VFB (Flemish Federation of Investors) e-Flash number 15, April 2014
VFB interview with Eduardo Bravo, TiGenix CEO

VFB: On 3 April, Tigenix announced the licensing of the marketing and distribution rights for ChondroCelect to Sobi. This triggered a negative reaction in the market and a decline in the TiGenix share price. What have investors misunderstood about the deal?

EB: Principally, I don't think investors have appreciated the positive margin impact on ChondroCelect for Tigenix with this deal. The margin contribution of ChondroCelect to TiGenix is undoubtedly higher under this new structure than if TiGenix had continued to commercialise the product itself. The success of ChondroCelect requires a substantial upfront investment to obtain reimbursement, to prepare the market, to open and train the medical centres, and to provide the medical education necessary to establish ChondroCelect as the gold standard for the right patients. Sobi has the right capabilities and experience, the necessary financial resources, a much broader geographic coverage and an already established infrastructure. With a royalty of 20% (22% for the first year) of a higher sales line, and with no longer any significant costs from the product, the bottom line for ChondroCelect with TiGenix will be positive from 1 June, and will certainly exceed what we were expecting without Sobi. At the same time, we have freed up significant resources which can be used to continue to develop our pipeline of adipose derived stem cell (eASC) products, which represent a much more attractive commercial opportunity, and the future, for TiGenix.

In short, quicker and higher profits for ChondroCelect, short and long term, and freed up resources for investing in attractive assets for the future. Sounds like a good deal to me.

VFB: one would normally expect to see an upfront payment in a deal like this with a marketed product. How come TiGenix does not have an upfront payment in this case?

EB: ChondroCelect is a very particular asset, being an autologous cell therapy product with a narrow indication, which implies a significantly lower than average gross margin. In addition, and as I mentioned before, there is still a significant investment to be made in developing the market, and there is risk for Sobi investing in securing market access for ChondroCelect in new territories. In these circumstances, an upfront payment is not appropriate, and TiGenix was happy to have a higher than standard royalty on net sales, and the reimbursement by Sobi of almost all of TiGenix' expenses related to the

product. Finally, it's easier for Sobi to make the necessary investments in ChondroCelect early on if it doesn't have the burden of an upfront payment.

VFB: But, why Sobi?

EB: Sobi (Swedish Orphan Biovitrum AB) is an excellent partner for ChondroCelect. With revenues of over Euro 200 million in 2013, Sobi is a leading European specialty pharmaceutical company focused on niche indications. The company has an excellent track record in securing market access and commercialising its partners' products in geographies where Sobi has a strong presence, generating approximately one-fourth of total revenue from these products. Sobi has a much broader commercial and regulatory reach than TiGenix, meaning that they should not only be able to grow sales of ChondroCelect in existing markets, but will also pursue approval and new patients in additional countries: namely, Europe (including non-EU countries such as Switzerland and Norway), Turkey, Russia, the Middle East and North Africa. Importantly, Sobi has committed to building a strong position in the orthopaedic market. Its first move came in July 2013, when Sobi announced it had entered into a long-term collaboration with Auxilium Pharmaceuticals for the development, supply and commercialisation of Xiapex for the treatment of Dupuytren's contracture. ChondroCelect is Sobi's next step for this strategy.

So what is the outlook now for the TiGenix income statement?

EB: TiGenix expects its revenue line (which will include both the royalty income stream and the reimbursement of ChondroCelect costs by Sobi) to continue to grow strongly in 2014, and the vast majority of its marketing and sales expenses to fall away.

VFB: So what else has changed at TiGenix?

EB: Nothing else has changed at TiGenix. In particular, the company still has its allogeneic expanded adipose stem cell (eASC) platform and its promising pipeline of new products, on which it can now fully focus. The European Phase III study of Cx601 for the treatment of peri-anal fistulising Crohn's disease is approaching full patient recruitment, and is expected to report its results in the third quarter of 2015. With the regulatory pathway to the US market now clarified by the FDA, TiGenix is re-opening discussions with potential partners for Cx601 in the US. Additionally, following its encouraging Phase II data, TiGenix is working up a broad development plan for Cx611 which could span several disease areas.

VFB: And what positive news do you expect to be able to give the market in the near-term?

EB: With our 2013 financial results, we communicated our near-term expectations for the next 12 months, which have not changed. They are:

- With Cx601, to finalise the recruitment of the phase III trial
- With Cx601, to initiate the technology transfer process with a Contract Manufacturing Organisation (CMO) in the US, and to submit an application for a Special Protocol Assessment (SPA) with the FDA in the US
- With Cx611, to complete and to communicate the post-Phase 2 development plan

And, finally, as promised, we have secured the future of ChondroCelect as a cash flow positive asset, and we look forward to communicating the sales development of the product as Sobi begins to open up new markets.