Marina Lugova – Executive VP Business Development, Synbias Pharma AG, Switzerland

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Marina Lugova, executive VP Business Development at API manufacturer Synbias Pharma, discusses why Switzerland was chosen as the company's headquarters, Synbias's internationalization strategy, and why it is the partner of choice.

Can you run us through, in broad brushstrokes, the story and *raison d'etre* of Synbias Pharma and why Switzerland was chosen as the location for your headquarters back in 2012?

The company was founded in Ukraine in 1995 by a team of a doctor, an oncologist, and several chemists. It was a very good combination of skills that allowed them to determine the niche they would do business in: the manufacturing of Active Pharmaceutical Ingredients (APIs). Synbias Pharma was therefore born, but it really got a boost in terms of business in 2003. At that time, Synbias got its first credit line from the European Bank for Reconstruction and Development (EBRD), which was a very important milestone for the company's development. Afterwards, we invested in our own fermentation plant, which allowed us to rely on our own raw materials. Later on, we received regulatory approvals from the FDA, EMA and PDMA. By 2010, Synbias Pharma was dominating the world market with its anthracycline antibiotics.

In 2011, the shareholders decided to relocate the company from Ukraine to Central Europe. They started doing research on activities related to sales, marketing, and business development, and decided to go to Switzerland. They chose Switzerland for several reasons: a stable political and economic environment, the fact many Big Pharma companies have offices there, the strong network of professional consulting services in Switzerland, its excellent infrastructure and finally, its talent pool. In Switzerland, it is possible to hire people with excellent education and experience of all nationalities.

Within Switzerland, we chose to set up base in Schaffhausen, Switzerland's northernmost canton, due to its financial stability and forward-looking spirit, the fact that it is considerably less costly to operate here than in Zurich or Geneva, the excellent infrastructure available, closeness to Zurich Airport, and the proximity to Big Pharma companies' headquarters. Johnson & Johnson is not far from us nor is Pharmacyclics. We therefore thought Schaffhausen was a good place to start.

In 2012-13 many changes took place in the company. You acquired a manufacturing plant in Germany and later on launched the R&D center in the Czech Republic. What constitutes the fundamental aspects of this strategy and how has this enabled Synbias Pharma's growth and development?

I will start off by explaining exactly what we do. We are not final dosage producers; but producers of highly potent APIs used for cancer therapy. We currently sell five main groups of APIs: Anthracyclines, Nucleosides, Alkilators, Plant alkaloids and Antineoplastic and immunomodulating agents. Additionally, we provide services, such as customer synthesis, contract manufacturing and finished dosage form development.

That being said, we are right now aiming to change our business model and see exactly how we can position ourselves to not only sell products but combine products with our services and benefit from what demand calls for. We are, therefore, in a transitional phase to determine the business model that best fits into the existing reality.

Our competitive advantage is our quality. Our products are standard in European and American pharmacopoeia. Our cost structure is another competitive advantage. We have a process innovation both in fermentation and APIs. This process innovation gives us the opportunity to have a lot of intellectual property, patents and patent applications. Our clients have known us for many years, and they do not want to change the good and trustful working relations they have with us, their supplier. Our team is also a great asset to us, as they are highly experienced, motivated and

very talented. We do not accept status-quo people. Currently we are a small company with 80 employees in total, spread between Germany, the Czech Republic and Switzerland. We think being small is a big advantage. As you know, many Big Pharma companies are suffering from a lack of innovation. Even companies such as Pfizer and GSK are currently spinning off parts of their business into start-up companies, and they emphasize the value of start-up culture. We have this culture.

Relocating the current business from Ukraine to Switzerland and the production center to Germany has allowed us to have a stable cashflow and some security. Our cashflow has been stable for the last ten years with a three percent growth. We forecast this trend to continue for the next 15-20 years, taking into account our very confident niche positions. We are currently in the process of launching and receiving regulatory approval in Germany, and once this relocation process has taken place, we will embark on a new business model.

Regarding our growth prospects, we are headed in three directions. Firstly, we want to further geographical expansion with our existing products. We are currently well known in Europe and in the US. However, we are still lacking in Asia and Latin America. Secondly, we want to develop and manufacture new APIs. Currently we are analyzing new technological platforms for several new products. Additionally, we have several technologies under development, and together with our partners, we co-develop dossiers with the idea of then licensing out the technology. We are not only on the generic side of business, we also provide services to innovators.

What is the split of the business between the generic side and the services to innovators?

That is a good question. I have spent much of this year looking at innovators' business models, and I have actually spotted some problems in terms of business. Innovator companies need to bring innovations. However, if you look at Novartis and CAR-T, what are their biggest challenges? Pricing and reimbursement. Several of these companies are proposing an outcome-based business model, but not all of them. Our strategy is therefore to observe the trends, while providing our services. We will continue to work with innovators but will wait a little bit before deciding which path to take.

Switzerland provides us with a good opportunity in terms of fundraising. Our short-term strategic goal is to build credibility and of course fundraising activities will take place. In terms of further development, we are currently looking at two main options: either we go public or we bring a strategic investor on board, who would invest and participate in the strategic development of

Synbias Pharma. If we do an IPO, we need to take a decision regarding a growth path.

What sets you apart from other API manufacturers and contract manufacturers out there?

The main difference is our quality and process innovation. This is reflected in our portfolio of different patents. Synbias's strategy ten years ago was to become a fully vertically-integrated company. When I mentioned the IPO, one of the growth scenarios was to vertically integrate and go forward because our capabilities started from API production and we integrated backwards into fermentation. The original strategy was therefore to further integrate and ultimately be able to produce final forms too.

Today, however, I feel that this is a matter of the past and we are evaluating other scenarios. There was a lot of debate regarding which path to take, but the shareholders haven't given their approval for this strategy going forward yet. Hence as I mentioned earlier, we are in a somewhat of a transitional phase. What is certain however is that we will provide services for both innovators and generic companies and our main challenge right now is financing. We have established initial relationships with Swiss banks for corporates and, this year, one of them opened a substantial credit line for us.

When will you reach a decision regarding these options?

We are currently launching a production plant in Germany. Once it is launched, we will take our decision. We are a very focused company and have clear future targets. Over the next two years, we are, for example, set to hire 50 more employees. We are currently expanding our management office in Switzerland and evaluating offers from several headhunters to help us find the right people. We are very selective in finding people with the right skills.

You have a three-way establishment of Germany, the Czech Republic and Switzerland. Why is this the right organizational model?

Well I've already explained the decision to move to Switzerland. The production site in Germany is actually in close proximity to our Swiss office and it really fits in our business model. Our current production plant is very close to that of Roche, hence all necessary infrastructure is available, and

the location is very good. Furthermore, we have received a lot of support from the local authorities.

The Czech Republic was a good business opportunity. We have an entrepreneurial spirit, so if a good opportunity arises, we seize it. We are for example considering investing in Spain and are in the negotiations and discussion phase at the moment. We also have some plans to invest in France.

What noticeable trends have you observed in the API market, in terms of what customers and partners are looking for?

The main criterion is quality, and the main challenge in our niche is the regulatory requirements. They are becoming stricter every year. The second most important criterion is safety. Our partners have been working with us over the last ten years and will continue to do so because of our top-notch quality. Our main criteria lies in the purity of our APIs, and our products are truly first class, matching the highest European and American standards.

You mentioned that Synbias Pharma plans to expand to Asia and Latin America. How exactly will that goal be fulfilled?

We will look for partners from each country and are currently working on such partnerships and strategic alliances, but they take time to put in place. Besides expanding the sales of APIs, the idea would be that we would develop together with our partner the full dossier that would allow us to get market authorization in different geographies and to sell the final drug. Then, depending on the type of project, we could have all sorts of partners; a good partner could be one who is able to sell, it could be a partner who is willing to take a risk and share it with us. In Asia we are of course targeting China. In Latin America, we are looking at Brazil and Argentina.

What are your three main objectives for the next five years?

The first objective is to technically launch our production in Germany and to get all the regulatory approvals. This we hope to have in the next year. Our second goal is to go public in five years or bring a strategic investor on board. In any case, strategically, we are moving into the direction of targeted therapy. The third goal is to develop targeted therapies and to look at the possible scenarios there.

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