Interview: Thomas A. Tóth von Kiskér – CEO, Tillotts Pharma, Switzerland



From a product development perspective, as regulatory hurdles are constantly increasing, so is the price of the development: the average cost of developing a drug with a new chemical entity has surpassed USD 1.5 billion

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Backed by the Japanese Zeria Group, fast growing gastrointestinal (GI) specialist Tillotts Pharma is looking to acquire further GI assets after its recent USD 200m M&A deal. The company is looking for assets which generate a turnover of EUR 50 - 150 million in Europe and/or Japan, and also to enter into a strategic partnership with a GI focused US based company. CEO Thomas A. Tóth von Kiskér discusses some of the barriers to growth that SMEs face today in an increasingly consolidated industry.

As the CEO of Tillotts Pharma – a GI focused Swiss pharma company with about 300 employees – what would you highlight as some of the greatest barriers to growth which you must work to overcome?

SMEs are increasingly facing an environment which features significant barriers for smaller players, where companies without a certain size and financing capacity may find it difficult to compete. This becomes clear when looking at the challenge of building a pipeline, which ultimately any pharma company that wants to grow, or avoid seeing revenues decline, must do to balance out the effect of patent expiration and the introduction of newer, more effective competing products. There are two ways companies can fill their pipeline with new products, either by in-licensing/M&A, or developing them internally.

From a product development perspective, as regulatory hurdles are constantly increasing, so is the price of the development: the average cost of developing a drug with a new chemical entity has surpassed USD 1.5 billion. With that in mind, many small companies are being pushed to riskier and riskier areas of innovation, and some have been very successful, but here the mentality and business model has shifted towards the eventual goal of going public via an IPO or being acquired.

How has it grown more difficult to license in products?

The market for acquiring product licenses has changed substantially since the year 2000, back when I worked in a business development and licensing capacity. At this point, it was still common to be able to acquire the license for a product in a single market, and in fact one of the challenges we faced then was that most pharma licensing groups were only nationally focused. It was in response to this strong national focus that we established the Swiss Pharma Licensing Group in the late 90s – now the Swiss Healthcare Licensing Group – as an internationally focused, English speaking platform for networking and education, facilitating the identification of effective licensing opportunities internationally.

Today, this situation has changed completely, and it is uncommon to be able to find opportunities to acquire licenses for individual European markets, or even small groups of countries. Instead, we see many more global deals, or regional deals covering massive regions like Europe, the Middle East and Africa. With these larger deals come larger price tags, which have escalated alongside M&A transactions to dizzying levels, with valuations that don’t necessarily reflect reality. In the case of M&A, for example, the valuations for some of the larger publically known acquisitions are such that it would take the buyer at current profitability up to 100 years of EBIT to pay back the share value! With deals covering such large regions and valuations at very high multiples, it has become extremely difficult – not only for smaller pharma companies – to find opportunities to license or acquire products or companies for a reasonable price.

Is there a clear solution for SMEs to counteract this “size effect”?

There certainly is; with the trend towards global licensing deals and escalating valuations, it is critical that SMEs such as Tillotts Pharma forge strategic alliances with one another. By collaborating with each other, SMEs can cover the whole world or large regions, and either afford the high price-tags to acquire suitable products or jointly develop them. Doing so, they can share

risks, costs and profit from each other's specific expertise, be it in marketing, regulatory or other fields.

This is where we are left in a challenging situation. Surprisingly, it can be incredibly difficult to find feasible and suitable strategic partners. In part, the mentality for more and more pharma SMEs in today's world is not to build a sustainable business and long term alliances, but to find a profitable exit opportunity as early as possible. Moreover, in Tillotts' experience we have seen several suitable candidates acquired by larger companies shortly after we have identified them. The pace of change and movement is greater than ever.

How has Tillotts navigated around these barriers and found a feasible way to expand its portfolio and grow?

Tillotts Pharma, as a company, does want to build a sustainable business, and as such our appetite for risk is not that of a biotech startup. As such we have a balanced strategy, with our own in house R&D activities as well as a fairly aggressive in-licensing strategy. That said, we are investing in our own pipeline and have recently submitted a product we developed in house – TP05 – for registration, and have taken the big step of starting pre-clinical development on a biologic compound, TP10.

A few years ago, Tillotts faced a big challenge – typically for a growing SME – on the in-licensing front, primarily being that we did not have enough affiliates covering Europe to enable us to generate the needed turnover and cash flow to make it financially feasible to support large pan-European licensing or acquisition deals. At the same time, without acquiring products, we did not have a big enough marketable portfolio to make the math work for establishing additional affiliates… The only way out of this "catch 22" situation was to be brave, take a risk, and break through one of these barriers!

That breakthrough was achieved mid 2015 with a major milestone in the history of Tillotts, the acquisition of ex-US rights to Entocort from AstraZeneca. This was a product we had kept an eye on for years and lobbied AstraZeneca proactively for, even before it was up for sale. When they finally did decide to divest the ex-US rights to this product, the final price ended up being well above that of one year of our company revenue, and was even above the price of what our Japanese parent company Zeria Pharmaceutical Co., Ltd. (Zeria) paid for Tillotts when they acquired us back in 2009. This acquisition is helping us to generate enough revenue in markets, where we previously had to partner with 3rd parties to promote our products. Through the acquisition of Entocort (ex-

US), we reached critical mass in strategically important markets for Tillotts, enabling us to open new affiliates in e.g. Germany and France. Now having established ourselves in these markets, Tillotts also becomes much more attractive as a licensing partner in Europe.

To be clear, this acquisition was only possible because of the financial support we received from our parent company, Zeria, and the strong and trusting relationship between us and them. It is also worth noting that as this deal was financed with the support of a Japanese bank, we were able to secure far better interest rates than American or European competitors, and a few percentage points lower interest on a principle in the hundreds of millions makes a big difference on your P&L statement.

How would you assess success of product acquisition, and in terms of learning from the experience, what might you do differently next time?

This was a very successful acquisition that we would certainly do again for the same terms. Tillotts is specialized in gastroenterology, with a strong presence in the Inflammatory Bowel Disease segment, and this segment has two separate indications: Ulcerative Colitis and Crohn's disease. Our product Asacol™ is first line treatment for Ulcerative Colitis in many countries. Entocort™, on the other hand, is first line treatment for Crohn's in many countries. The relevant target group for promotion is the same, gastroenterologists and gastro-nurses, so it had perfect synergies with our other products: in the end, we only needed to employ 8 more employees to integrate, promote and run this product on a worldwide (ex-US) basis.

One thing we did learn, however, was the complexity of integrating the product from a regulatory and manufacturing standpoint. I believe we may have underestimated the challenges in this regard. Learning the ins-and-outs of the product was more challenging than we expected, so there were some delays when it came to finding, updating and transferring the 46 different marketing authorizations in different countries. In terms of manufacturing, AstraZeneca had very complex supply arrangements for Entocort with a number of different manufacturers doing different bits and pieces. We therefore had to consolidate the manufacturing activities which was quite challenging. As a smaller company without a massive external supply chain organization like AstraZeneca's, it wasn't logical to replicate their supply chain, and making new supply arrangements was time consuming.

Thus, in retrospect, these are two details that we would look at more closely and more deeply next time around. That said, in these product acquisition deals there are strict timelines and there is a

lot of pressure, so once it is time to do the deal, it is too late to adapt. This is why we originally hired several very experienced professionals years in advance of the Entocort acquisition, who had experience in doing this kind of deal, and now with the Entocort acquisition behind us, we have now developed even more capabilities and expertise to put towards our next acquisition.

Looking forward, what will be the next steps in terms of growing the business? What type of opportunities are you looking for?

The first step we are looking for is a product, product portfolio, or company with approximately EUR 50 up to EUR 150 million (USD 53 to USD 160 million) in sales within the digestive system such as gastroenterology or hepatology. Moreover, of course, the price tag would have to be reasonable and make sense from our perspective. That being said, acquiring a product or products with EUR 150 million (USD 160 million) of revenue would be quite a significant commitment from our side.

The other very significant priority for Tillotts going forward is finding a strategic partner in the US; as Tillotts covers Europe, the Middle East and Asia, and our parent company Zeria Group covers Japan, if we are able to establish a strategic alliance with a US-based partner, we would not only become a global player, but could also share cost, risk as well as expertise developing new compounds.

We were very lucky with the Entocort acquisition that AstraZeneca was willing to sell the rights to the product, for all markets excluding the US. Acquiring the product with the US rights included would have at least doubled the price tag, and put us under immense pressure to quickly find a partner who could commercialize the product in the US, and from whom we could get enough margin to pay off the associated acquisition cost. If you wait to find the right partner until you need one, it is too late! Thus, we are constantly keeping our eyes open for a US-based company in the gastro field with whom we can develop a strategic relationship. Ideally this partner would also be interested in the co-development and co-financing of new products, and of course be able to manage relationships with the FDA and other regulatory bodies. In return, we would offer the opportunity to cross license products for the European as well as Asian and Middle East markets, and perhaps co-development of assets on their side as well.

Unfortunately, and this is where reality hits, there are not many companies that fit this description and those that we have found thus far have mostly been acquired just after we identified them.

Finally, we understand that prior to being acquired by Zeria, Tillotts Pharma was in fact owned by the management, and as such has a strong entrepreneurial culture. What does entrepreneurialism mean to Tillotts Pharma?

Indeed, when I joined the company 20 years ago, we were all generalists, and the environment was very entrepreneurial. We all did everything, from finance to marketing to washing the dishes! When we eventually went through the management buy-out, that of course reinforced the entrepreneurial spirit because suddenly our savings and retirement funds were on the line and the business was indeed ours.

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As such, today, we highly value entrepreneurialism in our employees. With this spirit, they take responsibility, and they come into the office each day not asking what they need to do to get paid, but what they can move, change or have an impact on that day. They bring passion and creativity to their work, and tend to think more outside of the box. The great thing is that while such people are rare, they often do not fit with the corporate mentality at a big pharma company. Instead they look for opportunities where they can leave a footprint, and where their contribution is visible and much appreciated: this is the climate of entrepreneurship, which we at Tillotts actively foster.

However, as we have grown in size, we have come to recognize the value of experience and expertise, particularly in areas like regulatory affairs or M&A. Having the right people in such fields, with the right experience is critical, as they can warn you of potential pitfalls ahead of time, saving you the time and effort of learning things by doing things the hard way, as entrepreneurs often have to. However even among our experts we value creativity and flexibility and the ability to handle a wide breadth of challenges in their field – a finance professional who only knows treasury functions is not very useful for a company of 300 people. As such, we often find that the experts that fit best with our mentality and stage of development do not come from big pharma, but from companies that are five to ten years of growth ahead of us, with maybe 500 to 700 employees.

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