology to our customers and helping heart failure patients, that this gives a much higher likelihood that we will be appropriately financed to work on our portfolio products, and so it s a significant upside to our current shareholders, with meaningful risk reduction downside protection.

#### **Spencer Nam** Summer Street Analyst

I appreciate that. And then question to Gary. So we have been hearing that there was some centers, major centers, who were going to exclusively work with HVAD in their BTT trial, and not really get involved with HeartMate II, and we it still sounded like the HVAD enrollment was going to be quite rapid. What happens here is if the enrollment actually does take off, and let s say it got completed by early Q4, we could be looking at HVAD being approved for BTT almost the same time frame that HeartMate II is going to be approved for destination therapy.

We ve already seen that the HeartMate II is being used in DT environment, most the (inaudible) has ever done, what are your thoughts in terms of dealing with that situation? I know it searly, but you must have thought through that aspect that potentially there could be not necessarily confusion, but two products with excellent data overlapping each other. How do you foresee this resolving this issue, particularly with HeartMate II sort of overlapping HVAD, (inaudible) HeartMate II, potentially some of the HeartMate II data points, and creating a competitive situation within the same product line?

#### **Doug Godshall** HeartWare International President, CEO

Let me first clarify time lines, then I ll let Gary, to the extent that he s able to at this early planning stage, address how we envision the portfolio in the future. But if we complete enrollment, our guidance on completing enrollment is we would complete as soon as December of this year, as late as April of 2010.

We then have to follow the patients for six months, then put a submission together. So the soonest we would envision submitting a PMA is in the sort of August/September of 2010 time frame, as late as January 2011.

Then we get to wait for the FDA to review. We would imagine, as potentially the first centrifugal pump to hit the FDA, or second, depending upon how things turn out with the other company out there, in Australia that is, then we would anticipate we will have a panel. So our earliest approval would probably be September 2011 and ranging that out to January 2012. So I think the market reality is that we will be in a trial and then hopefully in a continued access protocol until late 2011.

#### **Gary Burbach** Thoratec Corp. President, CEO

Thanks, Doug, for that clarification. Just a few additional comments to your questions.

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One, HeartMate II is in pretty much every high-volume bridge to transplant center in the United States as of the end of last year. So there may be a number of those centers that are quite enthusiastic about HVAD, and about their expectations about enrollment.

But there is inclusion/exclusion criteria in a trial. There s a substantially broader population of patients that they have opportunity to implant that HeartMate II can address. So I m certainly not familiar with any center that would have the characteristic of what you described.

In terms of the kind of overlap, Doug mentioned, his expectation of something like a second half to late 2011 approval for bridge for HVAD. Our approval expectation for destination therapy is the first half of 2010. So you have roughly 1.5 years time line between DT approval for HeartMate II expectation, and similar expectation for bridge for HVAD. So there really is a quite significant gap there. And the other thing that I would point out, I think there are we talked about kind of this gray area where physicians will expand their utilization of a good device from a clinical trial with a bridge approval, as we ve seen with HeartMate II, but in terms of kind of then moving into what s kind of the big pure destination therapy opportunity, our current expectation is that we will need an approval, a completed trial with long-term data for clinicians to actively embrace a device for that indication.

#### **Spencer Nam** Summer Street Analyst

Great, appreciate that. Congratulations again.

### **Operator**

Joshua Zable, Natexis Bleichroeder.

#### Joshua Zable Natexis Bleichroeder Analyst

Congratulations to everyone, thanks for taking my questions. I know a lot of my questions have been answered, but I just kind of want just some housekeeping items if you don t mind. So I think you guys alluded to the deal being closed second half of the year but obviously you can t give a direct timing. Is that correct?

## Gary Burbach Thoratec Corp. President, CEO

That s correct. Given that really the primary driver of the time line will be the FTC review, and that can go through different phases depending on some decisions they make. So it could be shorter or longer depending on that process.

## Joshua Zable Natexis Bleichroeder Analyst

Is it safe to assume that the loan wouldn t start until the deal closed, or would you guys start lending money earlier?

## Doug Godshall HeartWare International President, CEO

No, we ll start lending money earlier in that process. The idea was to give them a vehicle to ~ so they don t have to go out into the markets.

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**Joshua Zable** *Natexis Bleichroeder Analyst* So that would be effective immediately, basically?

### **Doug Godshall** HeartWare International President, CEO

It s not immediately. You Il see the documents, they re going to be filed a little bit later in today. I believe it s May when they would have access to those funds.

#### Joshua Zable Natexis Bleichroeder Analyst

Can you just give me the most up-to-date HeartWare shares outstanding just because I m trying to do the math here? I m just not getting proper

## Doug Godshall HeartWare International President, CEO

Our outstanding shares are approximately 310 million Australia so it s in Australia, 310 million shares with approximately another 30,000 options and restricted shares.

**Gary Burbach** *Thoratec Corp. President, CEO* 30,000 or 30 million?

## Doug Godshall HeartWare International President, CEO

I m sorry, million, yes.

#### Joshua Zable Natexis Bleichroeder Analyst

Okay, so that s where I m missing it. 30 million options. Perfect. Then just getting back to the FTC, I don t want to beat a dead horse here and I know some other people have asked. But it seems like that obviously that s the big hurdle to the deal here, or potentially could be.

I m sure you guys did your due diligence, and obviously you indicated you ve spoken to external council and done those sorts of things. But can you just give us a little bit more comfort as far as sort of even the case being made as to competition, etc. out there?

I know there is some but they re obviously significantly farther back than HeartWare was, and obviously you guys were. Can you give us a little bit of color of kind of what gives you guys some confidence here?

### Gary Burbach Thoratec Corp. President, CEO

I think the primary confidence comes from extensive consultation with external council that specializes in this area. We have spent quite a bit of time going through the details of the situation, the market, the competitors, etc. And they came back with a quite optimistic view of our prospects of successfully getting through this process.

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Joshua Zable Natexis Bleichroeder Analyst

Is it related to the size of the deal? Is it related to the fact that there are a number of competitors out there, even though they re behind you guys? Can you just give us a little better understanding?

### Gary Burbach Thoratec Corp. President, CEO

Yes, certainly there is a number of as you know, there are a number of competitors in this space. So it s not as if there are two or three players. There are a significant number of players that are in various phases of evolution. So we view that there certainly is a very relevant competitive landscape.

### Joshua Zable Natexis Bleichroeder Analyst

Great, well congratulations and thanks for taking my questions.

#### **Operator**

Erik Schneider, UBS.

#### Erik Schneider UBS Analyst

Good morning. Just a couple of quick questions for Doug. Was this a one-to-one negotiation, or part of a broader process?

## **Doug Godshall** HeartWare International President, CEO

No, Gary and I started speaking probably what? Last April, roughly? And started in earnest really around the October/November timeframe. And the synergies of the Thoratec's experience, market knowledge, technical capabilities, struck us as a really appropriate partner moving forward for our technology.

And as the terms came together, the significant premium for our shareholders was handsome enough that we did not enter into any sort of an auction process because we were not actually proactively looking to sell the Company. And certainly for Thoratec, it would have probably I cannot speak for them, but I don t think it would ve been a particularly interesting there would be less interest on their part if suddenly we said, well we re going to go into auction. I don t know that we would ever come to a point where we would ve reached terms.

#### Erik Schneider UBS Analyst

Given how concentrated some of those shareholders are, was there have you received a commitment from any of them in advance to vote in support of the transaction as structured?

### **Doug Godshall** HeartWare International President, CEO

Yes, as we will be disclosed in the public filing, our largest shareholder, Appletree Partners has signed onto the transaction.

## Erik Schneider UBS Analyst

Great, thank you.

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#### **Operator**

Duane Nash, Pacific Growth.

### **Duane Nash** Pacific Growth Analyst

Congratulations. One question is does this transaction change at all the calculus of comparing the HVAD directly against the HeartMate II in the planned HVAD destination therapy trial?

## **Doug Godshall** HeartWare International President, CEO

We had not until today, we had never publicly described plans to randomize against HeartMate II, that we ve really been coalescing around that concept over the past few weeks, particularly with the very positive signaling that has come out of Thoratec. And if anyone is interested, I still don t know their data for destination therapy, although I m dying to hear it, because I gather it s really good.

So my sense is our clinical community would vastly prefer a randomized trial of HeartMate II versus HeartWare HVAD, so our plan has been to do is now as of the past week or so, to do that trial. My sense from Gary s comments earlier is that he would likely will likely do the same thing, assuming we come together.

## **Duane Nash** Pacific Growth Analyst

Great. One possibility this creates is I know this is in essence pie in the sky, but it creates the possibility of an XVE situation, where the HeartMate II was found to the superior to the XVE. And in comparing head-to-head, there s the potential for a similar outcome. In that case, one would assume that the Company would then have to choose one device to continue to pursue. Can either of you comment on that?

#### **Doug Godshall** HeartWare International President, CEO

I would comment that we are encouraged by our data, but we ve only treated 50 patients internationally and 11 in the US. So we are still frankly coming up the learning curve in some respects on the intricacies of managing our patients, and yet thus far the data has been quite encouraging.

I don t think there is any there s nowhere near enough evidence to suggest that in our 61 patients, that we have or will have better outcomes in HeartMate II, and with their 2000 less patients, they certainly have a much greater body of data to support their device. So clearly if somebody, whether it s HeartWare or one of the other companies, came up with a technology that had vastly superior results in a randomized trial, then they would probably be in a position where they would stop the trial early and do the kind of thing that Thoratec was able to do in their destination therapy trials. So I think it s just too early to postulate as to whether we will have better data or not.

**Duane Nash** Pacific Growth Analyst Thank you.

## **Operator**

Greg Simpson, Stifel, Nicolaus & Co..

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#### **Greg Simpson** Stifel, Nicolaus & Co. Analyst

Congratulations guys, good morning to all of you. There s actually a couple of interesting things here I hope to ask. Specifically, and again maybe you guys can t comment too much on this until after the deal closes. But Gary and Doug, what are the opportunities maybe on a more near-term basis to use some of the HeartWare technology, or elements of the HeartWare device specifically, I guess, I m thinking leads and things like that and incorporate them into HeartMate II as the HVAD progresses through the trials?

## **Gary Burbach** Thoratec Corp. President, CEO

I guess so incorporating elements of the HVAD into HeartMate II, is that the question?

### Greg Simpson Stifel, Nicolaus & Co. Analyst

Is there any ability to upgrade HeartMate II? Leads are obviously an area that you guys have identified that you re working on. Are there any elements of the HVAD that could be appropriate to help upgrade HeartMate II in the meantime?

## Gary Burbach Thoratec Corp. President, CEO

I don't see any I wouldn't expect that kind of synergy early on. I think we have a very good set of programs to continue to advance HeartMate II that we re driving forward quite aggressively, the percutaneous lead as you mentioned. We will have that either submitted to the FDA or just about to submit to the FDA as we get to close. External peripherals will be launched. So really the core elements of the system that we re looking to upgrade on HeartMate II would be largely accomplished as we look toward a closed kind of timetable.

#### **Greg Simpson** Stifel, Nicolaus & Co. Analyst

Got you. Gary, you guys had alluded to last week, you made some general comments about a next-generation device. What does this acquisition due to those plans? Does that work continue, or does this deal today negate the need to pursue that?

#### **Gary Burbach** Thoratec Corp. President, CEO

No, that work definitely continues. So that s the HeartMate III program, which we had taken back into the lab a while ago to take some of that core mag lab technology, downsize it substantially. We think there s some very interesting elements to that programs. So we re going to continue to aggressively drive that forward.

And post-close, I think we will continue to drive that along with the MVAD forward as kind of next-generation possibilities to really take another step forward relative to HeartMate II and HVAD. And it will take some time to sort through kind of do those both make it all the way to market, or kind of how far does it make sense to progress those programs. But at least for the near-term, our expectation would be to continue to invest and drive both HeartMate III as well as post-close the MVAD program forward.

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**Greg Simpson** Stifel, Nicolaus & Co. Analyst

And then, David, one final one. Obviously this deal makes a ton of sense on a long-term basis for both parties. When would we get any greater detail on the level of dilution associated with the deal? Would that be after the close?

#### **David Smith** Thoratec Corp. CFO

Yes, it is likely to get the full granularity obviously after the close. We ve got to go through the purchase accounting mechanics that everybody is aware, where you ve got to shift to 141R, so there is some newness in that, and work through the integration process as well, which will help illuminate. I think Doug gave a little bit of visibility early on in the call today about some of his expectations for the operational side of the business and the financial effect. So to the extent that we have meaningful clarity that we can provide, as the process moves along, we will certainly do so.

## Greg Simpson Stifel, Nicolaus & Co. Analyst

Great, thanks very much and congratulations to all of you.

## **Operator**

That will conclude the question-and-answer session. I ll turn the call back over to your host for closing remarks.

#### Gary Burbach Thoratec Corp. President, CEO

Great. I would just like to say thank you for joining us this morning. We are obviously very excited about this announcement and the potential to bring Thoratec and HeartWare together in the future, and we will look forward to keeping you apprised as the process moves ahead.

#### Operator

That will conclude today s conference. We thank you for your participation. Everyone have a wonderful day.

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annual reports on Form 10-K and quarterly reports on Form 10-Q, their current reports on Form 8-K and other SEC filings. These forward-looking statements speak only as of the date hereof. Thoratec undertakes no obligation to publicly release the results of any revisions or updates 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.

## Additional Information and Where You Can Find It

Thoratec will file a Registration Statement on Form S-4 containing a proxy statement/prospectus and other documents concerning the proposed acquisition and HeartWare will file a proxy statement and other documents concerning the acquisition, in each case with the Securities and Exchange Commission (the SEC). Investors are urged to read the proxy statement/prospectus when it becomes available and other relevant documents filed with the SEC because they will contain important information. Security holders may obtain a free copy of the proxy statement/prospectus (when it is available) and other documents filed by Thoratec and HeartWare with the SEC at the SEC s web site at http://www.sec.gov. The proxy statement/prospectus and other documents may also be obtained for free by contacting Thoratec Investor Relations by e-mail at ir@thoratec.com or by telephone at 925-847-8600 or by contacting HeartWare Investor Relations by e-mail at enquiries@heartware.com.au or by telephone at 61 2 9238 2064.

Thoratec, HeartWare and their respective directors, executive officers, certain members of management and certain employees may be deemed to be participants in the solicitation of proxies in connection with the proposed merger. A description of the interests in HeartWare of its directors and executive officers is set forth in HeartWare s proxy statement for its 2008 Annual Meeting of Shareholders, which was filed with the SEC on April 8, 2008 and the Annual Report filed with the SEC on February 28, 2008. Information concerning Thoratec s directors and executive officers is set forth in Thoratec s proxy statement for its 2008 Annual Meeting of Shareholders, which was filed with the SEC on April 16, 2008. This document is available free of charge at the SEC s web site at www.sec.gov or by going to Thoratec s Investors page on its corporate web site at www.Thoratec.com. Additional information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of proxies in connection with the proposed merger, and a description of their direct and indirect interests in the proposed merger, which may differ from the interests of HeartWare stockholders or Thoratec shareholders, generally will be set forth in the proxy statement/prospectus when it is filed with the SEC.