THE WALL STREET TRANSCRIPT
Connecting Market Leaders with Investors

Elutia Inc. (NASDAQ:ELUT)

DR. RANDY MILLS is co-founder of Elutia Inc. and has served as CEO since June 2022. Dr. Mills is an internationally recognized expert in regenerative medicine who led three companies through IPO, creating more than $1 billion in shareholder value. He ran some of the nation's most respected medical institutions, including the $5.5 billion California Institute for Regenerative Medicine and Be The Match. He also serves as a Command Pilot for Angel Flight, transporting patients in remote locations to treatment facilities. Dr. Mills holds a Ph.D. in Pharmaceutical Science and a B.S. in Microbiology from the University of Florida and completed an internship in Clinical Pathology at Shands Hospital at the University of Florida.

SECTOR — MEDICAL DEVICES

TWST: Thank you very much for joining us today. So to start things off, last September, Elutia changed its name from Aziyo Biologics. What was the rationale behind that name change? What is "elution" and how is it connected to your company?

Dr. Mills: The change was really driven by focus. I'm a big believer in prioritizing business units that are going to drive disproportionate increases in value. When I came in as CEO last year, we had four pretty distinct businesses without much overlap or synergy.

Two were well-positioned for high growth: Those were our CanGaroo and SimpliDerm product lines, and both were used in focused but sizable markets. And I like that. CanGaroo is used to facilitate pacemaker implantation and SimpliDerm is used in breast reconstruction.

Furthermore, both markets shared a similar need and that was for the introduction of a drug-eluting component to the technology that could address post-surgical infections. And so we made the decision to focus on these two product lines, SimpliDerm and CanGaroo, and go full-throttle developing the drug-eluting, or said differently, the drug-releasing, version of both of these.

That's where the name Elutia comes from. We're combining the power of drug therapy with a biologically-based material and pioneering what is the drug-eluting biologic.

TWST: Now you say that you became CEO last year, but I understand that your relationship with Elutia predates that. Could you tell me more about your background and how you joined the company?

Dr. Mills: Sure. I have a Ph.D. in drug discovery and development from the University of Florida. More specifically, my research was centered on the creation of drug-eluting biologic constructs to address infections in orthopedic surgery.

I was a founder or CEO of three public companies, starting with a company called RTI Surgical, a company I helped start with Jamie Grooms at U.F., and was ultimately sold to a private equity firm for $440 million.

After 10 years of growing RTI, I went on to Osiris Therapeutics as CEO, took them public, and led a team that really created a commercial revolution in the use of biologics in orthopedics and wound care. Osiris was eventually sold to Smith & Nephew for $660 million. And so that was the first 20 years of my career.

From there, I went into public service and ran some of the country's most-respected medical institutions, including the California Institute for Regenerative Medicine, or CIRM, and Be The Match, an organization that handles all bone marrow transplantation in the United States. And it was during that time that I co-founded Elutia with Kevin Rakin.

I came in as CEO last year, mostly because we saw an opportunity to create another revolution in the industry, by returning to where I started my career with drug-eluting biologics. And I think this is our biggest opportunity yet.

TWST: Why did you select breast reconstruction and cardiac device implantation as the first types of procedures to target?

Dr. Mills: I believe in pretty serious market discipline. We won't take our technology into a market where we don't see it offering a pretty clear and obvious value proposition, to either the patient, the physician, or the payor.

In the case of CanGarooRM, Medtronic has actually done a beautiful job of demonstrating the market demand for a drug-eluting envelope in the pacemaker and internal defibrillator space. We estimate

that they have about $300 million in sales of their antibiotic-eluting pouch. They're the only company with an antibiotic-eluting pouch on the market right now in the space.

But their pouch is made of a synthetic polymer that dissolves and degrades in the body over time. Our data demonstrates that if you make that pouch out of a natural biologic material instead, it will remodel into the patient's own healthy tissue.

That leads to less scar tissue being formed around the device. It makes things like pacemaker change-outs easier for the patient and the physician.

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The second has to do with the anti-inflammatory properties of using a biological material versus a synthetic. Reducing inflammation ultimately leads to less fibrosis or scar tissue formation. Again, whether it's a pacemaker or it's a breast implant, pathologic fibrosis can actually have pretty serious consequences for the patient.

In breast reconstruction, this leads to something called capsular contracture, which oftentimes will require an additional surgery to explant the device.

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We also have a lot of market data that shows that while physicians like the idea of using an antibiotic pouch, for the remodeling benefits I mentioned, they would much rather use a pouch made from a biological material versus one made from a synthetic material that dissolves in the body.

We view this market dynamic as highly advantageous for us. There are currently only four primary players in the pacemaker industry. Medtronic has about 35% of that market and offers its own antibiotic envelope. We think the addressable market for antibiotic-eluting envelopes is about $600 million in the U.S. alone with the majority of that untapped.

We plan to introduce CanGarooRM into this market, not as a follow-on or as a me-too, but as a superior product. We estimate that we will essentially have the remaining 65% of the U.S. market as white space without any direct competition.

TWST: And geographically speaking, are you focusing solely on the U.S. market or are you looking at other geographies where you might be able to sell?

Dr. Mills: We currently have CanGaroo on the market in the United States and throughout Europe, but we're a relatively small company and have limitations with regards to bandwidth on what we can do really well. For the launch of CanGarooRM, we'll be focusing primarily on the U.S. market, at least initially.

TWST: Can you tell us a little more about the advantages of CanGaroo and SimpliDerm compared to alternative treatments, and sort of the state of the competition? Aside from the synthetic versus biological makeup, can you point to any other benefits to users of your products?

Dr. Mills: Sure. Our proprietary biomaterials have three key advantages. First, they're excellent at device stabilization. For example, with a pacemaker being placed into someone's chest wall, oftentimes that pacemaker will migrate down the patient's chest as a result of gravity and motion, and that can actually cause tension and pull on the leads and actually dislodge them from where they're supposed to be making contact in the heart. And that can lead to device failure.

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There's also capsular formation around the pacemaker, which makes change-out of the pacemaker very difficult and increases the chance of infection. So, reducing inflammation and fibrosis is the second key benefit.

The third is preventing device erosion. If you've ever seen an older patient with a pacemaker that has really thin skin, where the pacemaker rubs up against the patient's skin, they actually have a pretty significant chance of eroding through and being expelled. Putting a natural biological pouch around these devices helps decrease the chance of erosion and significantly increases patient comfort.

TWST: Pulling back a bit, you had talked about transforming Elutia into a drug-eluting biomatrix focused company. In terms of that transition, what remains to be done and what is your timeline?

Dr. Mills: Our R&D teams have been developing this drug-eluting technology for some time now. The CanGarooRM line for pacemaker protection is by far our most advanced. In fact, we actually have a drug-eluting version of it on the market in Europe and have had that since 2021.

In the U.S. though, we will file for market clearance of CanGarooRM with the FDA this quarter and we hope to have that review complete and have a favorable decision within the first half of 2024.

Approval of CanGarooRM — and it's named RM because it slowly releases the powerful antibiotics rifampin and minocycline — would give us a launch of what we would expect to be our first blockbuster product, with sales reaching potentially into the hundreds of millions of dollars. Behind that, we have SimpliDermRM for use in breast reconstruction.

I think it's probably worth pointing out that both of these drug-eluting versions are actually being built on the back of already successful products that are on the market and generating sales of over $25 million annually and are growing without the drug-eluting version in excess of 20%. We really see this as a good-to-great story.

TWST: Certainly you've spoken to some of the opportunities that CanGaroo and SimpliDerm offer in terms of driving Elutia's growth. What potential challenges do you anticipate as you continue the development process for these products and their systems?

Dr. Mills: With regards to CanGaroo, the development phase is really over. Our R&D teams are in the process of finalizing and submitting the complete package to FDA for review. Our challenge, and we hope our opportunity, will be commercial execution.

The only other product in the field is sold by Medtronic, and our market intelligence tells us that's a product generating sales of approximately $300 million. Our market research also tells us that a large majority of physicians would prefer to use our product over the competitor's.

This is a situation where there's a real opportunity to capture a significant chunk of this market rather quickly. It's one where it could make sense to do that by partnering, or we could even sell this product line outright, but only if we got an exceptional offer.

For now, our challenge, our opportunity, and our plan is to go full speed ahead commercially. We have our own direct sales force for the CanGaroo product line, and they have been doing an awesome job. We're super excited about what they will do with CanGarooRM in this spring-loaded market.

themselves how well SimpliDerm has incorporated and vascularized, and how healthy the tissue pocket that's been created is, they continue to use the product again and again.

If you look at the sales trajectory of SimpliDerm, that's what it says is going on. We're not spending an enormous amount of money on marketing. We're focusing our efforts on getting physicians to just try the product and see the results for themselves. And when they do, they become repeat loyal customers.

TWST: Switching gears some, I wanted to get into the financial side. Would you say that the expansion of sales for your products has been able to cover any of your operational needs? Do you anticipate any need to secure additional funding in, say, the next year or thereabouts?

Dr. Mills: We actually just did an equity financing last month, so we don't see the need for an additional transaction over the next year, at least as we sit here today. As part of focusing the business, we've been working on divesting a few of our non-core assets, and that's helped provide some of the capital that we've needed for R&D and market development.

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TWST: In terms of capitalizing on opportunities, what actions has Elutia taken perhaps to raise its profile among health care providers and generally get the message out on the superiority of your product?

Dr. Mills: We are a science-based, evidence-based company and we believe that the best marketing for our company is the outcomes and the data the products generate. We have been working with a number of physicians in the pacemaker space to generate and publish data, which we do on a rather routine basis.

The major meeting for pacemakers is a meeting called the Heart Rhythm Society meeting, which was held in New Orleans earlier this year. There were several presentations at the podium about the benefits of using CanGaroo without the antibiotic delivery, just the base CanGaroo biomatrix. And that generated a lot of excitement amongst the electrophysiologists and the cardiologists that use the product.

On the breast reconstruction side, where we have our SimpliDerm product, we have the perfect opportunity to demonstrate the amazing benefits of the product directly to the surgeon. That opportunity comes from the way the breast reconstruction procedure is normally performed.

An example is a woman who's been diagnosed with breast cancer. Unfortunately, she's gone in for a mastectomy. After they remove the breast tissue, they actually do the reconstruction in two parts.

In the first stage, they place a tissue expander into the remaining breast tissue, along with the SimpliDerm product. It takes about six months for that expander to do its job, at which time the surgeon goes back into the procedure, removes the expander, and puts the permanent implant in.

It is at that time when the surgeon is afforded an opportunity to see the performance of the implanted product. At that time, the surgeon can directly visualize how well SimpliDerm has integrated.

What we've seen is that when a surgeon uses SimpliDerm in breast reconstruction, and they come back six months later and see for

From our perspective, in today's market, that's a preferred route of generating the additional capital that we may need for growth.

TWST: Given that you are divesting these non-core businesses, is your ultimate goal — or at least your medium-term goal — to be solely focusing on the development of the CanGaroo and SimpliDerm systems?

Dr. Mills: We see a lot of opportunity with these two platforms. While we think about market expansion, we will be approaching that market expansion with the same discipline that I mentioned before. When we go into those spaces, we expect our products to offer a significant value proposition to the patient, physician and payor.

For us, there is an obvious set of markets that are adjacent to the pacemaker field. These are things like spinal cord and neurostimulation.

For instance, in sleep apnea, there are approximately 30,000 implants performed each year with a stunning 42% complication rate and we believe that CanGarooRM can have a significant impact in this field. Likewise, spinal cord and neurostimulators, where there are north of 40,000 implants annually, have about the same 30-40% complication rate.

There's a compelling need for CanGarooRM to help improve outcomes in these procedures. That's an added benefit of entering an adjacent market that actually doesn't require much additional R&D spend to gain entry.

In fact, our current FDA submission for CanGarooRM includes these adjacent indications. We believe that with a CanGarooRM clearance in the first half of 2024, not only will we be set up to capture pretty significant market share in the pacemaker space that we've spent time talking about today, but we will actually be able to transition into these other adjacent markets, such as sleep apnea and neurostimulators in a very fast but efficient manner for us.

TWST: Fast meaning in this case, perhaps, what, one to two years, five years?

Dr. Mills: We're talking about having market clearance for those at the end of the first half of next year. So, naturally, leading up to that, we're saying to ourselves, "OK, what would be the best way for us to go capture that opportunity? Would it be for us to organically grow into those fields with our own sales force, or perhaps would it make sense to do some sort of partnership with a leader in one of those spaces, an Inspire, for example, in sleep apnea, or a Medtronic in spinal cord stimulation."

TWST: Aside from the results that you are delivering in terms of developing SimpliDerm and CanGaroo, how do you hope to drive investor interest in Elutia and why should investors consider buying Elutia shares?

Dr. Mills: It's a completely fair question. We don't think the investment thesis in Elutia needs to be any more compelling than what comes from CanGarooRM, but it is.

Several years ago, Medtronic paid $200 million to acquire their antibiotic-eluting pouch technology before that market ever existed. Right now, they're the only ones who have that technology, and they've grown it and demonstrated that that market is at least a $600-million opportunity in the U.S. alone.

We're going to be the second one to enter that market, and we're going to do it with a superior product. There are only four players total in that market, so it's a little bit like a game of musical chairs. None of these major pacemaker players want to be left without an antibiotic pouch when the music stops. We think it's not unreasonable to value just CanGarooRM at $400 million to $500 million alone upon its approval.

Behind that, we would have our second blockbuster product line, SimpliDermRM, and the team and the infrastructure in order to be able to get that job done. It's a great time to invest in Elutia.

TWST: Thank you. (RP)

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Forward-Looking Statements

This report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements can be identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "promise" or similar references to future periods. All statements contained in this report that do not relate to matters of historical fact should be considered forward-looking statements, including any statements and information concerning our expectations for the addressable market for antibiotic-eluting evelopes, our plans for the introduction of our CanGarooRM product in the antibiotic-eluting envelope market, the markets in which we plan to focus the launch of our CanGarooRM product, the effectiveness and expected advantages of our CanGarooRM and SimpliDerm products, our expectations for filing for clearance with the FDA for our CanGarooRM product and the outcome and timing of the FDA's review of that filing, any milestones, projections or expectations for sales of our CanGarooRM or SimpliDermRM products, the growth of our other products, our ability to successfully execute on commercializing our CanGarooRM product, our capital needs for 2024 and beyond, and the projected value of CanGarooRM upon approval by the FDA. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect our business, strategy, operations or financial performance, and actual results may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, and other important factors that may cause actual results, performance or achievements to differ materially from those contemplated or implied in this press release, including, but not limited to: risks associated with shifting focus to our drug-eluting biomatrix solutions in the cardiovascular and breast reconstruction areas and away from our now-divested Orthobiologics business; the risks of an adverse determination by the FDA in connection with our 510(k) submission for our CanGarooRM product and other products; risks relating to the potential removal of our securities from listing on the Nasdaq Capital Market; the impact of future revenues of our disposed-of Orthobiologics business on "earn out" provisions in the related acquisition agreement; risks regarding the ability to successfully execute or realize the anticipated benefits under our distribution arrangements with LeMaitre Vascular and Sientra; our inability to generate sufficient revenue to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; our ability to continue as a going concern; our ability to successfully achieve expected benefits from the divestiture of our Orthobiologics business; our products and our ability to enhance, expand, develop and commercialize our product offerings; the impact on our business of the recall of a single lot of our FiberCel product and the discontinuation of its sales by our distribution partner; consequences of our recall of a single lot of one of our viable bone matrix products and market withdrawal of all of our viable bone matrix products; our dependence on our commercial partners; the impact of the bankruptcy of Surgalign Holdings, Inc., a significant customer of the Company, on our future revenues; physician awareness of the distinctive characteristics, and acceptance by the medical community, of our products; the ability to obtain regulatory approval or other marketing authorizations; risks related to our intellectual property rights; and other important factors which can be found in the "Risk Factors" section of Elutia's public filings with the Securities and Exchange Commission ("SEC"), including Elutia's Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in Elutia's other filings with the SEC, including Elutia's Quarterly Reports on Form 10-Q, accessible on the SEC's website at www.sec.gov and the Investor Relations page of Elutia's website at https://investors.elutia.com. 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