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NuVasive
chairman and CEO
Alexis V. Lukianov
on growth amid
fierce competition

Growing with a Difference

For a start-up medical device operation to compete effectively in a mature product sector dominated by established industry giants, the company must have not only a promising technology base, but also experienced executives who know how to maximize market penetration. Under the leadership of chairman and CEO Alexis V. Lukianov, NuVasive Inc. (San Diego) has both.

Founded with the vision of redefining the minimally invasive spine surgery market, NuVasive's evolution from a niche player to a noteworthy competitor in the spine sector was especially evident during 2006. During the year, NuVasive generated total annual revenues of \$98.1 million, representing a year-over-year increase of 57%. Further, the company launched nine new products, and was able to initiate enrollment for its NeoDisc clinical trial ahead of schedule.

The company also surpassed its goals for training surgeons and developing an exclusive sales force. During 2006, NuVasive trained more than 500 surgeons on its maximum access surgery (MAS) platform and grew its sales force to more than 200 professionals.

Throughout 2007, NuVasive plans to continue its rapid pace of revenue growth and technology development. The company is forecasting year-over-year revenue growth of greater than 40% and expects to turn the corner into profitability this year. The company also plans to increase the breadth and depth of its existing product offerings through a series of strategic launches.

In this excerpted interview with *MX* editor-in-chief Steve Halasey, Lukianov discusses his company's strategy for growing into a strong competitor in medtech's heated spine sector. The full text of the interview can be accessed via the *MX* Web site at www.devicelink.com/mx.

MX: How did NuVasive get its start?

Alexis V. Lukianov: NuVasive was founded by a local orthopedic surgeon who was not an expert in the spine arena. He actually had more of a background in sports medicine. He came up with the concept of marrying neurophysiology together with spinal instrumentation. And basically what that means is, he came up with the idea of how to make instruments smart so that they can detect nerves and safely penetrate the pathology.

The surgeon was able to obtain some initial seed funding from a local

venture capitalist (VC) who represented Enterprise Partners. That came about, literally, as the result of a conversation during a kids' soccer match. After hearing about the concept, the VC decided to provide some seed capital. Enterprise Partners had done a lot of deals with Kleiner Perkins, so they brought that firm into the deal as well. And that, finally, was what led to my involvement with the company. I was recruited to come here by Kleiner Perkins.

Where were you at the time?

I had previously been president

of Medtronic Sofamor Danek USA for several years. When I left the company, I had a three-year noncompete agreement that prevented me from being active in spine devices in particular. So I started a small company in the physician practice management arena that was focused on spine surgeries, which I subsequently sold to a Robert Bass company.

Around the time that my non-compete agreement came to an end, I started getting phone calls from a number of different companies and their headhunters. And that's when, most notably, the Kleiner Perkins

A man with a beard and glasses, wearing a dark suit jacket over a light blue striped shirt, stands in front of a modern building. The building has large glass windows and a sign that reads "NUVASIVE Creative Spine Technology". The man is looking upwards and to the right.

NUVASIVE
Creative Spine Technology

**NuVasive's
Alexis V. Lukianov**
on building a new
competitor in
medtech's heated
spine sector.

Interview by
Steve Halasey

opportunity came around.

In terms of its intellectual property strengths and market potential, how was NuVasive presented to you, such that you became convinced that this was your next opportunity?

The entire concept was extremely novel. Nobody else was thinking about anything like the marriage of neurophysiology with instruments that NuVasive was proposing. On the IP side, they had done some pretty good work in obtaining freedom-to-operate opinions. And they had put together some preliminary patents.

The whole package looked very encouraging. And what was exciting was not just the marriage of neurophysiology with instruments, but the possibility that this approach could bring about the next Eureka! point in the spine world—that is, a way to bring forward minimally invasive spinal surgery, which had not previously really taken off.

I had previously been involved with mostly larger companies. And, of course, I helped to build Medtronic Sofamor Danek and drive that company to a number-one market share. Now it's the world's largest spine company—and an active competitor for NuVasive.

Ultimately, what attracted me to the Kleiner Perkins offer was the opportunity to build the company from the ground up—as a true start-up—and to take it to whatever level I could. For me, that seemed like a terrific opportunity—a chance to build a company from a cultural, philosophical, and ideological standpoint the way that I really wanted to do it.

What was the trigger for NuVasive deciding to go public in May of 2004?

The thing that every company worries about as it goes public is the possibility of disappointing investors. As we went public, we were still on

Product Pipeline

NuVasive is constantly seeking to further its penetration of the minimally invasive spine surgery marketplace. Introducing differentiated products is instrumental to this initiative. By increasing product breadth, NuVasive can increase its penetration into a spine surgeon's business by moving further up the spine into cervical, thoracolumbar, and adult degenerative scoliosis cases.



The evolution of the NuVasive product suite has enabled the company to become a one-stop shop for spinal pathologies, addressing more than 90% of potential spine surgeon business. In 2006, NuVasive launched nine products, including the MaXcess III.

Building on the company's previous systems, MaXcess III uses a split-blade design that enables surgeons to gain maximum access to the spine with minimal soft-tissue damage, and incorporates the company's NeuroVision nerve avoidance technology within the posterior retraction blade. MaXcess III adds a removable fourth blade, which provides greater posterior surgical options and incorporates an improved tilted blade-locking mechanism.

NuVasive plans several launches in 2007. These launches will focus on NuVasive's maximum access surgery (MAS) platform to further increase implant choices through its unique surgical access for lumbar surgery, while also increasing the breadth of the company's cervical and motion preservation product offerings.

somewhat wobbly legs—just as most companies are when they are going through normal growing-pains issues. But frankly, I felt that we were in a good enough position to be able to put forward the kind of revenue that people expected from us.

As NuVasive has grown, how did you go about building your executive team to flesh out the company?

Most of the key executives I brought over were people from Medtronic Sofamor Danek, and others I've known and worked with in the past. And I think that I was able to demonstrate to them that my dream and vision were probably no different than theirs, in terms of being able to build the company the way we would all enjoy seeing it come together.

So what brought these executives on board was an understanding that

the technology had promise. But more important was the belief that we could build a top-notch team with the kind of culture that would take us wherever we set our sights on going.

The Spinal Product Pipeline

Tell me about the core products and procedures that NuVasive was founded on, and how the company has expanded on that base over the years.

Minimally invasive surgery had never really taken off in the spine world, and the reason is that it was technically very challenging. It had been difficult to provide spine surgeons with a safe and reproducible technique that could be performed by the masses of surgeons.

NuVasive's approach of marrying neurophysiology with spinal instru-

mentation—creating smart instruments that enable the surgeon to navigate down to the spine—opened up a whole new surgical technique. That surgical technique entails being able to come at the spine from the side, versus the traditional approaches, which are from the back (posterior) or from the front (anterior) directions. Coming in from the side with NuVasive’s smart instruments—the NeuroVision and neuronavigational technology—enables the surgeon to penetrate to the point of the spinal pathology very quickly.

The next steps make use of an entire suite of NuVasive products designed to prepare the surgical site for a standard fusion procedure. This procedure stops the motion in between the vertebral bodies, which is creating pain, and relieves pressure on the nerves, which causes the pain. The spinal fusion procedure is widely used today for patients that have chronic back pain that has not been resolved by any other means.

In creating its new surgical technique, NuVasive relied on intelligent engineering and significant input from spine surgeons. And those surgeons have been equally excited about the technology and its potential for addressing an area of unmet need in spine surgery.

The technique enables surgeons to perform a fusion procedure 50% faster than before. And it permits patients to recover virtually on the same day and, so far as ambulation is concerned, even within hours after surgery. And, of course, because the technique is significantly faster, it also ends up saving money for the operating room. So it’s a hugely significant advance in spine surgery.

And along the way, the surgical technique is reproducible by the masses of spine surgeons, is that correct?

Yes, and that’s a key feature. To

make this possible, we conduct surgeon training here at our own facility, where we have six operating rooms equipped for cadaver surgeries. Surgeons come here for training, which usually takes just one day. And during that time, they are exposed to the technology and shown how to apply the surgical technique.

In our experience, after surgeons leave here and head home to apply the technology, they get the exact same results as surgeons that have been doing the procedure for the past several years. So there really is not a lengthy learning curve. Once trained,

“In creating its new surgical technique, NuVasive relied on intelligent engineering and significant input from spine surgeons.”

the surgeons are able to perform the surgery and help their patients right away, and they get positive results immediately, right out of the chute.

You alluded to NuVasive’s interest in nonfusion techniques. Can you talk a bit about how that is developing?

In developing NuVasive’s unique minimally invasive way of accessing the spine, we also realized that we were really providing just a part of the procedure. So, about four years ago, we changed our strategy to make sure that we provided the entire technique—and all of the instrumentation to go with it.

Since then, we’ve come up with a wide range of instruments for performing spinal procedures, including unique forms of retraction and all the

different types and sizes of preparation instruments that surgeons need. The whole array would literally cover a large conference table. So we’ve taken a very comprehensive approach, instead of just offering a couple of instruments.

Taking such a comprehensive perspective has enabled NuVasive to achieve a strong position among the top companies in the field. Even though we are not that big from a market share standpoint, surgeons appreciate that we offer a full scope of products just like the larger companies.

At the same time, we’ve also been designing more and more products to put through our unique access channels. These have included different types and styles of implants, implants that enable the fusion procedure to work even better and faster, and so on.

Most recently, we’ve also begun to develop motion preservation products that can be implanted using NuVasive’s minimally invasive approach and the resulting access channels. The idea is to use the company’s approach, which we call maximum access surgery, to enable surgeons to implant a lumbar total disk replacement or even to work on a patient’s neck.

Right now, we are conducting U.S. clinical trials of a product called NeoDisc, which is a nucleus-like total disk replacement. The product consists of a silicone core with embroidery material around it. And it is really intended to replace just the core of the disk.

Over the next several months, we expect to start clinical studies for two other products. The first is the CerPass device, which is another type of motion-preserving implant for the neck, using a ceramic-on-ceramic design. And the second product is the Lateral total disk replacement for the lumbar spine.

Approaching Profitability

NuVasive's guidance for full-year 2007 revenues is between \$139 million and \$143 million, which would represent growth of more than 40% over 2006 revenues. And, perhaps even more significantly, the company expects to tip over into profitability during the year.

In 2006, NuVasive experienced year-over-year revenue growth of 57%. For full-year 2006, the company reported a net loss of \$47.9 million on revenues of \$98.1 million. During the year, the company also completed its transition to an exclusive sales force, a move that has led to increased vertical integration of hospitals using NuVasive products.

"The strategy of bringing to market differentiated products to further our penetration of the minimally invasive spine surgery marketplace has, and will continue to be, a key initiative for NuVasive," said NuVasive chairman and CEO Alexis V. Lukianov. "Building on our nine product launches in 2006, we plan to execute a host of launches in 2007."



Share price of NuVasive Inc. (Nasdaq: NUVA) from its initial public offering in May 2004, with an opening price of \$11.05, though early May 2007, with the price above \$25.

For the first quarter of 2007, NuVasive reported a net loss of \$4.4 million on revenues of \$33.2 million, compared with a net loss of \$8.1 million on revenues of \$19.7 million in the year-ago period. The revenue increase represents 69% growth over first-quarter 2006 levels.

In January 2007, NuVasive announced that it had acquired technology and assets from Radius Medical LLC, including exclusive license and marketing rights to the Formagraft bone graft biologic product and the underlying collagen technology.

"Our robust first-quarter results were driven by the increased effectiveness of our exclusive sales force on MAS products and the early success of SpheRx II, XLP Lateral Plate, and Formagraft," Lukianov said. "These innovative products were released on a limited basis during the quarter and were particularly well received by spine surgeons. We remain excited about these products and the revenue they will bring starting in the third quarter, by which time inventory will be substantially increased."

NuVasive acquired the NeoDisc product last year from Pearsalls Ltd. (Taunton, UK). How many people are enrolled in the clinical trials for the device, and what is the status of

the trials?

The total study involves 500 patients. We are now about 25% of the way through, and we expect to finish the study over the course of the

next nine to 12 months—sometime during the first or second quarter of next year.

And after that, how long before the product is likely to be commercially available in the United States?

We need to complete a two-year follow-up on the study patients. So we are figuring about 2010 for possible commercial release, if everything goes well with the clinical trial and FDA process.

We do have CE marking for our products in Europe. And we are adding motion preservation devices to that armamentarium. So, for the international arena, we anticipate launching our extreme lateral interbody fusion (XLIF) technique with motion preservation technologies during the fourth quarter of this year.

So the products will be available in Europe in the fourth quarter of this year?

Yes, but we will not be conducting a full international launch. The key centers we'll be targeting will be mostly the German- and English-speaking countries in Europe. That will be the primary area. But we're also working on our registrations for Japan, so we intend to launch in the Far East a little further in the future.

What is the overall market opportunity for NeoDisc, in terms of number of procedures, or revenue potential?

NeoDisc is intended as an alternative to fusion procedures for the neck. In the United States, approximately 250,000 such procedures are performed each year, with a market value totaling about \$1 billion. As this market changes with the advent of motion preservation devices like NeoDisc, we anticipate that somewhere in the neighborhood of 40% of the current number of fusion procedures will move toward motion

preservation. So, in other words, the market opportunity is somewhere around \$400 million.

I see NeoDisc as the kind of product that is so unique that it has a good chance of capturing a significant portion of that opportunity very rapidly following its U.S. launch.

The other two products that you mentioned—the CerPass and the Lateral total disk replacement—were those also acquisitions?

No. Like the vast majority of our products, those were developed organically. Just about everything offered by NuVasive has been developed by our engineering and our marketing teams.

What percentage of revenues does NuVasive invest in R&D?

Right now we are in the high teens, as a percentage of revenue. I expect for us to stay in that mid-teen range for the next several years.

Meanwhile, NuVasive is also continuing to acquire. Earlier this year, the company acquired the Formagraft line of biologic bone-void fillers from Radius Medical (Newport Beach, CA). Had you also been watching that product for some time?

We had been looking for about a year to find a new biologic that we could put into our armamentarium of products. We did not have a biologic component, so we saw the Formagraft line as an ideal product that we could use to add revenue on a per-procedure basis. We also made an investment in the manufacturing side of it, which is located in Taiwan.

Our inventory for the product is just beginning to scale up, and we believe there is an opportunity to achieve revenue in the short term, perhaps on the order of \$4 million to \$5 million this year.

But what excites us about the

Formagraft technology is the potential for future applications of the material. Ultimately, it may be used as a coating for implants or even to deliver things like stem cells. There is a lot of upside to this technology.

And from a business perspective, it represented a good deal. Compared with the premiums that we've seen paid for a lot of other companies, we've done well with the acquisitions we've been able to complete, including both NeoDisc and Formagraft.

Some of the areas you mentioned take NuVasive away from traditional device areas and into the realms of biologicals and combination products. Does NuVasive watch those areas closely or invest in them in any way?

Well, we've started really paying attention to those areas. And the acquisition of the Formagraft line from Radius moves us a lot further in that direction. In the future, we expect to open up some full-fledged research in the area.

Seeing how well Medtronic Sofamor Danek has done in selling its bone morphogenic protein (BMP) product over the last several years, it's apparent that there are opportunities to take things to the next level by combining implants and biologics.

Spreading the Word

NuVasive has an impressive facility for training clinicians. How have the company's activities related to surgeon training affected the clinical adoption of the company's products overall?

The effects have been terrific in a lot of ways. First and foremost, the level of expertise that we have at our company is tremendous. Last year we trained close to 600 surgeons through our facility. So you can just imagine all the engineers and marketing folks that are there in the operating room,

helping the surgeons.

Of course, with this kind of facility, every time we launch a new product we can work very closely with surgeons to perfect it pretty much on-site. And we think that's a very big competitive edge.

In general, surgeons walk away from their training here feeling enthusiastic and very comfortable about applying the technology. Consequently, our conversion rate has been quite high. Of the surgeons who have been trained here, about 70 to 75% apply the technology within the first 30 to 90 days. So we are very pleased with that.

The company also has an impressive clinical advisory board of orthopedic and neurological spine surgeons. How did you bring that board together? What role does the board play in helping you to develop future products, and driving the adoption of those products?

All of our products are developed in concert with surgeons, so the involvement of these advisers is critical. Fortunately, our team has been doing this for quite some time, and we have very strong track records with many of the country's top-ranked surgeons.

Those same surgeons have been attracted by the things that we do at NuVasive, one of which is to produce products faster than our competitors. We see that as an obligation as well as an edge in the marketplace. Surgeons absolutely love it when they can work with a company that looks to rapidly introduce new products.

Surgeons also love coming here. This is the finest spine surgery training facility in all of North America. None of the big companies have invested in anything like this. So again, it differentiates our service and our commitment to new product development.

NuVasive started with a core of intellectual property, but it is clearly building a significant portfolio around that. Can you describe what that portfolio looks like now?

NuVasive's patent portfolio has grown dramatically. The company now has 48 issued U.S. patents and 197 patents pending. Those have been developed mostly around our technologies in neurophysiology, fusion products, and our motion preserva-

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tion implants. We recently also moved into cervical products.

And for all of these intellectual properties, is the vast majority of your development done internally?

That's correct. If we were to put a number on it, our organically developed intellectual properties would certainly be in the 90% range. Really, the only two NuVasive products developed externally are the NeoDisc and Formagraft products that we just acquired.

Exclusive Growth

NuVasive has invested heavily in developing its own direct sales force. Why did the company decide to make that move, and how is it working out?

We made this investment because there was no way for NuVasive to achieve robust long-term growth with a nonexclusive sales force.

We would like to continue growing our top line at the same kinds of rates we've had in recent quarters, as typified by 60% top-line growth last

year, and 70% top-line growth for the first quarter of this year. We expect to be able to grow at rates like that for the foreseeable future.

Because it would be prohibitively expensive to start off with the expense of building a large exclusive sales force, almost every new company begins life with a nonexclusive sales force, just as NuVasive did. A nonexclusive sales force has the advantage of putting the company's

products into the hands of more sales reps. But over time, that sales force will begin to carry multiple product lines, and the company will end up competing for the attention of both the sales reps and their customers. In short, a nonexclusive sales force just can't give an emerging company the sort of attention that it needs to significantly ramp sales.

So, clearly, building our own exclusive sales force—which is about 50% direct and 50% exclusive distributors—has completely transformed our company. I felt very strongly about this strategy when we began down this path a few years ago, and we had absolutely no difficulty convincing people of the need to spend dollars on it. And we did. We have been very aggressive, and it has cost us millions of dollars. But I think the benefits of the strategy are already coming to pass.

We completed our transition to an exclusive sales force in June 2006, and we've seen nothing but record quarters ever since. Today, we have about 200 people in that sales force,

and I think they are all very pleased to be representing NuVasive on a full-time basis.

Is the company using the same strategy overseas?

Overseas we are using a combination strategy. We are not immediately going to be able to get the kind of volume that would justify creating an exclusive sales force. But we will be using some direct sales folks in Germany.

Has NuVasive grown to the point that it is now an acquisition target? Would that be a desirable outcome for the company?

We are not looking to sell the company, and we certainly don't want to be an acquisition target.

Over the next few years, we want to become a \$500 million company. And with that, we want to maintain the culture that we've been proud to put together here. We want to offer the kind of products that we feel are critical to long-term success, and we have spent considerable time developing a strategy to achieve these goals.

We have enjoyed being consistently ranked very highly by the financial community—from number three to number five—among the top innovators in the spine field. But what's really driving the NuVasive team is that everybody is enjoying the way the company is growing.

So NuVasive's success is not measured only by hitting financial targets. It's also seen in how the company has grown, its strong culture of high performance, its commitment to serving customers, and a lot of other factors that you've heard a million times from many different companies.

But I will tell you that people here really live it. NuVasive is a different kind of place from what most people are accustomed to. We are proud of that, and we want to perpetuate it. ■