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## PERSPECTIVE

### AAOS 2021 - An Interview with Anika's Cheryl Blanchard, PhD

Cheryl Blanchard, President and CEO of Anika Therapeutics, discusses the Company's metamorphosis from a partnered, single product company into a customer-facing, global joint preservation market player, in an interview with SmartTRAK.

By Freddy Buntoum, Senior Analyst, Orthobiologics and Regenerative Medicine  
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Cheryl Blanchard, Ph.D., President and CEO of Anika Therapeutics, discusses the Company's remarkable achievements amid a global healthcare crisis and progress made as Anika continues to execute on its *Transformational Growth Strategy* and grand plan in an interview with SmartTRAK at the American Academy of Orthopaedic Surgery (AAOS) 2021 in San Diego, California. To find out more, click on the following audio recording. A transcript of the interview is also provided below.



## Evolution is Inevitable: Transforming Anika

An interview with:

### Cheryl Blanchard, PhD

President and CEO  
Anika Therapeutics



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Freddy Buntoum here with BioMedGPS, and today I am at AAOS 2021 Annual Meeting in San Diego, California. I have the pleasure to talk with Cheryl Blanchard, President and CEO of Anika Therapeutics. Cheryl, thank you for talking with me today.

Cheryl Blanchard: My pleasure.

You were elected President and CEO of Anika. Tell us a little bit about yourself and how you made your journey to the CEO position at Anika, please?

CB: Yeah, I'm happy to. So, my background and training is as an engineer. I have three engineering degrees. The last one is a Ph.D. in Material Science and Engineering. I was always fascinated with the biomedical space and spent a number of years at a company called Southwest Research Institute, running the biomedical practice there. I had clients across a lot of the different therapeutic spaces, but I loved orthopedics. It just was a great fit for me. It really leveraged all of the engineering, and all of the patient factors, and the material

science stuff that I studied. At a certain point in my career, I went to Zimmer and was eventually the chief scientific officer at Zimmer, and really had responsibility for a lot of the new product development and strategy around innovation there. And really fell in love with the regenerative solution space, the early intervention space, trying to figure out how to focus on bringing meaningful solutions to get patients active faster. And try to do it in a way where there was value brought to the whole healthcare system because I think without that a product doesn't work.

**CB:** It was really that, that led me into management and leadership, and made me realize that I really wanted to continue to move in that direction and bring great therapies to patients, bring great value to shareholders. After Zimmer, I ran a small drug delivery company called Microchips Biotech, sold that back in 2019. I had joined the board of Anika a couple of years before that, and when the position came open, I threw my hat in the ring, and here I am.

**CB:** Really at a great time for the company. And I know one of your questions is about our transformation that we're going through. So I can jump into that if you want me to.

**Anika acquired two companies, ArthroSurface and Parcus Medical. Then you launched multiple new products and assembled a new team. Can you tell me how you were able to accomplish such a feat, all in the midst of COVID-19 pandemic?**

**CB:** Well, I have accomplished such a feat with a great team. I will tell you it's been a lot of work. Doing two acquisitions and embarking on a big transformation is already a lot of work, and something not to be entered into lightly, but to have COVID hit right when we did that, was definitely an added challenge, more than just running a company through COVID. Notwithstanding that that wasn't easy either. Frankly, we stepped back and said, "Okay here's what we've got. We got integration in front of us. We've got a lot of new product development in front of us, and so let's double down on what we can get done, and not pay attention to what we can't get done, because we can't control that. And so, we really took the opportunity to accelerate our Salesforce integration, to focus on our strategy and the new product development pipeline, and to take the time to implement the systems, processes, and people that we needed to execute on our strategy.

**CB:** So, we did that. And we've made great progress. We're really excited. If you walk around the booth today, you can see that we've really, in the first instance, put together a great portfolio of products that span that continuum of care in early intervention joint preservation. We do that on the surgical side with regenerative solutions, with sports medicine, soft tissue fixation, and with bone preserving implants. Then of course, the least invasive is our injection business, which we'll talk about separately, the joint pain management part of that. But that's really the portfolio that we assembled. The new product development pipeline follows along that, with a lot of innovation. And the fact that we're a fully commercial organization now, which we were not before.

**Right.**

**CB:** We got a lot done in the last year.

**Absolutely, congratulations! Now, moving forwards. Can you expand a little bit on Anika's short-term goals, and then what are the long-term goals say, 2024, beyond 2024?**

**CB:** Sure.

**Especially as it relates to expanding and outpacing the competition, particularly in your Joint Pain Management, and then in your Regenerative Solutions.**

**CB:** Sure. So, on the Joint Pain Management part of the business, in the United States, JNJ/Mitek is our marketing partner for that set of products, so ORTHOVISC and MONOVISC. So those products are sold by JNJ/Mitek in the United States, and we are their manufacturing and supply partner in that regard. But the products are Anika's products. We hold the registrations, but they are the commercial-facing entity for those products. We've talked about that business in the sense that, COVID obviously impacted it, but we feel like it's now moved into a time where it's stabilized. Obviously, COVID continues to impact it, with this recent pop of the Delta variant, we still see that it's effectively stabilized, but those procedures, even though they're in-office injection procedures, they get impacted by COVID also.

**CB:** Outside the United States, we sell ORTHOVISC, MONOVISC, and CINGAL, which is our second-generation Viscosupplement that combines Viscosupplement with Triamcinolone Hexacetonide, a steroid. We sell that in over 30 countries, outside the United States. It's a great product and we're in a clinical trial to bring that into the United States. So that's the Joint Pain Management side.

**CB:** On the Joint Preservation side, that's really the surgical business, where we've combined Tactoset, which is our injectable, settable bone void filler, that is used primarily to treat insufficiency fractures. That product is doing very well in the United States. We launched it in late 2019, right before COVID hit. But now with COVID recovery, we're really starting to see some nice acceleration of that product. Again, it fits really nicely in the portfolio of the Soft Tissue Fixation and Bone Preserving Joint Technologies because it's really that Joint Preservation call point across all the joints. And the fact that we're very focused on the ASC setting. Those are nice outpatient procedures.

**Okay.**

**CB:** So, with Joint Preservation, we've put together that nice portfolio, but we have some real innovation in the pipeline there too. Like HYALOFAS, which is our single-stage Cartilage Repair product, also a regenerative solution based on HA, that we have in a phase III clinical trial in the United States. We sell that in over 30 countries, outside the United States, also.

**Moving on closer to the HA market. Several states are seeing alarming numbers of Delta variant cases. Do you believe that we will see another extended period of clinics, physicians' offices closing? And how might this impact or not impact the results for Anika in 2021?**

**CB:** Yeah. I mean, what we see today, and who knows tomorrow, I don't know any more about COVID than anybody else does, that reads the news. But what we see happening in the market today, is that the larger healthcare system is managing it, and continuing to keep some level of patient flow going through. I mean, you've seen recently in the news that there are states and hospital systems that have delayed elective procedures, because of the Delta variant. A lot of our procedures though are also done in the ASC setting, and they by and large have continued to operate. We haven't seen them really be impacted by the Delta variant popping.

**That's an interesting statement. I heard recently that Texas has enacted the ruling that elective procedures in the ASC settings would be held back.**

**CB:** And it is by state, it's very state-specific and sometimes very city-specific, depending on what's happening.

**Again, on the HA market, over the past several years, we've seen the migration from multi-injection therapy options, moving to single injections. Do you see this continuing forward and how this might be impacting your three-injection segment?**

**CB:** I think that shift happened over the last few years. We have not really seen a big shift here recently. I think we've seen even stabilization of the three-injection market in the last couple of years.

**Okay. Now, with regards to the CMS proposed rules to mandate reporting of ASPs, that would be impacting several of the players within the HA market. Can you comment on that and give us the Anika perspective?**

**CB:** Sure. I mean, again, we're not in the United States where that applies, we're not selling the product to the end-customers. That's JNJ's purview. It's obviously though, a dynamic that we've tracked, and our high-level view on it, is that it will level the playing field. I think there's been a bit of an unlevel playing field there with the reporters versus the non-reporters. And so, what that means exactly, we don't know. The final rules haven't been issued and won't be until Q4. So how that plays out, I think is still a little bit of a question.

**Do you believe that CMS will actually... this will take place?**

**CB:** Well, I mean, a law went into effect, so they're going to have to implement the law. What's the specific rules around the law are, is what the question is, that still remains.

**Okay. Also, can you give us your perspective on how does Anika competes? The PRP market is becoming an increasing threat to the HA market, and we've seen some encroaching. How does Anika compete against this and other Regenerative Medicine solutions like Amniotic Injectables and other types?**

**CB:** Yeah, all the PRPs and the Amniotic injections are private pay. You could lump Lipoaspirate in that category too. It's all private pay. So, it limits their ability to really grow that market, but certainly, the lion's share of injections are either steroid or HA, because they get reimbursed by insurance. I think that dynamic will limit what the private pay options can do. The Amniotic products aren't supposed to be sold into that indication anymore. What happens there? I don't know, but the FDA has been pretty clear about what's not supposed to be happening there. But you look at the market data more than we do. The HA market is pretty stable. So, I think the private pay aspect of those other products limits their ability to grow until they get some reimbursement.

**Can you give us an update on the progress for moving towards the approval of CINGAL in the United States? And I think one of the biggest questions in the market is, on the US, how will it play with your relationship with JNJ/Mitek selling MONOVISC and ORTHOVISC, and then having the combination CINGAL product that will be sold through Anika directly?**

**CB:** Well, so first of all, we sell CINGAL, outside the United States, along with MONOVISC and ORTHOVISC, we have not seen CINGAL cannibalize ORTHOVISC and MONOVISC. It cannibalizes the steroid market. So, we think it's very much an additive opportunity in the United States, just like we see outside the United States. We sell all three products into the same markets outside the United States. So, we have pretty good visibility to that.

**CB:** It's an exciting product. We can't wait to get it into the United States. We gave an update on timing in our investor day. You want to look at our investor deck, we're looking at an estimated NDA filing of 2026 for CINGAL right now. We are enrolling in a pilot clinical trial today, and that will have to be followed up by a pivotal trial. So that's the timing we're looking at. Still very excited about it. That timing actually is still very competitive relative to other competitive products that would be coming along. So we chug along with it, getting it into the US.

**On the Regenerative solutions, can you give us an update on the progress with HYALOFAST for the US? And can you tell us how this product differentiates from the other products on the market?**

**CB:** Yeah, absolutely. So HYALOFAST is another product we're really excited about. It is a single-stage cartilage repair product. So only one surgery. We sell that product in over 30 countries, outside the US today. And it is a great product for us that we look forward to bringing to the US. In the US, it will compete with MACI, which is a two-stage procedure, very costly product to purchase. So, we look forward to having a product off the shelf in the OR that the surgeons can grab in surgery without having to take a biopsy, send it back and schedule a second surgery. We are actively enrolling in a phase III clinical trial in the United States today. That clinical trial has been impacted by COVID. We've talked about that. It's been frustrating, but we're managing through it, and we continue to enroll patients. And right now, our timing on that is filing a PMA in 2025.

**I have one more question with regards to HYALOFAST. You said it would be competing with MACI? In terms of the price point, how competitive are you planning to be?**

**CB:** We will be able to be very competitive and still provide a lot of value to the healthcare side, with our product.

**Can you give us a percentage range?**

**CB:** We haven't talked about that publicly.

**Okay. What other development is Anika working on with regards to Regenerative Medicine, specifically?**

**CB:** We launched Tactoset, which I mentioned earlier, which is our insufficiency fracture treatment. We have talked about the fact that we're building on that franchise with additional 510(k) filings. So, there's more to come with Tactoset. That's a franchise that we like, and we continue to invest in developing additional things around it. We are working on a Rotator Cuff Repair system, that uses the esterified polymeric version of Hyaluronic Acid just like is in HYALOFAST. But it is a system that includes a patch and fixation and instrumentation that will be kitted up for the ASC setting. So that's another thing that we're focused on, and we're moving through. Then we have other things in the pipeline that we haven't named exactly what they are yet, but more in the Soft Tissue Fixation and Enhancement area.

**Can you give us an indication on within the Soft Tissue Fixation, whether it's going to be towards the knees, the shoulders?**

**CB:** So, we are working across all joints.

**And what's the plan for announcing those further development?**

**CB:** Yeah, so we've talked about other Soft Tissue Augment and Repair scaffolds in the 2023 timeline and other Soft Tissue Repair sutures that are in that category, in the 2024 timeline.

**Anika recently launched the Wrist Motion. Can you tell us about this new product, and how is it setting Anika apart from the competition?**

**CB:** Yep, absolutely. We're excited about that product because the competitive products that are out there today are older designs that the surgeons don't love. They have some chronic issues with them around fixation and function. Still today, most wrist arthritis is treated with fusion. Most of the procedures are fusion, not arthroplasty. So, we love this product, because it was designed with really great biomechanics to give really great range of motion, with the same fixation that we have in the rest of our ArthroSurface product line with that single post-screw that works really well. We've got a lot of clinical data on that fixation methodology. And a lot of careful thought went into the design elements and being able to have an implant that also is ASC-friendly. So, we are in the limited launch phase right now, we'll be in full launch in September. *[turns to speak with Ben Joseph, VP US Commercial and Global Management]*.

**Ben Joseph:** The ASSH meeting in San Francisco.

**CB:** Yep, so that's where our full launch will be. But our plan is to really focus, not just on, "Hey, this is the new implant in competitive convergence, but let's not fuse your patient. Let's give them range of motion and the ability to continue to use their hand."

**What keeps the CEO of Anika up at night?**

**CB:** I think one of the big things that I think about, is just making sure that the team at Anika is building a company that is developing really meaningful solutions for all of our stakeholders, patients, surgeons, and the healthcare system. Because I think unless everybody wins, you don't have a great and winning strategy. So, thinking about how we can best serve the fact that a lot of these procedures are moving into the ASC, and how can you make the economics work in doing that? How can you still provide great products that have great clinical outcomes? And how do you make the right decisions about what those products are, so that when the company and the investors and the employees all move things in the right direction? It's really how all that ecosystem fits together and making sure that we're making the right decisions to move that strategy forward.

**In closing, is there anything else you want to share with SmartTRAK today about Anika and its grand plan?**

**CB:** Yeah, I mean, I think just that for us, at this Academy meeting, this is kind of our coming-out party, right. Anika really hasn't had a presence at Academy before. And just to have people see who we are as a company now, that we're all about Joint Preservation. That we are a company that has products across Joint Pain Management, Regenerative Solutions, Soft Tissue Repair, and Bone Preserving Implants, really providing solutions along that entire Joint Preservation continuum. We're here, and we're growing, and we're making huge investments in our R&D pipeline. We're just excited to have people be able to see what we've been doing under the cover of COVID.

**Well, thank you very much, Cheryl. It was a true pleasure.**

**CB:** Thank you.

## Other Perspectives

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by [Freddy Buntoum](#)

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