PRESS RELEASE

November 9, 2012

SpinalCyte, LLC Profiled In Medical Device Daily

HOUSTON--(BUSINESS WIRE)-- **SpinalCyte, LLC**, a spinal technology company focused on autologous regrowth of the spinal disc nucleus using human dermal fibroblasts, was profiled in the November 9, 2012 issue of *Medical Device Daily* in a featured "New Company On The Go" interview. *Medical Device Daily*, the world's leading med-tech news and information source, is the daily source for world-wide developments in the medical community. SpinalCyte has successfully completed its first round of animal studies with Howard An, M.D. at Rush University in Chicago. Using intermittent hydrostatic pressure, the dermal cells have successfully differentiated into cartilage type cells necessary to regrow the nucleus pulposus.

The nucleus pulposus is a gelatinous material that acts as a cushion or shock absorber to the spinal column. It functions to distribute hydraulic pressure in all directions within each disc under compressive loads. The nucleus pulposus consists of chondrocytes, collagenfibrils, and proteoglycan aggrecans.

"This featured article gives international exposure to our emerging technology," said Pete O'Heeron, Chief Executive Officer. "We feel a cell-based solution for degenerative disc disease is the future treatment of choice and our autologous cell-based solution is a leader in the efforts to find a biologic therapy to regenerate the disc".

About SpinalCyte, LLC

Based in Houston, Texas, SpinalCyte, LLC is a spinal technology company founded in 2007 for the purpose of developing an innovative and autologous solution for nucleus replacement technology using human dermal fibroblasts. The goal of SpinalCyte is to develop a nucleus regrowth technology using autologous dermal cells harvested from the patient. SpinalCyte is currently seeking additional funding for its final animal trials. To date, SpinalCyte has been funded entirely by angel investors.

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Friday, November 9, 2012 Vol. 16, No. 218 Page 1 of 10

Deals roundup

Boston Scientific to pay up to $425M for Vessix Vascular

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

It was never a secret that **Boston Scientific** (Natick, Massachusetts) wanted to dip its fingers into the strategically critical renal denervation pool – the company already has a renal denervation system in development with a CE mark planned for next year – but analysts and other industry watchdogs were a bit surprised Thursday morning when the company reported an agreement to acquire **Vessix Vascular** (Laguna Hills, California) for up to $425 million. The acquisition is expected to close by the end of the month.

The agreement calls for an up-front payment of $125 million, plus additional clinical – and sales-based milestones aggregating a maximum of $300 million

See Deals, Page 6

NewCo on the Go

SpinalCyte uses cells instead of implants to treat degenerative disc

By OMAR FORD
***Medical Device Daily* Staff Writer**

While there's currently some debate on level of interest in the spine market right now – one thing is for certain, and that's the fact that there has been a decrease in activity in recent years. But one small med-tech firm has a solution that it thinks will not only increase interest in the spine market, but will be a game-changer for the space as well.

SpinalCyte (Houston), a private company that was founded in 2007, is developing an application to treat degenerative disc disease using cells derived from human skin. Specifically the application would promote autologous regrowth of the spinal disc nucleus using human dermal fibroblasts (HDF).

"What we do with out company is take very early ideas –

See SpinalCyte, Page 7

Report from Europe

RainDance Technologies places ThunderStorm in France, Italy

A *Medical Device Daily* Staff Report

RainDance Technologies (Lexington, Massachusetts) reported new placements of its ThunderStorm system at the LIGAN-Personalized Medicine Equipment of Excellence at the Pasteur Institute of Lille in France and Ceinge Biotecnologie Avanzate in Naples, Italy. The ThunderStorm system is a fully automated high-throughput targeted sequencing solution that enables researchers to determine all variation contained in any region of the genome faster and easier than ever before.

Leveraging RainDance's proven single-molecule picodroplet PCR technology, the ThunderStorm system supports a wide range of sequencing applications, including candidate gene screening, deep sequencing

See Europe, Page 8

Washington roundup

Industry blowback on draft UDI guidance hints at redo

By MARK McCARTY
***Medical Device Daily* Washington Editor**

The draft FDA guidance for unique device identifiers (UDIs) took five years to cobble together, but two trade associations have filed a laundry list of comments suggesting a need for another intensive look at the document. FDA is statutorily required to publish a final guidance six months after the unveiling of the draft, but the amount of pushback suggests the agency will have to rewrite some of the guidance and hence will have to devote substantial resources to the task in order to get the job done by early January.

The legislation calling for a UDI system was the Food and Drug Amendments Act (FDAAA) of 2007, and the Food

See Washington, Page 9

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INSIDE:

AHC Media

SpinalCyte

Continued from Page 1

literally from the back of the napkin from a doctor all the way to the finish line," Pete O'Heeron, SpinalCyte CEO told *Medical Device Daily*.

In recent months the company has been working hard on securing patents for the HDF technology in healthcare markets throughout the world. Earlier this week, the firm reported that it had secured a patent in the U.S. for using intermittent hydrostatic pressure to regrow the nucleus pulposus. The patent describes various compositions and constructs for scaffolding used to transfer pressure from the vertebra to the nucleus pulposus.

The nucleus pulposus is a gelatinous material that acts as a cushion or shock absorber to the spinal column. It functions to distribute hydraulic pressure in all directions within each disc under compressive loads. The nucleus pulposus consists of chondrocytes, collagenfibrils, and proteoglycan aggrecans.

"We came across a theory that said you could take human dermal fibroblasts and then in a low oxygen mechanical stressed environment [those] fibroblasts would turn into cartilage cells," O'Heeron said describing the science behind the firm's approach. "That was the theory. We looked all over to see if there was anything else out there like it and it seemed completely unique and novel. Then we started with the approach . . . if this works, what does it mean?"

He added, "it's a game changer in the truest sense that's disruptive to the entire spine industry, because we would be regrowing your disc using your own skin cells. So in essence what you'll be doing is pulling a small dermal paunch essentially from your lower back. So you would come in two days pre-op and the [surgeon] would pull a small dermal paunch about half the size of your pinky fingernail. We would remove the fibroblasts and we would inject them into the nucleus of the disc. Then the intermittent, hydrostatic pressure of the spine in a low oxygen environment seems to make these cells regrow the nucleus of the disc."

Results from *in vivo* animal studies completed at **Rush University Medical Center** (Chicago) earlier this year, under the direction of Howard An, MD, show that cell therapy using HDFs promoted cell differentiation into chondrocytes and proliferation within the disc nucleus over an 8 week period. Additionally, the therapy resulted in an 80%+ restoration of disc height.

"I think that we're really excited about the final round of animal trials . . . and we [want to] make sure what we saw in the initial animal trials we see in the final round."

As to when the therapy could be used in human patients in a trial – that could be about two years out, O'Heeron told *MDD*.

"I think that the regulatory path is still undetermined, untested and unproven," he said. "This is a very new area but it's an area that's torn between pharmaceutical and device, leaning more torward the pharmaceutical side. Cell therapy especially if you do any additional manipulation of the cells outside the body . . . if you take autologous cells and you manipulate them in any manner and put them back in the body you're going to have to answer the questions; what did you create; what does the FDA want to see about what you created? Those are all new areas for the science and for the regulatory community. It's an undetermined path at this point, but it's a certain direction that we have to go [in]."

The company would not discuss specifics when it came down to how much money it has raised - but O'Heeron indicated that it was in the millions. He noted that funding up to this point was done completely by angel investors. He said that the firm was literally just beginning another round of funding to help pay for the next animal trial.

O'Heeron, who comes out of the healthcare delivery field, with a background in hospital administration, said that the HDF therapy has the ability to generate a great deal of interest back in the spine market and in healthcare facilities that offer the treatment. He added that healthcare facilities should always want to procure the technology that would allow them to receive the first phone call from patients.

"This is one of those technologies that once you establish and commercialize this, you could literally gain back all the back patients in a community because it's a front door procedure," he said. "Once you tell the community, if you have back pain, we're going to fix your back pain by using your own cells . . . then you'll get all of the back patients. The ones that are a candidate for this procedure will get the procedure and the ones that aren't still stay in your network because you got the first phone call. It's the Holy Grail of therapy and also the Holy Grail of healthcare delivery." ■

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Restructuring roundup

Wright Medical splits into two orthopedics groups

A *Medical Device Daily* Staff Report

Wright Medical Group (Arlington, Tennessee), which reported another quarterly drop in sales on Monday, said it is splitting into two U.S. divisions in a move to reverse the company's recent losses.

Wright will now have an orthopedic reconstruction group focused on its line of hip and knee products and it will have an extremities division focused on its growing foot and ankle products.

Eric Stookey, now Wright's chief commercial officer, will be promoted to president of the extremities division. Timothy Davis, Wright's senior VP for corporate development, will be president of the orthopedic reconstruction group. Each will report to a new chief operating officer, a position Wright leaders said is close to being filled. ■