Company: Thoratec Corporation (THOR)
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We recently identified Thoratec Corporation (THOR) for review under a long thesis, testing in part, our rough screen for medical device companies with 1) strong revenue growth (not necessarily profitable) based on 2) a dominant competitive position. Historically, device companies with these attributes, especially in cardiology or orthopedics, have been acquired by larger firms in search of growth such as Medtronic, Guidant, St. Jude, Boston Scientific, Baxter, Becton Dickinson and Johnson & Johnson. Growth of the cardiovascular oligopoly continues to this day.

On April 22, the Company announced first quarter results with net income of $1.4 million ($0.03/share) on revenues of $36.1 million (58.7% GM; ≈ 17% OUS) versus a net loss of $1.8 million (-$0.03/share) on revenues of $29.6 million (55.6% GM; ≈ 17% OUS) for the same period last year. At March 31, Thoratec reported $48.7 million of cash and equivalents, 55.5 million shares outstanding with 37.1 million in the float. At June there were 2.96 million shares short for a short ratio of 5+ days.

Conclusion: Thoratec is best-of-breed in a narrow sector of cardiovascular devices. The only pure-play, publicly-traded competitor is microcap Abiomed (ABMD). Arrow (ARRO) also competes and is of similar size (market capitalization) to Thoratec. Ventricular assist devices (VAD) are the most expensive devices in medicine averaging $50,000-$60,000 each plus another $75,000-$150,000 for surgery. As such, VADs, regardless of indication or reimbursement, will remain the device of last resort. Historically research-driven, Thoratec grew its commercial operations and solidified its market dominance by acquiring Thermo Cardiosystems ("TCA" part of the Thermo Electron family). Curiously, Thoratec and Thermo Cardiosystems each have/had "secondary" businesses, synthetic vascular grafts and ITC's blood coagulation testing, respectively; however, Thoratec's future and valuation reside in the VAD business. With a recent stock price of $15.85 (July 14), Thoratec is fairly valued; however, building a long position beginning closer to $13.00 (technology value < 5.0x LTM revenues) is strongly recommended.

Introduction:

Founded in March 1976, Northern California-based Thoratec is one of the few companies to have successfully pursued the laboratory and clinical development of a ventricular assist device (VAD). The VAD evolved from numerous failed efforts over 30 years, initiated by NIH in 1964, to develop a total artificial heart (TAH). In November 1992, the FDA cleared the first VAD (Abiomed's BVS-5000), as a bridge-to-recovery after heart surgery. In September 1994, the FDA cleared the second VAD (Thermo Cardiosystem's HeartMate IP), as a bridge-to-transplant, the first device with this indication. Thoratec's VAD was FDA cleared in December 1995 for the same indication. Thoratec has received expanded FDA clearances for its (or Thermo Cardiosystems') VADs with bridge-to-recovery (May 1998) or destination therapy (November 2002) labels.

In February 2001, Thoratec acquired profitable Thermo Cardiosystems for $346 million in stock (32.2 million shares at $10.74) valuing TCA at approximately 4x it's LTM revenues of $83.7 million and 46x TCA's earnings of $7.5 million. Note that Thoratec's original offer for TCA was for $572 million in an all stock transaction. The offer valued TCA at $14.82 per share, a 77 percent premium to TCA's $8.38 prior close. In January, TCA rejected a $444 million (15% cash) offer from Abiomed.

VAD Market

Cardiovascular disease (CVD) was the number one cause of death in the United States in every year of the twentieth century except one (1919). Balloon angioplasty ("PTCA" at $15,000) and coronary artery bypass graft ("CABG" at $55,000) are the primary surgical procedures to treat CVD due to arterial insufficiency. Implantable cardioverter-defibrillators (ICDs at $25,000) are used to detect the heart's sudden electrical failure and shock it back to normal rhythm. However, when all else has failed, a heart transplant (2,000 per year in US at $100,000 each plus $35,000/year for immunosuppression) has been the final option. On average, 91 percent of heart transplant patients survive one year, 85 percent survive 5 years and 50 percent (the median survival time) live 10 years. The dearth of hearts available for transplant has driven efforts over the past 40 years to develop a totally artificial heart. Leading this effort is Abiomed,

which since July 2001 has implanted 10 TAHs (called AbioCor). Two AbioCor recipients were alive as of May 1, 2003. With the TAH still a device for the future, the VAD has evolved as the auxiliary heart support device of choice.

Thermo Cardiosystems' first VAD approval in late 1994 was for its HeartMate IP (implantable pneumatic) device. Fourteen months later, the Thoratec VAD was cleared for the same indication. Since then, clinical trial results have demonstrated VADs' efficacy in two additional indications: 1) *bridge-to-recovery* in, e.g., post-cardiotomy patients, and 2) for long-term use in patients with end-stage heart disease (ESHD), so-called "*destination therapy*." The second and third indications each represent significantly larger market opportunities than the bridge-to-transplant. Thoratec has all three uses approved. Abiomed only has FDA approval for its BVS 5000 Bi-ventricular support as a bridge-to-recovery and, as noted above, is pursuing the TAH.

And yet, the VAD market opportunity, especially for destination therapy, remains most unclear. While no one doubts the need for and clinical benefit from replacing a failing heart, VADs' long-term durability and ultra high costs create a dilemma for the health care system. In particular, since most VAD recipients are likely to be eligible for Medicare, reimbursement takes on even greater importance. The most robust clinical data are from Thoratec's REMATCH trial, the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure. REMATCH results, as reported in the November 2001 New England Journal of Medicine are summarized below.

11/13/01: WSJ NEJM; Thoratec/Thermo Cardiosystem's HeartMate SNAP-VE, *REMATCH data* in 129 "NYHA Class 4" Pt.s w/ ESHD at 20-22 US sites ↓ death; LVAD (68 Pt.s; *48%* mortality) vs SOC (61 Pt.s; *75%*) at *1yFU* (p=0.002); Also, LVAD (77% mortality) vs SOC (92%) at *2yFU* (p=0.09); Median survival w/ LVAD (408 days) vs SOC (150 days); LVAD AEs (sepsis infection (41% of deaths), device failure (17%; 10 Pt.s needed replacement devices) were 2.35x those receiving SOC (terminal heart failure was #1 cause of death);

The trial enrolled patients over 39 months beginning in May 1998. Enrollment stopped once the predetermined number of 92 deaths had occurred. Clearly, with only 61 patients receiving an experimental device, the study was small. More importantly, *there was no statistically significant improvement in survival between device recipients and those receiving optimal medical care at two years (p=0.09).* Although a survival benefit and four of five QOL measures were significantly superior at one year in device recipients, these results are modest in lieu of the high costs involved.

Thoratec has demonstrated its intent to constantly improve and expand its VAD platform. Survival benefits and decreased adverse events will result from serial incremental improvements in the underlying technology. History has shown how slow the process is. More importantly, the Company will benefit from the expected robust improvements in lowered mortality and morbidity based on expanded clinical utilization and experience. Both technological and clinical progress will put Thoratec further in the lead with little possibility of a competitor suddenly able to leap-frog ahead. Specifically, Arrow Internationalm, in Phase 1, has implanted its LionHeart VAD in only eight patients in the US. Abiomed has shifted its primary focus to the AbioCor TAH. World Heart is on the verge of bankruptcy.

Thus, Thoratec is likely to post 20-30 percent year-over-year top line growth, off a relatively small base, in the next 3-5 years. With operating leverage typical for sophisticated medical device companies, earnings could grow at a 40 percent premium to the top line growth rate.

Thoratec is the role model for a successful acquisition scenario in the medical device field. Even if Thoratec remains independent, its future seems secure with strong potential for significant stock price appreciation, i.e., a doubling within two years.

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Investment Risks

- *Regulatory action:* Thoratec's devices are among the most sophisticated medical devices in medicine and are used to treat the sickest patients. As such, Thoratec can not escape the heightened risk of an FDA action halting implants for some period of time. With increased usage (more patients for a longer time) the risk of an adverse event increases. No mechanical substitute (hip, knee, pacemaker) has ever proven superior to the natural structure. The VAD is no exception.

- *Reimbursement:* The cost/benefit ratio for VAD use has not been fully evaluated. The situation is somewhat analogous to that in the late 60s regarding dialysis. In 1972, Congress decided to cover, via Medicare, dialysis treatments for end-stage renal disease (ESRD) for everyone, regardless of age or wealth. The estimated cost was $250 million per year. In 1974, when coverage actually began, there were 600 patients on dialysis in the US. In 2002, roughly 375,000 in the US were on chronic dialysis at an annual cost of ≈ $13.5 billion. ESHD may become only the second disease to be fully covered by the government.

Investment Merits

- *Sector leader:* By virtue of outlasting many other companies, then acquiring Thermo Cardiosystems (part of Thermo Electron's "spin-in or divest" strategy at the time), Thoratec has risen to the top of the VAD heap. There appears to have been no shortcut to success and many firms have vanished in the process. Academic research continues at a few select institutions worldwide, but these discoveries are likely to find their way to Thoratec, since it provides the most likely path to commercialization.

- *Financial strength:* Unlike the few, much smaller, unprofitable or closely held competitors (Abiomed, World Heart, Cardiowest, MicroMed Technologies, Berlin Heart, Medquest, A-Med Systems), Thoratec is profitable with a strong balance sheet.

- *Attractive sector:* The most successful medical device companies (Medtronic, Guidant, Boston Scientific, St. Jude Medical) treat heart disease. Each of these companies has grown both organically and by acquisition. With few successful VAD companies extant, Thoratec is essentially the only Rembrandt on the wall.