Consolidation of the Mechanical Circulatory Support Market
Preface January 24, 2012 (rev 32) and (date of first publication of this white paper (rev. 1), February 12, 2009))

This white paper chronicles the development, evolution and current status of the Mechanical Circulatory Support (MCS) segment of the medical device industry.

For a comprehensive description of the past, present and future of the Mechanical Circulatory Support business, please read this document from beginning to end. The information presented here will bring you to the conclusions and predictions presented below (and also at the end of this document).

Consolidation was triggered and signaled by the merger of Thoratec and Thermo Cardiosystems in 2001. This merger created a suite Left Ventricular Support and BiVentricular support products and laid the foundation for the competitive landscape of the MCS space.

Until human hearts can be rebuilt with stem cells and scaffolding, the conclusions below establish the necessary foundation for financial survival in the field of Mechanical Circulatory Support, and provide the key considerations to guide your investment decisions in this field.

Conclusions:

Conclusion 1 – Biventricular failure is the final common pathway to death.

Just 2,100 useful donor hearts are available each year in the United States. It is estimated that 5,000 donor hearts are available worldwide.

As the number of patients on LVAD and BiVAD support increases, waiting times to transplant increase. The denominator remains constant (number of donor hearts), and the numerator continues to grow (patients on support listed for transplant). The waiting time grows and grows…the simple calculation of dividing the numerator by the denominator will determine time required to wait for a donor heart.

The LVAD or BiVAD bridged patient must wait longer and longer for a donor heart as the patient’s heart, although supported, continues to decline. Supported or not, biventricular failure is the final common pathway to death.

Conclusion 2 - Size Matters – And It’s Better to be Up than Down - Small and Within the Pericardial Space.

LVADS that must implant below the diaphragm will lose popularity and fail. LVADs of the 4th and 5th generation will survive.
The detail of each LVAD reveals that five functional generations of LVADS exist:

1. Original large and cumbersome devices, such as the HeartMate I and Novacor
2. Axial flow pumps, such as the Thoratec HeartMate II and the Berlin Heart INCOR – smaller devices, yet requiring a pocket below the diaphragm and plumbing to the pericardial space
3. Centrifugal pumps, such as the DuraHeart, or the VentrAssist, are implanted below the diaphragm in a pocket and plumbed through the diaphragm into the pericardial space
4. Axial flow or centrifugal flow pumps, such as the HeartAssist5 by MicroMed and the HVAD by HeartWare, implanted within the pericardial space
5. Axial flow or centrifugal flow pumps with accurate flow measurement and implanted within the pericardial space, such as the HeartAssist 5 (the only product that meets the test for level 5)

Predictions for 2012 - 2014

1. Thoratec may be purchased by a “Large Med Tech” company that will “buy” its way into a proven and large market….however if that occurs, the purchaser will be burdened with the challenge of upgrading to a device that implants within the pericardial space. The HeartMate II is too large and a new pump must be designed, tested and studied to gain approval.

2. SynCardia may be purchased by a company interested in entering the mechanical circulatory support market or it may be purchased by a company in the MCS space.

3. HeartWare may be acquired or they may use their public currency to build a suite of products that broaden their competitive reach,

4. All but one of LVADs that implant below the diaphragm will be discontinued

5. The potential combination of SynCardia and an above the diaphragm LVAD (MicroMed or HeartWare (pericardial space LVAD)) could an ideal combination of products for the Transplant Center OR suite.

6. The TAH will become more common and be accepted similar to the acceptance of ventilator, portable oxygen or artificial knee or hip – a prosthesis. Biventricular failure is the final common pathway to death and can be treated with a prosthesis. Alert: MicroMed may have the TAH of the future.

7. All four companies are guided by capable CEOs:

Thoratec - Gerhard (Gary) Burbach joined Thoratec as president and chief executive officer in January 2006, at which time he was appointed to the board of directors. Prior to his arrival, Burbach served as president and chief executive officer of Digirad Corporation, a leading provider in solid-stage cardiology and nuclear medicine imaging
products and services, and continues to serve on the board of directors. Burbach has held executive positions at Bacchus Vascular Inc. and Philips Nuclear Medicine, as well as the consulting firm of McKinsey & Company, Inc. He has a bachelor's degree in industrial engineering from Stanford University and a master's degree in business administration from Harvard Business School.

**HeartWare** - Doug Godshall, age 46, has been the Chief Executive Officer of HeartWare Limited and subsequently HeartWare International, Inc., since September 2006 and became a director of HeartWare Limited and subsequently HeartWare International, Inc., in October 2006.

Prior to joining HeartWare Limited, Mr. Godshall served in various executive and managerial positions at Boston Scientific Corporation, where he had been employed since 1990, including as a member of Boston Scientific's Operating Committee and since January 2005, as President, Vascular Surgery. Prior thereto, Mr. Godshall spent five years as Vice President, Business Development, at Boston Scientific, where he was focused on acquisition strategies for the cardiology, electrophysiology, neuroradiology and vascular surgery divisions.

Mr. Godshall has a Bachelor of Arts in Business from Lafayette College and Masters of Business Administration from Northeastern University in Boston, Massachusetts

**SynCardia** – Michael Garippa, age 57, CEO of SynCardia Systems Inc.

Michael Garippa is the former CEO and President of TandemHeart. He was recruited by TandemHeart in 2002 as a turnaround expert and stayed on as CEO and President. He progressed TandemHeart from an R&D firm that had lost an aggregate of $50 million and had no commercial sales to a successful company with over $6 million in net income in 2010.

Prior to joining TandemHeart, Mr. Garippa served as CEO and President of Gateway Home Care. In addition, Mr. Garippa was Founder and CEO of Millennium HomeCare and The Prompt Care Companies. His background also includes being National Sales Manager at Omni Medical and Senior Analyst with the NYC Health and Hospitals Corporation. Mr. Garippa holds a B.A. degree from Rutgers University and a master's degree from New York University

**MicroMed** - David Mackstaller, age 69, CEO of MicroMed Cardiovascular. Mr. Mackstaller holds a B.A. degree in Economics from the University of Michigan and a Juris Doctorate, Cum Laude, from the University of Michigan Law School. He practiced law with a Detroit Law firm from 1968 to 1970, there specializing in real estate law, with particular emphasis on partnerships, corporations, and taxation.

From 1984 until 1991, J. David Mackstaller was the Executive Vice President and a 50% owner of the Schomac Group, Inc., and National Self Storage Management, Inc. He was a co-founder of both companies. Mr. Mackstaller was co-founder of Anthem Equity Group, Tucson Arizona in 1991.
Mr. Mackstaller is the Vice President of Business Development at SynCardia Systems. There he and his longtime partner Mr. Ford raised the capital which funded SynCardia during its development and launch of the Freedom portable driver, the world’s first wearable power supply for the Total Artificial Heart.

Mr. Mackstaller co-led the acquisition of MicroMed Cardiovascular in 2008. MicroMed was a public company acquired by E-Wilson LLC, a group formed for the purpose of acquiring the outstanding public shares.

**Consolidation of the Mechanical Circulatory Support Market**

1. **SynCardia Formation and Historical Overview**

   SynCardia Systems, Inc. was formed in August of 2001 by Marvin J. Slepian, MD, Jack Copeland, MD, and Richard Smith, MSEE, CCE, who were then and are now employed by the University Medical Center (UMC), Tucson, Arizona.

   Robert Sarver, a successful businessman and native of Tucson, provided SynCardia’s initial capital and an “A” round of $2.7M in September of 2002. Sarver had previously funded the Sarver Heart Center at UMC, where Dr. Copeland had treated his father, Jack, for heart disease.

   SynCardia was formed to commercialize the CardioWest Total Artificial Heart (TAH) and began by purchasing the TAH technology from UMC’s subsidiary, CardioWest. The assets acquired by SynCardia included:

   1. A high tech manufacturing facility located in Tucson, AZ 85713;
   2. Know-how to manufacture the 70cc TAH and drive the TAH.
   3. Manufacturing equipment;
   4. All the design records and experience from the preceding owners, *i.e.*, CardioWest preceded by Symbion (Jarvik); and
   5. A small core team of individuals who had been with the project for a substantial amount of time, including some employees from the Symbion era.

   Almost 10 years prior to SynCardia’s purchase of these assets, UMC had purchased the cardiac support business of the Symbion total artificial heart from Symbion, Inc., following its liquidation in 1991. By 2007 in excess of $200MM had been invested in the project.

   From 2004 to 2005, SynCardia raised an additional $20.5M through a “B” round of financing, and many new SynCardia investors joined the original group.

   Rodger Ford, an “A”, “B”, and as of December of 2010 a “C”, “D” and “E”) round investor, was appointed to the Board of Directors of SynCardia in late 2002. In October
of 2004, SynCardia received PMA approval from the FDA for the CardioWest TAH. The company received full CE (European) approval for the TAH in 2005.

Before deciding to invest in SynCardia, most individuals concluded that there were a few key elements that made SynCardia an exceptional opportunity. These included:

1. **No Competition**

   SynCardia and the CardioWest TAH had no competitors. While several companies were attempting to develop technology to assist a sick and weakening heart (Ventricular Assist Device – VAD), no other company had a workable means of replacing a failed human heart (Biventricular Replacement) with a mechanical heart.

   A few companies tried to address this need, but none of them became commercially successful. The AbioCor fully Implantable Replacement Heart, manufactured and marketed by Abiomed, initially appeared to show promise, but has been shelved because of technological and cost limitations. The AbioCor weighs 2.5 pounds and as of November of 2011, has been implanted in only 15 patients, with results that did not warrant any further use of the device. At one FDA hearing for the AbioCor it was said that “... It was unclear if the AbioCor prolonged life or prolonged death.”

   SynCardia remains one of a kind, and by the spring of 2003, over 500 patients had received a CardioWest TAH, and the gift of life. By the end of 2011 the patient count benefiting from SynCardia TAH will exceed 1,000

2. **FDA Approval**

   While FDA PMA approval for the CardioWest TAH was not certain, the SynCardia founders believed it to be very likely. At that time, the CardioWest TAH had already been implanted successfully as a bridge to transplant in more than 500 patients since 1988. The bridge to transplant success rate of 79% for the CardioWest was twice the rate of the most effective alternative therapy (Thoratec biventricular support system).

3. **A Solid History of Research and Development of the TAH**

   It had been estimated by SynCardia management that since the early eighties more than $200MM had been invested in furthering the development of the TAH, originally known as the Jarvik 100. The major development efforts that provided the foundation for SynCardia were:

   a. **Willem Kolff Design (b. 1912 – d. February 12, 2009)**

      The inventor of the Jarvik TAH, Kolff began his work on the Artificial Heart in 1948 and gave credit to all who supported him in his work, including Dr. Robert Jarvik at the University of Utah in 1978. [http://en.wikipedia.org/wiki/Willem_Johan_Kolff](http://en.wikipedia.org/wiki/Willem_Johan_Kolff)

   b. **Symbion Development**
A public company formed to further develop and market the Kolff TAH, which became the Jarvik-7.

c. **University Medical Center Clinical Leadership**

UMC and its investment in the CardioWest TAH, previously the Jarvik 100 and the Jarvik 7.


4. **Historical Proxies for SynCardia’s Value (2004 proxies)**

Because SynCardia is a private company, its value is not reflected on any exchange or by any direct means. Therefore, in 2003/2004, the best bellwethers or proxies for SynCardia’s value were the few public companies that occupy the “Mechanical Circulatory Support” sector of the medical device industry.

a. **Thoratec – Market Cap - $600MM – Mechanical Circulatory Support**

i. HeartMate I – implantable, electrically powered, continuous flow LVAD weighing over 1100 grams.

ii. iVAD and pVAD – pneumatic, pulsatile biventricular support systems.

iii. Thoratec had received approval from the FDA to discharge patients to home with a mobile pneumatic driver that powered their biventricular support systems.

iv. Thoratec had received PMA approval from the FDA for their pneumatic pulsatile BiVADs and the electrically powered continuous flow HeartMate II LVAD.

b. **Abiomed – Market Cap - $300MM – Mechanical Circulatory Support**

i. Pneumatic pulsatile BVS and AB 5000 BiVAD system.

ii. AbioCor Implantable Replacement Heart. To date, the electrically powered pulsatile AbioCor has been implanted only 14 times, the last one in 2004.

c. **World Heart – Market Cap - $400MM – Mechanical Circulatory Support**


d. **Arrow International - Market Cap - $1.6B – Tube Set and Balloon Pumps**

i. LionHeart - electrically powered, pulsatile.

ii. CorAide - electrically powered, continuous flow.
iii. Arrow pulsatile balloon pump – sales of $65MM.

e. Terumo – Market Cap – $6.2B – Catheter and tube sets
   i. DuraHeart - electrically powered, continuous flow – one of many products, CE approvals and little penetration. Only 25 implants as of 2003.

f. Berlin Heart GmbH – Private – Mechanical Circulatory Support
   i. INCOR™ electrically powered, continuous flow LVAD, just beginning to be distributed, CE marked and surprisingly similar to the MicroMed DeBakey LVAD, although 3x larger.
   ii. Biventricular pneumatic pulsatile support, powered by the IKUS and EXCOR drivers.

g. MEDOS GmbH - Private – Mechanical Circulatory Support
   i. Heimes pneumatic pulsatile drive system.
   ii. 6 sizes of extracorporeal pneumatic pulsatile biventricular pumps.

h. Ventracor (Aus) – Market Cap - $500MM (AUS $)– Mechanical Circulatory Support
   i. VentrAssist electrically powered, continuous flow LVAS.

i. HeartWare (Aus) - Market Cap - $100MM (AUS$) – Mechanical Circulatory Support
   i. MVAD – LVAD.

j. Sunshine Heart (Aus) - Market Cap - $16MM (AUS$) – Mechanical Circulatory Support
   i. LVAD-pulsatile – odd device that surrounds the aorta and behaves more like an outside-in balloon pump.

k. DataScope - Market Cap - $500MM – Mechanical Circulatory Support
   i. DataScope – pneumatic pulsatile balloon pump.

l. MicroMed – private - Mechanical Circulatory Support
   i. DeBakey electrically powered continuous flow LVAD.

II. Milestones

Many “B” round investors joined SynCardia as it was being transformed from a science project to an operating and the promise of a profitable company (not a small task). It was
clear that there were only three major milestones to creating value for SynCardia, and widespread deployment of the CardioWest TAH would follow.

A. The Steps

1. Approval

FDA approval of the CardioWest TAH.

2. Drivers

Alternative driver technology to replace the limited number of “Big Blue” TAH pneumatic drivers. Only 36 drivers existed in the SynCardia fleet as artifacts from Symbion. This limited number of drivers constrained the number of patients SynCardia could help and the number of TAHs SynCardia could sell.

The driver technology was obsolete, more drivers could not be manufactured, and alternative drivers had to be sourced or designed and manufactured. A contract for an alternative driver had been entered into between SynCardia and MEDOS of Germany in early 2003 for the modification of the Heimes HD8 biventricular support driver, which was used at that time to drive the MEDOS pneumatic pulsatile BiVADs.

3. Reimbursement

CMS, Medicare and Medicaid reimbursement (a source of payment) to encourage private insurance companies to follow with a payment schedule. CMS was reimbursing BiVADs and LVADS, but not the Artificial Heart.

B. The Outcome

1. Approval

FDA granted the CardioWest TAH a full PMA approval on October 15, 2004. This signal event would normally have been the inflection point to ignite availability of the SynCardia CardioWest TAH worldwide. This did not happen because the world distribution opportunity and value of SynCardia was suppressed by the two remaining milestones.

2. Drivers

MEDOS had made no progress on converting the Heimes HD8 driver to drive the CardioWest TAH. The project was terminated in the early spring of 2006.

However, promising news had surfaced from the collaboration of Berlin Heart GmbH and the Heart and Diabetes Center NRW in Bad
Oeynhausen, Germany. A “skunk works” thrust forward by the determination of Aly El Banayosy, MD, converted the Berlin Heart EXCOR® pneumatic pulsatile BiVAD driver to power the CardioWest TAH. Stable TAH patients supported by the “Big Blue” drivers were transferred to EXCOR TAH drivers and were discharged from the hospital to recover at home while awaiting a donor heart.

Dr. Banayosy’s work proved that stable TAH patients would recover and thrive out of the hospital. The EXCOR driver was only suitable for stable TAH patients and it did not have the range of adjustment or power to satisfy the requirements of the Operating Room or Intensive Care Unit.

3. Reimbursement

By 2005, SynCardia management began working to overturn the CMS Non-Coverage Decision that excluded reimbursement for the TAH, while allowing reimbursement for BiVADs and LVADs.

The non-coverage decision was astonishing, considering the bridge to transplant record of the CardioWest TAH relative to LVADS and BiVADs. The non-coverage decision had not previously been challenged because there was no FDA approved artificial heart that would require reimbursement.

Thus, in November of 2004, it was very clear that, for SynCardia to launch a successful IPO or engineer a sale to an eager buyer,

- **alternative drive systems** would be needed to support the TAH;
- Medicare (“CMS”) **reimbursement** would be required to stimulate the use of the TAH, and
- additional effort would be necessary to prepare SynCardia to succeed, as the company had to become an **efficient and systemized operating unit** to leverage human capital.

- **Sales** must demonstrate velocity, volume and pricing power

III. **May 2005 to May of 2011**

David Mackstaller and Rodger Ford joined SynCardia full time in March of 2005: David as VP – Development, and Rodger as CEO. They set out to install reliable business systems to leverage human capital and complete the three remaining hurdles:

1. Reimbursement from CMS; and
2. Replacement drivers and evolution of the TAH
3. Generate sales
October 2008 marked a significant milestone in the maturity of the SynCardia and the CardioWest TAH. The Centers for Medicare and Medicaid (CMS) granted a record level of reimbursement to the SynCardia TAH and declared, "The TAH fills a role that no other mechanical circulatory support device can for patients in irreversible biventricular failure."

Reimbursement in the amount of DRG 1 (up to $292,000) was available, plus a new technology add-on payment of $53,000, for a total of up to $345,000. The payment would be awarded if the patient was discharged, and an additional payment of up to $292,000 would be awarded at the time of transplant, replacing the artificial heart with a donor heart. The reimbursement amounts to as much as $637,000 paid to the Hospital for each patient discharged and re-admitted for transplant. If the patient was implanted and transplanted without discharge from the hospital until after the transplant of the donor heart, then the maximum reimbursement would be $345,000.

The BTT results produced by the SynCardia TAH must have compelled CMS to provide the reimbursement award. The reimbursement award is made powerful by discharge and ultimately a destination label.
B. Replacement Driver(s)

At the moment of CMS approval, the discharge driver became even more important for hospitals and patients. CMS had realized the value of the TAH in reducing the cost of end stage heart failure (biventricular failure). Patients quickly recovered after receiving a TAH and, if discharged to home, the cost of patient care would be substantially reduced.

Now, after more than $15 million and 44 months of development, the Companion Driver is released in Europe and was submitted September 9 of 2009 to the FDA as a supplement to the SynCardia TAH PMA.

The elegant Companion driver will replace the limited supply of “Big Blue” drivers and, when undocked from the Hospital Cart and mobilized on a Caddy, will become each patient’s “Companion” within the Hospital.

Simultaneously and since August of 2007, the company has been working on a truly portable driver. The 12.5-pound Freedom driver planned for introduction immediately following the Companion. The Freedom was submitted to the FDA and CE in the first quarter of 2010. At just 12.5 pounds, the Freedom driver is a “lifestyle” driver that provides individuals with a wide range of lifestyle options. Someday the TAH, driven by the Freedom, may be as common as an artificial hip or knee.
By March of 2012 SynCardia will serve 100 transplant centers worldwide. SynCardia has been held back in meeting demand until the new driver family was complete and released.

Until the launch of the new driver family, the 19 centers implanting the TAH were required to share the limited population of Big Blue drivers, shipped from one transplant center to another as urgent requests for drivers bombarded the SynCardia dispatch team. During 2009, SynCardia will invest $680,000 in Federal Express shipping charges moving the 450 pound Big Blue (as big as a commercial washing machine) from one transplant center to another, just in time for an implant of the CardioWest TAH. A number of potential patients have died because of the lack of available drivers to power the TAH.
Summary and update to Drivers: As alternative drivers were designed and tested by SynCardia. The effort led to the Companion and Freedom series. The Companion became the replacement to the “Big Blue” driver. First released in 2009 to Europe as the Companion 1, a follow-on Companion 2 was developed, tested and approved in Europe the second quarter of 2011 and FDA approval is expected first Quarter of 2012.

The Freedom 1 driver was designed and tested in 2008 and 2009. The Freedom now fully approved in Europe and in FDA trial in the US allows patients to leave the hospital and live a more normal life and enjoy the normal course of life. Full PMA supplement approval for the Freedom Driver/TAH system is expected in 2012.

The Freedom2 has been designed and built and will enter reliability testing in 2012. This driver will have a service interval of 2 years instead of 90 days and cost the same to build as the Freedom 1; just $5,000. Each time a Freedom 1 is serviced the cost is another $5,000. Over the course of two years a Freedom 1 may cost a total of $40,000 while the Freedom 2 will cost only $5,000.

This single category of cost savings may improve the SynCardia contribution to profit and overhead as much as, 3,000 basis points.

Summary and update to the SynCardia TAH known as the TAH2
The FDA granted the CardioWest (SynCardia) TAH a full PMA approval on October 15, 2004. This signal event would normally have been the inflection point to ignite availability of the SynCardia CardioWest TAH worldwide. This did not happen because the world distribution opportunity and value of SynCardia was suppressed by the many remaining milestones.

As drivers evolved and the Freedom driver opened up the opportunity for a patient to live away from the hospital supported by the small portable driver the demand surfaced for an
additional indication. The SynCardia TAH was approved by the FDA as a “bridge to transplant for patients suffering from irreversible biventricular failure who were at imminent risk of death”. Patients began to surface that were not transplant eligible and the waiting time on the TAH for a human heart (donor heart) replacement grew from 90 days in Germany to nearly 2 years.

The change in donor heart availability along with the need for the TAH to support patients for the remainder of their life lead to a new submission to the FDA. Europe makes no distinction between bridge patients and destination patients but the FDA does.

In August of 2011 a request was made of the FDA to allow the SynCardia 70 CC TAH the label of destination - the last heart an individual may enjoy. SynCardia expects approval of the TAH as a destination device by Q 1 of 2012.

SynCardia is also beginning the manufacture of the 50 CC designed for pediatric use. The new 50 CC will also fit in individuals with a smaller frame such as women and smaller men. SynCardia expects approval of the 50 CC for pediatric use by mid 2102 and further expects the pediatric approval to lead to approval for the BTT and Destination use of the 50 CC.

C. Summary and update to Sales: Michael Garippa (former CEO of Tandem Heart) joined SynCardia in July of 2010 as President. He was appointed to the position of CEO and President in May of 2011 and also appointed to the SynCardia Board of Directors. The combination of the Freedom/Companion driver family and the sales, customer management and leadership skills of Michael will drive SynCardia forward.

IV. Market Consolidation
Circumstances have changed since 2003, and the consolidation of the mechanical circulatory support market has moved quickly. Flawed products and errors in company strategy have been amplified by the current worldwide economic slowdown and credit crisis. The investors of today are seeking real returns rather than euphoric promises that may come true in the distant future.

SynCardia and MicroMed continue to educate investors and analysts on the distinction between ventricular support by a ventricular assist device (VAD for left, right or both) vs. biventricular replacement (total replacement of ventricles with the artificial heart). Thoratec and HeartWare have drawn attention to the LVAD space as it is becoming white hot. SynCardia and MicroMed continue to reassure investors that the SynCardia TAH is the only artificial heart and the unique features of the MicroMed HeartAssist5 set it apart from all other LVADs. Recent articles and opinions similar to the one below by Timothy Lutts incorrectly refer to LVADs as artificial hearts.

LVADs are “booster pumps,” used to support a native heart in decline, often with very little success. The mid-2008 Thoratec HeartMate II PMA approval was for the indication
of bridge to transplant. The article below indicates that the Thoratec LVAD is awaiting an FDA approval for destination therapy for patients who do not qualify for a transplant.

“Apple's (the Stock) Best Days May be Behind It - Try Thoratec Instead

by: Timothy Lutts January 13, 2009 | about stocks: AAPL / THOR

It's Thoratec (THOR), and it was last mentioned here on December 11, when it was trading at 28. Today it's just a little higher, so it hasn't gotten away. But the stock's main trend is up, and thus the odds are very good that the stock will break out above its recent high of 33 before long (as long as the market cooperates).

The company's business is artificial hearts (see above – their business is not artificial hearts) and heart pumps, a business where demand is driven by unstoppable demographic forces. The stock was featured in Cabot Top Ten Report on December 22, and here's some of what editor Michael Cintolo wrote:

‘For heart patients awaiting transplants, Thoratec's HeartMate ventricular assist pumps are a literal lifesaver, helping one chamber of the heart pump enough blood until a donor is found. The big buzz now is that patients too ill for transplants have a significantly higher chance of long-term survival (without suffering damaging strokes) when they use Thoratec's HeartMate II rather than the older HeartMate XVE. The company is waiting for FDA approval for this new usage, and investors are anticipating that it will be received. In the meantime, Thoratec has replaced Dun & Bradstreet in the S&P MidCap 400 Index and UBS has picked up coverage of its stock. Everything seems to be breaking Thoratec's way.’”

The market for an assist pump (LVAD) to support a failing left ventricle has been declared to be enormous by the influential analysts who cover the mechanical circulatory support space. Their optimism has been fueled by the recent success of the Thoratec HeartMate II LVAD (not an artificial heart).

- Bob Hopkins-Bank of America - October 27, 2008

— “The market is at least 15,000 to 20,000 units per year and only 2,000 were implanted in 2007....”
Greg Simpson-Stifel Nicolaus - November 13, 2008

“....one of the next multibillion markets within medical devices over the next several years.”

Jason Mills-Canaccord Adams - August 1, 2008

“The patient population is still extremely under-penetrated: market opportunity exceeds 25,000 patients or $2.5B in the US in our estimation....”

Mimi Pham – JMP Securities – March 17, 2009

- “The key downside risk for Thoratec shares, in our view include: ........
  2) larger-than-anticipated decline in PVAD/IVAD sales (for short and medium (biventricular support)

Of the nearly 1,000,000 annual deaths attributed to heart disease, it is estimated that 100,000 deaths result from biventricular failure (a subset of heart disease).

SynCardia’s TAH replaces the failing human ventricles and is more likely to successfully bridge a patient to transplant than any other alternative. Again to quote CMS: “The TAH fills a role that no other mechanical circulatory support device can for patients in irreversible biventricular failure.”

Empirical data published on December 1, 2008 by a group of European transplant surgeons and, in a second report by a group of US transplant surgeons revealed:

- **Europe:** “Right ventricular (RV) dysfunction develops in 20% to 50% of patients after LVAD implantation (biventricular failure), leading to prolonged ICU stay and elevated mortality.”

- **USA:** “Despite increasing experience, right ventricular (RV) failure occurs in 20% to 30% of the LVAD recipients (biventricular failure).”

Apply a 20% failure rate to the market that analysts estimate to be 25,000 LVADs annually, and the TAH would be the only available option for the 5,000 patients whose LVAD implants revealed right heart failure.

It has been estimated that biventricular failure, a subset of heart failure, represents 100,000 deaths per year. With another 5,000 deaths from LVAD-revealed right heart failure, the total is staggering. Most find it astonishing that the SynCardia TAH was implanted just 80 times in 2008. The SynCardia TAH is the only device for biventricular replacement, and less than one tenth of one percent of the US latent market was satisfied by SynCardia in 2008.
The mechanical circulatory support market is divided into three segments:

1. Bridge to Decision (Balloon pumps and the Impella);
2. Left Ventricular Assist (LVAD); and
3. Biventricular Failure (BiVADs and the TAH).

Figure 1 – Report by US Transplant Surgeons

Figure 2 – Mechanical Circulatory Support Market
### Mechanical Circulatory Support - $4B USA

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- 3 of 27 remain
- If Terumo and World Heart are Excluded
Segment 1. Bridge to Decision (Balloon Pumps and the Impella) and more

a. DataScope - Purchased by Getinge

Forbes September 16, 2008: “Datascope's businesses meaningfully expand Getinge's cardiovascular business worldwide, reinforcing the company's focus on both cardiac surgery and vascular interventions. The Swedish company said it saw 'significant synergies' from the acquisition which it expected to contribute to group earnings per share, after amortization and financing costs related to the deal, starting in 2010.”

b. Arrow International - Purchased by Teleflex

October 3, 2007 Research Triangle Park, NC —“Teleflex Medical announced today the completion of the acquisition of Arrow International, a leading global provider of catheter-based access and therapeutic products for critical and cardiac care. With this transaction, Teleflex Medical becomes a $1.4 billion medical technology business with a leading position in disposable products for critical care and surgical applications. The combined company has more than 11,000 employees worldwide and operations in more than 20 countries.”

c. Impella: Purchased by Abiomed

April 27, 2005 – “ABIOMED, Inc. a manufacturer of products for circulatory care and support, announced that it has entered into a definitive agreement to acquire Impella CardioSystems AG, a privately held, venture-backed company affiliated with Accelerated Technologies, Inc. (ATI) and located in Aachen, Germany. Impella manufactures and commercializes the world's smallest, minimally invasive, high performance micro blood pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. These circulatory assist devices are used by cardiologists in the catheterization (cath) lab and are inserted percutaneously into patients, similar to a standard balloon pump (DataScope and Arrow) procedure, in order to help restore blood flow. Impella has CE marks for each of its devices and currently markets them throughout Europe and markets in the USA as a 510K product (others provide the same function)

Abiomed has been very successful with the Impella with annualized sales reaching to $100,000,000 as of 2011.
Abiomed was founded on biventricular support with the Abiomed BVS 5000 system and the Abiocor TAH. The BVS 5000 and its successor the AB 5000 once represented $35,000,000 in sales to Abiomed. The Abiocor TAH has only been implanted 15 times with the last implant in 2006. The Abiocor was not reliable and much too large.

By 2011 the biventricular support (AB 5000) has declined to represent just $2,500,000 or under 3% of the Abiomed sales.

d. **Maquet Cardiopulmonary (division of Getinge)** Data Scope is part of this group and was purchased by Getinge

Maquet GmbH, a subsidiary of Getinge is building a suite of bridge to decision products. LVADs often reveal and less often contribute to right heart failure. The Maquet ECMO system is targeted at this emerging need. Until the ECMO AND LIFE SUPPORT SYSTEMS QUADROX PLS AND ROTAFLOW RF, ECMO was made up of one companies oxygenator and another companies centrifugal pump. An all in one system including a driver and disposable pump and oxygenator is available from Maquet. ECMO is rapidly becoming popular in support a weak right heart.

e. **TandemHeart**: CardiacAssist, Inc., Pittsburgh

The TandemHeart PTVA System is comprised of three sub-systems. Its purpose to help heart failure patients survive heart attacks, high-risk procedures and other cardiac interventions without undergoing major surgery. The TandemHeart is frequently deployed to support right heart weakness induced or revealed by the implantation of an LVAD. This company was operated by Michael Garippa for the years 2003 through May of 2010. It competed head to head with the Abiocor Impella until the benefits of the Impella trumped the aged and antiquated deployment system of the Tandem Heart. The Tandem Heart has declined in anualized volume of $13,000,000 to under $10,000,000.

1. The TandemHeart System Pump provides the circulating power to pull oxygenated blood from the left atrium and to return it to the systemic arterial circulation.

2. By way of two percutaneous access points in the patient's groin, the TandemHeart Cannula Family connects the pump to the body.

3. The TandemHeart PTVA System Controller provides operating power to the pump, provides a controlled flow of lubricant to the pump, and also
provides automatic system monitoring and alarms indicating conditions that require attention.

**f. Levitronix CentraMag, Inc., Pittsburgh**

The Levitronix CentriMag is a continuous-flow, centrifugal-type rotary blood pump that is placed outside the body (extracorporeally). The pump housing and rotor are made of medical-grade polycarbonate and designed for single-use. The pump is often used in conjunction with an oxygenator. The pump is distributed by Thoratec for the primary purpose of temporary treatment of right heart failure or weakness revealed or caused by a HeartMate II implant.

In the United States, the Levitronix CentriMag LVAS is used as a short-term device that would provide circulatory support of up to 14 days for patients with postcardiotomy cardiogenic shock (those who have developed heart failure as a result of heart surgery).

Levitronix is also developing a small, lightweight, Extracorporeal Long-Term Blood Pump based on our bearingless motor technology. The device is fabricated from titanium, and is designed to provide circulatory support for pediatric to adult-sized patients. This pump is being manufactured for Thoratec as a competitor to the HeartWare HVAD. It was believed by Thoratec as a result of the HeartWare success that the centrifugal pump may have benefits over an axial pump. Field results are proving otherwise and the axial flow pump is superior to a centrifugal pump.

**Segment 2. LVAD**

The greatest consolidation has occurred in the LVAD space. Many companies and or products dedicated to the space at the beginning of 2000 have dropped out.


“The Arrow LionHeart™ LVAS provided a pulsatile supplement to the patient’s natural cardiac activity, as compared to several other heart-assist devices, which provided relatively pulseless support or natural pulse over continuous flow.
LionHeart™ LVAS used a transcutaneous energy transfer system to charge internal batteries and power the blood pump. Internal batteries allowed the patient to "de-couple" from all external components of the system, allowing "tether free" mobility for a specified amount of time.

The main distinction between the Arrow LionHeart™ LVAD and other heart assist devices is that the Arrow LionHeart™ operated with no lines or cables protruding through the patient’s skin. This feature eliminated a source of potentially life-threatening infections. By operating with no lines or cables protruding through the patient’s skin, Arrow LionHeart™ recipients could de-couple their external power sources for periods of time, allowing them to engage in normal activities, such as taking showers and baths, without requiring special preparations for the device.”

In January of 2005, Arrow announced that the CorAide LVAD belonged to a new generation of magnetically suspended pumps. Arrow explained that the CorAide was completely insusceptible to wear and tear, and consumed little energy. Unlike other LVADs the CorAide adjusted to the blood requirements of the patient and when activity increased, the rotor increased its number of revolutions and the system ejected more blood into the circulatory system.

Many adverse events occurred during the months and years that followed. Most of the implants of the CorAide occurred in Germany. Coincident with the sale of Arrow International to Teleflex, the CorAide was returned to the Cleveland Clinic. The CorAide had been licensed to Arrow by the Cleveland Clinic.

b. World Heart (WHRT NASDAQ) enjoyed a market value of over $500,000,000 in 2004. By February of 2009, after many changes in direction and ownership structure, the company had both raised an additional $100MM and declined in value by $560MM. May 2009 and controlled by Abiomed and Venrock, the company had declined in value to just $33.1MM (the sum of the Venrock and Abiomed investment of $30MM and $3.1MM).

The syndicate that include Venrock invested an additional $29MM in WorldHeart in 2010. WHRT was delisted August of 2011.
WorldHeart's roots in heart-assist device technologies go back over 35 years. In 1969, scientists in Berkeley, California began developing a Left Ventricular Assist System (LVAS), based on a pulsed-solenoid driver concept. Development was initially funded by research contracts from the U.S. National Institutes for Health (NIH). By 1977, the world's first integrated electrical LVAS had been designed. With additional venture capital funding, the system was refined and qualified for clinical use.

In 1984, the Novacor® LVAS was used in the world's first successful Bridge-to-Transplant (BTT) operation. In 1988, Novacor Medical Corporation was acquired by Baxter Healthcare Corporation. With Baxter's support, the product was enhanced, and clinical use spread outside of North America. In 1994, the Novacor® LVAS received regulatory approval for European commercialization (CE Mark) for use as both a bridge to transplant and as a long-term alternative to medical therapy (destination therapy). In 1998, the Novacor® LVAS received FDA approval for U.S. sales as a bridge-to-transplant system for use inside and outside the hospital.

In 2000, shortly after Baxter's cardiovascular products division was spun off to Edwards Life Sciences, LLC, the Novacor Division was acquired by WorldHeart Corporation (WorldHeart). WorldHeart was established in 1996 to develop the HeartSaverVAD™ technologies originated by the Cardiovascular Devices Division (CVD) of the University of Ottawa Heart Institute (OHI). OHI is one of Canada's leading cardiac centers, and is an international center of excellence for
the diagnosis, treatment, rehabilitation from and prevention of heart disease through patient care, research and education.

The technologies embodied in the Novacor® LVAS and the HeartSaverVAD™ are now being amalgamated in the development of the Novacor II LVAS. This effort is being led by members of the original Novacor® LVAS development team, with 200 collective years of LVAS design experience. The Novacor II LVAS will maintain the current device's unparalleled reliability and durability, while providing a system that is smaller, totally implantable and more economical.

In 2005, WorldHeart acquired the assets of MedQuest Products, Inc. (Salt Lake City, Utah), adding a rotary pump to the WorldHeart VAD platform. The acquisition broadens the WorldHeart product offering and helps to make real the promise of destination therapy as a widely adopted treatment.

In 2006, the first human implant of the Levacor VAD was performed by the surgical team at St. Luke's Hospital, Tessaloniki, Greece. The implant marked the start of a feasibility clinical trial. In 2008, WorldHeart submitted an IDE application to FDA to begin a clinical study of the Levacor in the US. The trial was eventually approved and Bridge to Transplant trial began in early 2009. Numerous complications with magnetic levitation and driver caused the trial to be discontinued by WHRT early 2011. The company has little cash remaining and no product. They are public and may have some value as to a combination with another company in the MCS space.
c. **Ventricor** (VCR: Australian Stock Exchange) did market the VentrAssist LVAD. Ventracor enjoyed a market value of $540MM (Aus) in 2004. The company has steadily declined in value to the point of complete liquidation by August of 2009.

Ventracor’s heart gives out

Ventracor in voluntary administration after failing to secure funds

**Kate McDonald (Australian Life Scientist)** March 19, 2009

“Ventricor is the first small cap biotech to fall victim to the venture capital drought, placing itself into voluntary administration today after failing to secure money to keep it a going concern.

**Ventricor has been on the critical list for some time, with a product safety recall issued in February, just after calling a halt to trading. It voluntarily suspended from quotation on February 10.**

**Despite actual revenue from sales and achieving a key milestone in completing patient recruitment for its bridge-to-transplant clinical trial in the US, the company said in a statement today it was unable to raise enough capital or find a buyer. It said it preferred that an administrator be appointed now before the company became insolvent.**

**The writing was on the wall for the company for some time, with major staff turnover issues affecting confidence in the last two years. The company still hopes that its VentrAssist left ventricular assist device will be successfully commercialised at some stage.”**

For an update see [http://www.saveventracor.com/](http://www.saveventracor.com/). Ventracor began official liquidation on July 10, 2009 and all of the assets will be sold to the highest bidder including desks, chairs and office supplies and IP…………………………………
d. Berlin Heart GmbH, MEDOS Medizintechnik GmbH and TERUMO MEDICAL CORPORATION, Sunshine Heart have all but dropped out of the race. Berlin Heart has not been able to manufacture drivers to power their adult and pediatric BiVADs. The EXCOR BiVAD is rapidly declining in popularity. The INCOR LVAD is very large and implants below the diaphragm. Berlin Heart was sold in 2009 and has declined to a shadow by 2011. The INCOR has been trumped by the HeartMate2, HVAD and the HeartAssist5. The Excor by the SynCardia TAH.

e. MEDOS has discontinued the effort to manufacture the HD8 as a replacement for their scarce and antiquated BiVAD driver. MEDOS is instead determined to concentrate on their popular oxygenator, known as the HILITE.
f. **Jarvik 2000 – Size matters and speed kills.** While the Jarvik 2000 is elegant in appearance and small in size it does not provide adequate output to produce lifestyle blood flow. Capable of a supplemental flow of 2 to 3 LPM when supporting a native ventricle that is moderately productive. If more flow is required the Jarvik must be operated at blood damaging speed of 18,000 rpm and speed kills.

Dr. Robert Jarvik developed this pump after his experience with the Jarvik 100 and 70 TAH. The concept remains contemporary but the miniaturization has gone too far (too small).

g. **Terumo** and the DuraHeart have met with very little acceptance since the approval of a bridge to transplant trial for the DuraHeart by the FDA. The DuraHeart is very large, approaching the size of the older Novacor and HeartMate I and Heart Mate XVE LVADs. This pump will not gain traction. Terumo is determined to introduce a new and smaller LVAD by 2015.
h.  **Sunshine Heart Inc.** (SHC: Australian Stock Exchange) is currently pursuing venture capital, institutional investor awareness, M&A advisors, and strategic/corporate partners. For the reporting year just ended, Sunshine Heart lost $11.6MM (Aus). Sunshine currently has a market value of $16.1MM (AUS) and in US $ just 10.7MM.

The implantable Sunshine Heart C-Pulse is a pliable, inflatable cuff that is wrapped around the patient's ascending aorta before the sensing lead is attached to the heart. It resembles a balloon pump that is around the aorta rather than within the aorta. It is designed to increase coronary blood flow and improve patient quality of life, as well as to provide immediate and sustained symptom relief.

Through the use of counterpulsation technology, C-Pulse is designed to increase cardiac output while reducing the heart's workload for ventricular loading. The less invasive non-blood contacting features of the device make the C-Pulse unique, as it augments the heart's function while reducing risks such as bleeding and stroke. The device can be turned off and detached safely. In failure modes, C-Pulse is considered to have an associated low risk of death or disability.

C-Pulse is uniquely positioned to fulfill the unmet clinical need between CRT Pacemakers and end stage therapies, a market worth over $1 billion annually. The simple, safe, straightforward and cost-effective implant procedure carries long-term measurable benefits to the growing number of patients with moderate to severe heart failure that is refractory to drugs.

Sunshine Heart announced in September 2008 that it had received an Investigational Device Exemption (IDE) from the FDA to begin its first clinical feasibility trial for the C-Pulse device, involving 20 patients in six university.
medical centers across the United States. Additionally, Sunshine Heart became listed on the Australian Stock Exchange in September 2004 and has a growing presence in Australia, New Zealand and the United States of America. The company has scheduled its first implant for January 2009.

i. **Thoratec Corporation** (THOR: NASDAQ) is firmly in the lead with HeartMate II due to their recent FDA PMA. The HeartMate II is a second functional generation device and its success demonstrates the power of an FDA-approved PMA.

“By Kurt Heine

Aug. 1 (Bloomberg) -- Thoratec Corp., the maker of a small mechanical heart, gained the most in a decade in NASDAQ trading after the company raised its 2008 earnings forecast on sales of the new device.

Thoratec, based in Pleasanton, California, raised $3.75, or 20 percent, to $22.51 in composite trading at 11:14 a.m. EST. Earlier, the shares rose 27 percent, the most since Oct. 12, 1998.

The company's HeartMate II, smaller than a D-cell battery, was approved for U.S. sale in April for heart patients awaiting a transplant. Profit in the Second Quarter rose almost six-fold to $8.65 million, or 15 cents a share, from $1.25 million, or 2 cents a share, a year earlier, the company said in a statement after U.S. markets closed yesterday. Thoratec raised its 2008 adjusted profit forecast to 47 cents to 52 cents a share and said revenue would be $285 million to $295 million.

“The key contributor to this growth was our successful launch of the HeartMate II,” said Chief Executive Officer Gary F. Burbach, in the company's statement. He said patients and doctors accepted the pump faster than the company expected and insurance company reimbursements had “improved.”

And only seven trading days later, Thoratec had risen in market cap to over $1.25 billion – nearly a 50% increase in just a few days. The market has confirmed that the cardiac assist space is a worthy place to invest.

Thoratec subsequently reported two additional consecutive quarters and has traded to an all time high of $33.00 and a market cap of $1.8B prior to retreating to a market value of $1.4B. After the Q2 of 2008 record breaking results Jason Mills of Cannacord Adams reported:
Life Sciences -- Biomedical Devices and Services

PARADIGM CHANGING Q2 RESULTS

Event - THOR Q2/08 results crushed expectations; raised 2008 guidance more than Q2 upside, driven by successful launch of HM-II.

Action - Buy on strength. Increase 12-month target to $26 from $22.

Paradigm-changing Q2 results. After-hours trading suggests the stock could be up 20%+ after reporting blowout Q2/08 results: revenue/EPS of $83M/$0.20 crushed us/consensus (CA: $65M/$0.09; FC: $64M/$0.09).

Seven reasons we recommend buying THOR even on strength.

1) Utilization: VAD utilization trends accelerated (upside NOT just new center adds). 2) Huge/homogenous patient population: Consistent with our thesis, Q2 offers strong evidence HM-II is expanding the purview of the ETT indication (i.e. ESHF pt-pop homogenous, DT approval less pertinent). 3) Reimbursement: CMS released final F2009 DRGs last night: LVAD DRG payment $131K (+5.4% Y/Y) and above proposed $129K. 4) Customer base has increased ten-fold: THOR added 26 new HM-II centers (12 estimate) bringing total to 66, yet still >50 transplant and 1,000 open-heart potential customers. 5) Leverage: Q2 gross/operating margins of 62%/16% dusting our estimates of 58%/3%, showing leverage capacity of the model as HM-II kicks in. 6) Upside potential still exists: THOR increased 2008 sales guidance to $285-295M from $255-265M, albeit we still found it difficult to stay within this range given the significant change in the fundamentals via HM-II uptake in Q2. 7) Take-out target: Significant call-point synergies with one of the “Big 3” TCD players.

Unprecedented start to HM-II launch. 26 new HM-II centers, each of which stocked two units each, only partially explains 154-unit upside in Q2 VAD units sold (599 vs. 445 estimate). Procedure volume acceleration (i.e. utilization) at both existing/new centers was the real story. Strong new center adds and strong utilization are both sustainable, in our view.
Levitronix is developing a long-term implantable centrifugal LVAD (HeartMate® III) in collaboration with Thoratec Corporation (www.thoratec.com). Similar to the Levitronix CentriMag® extracorporeal blood pump, Thoratec HeartMate® III System is based on bearingless motor technology that combines drive, magnetic bearing, and pump rotor functions into a single unit.

The HeartMate® III is fabricated out of titanium and all of the blood-contacting surfaces are created using a unique textured surface. The resultant textured surface is reported to promote the formation of a thin layer of compact fibrin and collagen. Over time it is believed that this surface will evolve into a pseudoneointima lining much like the inner surface of natural blood vessels.
Segment 3.  Biventricular Failure

Until 201, Thoratec is the leading supplier of biventricular support systems to the world. Two systems continue to be available: the IVAD and the PVAD.

The IVAD (Implantable Ventricular Assist Device) is the only implantable and BiVAD indicated for post-cardiotomy recovery and bridge to transplantation inside and outside the hospital. The IVAD has been used in more than 500 patients worldwide who require intermediate-to-chronic circulatory support.

With more than 20 years of clinical use, the Thoratec PVAD (Paracorporeal Ventricular Assist Device) provides acute-to-intermediate support in patients of virtually any size from child to adult. The PVAD has been proven in more than 240 centers and 4,000 patients worldwide.

It is important to point out that the safety and effectiveness of Thoratec PVADs in the pediatric population has not been established. Thoratec does not manufacture either an IVAD or PVAD for infants and small children. Only Berlin Heart GmbH and MEDOS Medizintechnik GmbH have supplied small 10 to 30cc pediatric PVADS.

j. MEDOS has all but abandoned the PVAD market because of the cost and time to design, build and seek approval of a modern pneumatic driver. MEDOS manufactures PVADs in 6 sizes and in the past has aggressively marketed them throughout Europe.

The IKUS pneumatic driver is designed for the stationary use of the Berlin Heart EXCOR® and EXCOR® Pediatric blood pumps. While operating in biventricular mode, both blood pumps can be controlled separately.

The pneumatic system of the driver is constructed so that in case of malfunction, it automatically switches to the redundant system without interruption. In case of a breakdown of the supply voltage, the installed charging unit takes over the power supply. Acoustic and visible warning signals on the monitor inform the user of the current condition of the system.
The Berlin Heart PVAD is needed by pediatric transplant centers throughout the world. The IKUS driver is rumored to cost in excess of $200,000 to manufacture. The private ownership of Berlin Heart GmbH has not made a public statement regarding their unwillingness to build more IKUS drivers. It is only speculation that the owners have other uses for their capital in the modern economy.

The **SynCardia Companion** driver will drive the **SynCardia 10cc pediatric VAD**, which is under development and now in advanced animal testing. It is expected that by the summer of 2012 adult/pediatric and stand-alone pediatric heart centers served by SynCardia will enjoy the benefit of the Companion Driver and the lifesaving 10cc pump. SynCardia will seek approval from the FDA under a Humanitarian Device Exemption Q1 of 2010.
k. Abiomed – until recently Abiomed has been Paralyzed with Possibilities

**Abiomed Inc.** (ABMD-NASDAQ) The AB5000™ Circulatory Support System and the BVS® 5000 Biventricular Support System provides temporary support for one or both sides of the natural heart in circumstances *where the heart has failed but has the potential to recover. Abiomed promotes recovery of the Human Heart.*

The BVS 5000 is the most widely used advanced cardiac assist system in the world, installed in more than 700 leading medical centers worldwide. The AB5000 is Abiomed's advanced technology offering, approved by the FDA in 2003. It is designed to provide improved patient mobility, comfort and ease of use and can be used either in the hospital or for transport of patients between hospitals.

Abiomed experiences difficulty staying the course and has been diverted with multiple products and market penetration strategies. It has been said that Abiomed is paralyzed with possibilities. The capital structure of Abiomed and the unforgiving capital markets of the new economy have called into question the survivability of Abiomed. From 2005 to 2010 their sales and margins are not adequate to support their fixed and variable cost, and Abiomed has required $30MM per year in new capital to remain viable.

Abiomed's key to growth has been the Impella 2.5, and successive quarters since 2008 have produced a steep decline in legacy products. Hospital capital budgets have been constrained by the new economy, and hospital capital budgets may have played a part in delaying console sales. Given the Abiomed's dependence on disposable pump sales, it is not completely apparent that weaker hospital spending on capital equipment was the sole reason for the shortfall. On a positive note, Abiomed produced sales of $25MM in Quarter 3 of 2011 and produced positive cash flow. Abiomed may not need additional financing anytime soon and seems to be progressing toward earning a substantial profit. The Impella in combination with a superior LVAD and a working TAH may move Abiomed into the dominate player in the MCS space.

Abiomed does not have an LVAD in its portfolio. It invested in WorldHeart. Regardless, the World Heart LVAD was way behind developmentally, with only two implants having been performed by early 2009 and Abiomed sold their investment ($5MM) in mid 2009.
Size Matters – And It’s Better to be Up than Down - Small and Within the Pericardial Space

HeartWare International Inc. (HIN: Australian Stock Exchange) and MicroMed Cardiovascular are ABOVE THE DIAPHRAGM in the pericardial space.

1. The HeartWare Left Ventricular Assist System is a small implantable centrifugal blood pump called the HVAD. The pump is designed to draw blood from the apex of the left ventricle and to propel it through an outflow graft connected to the patient's ascending aorta. Provided that a patient’s natural right ventricle can make up flow to the assisted left ventricle, the HVAD is claimed to be capable of generating up to 10 liters per minute of blood flow.

The HVAD weighs 145 grams and is designed to be implanted in the pericardial space, directly adjacent to the heart. Implantation above the diaphragm is expected to lead to relatively short surgery time and relatively quick recovery.

The Valuation of HeartWare Holds up - - ASX ANNOUNCEMENT
17 August 2009
HeartWare International, Inc.

Announces US$60 Million Financing Closing

FRAMINGHAM, Mass., and SYDNEY, Aug. 17 /PRNewswire-FirstCall/ -- HeartWare International, Inc. (Nasdaq: HTWR) (ASX: HIN) announced today the completion of its offering of approximately 2.7 million shares of its common stock in a private placement in the United States and Australia (the "Offerings"). Investors in the Offerings purchased the shares at a purchase price of US$22.00 per share resulting in gross proceeds of approximately US$60 million to HeartWare, before deducting the placement agent's fee and estimated offering expenses.

The issuance of approximately 1.39 million of the total number of shares that investors have committed to purchase in the Offerings is subject to approval of HeartWare’s stockholders in accordance with Australian Securities Exchange Listing Rules and Nasdaq Stock Market Rules and, as a result, approximately US$30.5 million of the proceeds Offerings will be held in escrow and will be released if and when stockholder approval is obtained. The meeting of the stockholders was held in December 15, 2009. The raise was approved.
Early 2010 HeartWare raised $139MM USD to shore up their war chest. HTWR is now producing annualized volume of $100MM with an annualized loss of $42MM.

Their US clinical trial of the HVAD as a Bridge to Transplant has produced results of 94% transplanted or alive after 180 days. The results have however displayed thrombus occurring 9.3% and extensive anticoagulation measures are required.
Thoratec must move above the diaphragm and into the pericardial space. Their future depends on moving up. Thoratec announced its intention to purchase HeartWare on Friday February 13, 2009. Thoratec has indicated that the purchase is intended to close in Q2 2009. Thoratec intended to purchase HeartWare to avoid the long development cycle of the HeartMate III and move into the pericardial space with the HeartWare HVAD. The FTC had other ideas and on July 30, 2009, filed a formal objection to block the merger.

Thoratec has continued to prosper and gain sales growth.

m. MicroMed Cardiovascular (Private)

MicroMed Cardiovascular, Inc. (MMCV) is a pioneer in the accelerating field of mechanical circulatory support. The DeBakey Heart Assist 5 LVAD is the smallest of all LVADS, weighing just 92 grams. The DeBakey Heart Assist 5 LVAD includes as part of its CE approved and FDA approved (pediatric) design a very accurate flow measurement sensor. Accurate flow sensing is not available on any other LVAD. Flow sensing assists in preventing right heart failure common with many LVADS.

The DeBakey VAD and its related technology were developed in an exclusive partnership with NASA. In 1998 the DeBakey VAD became the first device of its
kind to be used in humans. Since then it has been implanted over 449 times. This is exceeded only by Thoratec’s HeartMate II.

In April of 2007, MicroMed had a market cap of approximately $175MM US. Because of the convergence of several unanticipated circumstances, a “perfect storm” hit MicroMed and its stock fell to a market cap of $50MM over a period of three months.

In the calm before the storm, MicroMed had completed the important redesign of two components of its Generation 3 DeBakey VAD that could further propel it ahead of its competition. MicroMed was relying on its major (67%) shareholder, Absolute Capital Management (“Absolute” - a hedge fund owning stocks and bonds), to support the roll out of its fully approved Generation 3 DeBakey VAD in Europe and the expansion of its FDA trials in the United States. In early 2007 Absolute began to ignore the funding requests of MicroMed.

As the sub prime debacle gained momentum, giving rise to capital scarcity and the new economy, hedge funds began to suffer. An internal dispute erupted within Absolute’s top management. The founder of Absolute resigned and wrote a self righteous and disclosing letter to Barron’s. Barron’s reported the situation and Absolute’s value immediately declined. The share price of Absolute plummeted 90% over a period of 4 weeks. The collapse in value of Absolute sealed the fate of MicroMed.

Absolute’s demise provided SynCardia with the opportunity to acquire MicroMed without having to pay the cumulative price of time or money - - over $106MM, according to the balance sheet of MicroMed published mid 2007.

Several SynCardia shareholders understood the powerful synergistic benefits of a future combination between MicroMed and SynCardia. A separate entity was formed to acquire MicroMed, retire all of its public shares and convert MicroMed from a public to a private company. SynCardia and MicroMed are separate companies with many common shareholders. The door has been left wide open to explore the topic of a future combination. In the meantime, both companies are committed to staying on track and accomplishing their own objectives.

MicroMed, along with the Texas Heart Institute, Rice University, and the University of Houston, are currently in collaboration on the development of a total artificial heart (TAH) through a $2.8 million federal grant from the National Institutes of Health.

The MicroMed TAH is proving to be a real contender. Recent animal(s) implanted with the MM TAH have proven to do well with this tiny replacement of the much larger Human Heart.

This important collaboration, made possible in part by the flow sensing device of the DeBakey Heart Assist 5 LVAD, may lead to the simultaneous use of two DeBakey pumps as an artificial heart. While
many years of development may be necessary to produce the physiologic response feedback loop to emulate the human heart, this LVAD has two important advantages now: flow monitoring, and it is the smallest of all LVAD devices – **Size does matter!**

The MicroMed HeartAssist5 has progressed during its final development (2009 to 2011) Changes to the pump and controller have produced features and corresponding benefit that are not available in the THOR and HTWR devices. Size matters and so does true flow measurement, remote monitoring and pulsatility. The HA5 passes the pressure of the native heart when contracting (pumping-systole) through the HA5 LVAD and into the human body thus preserving the pulse.

**V. Conclusions:**

**Conclusion 1 – Biventricular failure is the final common pathway to death.**

SynCardia is the only Total Artificial Heart. The SynCardia Heart is approved in USA, Canada, Europe and ANZ. Only 2,200 donor hearts are available each year in the United States. It estimated that 5,000 donor hearts are available worldwide. More than 100,000 people die of biventricular failure each in the USA.
As the number of patients on LVAD and BiVAD support increases, waiting times to transplant increase. The denominator remains constant (number of donor hearts), and the numerator continues to grow (patients on support listed for transplant). The waiting time grows and grows…the simple calculation of dividing the numerator by the denominator will determine average time required to wait for a donor heart.

The LVAD or BiVAD bridged patient must wait longer and longer for a donor heart as the patient’s heart, although supported, continues to decline. Supported or not, biventricular failure is the final common pathway to death.

**Conclusion 2 - Size Matters – And It’s Better to be Up than Down - Small and Within the Pericardial Space**

LVADS that must implant below the diaphragm will lose popularity and fail. LVADs of the 4th and 5th generation will survive.

When examining the product features or each LVAD it is apparent that five functional generations of LVADS exist:

1. Original large and cumbersome devices, such as the HeartMate I and Novacor
2. Axial flow pumps, such as the Thoratec HeartMate II and the Berlin Heart INCOR – smaller devices, yet requiring a pocket below the diaphragm and plumbing to the pericardial space
3. Centrifugal pumps, such as the DuraHeart, or the VentrAssist, are implanted below the diaphragm in a pocket and plumbed through the diaphragm into the pericardial space
4. Axial flow or centrifugal flow pumps, such as the HeartAssist5 by MicroMed and the HVAD by HeartWare, implanted within the pericardial space
5. Axial flow or centrifugal flow pumps with accurate flow measurement and implanted within the pericardial space, such as the HeartAssist 5
Figure 3 – The Five VAD Functional Generations
VI. Predictions

The Thoratec HeartMate II with the PMA approval of 2008 is assured success even though it is less feature rich than the HeartWare HVAD or the MicroMed DeBakey HeartAssist 5. Thoratec must move into the pericardial space with a next generation LVAD to insure long term viability. It would have been less expensive to acquire HeartWare HVAD than design, test and trial HeartMate® III. February 14 Thoratec and HeartWare agreed to merge:

“Thoratec (THOR) and HeartWare International announced that they have entered into a definitive merger agreement under which Thoratec will acquire HeartWare for a consideration currently valued at approximately US $282 million, of which approximately 50% will be paid in cash and approximately 50% will be paid in shares of Thoratec common stock.
Thoratec said it expects the transaction will be dilutive to earnings on both a GAAP and non-GAAP basis into 2011.

**UPDATE** - - MELBOURNE, Jul 30, 2009 (Asia Pulse via COMTEX) --

Shares in Australian company HeartWare International Inc (ASX:HIN) deflated after US authorities said they would challenge the proposed acquisition of the heart pump developer by US-based Thoratec Corporation.

"Thoratec and HeartWare International are disappointed with the FTC's (US Federal Trade Commission) decision to challenge the acquisition," HeartWare said in a statement on Thursday. "The companies intend to review the FTC's decision and mutually assess the appropriate next steps and promptly communicate their intentions to the market once a decision has been made." Shares in HeartWare fell 12 cents, or 15.58 per cent, to 65 cents on Thursday. In February, HeartWare announced it had entered into a merger agreement under which Thoratec would acquire HeartWare for US$282 million: about 50 per cent in cash and about 50 percent in Thoratec shares. Thoratec was also to provide HeartWare with a convertible loan facility of up to US$28 million to fund ongoing operations until the close of the transaction, which had been expected too occur in the second half of 2009. Thoratec, which is based in California, specializes in developing mechanical circulatory support for patients suffering heart failure.

Five months following the announcement of the HeartWare and Thoratec agreement to merge the FTC filed a formal objection to block the merger.

**HeartWare International Inc. and Thoratec Corp. End Deal**

**August 03, 2009**

by Joan Trombetti, Writer

Dotmed has learned that after strong opposition from the Federal Trade Commission (FTC), HeartWare International Inc. and Thoratec Corp. have ended their plans for $282 million merger. Saying it would substantially reduce competition in the United States Market for left ventricular devices, the FTC stated that Thoratec "already enjoys a monopoly on the sale of LVADs in the U.S. and would only increase its hegemony if the merger is consummated."

Thoratec of Pleasanton, CA and Heartware of Framingham, MA, make implantable heart pumps, which are miniature devices designed to take on the role of the left ventricle pumping blood throughout the body.

Both companies expressed disappointment by the decision and, although supportive of the squelched deal, decided that it was in the best interest of shareholders not to pursue "what would likely be a protracted, costly and unpredictable litigation process."


More information about HeartWare can be found at http://www.heartware.com.au.
Information about Thoratec can be found at http://www.thoratec.com/.

Both companies experience dramatic increase in value following the FTC decision and objection to the merger of THOR and HTWR.

World Heart traded in harmony with THOR and HTWR since the FTC objection to the merger of THOR and HTWR.
“Advanced heart failure is never a laughing matter, but investors in Thoratec (Nasdaq: THOR) had something to smile about after the therapeutic device maker reported second-quarter results late Wednesday. Although the company recently dropped its takeover bid for HeartWare International (Nasdaq: HTWR) in the face of a challenge from the FTC, strength in Thoratec's cardiovascular division drove solid revenue growth, and the company's shares responded by soaring 13% Thursday.

Heart pump sales helped increase overall revenue by 11% to $92 million. On a GAAP basis, though, earnings fell to $0.03 per diluted share, a 76% drop from the same quarter last year. That plunge largely owed to one-time costs of $7.4 million related to the cancelled HeartWare deal.

The heart of the matter
Given that mixed picture, why did the market so enthusiastically bid up Thoratec shares? Even looking at its non-GAAP results, which took the failed merger costs and other items, earnings per share still came in a penny below consensus estimates.

But the success of its cardiovascular division left investors hopeful for the future. The company raised guidance on full-year earnings and sales. So far, its HeartMate II devices have only been approved for use by potential heart-transplant patients, but that situation could be changing. By early 2010, management expects FDA approval to use the products for destination therapy patients, which would expand market share even further.

Sharks in the water
However, competition is fierce in the health-care industry, and heart-device makers are no exception. Numerous small companies such as Abiomed (Nasdaq: ABMD), as well as various divisions of big fish like Medtronic (NYSE: MDT) and Abbott Labs (NYSE: ABT), compete for Thoratec's sales.”

SynCardia is virtually the only company in the business of biventricular replacement. The SynCardia CardioWest enjoys full PMA and CE approval and a new fleet of modern hospital and discharge drivers that were released 2010. The follow-on Freedom2 and Companion2 will allow SynCardia to penetrate most all Transplant centers of choice and become the “Standard of Care” for biventricular replacement world-wide.

CMS reimbursement was awarded for the SynCardia CardioWest TAH-t as a DRG1 with a new technology add-on payment of $53,000 for a total of up to $345,000 if discharged with the TAH-t on a mobile or portable drive unit: Companion or Freedom. To repeat the
words of CMS: “The TAH fills a roll that no other mechanical circulatory support device can for patients in irreversible biventricular failure.”

SynCardia together with HeartWare or MicroMed present an opportunity to an acquirer to form a formidable foundation in the MCS space. Together in in the hands of a strategic buyer SynCardia and MicroMed or SynCardia and HeartWare form a category killer.

Thoratec dominates the LVAD space with a device that is second generation, implants below the diaphragm and is double the size of the HVAD and triple the size of the MicroMed HeartAssist5. Thoratec must innovate and develop a smaller pump that implants within the pericardial space.

HeartWare and MicroMed have the only generation 4 or greater LVADs

There are many companies that may now consider becoming involved in the exploding field of mechanical circulatory support.

1. Thoratec may be purchased by a “Large Med Tech” company that will “buy” its way into a proven and large market….however if that occurs, the purchaser will be burdened with the challenge of upgrading to a device that implants within the pericardial space. The HeartMate II is too large and a new pump must be designed, tested and studied to gain approval.

2. SynCardia may be purchased by a company interested in entering the mechanical circulatory support market or it may be purchased by a company in the MCS space.

3. HeartWare may be acquired or they may use their public currency to build a suite of products that broaden their competitive reach,

4. All but one of LVADs that implant below the diaphragm will be discontinued

5. The potential combination of SynCardia and an above the diaphragm LVAD (MicroMed or HeartWare (pericardial space LVAD)) could an ideal combination of products for the Transplant Center OR suite.

6. The TAH will become more common and be accepted similar to the acceptance of ventilator, portable oxygen or artificial knee or hip – a prosthesis. Biventricular failure is the final common pathway to death and can be treated with a prosthesis. Alert: MicroMed may have the TAH of the future.

7. All four companies are guided by capable CEOs:

Thoratec - Gerhard (Gary) Burbach joined Thoratec as president and chief executive officer in January 2006, at which time he was appointed to the board of directors. Prior to his arrival, Burbach served as president and chief executive officer of Digirad Corporation, a leading provider in solid-stage cardiology and nuclear medicine imaging products and services, and continues to serve on the board of directors. Burbach has held executive positions at Bacchus Vascular Inc. and Philips Nuclear Medicine, as well as the
consulting firm of McKinsey & Company, Inc. He has a bachelor's degree in industrial engineering from Stanford University and a master's degree in business administration from Harvard Business School.

**HeartWare** - Doug Godshall, age 46, has been the Chief Executive Officer of HeartWare Limited and subsequently HeartWare International, Inc., since September 2006 and became a director of HeartWare Limited and subsequently HeartWare International, Inc., in October 2006.

Prior to joining HeartWare Limited, Mr. Godshall served in various executive and managerial positions at Boston Scientific Corporation, where he had been employed since 1990, including as a member of Boston Scientific's Operating Committee and since January 2005, as President, Vascular Surgery. Prior thereto, Mr. Godshall spent five years as Vice President, Business Development, at Boston Scientific, where he was focused on acquisition strategies for the cardiology, electrophysiology, neuroradiology and vascular surgery divisions.

Mr. Godshall has a Bachelor of Arts in Business from Lafayette College and Masters of Business Administration from Northeastern University in Boston, Massachusetts

**SynCardia** – Michael Garippa, age 57, CEO of SynCardia Systems Inc.

Michael Garippa is the former CEO and President of TandemHeart. He was recruited by TandemHeart in 2002 as a turnaround expert and stayed on as CEO and President. He progressed TandemHeart from an R&D firm that had lost an aggregate of $50 million and had no commercial sales to a successful company with over $6 million in net income in 2010.

Prior to joining TandemHeart, Mr. Garippa served as CEO and President of Gateway Home Care. In addition, Mr. Garippa was Founder and CEO of Millennium HomeCare and The Prompt Care Companies. His background also includes being National Sales Manager at Omni Medical and Senior Analyst with the NYC Health and Hospitals Corporation. Mr. Garippa holds a B.A. degree from Rutgers University and a master's degree from New York University.

**MicroMed** - David Mackstaller, age 69, CEO of MicroMed Cardiovascular. Mr. Mackstaller holds a B.A. degree in Economics from the University of Michigan and a Juris Doctorate, Cum Laude, from the University of Michigan Law School. He practiced law with a Detroit Law firm from 1968 to 1970, there specializing in real estate law, with particular emphasis on partnerships, corporations, and taxation.

From 1984 until 1991, J. David Mackstaller was the Executive Vice President and a 50% owner of the Schomac Group, Inc., and National Self Storage Management, Inc. He was a co-founder of both companies. Mr. Mackstaller was co-founder of Anthem Equity Group, Tucson Arizona in 1991.

Mr. Mackstaller is the Vice President of Business Development at SynCardia Systems. There he and his longtime partner Mr. Ford raised the capital which funded SynCardia
during its development and launch of the Freedom portable driver, the world’s first wearable power supply for the Total Artificial Heart.

Mr. Mackstaller co-led the acquisition of MicroMed Cardiovascular in 2008. MicroMed was a public company acquired by E-Wilson LLC, a group formed for the purpose of acquiring the outstanding public shares

What is on the horizon?…………………..

The rebuilding of hearts with scaffolding and stem cells may become an integral component of heart failure therapy, 2030. “…give nature the tools, and get out of the way.” Dr. Doris A. Taylor, January 14, 2008.