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CollaMedix—biotech startup founded with technology invented at Case Western Reserve and University Hospitals—reaches exclusive licensing agreement

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New technology, jointly created by Case Western Reserve University and University Hospitals Cleveland Medical Center, offers a promising potential solution to women’s pelvic health disorders, including stress urinary incontinence and pelvic organ prolapse.

That technology is the basis for a medical device being developed by CollaMedix Inc. Now, the Shaker Heights, Ohio-based biotech startup has reached an exclusive licensing agreement with the Case Western Reserve Technology Transfer Office (TTO), allowing the company to secure additional funding.

Women’s pelvic health disorders have been surgically managed with a variety of devices and mesh products. These devices—especially in patients with pelvic organ prolapse—have been associated with chronic pain, inflammation, erosions and other conditions that call for alternatives like those being developed by CollaMedix.

The startup's main product, the medical device known as CollaSling, aims to treat stress urinary incontinence in women—urine leakage coinciding with laughing, coughing, sneezing, lifting and exercise—by using proprietary collagen-based materials to provide structural support to human tissue.

"This common condition affects both the young and elderly, yet current treatments are ineffective and unsafe," said Subba Shankar, the company's chief technology officer. "Our technology will allow more women to fully engage in all of life's activities without hesitation, avoiding the withdrawal, isolation and depression that they presently endure."

Billion-dollar market

The potential market for the company's products is immense, largely because current devices and surgeries used to treat women's pelvic health disorders have been associated with chronic pain, inflammation and other conditions.

In fact, manufacturers of transvaginal surgical meshes have been ordered by the U.S. Food and Drug Administration (FDA) to stop selling and distributing their products for some uses. Such polymer-based meshes already have been banned in some countries and are the subject of a class-action lawsuit in the United States.

The expected market for implants that address stress urinary incontinence in women will surpass \$1 billion in the next half decade, the company estimates.

"We are responding to substantial demand for an alternative device," said Shankar. "The market will also expand as more women seek treatment with a more natural, biocompatible product without the harsh side effects of current mesh implants."

CollaMedix also plans to expand into additional markets, applying its technology to implants for hernia repair and orthopedics.

Novel product—novel production process

The implantable medical devices are made with pure collagen threads formed by a novel, patented electrochemical compaction process. The threads can be formed into a strong biofabric that has shown to be effective in long-term animal studies, which also demonstrated durability comparable to existing polypropylene products, while showing better integration with tissue.

The technology was developed and refined by Ozan Akkus, the Leonard Case Jr. Professor in the Case School of Engineering, in collaboration with clinicians at University Hospitals Cleveland Medical Center, including Adonis Hijaz, director of female pelvic surgery and vice chair of academics and research for the UH Urology Institute.

In late 2018, CollaMedix was awarded \$150,000 (phase II) by the Ohio Third Frontier Commission as part of \$3.15 million in awards targeted to help entrepreneurs and technology startups statewide.

Meanwhile, to produce the pure collagen threads on an industrial scale, the startup is also focusing on validating a proprietary mass manufacturing process. To that end, National Science Foundation Small Business Innovation Research program funding of \$225,000 was awarded in June to further test CollaFabric's safety and efficacy to collect data toward eventual application for FDA approval.

Also, a \$150,000 non-dilutive (phase I) Ohio Third Frontier Technology Validation and Start-up Fund award—with \$75,000 from the state and \$75,000 from UH Ventures—helped to fund early business planning and animal studies of the CollaFabric. The startup also received a \$25,000 grant from Lorain County Community College's GLIDE initiative in 2018.

CollaMedix was formed in September 2018 after an option agreement for the technology was executed by TTO.

“This is a great example of a technologist and clinicians working together to advance a remarkable device to market in partnership with a new startup company for the public good,” said Mike Allan, senior licensing manager in the CWRU Office of Research and Technology Management. Allan has worked with Akkus to patent and license the technology since 2011.

“We appreciate the opportunity to partner with CWRU and CollaMedix to bring this product to market, creating hope for women who suffer from stress urinary incontinence,” said Neil Wyant, managing director of UH Ventures.

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