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Device M&A Rebound Continues: With Ardian, Sadra Deals Show Appetite For Big, Early-Stage Acquisitions

By David Cassak, Tom Salemi, *In Vivo* 12/01/2010
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EXECUTIVE SUMMARY

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The acquisitions add to what already has been an improved year for medical device

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mergers and acquisitions. (*See "Stryker And St. Jude Acquisitions Signal Year-end Uptick in Device M&A,"* IN VIVO *, November 2010 [**20108000187**].*) The deals also are good news for start-up companies generally by showing that both of these large companies continue to be active acquirers at a time when questions had been raised about both companies appetites for new deals – Medtronic because of the potential need to integrate its recent major acquisitions in transcatheter valves and atrial fibrillation, and Boston Scientific because of the company's ongoing financial concerns.

Ardian ultimately may command one of the highest – if not the highest – prices for a venture capital-backed medical device company. The company has developed a novel percutaneous approach for lowering hypertension in patients for whom medical therapy, the primary treatment for high blood pressure, has proven ineffective – a huge and growing market. The device utilizes the body's nervous system, specifically the renal nerves, to lower hypertension through a process called renal denervation. Medtronic paid $800 million up front for the 89% of the company it didn't own. But shareholders in the company are hoping the final price tag will pass $1 billion when milestone payments are paid. ‹‹Hank Plain››, general partner at Morgenthaler Ventures, a seed investor through the incubator **The Foundry Inc.**, estimated the additional payments could hit $500 million. The final payments are equal to revenue growth Medtronic will earn selling Ardian's *Symplicity* catheter system in Europe, where it already has CE mark. The revenue expectations are based largely on sales as a treatment for hypertension, but Medtronic could potentially tap into other sizable markets for Ardian's technology including most notably diabetes, where the company already has collected some early data.

Ardian, like Sadra, doesn't yet have FDA approval for its lead device, the Symplicity system. The device, delivered by a catheter into the kidney, administers a low dose of radiofrequency energy to disrupt the renal sympathetic nerves, which in turn lowers blood pressure. The company released data at the American Heart Association in October showing that after six months, patients treated with Ardian's device experienced a drop in blood pressure of 32 points compared to an increase in blood pressure in a control group. The results were promising enough to spark a bidding war for Ardian by several medical device and pharmaceutical companies, according to CEO Andrew Cleeland. Cleeland sought out pharmaceutical companies as potential investors in the company's most recent financing round, but Medtronic ultimately led the deal, acquiring 11% equity and certain distribution rights in Asia. [**200930093**]

Chad Cornell, vice president of corporate development for Medtronic, said the company has been acting earlier when it identifies an area with huge market potential, like hypertension in the case of its recent proposed acquisition of Ardian. The company felt comfortable acquiring CoreValve Inc. (now **Medtronic CoreValve LLC**) and Ventor Technologies Ltd. in transcatheter valves, and Ablation Frontiers Ltd. (now **Medtronic Ablation Frontiers LLC**) and CryoCath Technologies Inc. (now **Medtronic CryoCath LP**) in atrial fibrillation

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- Ardian Inc.
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- St. Jude Medical Inc.
- AGA Medical Holdings Inc.
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- Symetis SA
- The Foundry Inc.

when none of them had FDA approval. "What you're seeing is in certain areas where we feel that we know the market, we understand it and we understand the risks, we're willing to move earlier," Cornell says. "And those also happen to be areas where they're PMA products that require significant clinical studies, which is a competency that we're looking to leverage in these deals." **[200910024]** **[200910025]** **[200910002]** **[200810168]**

Sadra Medical, like CoreValve and Ventor, is an aortic transcatheter valve company. Boston Scientific acquired Sadra for $193 million and $193 million in milestones. (Boston Scientific already owned 14% of the company, making the actual total purchase price $450 million.) For Sadra Medical, the acquisition by Boston Scientific marks the next step in a continuing trend: large cardiovascular giants, most notably interventional device companies, staking their claim in a space, percutaneous valves that just a few years ago they seemed unlikely to contemplate. Indeed, through the 1980s and 1990s, as interventional tools and techniques were enhanced and improved upon, percutaneous procedures made significant gains in revascularization, dramatically reducing surgery as a treatment option for all but the most severely ill patients and those with complex coronary disease. Surgeons who saw their CABG procedures decline dramatically had one solace: their role in repair and replacement of valves would go unchallenged.

Thus, we've seen the significance of the rising tide of TAVI (transcatheter aortic valve interventions) over the past several years. In large part because of a more cautious FDA, the roll out of percutaneous valves has differed from that of percutaneous revascularization devices in one important way: instead of initially targeting the broadest, least acute patient population, the way stents were, transcatheter valves are first being employed as a kind of last-option resort for patients who otherwise can't tolerate surgery. But the interest shown in percutaneous valves by Boston Scientific in this deal – and earlier by **Abbott Laboratories Inc.** in its 2008 acquisition of **Evalve Inc.**, though a mitral valve play – leaves little doubt that the big interventional players see the potential for TAVI making greater and greater in-roads into less high-risk valve patient populations. **[200910100]**

Boston's interest in Sadra wasn't new. The company had long had an investment in Sadra and, indeed, several years ago, when BSC largely divested itself of its portfolio of minority investments, it kept its holding in Sadra, reflective even then of the promise the large company saw in the TAVI opportunity. (*See "Boston Scientific Shuffles and Sells in Bid to Right Ship"* IN VIVO, *December 2007. **[2007800191]***.) Leslie Bottorff, general partner at Onset Ventures and an early investor in Sadra Medical, said Sadra didn't seek bids from other buyers. "We'd been partners with Boston for four years," Bottorff says. "I guess they decided that the time was right." She declined to provide any details about the process but did say that Boston Scientific didn't have a pre-existing right-of-first refusal. Like Ardian, Sadra's acquisition was preceded by a positive clinical development. The company had just completed enrolling patients in its feasibility trials in Europe. It

expects to begin trials for a CE mark next year.

While both companies did make progress in clinical development, both face a long road ahead. The FDA still hasn't approved a device in either product area. Ardian's application of radiofrequency energy to the kidney's renal nerve is a novel approach, although the concept behind the procedure does have some surgical precedent. But the potential markets for both Ardian's and Sarda's devices constitute very large opportunities. In Ardian's case, in addition to the huge hypertension market, since hypertension is an underlying mechanism for other serious chronic conditions, including heart failure, kidney disease and diabetes, the company is hopeful that this device-based therapy may be effective in treating those diseases as well. *(See "Ardian: Succeeding Where Drugs Fail - Treating Hypertension in the Cath Lab,"* IN VIVO, *November 2009 [**2009800207**].)* Medtronic's Cornell saysthe company paidwhat it did largely for opportunities in treating hyptertension, but the otherareas are certainly attractive.

Under the terms of the acquisition, Medtronic agreed to pay for future revenue growth of Ardian's Symplicity device until 2015. So if the company's sales grow from $10 million this year to $20 million next year, investors will be paid $10 million. These payments continue until 2015. ‹‹Plain›› says investors estimate the additional pay out could reach $500 million, but that depends largely on Medtronic's commercialization plans. "I give credit to Medtronic for proposing a creative structure," says ‹‹Plain. "It's always hard to sort out what the value of a company like this is, where we obviously have high expectations for what the sales ramp could look like, especially if we're successful in getting a US approval and launching in 2013, because that obviously would be the real kicker that would drive the upside."

Meanwhile, percutaneous aortic valves like those developed by Sadra hold promise to be the next potential blockbuster interventional device. **Edwards Lifesciences Corp.** and Medtronic CoreValve are the leaders in Europe, and Edwards has a significant lead in the US, where it has already reported initial clinical data, while Medtronic is about to begin its US trial. (*See "Edwards: Transcatheter Valve Leader Proves You Can Go Home Again,"* IN VIVO, *November 2010 [**2010800180**].)*

This broad confidence in transcatheter valves is, as noted, very likely good news for the remaining venture-backed valve start-ups in this space, including **Direct Flow Medical Inc.**, **JenaValve Technology GMBH**, and **Symetis SA**, as companies like **Cordis Corp.**, a **Johnson & Johnson** operating company, and Abbott, looking to add aortic valve technology to its mitral valve portfolio, seek to take advantage of the move toward TAVI – now clearly one of the hottest spaces in medical devices. Johnson & Johnson has publicly announced that it has discontinued its in-house percutaneous valve program, leaving M&A as the company's potential path to enter this market. Some venture investors insist they're shying away from new aortic valve plays, and prefer to focus on technologies that enable TAVI. But at least transcatheter valve plays, certainly aortic and likely mitral and even pulmonic as well, offer venture investors

something they love to see: an almost assured exit to an eager acquirer.

All of which leaves, interestingly, market leader Edwards in an enviable, but perhaps at the same time, the most uncertain, position. Just over a decade ago, soon after spinning out of **Baxter International Inc.**, Edwards crafted a careful strategic plan that saw the company focus on patients suffering from long-term coronary disease and structural heart problems. The strategy had two primary virtues. First, and foremost, it would build significantly on the company's technology strengths – most notably its leadership in valve repair and replacement – and take advantage of its strong relationships with surgeons. But just as importantly, the strategy enabled Edwards to build a robust business steering clear of the large cardiovascular device companies who for much of the past decade have focused on interventional cardiology and, to an almost equal degree, drug-eluting stents – the first blockbuster cardiovascular device category. [**200030278**]

Now percutaneous valves holds promise to be a blockbuster in its own right, and for now, Edwards stands poised to take advantage. But the turn of events has interesting implications for Edwards. No one would suggest that Edwards had any other option than to push forward in its goal of taking a leadership position in percutaneous valves, even given the risk of alienating their surgeon customer base. But as the BSC/Sadra deal illustrates, in doing so, it has clearly been forced to alter its earlier strategy.

Edwards officials themselves note that three years ago the company didn't even take booth space at major interventional cardiology meetings like TCT and PCR. Today, Edwards is a major presence both on the exhibit floor and on the clinical program. Indeed, results of its PARTNERS trial have been the highlight of both meetings this year and arguably one of the most anticipated clinical trials over the past several years in interventional cardiology, the evidence-based specialty with probably the largest number of clinical studies. PCR this year launched its clinical program with what it billed as "The Great Debate," asking whether TAVI is truly a viable option – a debate that, as the session played out, really wasn't much of a debate as both interventionalists and surgeons appear convinced that adoption of this technology is more a matter of when than if. (*See "At PCR, Valves Steal The Show, But DES Shine,"* IN VIVO *, June 2010 [**2010800110**].*)

As TAVI has become a major focus of percutaneous medicine, Edwards has found itself drawn into the world of interventional cardiology, whether it likes it or not. The notion that the company can continue to build on its leadership in valves and, at the same time, avoid head-to-head confrontation with the big players seems increasingly unlikely. Discount Medtronic, which was itself a major player in valves – looking ahead, Edwards is likely to find itself competing directly with Abbott and Boston Scientific as they seek to build out their percutaneous valve portfolio. Even more threatening to Edwards: rumors that circulated at TCT that Abbott was preparing to make a takeover bid for the company in order to complement its mitral valve business. This on the heels of earlier rumors that J&J is also interested, as Cordis, too, seeks to find a footing in TAVI. If it winds up being

acquired by a large competitor, Edwards – and its shareholders and executives – will almost certainly reap huge rewards. But will the company have won the battle in percutaneous valves, but lost the war?

Ardian and Sadra, with technologies capable of altering how care is delivered to large patient populations, will generate significant returns for their investors, having raised $66 million and $54 million, respectively. **[200930093]** **[200430481]** **[200630383]** **[200930779]** **[201030431]** The improvements in care that these companies' technologies offer appear to be significant enough to allay rising concerns over whether the creation of innovative new devices will be rewarded with premium pricing and adoption. Indeed, these acquisitions clearly show that despite the fears of new technology increasing the costs of health care, strategic buyers are willing to loosen their purse-strings when the opportunity warrants.

– David Cassak and Tom Salemi