

ReShape Lifesciences Inc. (NASDAQ:RSLS)



BARTON P. BANDY is President and Chief Executive Officer of ReShape Lifesciences Inc. Mr. Bandy brings extensive leadership experience in health care, specifically in the bariatric and minimally invasive surgery segments. Most recently, Mr. Bandy was President and Chief Executive officer of BroadSpot Imaging Corporation, a privately held ophthalmic imaging company, and prior to that he was President of the Wellness Division at Alphaeon Corporation. He previously spent 10 years as the senior executive leading the Inamed and Allergan Health Divisions through the launch, growth and transition of LAP-BAND[®]. Mr. Bandy formerly held positions of increased responsibility in sales, marketing and professional education at Ethicon Endo-Surgery and Karl Storz Endoscopy, America.

SECTOR – HEALTH SERVICES

TWST: Let's start with a brief historical overview of ReShape Lifesciences. How has it changed over the years? What's its focus now?

Mr. Bandy: Originally, it started out as EnteroMedics, and EnteroMedics had a neuromodulation device, a gastric pacing device, where the leads, instead of being connected to the cardiac tissue or anatomy, were connected near the stomach, near different nerves that were to impact or affect hunger or appetite. And it did receive FDA approval, so its safety profile was good, but it didn't really have the efficacy of other procedures, and therefore it wasn't really able to be highly commercialized.

So the company bought a couple of other technologies over a period of time, trying to use that experience and those resources they developed for the weight loss or bariatric surgery market. They bought one called BarioSurg, which is the gastric vest that's being used in Europe for clinical trials. And then, they bought ReShape Lifesciences. So ReShape Lifesciences became the new company.

ReShape had an intragastric balloon used for temporary weight loss. It had a six-month implantable indication where people could have the device implanted endoscopically, six months later have it removed, and while in place it would fill up space in the stomach and therefore allow a reduced amount of food to be consumed. So that was where the company was in 2018.

They had an opportunity to divest that balloon technology to Apollo Endosurgery. Apollo had a product called the Lap-Band which was already FDA approved, had reimbursement and just wasn't really being marketed. So it was kind of an opportunity to bring a device that was already on the market up to a higher standard or a higher demand and to get the company going.

In December of 2018, ReShape sold their gastric balloon to Apollo and purchased the Lap-Band. And unfortunately, in December of 2018, they were also delisted from NASDAQ because the company had gone through some challenges over time, and they looked at bringing in new leadership and a new management team. I was the original senior executive for the Lap-Band the first time we launched it in the U.S. and took it from zero to \$300 million as a company. We were part of the \$3.4 billion acquisition by Allergan. They were more interested in our other division, Inamed Aesthetics, which had breast prosthesis and collagen. At that time, they wanted to bring those products in and incorporate them with Botox to create a powerhouse of aesthetics products.

Our Inamed Health division was kind of like the sidecar on the motorcycle, but we actually came in and we learned a lot from Allergan, as they were so good at doing consumer marketing of health care products. Botox was number one; Restasis for dry eye was number two. And we launched a major national campaign for the Lap-Band, which was the very first medical device to be on all three major networks during primetime back then. So that was a major, major achievement for the company and ended up being very successful.

When ReShape brought me back in, I said, OK, well, let's look at this. You have doctors that are already trained, you have FDA approval, you have reimbursement, just no patients asking for the procedure. I personally went out and I talked to quite a few of the doctors I've known for 20 years, asking, "Why aren't you using the Lap-Band anymore?" And many of them said, "I love the Lap-Band, but nobody asks for it anymore."

So that told me right away, OK, I remember three big inflection points from the success history of the Lap-Band, which were FDA approval, gaining reimbursement coverage — which took significant investment and another three or four years — and then when we implemented the consumer marketing system used at Allergan, learning from them and launching national consumer direct advertising programs.

When our executive team at ReShape reviewed that history, we all said, let's do that again. Prior to this we brought in a great CFO, Tom Stankovich, who has great experience in the markets with public and private companies, IPOs, M&A, and I needed somebody with that kind of financial aptitude who could help develop that part of the strategy, supporting what we needed to do in order to execute efficiently as an organization.

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We also brought in a very strong leadership team during the past couple of years, people in our operations department, regulatory, commercial. Across the company, we brought in the best of the best, people that we've known for years, people who felt that there was unfinished business, that we have more to accomplish and a lot of people that we could help, which is part of our vision and mission, because everybody always talks about 1% of the people who could qualify for weight loss surgery pursued each year, and that hasn't changed in over a decade.

We knew as an organization, there were so many more people we could help, that were probably in that gap between diets — that don't work or it wouldn't be a \$300 billion industry — and really aggressive surgeries where you have your stomach amputated and your intestines rerouted, bypasses, sleeves, and similar procedures. Most people just don't jump that far, from a diet to a big procedure like that. Therefore, a huge gap was identified and we said, let's test it.

During the pandemic, we tested it and realized very favorable results — what kind of web traffic we could drive, what kind of leads we were generating. We tested on a small scale due to financial controls, but in a very metrics-driven manner across the nation, with accounts at all different levels of Lap-Band use. Very soon we saw that we were getting very, very good results that tracked with our historical experience with patient direct marketing. This data supported the development of our strategy — we needed to get back on NASDAQ and we needed to bring capital in that would allow us to execute on the commercial campaign. And we needed to move fast.

I'm really proud of what our team accomplished in spite of the pandemic. In June of 2021, we got back on a major market through an M&A transaction with Obalon, and we became RSLS on NASDAQ. A few weeks later in the same month, we also brought in a little over \$46 million in funding.

all in. We knew it was the right thing to do based upon our own metrics, plus the historical inflection points and metrics that we could track from the first time the band was released and became quite successful. So everything worked out really well.

We also know that there's a four- to six-month mandatory waiting period that's imposed by the insurance carriers. What I mean by that is most insurers will require a patient to go through significant steps, behavioral analysis, physical analysis, perhaps trying to medically manage a weight loss program one more time to make sure that they can't lose weight that way and need surgery. Knowing that, and if we started in that October/November timeframe, we went dark in the second half of December because of the holidays, and in January, February, and March, we really hit it hard again, because that's when people really have a focus towards weight loss with New Year's resolutions, etc. And so, we really hit it hard.

Now we're just getting to the point where the patients are seeing the doctors as Omicron really had a big impact on our industry — in fact, the whole elective surgery industry — for December, January and February. Many doctors didn't come back to work until March, but now they're seeing those patients, they're working them up, they're doing the consultations, they're scheduling. Over the next few quarters, we expect to see the results from all of the marketing that we did, getting patients connected and educated on our websites, verifying qualifications for the procedure. And then we do warm transfers to the practices with doctors that are certified.

As this process is starting to flow now, we're really excited to see what the next few quarters are going to look like with all the positive anecdotal feedback we're receiving, and the initial metrics we're tracking. Today we can track website traffic, leads and warm transfers with a high level of confidence.

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TWST: How did the merger with Obalon come about?

Mr. Bandy: We tried to look at ways that we could get back on the market, but we also wanted to find something that had some synergies, providing an opportunity for us to potentially integrate that portfolio, and work with the same customer demographic, with the same patient population. We looked at a number of different companies. We looked at pharmaceutical companies and other industries that just really didn't align well with us. And at the time, our financial position wasn't the strongest and it was challenging to become, I guess, a favorite option for some of those companies. But with Obalon, it made sense. We were able to work it out.

It's funny. They were only 25 miles apart from us in Southern California and we conducted the entire process during the pandemic, which is really, I think, an accomplishment, because the bankers, the attorneys, both companies, never met in person. Everything was done virtual. That's a pretty big shift. And then, we had some good investors that really believed in us. We did a warrant exchange, brought in a very good raise, and really just set ourselves up to execute.

As we already had our strategy in place, and because we knew how we needed to execute, we had our first ads in print and television premiere in October, but we had to go through medical review boards and other steps to gain access to most of the major publications and television channels, accomplishing most of that in November. The ability to build your ads, secure the media placements, working through regulatory and quality processes to ensure we were compliant required a tremendous amount of work, but the entire organization was behind it, For the consultations and the procedures, we have to work with the doctors to get that information and understand what those metrics look like and that's starting to flow through now. Our confidence levels in those areas of the metrics reporting will continue to firm up and be actualized. And so, over the next few quarters, from what we're seeing, and from our historical experience, we know that we're on track for positive returns and the opportunity to really help a lot of people.

It's an exciting time for ReShape. There's not a lot of similar competitors out there. That's good news as there's not really anything in the works for laparoscopic or minimally invasive laparoscopic surgery that will be competing against us. And even if something was to get through the FDA process and get an approval in the next year or two, it's going to take them significant time and cost to gain reimbursement from the insurance carriers. We're really creating a new market, an expanded market.

We're not going after the existing market — that's controlled by stapler companies led by J&J and Medtronic. Trying to go to war with them and compete for five minutes in the OR with a surgeon to try and change their preferences — that's just not the model that was going to work for us. Therefore, focusing on the patient flow and guiding these patients to their practices, in addition to the patients that these practices were seeing for their stapling procedures is additive. It's helping more people, it's creating a new market, it's creating more business for the practices, it's providing education to patients that maybe didn't know they had preferable options before.

We did some focus groups and many people in their 30s didn't even know what the Lap-Band was, because for the last decade

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or so, it wasn't really marketed well, and people now in their 30s were in high school or college back then. Weight loss and bariatric surgery wasn't really part of their attention span. For some, now it is. And our demographic, primarily, is a female that's 30 to 50 that has gotten to that point where they want to do something, but they don't really want to have something that's major or aggressive surgery.

We have so many benefits with what the Lap-Band offers. It's often performed in an outpatient setting. Doctors and patients both like that, especially in the wake of COVID, they don't have to go to the hospital. You can go in and get your procedure in the morning, go home that afternoon, and in a few days go back to work. It's very confidential and it's not a big disruption to your life and your responsibilities. That's something that's highly desirable to many.

It's adjustable with a small port connected to the Lap-Band that's just on top of the abdominal wall underneath your skin. With a simple office procedure, the doctor can either inject or remove saline from the inner balloon of your band, allowing it to be tightened or opened. What this facilitates, if you think of a sand timer with the Lap-Band around the top of your stomach, you have a much smaller stomach to fill up with that same sensation of being full. So you become full faster. People also think that with the Lap-Band, they still have control. They are using a tool to help them achieve their weight, their health goals, as opposed to just having something done to them. And mentally, that has a big impact on people making these decisions. Being in control and still participating through using a tool versus having something done to you can have a big, big impact in the evaluation process.

But again, with so many people that can benefit from weight loss surgery, we're not going after the people that may have already decided they want stapling or are going to doctors who are doing stapling. We're not necessarily competing against those procedures. We're creating a new market for people that don't want those procedures and may be giving up on diets. So it's a whole new twist, a blue ocean theory versus a red ocean theory and we're really excited about that.

Additionally, we just launched Reshapecare — as the doctors we interviewed told us they'd like support with managing patients after their procedures. And what I mean by that is the aftercare. Helping them with their behavior changes, helping them with their nutrition or exercise, whatever they might need to help them be more successful with this decision they've made for their life. And so, we created a digital therapeutic platform or a virtual health care program called Reshapecare.

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But then, how fast that food flows through the inner diameter of the band is controlled by an inflatable balloon that's attached to a catheter attached to an injection port. Making that balloon tighter makes the food, think sand, flow through slower and opening it allows it to flow faster. So basically, the Lap-Band makes you full faster and can keep you full longer.

But we can also do it in a healthy manner because if it's too tight, that's not necessarily going to make you lose weight faster. It's going to make you miserable; you're going to be hungry; your body may tell you to start eating bad foods that are highly caloric just because it knows it needs more nutrition. Your doctor will try to find that right adjustment for each patient, and it's also adjustable with your life needs.

Imagine a young woman who may become pregnant after she's had the Lap-Band, and her doctor can simply remove some saline in his office through a simple port access with a needle, remove some saline and open the inner balloon up to provide better nutrition during her gestation period. And then after she gives birth, go in and inject some saline back through the process to tighten that inner diameter of the band, helping her to continue her weight loss journey.

No other surgical procedure for weight loss can do that. Once you get a stomach stapling procedure, that's permanent, you can't adjust that. These unique benefits are really attractive to patients.

The Lap-Band also has the safest procedural profile of anything out there for weight loss surgery, proven with clinical data. And the Lap-Band has very durable weight loss maintenance. A recent report just came out showing that after 10 years, our weight loss and durability, or time maintained of weight loss, is just as good if not better than some of the stapling procedures. There's a lot of attention on weight regain in our industry today.

The Lap-Band is also reversible, as we're not changing your anatomy. You can go back in and remove that band. Not that we believe the Lap-Band is going to have negative results, but let's say a magic pill or a magic injection comes out down the road that could help people lose weight or replace surgery. If you choose to have our Lap-Band taken out, your body is the way you were born. As the program is accessed through a prescription by a doctor, it's physician led. After a doctor prescribes it, we have board-certified health coaches that work on the behalf of the doctor and his practice to provide this type of support to their patients. We have a clinical coordinator that works with the patient to find what their individual needs might be because it has to be individualized. Weight loss surgery is not one-size-fits-all. The coordinator connects the patient with coaches that could be a dietician and exercise physiologist or both; it could be a behavior therapist; it could be other resources.

Reshapecare is a step up from other programs or a third-party website with a library and a Bluetooth scale. This is real health care that's provided by board certified health coaches, under the authorization of a doctor, who also monitors everything on his Reshapecare dashboard. There are points where a matter may be escalated and the doctor or someone on his staff may need to jump back in and work directly with patients, for instance an adjustment to the Lap-Band.

TWST: I was wondering if you could talk about how the Lap-Band technology has evolved over the years and if there's anything else you have coming down the pipe in terms of new technology?

Mr. Bandy: The Lap-Band has had some improvements over the years, a lower profile port, so that when the patients lose weight, they don't see a button on their stomach. It's had improved design factors, understanding silicone as well as we do as an organization to make sure that you don't have contact points or things that might abrade, because if silicone touches itself, it can cause erosions.

We've made several improvements from a technical perspective and we have some potential advancements down the road that we're looking at, but right now, our focus is on this wonderful product with over a million placements around the world, and very successful patients for over 20 years, and building a sustainable foundation for our company to optimize our revenue and profitability opportunity. Focusing on the main thing and doing the main thing well. That's what we're doing with the Lap-Band today. And then other products, including our vest and neuromodulation technologies for diabetes, will move forward in our strategy.

TWST: That's the ReShape Vest system?

Mr. Bandy: Yes, that's the vest system. but some people think of it more as a corset. With some stapling procedures, primarily the gastric sleeve, if you don't have the right behavior changes, you can stretch your stomach back out and regain your weight. So we think that the vest may have some applications to help support a surgically reduced stomach in place so that it doesn't stretch back out, similar to a corset.

To that earlier question on the EnteroMedics transition to ReShape Lifesciences — there was a neuromodulation technology that they used for the gastric pacing-induced weight loss. Although it didn't really have great efficacy for that purpose, some really, really smart people with renowned clinical advisors adjusted the software on that product and were able to simultaneously block and stimulate different parts of the anatomy to address insulin control and we submitted that to the NIH for a grant.

We completed that first phase study, receiving very positive feedback and meeting all of our objective endpoints. We've recently submitted for Phase II of that study. We already had the technology that just needed some adjustments and new IP. And we have some team members who really understand the neural modulation field and were able to move this project forward in a non-dilutive manner.

And we're always looking at new technologies. Companies often approach us about ideas or technologies they have. Right now, we're not focused on jumping into any big R&D or PMA programs, because they're very cash intensive and take significant time. Right now, if we do look at something, it needs to be more along the lines of something already commercial, that we can grow with our expertise in consumer marketing or with our relationships that we have in the market

TWST: You moved your manufacturing from Costa Rica to a new U.S.-based supplier. What was the motivation behind that?

Mr. Bandy: We wanted to have better controls over our technology. We had some vendors up here that were already doing different components for us that were able to incorporate the final stage of the process, which is basically assembly, sterilization and packaging. It wasn't a big jump, but because we had those people that were already working with our product, it reduced the amount of shipping that we were doing and it gave us better controls over the quality monitoring.

We also felt that that would be much easier for us to manage scale needs, because until the product is finally assembled and sterilized and packaged, it doesn't start the shelf life. From a planning process using our ERP system, we're able to know exactly how many we have to put into final build. We're also able to work with the vendors much easier up here in the U.S., with reduced overhead, improving our margins and efficiencies.

TWST: Have you faced any issues with the supply chain?

Mr. Bandy: Great question. We looked at that. And some of the contract manufacturers were having some issues — staffing, trying to coordinate all the different kinds of materials that they had to procure for everybody they serviced and trying to prioritize those needs. Our operations department wanted to de-risk that factor and we now buy the raw materials ourselves to make sure that we're in control. That was another benefit of having everything up here in the States. And this was, honestly, before all the freight issues that you're hearing about from COVID. So we were kind of ahead of the game on that one.

TWST: What are you most worried about going forward?

Mr. Bandy: Honestly, the unknowns. Is there another variant of COVID that's going to shut down elective surgeries again? What's going to happen with inflation, and the war over in Ukraine? These events can also keep focus away from what we're trying to accomplish. COVID had a big impact on our business as bariatric surgery is considered elective. If the next few quarters normalize, and we keep moving, I think you're going to see some really amazing things from ReShape and from the Lap-Band.

TWST: What sets ReShape apart from its competitors?

Mr. Bandy: I think the fact that we have the FDA approval. We have regulatory approval around the world. We have reimbursement in place, which is crucial. It's a kind of a revival story. A majority of the work and expense was previously conducted through other companies who owned the Lap-Band at the time. Thousands of doctors were trained and we don't have to budget for big professional education programs. We don't have to pursue regulatory approval or reimbursement. We have a proven product with a strong ASP, solid margins now under our direct control and a huge patient-direct commercial opportunity.

Additionally, the incredible commitment and passion we have within our organization, having stuck together through all the challenges over the last few years while successfully developing and executing on our strategy brought all of us to this point where we're seeing really positive results and the entire organization knows that we're helping to address the horrible and growing epidemic of obesity and its associated comorbidities.

I think that from a cultural perspective, when we look at it, it's not just a product that helps a procedure. We actually work with doctors to help save and improve lives. When you have an entire organization that understands how important our mission is, and what a great opportunity it is for us to help people around the world, you have a different kind of an attitude, and you have a different capability because people get out of their comfort zones. Nobody wears one hat here. Everybody wants to keep moving things forward.

We all knew before the pandemic just how many people were overweight or obese. Right now, they say 30% of the world is overweight or obese and that's supposed to be 50% by 2030. And you have types of cancer, diabetes, heart disease and now COVID associated. Studies have shown that 78% of the people hospitalized or who died from COVID were overweight or obese, a huge risk factor. Now we even see the correlation of obesity with orthopedic issues. A paper just came out this month showing that there was a huge resolution in the need for joint replacement for people who had Lap-Bands and lost the weight that was creating stress and pressure. There are so many things that we can help with weight loss, including the whole mental health aspect of it, confidence, improved qualities of life.

I think as an organization, a term keeps coming up that you hear from all of us is unfinished business, because we know there's so much more that we can do and so many more people that we can help. We have one product. It has no direct competition. And what we build and what we do comes directly back to us. We're creating new opportunities and helping practices to be more successful because they also took a big hit with elective surgeries being canceled over the past two years. Everybody has to move from survive to thrive, and we're helping by bringing increased patient flow back to their practices.

There are so many different things that separate us and make us stand out. We've had very positive discussions with investors who see what we're doing and are excited about our strategy and execution, realizing that there's nobody with a bigger addressable market. There's nobody with a better product or safer procedure and there's nobody with more passion and commitment than ReShape.

TWST: Thank you. (CJ)

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