Jan de Backer – CEO, Fluidda

What we see clearly with COVID is the need for better technology and approaches to respiratory disease

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Fluidda is the world leader in the field of functional respiratory imaging which combines HRCT scans and computational fluid dynamics technology. CEO Jan de Backer outlines the major developments of the Belgian firm's recent history including expansion into the US, how a USD ten million injection of Series A financing could catapult Fluidda to the next level, and why COVID-19 should be the watershed moment for innovation in the respiratory space.

Fluidda has its roots in Belgium but has increasingly focused on the US market in recent years. What was the initial driving force behind this expansion?

The US market is still the biggest market in healthcare, with a lot of decision-makers based there. The market is also quite dynamic and good for innovation. For these reasons, in 2012 we decided to open our first US offices as to be successful in this market it is important have a presence on the ground.

How have you gone about introducing the concept of Fluidda in the US? Did you market the company as a CRO and how has your strategy evolved?

Introducing innovation in the medical field can be very difficult. Hospitals and physicians have a certain way of doing things and unless there is a very compelling case it is hard for them to

change. That is why we have proposed a CRO model bringing together both our technology and our services in clinical trials onwards. We were initially focused on clinical trials to understand disease and treatments, and we now have the knowledge and scale to roll it out for use in clinical practice.

This has worked quite well and has led to more projects, more revenue, and more data, which is crucial as the future competition between groups in the healthcare space will be around knowledge and data derived from the technology rather than the technology itself.

Our technology provides unparalleled insight into lung diseases that we believe could help redefine or reclassify these diseases to optimise the treatment.

What is your main source of data gathering and how do you assess its quality?

Our data comes from clinical trials sponsored by pharma companies that want to study their drug, investigator-initiated trials around the world investigating specific questions with our technology, and our own Fluidda-sponsored trials focused on validation questions around certain part of the technology.

We actually go to all the hospitals and clinical sites that perform the analysis, making sure that the radiology has the right equipment, that the settings in the scanner are correct, and that the uploads from the site to our servers work. Fluidda invests a lot in local quality assurance, which adds a lot of value to the data.

Despite the noise, it is hard to analyse the true impact of AI and Big Data on clinical development, especially in the multi-payer US healthcare system. Does this ring true to your experience?

It is hard to generalise. It really depends on how you approach the clinical trials. A big difference between the trials that we do and more traditional trials is that by using our highly sensitive technology the number of sites and patients can be quite substantially reduced; typically, we require up to five to ten times fewer patients in a study on spirometry.

That means that instead of going to 200 sites, we can go to just 10-20 and have a well-powered study with the right centres for specific trials selected which increases the quality quite substantially. It is difficult to have a very homogenous 200-300-strong global hospital network, but less so with 10-20 sites.

How are the sponsor companies that work with you able to justify trials with fewer participants to the regulators? How can you explain your technology to different stakeholders to allow them to understand its value?

The regulatory agencies look at Phase III data for the pivotal, registration trials, where we are not currently active. They also say that whatever is done in Phase II or Phase IV is up to the sponsor company. We are currently working hard to become a regulatory endpoint for Phase III and for indications like fibrosis we have made good progress, but currently, companies are using our technology in Phase II to really understand the potential of compounds and de-risk the drug development. Phase III is extremely expensive, so sponsors need to find out the probability of success in Phase II.

We are also very active is in Phase IV, where products already on the market need to be compared to another standard of care or competitor on the market.

In which therapeutic areas within pulmonary diseases does Fluidda excel and what is the logic of moving towards Phase III trials?

We cover all lung diseases with a lot of activity in idiopathic pulmonary fibrosis (IPF). There is a resurgence in research for chronic obstructive pulmonary disease (COPD) which represents the highest unmet need of all lung diseases and is associated with conditions such as pulmonary hypertension. Treating asthma with biologics is a focus point as is cystic fibrosis with newer drugs coming to market that are quite effective but come at a high cost of up to USD 400,000 per patient per year.

We are working hard to become that regulatory endpoint because the more treatments that are being developed using imaging, the easier it will become to match the right patient with the right treatment in the clinical practice. Today, this process is akin to trial and error as the clinical trials do not really specify which types of patients would benefit from a drug. With biologics and antifibrotic drugs, it is about searching for these responders.

What does this shift to Phase III trials mean for Fluidda in terms of financing needs and readjustment of strategy?

There will certainly be a need for additional capital, and we are currently in fundraising mode to facilitate that. We currently have a very good team of people conducting trials that are highly skilled and highly knowledgeable, but if the volumes increase by five or ten times, we need a system that ensures that that quality is maintained, which requires additional investment.

That will be both from the clinical trial and clinical practice perspective. If we are developing more drugs using imaging, it is important that the same type of technology is also readily available in hospitals to make the selection of the right drug for the right patients. We also need to be active there to make sure that the technology is scalable and integrated into the radiology workflows, making it easier for the physician. The technology also needs to be easy to use, without the need for extensive training programs or a lot of additional work.

For this reason, the initial investment will go into expanding clinical trials and really facilitating the implementation in the clinical workflow in as seamless a manner as possible.

How much money are you looking for and how are you looking to allocate it?

We are looking to raise USD ten million Series A financing to build a network of centres of excellence with good pulmonologists and radiologists that can participate in the clinical trials, generate more data about the utility of the technology and the treatments that are being studied with it. They will also be the first ones to use it in clinical practice and generate evidence.

We are actually growing quite nicely in terms of revenue with a profitable clinical trial business. The addition of an additional USD 10 million on top of that should get us to the next value inflection point.

Do you have plans to split the clinical trial and clinical practice businesses in the future?

It is true that these are two different businesses. We will keep the two together as long as one provides a lot of value to the other, which is the case for the foreseeable future as the knowledge from those clinical trials informs physicians in the clinical practice. The flow of information needs to be there.

Potentially, in the long-term they could be separated with one operating as a CRO business and the other as a digital health business, but for now they provide so much value to one another that we will keep them together.

COVID-19, in many ways, is a respiratory pandemic. What work have you been undertaking to rise to this challenge and capture any opportunities?

When it became clear that this was going to be quite a severe pandemic, we started an initiative to collect HRCT scans from COVID patients all over the world. At the end of March, we saw that this was not just a respiratory disease but that COVID patients were also suffering from vascular issues.

In April, we saw that even early in the disease stage, the blood vessels in patients' lungs were quite constricted and occluded. That has now been confirmed in many other studies which is quite important because if you have constriction and your blood vessels are too small to begin with, on top of that you develop the viral pneumonia that requires mechanical ventilation. Mechanical ventilation actually causes more constriction as the pressure in the lungs constricts the vessel even more. That is the reason why in the initial stages a lot of patients had very poor outcomes on ventilators. People are getting more knowledge about it, including from imaging and other types of studies which highlights the need for better technology to understand specific diseases.

In this case it was the underlying vascular element that was unexpected because it does not occur in typical viral pneumonia. This would have been hard to detect without imaging and is a nice example of imaging leading to a better understanding of a disease and allowing for treatment to be optimised.

What we see clearly with COVID is the need for better technology and approaches to respiratory disease. It is no different to what we see in other diseases like IPF and severe COPD, but for these diseases it takes a longer time for the patient to die and there is less attention from the media. However, the principles are the same – the underlying disease is usually poorly understood and the treatment is sub-optimal; that is where there is a huge opportunity and room for improvement if we introduce this type of technology in a sustainable fashion in the respiratory space.

What has been the impact of the pandemic on your business?

Our non-COVID trials were put on hold, as they were for other companies across the world. However, we are receiving many scans every day, much more than before, from the clinical practice side. That part of the business picked up substantially and the insight that we gained from those scans is something that pharmaceutical and biotechnology companies are very interested in. These companies now have to make decisions as to how far they go into drug development in

areas like lung fibrosis, pulmonary hypertension, and long-lasting lung damage post-COVID.

Because of this, we developed a COVID-19 drug consortium where industry partners can join and get insights which they can use for their internal decision-making processes on their own pipelines.

There has been a lot of talk about COVID-19 vaccines, but very little on drug repurposing. Do you foresee a greater number of trials focused on the repurposing of existing drugs?

Absolutely, I think it is possible and necessary. There is an important vascular element to this disease, which is good news for the number of options in inhaled medication out there which are inexpensive and relatively easy to repurpose. There should be an increased effort into seeing what types of drugs could work. There has been a lot of work undertaken on remdesivir and hydroxychloroquine already, for example.

It is not an easy environment to do proper clinical trials in but finding treatments for these types of viral infections while waiting for a vaccine is incredibly important. Developing a vaccine takes time, so there is still need for treatments for these viral infections.

If technologies like ours can indicate that certain elements are important, it informs which types of candidates should be assessed in more detail. We know that once a patient enters the intensive care unit (ICU), it becomes very difficult to treat them and becomes a case of hoping that the patient survives and supporting them in the disease. Early on, if we are able to take away underlying conditions as much as possible, the outcome can hopefully be improved.

How will COVID-19 change attitudes to innovation in your field and what will be the roles of the US and Europe?

COVID-19 should be the watershed moment for innovation in the respiratory space. We must ask ourselves how it came to be that the entire world needed to be locked down because of a respiratory virus. Part of the reason is that we in the respiratory world we did not do enough to prevent it or to understand viral infections, what they do, and what acute respiratory syndrome (ARS) actually is.

Innovation in the medical field should be global but the US, being the largest market, should take a prominent role in the adoption of this type of technology. However, Europe has the advantage of a

more uniform healthcare system, meaning that once innovation is accepted it is easier to roll out. In Europe, we need to accept new medical innovations more quickly, otherwise we will be doomed to repeat the same mistakes and be ill-prepared for future pandemics.

China is perhaps the respiratory market with the greatest potential globally, with a high level of unmet need. Is this a market that Fluidda will be looking at in the future?

Absolutely. China is the obvious market for respiratory diseases for many reasons. One is the air pollution; another is the fact that people still smoke a lot there so COPD is very prevalent. From our fundraising round we are talking to Chinese funds and seeing if we can partner up with them. This is an important element – to enter the Chinses market there is a need to find a good and knowledgeable domestic partner as it is not an easy market for a foreign company to navigate alone. It is definitely an area where innovation in the respiratory space can lead to better care for many patients.

We have already established an office in Singapore which is helping provide additional data from Asian patients and healthy volunteers in anticipation of a greater role in the Asian market.

What do you hope is learnt from the COVID-19 crisis we are currently living through?

The important thing is that this should be the watershed moment for innovation in the respiratory space. When the dust settles, we should do a proper analysis of how we got into this situation and where we can do much better in the future.

That message should resonate with all stakeholders – physicians, innovators and regulators – that need to support certain types of innovation. More lockdowns with second waves or other pandemics will lead to massive economic damage on top of the loss of life. I am not sure how many times we can survive that. We need to get our act together and do better. It is now or never.

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