

Company: Cambridge Heart
Ticker: CAMH on the OTCBB
Investment Proposal: Long
Date: January 15, 2007

Current Price: \$2.32
Target Price: \$3.16
Market Cap: \$145.0M
Enterprise Value: \$136.9M

Investment Thesis

Cambridge Heart is a medical device company presenting value through 1) a large moat in the form of a unique heart test recently approved for reimbursement by Medicare and private health insurance companies, 2) a price consistent with an annual rate of return of 36% based on a comparison with a more mature medical device companies with a similar business models. The company is relatively unknown and difficult to understand, and as such represents a special opportunity for those willing to dig into medical economics.

Overview and Background

Cambridge Heart is one of two manufacturers (the other being General Electric) of a test that detects tiny variations in the electrocardiogram called microvolt T-wave alternans (MTWA), which is used in ruling out patients at risk for sudden cardiac death. Its MTWA test analyzes data its data using a proprietary algorithm called the “spectral analytical method”, which differs from GE’s test, which uses the “modified moving average method” (MMA). This distinction is important, because it is only the spectral analytical method that is reimbursable by Medicare and other insurance carriers. In addition, nearly every clinical study that has been performed on the MTWA test has been with the spectral analytical method and Cambridge Heart’s equipment, furthering their competitive advantage. Furthermore, the company manufactures special noiseless, one-time-use electrodes that allow them to obtain recurring revenue from each MTWA test that is performed.

The MTWA test was developed by Harvard-MIT professor Richard Cohen in the 1980s. The company was founded in 1992 and was plagued by difficulties, including having to restart a clinical study (1997), discontinuing a promising product line, cash flow shortages, and slow adoption of the MTWA test by the medical community. By far the biggest problem facing the company was limited reimbursement by insurance carriers. Consequently, the stock price fell, investors lost interest, the company was delisted from Nasdaq, and as a penny stock it was largely forgotten.

Two landmark cardiology trials unrelated to the company – the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) in 2002 and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) in 2005 – introduced a new market opportunity for the MTWA test. These two trials showed that certain patients with implantable cardiac defibrillators (ICDs) survived longer than patients without them. The major problem these studies was that the number of implants per life saved was too high, with fully 18 implants required in order to save one life¹. Physicians were reluctant to have their patients undergo such an expensive procedure, at an average cost of \$50,000-\$65,000² with such a low yield.

Research cardiologists discovered that Cambridge Heart’s MTWA test could be used to help differentiate among those patients who didn’t need the test and those who did. In fact, by using the MTWA test, the number of implants needed to save one life falls to seven³. Thus, the argument for using the test from an

¹ Moss AJ, Zareba W, Hall WJ, et al, for the Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med. 2002;346:877-883.

² Healthcare Cost & Utilization Project (<http://www.ahrq.gov/data/hcup/>)

³ Bloomfield DM, Steinman RC, Namerow PB, et al. “Microvolt T-wave alternans distinguishes between patients likely and patients not likely to benefit from implanted cardiac defibrillator therapy: a solution to the Multicenter Automatic Defibrillator Implantation Trial (MADIT) II conundrum.” Circulation 2004;110:1885-9.

economic standpoint is compelling. A single \$322 test can save tens of thousands of dollars in healthcare costs.

Medicare, likely realizing the validity of the test and the amount of money it could save, issued a National Coverage Determination with language highly specific for Cambridge Heart's MTWA test in March 2006. This was an important milestone in the company's development, because private insurers generally follow the lead of Medicare. Private insurers such as Aetna, CIGNA, Humana, HCSC, independent Blue Shield/Blue Cross carriers, and Wellpoint issued coverage decisions later in 2006. Wellpoint is the largest private insurer in the US. In 2006, the test has expanded from approximately 16% of covered lives to approximately 52%. Insurance coverage is highly important for the company, as it allows physicians to be reimbursed for performing the test.

The clinical evidence for adoption of the MTWA has been mounting. Clinical guidelines jointly authored by the major cardiovascular professional societies have incorporated the proprietary MTWA test. A separate clinical trial demonstrated that MTWA testing was just as effective as the current "gold standard" invasive electrophysiological testing. It has been suggested from these studies that the test should be repeated every 1-2 years, providing a source of recurring revenue for the company.

Revenue Sources

The company makes money by selling its HeartWave II system for \$29K. Special single-use electrodes, at a cost of \$84 each, are required in order to use the machine. The physician is reimbursed \$322 for performing the procedure. Gross margins are 60-70%. The revenue composition is currently 70% systems and 30% electrodes. There is an installed base of 650 units outstanding. Guidance for 2007 suggests \$12M in revenue, which corresponds to 280 HeartWave II systems and 48,000 tests done this coming year.

Market size

The company is targeting the 9000 cardiology practices in the United States. They believe that 10 to 12 million patients in the US can benefit from MTWA testing.

Competition

General Electric has a similar product which is based on Modified Moving Average technology, instead of the spectral method. Few clinical trials have been performed with their product, and any studies doing so would require years to conduct. Insurance approval would take even longer. Thus, the only competition to the test is the standard electrophysiological study, which was already shown to be equivalent. Other methods for ICD risk stratification include heart rate variability and baroflex sensitivity.

Valuation

To be realistic, the company will be overvalued by any conventional metric (P/E, P/B, P/S). The only way that the company can be considered undervalued is with assumptions of buoyant future growth. This assumption may raise nightmares of the dotcom bubble in some people, but we believe that the company's monopoly like position backed by the federal health system will allow it to pursue such growth freely.

The value of the stock depends upon how quickly the test is adopted in the medical community. Growth rates of medical companies with similar business models – Intralase and Intuitive Surgical – will be used as rough guides.

IntraLase (ILSE) – This seller of lasers for LASIK flap creation has a business model where they sell laser units at \$300,000 each with a \$118 per procedure fee. They had captured 25% of the 1 million LASIK procedures as of 2005. Since 2002, the number of procedures done with their equipment grew from less than 3% in 2002 to more than 25% in 2005. In 2005, IntraLase had sold 156 laser units with a total installed base of 373 laser units to a market of 1970 LASIK practices worldwide. This is an installed base of 19%.

Intuitive Surgical (ISRG) – This seller of robotic surgery equipment has a business model where they sell robotic surgery units at \$1 million each with an average \$1750 per procedure fee. As of 2005, they have

captured 20% of the US prostatectomy market since FDA approval for the procedure in 2001. In 2005, the company had sold 115 surgical units with an installed base of 401 surgical units.

Assuming that the MTWA test will have similar a adoption pattern at roughly 20% of the market in 4 years, we would expect approximately 2,000,000 tests per year at \$84 per procedure. The procedure revenues would provide recurring revenue of \$168M. We can also assume testing unit sales of 600 units in the 4th year with a total installed base of 1800 units, roughly 20% of the 9000 cardiology practices. Sales of testing units would generate \$18M. Estimated total revenue would be \$186M. Multiplying by a conservative P/S ratio of x2.5-3.0 would suggest a market cap in the range of \$465-558M (per share price \$7.44 - \$8.80). The growth in market cap from today's \$145M to \$500M would suggest a annual rate of return of 36%.

The target price of \$3.16 was arrived by taking today's price and adding an annual return of 36%.

The \$3.16 value is a bit lower than the \$3.50 target price placed by the sole analyst following the company. It is also interesting to note that Laurence Blumberg, recently appointed current Vice President of Business Development, and member of AFB Fund, LLC, an 8% shareholder of the company, has stock options, the majority which will only be exercisable if the company's stock trades above \$6.60 per share before Dec 31, 2011.

The company has \$66 M in losses that can be used to reduce income taxes once they reach profitability.

Relatively Unknown Stock

The company is relatively unknown, as it trades on the OTC Bulletin Board and is covered by a single analyst. There are few institutional holders. Discussion is limited to three message boards (RagingBull, InvestorVillage Yahoo opened one up recently). The company has no profits and high price/book ratio, so it will not show up on standard value investor screens. Interestingly, Cambridge Heart is rarely mentioned in discussions and analyst reports about ICD manufacturers Boston Scientific, Medtronic, and Saint Jude.

Patent protection

The company has an exclusive license agreement with MIT on the original MTWA patent until the year 2007. However, the company has 15 other patents, including patents on improvements of the MTWA method and the noise-reducing electrode design that maintain competitive advantage through intellectual property.

Risks

Share Dilution

The board of directors has not been conservative with share dilution, as shown by the compensation package of the ex-CEO. The company's share count is currently at 60M and the board has the authority to issue 150M total shares total.

Management Changes and Poor Execution

The company has had undergone rapid changes in management the past year with no reasons specified. Rumors have suggested that the CEO and directors have different goals for the company. Currently, the major shareholders are running the company on an interim basis.

Reliance on ICD adoption

The major application of the MTWA test is to find patients suitable for ICD placement. Thus, the test is closely linked to the risks associated of the ICD market.

Catalyst

Recent coverage by health insurers this past year should drive sales to cardiology practices the current year. In addition, Kaiser Permanente and United Healthcare, two major health insurance companies, will review their coverage policies this year and likely approve the test. Clinical data on the test has reached a critical mass and should encourage rapid adoption. In addition, the stock has yet to be listed on Nasdaq.

Conclusion

Cambridge Heart may not be a value play in the traditional Grahamian discount to net asset value or low price to normalized earnings sense. However, it does represent a special situation which has a “margin of safety” in the form of a large degree of protection from competition through highly specific health insurance reimbursement policies and a large body of clinical literature supporting its product. Thus, the company should be considered a to have a “wide moat” with predictably strong revenues in the future.