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TFS is a leading mid-size CRO providing clinical development solutions to biopharmaceutical companies. Headquartered in Lund, TFS serves global clinical trial markets with local expertise and worldwide project delivery. János Filakovský, MD, Ph.d. MBA, CEO of TFS, discusses the company's unique capabilities and analyzes the Swedish life sciences industry's potential to become the leader in e-health and new treatments.

What were your first impressions of TFS after your initial months as a CEO?

Firstly, I am very proud to be a part of TFS, one of the leading Swedish life-science companies with over 20 years of market presence. TFS is a true success story. I am a neurologist by education, and I joined the clinical research industry more than 25 years ago. I had the opportunity to work in all its segments, including each phase of the drug clinical development. Now, being a part of the Swedish life science ecosystem is very exciting to me. I joined TFS over one and a half years ago having moved from Austria; however, I had prior experience in the Nordics. Sweden is robust in terms of innovation and the industry is continuously evolving creating opportunities for service providers such as TFS.

TFS grew from a local full-service provider to a true international contract research organization (CRO). Our service offering is very comprehensive and we have substantial experience in all phases

of clinical drug development with particular strengths in Phase I/II and Late Phase, NIS and RWE trials. Over the last five years, TFS has been involved in approximately 1,100 studies and currently conducts trials in 40 countries across Europe and North America.

We have a well-established collaboration model with biopharma and biotech companies. The partnering approach to customers is based on our four business principles – commitment, flexibility, value creation and global reach. TFS is recognized for its unique customer, geographic and therapeutic focus. In the first months after joining the company I was impressed by the committed team, their unrivaled experience and scientific excellence. This is what differentiates TFS.

So, TFS is the perfect partner for companies wanting to make a transition from Sweden to the rest of the world?

Exactly. TFS is aligned to the needs of SME Pharma and Biotech Companies. We are their trusted partner. For example, in therapeutic areas like oncology or immuno-oncology, you need to have access to patients beyond Swedish borders. We are proud to work with customers that have highly innovative compounds, but they have a limited access to patients in the Nordics and they need to go pan-European or to North America. TFS is the perfect partner in that sense.

I would like to stress that TFS is a customer-focused organization offering hybrid and full solutions in clinical development and strategic resourcing. We build long-term relationships through two major service models. The first is called Clinical Development Services (CDS) and provides an offering that includes full-service support for all or parts of the clinical development process – primarily targeting small and medium-sized pharmaceutical and biotechnology companies. We are proud to say that TFS is the only CRO that can actually provide a locally- sourced full service for clinical trials in the Nordics. Full-service means providing clinical monitoring, study start-up services, regulatory and medical affairs, biometrics, data management, and pharmacovigilance but also understanding the local culture.

The other offering is Strategic Resourcing Solutions (SRS). It is a flexible and tailor-made resource solution with a fully operational team of clinical professionals experienced in all functions and therapeutic areas. In short, we provide customer- managed trained professionals that help them with the know-how, whether it is trial design, regulatory affairs, biometrics or clinical services. We recruit the right talents for our customers.

We are well positioned to help our customers make the expansion from Sweden or the Nordics to the rest of the world. But, it also works the other way around. We can help companies start in the region; plenty of our customers prefer to perform early clinical phase of the development in this region and TFS has an experience in helping them to take the right strategic decisions from planning to study execution.

TFS was the first CRO to offer Functional Service Provider solutions to customers in this region. What are the benefits of FSP for your partners?

TFS, historically, started as a regional service provider and, as such, we offered functional services, data management, biometrics, and pharmacovigilance. Our customers tell us that the clinical development and the functional resourcing services are complementary for them. Many need both, others one at a time. TFS provides the right solution at the right time. We are partner when there is a need for a full project delivery, so called end-to-end solution, however, we can also establish a relationship with the customers through flexible and customized resourcing programs.

TFS’s motto is “it’s all about trust”, how do you work to continue gaining the trust of the industry?

The biopharmaceutical industry is continuously changing and we realize how important it is to support our customers throughout their clinical development journey. TFS has substantial experience across all phases of clinical drug development with particular strengths in Phase I/II and Late Phase, NIS and RWE trials.

In Sweden, we have a very robust and innovative biotechnology and medical device development ecosystem. The regulatory, the academic research, the investors, and the spinoffs from academia all come together to create opportunities and boost innovation. TFS recognizes that early engagement as well as a lasting partnership between CRO and customers are essential to the successful product development and delivery of the clinical trial. We work very closely with our customers. We have learned that apart from demonstrating efficacy and safety, biotech companies have to prove their commercial value early on while facing a very complex regulatory environment at the same time. TFS provides support in the study design, medical regulatory affairs and collaborates in the early phase to successfully advance the project from pre-clinical to clinical development phase. Our customers greatly appreciate our tailored service offering. To us, it is

about partnership.

TFS has offices across North America and Europe and conducts clinical trials in around 40 countries. What are the best performing markets at the moment?

TFS serves global markets with local knowledge and expertise in executing clinical trials worldwide. Our competitive advantage is the team of highly experienced professionals who build international teams. Such cross-functional teams not only share therapeutic expertise but also apply the local knowledge to multinational studies. We are well established in the Nordics. In Sweden, we have offices in three cities. Other parts of Europe are also important, with a significant presence in Spain, Germany and the UK. However, we operate successfully and continue to grow across other geographies including North America.

You mention TFS’s plans to expand geographically, but how do you balance that with also expanding your service offering?

Our overall strategic goals are for TFS to become the mid-sized CRO of choice and the market leader in this sector. This will be achieved through sustainable organic growth and strategic acquisitions, enhanced by a corporate culture. TFS continues to enjoy a high level of growth due to our continual focus on customer needs.

Moreover, we expand our therapeutic offerings, we invest in our people but also in new technology to support project planning and execution. As a mid-sized CRO, TFS is large enough to deliver value through our extensive geographical capabilities; however, we still remain the right size to leverage our unique local experience and partner the customers. TFS has scientific and medical competence across a broad selection of therapeutic indications with industry-leading capabilities within the core areas: Dermatology, Oncology, and Ophthalmology.

TFS operates in a market that is rapidly growing, mainly because pharmaceutical companies are increasingly focusing on their core operations and outsourcing R&D and the complexity of regulatory framework. How do you see the demand for CRO services evolving moving forward, both in terms of growth rate and nature?

The estimated value of the global clinical CRO market in 2019 is approximately USD 35 billion. The expanding market is driven by pharmaceutical companies increasingly focusing on their core competencies of R&D, Sales & Marketing, as well as the need to adhere to the increasing requirements and complexity of the regulatory frameworks. TFS's core expertise lies in serving pharmaceutical, biotechnology and medical device companies where there is a growing outsourcing trend for clinical trials. CAGR for the CRO market is expected to be approximately 7% (between 6–8%).

It is a great environment to be in and there are key factors for its growth: life expectancy continues to rise, and new technology and science evolve. E-health and big data is another key growth factor. We still have many unmet needs in indications such as neurology, cardiovascular, oncology, diabetes and other areas, which are important for patients worldwide.

TFS focuses on innovation through an efficient clinical development execution, which means accelerated time to market. It is said that 70% of the compounds in early development phases are with the biotech and mid-size companies and TFS is of the right-size and well-positioned to serve their needs.

How do you assess the Swedish industry's strengths compared to other European and Asian countries?

We see an increasing complexity in clinical trials in general. The protocol designs are more demanding, the trial diagnostic and laboratory tools are more advanced and the logistics of the studies are more complex. Studies require dedicated research centers and experienced teams. A well-established regulatory environment is critical. Sweden, with its scientific and academic centers, fulfills all the criteria for high quality clinical research. Sweden is one of the most advanced countries in terms of innovation and E-health. We work closely with the academic centers and universities.

Can you mention some trends driving the Swedish industry that you believe are being overlooked?

Firstly, the country has a high density of innovative startups and it important that they attract more financial investment from private institutions to help shape the environment. There is also an ongoing competition for industry professionals and Sweden has the capability to develop and

attract more highly-skilled individuals. TFS's intern program is one of way of providing the opportunity to life science university graduates to start their professional careers in the clinical research industry.

TFS believes that the core of its success is being "global in mind and local at heart." What does that phrase mean to you?

TFS is a customer-focused organization providing a tailored approach to help clients develop successful strategies by being present physically, understanding the regulations, and understanding the way they do business. That is the core behind "local at heart, and global in mind". To be specific, the flexibility and agility of our teams allow us to keep short communication lines while ensuring consistent quality outcomes. In short, TFS works with its customers to understand their needs and to provide the necessary support. We speak the local language, we know the local regulations, we built a network of sites and investigators as well as understand the patients' pathways. Understanding the local environment speeds up the study startup phase, being a part of a clinical site network accelerates patients recruitment and these two factors are critical to a clinical trial success.

One of TFS's values is that "it has to be fun", what does that really mean?

It takes passion to accomplish great things and a company's success depends on the commitment of its employees. Our teams are chosen not only for knowledge and capability but also for their passion. We value a positive and committed attitude and we celebrate the achievements, internally and with our customers. Devoted and engaged employees contribute to our customers' success. The work we all do is meaningful and brings satisfaction and joy.

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