Anil Okay – General Manager, Adalvo & Chief Commercial Officer, Alvotech



We position ourselves as a pure play, differentiated, fully vertically integrated biosimilars development and manufacturing company that goes global with partners that are regional champions

02.02.2021

Tags: Switzerland, Alvotech, Biosimilars, Manufacturing, Strategy

CCO Anil Okay introduces how Alvotech's focus on biosimilars, comprehensive platform, differentiated portfolio approach, and commercial strategy differentiates the company and allows it to compete with the Big Pharma players also present in the biosimilars space.

Speaking as Alvotech's chief commercial officer and on the back of the recent JP Morgan Healthcare Conference 2021, what is the company's investor pitch in a nutshell?

There is no one specific thing about Alvotech that differentiates us, but rather a combination of traits that make us special. The first is that we focus on biosimilars, which we believe is essential for long term success on that front. The focus of our resources from R&D and manufacturing capacity will be required for long-term success in biosimilars.

The second trait I would point out is our comprehensive platform. One of the reasons that large pharma has dominated the biosimilar space thus far is their access to scale and capital, which for biosimilars requires a lot. This challenge has also meant that many firms have not been able to jump with both feet into biosimilar development, and some rely on a more virtual set up to get around the barrier of scale, which of course comes with its own set of challenges. Alvotech, through shareholder, partner, and investor support has been able to create and invest on a scale that we believe will be necessary for the next ten years of our life cycle.

The third trait is a differentiated portfolio approach. Biosimilars stand to be the single largest and fastest genericization event of my lifetime. However, at Alvotech we don't necessarily believe that every market consists of equal products or approaches. There are ways we believe that a company can differentiate itself from others within a biosimilar market and that strategy starts with the development program itself and continues through the commercialization phase.

The final piece to our puzzle is our commercial strategy. Earlier in the life of Alvotech there was a healthy debate as to whether we should seek a global partner, operate alone in some or most of the markets, or seek out more local champions. Ultimately, we decided on the local approach, where we have partnered with top firms from around the globe in markets where they dominate. This allows us to maintain a singular focus on what we do best, which is develop, and allows Alvotech to rely on the scale of our partners, which we also think is key. And selecting local and regional players allows us to work with the best in each region rather than dilute the focus with a single global partner.

We position ourselves as a pure play, differentiated, fully vertically integrated biosimilars development and manufacturing company that goes global with partners that are regional champions. While several biosimilar companies prioritise the US market, we go global in collaboration with regional champions; something which has never been done before in the scale that Alvotech does including US/EU/JP/China/Canada and several emerging markets coverage which represents a big hedge for Alvotech's business model. In contrast to the Big Pharma players with biosimilar portfolios, our single focus is biosimilars and we apply portfolio differentiations to maximize the value.

In which geographies does Alvotech currently have a footprint and what was the rationale behind selecting them?

Having focused on differentiation from the beginning, Alvotech has managed to build up a unique technology platform. We already have a manufacturing facility in Iceland which is GMP approved and are creating a new site in China with our joint venture partner CCHT with USD 200 million investment, that will allow us to manufacture in China, for China. To be competitive in the Chinese market, it is vital to manufacture in China itself. Additionally, we will integrate the China site as a manufacturing hub to our manufacturing network for supplying to select international markets.

Elsewhere, Alvotech has two R&D sites in Germany for pre-clinical development and bases its clinical operations and medical affairs functions out of Switzerland, where we have over 40

employees. Switzerland is a great clinical research hub primarily due to its talent pool. The fact that biosimilars are biologic drugs means that we have to do Phase III studies and spend anywhere between USD 40 to 60 million on clinical trials for a single Phase 3 study. Being able to draw on a rich pool of talent, given the country's positioning as a life sciences research hub, means that Switzerland is a natural location for this important part of our value chain.

In the future, we are exploring the possibilities of moving commercial operations to Switzerland as well. The country's dense network of global trade agreements would be a huge advantage as we bolster our global footprint and begin generating revenues from product sales (we already have over 3 digit millions in revenues via global partnerships and license fees) in the next few years.

How does Alvotech's business model differ from those of its biosimilar competitors and how does your role as chief commercial officer sitting in Switzerland fit into overall strategy?

Geographically speaking, I sit in Switzerland, and Iceland remains our HQ; and I am tasked to manage a very global team across more than 15 countries including Netherlands, Germany, the UK and Spain.

Alvotech is different in three key segments; one is Alvotech's fully vertically integrated platform – cell line development up to finished product is all done in house – which allows us to control whole value chain and the manufacturing technology which is key for biosimilars.

Secondly, our go to market model is also unique. After conducting a lot of assessments, we concluded that biosimilars marketing is a hybrid space with a branded approach where you need to visit physicians as well as tender-driven (or payer) approach where listing capabilities and commercial savviness is key. A unique mindset is needed to manage both market dynamics globally.

It is for this reason that we decided to partner with what we called regional champions for commercialisation globally. In the US, TEVA is our commercial partner, in Europe it is STADA – a German company with revenues of over USD three billion – and in Japan it is Fuji Pharma – a stock listed company which is a four percent shareholder in Alvotech and several other local champions in the emerging markets.

The latest partnership, announced at the end of 2020, is with Yangtze River Pharma, one of the top three pharma companies in China with high brand loyalty and a commercial engine of over 10,000

sales reps. The logic behind this partnership is the same as the others; our strength is in development and manufacturing, rather than commercialisation, so we focus on the strengths of both organizations.

Thirdly, Alvotech's differentiated broad portfolio with unique vertically integrated set-up stands us different than our competitors.

With this in mind- would you define the company as a CMO?

No, we are a pure play biosimilar development and manufacturing company. We generate our own IP, whereas CMOs use someone else's IP and manufacture for them. Having said that, we do have CDMO service offering for our China site and will consider taking CDMO projects selectively for our Iceland facility to support our capacity utilization.

Which therapeutic areas is Alvotech engaging in, how are they selected, and what is your value proposition to commercial partners?

We have a targeted portfolio of selected biosimilar candidates, which is an important part of our value proposition.

Our focus has been on immunology, although our portfolio selection process is not about only going after specific therapy area with large brand sales but we rather focus how we can differentiate ourselves by offering low competition assets or by making some adjustments to either the product itself or the device with which it is administered or come up with an attractive market access strategy.

Two factors make Alvotech stand out from the crowd. The first is that of the products in our portfolio, half have a device platform; a concept that is especially relevant in a post-COVID world where the hospital visits are minimized.

Some products require an injection every two weeks which is a big hassle for the patient and the hospitals. Device platforms minimize hospital visits of chronic patients and allow them to self-administer at home with our biosimilar candidates, for example, which comes in conjunction with a user-friendly device from Ypsomed, a Swiss market leader in device development.

The second differentiator is on the technology side, we have invested in 2 major cell-line development platforms that is allowing us to develop ultimate sameness with the biological medicines and also we have invested into 2 different manufacturing processes that allows us to be different than our competition

Last but not least we have also looked into the products which are not the biggest revenue makers today but have the biggest potential to grow. We have an excellent KOL network as well as strong portfolio, medical and market intelligence functions that are supporting our portfolio selection process along with our partner insights. We are already screening Phase II stage assets strategically and tracking them across the lifecycle. For instance, we have a gastroenterology asset in our portfolio which, when we chose the product, had sales of around USD one billion. It is now projected to have sales of USD 6.5 billion by 2026 when we are aiming to be in the market.

Other drug-device platform players that we have talked to have highlighted the complexity of the field, especially for the sales reps and also for patient adherence. How is Alvotech working to ensure that its commercialisation partners, many of whom may be generic players, have the bandwidth to deal with these products?

That is in fact a great point and one that we have been aware of in our partner selection process. I have no doubt that our partners have the infrastructure and know how to manage and maximize the platform that we have created. Commercial strategies are multi-prong and the scale and history of our partners suggest that they are able to manage all facets as needed in each individual market. Teva has significant experience in specialty and devices for the US market as evidenced by Copaxone and others, not to mention biosimilars as well. STADA manages across tender and retail channels across Europe alike and has a substantial commercial sales force, also STADA is a market leader with another drug-device combined biosimilar in Europe. In China, we think that our device platform is a differentiator versus those biosimilars that don’t have a differentiated autoinjector, in a market where home administration is only starting to take form.

With such a commercialisation model, who takes charge of market registration and pricing in the markets in which Alvotech’s products are present?

As of today, we have 13 strategic commercial partnerships with regional champions in the US, Europe, Japan, China, Australia, Canada and in other emerging regions.

In terms of market access, for the US market Alvotech has an office with regulatory infrastructure that handles registration, filing, and FDA interactions itself.

In China, we have a market access team on the ground through our JV , and we are going to be the MA and trademark owner, but in the rest of the world, we transfer those responsibilities to partners who file and get the marketing authorizations in their name and are responsible for respective market access in their home markets.

How are your products branded once they reach the market and is this an important issue for you?

We have been relaxed on this point. The brands are very regional, and one brand would not fly everywhere. Also strategically we do not think one global brand policy is necessarily the right one as it brings other limitations to the medico-marketing story in each individual market. Therefore, we have applied a flexible approach to our relationships with these companies. In some cases, we have mandated a brand name to the partners, they have liked it and started to use it, but in others, the partners chose their own trademark.

Having said that it is important that Alvotech products are associated with highest level of quality standards across its portfolio and in all markets as sole manufacturer. We think that association is key in all markets, but can provide incremental differentiation in certain markets where we might be challenged by local competition, for example, China.

What is the motivation of those so called “regional champions” to partner up with Alvotech and not simply acquired and unrolled their own biosimilar portfolio?

You have to remember that biosimilars are somewhat of a new industry. And that the lead time and cost to develop biosimilars is long and high. Many companies did not look to invest and in some cases over invest into biosimilars because of those factors. This is true for companies that are global and particularly true for those companies that are very strong in a home region. Alvotech provides a turn key solution for our partners and can add instant scale into biosimilars. Our larger partners such as Teva and STADA have broad biosimilar strategies, and Alvotech was a convenient way to add broad portfolio, very quickly.

Teva is of course doing in house development of biosimilars, as is STADA. However, it really comes down to two things. The first is that these companies have a different portfolio selection approach for in-house developments. There are several assets which they will not develop in house due to technology limitations, volume requirements, capacity constraints or other strategic reasons or simply timing might take longer for an in-house setting.

Secondly, because biosimilars are biologics, production is complex and needs to be tightly controlled. That is what we have done at Alvotech, with a brand-new facility in China in addition to our facility in Iceland. Setting up and running a biotech facility for 20 to 30 products Is really a complex task hence out-sourcing and licensing will continuously be a fundamental leverage for many companies to fill their portfolio gaps as there are many product pipeline options to choose from and one cannot do everything alone.

More than 50 percent of global pharmaceutical pipelines are in the biologics space, it is an extremely dynamic space with changing treatment guidelines, continuous clinical advancements, continuous innovation requires smart portfolio decisions which makes Alvotech’s business model very attractive for future growth.

Alvotech is betting strongly and making large investments. What will be the turning point in the next few years?

If you look at the macro factors of biologics, the trends are clear. Eight out of the top ten products and ten out of the top 15 products globally, in terms of sales, are biologics. In the last five years, 37 percent of all approved products out of the FDA are biologics, which is up two times versus the prior 15 years. Innovator pipelines are packed with biologic developments. 42 percent of pharma spending in the US is related to biologics, which is significantly higher than the rest of world, and particularly in emerging markets.

The turning point as we see it, which has already started, is the opening up of the US markets to biosimilars. If you look at the recent launches in 2019, products are converting to biosimilars extremely quickly as in the case of Avastin, where over 40 percent converted to biosimilar in a span of 12 months. Interchangeability should also drive adoption in certain markets and create opportunities for differentiation. The other turning point, we believe, is the expansion of the overall market globally through the introduction of biosimilars leading to expanded access. While spending in US is high on biologics at 42 percent, in China, for example it is seven percent. There is opportunity to create markets that are not necessarily derivative in nature and together with our

partners, Alvotech aims to see through that reality.

Alvotech has invested approx. USD one billion from its foundation to today. We have a strong and large shareholder base including our founder and Chairman Robert Wessman, private equity firms Temasek and CVC, and minority shareholders like Fuji Pharma, YAS Holding, Baxter, ATHOS Holding, Shinhan bank.

This year, we are advancing our pipeline with three more clinical stage assets that will fuel Alvotech's growth in the years 2023 and beyond.

Next year we are aiming to commercialise our first product, hence commercial launch readiness is one of our corporate priorities within 2021.

In the next five years, Alvotech will be completing R&D phase for all of its biosimilars portfolio and six of them will be in the commercial phase , our China facility will be up and running and we will be having new clinical stage assets entering into our portfolio that will represent Alvotech's strong presences in the biosimilars industry.

It is important to note that we are operating in a very promising space – our respected peer biosimilar companies like Celltrion and Samsung Biologics have market caps of double digit billion USD – where our fully integrated production line, broad portfolio, and global network of partnerships stands us in good stead among our peers.

How will the therapeutic areas in which you are engaged evolve?

We strategically prefer the immunology space, where we can differentiate ourselves through various regulatory pathways, technology, device or market access strategies.

We are also strategically looking into primary care space which is a new area for biological products and we believe this space will be the next value driver.

We are sceptical about the oncology space that is still dominated by hospitals/clinics and/or central purchasing groups and considered as competitive.

Additionally, big pharma portfolio innovation in oncology is changing very rapidly that creates risks for biosimilar developers. Strategically we will target primary care and immunology space but will selectively screen first in class oncology treatments which will have longevity in the market space. Having said that, as a vertically integrated company we do have agility to follow any new product

trends and adapt very quickly to the changing environments.

How will your position as chief commercial officer evolve in the next few years once the company is revenue making and have reach scale of global partnerships?

My team and I have been very busy over the last two and a half years setting up our global commercial partnerships Where we have closed 13 strategic partnerships and I am happy to say that we have a coverage of more than 80 countries and proud of having such a valuable chance to reach more patients with our high quality affordable biosimilars.

Now, my role is moving into a second phase which is about alliance management and commercial readiness of Alvotech for successful launch of our products into the market. I will also continue to support our corporate strategy, long-term business planning as well as ensuring best market access strategy across the regions.

We are also trying to differentiate ourselves in the commercial department to help our partners deliver consistent messages across the world. We are trying to educate our partners on the messages that they can use for our products, not only medically but also how they can pitch our technology and device differentiations to healthcare professionals to ensure ultimate patient experience.

We are living through incredible times, what message would you like to share with your fellow pharma executives around the world?

COVID has shown us that collaborations are the future; we must collaborate at every level, from science to manufacturing and beyond. There are so many collaborations that will come into pharma and push us to work with each other rather than compete against each other. Pharma industry leaders should be very open to collaborations, even with competitors. We have to take this as a new normal and embrace this experience in the pharma industry.

See more interviews