

Equity Research

HEALTH CARE
Medical Devices

June 13, 2008
Research Note

Ticker: CRDC
Market: NASDAQ
Price: \$9.85
52-week: (\$5-\$15)

Stock Rating:
Outperform

Company Profile:
Aggressive Growth

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Cardica, Inc.

PAS-Port Data Set as Expected, Compelling Thoughts From Physicians During Investor Meeting

FINANCIAL SUMMARY

Fiscal Year Ends:	June	Dividend/Yield:	\$0.00/0.0%
Long-term EPS Growth Rate:	35%	Market Value (mil.):	\$154

ESTIMATES*

FYE	Q1	Q2	Q3	Q4	Annual	P/E
2007A	(\$0.37)	(\$0.23)	(\$0.31)	(\$0.34)	(\$1.25)	NM
2008E	(\$0.27) A	(\$0.29) A	(\$0.35) A	(\$0.28)	(\$1.19)	NM
2009E	(\$0.28)	(\$0.26)	(\$0.25)	(\$0.22)	(\$1.02)	NM
Cal2008					(\$1.17)	NM
Cal2009					(\$0.75)	NM

* Estimates do not reflect the adoption of FAS 123R.

- Yesterday, the full data set from CRDC's key EPIC trial was presented at the International Society for Minimally Invasive Cardiac Surgery (ISMICS) meeting.
- Patients receiving an automated anastomosis with Cardica's PAS-Port product were shown to have patent (open) vessels 80.3% of the time at the nine-month follow-up, compared to 82% in patients receiving a hand-sewn graft, which met the primary endpoint for the trial (non-inferiority to hand-sewing).
- We were not surprised that the patency rates from the PAS-Port arm of the trial came in lower than the single center results observed internationally, as randomized clinical trials are conducted with stringent review protocols, which in the case of the EPIC study included independent core lab validation.
- ***With the trial meeting secondary endpoints of shorter anastomosis times and lower major adverse cardiac events, we believe, and our channel checks with surgeons during the meeting indicate, the result of non-inferiority to hand-sewing from the trial, along with the critical avoidance of clamping the aorta during the procedure, will lead to significant uptake of the PAS-Port once approved (likely around October 2008).***
- Following the release of the data, the company held an investor meeting where several thought-leading physicians discussed their use of Cardica's distal anastomosis devices and noted that they had incorporated these products into their practices as they facilitate less invasive bypass revascularizations, which they view as the future standard of care in this area.

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- As essentially the only provider of automated anastomosis products in the world, at a time when these products should see significantly increased demand as surgeons move toward less invasive coronary bypass, we believe Cardica's premium valuation (4.8 times our 2009 revenue estimate of \$27 million) is warranted, and we would build positions at current levels. We reiterate our Outperform rating.

Investment Thesis

Yesterday, the full data set from Cardica's EPIC clinical trial to measure the safety and efficacy of the company's PAS-Port proximal anastomosis product was presented at the ISMICS meeting. The data demonstrated that bypass vessels attached with the company's automated anastomosis product were patent 80.3% of the time at the nine-month follow-up, compared to 82% for hand-sewing, which met the primary endpoint of the study, statistical non-inferiority. Though some investors may have expected the trial results to mirror the high rates observed internationally, we were not surprised to see the patency rates come down during the company's rigorous clinical trial, which employed core labs to review the results rather than a surgeon's eye on a CT scanner. The PAS-Port also produced shorter procedure times and reduced MACE rates in the automated anastomosis arm of the trial. ***Our channel checks during the conference indicate that the non-inferiority claim and, more importantly, the ability to avoid manipulating the aorta, which often results in neurological damage to the patient, is exactly what surgeons are looking for in a proximal anastomosis device,*** and many indicated that they would begin using the product once approved in the United State (we expect October 2008).

Cardica held an investor meeting following the release of the EPIC data, which included comments from several surgeon thought leaders. All of the physicians noted that many surgeons and hospitals are moving to incorporate less invasive bypass into their revascularization programs as patients are increasingly demanding this approach, due to lower complication rates and a meaningful reduction in the length of stay required following the procedure. The surgeons also noted that once the savings associated with shortened OR times and hospital stays were factored in, performing less invasive bypass was significantly more profitable for the hospital compared to a traditional open procedure. More importantly, the surgeons noted that Cardica's distal anastomosis device has been a key facilitator in their move to less invasive revascularization of diseased coronary arteries and that they expect widespread adoption of the company's automated anastomosis products in the future. Though the surgeons admitted that it will take time to change the practice of therapy that many physicians have grown accustomed to, they all expressed their belief that less invasive bypass would eventually become the standard of care in the coming years. We anticipate that the confluence of these factors (patient, surgeon, and hospital demand for less invasive CABG) will lead to robust unit growth in Cardica's PAS-Port product (once approved) and C-Port devices in the coming quarters.

Stock Thoughts/Valuation

Shares of Cardica rose significantly in the days leading up to the release of the full data set yesterday. With the device proving non-inferior to hand-sewing, coupled with the crucial ability to avoid clamping the aorta, we anticipate that the product will generate significant uptake once approved later this year. The stock currently trades at 4.8 times our calendar 2009 revenue estimate of \$27 million (up 170%), which is a premium to a group of similar fast-growing medical technology companies. However, we believe the premium valuation is warranted, as CRDC is basically the only provider of automated anastomosis products in the world at a time when, in our view, less invasive coronary bypass is set to proliferate and performing these procedures is technically challenging without an automated anastomosis device. We reiterate our Outperform rating and encourage investors to build positions at current levels.

Strong Nine-Month Results from the EPIC Trial

During the meeting, the trial's lead investigator (Dr. John Puskas, no financial relationship with CRDC) detailed the nine-month follow-up results from Cardica's EPIC trial to measure the safety and efficacy of the PAS-Port proximal anastomosis device. The initial trial design included 220 patients, with each receiving an automated anastomosis with the PAS-Port and a second bypass graft, sewn by hand. As is typically the case with all clinical trials, there was falloff in patient participation throughout the

duration of the study, but a total of 183 patients did return for an angiographic evaluation of both grafts. At the nine-month follow-up, the automated anastomosis conduits were patent 80.3% of the time, compared to 82% for hand-sewing, which met the trial's primary endpoint (statistical non-inferiority to hand-sewing). We point out that the trial was only powered to demonstrate non-inferiority and not superiority to hand-sewing, as the size of a study regarding the latter would likely have to include thousands of patients. We were not surprised to see the results of the data come down from the mid-90 percent levels seen in several single center studies conducted in Japan in recent years, as the review criteria in clinical trials are much more stringent than an independent physician review of an angiogram. Specifically, Cardica used independent core labs to review the results of the clinical trial, which include a multilevel analysis of the follow-up angiograms. We view CRDC's decision to use an independent core lab as a smart move by the company as surgeons have become increasingly skeptical of trial results that are interpreted by physicians participating in the trial and the sponsor company.

The PAS-Port arm of the trial also demonstrated a reduction in anastomosis time of roughly five minutes when creating the new conduit and a reduced rate of myocardial infarction (heart attack) and major adverse cardiac events (MACE), which were secondary endpoints. While the data did not include any analysis on the reduction in neurological damage (stroke) from the avoidance of cross-clamping the aorta with the PAS-Port (with each patient receiving an automated and hand-sewn anastomosis, there would have been no way to determine which connector released emboli into the brain), several surgeons who we queried during the meeting indicated that there was no doubt that eliminating the need to clamp the aorta would reduce the incidence of stroke in patients receiving a coronary bypass, which is a key feature of the PAS-Port device.

Seven patients in the trial died following their procedure, with three listed as "possibly" device related, but the overall mortality among the patient cohort mirrored other clinical studies of coronary revascularizations. Dr. Puskas reported one case of an aortic dissection in one of the grafts attached using the PAS-Port. During the post-mortem examination, it was revealed that the end of the graft connected with CRDC's PAS-Port had remained connected to the aorta and that the tissue had torn away from the vessel wall (actually on both the proximal and distal ends of the new conduit).

Importantly, the anastomosis made by the PAS-Port had worked properly but was likely caused by a graft that was inappropriately sized for the length of conduit needed for the patient. Despite this likely human judgment error, the trial requires the PAS-Port arm be assigned the dissection. Though this incident was cited in the final analysis of the data, it should not impact the approvability of the device as the trial is designed to measure non-inferiority of the PAS-Port to hand-sewing.

Market Opportunity for Pas-Port

To attach a saphenous vein graft to the aorta, the surgeon will clamp off part or all of the aorta to prevent blood from flowing freely out while she is suturing the vessels together in a T-shape. This clamping action is known to be associated with a significant risk of emboli breaking off the inner surface of the aorta and flowing downstream, either down to the body or up into the brain, where it can block smaller vessels and cause minor and major neurological complications including stroke. The inner lining of the aorta is often referred to as being like an eggshell, particularly in older patients who are likely to have buildup in their coronary arteries that require CABG surgery. The rate of stroke and other neurological effects observed with this clamping following CABG is known to be significant, between the low single digits and up into nearly double digits. Most patients come out of CABG surgery in great shape, but many have neurological effects that are subtle, but non-trivial. Grandma's heart may be well perfused, but she can no longer remember her phone number. For this reason, surgeons are motivated to avoid manipulating the aorta any more than necessary, and Cardica's PAS-Port proximal anastomosis device requires no cross clamp, and allows the surgeon to create a complete anastomosis in a single, quick movement. **Our channel checks, both during the meeting and in recent weeks, indicate that the combination of non-inferiority to hand-sewing and, more importantly, the avoidance of cross-clamping are what surgeons demand in an automated proximal anastomosis device and that uptake should be robust once approved later this year.**

We expect the company to receive FDA approval for PAS-Port in October and immediately launch the product (the company is already selling the device internationally and is currently building inventory for

a U.S. launch). Importantly, when CRDC receives approval for the PAS-Port, the company will have a sizable base of surgeons (roughly 350) already using its distal product. We point out that we had previously expected the company to only have a surgeon base of 300 at the time of approval but following strong physician interest at the Society for Thoracic Surgery in late January, the number of physicians trained accelerated meaningfully. We believe this speaks to the underlying physician interest in automated anastomosis products, particularly in facilitating less invasive approaches (either manually or with Intuitive Surgical's [ISRG \$269.66] da Vinci system through dime-sized access ports). We look for CRDC to initially focus on cross selling the PAS-Port to this group of physicians. Although we model brisk unit uptake of the product during its initial launch phase, as seen in the table below, our estimates assume relatively low penetration rates among our anticipated physician base for Cardica in the coming quarters.

Cardica, Inc.
Analysis of Pas-Port Uptake Among Existing Physician Base

	Q2 (E) Dec-08	Q3 (E) Mar-09	Q4 (E) Jun-09	Q1 (E) Sep-09	Q2 (E) Dec-09	Q3 (E) Mar-10	Q4 (E) Jun-10
Number of Surgeons Trained (Beginning of Period)	336	364	392	420	448	476	504
Total Procedures Performed / Quarter	25	25	25	25	25	25	25
# Procedures Performed by CRDC Trained Surgeons	8,400	9,100	9,800	10,500	11,200	11,900	12,600
# of Proximal Anastomosis Per Procedure (Avg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Proximal Anastomosis Opportunity	12,600	13,650	14,700	15,750	16,800	17,850	18,900
Current William Blair & Company LLC estimates	1,923	3,077	4,231	5,154	5,769	6,154	6,923
% Penetration of Proximal Anastomosis Opportunity	15.3%	22.5%	28.8%	32.7%	34.3%	34.5%	36.6%

Source: William Blair & Company LLC estimates

Longer term, we believe the PAS-Port will allow CRDC to penetrate new accounts as it alleviates the "boring" anastomosis component of bypass surgery, while importantly improving vessel patency and reducing the likelihood of potentially damaging embolization. Further, we believe the company's salesforce will be able to pull-through sales of its distal product after initially opening the door with new accounts and that Cardica will enjoy significant leverage from this activity.

Thoughts from Investor Meeting

Following the release of the company's EPIC trial results, Cardica held an investor meeting, which included a panel of three thought-leading cardiothoracic surgeons offering their views on CRDC's distal anastomosis products (known as C-Port). The physicians noted that Cardica's products have enabled them to perform less invasive approaches to coronary bypass at a meaningfully reduced cost. Similar to the comments from surgeons at the Society for Thoracic Surgery in late January, the surgeons on the panel noted that they have seen an uptick in the number of referrals they have received from interventional cardiologists due to their ability to perform less invasive revascularizations. Additionally, the panel surgeons noted that patients are becoming increasingly aware of the less invasive approaches to coronary bypass and are traveling from different parts of the world to get access to surgeons performing these procedures.

While all three members of the panel are distinguished surgeons, we view the comments from Dr. Sudhir Srivastava from the University of Chicago as extremely compelling. Dr. Srivastava is world renowned for his approach to coronary bypass, where he only performs less invasive revascularizations and does not offer traditional open procedures. He noted that he had been watching Cardica for some time, but only recently decided to try the C-Port distal anastomosis product (the company's other offering) following his observation of a live case. He has now used the device in 20 cases (primarily on Intuitive Surgical's da Vinci robotic system) over the past two months, with all of the vessels remaining patent at follow-up. He has seen a significant reduction in the length of hospital stays from using a combination endoscopic approach with ISRG and CRDC, with one of his patients

leaving the hospital in 23 hours and most returning to nearly full activity within a matter of days (compared to several weeks with an open procedure). While the patient clearly benefits from this less invasive approach, the hospital also wins as shorter lengths of stay post-procedure improves the profitability of the case under the current fixed DRG reimbursement system.

Dr. Srivastava also stated that he is now using Cardica's C-Port product in most of his cases and our channel checks indicate that the Cleveland Clinic and Mayo Clinic are now emphasizing less invasive CABG in their revascularization programs. With these high-profile facilities migrating toward less invasive coronary bypass and thought leaders such as Dr. Srivastava using and educating surgeons on this approach, we anticipate that momentum will continue to build in performing these procedures in the coming months. We continue to expect this conversion to be gradual, as surgeons typically need to deploy the C-Port on at least 10 "ideal" vessels before becoming proficient with the use of the device. However, in our view, less invasive bypass will become the standard of care in treating patients in the coming years as patients increasingly demand these procedures rather than having their chest "cracked" open, physicians realize that they must employ the technique or risk losing cases from their interventional cardiology referral network that have taken years to develop, and hospitals push for less invasive approaches in order to improve profitability. As essentially the only provider of automated anastomosis devices, which are key facilitators of less invasive coronary bypass procedures, we believe that Cardica should meaningfully benefit from this building movement towards these less traumatic approaches and that unit growth should be significant in the coming quarters.

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