Interview with Markus Fido, CEO, Vela Laboratories

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Tags: Vela Laboratories

Prior to founding Vela, you worked in a number of different positions with various companies such as Baxter and Octapharma. What opportunities did you see in founding your own company?

The opportunity to found Vela arose while working at Igeneon, when upper management there filed insolvency and liquidator takes care about the company. With assets in place, we established a new entity, and within a few weeks we receive the possibility for a GMP certification from AGES, we started to build the company. In the beginning it was absolutely necessary to start with a service business. Vela had state-of-art labs in-house, and we decided to provide analytical services and expertise to customers and potential clients. This was the first source of sales and revenue in the industry. Insolvency needs a lot of time and later on also additional assets from the insolvency mass of Igeneon were offered. We were able to successfully bid for this assets therefore Meridian was established in 2008 as an R&D company for cancer therapeutics, but Vela still focuses solely on analytical services and helping clients from preclinical/clinical development to market release. My vision was to serve here in Austria as a main player in analytical services and consulting especially, for Biopharmaceuticals, Biosimilars and Biologics. Vela’s logo represents protein profiling and developing, and this is the segment on which we concentrate the most. This was the starting point for Vela with four founder and four employees , until now we has grown to 40!

When you started Vela, did you feel that there was any risk in moving from an established company to something completely new?

Of course; at the beginning I was new in the business and field. I had been an employee in big pharma for almost ten years, but to have my own company and start a business from scratch, particularly in terms of finance and investing, was high risk. That, coupled with stories of insolvency and the drop down of the former company made it not easier. The first step was to look for regional grants from LISA/ZIT Vienna and seed financing from AWS.

How did Vela originally start funding itself- was it through Government support, or private funding?

Vela was founded in 2006, and the first endowment we received was a milestone dependent Seed Financing loan from AWS. Investments of atypical silent investors contributed to the company's startup funding. These 27 private investors who joined the business during the company's infancy serve as a basis for establishing the business. We did not approach venture capitalists, which are primarily used by companies that want to develop their own product pipeline, rather than a company like Vela who provide specific services.

Can you describe to our readers the main scope of activities that you are involved with here, as well as the organizational structure of the company and what you see as the main growth drivers for 2013?

The main focus for Vela is an analytical core business, starting from analytical development to quality control and product release in the European Union. Vela also focuses on having qualified personnel for being a vital partner for preclinical and clinical services. The business runs with all essential parts, quality assurance, regulatory affairs, project management and facility management in-house as well as marketing and IT. More than 50 percent of the employees work in our labs – technicians, graduates from applied universities and PhD´s shared with experienced individuals from pharma or biotech industry. The structure of the company is built in such a way that Vela will grow slowly, but steadily.

According to sales and revenue, Vela's customers can be categorized into larger pharmaceutical companies, and small biotech companies. Vela's biggest pharma client is Canadian-based company, and we also service businesses in a number of other countries including India, Spain, Turkey, Germany, Suisse and Russia. Vela's biotech business involves outsourcing some activities, but this Is limited to sterility testing and structural analysis of proteins, e.g. mass spectroscopy. In-house, Vela distinguishes between product and process-related analytics, and preclinical/clinical services. Vela is also split into different lab departments – analytical development and quality control – even for clinical and non-clinical purposes. Half of the labs is non-GMP so all the development work is done, and then these methods finish in the QC department. Finally we offer

release of qualified/validated methods through our QA department and our Qualified Persons. This is the last service we offer. It is my intention to guide my clients from the early beginning of development to the end, submission and product launch. Most of our clients outsource distinct projects, such as comparability studies of Biosimilars, or complex bioassays for monoclonal antibodies or immunogenicity testing. Small companies sometimes do not have the resources or experience for such studies or assays, and this is where Vela comes into play.

My expectations for 2013 include, among other things, successfully penetrating the Russian market. Vela started with one customer in Moscow, but there are several more Russian companies very interested in working in partnership with Vela. Additionally, Vela intends to enhance activities in India, Canada and South America, where also clusters like LISA Vienna also wants to have a particular focus in the next one to two years, especially Brazil.

What is it about Vela that makes the company such an attractive international partner, compared to your competitors here in Austria?

There are limited competitors in Austria that work in such a specialized field of analytics, even in this small market segment. Pharma companies can also offer similar services; for instance, if Böhringer offers manufacturing activities, in most cases they will be coupled with an analytical portfolio. As a small and flexible company, we have no direct competitors here, in some cases portfolio can be combined with other companies which can be a starting point for a co-operation. In Germany there are a few companies with similar services or spin-offs from clinical departments, which focusing on pre-clinical and clinical analytics.

Why are there not more of these companies in Austria?

Vela’s history and situation is special – receiving a GMP certificate from AGES two months after the foundation of the company rarely ever happens. Usually, this process takes two to three years. Besides this, there are many companies that focus on analytical services, but only in terms of R&D exploratory research and outside the GMP area. This is something special that Vela can offer in this analytical segment. As a contrast, Eastern European countries’ price levels are such that companies can offer similar services at an inexpensive level, which means that Vela’s competitors are growing in Hungary, Czech Republic, and Poland.

Jan Huber told us that while Austria is a relatively small country and that only €200-400 million are invested every year in clinical research, it is still attractive for investment because physicians, legal bodies, and ethics commissions all work in a professional and timely manner. To what extent do you agree?

Vienna as a city is in an excellent location, particularly in relation to Eastern Europe. Many university-driven clinical departments do an excellent job for preclinical and clinical trials here. That being said, many companies have closed here in Vienna because the pricing in Eastern Europe is vastly cheaper. For preclinical research, Austria has received some initiatives from the government, but I imagine this is underrepresented in Vienna. Vienna represents 60-70 percent of all these initiatives, while the rest are in Graz, Innsbruck, Linz and some cities of Lower Austria.

The biotech industry is continually developing products, but many of these small companies do not reach the clinical hurdle. It has totally changed from the big pharma's side – they want to see efficacy data in clinical Phase 2. We have had a similar issue with Meridian, which developed monoclonal antibodies in the field of immunotherapy, but big pharma wants to see efficacy data of Phase 2 first. This requires investments of €5-15 million. My estimation of the market situation is that there is a gap between early clinical phases and safety data, and efficacy data generated during clinical phase 2 and 3. I think that if you are successful and have clinical Phase 2 data, you are almost forced to give the project to big pharma.

Dr. Szolar told us that Austria was becoming less of a hub because of excellent education systems and centralized healthcare in Eastern Europe, where companies are looking to establish hubs. How can Austria continue to assert itself in the face of this competition?

For clinical Phase 1 or 2, Austria functions very well. In some cases we have clinical sites in places like Budapest, and many customers have decided to have two or three clinical sites; one in Budapest, one in Prague, and one here in Vienna. This works well, as the connections for clinical development in these countries are excellent. The big pharma industry is performing clinical Phase 3 trials in Eastern European countries, and even in Russia. Boehringer Ingelheim and Baxter have a big department for clinical development throughout Eastern Europe. In order to run clinical Phase 3 trials, it has always been the case that Austria needs to recruit a large number of individuals and patients, so it is not easy.

You have been working in the Austrian pharmaceutical industry for many years. Can you comment on the evolution of the regulatory environment in Austria, and if you would do anything to change it?

It has changed dramatically already. When I started at Baxter, most of the regulatory activities came directly from the Ministry of Health, who later decided to give all regulatory activities in this field to AGES and PharmMed. Now you have one specialized company guiding the biotech and pharma industry in Austria, and there is also a centralized submission procedure for the European

Union. Nearly all Vela products are part of this centralized procedure – there are no more local product submissions in the field.

How do you go about searching for your international customers?

Despite Vela's small reputation, the company's marketing strategy simply involves convincing customers of Vela's excellence and experience in the analytical field. Most companies have a need for analytics, to understand analytics, how to make a bioassay; this is extremely complex. In some cases, when a product is developed at an early stage, even according to new guidelines, 30-40% of development costs are given to analytical characterization. In some cases, for special products, there have been discussions regarding quitting the preclinical phase because the emphasis is on in-vitro tests and analytical characterization. Vela has built up a cell culture department in which we simulate every possible situation of a product in the body in in-vitro assays, which is very important for Vela. Building up a network has also been critical to creating an international client base. I travelled to Turkey for networking, and have attended many conferences in the United States, India and Eastern Europe, where you can meet clients and look for new potential.

Looking back over the last six years, what advice might you give to a young entrepreneur looking to start up a similar company?

Most start-ups have founders who come from the field of R&D or universities. From the beginning you need someone experienced who can take care of finances. In Vela's first month, I tried to operate finances myself and decided that without capital from the outside, experience partners managing the business would be impossible. For a service company like Vela, there are other prerequisites, particularly for those that are developing their own products. We have to look at revenues, and invest in equipment, lab technology and new personnel where it is needed most. Planning is good, but implementation only happens when money is on the table. Often, contracts are written without having a stable budget for the immediate future. Most individuals coming from research departments have technical knowledge but not a financial background. Additionally, Austria is a very small market, so it was very important for Vela in the beginning to look at the United States, where the biggest pharma market presides. It is headed by the Food and Drug Administration, and most of this organization's rules are applied in Europe. Additionally, the GMP business started in the US, and was brought to Europe. Personally, I learned most of the necessary management skills to run a business during my time in an international company.

If we were to return to Austria in three to four years, where can we expect you to have taken Vela by that point, both in Austria and internationally?

Vela will expand slightly in terms of number of employees. The company has a strategic alliance with a German company called Protagen in Dortmund, who are specialists in structurally-related analytics, which Vela does not currently have in-house. I want to be able to offer an entire portfolio to my clients and customers. This is very important for the near future: networking, cooperation with other small companies, especially with CMO´s by obtaining large projects in the field of process development. Similarly, I want to do the same on the clinical side with CRO´s, who are performing preclinical and clinical studies for product owners. Vela intension is to work closely with such an organization focusing on analytics but also be involved in logistics, sample delivery and storage internationally. These are the areas in which Vela will continue to improve and I look forward to make success happen in the future.

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