Interview with Jan De Backer, CEO, FluidDA

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Tags: FluidDA

Dr De Backer looking into your background, we see that you have a background in aerospace engineering and applied biomedical computational fluid dynamics that is riddled with awards for your innovative research. Given your commendable achievements, what would you say motivated you to found FluidDA in 2007?

Over the course of my trainings in aerospace engineering, I came across the computational fluid dynamics (CFD) field of study, which is applied in the industry for the design of aircraft wings. This technique caught the attention of my father, who is heading the respiratory department at the Antwerp University Hospital, and became interested to see if it could be applied in the respiratory system. We thought this was especially worth looking into since my father is also involved in the regulatory procedures of the EMA in the registration of new drugs. In that role, he had observed how it was becoming increasingly difficult to measure the efficiency of new interventions in the respiratory system using the classical outcome parameters. As a result, we recognized the need for new outcome parameters as well as potential applicability of flow simulations for a better understanding of what actually occurs in the respiratory system the could subsequently lead to enhanced solutions.

That said, we decided to explore this opportunity and began by enrolling in a PhD program in Biomedical Physics while simultaneously also founding FluidDA in 2005. In due course, we began to evaluate the possibility of combining flow simulations with the CT scans, or the conventional imaging modalities, to come up with some personalized medicine. The basic idea here was to

phenotype the given patients and determine whether these new output parameters can be used to detect the efficiency of new medications with high sensitivity.

In due course, we were successful in developing the technology, achieving favorable preliminary results, and we conducted some proof of concept trials and expanded the validation portfolio. Up until today, we have been active in this field for more than six years now, attributing FluidDA with a consistent growth rate of approximately 30% per annum. In addition to the impressive growth figures, we have seen increased interest and acceptance of this technology from the broader community. Needless to say, this is more than desirable since nascent and innovative technologies do tend to face some level of resistance and conservatism.

Throughout your five years as CEO at FluidDA, how would you describe the company’s key milestones and what are your proudest achievements?

As a young and fast growing company, I would highlight the fact that our first ever clients eventually came back to us for a second round of studies. In a repetitive business such as ours, I believe this demonstrates that the customer has clearly identified the added value in our services.

In addition to this, the pharmaceutical industry operates in a relatively slow moving environment with typically lengthy product development cycles lasting anywhere between 10 to 12 years. As such, innovative companies often tend to burn through vast sums of cash in order to be able to be active in the field for a long and seize their opportunity at the right moment whenever it might appear. In this respect, having repeat business from our clients was a very encouraging signal that we were indeed on the right track.

Another cornerstone in FluidDA’s development includes the successful publication of our validation trials in prominent scientific journals. This is absolutely critical since this allows us to convince the scientific and regulatory community of the validity of our technology and techniques.

Today, FluidDA acts as a CRO to support the implementation of its imaging biomarkers into clinical trials and clinical practice. However, how comprehensive is your offerings portfolio in the Belgian context?

At FluidDA, we are taking the one-stop-shop approach to our portfolio of offerings. That is, today’s technology, with its cloud computing capabilities, data centralization, and the drive towards personalized medicine fits perfectly into our domain of activity. For our clinical trials activities, in the same way that everyone is accustomed to sending their blood samples for analysis to laboratories scattered around the world, we intend to apply that same model to bioimaging

modalities. In other words, CT images will be sent to our central laboratories where we will carry out the required analysis and send the report to the respective physicians via an online system. In that respect, I believe that this model is highly scalable which will allow us to take a global approach.

On the other hand, in terms of our clinical practice applications, which is also the largest market, we will have to contend with the reimbursement authorities and policies and find some innovative solutions to successfully gain reimbursements for candidate drugs. In today's climate, this is a formidable challenge, considering the authorities inclination to save costs and control their budgets. Hence, we are making the case that by using our technology, they are able to lessen the burden on their budgets over the long term. Of course, this is an on-going process and we are in constant discussions with the relevant authorities and insurance companies, demonstrating through research studies the added value the technology presents to the patient and its capacity to lower costs. To illustrate, based on sample size calculations of clinical trials, we are for instance able to reduce the number of patients by a factor of five to ten. This undoubtedly represents a significant cost saving when you consider that the average cost per patient in a given phase-II clinical trial costs about $36,000, according to a recently published report. Furthermore, if you are presented with a smaller clinical trial, this will also allow us to accelerate the introduction of the given drug to the market under the protection of a patent due to a more efficient process.

Have you identified any new therapeutics areas or activities that you can expand into?

Initially, considering the standardized approach of CFD, we had envisioned applying it to other relevant domains including cardiovascular for instance. However, as we developed the company, we decided to focus our efforts since it had become clear that it is of the utmost importance to obtain clinical validation trials. As this requires a lot of time and effort, we decided to focus on the respiratory field and establish FluidDA's brand name and positioning in the market.

Nonetheless, the respiratory field involves a number of closely related areas in which we could easily branch out to. For instance, in the field of sleep apnea, one of the potential therapies is the maximum mandibular advancement surgery, which basically involves the replacement of ones lowers jaw. Here, we are able to make significant contributions by making the necessary pre-operative plans, also on a personalized level, to ensure the optimal positioning of the jaw. Having said that, we are gradually making the transition from the respiratory field, into the musculoskeletal field. In a similar way, we also intend to branch out in to other connected or related fields, such as cardiology, as we continue to develop FluidDA and fully establish the validity of our technology. Indeed, I believe that there is a myriad of potential applications for this

technology, however, we also intend to develop the company one step at a time.

Turning our attention to the regulatory environment, what effect do you think the up coming EU regulation on the harmonization of clinical trails procedures will have on local CROs and Belgium’s competitive advantage of rapid approval processes?

Generally speaking, I think that Belgium has somewhat of a head start in this respect owing to its familiarity with rapid approval procedures for clinical trials. On the other hand, if certain countries are currently accustomed to a three-month time frame for instance, then it will be very difficult for them to quickly adapt to the new time frames. Illustratively, we carry out a number of multi-center clinical trials in Europe as a whole and the differences between Belgium and the Netherlands for instance is huge where these procedures require extended time periods. That is, there is an underlying dissimilarity in mentalities towards these activities. Therefore, even with the introduction of the new policies, I do not believe that the respective peoples attitudes will change as easily.

In this regard, I do not believe that we will be impacted to a large degree following the implementation of these new regulations, over the short to medium term. In addition to this, I believe it is necessary to speed up these procedures in general for the benefit of all stakeholders. At the same time however, there is not much benefit to be derived from a rapid approval process for clinical trials, if these trials themselves take an unnecessarily long times because of their insensitive endpoints. Conversely, we offer highly sensitive endpoints that can reduce the size of clinical trials. Following that however, the time period in which we wait for the ethical committees approval of a trial becomes very important since one month versus a year is a world away from one month versus ten years for instance. Therefore, I believe these considerations go hand in hand in relation to whether or not these measures represent real added value for drug development.

Of course, FluidDA has experience in collecting, storing, managing and analyzing data coming from a variety of imaging modalities. But considering your pioneering approach, to what extent do you work together with med-tech companies to develop either of your products or services?

In this context, we do work closely with one company, called Materialize, in the development of the software processes, as they are active in rapid prototyping as well as orthopedics. At this stage however, we have not yet engaged in too many discussions with the major developer of medical technologies such as GE Healthcare. The primary reason for this relates once more to the necessity of acquiring the adequate and complete clinical validation studies. That is, once we are prepared, we want to be able to approach them with a convincing and established technology and value

proposition with a clear strategic path and framework. In addition to this, I believe the potential value for FluidDA is far greater if we are able to develop these technologies on our own in an independent manner. As with the story of David and Goliath, the pharmaceutical industry is dominated by large MNCs and as such, we need to proceed carefully when engaging in collaborative activities.

Exactly how far away is FluidDA from obtaining solid clinical validations for its technologies?

So far, we have conducted approximately 20 clinical validation trials in more than 700 patients and thousands of CT scans. Having said that, we expect to publish a growing number of new scientific publications and I believe that we are getting very close to obtaining our clinical validation. Moreover, we are discussing with the EMA and FDA the possibility of obtaining endorsement for our biomarkers. Although this is not necessary for clinical trials, I believe it is an important step in the development and implementation of FluidDA's technologies.

FluidDA has built up a network of international clinical centers that are well equipped to perform high quality imaging studies. However, what criteria do you look for in these research centers and what would you say makes FluidDA a partner of choice?

We typically seek centers that are adept at conducting clinical trials, especially in our field of relevance. In addition to this, we also target those that are more academically inspired. This is because we want to work together with clinicians that are motivated to carry out such pioneering work by the opportunity to gain scientific recognition that can go far beyond financial motivation. I believe that this is a very important factor to take into account because we need to have properly inspired people working towards a common goal.

On the other hand, as a pioneer in its field, I believe FluidDA is the right partner of choice because we are a unique company that is able to deliver an unrivaled service in the field. In terms of international presence, we see that FluidDA has a presence in India and more recently in the US. What is the strategic importance of these markets to FluidDA and what can you tell us about the company's internationalization strategy? Broadly speaking, I believe the choice to set up offices in India and the US is the obvious choice for someone seeking to penetrate the emerging and established markets. As such, our internationalization strategy began with establishing our first office in India in 2010. On the one hand, this was because part of the image processing is conducted there with great efficiency. In addition to this, India also boasts an abundance of highly skilled and motivated people that are up to the task. On the other hand, India as a whole is increasingly growing in wealth and as a result have a growing need for quality healthcare. In this

light, we also wanted to establish a foothold in the Indian market since we believe there are a wealth of opportunities to be had. Looking into the future, I believe it is important to first consolidate our presence in the markets in which we are present in before considering penetrating other markets. Besides, emerging markets tend to follow the path of the developed ones, therefore necessitating the need to achieve recognition in the developed markets, followed by entries into other markets. Once we have established this, I believe the BRICS represent great opportunities for FluidDA over the long term.

Having established that FluidDA is a very innovative company in its field, which by definition makes it rather atypical, how would you like to brand FluidDA? What image would you like it to portray?

I believe we at FluidDA have the real opportunity to be among the first to make personalized medicine a reality. Historically, innovation typically occurs at the cross roads of two different industries or domains. This is a reflection of the cross roads of the engineering and biomedical domains that defines FluidDA. In addition to this, in today's world of previously inconceivable cloud computing capabilities and the advances in ICT, I believe we are in the right time and place to merge these industries together and produce highly innovative and cutting edge results. In this respect, I believe we will be able to make the value proposition for personalized medicine a certainty and create a lot of value at least within the respiratory field initially.

The way to achieve this is by having the right combination of the CRO, starting with the clinical trials and then leveraging that information to subsequently reach the clinical practice and patients worldwide. This is the heading that FluidDA should take going into the future.

The polarization of the CRO market into global companies and niche providers is a trend to observe. As a highly specialized CRO, do you think this consolidation trend will continue over the coming years?

I hope that the trends that have occurred in the pharma world are not applied to the CRO industry. Today we have a number of huge CROs that often acquire smaller niche players. However, in the worst cases, the developed technologies of these niche players can sometimes end up unutilized or wasted. In that respect, I believe consolidation can be advantageous in the cases where consolidation will lead to the leveraging of new technologies.

In addition to this, I believe that the relationship dynamics between the pharma and CRO industry is akin to a pendulum in which the pharma industry began outsourcing their activities to CROs as they grew ever larger and began looking for ways to save costs. After all, this is perhaps one of the primary driver of growth for the large CROs of today. This created a trend where the number of

people working in pharma declining, while the CRO workforce increased in size. In this respect, I think this will naturally come to balance and I think we will see the added value of the CRO industry begin to plateau.

In conclusion, where would you like to take the Belgian operations of FluidDA over the following 3 years? What goals would you like to realize?

My goal is to consolidate FluidDA’s activities in the CRO field and become recognized as a valuable outcome parameter in clinical trials. Once we are successfully able to achieve this, I believe the broader implementation of our operations becomes feasible and we can become a leading CRO in our specific niche. In addition to this, we intend to leverage that positioning in order to implement the application in the clinical practice where I believe the potential for creating added value truly lies. Once we have successfully covered these developmental steps in our company, we will begin to analyze the best way forward for the company and determine the most efficient way to introduce this technology to as many patients as possible.

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