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Rita Medical Systems (Nasdaq: RITA) - \$3.02 (10/6/03)
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RITA Medical Systems (Nasdaq: RITA) is an interesting investment for those who don't like to follow the crowd. This medical device company has hit a snag in its sales, leading to a postponement of profitability. But being led by a new CEO with sales and marketing experience, shares of Rita look attractive for the investor who has the patience and a time horizon of 24-months. The company has sales and the company's core technology can be branched out to several other markets in addition to the two current markets Rita promotes: liver cancer and metastatic bone cancer. The company trades a mere 2.4x EV/Sales and has \$12.2 million in cash, enough to last 5-6 quarters, assuming sales remain flat.

It is very rare within the medical industry that (aside from Viagra, and no pun intended here) we see sales ramp straight up (aka – like a hockey stick). Rita is going through some growth pains, but has a great technology that can be expanded to multiple markets. In addition, it seems that the bad news is in the stock and hopefully behind the company. Equipped with a new CEO, and the settlement of a patent dispute, Rita is ready for the open road. Insiders agree, with making open market purchases recently, a rarity in today's market.

These few catalysts should get the stock to bounce of its \$2.40 low, which it already has trading recently around \$3. With the expectation of hearing more positive news on Rita's technologies treating lung cancer, that should easily fuel shares back to the \$4-5 range in the near-term.

Business Description

RITA Medical Systems develops, manufactures and markets innovative products for patients with solid cancerous or benign tumors. The proprietary RITA system uses radiofrequency energy to heat tissue to a high enough temperature to ablate it or cause cell death. While the Company's current focus is on liver cancer and metastatic bone cancer, the Company believes that its minimally invasive technology may in the future be applied to other types of tumors, including tumors of the lung, breast, uterus, prostate and kidney. The Company has received regulatory clearance in major markets worldwide, including the United States. In March 2000, RITA became the first radiofrequency ablation company to receive specific FDA clearance for unresectable liver lesions in addition to its previous general FDA clearance for the ablation of soft tissue. In October 2002, RITA again became the first company to receive specific FDA clearance, this time, for the palliation of pain associated with metastatic lesions involving bone. The Company has sold over 45,000 of its disposable devices throughout the world.

Rita estimates that the worldwide market opportunity for the radiofrequency ablation of unresectable liver cancer is approximately \$500 million annually and \$600 million annually for the radiofrequency ablation of painful tumors that have metastasized or spread to the bone.

Liver Cancer Market

There are two forms of liver cancer: primary and metastatic. Primary liver cancer originates in the liver. Secondary, or metastatic, liver cancer originates elsewhere in the body and spreads to the liver. A significant number of patients treated for primary and metastatic liver cancer experience a recurrence of their disease.

The worldwide incidence of primary liver cancer is estimated to be one million new patients each year. The vast majority of primary liver cancer patients are located outside the United States, particularly in Asia and Southern Europe. Approximately 90 percent of patients diagnosed with primary liver cancer will die within five years. Due to a rise in the number of worldwide cases of Hepatitis B and C, both of which are correlated to the development of primary liver cancer, Rita believes that the incidence of primary liver cancer may increase in the future.

It is estimated that there are almost as many cases of metastatic liver cancer worldwide as there are cases of primary liver cancer and approximately 300,000 annual cases in the United States alone. The liver is one of the most common sites for the spread of cancer. For example, one of the most common forms of primary cancer is colorectal cancer, and

approximately 60 percent of these patients will develop metastatic liver tumors. Due to numerous factors, including the absence of viable treatment options, metastatic liver cancer often causes death.

Competition

The medical device industry is subject to intense competition. Accordingly, Rita's future success will depend on its ability to meet the clinical needs of physicians, improve patient outcomes and remain cost-effective for payors. There are a limited number of treatment alternatives available to patients with liver cancer. The traditional treatment options include surgery, chemotherapy, cryosurgery, percutaneous ethanol injections and radiation therapy. There are a limited number of treatment options available to patients with painful bone metastases. These options include radiation therapy and analgesics. Rita does not believe any of these treatments are directly competitive with its products, as none are intended to use heat to ablate liver lesions or painful bone metastases. Further, these treatments generally have limited efficacy and/or applicability.

RadioTherapeutics Corporation, a division of Boston Scientific Corporation, and Radionics, a division of Tyco Healthcare, which is a division of Tyco International, are the two companies whose products compete directly with ours in the United States and overseas. Both companies offer systems that include a generator and disposable electrodes and use radiofrequency energy to ablate soft tissue. However, neither system is designed to provide physicians with the temperature feedback throughout the tissue that we believe is important to help ensure successful tissue ablation.

The RITA Solution

Rita's proprietary system is designed to use radiofrequency energy to provide a minimally invasive approach to ablating solid cancerous or benign tumors. Its system delivers radiofrequency energy to raise the temperature of cells above 45 to 50 (degrees) \pm C, causing cellular death. The physician inserts the RITA disposable needle electrode device into the target body tissue, typically under ultrasound guidance. Once the device is inserted, pushing on the handle of the device causes a group of curved wires to be deployed from the tip of the electrode (see picture). When the power is turned on, these wires deliver radiofrequency energy throughout the tumor. In addition, temperature sensors on the tips of the wires measure tissue temperature throughout the procedure. During the procedure, Rita's system automatically adjusts the amount of energy delivered in order to maintain the temperature necessary to ablate the targeted tissue. For a typical five-centimeter ablation using Rita's latest product, the ablation process takes approximately ten minutes. When the ablation is complete, pulling back on the handle of the device causes the curved wire array to be retracted into the device so it can be removed from the body. Rita's disposable device can cauterize the tissue along the needle tract, which we believe kills any residual cancer cells that might be removed from the tumor.



Benefits of the RITA System

- . Effective Treatment Option – Rita's system provides an effective treatment option to liver cancer patients who previously had few options available to effectively address their unresectable liver tumors. Further, its system provides an effective treatment option for patients whose tumors have metastasized to the bone and cause pain that cannot be adequately relieved by other means. In the future, its system may offer patients with other types of tumors a better treatment option.
- . Minimally Invasive Procedure - The RITA system offers physicians an effective minimally invasive treatment option with few side effects or complications. Its products can be used in an outpatient procedure that requires only local anesthesia, and patients are typically sent home the same day with a small bandage over the entry site. Alternatively, patients can be treated with just an overnight hospital stay either through a small puncture in the skin or laparoscopically through several small incisions. Compared to existing alternatives, Rita believes its minimally invasive procedure is cost effective and can result in reduced hospital stays.
- . Proprietary Array Design and Temperature Feedback Provide Procedural

Control - Rita's array design enables the physician to predictably ablate large volumes of targeted tissue. In addition, Rita's temperature feedback feature allows physicians to ensure that the temperature is high enough throughout the tissue to achieve cell death.

- . Repeat Treatments Possible - Cancer is a recurrent disease. However, due to the invasive nature of other treatment options, such as surgery, the majority of patients who undergo traditional therapies cannot be retreated in the event that new tumors appear or previously treated tumors reappear. Because of the minimally invasive nature of our procedure, patients treated with Rita's system can often be retreated.
- . Broadly Applicable Technology – Rita's significant clinical experience with liver tumors and bone tumors as well as feasibility studies in other organs indicates that our technology may in the future be broadly applied to the ablative treatment of solid tumors in the lung, uterus, breast, prostate and kidney.

Recommendation

After reading Rita's company description one would think buying shares is a no-brainer. It probably is, but not for those reasons alone. Shares have bottomed-out after the company pre-announced its Q2 results, which were lower due to a longer selling cycle domestically, which resulted in fewer new accounts for the period than expected and lower international sales reflecting the intermittent nature of shipments to the Company's Japanese distributor.

With that news behind us, shares of Rita have seen a dead cat bounce of approximately 25%. Still, due to three major recent catalysts shares may prove attractive in the near-term:

- 1) Hiring of a new CEO
- 2) Insider Buying in the open market
- 3) The settlement of the Company's patent dispute with Boston Scientific

For the last three years Rita has been busy making awareness for its ablation products, starting with the liver cancer market. Since then the company has matured into a sales & marketing company, something Joe DeVivo, Rita's new CEO has experience in. From August 2002 to June 2003, DeVivo served as President, Chief Operating Officer and Director of Santa Barbara-based Computer Motion Incorporation (CMI) where he led the turnaround and successful merger of the medical device company with Sunnyvale, CA-based Intuitive Surgical, Inc. (Nasdaq: ISRG). (Off topic – ISRG, also a medical device company, trades 5.7x EV/Sales, more than double Rita's 2.4x). While DeVivo was at CMI, the company exceeded sales guidance, reorganized and focused its organization, secured additional funding and enhanced shareholder value. Prior to CMI, DeVivo served as Vice President and General Manager of a \$350 million annual revenue division of TYCO International's Healthcare Business, U.S. Surgical/Davis and Geck Sutures. In this position, he was responsible for all areas of the division including sales, marketing, research and development, and finance.

In his short tenure (2 months) at Rita, Joe has made two key hires to bolster sales & marketing. It is only fair to give Joe a few more months to re-cast Rita's business. At that time, which will likely be in early Jan. 04, one can expect Joe to give his guidance for Rita's expected 2004 performance.

At a time when insiders have been selling their stock at an unprecedented level, two insiders have bought Rita stock in the **open market**. Don Stewart, Rita's CFO, purchased 16,000 shares or about \$41,000 worth. Mr. Stewart's salary in 2002 was \$188,885. In addition to Don's purchases, Randy Lindholm, a director, bought 10,000 shares at \$2.796. Back in May Mr. Lindholm purchased 5,000 at \$2.99 and 5,000 at \$2.75. Since these purchases appeared in late August, the trading window for insiders has closed.

Back in April Rita settled a fierce and costly patent dispute with Boston Scientific, a major positive for Rita. Rita did pay a one-time payment of \$2.65 million, but the total legal expenses associated with the dispute would otherwise have been expected to be around \$4-5 million in 2003 alone. It is positive that this 'black eye' has been put behind the company and also it will significantly lower the cash burn as well.

Long-Term Catalysts

About one year ago Rita received FDA approval for the metastatic bone cancer market. Sales have been slow as oncologists have yet to adapt Rita's technology, but the company continues to see good progress in this market. Rita is seeing that its products have had positive effects on end-stage patients with bone cancer and is being used more as a 'quality of life issue.' Meaning that end-stage patients, are usually highly medicated in the last year of life due to the severe pain that arises, but lately patients have been using Rita's RF ablation as a pain-killer. Hope to see Rita make continued in-roads with regard to this market in the coming year.

Another positive point for Rita is that they are a medical device company and don't have to go through multiple phases for FDA approval. In addition, the company is dealing with a huge population and getting patients for studies has not been a problem. Expect to see more and more data throughout the next year, especially for lung cancer. The company has an ongoing clinical study for lung cancer, mostly being done in Europe and Australia with the results focusing on the survival impact of using Rita's product. Rita has more than 60 patients in the lung cancer study so far and may not need many more for a nod from the FDA. Reason being that Rita got its liver cancer approval after 60 patients and only needed 45 patients in the bone pain study. Rita is currently in discussion with the FDA what the next steps may be.

Here is some significant data that was released this past June with regards to Rita's RF technology and how effective it is at destroying lung tumors:

One part of the study, including 30 patients (21 males and 9 females aged 50-83 years who had exhausted radiation and chemotherapy alternatives), focused on non-small-cell (primary) lung cancer showed that ablation was successful in all cases (32 of 32 lesions) and complete ablation of treated lesions was confirmed by the absence of tumor re-growth over a follow-up period of six months or more in 13 (93 percent) of 14 lesions in 14 patients. The study was led by Professor Riccardo Lencioni, M.D., a Professor of Diagnostic and Interventional Radiology at the University of Pisa, and included patients of Robert Suh, M.D. of the Department of Radiological Sciences at the UCLA School of Medicine.

"We continue to see remarkable results with the RITA system and very few complications," Professor Lencioni said. "I believe the RITA system is an important and effective alternative for many lung cancer patients, especially when you consider most of them are not candidates for surgical resection and chemotherapy and radiation have not been entirely satisfactory in terms of long-term survival outcomes."

The data in another part of the study, including a total of 33 patients (69 tumors) with colorectal metastases to the lung who had undergone prior chemotherapy (64 percent), surgery (13 percent) or radiation therapy (6 percent), showed that 94 percent of the tumors showed a positive response (stable or decreased size) in follow-up examinations after six and 12 months. This part of the study was led by Derek Glenn, M.D. of St. George Hospital, Dr. Suh of UCLA and Caroline Dereskewitz, M.D. of the University of Essen.

"RF ablation provides effective local tumor control with low morbidity and may prove to be an important adjuvant therapy in patients with colorectal pulmonary metastases who are not candidates for surgery," Dr. Glenn said.

In addition to lung cancer, Rita is also looking to apply its technologies to other types of tumors, including tumors of the breast, uterus, prostate and kidney, which combined are worldwide multi-billion dollar markets.

Rita also has some NOLs. As of the end of last year Rita had \$57.5 million in federal NOLs, which expire between 2011 and 2022. That's very significant considering Rita's market cap is \$53 million.

Wall Street is a herd mentality and right now the herd is not following Rita (sell-side included given their neutral ratings). That being said, there still will be some overhang of stock with institutions (aka – the herd) unloading shares, although most of the selling has seemed to subside. BUT for value/GARP investors, Rita is an interesting investment with revenues and some interesting technologies to help revenues grow within a multi-billion dollar marketplace.

Dates to remember:

October 17-18 – Oncologic Interventions
Society of Cardiovascular and Interventional Radiology (IR)
Chicago, IL

Week of Oct. 20th – Q3 Financial Results
Cash burn should be slightly better than Q2.
Company also presenting at the Rodman & Renshaw Conference in Boston.

October 19-23 – American Society for Therapeutic Radiology and Oncology
(ASTRO), Salt Lake City, UT

November 30-December 5 – Radiological Society of North America (RSNA)
Chicago, IL

Jan 04 – Hope to hear guidance from new CEO Joe DeVivo for 2004 expectations.

Company Chart Since IPO on 7/26/00 – 3.6 million shares @ \$12 per share

RITA MEDICAL SYS INC
as of 6-Oct-2003



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