

Mossberg's Investor Digest

Best Idea Profile:

Sunshine Heart, Inc. (NASDAQ:SSH)

DESCRIPTION:

Sunshine Heart is developing a heart assist device for Class III and ambulatory Class IV heart failure patients; those patients unable to perform daily activities or moderate exercise without experiencing symptoms related to heart failure such as fatigue and breathing problems, but that are not sick enough for approved Class IV devices. Sunshine Heart's C-Pulse Heart Assist System is implanted with minimal invasiveness and uses balloon counter-pulsation technology to assist the heart by reducing the workload of the left ventricle. The balloon is inflated and deflated in synchronization with the patient's heartbeat. Sunshine's vision is to "Offer a minimally invasive therapy for moderate to severe heart failure that provides symptomatic relief and halts the disease progression." Sunshine Heart's stock is dually listed on NASDAQ and the Australian Securities Exchange; however, approximately 90% of the shares are on NASDAQ and the remainder is expected to delist from ASX this year. The company was founded in 1999 and is headquartered in Eden Prairie, Minnesota.

KEY INVESTMENT CONSIDERATIONS:

Growing Epidemic of Heart Disease – Heart failure is the leading cause of hospitalization in the United States, costing more than \$33 billion annually. There are more than 5 million cases of heart failure in the U.S. and approximately 33 million worldwide. Heart failure is complicated by its progressive nature, as measured by categorizing as Class I through Class IV. As the disease progresses, drug therapy becomes less effective. Nearly half of Class III patients will not benefit, or benefit marginally, from pacemaker therapy. They are left with minimal therapeutic options and therefore represent a significantly underserved market.

Uniqueness of Product – Sunshine's C-Pulse is unique among other heart disease products in that it has no contact with the blood stream, thereby reducing the risk of stroke and complications of blood thinners. Additionally, the device can be implanted in a minimally invasive procedure that takes about one hour to complete and results in a much shorter hospital stay. Additionally, C-Pulse is the only blood pump that can be disconnected temporarily without fatal consequences.

Dynamic Market Opportunity – The target market for C-Pulse in the U.S. alone is estimated to be approximately 130,000 patients. Sunshine is currently selling the units in U.S. clinical trials at a discount for \$59,000. Management indicates the system at full price

would be \$70,000, representing huge upside from the \$7.6 billion market opportunity during the product trials. Additionally, Sunshine is in various stages of trials in Germany, Italy and the United Kingdom. Germany and Italy have the highest number of bed days/year in the hospital for heart failure in Europe.

Affordable Care Act Could Be a Benefit – The threat of Medicare reimbursement reductions, which are required under this law if hospitals exceed certain re-admittance rates, will spark hospitals to address options for heart failure patients, as they have the highest re-hospitalization rates in the U.S. because of the progressive nature of their disease.

VALUATION:

With device approval in the U.S. expected in 2017, SSH is a stock for patient investors. The public offering in April 2013 generated enough cash to fund operations through the second half of 2014. The upside is the uniqueness of this product and the huge underserved market that is just over the horizon. The company, as well as the stock, will continue to gain public and investor attention and could attract a potential buyer. Another medical device company addressing heart failure patients, Heartware (NASDAQ:HTWR), received an offer of \$300 million during its product trials, and was worth \$1.2 billion when it ultimately received FDA approval for its device.

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Investment Data (as of 07/29/13)

Recent Price	\$7.37
52-Week Range	\$4.85 - 10.25
Fiscal Year End	Dec
Dividend	NA
Yield	NA
Shares Outstanding	12 M
Average Trading Volume (3 mos)	81 K
Market Capitalization	\$91 M
Cash	\$11 M
Long-term Debt	0
Enterprise Value (EV)	\$81 M
Book Value	\$1.04
TTM Revenue	N/A
P/ Revenue	N/A
TTM EPS	\$(1.82)
P/ EPS	N/A
TTM EBITDA	\$(15) M
EV/ EBITDA	(5.4)

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