ceocfointerviews.com

Issue: November 23, 2020

# MY01, Inc. is arming Physicians with the Data needed to make Informed Clinical Decisions from Physician to Patient Engagement

**Charles Allan, M.Eng**
**Chief Executive Officer**

**MY01, Inc.**
**www.my01.io**

**Contact:**
**+1 (855) 799-6901**
**info@my01.io**
**400 Boul de Maisonneuve Ouest, Suite 700**
**Montréal, QC H3A 1L4**

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

**"We believe that physician/patient engagement is key to effective healthcare. At My01, we believe that healthcare is human, it's a person to person experience." Charles Allan, M.Eng**

**CEOCFO:** ***Mr. Allan, according to your site, "MY01 is on a mission." What is the idea behind the company?***
**Mr. Allan:** We believe that physician/patient engagement is key to effective healthcare. At My01, we believe that healthcare is human, it's a person to person experience, and there is a lot of qualitative assessment that happens at the bedside. We believe that if we can get reliable data at the bedside during those meetings, that we can improve patient outcomes and the patient care experience. That is what we are trying to do.

We are trying to arm physicians with the data they need to make an informed clinical decision when they are doing those assessments. That's what we mean when we say that we're on a mission. We're on a mission to empower healthcare professionals with the ability to diagnose emergent medical conditions and improve patient outcomes.

**CEOCFO:** ***What types of data can you provide and in what format?***
**Mr. Allan:** We work on a variety of different sensors, but the MY01 device is currently being commercialized as a device that measures intracompartmental pressure, it is used for a problem called acute compartment syndrome, which is a trauma-related disease that happens when there is some type of high energy incident; whether that be a car accident or some type of sports injury or a fall from height or anything like that.

Our device detects the swelling and the inflammation that happens within the muscle and relays that information, the intracompartmental

pressure, to the physician, so they can make an informed decision about acute compartment syndrome, so it is used as an aid to diagnose.

**CEOCFO:** ***How might a doctor measure that now? What do they want to know?***
**Mr. Allan:** Today, the standard of care is a process called the 6 Ps, which is mostly based on qualitative assessment and the majority of it is based on pain and pain on passive stretching. They do not typically use pressure monitoring as much as they would like to, because there is not a very good tool out there to do pressure monitoring continuously, and that is what we provide.

**CEOCFO:** ***How does the device work?***
**Mr. Allan:** There is a video on the website that walks you through it, but it is the sensor at the tip of a device that goes in like an IV. The needle is removed when you insert the device in, so it is a minimally invasive product. Then there is a screen on the outside of the device that relays the information to the doctor when they are trying to make the assessments.
**CEOCFO:** ***Would this typically be done on the spot by an EMT maybe or would this be done in a hospital or a doctor's office? Where would the device be used?***
**Mr. Allan:** It typically begins with a trauma related event. When that event happens, the patient will be brought to an emergency room and the MY01 device will be used in the emergency room where it'll stay on the patient for eighteen hours. In the event that they end up becoming an inpatient, then the device will follow them through the care schedule.

**CEOCFO:** ***Why is this product your focus now?***
**Mr. Allan:** The product itself was a problem that one of our founders was dealing with on a regular basis. Dr. Ed Harvey is an orthopedic trauma surgeon at McGill Montreal General Hospital. He has been dealing with this problem for a long time and he thought that there must be a better way to help diagnose this. We then went on to develop a solution for him involving pressure monitoring, which has been accepted by the American Academy of Orthopedic surgeons as being a way to rule out compartment syndrome.

At that time there was not really a good tool to provide continuous pressure monitoring over the extended period to make it clinically useful. Therefore, that's why we set out to develop the MY01 device.

**CEOCFO:** ***What changes for you now that you have your 510K clearance? What are your next steps?***
**Mr. Allan:** We are commercial, we are working on scaling up, and bringing the device to as many surgeons as possible. Therefore, we are working with many leading trauma centers across the country, so we are working through the adoption cycle and then onboarding the hospitals. Right now, our goal is to make sure that the doctors are well trained on using the product and administering it in a way that makes it beneficial for them in their care practice.

**CEOCFO:** ***What is involved in the training? What do doctors need to understand?***

**Mr. Allan:** It is a very simple training process. We do it online. It takes about fifteen minutes. We are just doing that to ensure that the product is well received in the first few times.

It is very simple to use. If you can put an IV in then you can use this product, you just need to know basic anatomy. Therefore, any trauma surgeon is well equipped to be able to insert this product.

**CEOCFO:** ***Is this a disposable product?***
**Mr. Allan:** It comes as a single use unit, so it can be used for the full eighteen hours after which point the product will be disposed of. We have built them in sterilized packages, so it is very simple for the doctor to pull it off the shelf and administer it. That is something that we found with being in trauma settings, it is important that the process is streamlined and that in the event that you would want to use this product that you know where to find it. We sell it in boxes of six and so, it is on the shelf whenever the surgeon deems it necessary to use.

**CEOCFO:** ***With so much noise in the medical community, particularly under COVID, how do you gain attention so that the surgeons, hospitals and buyers are paying attention? How do you reach out?***
**Mr. Allan:** We are doing a lot of outreach on social media as well on through connections. We had already been doing a lot of clinical work with several key opinion leaders across the country and in Canada. We use those relationships and connections to continue to build relationships with the surgeons and bring our product to market. Much of this is done virtually at this point.

One of those is the Orthopedic Trauma Association meeting, which is a meeting that was supposed to happen in Nashville and we were going to do a big market release at that point with our key opinion leaders. However, because they went virtual, we are doing things a little differently now. Hopefully next year, once COVID becomes a little more under control, there will be a meeting that will not be virtual; there will be a physical meeting and it's where we will be able to do a proper American launch.

**CEOCFO:** ***Cost is always a factor, but for some items not as important as others. Where does this fall?***
**Mr. Allan:** Our device is a single use product, so we charge per unit. The value comes from providing the doctor with more information to be able to make a better clinical decision, so we are aiding in the diagnosis. In that case, there are two main places where much of the costs are borne for acute compartment syndrome, unnecessary correction and missed diagnosis. Unnecessary are cases where the diagnosis is unclear, either because clinical signs are not conclusive or the patient is unconscious and because of the poor outcomes and medical legal liability of compartment syndrome if not caught early, the surgeon will tend to over operate and over fix.

The corrective procedure for compartment syndrome is called a fasciotomy, it's a gruesome intervention where the surgeon opens the patient's affected muscle to relieve some of the pressure. If you talk to surgeons and in the literature, the surgeon will do twenty percent more

of the corrective procedures than needed. They feel that they need to and they do that because they are afraid of missing compartment syndrome. On the other side there are missed compartment syndromes that can eventually lead to amputations. Again, those are instances where it is a very expensive procedure to fix once you have missed acute compartment syndrome. Therefore, our device is there as an aid in order to reduce the number of unnecessary fasciotomies while reducing the chances of missing compartment syndrome. That is where the value comes from for our product.

**CEOCFO:** ***Why is eighteen hours the right amount of time?***
**Mr. Allan:** Typically, ACS can happen forty-eight hours following trauma, but the majority of the cases happen within the first twelve hours. Therefore, we wanted to give the surgeons a little bit more of a window of opportunity and that is where the eighteen hours came from.

**CEOCFO:** ***Do you need to maintain much inventory or will you be able to manufacture as needed?***
**Mr. Allan:** The bulk of the work that is being done internally is to scale up manufacturing. At this stage we do not see ourselves holding very much inventory. There is a lot of demand for our product, so we are basically working on meeting demand.

**CEOCFO:** ***What surprised you throughout the process of developing and now having FDA clearance?***
**Mr. Allan:** Everyday there is a challenge that you need to work on to get to the next level, in order to continue to move forward. I can say that there is never a day when I am not surprised in some way, but as an organization we have gotten so comfortable with being in that uncertain area and being able to see these problems and figure out ways around them, that I would say that we are comfortable being surprised. I'm surprised at how our team has grown and been able to rise to the challenge. As we move forward and gather more and more clinical data, and feedback from hospitals, that will become less and less of an event.

**CEOCFO:** ***Are you seeking funding, investment or partnerships? Development is always expensive, as is commercialization.***
**Mr. Allan:** We are fully funded in our current plan at this point. We would listen to companies if they see a strategic fit. However, at this point we are not seeking funding. We are going to continue to push forward in our current commercialization plan.

**CEOCFO:** ***What does the next year to eighteen months look like for you?***
**Mr. Allan:** The next year to eighteen months is really about focusing on sales and commercial development, so that is where our main focus is: to prove out the product and get it into the hands of as many surgeons as possible.

**CEOCFO:** ***What, if anything, might someone miss about MY01 that they really should understand?***
**Mr. Allan:** We do development work, but our team really built MY01 around clinical needs and because of that we have a full system in place, from engineering to production to commercialization and sales. We have

built out a full-scale organization. We work with contract manufacturers, but the majority of our expertise is internal. Therefore, that gives us the opportunity to work on a variety of different technologies and that comes back to the first question that you asked, about the mission and vision.

We are not a one product company, although we are commercializing our first product. We have a series of other sensor related technologies that we are developing today and you will see us release over the next few years.