

# VERTOS MEDICAL'S Blue Ocean Opportunity

*Vertos has a promising new device to treat spinal stenosis and a strategy that focuses not on spine surgeons, but on a new breed of pain specialists.*

BY DAVID CASSAK

- Spinal stenosis is a painful, debilitating condition that can seriously inhibit a person's mobility. Treated mostly by drugs and physical therapy, stenosis is now attracting more attention from device companies.
- Vertos Medical has a new approach, called minimally invasive lumbar decompression, that relieves pain and may help to hold off the need for surgery later on.
- But the company's earlier sales and marketing efforts ran into trouble because they targeted spine surgeons, who don't see enough of these patients who, most often, aren't yet candidates for surgery.
- Vertos has now re-vamped and streamlined its sales efforts, focusing on a small group of interventional pain specialists, who are more likely to treat these patients, thereby greatly expanding its population of potential patients.

Consider all of the things that have to go right to successfully develop and launch a new medical device: first of all, it has, of course, to be safe and effective, delivering on the therapy that its developers intended it to. If it passes those tests, it's likely to satisfy device regulators, but still has to prove to payors that it warrants coverage—something that used to be a given once FDA approval or clearance was gained but is no longer a sure thing. Finally, the device has to be one that physicians are comfortable with—unlike drugs, devices are tools in the hands of clinicians and if doctors find the device uncomfortable to work with or the procedure it requires too complex, many are likely to stick with an older device they're already accustomed to using.

Each of those issues presents a hurdle in its own right: in spine, one of the most fertile grounds for new device development over the past decade, add one more hurdle: a surgeon customer base that is, at once, overwhelmed by all of the new device options spine companies are creating, and a conservative mindset that requires substantial clinical proof of a device's effectiveness before surgeons feel comfortable adopting it. Indeed, given how many start-up companies and their investors have rushed into spine over the past decade or so, one might assume that getting spine surgeons to adopt new technology is relatively easy. Just the opposite, as evidenced by the fact that, less than five years after the launch of the first artificial disc was supposed to usher in the era of motion preservation, surgeons are still arguing for the benefits of fusion

over disc replacement—underscoring the tension between new devices and traditional therapy options.

Two other factors further play into the difficulty of a successful launch of a new spine technology: the strong role played by an entrenched distribution system, which has a tendency to bias in favor of technology and companies already well-established in the marketplace, and the complexity and myriad of spinal problems, many of which don't immediately require surgical therapy. What's a small company to do? There's not much it can do about the regulatory or reimbursement challenges. But one spine start-up, Aliso Viejo, CA-based **Vertos Medical Inc.** has found a creative way around the adoption issue. Promoting a novel approach to spinal stenosis, Vertos' solution to the distribution channel issue is to focus on the patient, rather than the surgeon, treating stenosis earlier in the continuum of care by reaching out to a new clinical specialty, interventional pain physicians.

## A MILD APPROACH

Vertos was founded in 2005 by two interventional neuroradiologists, Donald Schomer, MD, and David Solsberg, MD, who were looking for a way to treat cancer patients who had also developed lumbar spinal stenosis but, because of their cancer, couldn't tolerate surgery.

Spinal stenosis is a painful condition that results from a narrowing of the spinal canal; in effect, the nerves in the neural foramen and spinal canal become trapped and pinched when the canal narrows. Patients who suffer from spinal stenosis experience little or no

pain when seated because the foramen and canal areas open up, but have a hard time when standing because the trapped nerves are squeezed when the area narrows. (The pinched nerves can cause both pain and a feeling of weakness in the legs.) Thus, many patients with spinal stenosis use walkers to get around—the forced stooping the walker causes relieves the pain by keeping the foramen and canal areas from collapsing on the nerves.

Because it's a degenerative condition, spinal stenosis occurs more often in elderly patients, though it can occur in younger patients as well—as noted, Vertos' founders were targeting cancer patients, who can be of any age. Today, most therapy focuses on treating the pain, rather than the underlying cause, and includes non-surgical approaches such as anti-inflammatory drugs like NSAIDs, and epidurals, physical therapy, and lifestyle modifications. Such therapies palliate the pain, but they have a significant impact on the patient's lifestyle—spinal stenosis patients can no longer play golf or tennis and even are likely to cut back on walking.

For those patients who don't respond to drugs or physical therapy, there's always a surgical alternative: a laminectomy or surgical decompression to remove the hypertrophic ligament and bone, a procedure that is highly invasive and, like all surgeries, traumatic with a higher risk of complications. "In a laminectomy, you remove the whole ligament and bone, it does decompress the spine," notes Vertos president and CEO Jim Corbett. "But it also destabilizes the spinous process and can lead to the need for a fusion later on."

Vertos' device, which is called the *mild* system, uses a fluoroscopically guided approach to de-bulk the ligaments in the stenotic region that are pressing on the nerves, causing pain. After a trocar is inserted into the lamina space, a bone cutting device is used to clear space in both the inferior and superior parts of the lamina where the disc has collapsed or compressed. (The cutter also retrieves the bone shards since they can't just be suctioned out as they would in an open surgical procedure.) A proprietary sculpting tip is then used to allow the surgeon to reduce the size of the ligament; in stenotic patients, a ligament that is normally two millimeters thick, may expand to six or eight millimeters, which results in nerve compression. The de-bulking relieves the pressure and the resulting pain and an epidurogram tells the physician when he or she has removed enough of the ligament to achieve pain relief.

## RED OCEAN/BLUE OCEAN

Vertos is one of a handful of small spine start-ups—perhaps the most successful one to date has been St. Francis Medical Technologies, now part of **Medtronic Inc.**—that are targeting spinal stenosis as a primary opportunity. (See "St. Francis Medical: Staking Ground in Dynamic Stabilization," *IN VIVO*, March 2006.) And to realize that opportunity, the company a year ago turned to a seasoned device industry executive, Jim Corbett.

Prior to taking over as CEO of Vertos, Corbett had served as CEO of peripheral and neurovascular leader **ev3 Inc.**, helping to steer the company from its days as a start-up, along with ev3's other co-founders Dale Spencer and Paul Buckman, to a publicly traded company doing \$450 million in sales annually and generating \$80-100 million in cash. (By the time he was named CEO, Corbett was running ev3 himself, as Spencer and Buckman, now CEO of **Pathway Medical Technologies Inc.**, had moved on to other projects.)

Corbett's tenure at ev3 was by most measures a success—under his direction, the company established a new strategic direction focusing on peripheral and neurovascular devices and achieved significant sales growth. But by 2007, three years after ev3 went public, the fit for both Corbett and ev3 was becoming uncomfort-

able. Critics blamed Corbett for what was seen as an expensive, difficult, and perhaps ill-suited acquisition, that of peripheral atherectomy pioneer FoxHollow Technologies Inc. Though he insists that the FoxHollow deal was strategically sound, even Corbett concedes that "the front end of the acquisition was fairly bumpy." And Corbett himself had begun to feel the constraints of running a public company that was no longer a small, entrepreneurial start-up but rather had become a largely mature mid-cap company. (In addition, his stint at ev3 had the added strain of commuting regularly from his home in Southern California to the company's headquarters in Minneapolis.)

Prior to ev3, Corbett had played a key role in the launch and early success of SciMed Life Systems Inc., where he first worked with Spencer and Buckman, and he notes that the early days of companies are "the stage of company I most enjoy." About his departure from ev3, Corbett says it came as a result of discussions between himself and the board. "I like to build companies," he goes on. "And following the FoxHollow acquisition, the public aspect of the job just wasn't all that enjoyable. The company was still growing and I think we all felt it was time for a change."

Having left ev3, Corbett began to think about what he wanted to do next. Something in cardio- or peripheral vascular would have been a natural—even before he joined ev3, Corbett had spent formative years at American Hospital Supply's Edwards division. He also had stayed on at **Boston Scientific Corp.** following that company's acquisition of SciMed in 1995, where he became president of Boston Scientific International, helping to build the company's interventional cardiology business into a global leader.

But Corbett at the time was reading a book on business strategy called "The Blue Ocean Strategy." The book posits that there are two kinds of businesses: so-called Red Ocean plays where the businesses are more mature, the rules are well-known, and the fundamental issue becomes one of competition—winning by taking market share from well-entrenched players. "The perfect example is coronary stents," Corbett explains. "Getting into the coronary stent business requires an innovative design, huge amounts of money, deep investment in clinical research, and a massive commercial force."

Many start-ups target Red Ocean opportunities—they're often very large markets and therefore investment capital is readily available. But they can be challenging if not impossible for small companies as well because in well-established markets, finding truly novel, differentiated technology is difficult, and other costs, such as the cost of running complex clinical trials and building a sales and marketing force, can drain even the deepest-pocketed resources. Sticking with the coronary stent example, Corbett points to a company like Xtent, now defunct, whose innovative modular design was defeated, in large part, by the huge amounts of money required to bring its stent to market.

Most importantly, a lot of small companies target Red Ocean plays simply because they're well-established and "comfortable," Corbett says. "Their attitude is, 'Let's do something everybody else is doing. It'll be easy to do.'" Blue Ocean opportunities are just the opposite: promising areas with few competitors but also little in the way of established rules or reassuring role models or predicates. Blue Ocean opportunities don't have to be totally novel—they can be in familiar technology plays or clinical spaces. In fact, you want them to have some grounding in an established field otherwise you're doing missionary work—but they have to significantly alter the business model in well-established areas. But all Blue Ocean plays in some significant way re-define what otherwise looks like an obvious or conventional opportunity.

By way of example, Corbett points not to medical devices, but to circuses. Traditional big-tent, multi-ring circuses represent a huge industry—\$5 billion a year—and are built on some fundamental principles: make admission as cheap as possible and drive revenue and profits by getting customers to pay a lot for overpriced food and souvenirs once inside. Red Ocean circuses thus all look a lot alike and smaller competitors get in the game, hoping they can carve out a small share of the business dominated by well-entrenched competitors like Ringling Bros. and Barnum & Bailey while essentially playing by the same rules.

Blue Ocean circuses are more like Cirque du Soleil—elaborate, upscale productions that cost \$150 to view but are more like theater than conventional circuses. At Cirque, no one makes money selling popcorn or clown noses; people pay one high fee and then sit back and enjoy the show. Moreover, it’s a model that is replicable so that Cirque du Soleil can have multiple versions running in different cities across the country at the same time.

As noted, Blue Ocean opportunities aren’t completely novel or ground-breaking—in fact, part of their appeal is that they look a lot like conventional large opportunities. It’s just that success in Blue Ocean spaces rests on changing the rules in those large, established markets. Corbett argues that, in many ways, ev3 represented a Blue Ocean play in medical devices—it’s not that no one had ever tried to develop a company focused on peripheral vascular devices. But most big cardiovascular companies saw peripherals as a secondary or tertiary business opportunity, always taking a back seat to the coronary opportunity. Ev3 innovation was to identify the peripheral market as an opportunity around which to build a business by building devices specifically designed for that anatomy, rather than re-designing coronary products.

## A CATCH-22

The Red Ocean/Blue Ocean model resonated with Corbett when he began looking for something to do post-ev3. “I had a whole checklist of things I wanted to see in what I did next,” he says. “I wanted to find a unique opportunity, something very different, but one that isn’t so revolutionary that it would take 10 years to make it happen.” In a funny way, spine fit a lot of those criteria.

No one would possibly argue that novel technologies in spine are rare or hard to find. Moreover, the market today remains large and dynamic, still one of the fastest growing in all of medical devices despite its recent struggles. But if spine start-ups have run into problems lately, it’s because, in effect, this dynamic, growing market has taken on some very Red Ocean characteristics. For one thing, well-entrenched market leaders dominate the space. Perhaps more importantly, surgeons tend to be conservative in their adoption of new technology—often asking for years of clinical data proving strong outcomes—and to rely heavily on relationships with distributors in the selection of devices. For small companies in particular, there’s often a kind of Catch-22 in winning over distributors—most distributors are reluctant to take on a new line or technology unless there’s significant demand for it, and it’s hard to generate significant demand without a strong base of distributor support.

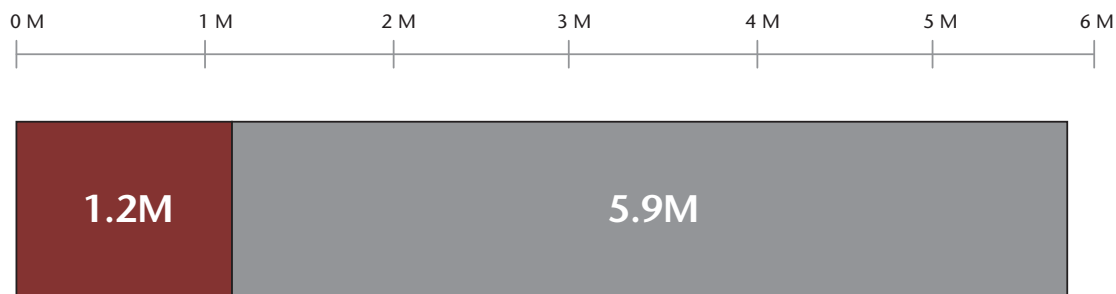
All of these factors add up to a market in which small companies—even those with clearly differentiable technology—can find it difficult to break in. Though the company was only three years old at the time, Vertos was already something of a later-stage company by the time Corbett arrived in 2008. Funded initially with some angel money, the company had raised a total of \$17.5 million in three venture rounds. Corbett closed a Series D round in October of this year that netted an additional \$15.5 million, a round led by Onset Ventures that included all of the insiders as well. When Corbett joined as CEO in November of 2008, the company was already selling its device, and he expects the Series D round should take Vertos to full commercialization and

will very likely be the company’s last private financing. “I don’t think we’ll need to raise any more money,” he says.

When he first started looking at Vertos, Corbett says he immediately saw the opportunity, but also quickly came to the conclusion that Vertos “needed to rethink” its market opportunity. Indeed, Corbett argues that there’s a kind of Blue Ocean quality to the clinical effect of Vertos’ fluoroscopically guided approach to stenosis. He notes that studies of thousands of decompression surgeries show around 10% intra-operative blood transfusion, a 9% incidence of dura tear, three-and-a-half days in the hospital, and a surgical procedure,

### EXHIBIT 1

## US Annual Incidence of LSS



- Low Back Pain physician visits: 31M<sup>1</sup>
- Symptomatic LSS patients: 1.2M to 5.9M<sup>2,3</sup>

#### SOURCES:

(1) Licciardone JC; *The epidemiology and medical management of low back pain during ambulatory medical care visits in the United States*. Osteopathic Medicine and Primary Care 2008.

(2) Kalichman et al; *Spinal stenosis prevalence and association with symptoms: The Framingham Study*. The Spine Journal 2009.

(3) *Treatment of Degenerative Spinal Stenosis: Evidence Report*, Agency for Healthcare Research and Quality (AHRQ) 2001 (www.ahrq.gov).

done under general anesthesia, that usually lasts two hours or more. By contrast, in the 300 cases Vertos had done as of early October of this year—one-third of which were done in September alone—there wasn't a single transfusion, intra- or post-operative, and very little tissue disruption or damage—with no dura tears. Moreover, 98% of the patients have gone home the same day as the treatment—all of which is due to the minimally invasive approach. Corbett points to one patient, an 87-year-old man, who could only get around using a walker. His procedure took under an hour, Corbett says. "Three hours later, he walked out of the hospital without his walker." More impressively, the procedure was performed on a Monday; the following Thursday, he played 18 holes of golf. "And that's a pretty common occurrence with our procedure," he notes.

## A NEW TARGET

But it is in Vertos' approach to the market that Corbett really saw the Blue Ocean opportunity and sought to shake up the rules about how spine start-ups launch products. That Corbett should focus most on Vertos' sales and marketing strategies wasn't surprising. It was Corbett's expertise in sales and marketing that attracted Vertos' investors in the first place—the company's Series C investors, led by two Connecticut-based VCs, CHL Medical and Foundation Partners, who invested, says Corbett, "with the intent of strengthening the management team to take the company forward," and in particular, sought someone with strong commercial experience.

In fact, with FDA approval in hand, by the time Corbett arrived in late 2008, Vertos had already hired a small team of reps to begin selling to neurosurgeons and spine surgeons. But Corbett says he immediately sensed that Vertos' sales strategy "needed to be repositioned." Asked why, Corbett says, "That's what I wanted to understand: where did the *mild* procedure fit?"

Soon after taking over, Corbett began some extensive market research, talking to doctors and reviewing the literature on compression fractures. Specifically, he wanted to find out how often spine surgeons actually see the patients for whom Vertos' de-bulking technology was most appropriate.

While surgery remains the most likely recourse for those patients who no longer respond to drugs and physical therapy, there are intermediate steps that can be taken. Corbett recognized that there is a continuum of care for spinal stenosis patients that runs from palliative measures like drugs and PT on one end to surgery, the most invasive therapy, on the other. In effect, patients turned to surgery only after other therapies no longer were proving effective.

In the middle of the continuum, patients were more likely to get epidural steroid injections to treat the pain and delay surgery. Surgery, Corbett concluded, wasn't so much an alternative to pain medication and PT as a kind of last-stage therapy. The key for Vertos was to get to patients earlier in the continuum of care, in that space before they got to surgery.

The notion of intervening earlier, pre-surgery, not only more appropriately places Vertos' procedure in the continuum of care, it also dramatically increases Vertos' patient base. As he interviewed surgeons and reviewed the clinical literature, Corbett discovered that the actual number of patients in Vertos' sweet spot that a typical spine surgeon sees each month is really very small. High-volume spine surgeons might do 300 procedures per year—of that number, around half, or around 150, will be spinal stenosis patients. And of that 150, another half might get fusion.

As Corbett continued to refine the target patient for most surgeons, he discovered that the number of cases in which a surgeon would use Vertos' technology is actually quite small. "I realized that if we were

going to call on spine surgeons, we could expect even the busy ones to see only a few cases per month," he says. And if the surgeon isn't a high-volume provider, he or she might only see one or two patients a month. About Vertos' early plans to target spine surgeons, Corbett concluded, "Our subsequent research and early commercial experience made it clear that we needed to shift the business model."

## TARGETING PATIENTS, NOT SURGEONS

Describing Vertos' target patients, Corbett notes that it becomes clear patients have developed stenosis when they have trouble walking or standing for 15 minutes. "It's when they're in so much pain they can't move, they have surgery," he says. But in between patients often undergo a number of other treatments rather than have surgery, often over a long period of time. Phrased differently, Corbett realized that there are only some 220,000 laminectomies and laminotomies performed each year, a relatively small base upon which to build a business and one that is highly competitive, with dozens of other surgical tools and devices a surgeon can use. But most patients may go three years from diagnosis to surgery, which means that at any point in time, there are something closer to 660,000 target patients for Vertos, all pre-surgery and all treated, currently, primarily with epidural steroid injections. As he reviewed all of the clinical data and longitudinal studies, Corbett concluded that that is the patient group Vertos should focus on.

Corbett's identification of a new, much larger patient base was Blue Ocean thinking in its own right; but there was an even more Blue Ocean-like quality to the plan that he was formulating for Vertos. If many of these patients are targeted before surgery, it means that spine surgeons aren't necessarily Vertos' best target customers. Not that they aren't important—they're simply not Vertos' primary targets. Toward that end, Vertos shifted from its original focus on spine surgeons and began to target a new specialty, interventional pain physicians—doctors trained primarily as interventionalists whose major aim was to relieve pain in patients who were not going to go for surgery. Though still small today, pain specialists are a growing group with their own specialty society, the American Society of Interventional Pain Physicians (ASIPP)—with 450 physicians at the most recent pain specialist meeting, "it felt a lot like TCT in the early 1990s," says Corbett, referring to an interventional cardiology conference that now regularly draws more than 10,000 attendees. (See sidebar, *Interventional Pain Specialists: A Physicians' Perspective*.)

Spinal stenosis patients might be referred by a GP or primary care physician before the patient even sees a surgeon or, if the PCP referred the patient to a surgeon, by the surgeon himself, if he felt the patient was in sufficient pain, but too early to require surgery. Interventional pain physicians are a doubly attractive audience for Vertos, first for their focus on patients earlier in the continuum of care and, just as importantly, for their familiarity with fluoroscopically guided procedures. In turn, Vertos is attractive to pain specialists: the technology not only expands their treatment options to include therapeutic intervention, but the *mild* procedure could also replace a series of epidural steroid injections with just one minimally invasive procedure, a therapy change that would be most welcome to patients.

Talking about this shift in Vertos' strategy, Corbett argues that, "Ultimately, it's not about the physician, it's about the patient." Still, Vertos has been careful not to position itself as an anti-surgery play. Indeed, several of the physicians on Vertos' SAB are spine or neurosurgeons, and Vertos' reps could honestly tell their spine surgeon contacts that they weren't even targeting the 220,000 patients who are candidates for surgery, but rather a larger group of patients who

## INTERVENTIONAL PAIN SPECIALISTS: A PHYSICIANS' PERSPECTIVE

Trained as an anesthesiologist, Lora Brown, MD, is one of a new breed of physicians, an interventional pain specialist, who will play a critical role in determining the success of Vertos Medical Inc.'s novel spinal stenosis technology. Interventional pain management is, she says, "a relatively young specialty" and "one of the most recent [clinical spaces] to be identified as a full-fledged specialty with board certification status," emerging only in the last 15 to 20 years.

Pain specialists treat patients suffering from any type of chronic pain, though Brown herself, like many of her colleagues, has a practice with a large number of patients with spine pain. A combination of an aging population and one that is increasingly sedentary has, she goes on, "led to a lot of degenerative spine disease," in the form of spinal stenosis, disc herniation, and other conditions. (Spine patients who've failed previous back surgery are also candidates for aggressive pain management.)

Spinal stenosis itself is "incredibly common," Brown continues, especially in the elderly population. "It's a disease we're all going to get if we live long enough." Some people get it earlier in their lives, she goes on, either for congenital reasons or because they are born with spinal canal spaces that are smaller in diameter. Patients with spinal stenosis experience severe back pain that is often provoked by standing or walking for extended periods of time. "The pain is immediately relieved when they sit or lean forward," she notes. "These are the folks that you see at the grocery store [who are] leaning on their cart the whole way through because when they lean forward, their spinal canal opens to maximum diameter, and it takes some of the load off the spine as well."

Spinal stenosis patients get to an interventional pain specialist in a variety of ways—they may be referred by a primary care physician, a neurologist, or even come through a surgeon referral. (As the specialty grows, they may also be referred by friends and family or seek out a specialist on their own.) Indeed, about her relationship with surgeons, Brown insists there's no turf battle for patients. Spine surgeons treat patients "at a different point in the continuum," she says, "and we each have our areas of expertise." She says she has good relationships with the surgeons in her community and maintains that there are times when spine surgery is absolutely called for. At the same time, there are also patients who don't really require a major, open procedure. Those patients, she goes on, "would benefit more from something like a minimally invasive

lumbar decompression procedure," that is the Vertos procedure.

Vertos aside, Brown says her treatment options for spinal stenosis patients are both therapeutic and palliative. "There are some patients who have problems that will simply not get better, and I treat those patients on a palliative basis to improve their quality of life and their level of function," she explains. "There are other patients who clearly have problems that can be fixed or remediated, and those patients actually do get better."

After employing a comprehensive diagnostic regimen to determine the exact source of the pain, Brown notes that interventional pain specialists typically have a number of different therapy choices: physical and occupational therapy, drug regimens, and injection therapies, such as epidural steroid and facet joint injections, as well as nerve ablation in the facet joints, all done on an outpatient basis under fluoroscopic guidance. Other device-related therapies include spinal cord stimulation for those suffering from intractable neuropathic pain, interthecal pain pumps, and vertebroplasty.

That said, Brown notes that "in the treatment of spinal stenosis, there hasn't been any significant device development or really any good options until recently." Brown, who now serves on Vertos' scientific advisory board, first discovered Vertos' *mild* system earlier this year at a minimally invasive spine workshop in Phoenix. A conversation with some Vertos reps led to an invitation to come to Orange County, CA, to learn more about the device.

Brown says that she "immediately saw the potential of [the Vertos device] and the synergies between what they were trying to do and what I believed needed to be done." She calls Vertos' novel approach "a potential game-changer in the way spinal stenosis patients are cared for." Brown notes that most patients who come to her office have had physical therapy and are looking either at epidural steroid injection therapy or some kind of surgery, either multi-level decompressive surgery or fusion surgery, the outcomes of which, she says referring specifically to fusion, "are not great."

"There's nothing in the continuum of care between epidural steroid injections and surgery," she goes on. "What this [i.e., Vertos' *mild* procedure] is going to do is fill that gap." In fact, Brown says, it's possible that Vertos could eventually come to replace epidural steroid injections altogether. "If patients come in with spinal stenosis, and they get an epidural steroid injection and do well for 12 to 24 months, that's a reasonable treatment," she says. "But there are a lot of folks who come in and get an epidural steroid injection, and do well for only one to three or four months, and they have to have them done repeatedly over time. That's

not great health care." If instead, patients could receive a one-time treatment that decompresses the spinal canal and alleviates pain, obviating the need for injections, and providing relief for years, "we've just revolutionized the way that patient is cared for."

The fact that *mild* is a decompressive procedure, creating structural change, makes all the difference. An epidural steroid injection, by contrast, "simply addresses intraspinal inflammatory changes and reduces swelling of the top tissue in the spinal canal," Brown says. Vertos' approach represents "much better therapy because you're actually decompressing, or removing the tissue that's causing the problem." (Patients with stenotic spinal canals have a kind of venous congestion, an obstruction of blood flow to neural structures at the top of the spine, she explains. And "prolonged standing and walking causes blood flow to be cut off from the nerve, which is what results in the pain, forcing the patient to either sit or to lean forward," she says.)

In Brown's view, there also may be benefits to the overall health care system from the Vertos procedure. She notes that spinal stenosis is "a pathology that traditionally has not had a definitive therapy until very late in the treatment process." Vertos' approach is, she says, "almost like a preventative medicine measure. If we can treat patients early enough, we might in the end save the health care system millions of dollars," by preventing repeated physician office visits, physical therapy sessions, and epidural steroid injections.

And Brown says the procedure itself is very easy to perform, especially for interventionalists who are adept at working under fluoroscopy. "There are different degrees of comfort with the different skills needed for this procedure," she says. Physicians not used to or comfortable with looking at the spine under fluoroscopy "may struggle a bit," she says. But "if you are a physician who has strong clinical anatomy knowledge and good fluoroscopic skills, this procedure is a piece of cake," because it "fits really well" with the other interventional procedures interventional pain specialists do all the time, including implanting devices for spinal cord stimulation and neurostimulation and, in particular, vertebroplasty, to which Brown says the *mild* procedure is most closely related in terms of necessary skills. Training, too, is quick and easy. Brown, who says she is one of those with strong interventional skills, "was comfortable doing this procedure after working on the cadaver once, watching a couple of cases, and working with a proctor."

weren't yet ready for surgery—though an effective Vertos therapy could likely delay the need for surgery, if not eliminate it altogether.

**WRONG MESSAGE, WRONG RESULT**

Still, Corbett concedes that Vertos worried surgeons might perceive what the company is doing as a threat—in part because Vertos' early selling efforts positioned the device as a new tool for surgeons. About the potential turf battles, Corbett says, "We work on that all the time." In part that means educating surgeons as to the real positioning of the procedure along the continuum of care. It also means finding a sales approach that doesn't focus exclusively on spine surgeons. Ultimately, he goes on, "We had to find a sales model where the solution was working with the neuro and spine surgeon as well as the pain specialist and to understand how to navigate the relationship between the two."

Other spine companies have faced similar issues—Kyphon Inc. may be the most successful example of a spine company that built a sales strategy based on embracing two different physician groups, targeting not just the spine surgeon, but also the GP who may not have recognized that for his patients with kyphosis, a condition resulting from vertebral compression fractures, there was a novel and effective therapy but they needed to be referred to a spine specialist. (See "Kyphon Steps Up," IN VIVO, May 2007 and "Kyphon's Move Into the Mainstream," IN VIVO, November 2004.)

Because of the central role that pain treatment plays in Vertos' approach, the company turned to another segment of the device industry for a model: neurostimulation. Corbett points out that neurostim companies like Medtronic, Advanced Neuromodulation Systems Inc. (now part of **St. Jude Medical Inc.**), and Advanced Bionics Corp. (whose neurostim business was acquired by Boston Scientific in 2004 and the remainder was just purchased by **Sonova Holding AG**) often target pain specialists who, in turn, often have to work with surgeons to implant their pain systems. "They could put in a lead on a temporary basis, but if it worked, they'd need the surgeon to implant the system," he explains. Thus neurostim became Vertos' model.

Vertos' novel sales strategy made sense for other reasons. For example, though Vertos is clearly pioneering a new spine therapy, Corbett says he realized early on that Vertos' technology looked nothing like the devices developed by most new spine companies. "We don't have an implant, and there isn't a lot of post-operative care," Corbett points out.

Moreover, the device isn't positioned, clinically speaking, like most spine devices. And that often led to confusion in the sales process. When Vertos reps would talk to spine surgeons about a minimally invasive procedure, many would insist they already do

such a procedure: a laminotomy. But, Corbett points out, while laminotomies may be performed in a more minimally invasive manner, they really aren't an alternative to the *mild* procedure which is fluoroscopically guided with a 5.1mm puncture and, as noted, targets patients earlier in the continuum of care. "We worked a lot on sales message," he notes. "When you go to the wrong guy and say the wrong thing, you're going to get the wrong result."

So here was Vertos' Blue Ocean: in the robust and growing area of spine, Vertos had a device that targeted different patients—those who were too early for surgery—and a different physician group—the interventionalists who specialized in pain therapy—who had different skill sets. All of which led to a new business model for Vertos, one that looked not like a conventional spine play, but like something else. Talking about Vertos' revamped sales strategy, Corbett notes, "What we needed to do was to find those doctors who have fluoro skills," and those are the guys who are implanting neurostim leads and neurostim devices." Vertos began by putting together a new sales team, beginning with a senior sales executive, Mike Enxing, who had been at ANS, and hired an additional 10 reps to begin calling on both pain specialists and spine surgeons.

Still, Corbett knew he had to pull all of this off without antagonizing or abandoning spine's core customer group: surgeons. In the end, he envisions a market in which pain specialists and surgeons co-refer, rather than compete for patients—that is, patients who present to the surgeon in pain but too early for surgery, will be sent to the interventional pain specialist and those who go to a pain specialist, who sees that the patient will only be helped by surgery, will be sent to a surgeon. "We just want everyone to work well together," he says.

**CALLING ON THE WRONG DOC**

For now, Vertos' targeting of interventional spine specialists represents a novel twist on a sales and marketing strategy for what is ostensibly a spine company, since most spine companies continue to focus on spine surgeons as their core customers. But interventional pain specialists like Lora Brown, MD, a member of Vertos' SAB, notes that as percutaneous or fluoroscopically guided approaches catch on in spine surgery, leading spine companies "are starting to call on me more and more," especially, she goes on, as her practice begins to look "a lot more like a minimally invasive spine practice than it did before."

Moreover, there's some evidence that the movement is going the other way as well. Brown notes that although she herself doesn't use surgical options in treating spinal stenosis, such as the *X-Stop* device from St. Francis Medical Technologies Inc.,

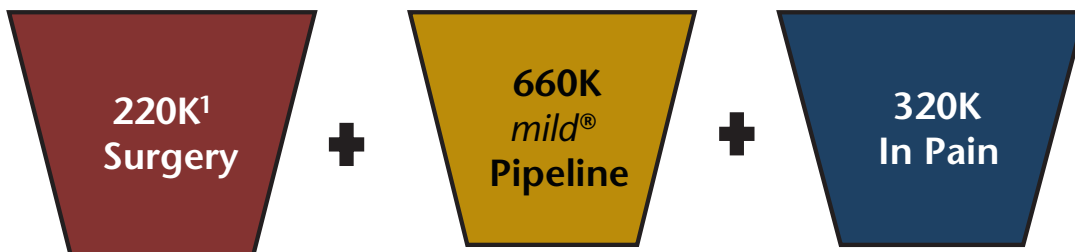
now part of **Medtronic Inc.**, she does know of interventional pain specialists who are training to implant the devices.

Indeed, while Vertos' sales strategy now seems starkly differentiated from other companies with spine technologies, it may not be for long. Brown trained on Kyphon's kyphoplasty system at the **Cleveland Clinic**—

EXHIBIT 2

**1.2 Million Symptomatic LSS Patients**

(DIAGNOSED WITH IMAGING UNDERGOING SOME FORM OF THERAPY)



(1) SOURCE: 2007 National Statistics. HCUPnet, Healthcare Cost and Utilization Project

as an interventionalist, vertebroplasty is an important part of her practice—and she argues that one mistake Kyphon made in rolling out its strategy was not to call on interventionalists from the beginning. “They were very successful in their marketing,” she says. “But the one thing Kyphon did not do initially, and it took them years to appreciate this, is that they really limited their marketing outreach to the spine surgeons. In my opinion, that was a mistake.” Thus, implementation aside, one issue Vertos faces is that as other spine companies, big and small, begin to focus on the benefits and opportunities of minimally invasive surgery, the company’s privileged relationship with interventionalists—its strategy of zigging when other spine companies are zagging—may be challenged by the very companies Vertos is now working around.

Speaking about Vertos’ new sales strategy, Corbett downplays any tension between surgeons and pain specialists by insisting that Vertos’ strategy is built around the patient and the continuum of care, not turf battles among different specialties. “We’re targeting patients,” he says. “And we’re focusing on the interventionalist because he has the patients.”

As noted, that gives a Blue Ocean feel to what Vertos has tried to do. But implementing Blue Ocean strategies can represent its own kind of challenge—particularly when coming new to a company whose employees and investors believed they had already figured out where the opportunity lay. By January of 2009, just a few months after taking the helm at Vertos, Corbett was ready to announce to the board that the company had a promising future—it just wasn’t the one they were counting on. “I showed up at the board meeting and said, ‘We need to shift strategy, and I’m going to change it. I haven’t figured out how to execute it yet, but it may involve changing the people we have,’” he recalls.

Corbett spent much of the early part of 2009 diving deep into billing codes and clinical literature, looking at longitudinal studies and talking to physicians and surgeons, all in an effort to more clearly define Vertos’ real customer and to get a better

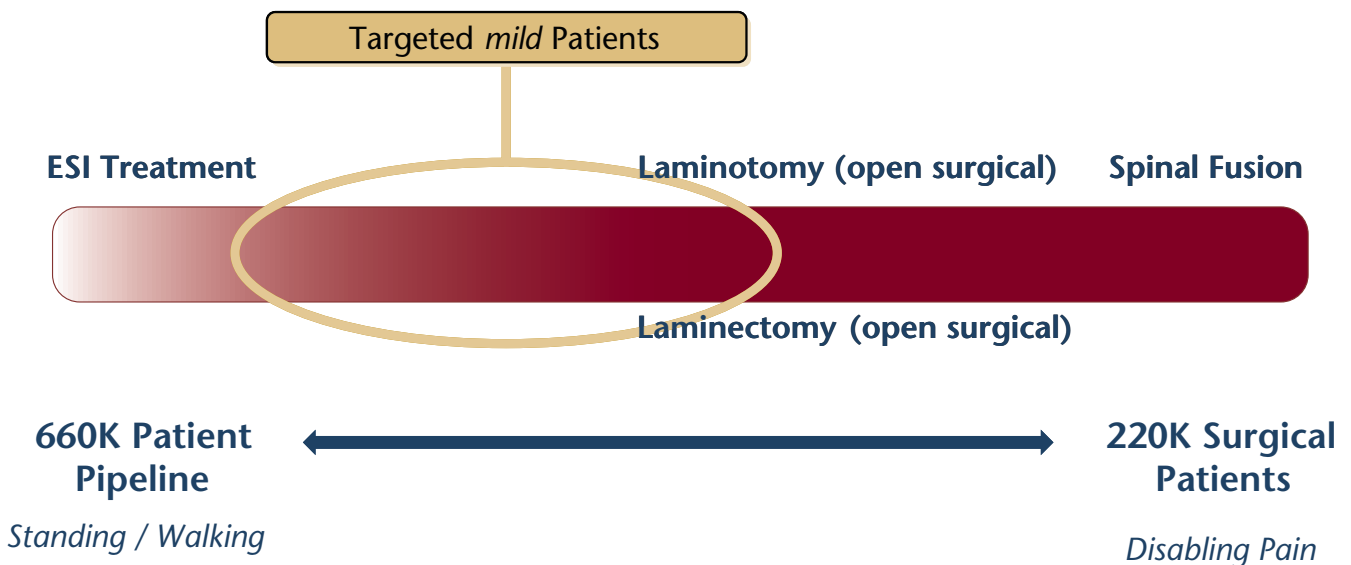
sense of the company’s opportunity and what exactly the clinical value proposition is. For example, looking at billing data, Corbett found that even within the interventional pain specialist community, Vertos’ target customer base is small—some 600 physicians out of a total of 8,000 do 50% of the epidural procedures. Some of these physicians are, in fact, surgeons who’ve developed a specialty in pain treatment; some are former anesthesiologists; and most are interventional radiologists. In addition, they may practice in academic medical centers, in large tertiary care hospitals, or in private practice in specialty pain centers, though private practice pain specialists represent by far the largest sub-group. For many of these physicians, neurostimulation devices have been the biggest device-based part of their armamentarium, though Vertos insists that the opportunity in spinal stenosis could eventually overtake their neurostim procedures. Notes Corbett, “This will be the biggest volume procedure for most of them once we get rolling.”

But getting rolling entailed more than simply formulating a new strategy. If Corbett’s view of Vertos’ opportunity had much of a Blue Ocean feel, Vertos’ previous strategy was pure Red Ocean: spine is a huge market, the reasoning went, and we’ll build a sales and marketing program around spine’s core customers. Indeed, the hiring of a new head of sales, with experience not in spine but in neurostimulation, was illustrative both of the new direction Corbett wanted to take and the challenges that he would face in executing on the strategy.

As noted, even before Corbett arrived as CEO, Vertos had already built a small team of six sales reps targeting neuro and spine surgeons. Corbett’s first message to the sales team was, he says, “Guys, we’re calling on the wrong doc because the one we’re calling on doesn’t have very many patients who are candidates for *mild*.” When Vertos’ reps worried that spine surgeons would get upset, Corbett assured them that they shouldn’t, but the reps were protective of their long-time customers and generally uncomfortable with the new approach.

EXHIBIT 3

***mild* Positioning**



SOURCE: Vertos

## PLAYING TO AN EMPTY ROOM

There were other issues as well. Vertos' training model was elaborate and expensive, calling for expenditures of around \$15,000 per training session, before travel and other expenses were calculated. But, Corbett quickly realized, such an expensive training approach wasn't going to work. "Economically, we couldn't afford it," he says.

Moreover, Vertos' original training approach wasn't just expensive, it could also be ineffective in a crowded market like spine where there are dozens of companies with novel technologies competing for surgeon attention and training time. Corbett recalls a sales training program scheduled in Las Vegas just around the time he joined the company. "We were supposed to train eight surgeons, and we spent \$15,000 to bring in a C-arm and some cadavers," he says. Moreover, everyone at Vertos was deeply invested in how well the training session would turn out; at the time, Vertos had 23 employees and nine of them were at the training session. But over the course of the session, only two of the eight surgeons actually showed up. "I realized this was not a good use of cash," Corbett says in a pointed understatement.

By early 2009, Vertos was looking for new headquarters—the company had been located in San Jose and Corbett wanted to move it closer to his home in Orange County, CA—and he began to think about building the new facility, with a specially designed training center. "I thought we should build something that's all about the customer," says Corbett, who says he looked to companies like Kyphon and Nuvasive as models. "The only way to do high-quality training economically is to centralize it." (Today, Vertos' R&D and engineering facilities are still in San Jose to take advantage of some employees who were located there, but all training, administration, clinical research, finance, and sales and marketing functions are located in Southern California.)

Corbett insists the training facility has been a success; rather than sitting around waiting for physicians to show up at a distant location, surgeons now come to Vertos and, as of early October, the company's training schedule was booked through the end of 2009. The company is now routinely training 30 physicians a month. It had reached a high of 41 in August, though Corbett says a number that high taxes Vertos' training capabilities and he has now set 30 per month as the upper limit. And, in fact, physicians trained in August liked the device but had problems with the training program. "The lesson was, 'Don't go too fast, do it well and do it right the first time,'" he says.

But early on, Vertos' reps protested; customers who were used to having spine start-ups spend a fortune to come to them would never take the time or make the effort to fly to Orange County, they argued. That debate was emblematic of a larger issue: the difficulty of getting Vertos' reps to buy into the change of direction Corbett was trying to introduce. "These were hardware guys," Corbett says. "They were high-service reps who sold implants, and they were good at it, but they didn't understand how to introduce and cause adoption of a novel idea." In the end, Vertos wound up replacing five of its six original reps—and the one who stayed had earlier worked for Medtronic in its neurostimulation program.

## SCALABLE SKILLS

In addition to expanding its customer base, Vertos' new sales strategy had one other virtue: it was much less expensive, allowing the company to burn less cash. Because *mild* is a simple, fluoroscopically guided procedure—the kind in which interventionalists are well-skilled—physicians trained quickly and didn't require sales rep support during each case. "Once the doctor is trained, our reps help organize promotional activities for the procedure and do outreach

and marketing, and there's also some logistical support," Corbett notes. "But after the second case, he's not needed in the room."

And the fact that *mild* targets the patient at a different point in the continuum of care—and therefore doesn't compete against dozens of other novel surgical devices—helps reduce rep time with any one customer and enables reps to cover broader territories. "Our rep doesn't have to be in the case to drive usage," Corbett goes on. "He or she doesn't have to be there to block the competitor because in a lot of cases, if your sales rep isn't in there with the physician all the time, someone else's rep is." As a result, Vertos was able to build an effective sales force that is much smaller than most spine sales forces. Recalling his days at ev3, Corbett says, "In the peripheral vascular business, I woke up one day and realized I'd need a 75-person sales force if I wanted to grow; anything smaller and it would take forever." With Vertos, he says, the number of reps can be smaller and the average territory much larger.

Given the importance of the focus on patients and the identification of a new target physician customer, Vertos' greatest challenge in implementing its new strategy lay arguably in the reshaping of the sales team. But in one way or another, Corbett faced similar challenges in other parts of the company as well. "On the positive side," he notes, "we didn't have a lot of employees at the time, maybe 25"—today Vertos employs just under 40 people—"and some of them stayed and some of them left."

In Vertos' case, the challenge was all the greater because, by Corbett's own admission, "I knew that the way we were doing things wasn't going to work, which is different than knowing what would work." He addressed the potential uncertainty by being very clear that he was still looking for answers. He talked to Vertos employees and went out into the field to visit surgeons, often going on sales calls. "I was very open about it," he notes. "I asked questions and did surveys. I told people I was still learning and talked about it all the time."

Moreover, many of Vertos' employees grew up in a small-company culture. To a degree Corbett wanted to preserve that culture and to avoid coming off as critical of those who stayed. But he also wanted folks with the skill sets who could help Vertos grow and who would thrive as Vertos began to drive sales in a significant way. "We were a small company with a lot of people with small-company experience," he recalls. "What we needed were people with skills that were scalable." Toward that end, when he began to recruit marketing folks, he turned not to people who had marketed other spine devices, but to someone who had previously worked at **SenoRx Inc.**, a breast diagnostics company—in part because Corbett is convinced that there will be an important consumer angle to Vertos' opportunity. When one of Vertos' board members questioned his moves, Corbett says he told him, "I can always get someone who will learn the spine business in no time. What I need is someone who has professional marketing skills."

But if Vertos' employees braced for a change in direction, what about its investors and advising physicians—all of whom had presumably signed on to what they believed would be a promising opportunity in the booming spine surgery market? Corbett insists that Vertos' board members and those on its SAB, including several prominent spine surgeons, immediately bought into the new strategy. "It was clear from any analysis that never in a million years would spine surgeons have enough patients for us to realize our potential," Corbett says, since most surgeons are occupied doing two to three surgeries a day several days a week. Interventional pain specialists on the other hand, he goes on, see 30 patients a day, "and the 500-600 doctors at the elite level are very high-volume and very skilled."

## WHERE'S THE EXIT?

Having defined the company's new strategy, having rebuilt and refocused the sales team and brought in new people with skills to grow Vertos' business, Jim Corbett cites two remaining challenges the company faces in order to fully realize the potential of the procedure: training physicians and continuing to fund clinical research. (Vertos has also recently submitted for FDA approval a second device, to treat foraminal stenosis, that company officials estimate could increase revenues by 50%.)

In its clinical research, Vertos has seven clinical trials of various sizes, including some registries and two randomized trials, one comparing *mild* with placebo, one with regular epidurals. "In every study we do, we're seeing no complications and significant improvements in patients, and that tells us we're on the right track," notes Corbett. "But our clinical research is still building; we've got more work to do."

But perhaps the biggest issue facing venture-backed start-ups like Vertos is the prospects for an exit. For more conventional spine companies, the days of assured, robust exits, either through an IPO or a trade sale, seem long gone. Today, the likelihood of a public offering seems remote for most companies, not just spine companies, as the prospects for an opening of the IPO window remain unclear.

That leaves acquisition as the most likely exit for device companies, and with, by some estimates, nearly 300 venture-backed companies now competing in spine, it's clearly a buyer's market—if buyers are even interested. Already this year, there has been some sign of interest—witness, for example, **NuVasive Inc.**'s acquisition of Cervitech or **Integra LifeScience Holdings Corp.**'s of Theken. But the M&A picture in spine may not be much rosier than the IPO picture. It was only two years ago that two deals in succession—Kyphon's \$725 million deal for St. Francis Medical and Kyphon's subsequent sale to Medtronic for \$4 billion—seemed to capture and express all of the promise of the spine market.

More recently, the deals haven't been as rich, and Abbott's recent departure from spine, combined with Kyphon's folding into Medtronic, raises questions not just about where deal valuations in spine are headed but also who the likely future acquirers are going to be. Compounding the exit problems for small spine start-ups have been the recent troubles of **Medtronic Sofamor Danek**, which has reportedly struggled mightily to integrate its acquisition of Kyphon and over the past couple of years has been losing market share—though it still maintains a large lead over its closest rivals.

The departure from the market of both Kyphon (as an independent player) and **Abbott Laboratories Inc.** has raised critical issues about who might step up as an acquirer in spine; in the past, MSD's market strength, with a dominant market share that is rare in the device industry, presented something of a mixed blessing for small companies: it made the company a formidable competitor in the marketplace, but also a major force in spine M&A. In effect, MSD could afford to pay a premium for novel technology because the company's powerful market position made any new technology a winner. But with its current difficulties, MSD not only can no longer justify higher deal values, it has less of an appetite for acquisition, focusing more on internal issues than external opportunities. (For a more complete discussion, see "Spinal Motion: Chapter 2 in Artificial Discs," *IN VIVO*, October 2009.)

## CASTING A WIDER NET

The saving grace for small spine start-ups will be the willingness of a host of other companies to step up as acquirers, companies that, sensing MSD's difficulties, begin to add to their product lines in an effort to capitalize on the leader's sudden vulnerability—

companies like Nuvasive and Integra, as well as large orthopedics companies like **Zimmer Holdings Inc.**, building on its recent acquisition of Abbott's spine business, and perhaps newly emergent players like **Globus Medical Inc.**

But for most spine start-ups, such a prospect is more hope than plan. Vertos' prospects for a turnaround in the M&A landscape may be no better—or worse—than any other company with a promising technology. But the company does have one edge: because of its novel commercialization strategy, the universe of potential acquirers is arguably larger than that of other spine start-ups. Because of the company's minimally invasive approach to pain therapy, Jim Corbett argues that interested acquirers are likely to include not just spine companies, but also orthopedics companies, particularly those looking to build on or enter the world of less-invasive therapies, and, perhaps most promisingly, neurostimulation companies, which also target interventional pain specialists, in a deal that Corbett says would be "a distribution channel play. ANS, Boston Scientific, Medtronic, are all calling on the same customer we are," he says.

For now, though, Corbett insists he's not worried about Vertos' exit. "For me, thinking about exits will cause bad behavior," he says. "All I want to do is build a good company and create real value for patients." There's much to Vertos' novel strategy that has a Blue Ocean feel—a focus on patients rather than surgeons, a move earlier in the continuum of care, a championing of a new clinical specialty, with the discovery of a new path to a robust market. Moreover, Vertos' focus on interventionalists will likely help the company avoid some of the obstacles that other spine start-ups face, such as overcoming a conservative clinical culture and avoiding the Catch-22 of entrenched distribution.

But perhaps the most novel aspect of Vertos' strategy lies in its implications for the company's exit. Jim Corbett may not be thinking about Vertos' ultimate exit, but by targeting a different patient population and a different clinical customer, Vertos may have made itself attractive to a wider group of potential acquirers in an M&A market that both in spine and outside has become suddenly constrained. In the process, it may effectively differentiate itself from the myriad spine companies that today are trying to figure out where their technology fits, not just on the clinical continuum, but also in the commercial marketplace.

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IV

COMMENTS: Email the author: [D.Cassak@Elsevier.com](mailto:D.Cassak@Elsevier.com)

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