

## **Aclarion and its Nociscan are Using Biomarkers to Help Physicians Locate Lower Back Pain Emanating from within a Disc**



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**Interview conducted by:**  
**Lynn Fosse, Senior Editor**  
**CEOCFO Magazine**

**CEOCFO:** *Mr. Ness, Aclarion is advancing the care of patients suffering chronic lower back pain. In what way?*

**Mr. Ness:** We assist physicians in their treatment planning process, by identifying discs that actually are filled with pain generating biomarkers. The problem that these physicians have is, it is very difficult to identify pain that is emanating from within the disc based on the biomarkers present; not from anatomically obvious issues that can be seen on a traditional MRI.

When you look at an MRI, you can see anatomical structural issues with the lower back but you can't see inside the disc tissue and quantify the types of biomarkers like alanine, lactic acid and propionic acid, or proteoglycan on the structural integrity side of the equation, to determine whether that disc itself might be the source of pain.

**CEOCFO:** *What have physicians been doing up until now?*

**Mr. Ness:** There is a technique called provocative discography. This technique involves pressurizing multiple discs to determine which of these discs under pressure, is the one that is producing the most pain. The patient is awake and lying on the treatment table, a needle is injected into the disc space and it is then pressurized. Then the physician will ask the patient how it feels and then go on to the next disc and again ask how it feels, and then the third disc. When the patient is screaming off the charts in pain, the doctor knows that this is the painful disc relative to the other discs evaluated.

That is one way and it has somewhat fallen out of favor because when you pierce the disc you potentially are beginning the degeneration process. Absent provocative discography, a physician would be left to just look at the MRI or the CT scan and try to effectively rule out anatomical issues to determine whether a disc is painful or not.

**CEOCFO:** *Would you tell us about NOCISCAN?*

**Mr. Ness:** NOCI is Latin for pain. You can think of Nociscan as a pain scan.

**CEOFO: *How does it work and why?***

**Mr. Ness:** A patient goes into an MRI machine and rather than creating a picture out of the data derived from the MRI, what the MRI machine does is use a sequence called spectroscopy. In this form, the MRI is simply quantifying the presence of different biomarkers within the disc. We have learned through significant testing and scientific research that a certain ratio of these biomarkers, correlates to provocative discography, so we have correlated back to that gold standard with highly accurate results. Now we can simply take this complex MR spectroscopy data up into the cloud where our augmented intelligence algorithms can make sense of data that is unreadable out of the machine as it is, and produce a pdf report, clearly outlining the quantification of these biomarkers and then depicting a graph that shows which of the discs is correlating to pain.

The other part of the study is an isolated structural integrity score. This helps the physician determine whether that disc has strong boundaries, whether it has a healthy perimeter, to keep nerves from growing into the disc space. It is this nerve growing into the disc space and hitting acids that causes the pain. The structural integrity score measures only proteoglycan which is the predominant biomarker involved in the structural integrity of the disc. Nociscan involves both a pain score and a structural integrity score that come together, derived from the data in the MR spectroscopy (MRS) data set that comes to us in the cloud. Unfortunately a clinician can't really read spectroscopy. A radiologist can't look at spectroscopy raw material and determine these pain biomarkers without Aclarion patented technology.

**"You don't get anywhere without the key opinion leader community, coming together and rallying around a technology that they believe will help people in the end. I am thrilled to see our KOLs go to the podium at multiple society meetings, and know that as we pursue this reimbursement strategy, their voices will carry a lot of influence into the broader physician community as we seek to fully launch commercially throughout the United States." Brent Ness**

**CEOFO: *What were the challenges in creating the technology, and was there a moment when you knew you were going in the right direction?***

**Mr. Ness:** Dr. Bradford, Jeffrey Lotz, Jim Peacock, as well as John Claude, out of the University of California San Francisco, were trying to solve this complex problem of why 54% of the patients that have fusion surgery are actually happy with the surgery, meaning having a positive outcome from a pain perspective. They realized that the anatomical assessment of where the pain is coming from was left wanting and many discs that need to be treated were being left untreated.

The challenges go all the way back to how do we know what a healthy disc biomarker composition looks like. What they did to do this was they took disc tissue out of scoliosis patients, young and otherwise healthy discs because that is a deformity issue, and they measured the biomarker contents in there and realized that high proteoglycan levels, low levels of pain generating biomarkers are present in healthy disc tissue. They then did the same thing with known painful disc tissues and realized that a very different chemical composition was occurring within these young healthy discs and the old degenerative discs that were removed, so they did that basically from a histology perspective. Then, when they came up with the ratios that are now in our product, they went about correlating those ratios to provocative discography.

We have been correlated to the gold standard. The challenge is time and money. The researchers had to rule in and rule out and go through the natural scientific process of identifying the variables, and how to control for those, just like any new invention. However, time and money I would say is the biggest challenge.

We knew we had something special when the results of the Gornet Trial demonstrated a significant improvement in patient outcomes when Nociscan identified discs were treated vs not. 97% positive outcomes vs 54% when there was a mismatch between treated levels and what Nociscan identified as painful.

**CEOFO: *Where are you today?***

**Mr. Ness:** We are FDA cleared. We have our CE mark in Europe, so we are in the market today. We have done approximately 1300 commercial scans. We are in this place where in the United States, we have this solution but we don't have insurance reimbursement yet. So we are building all of the peer reviewed published evidence for our key opinion leader physicians. We are really leaning in and we want to see this come to fruition for them because they recognize the

value of having this information as they are treating these complex cases. We are building the evidence that they can then take to the insurance companies, to gain positive coverage decisions. We will then fit right into the standard of care of how people order tests when the insurance companies pay for them.

We are fortunate in that three of the four largest private insurers in the UK have covered NOCISCAN. AXA, Aviva and Vitality are currently paying for NOCISCAN through the relationship they have with the London Clinic and the London Spine Clinic in particular. We have a proxy market out there showing that when NOCISCAN is reimbursed, volumes increase and physicians are accessing the technology.

With that, as a publicly traded company we did an IPO back in April of 2022. We are very thoughtful about identifying the catalyst of value that shareholders can look to as we go through this process of enjoying reimbursement in the UK while building the compelling reason for reimbursement, with US payers.

**CEOCFO: *What is the interest from the investment community in back pain?***

**Mr. Ness:** It is incredibly important. Back pain is the number one cost driver in all of healthcare. Chronic back pain is the number one cause of opioid addiction in the United States. Our market is absolutely incredibly huge. What physician or treating clinician, wouldn't want to know where the source of pain is coming from? Your right elbow doesn't get better if you operate on the left elbow. To improve outcomes, you need to pinpoint the pain.

From an investor perspective, I'd want to know how big the market is for this particular technology the company is addressing. Ours is absolutely huge. I want to know the margin profile of the business at scale. Ours is that of a SaaS based solution. I want to know some of the proxy companies that we can look to in the space, that have maybe traveled the journey before. When I say in the space, I mean in the SaaS space of healthcare, intersection of diagnostics and AI technology. At Aclarion, we look no further than Heart Flow, who did an IPO this summer, are enjoying an over \$3 billion market cap in what is really the exact same business model as what we are deploying our resources into, but a smaller market. From an investor perspective, I would think that those would be very compelling foundational blocks of consideration that I would look to. I would look to see if the company is doing what they said they were going to do and executing to the stated plan as well.

I would encourage any investor to look back over the multiple press releases that we have done over the last three years. You will see that we talk about building out a KOL (key opinion leader) community and then we execute to it. We talk about launching a national randomized control trial, CLARITY trial, and we execute to it. We talked about expanding insurance coverage and we did so in the UK. We will do so in the United States. We talk about scan volume growth, and we have enjoyed an uptick in scan volume growth over the last three quarters in a row. On a year over year basis, our scan volume is very compelling. From an investor perspective, that would be what I would point them to. We have also been in a highly volatile microcap market for a while and I think if you are staying up with the markets, you will see some favorability now, looking back towards the micro-caps; a little more tolerance for risk in the market.

**CEOCFO: *Should patients be made aware, and can they do anything to help increase the reimbursement?***

**Mr. Ness:** Absolutely, we are in the process of launching a direct-to-consumer informative campaign in the UK, where we have reimbursement. It will be interesting to see the results of that initiative. I think the patients need to ensure that their treating physicians have identified every opportunity to understand what is wrong with them. To that extent we will likely replicate that direct-to-consumer campaign that we will launch in UK, here in the United States in various markets where reimbursement occurs.

Over 266 million people around the world suffer from chronic low back pain. I am not talking about the kind where you had a hard week and your back is sore, I am talking about the type that keeps people from working, which keeps people from enjoying the lives that they are meant to live. It is an epidemic and one that we need to solve because the downstream cost implications to society, let alone the implications to each individual that suffers from this, are pervasive. We want to help solve that.

**CEOCFO: *What has been the response from the medical community in the US?***

**Mr. Ness:** It is wonderful. I cannot say enough about the physicians who have joined our cause. Those that are participating as investigators in the CLARITY trial, those that have been out on the cutting edge of this from the very beginning, their willingness to help us and their generosity with their time and their incredible insights, has been inspiring.

You don't get anywhere without the key opinion leader community, coming together and rallying around a technology that they believe will help people in the end. I am thrilled to see our KOLs go to the podium at multiple society meetings, and know that as we pursue this reimbursement strategy, their voices will carry a lot of influence into the broader physician community as we seek to fully launch commercially throughout the United States.

**CEOCFO: *Final thoughts?***

**Mr. Ness:** We have a passionate group of employees who have been here without turnover since I came onboard in 2021. This team is very focused on driving value, that we are prudent about the dollars that we spend and spend towards things that are going to make a difference in the achievement of these value building catalyst I have referenced. I am blessed to have a team of brilliant people working here at Aclarion, and we will execute over time.