



CRG EXECUTIVE Q&A

JOSEPH CATANESE

CEO, Calyxo

premier
healthcare
investment partner



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INTRODUCTION

CRG's Brian Englander sat down with Joe Catanese, CEO of Calyxo, to discuss the kidney stone market, his career, and how his team is working to change kidney stone treatment through its innovative technology, ultimately improving the quality of care for patients who suffer from kidney stones.



“OUR MISSION STATEMENT IS THAT WE ARE DEDICATED TO IMPROVING CARE FOR PATIENTS WITH KIDNEY STONES BY DELIVERING PARADIGM-SHIFTING SOLUTIONS THAT ENABLE UROLOGISTS TO SAFELY, EFFECTIVELY, AND EFFICIENTLY ACHIEVE UNRIVALED CLINICAL OUTCOMES.”

JOSEPH (“JOE”) CATANESE, PICTURED ABOVE

way. Thank you very much. At NeoTract, I was part of the founding team and one of the inventors of the technology. There, we invented a disruptive product for enlarged prostates called the UroLift System.

During my years at NeoTract, I was fortunate to serve in multiple different roles. Firstly, on the R&D team, then transitioning to help build out the sales organization, and finally moving into a more general management role for the last few years after we were acquired by Teleflex. Each of those roles were fantastic experiences. I kept moving from the best job in the world to an even better job in the world – so it was a great opportunity. I was fortunate to serve in each of those different roles, but ultimately, the most rewarding part was that we were able to treat over 400,000 patients with that technology, create 400 high-quality jobs, and create a lot of value for shareholders and for employees. It was an all-around great experience, and I would say that was the most formative experience for me.

BRIAN: That's great, and we certainly appreciate all the hard work to make NeoTract such a successful story. An instrumental part of our investment was again partnering with the team that made it such a dominant company. Transitioning a bit, how'd you get involved with Calyxo? What got you excited about it?

JOE: There are two parts to that question, and the answer to each part is really about the people.

First, how did I come to know about Calyxo? I was introduced to Jee Shin, the founder of Calyxo, by our CFO, Doug Hughes, who was also the CFO at NeoTract. When Doug left NeoTract, he had started working

Headquartered in Pleasanton, California, Calyxo is a commercial-stage urology medical device company focused on transforming kidney stone removal procedures. The Company, originally Kalera Medical, was formed in 2016 through IP licensed out of Massachusetts General Hospital. The Company's lead product, the CVAC Aspiration System, is a steerable vacuum used to aspirate stone fragments following the use of a laser during stone removal procedures. CVAC is the first steerable kidney stone removal system used during ureteroscopy procedures and received 510(k) clearance in May 2020. Today, the Company is focused on further driving adoption and plans to launch its second-generation, CVAC in 2024. The investment, which was completed in January 2022, was made out CRG's Fund IV.

BRIAN: Joe, I appreciate you taking the time to speak with me today, I know you're likely swamped with the equity raise. Maybe we start from the beginning, can you share a little bit more about your background, career, and how you got to Calyxo?

JOE: Thanks Brian and no problem at all. I'm an engineer by training, and my passion is bringing innovative technology forward to improve lives. Fundamentally, that's what I like to do.

I've spent the last 19 years in urology, most of that with a company called NeoTract, which had fantastic support from CRG, by the

with Jee. Jee and I met, and she shared the early data that she had and, more importantly, what she had uncovered about the unmet need. I found that very compelling. So that's how I came to know of Calyxo.

How did I come to join, or what led me to join Calyxo? Again, that was really about the people. The unmet need was very compelling. I really liked Jee and what she was doing, and she asked me to come on board as just an informal advisor during the Series A period back in 2018. I was happy to do that and help out wherever I could. I didn't know at the time, but it was actually the start of a recruiting initiative from Jee. When she raised Series B, she asked me to join the company, and it was an easy yes for me. I had made the decision already that the next thing for me wasn't in NeoTract. I really wanted to stay in urology to leverage all that I had learned about the urology space. It was a great fit, and I really enjoyed the people and the mission. I have been fortunate to be a part of it and build out the team.

BRIAN: It sounds like a very calculated move by the team, as you know, Doug was also instrumental in our introduction to Calyxo. You mentioned the mission, can you give a quick overview of Calyxo's mission?

JOE: Our mission is really simple, "To improve care for patients suffering from kidney stones" – so we try to stay very, very focused on that. There's a lot of opportunities that come our way. We have a lot of great people on the team. We meet with a lot of urologists, and a lot of them have fantastic ideas that maybe are someday items, but for now, we are laser-focused on improving care for patients suffering from kidney stones.

BRIAN: To that point, what are some of the ways Calyxo is uniquely positioned to address those gaps in kidney stones?

ADDRESSING KIDNEY STONE TREATMENT GAPS

IMPROVING QUALITY OF CARE AND DECREASING COSTS

5 MILLION

Adults in the U.S pass a kidney stone each year

28 MILLION

U.S. adults have been affected by kidney stones

\$4.1 Billion

Total direct costs of kidney stone treatment is expected to exceed \$4.1 billion by 2030

JOE: I think really what sets us apart in the space is we don't have the baggage of already having products in this space. What I mean by that is the kidney stone space is very crowded. There are a lot of companies selling medical devices in the space to help from a treatment standpoint, but each of those companies are tied to how things have always been done. They're really tied to incremental improvement and antiquated technologies.

We came into this with no skin in the game, which enables us to say, "Okay, what's the very best way that we can think of to treat kidney stones?" and develop towards that without worrying about cannibalizing prior products. So, in that way, we

have a lot more design freedom, if you will, to think creatively about really disrupting the market. I think that works to our advantage in a big way.

The other thing, as we started to build out our team, there's just a different mindset in a startup company, and particularly on the sales-force side, in terms of disruptive technology and how do you launch that. So, really, a key part of our differentiation, I think, is ultimately the people.

BRIAN: We certainly agree, it's not often you can enter such a large market that hasn't been improved upon in years, we think Calyxo has an excellent opportunity to innovate and lead the segment. Given Calyxo is a bit earlier stage than most of our portfolio, can you summarize a few themes of learnings and progress since you joined?

JOE: When I joined the company in early 2020, it was just prior to submitting the first product to the FDA for clearance. FDA clearance came about mid-2020, but there weren't a lot of kidney stone procedures happening at that time due to COVID. So, the first procedures didn't happen until December 2020, but we used that time to insource the product. It had previously been manufactured at a contract manufacturer and there were some quality concerns. So, we took the time to address those quality concerns before we started shipping the product. That was step one of the foundation for the business, and that has really been the theme over the past few years. We had to get the product right, so we did that. Then, we had to establish the clinical data to support the product, so we initiated the clinical study, and we've since completed that study. We also needed to have reimbursement in place. In summary, you've got to have the product, the infrastructure for payment and clinical data to support it.



CVAV 2.0 USABILITY HAS BEEN CONFIRMED, AND UROLOGIST FEEDBACK WAS POSITIVE WITH AN AVERAGE LIKERT SCORE OF 4.9/5.0.

That's been the effort over the past handful of years. We were fortunate in that reimbursement clicked into place for the product ahead of the clinical data, which was fantastic. It was a little bit of a surprise, but we worked towards it, and we were able to achieve that. That enabled us to bring in a small sales force to start to test the market in parallel with developing the clinical data. But we've been careful not to get ahead of ourselves. We now have the supporting clinical data. We've also been developing a significantly enhanced second-generation product which we will launch next year. All of those things come together to set us poised for the rapid growth that we have planned over the next few years.

BRIAN: We've been very impressed by the progress over the last few years. A lot of things are coming together and clicking. We know, however, nothing comes easy – could you touch briefly on some challenges you've experienced being in the growth stage?

JOE: I think that the biggest challenge over the past few years, which is now settling out, has been being a small company. Normally, you do things in series. You get the product refined first. We did that. After, you get clinical data, then you get reimbursement, followed by commercial launch. With reimbursement coming early and our clinical data coming after FDA clearance, we had a lot of priorities for a small company. Juggling those things has been a challenge.

We're through the pivotal study now and we achieved compelling results from that study. We're about to submit our second-generation product to FDA, so we're through the major product enhancement phase, and we're really going to be able to focus on just one thing, which is driving adoption and bringing this technology into the market in a high-impact way.

And then ongoing, I think the challenge for any high-growth company at this stage is balancing being capital efficient and not being too scrappy in ways where it can hurt the business. We want to make sure that we spend wisely and make the right investments.

BRIAN: Great. Well, that's all I have for us today. Best of luck with finishing out the Series D and thanks again for your time.

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