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For small- to mid-sized pharma companies, M&A might be a much better way to build a portfolio quickly and with less risk

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Thomas A. Tóth von Kiskér, longstanding CEO of Tillotts Pharma AG, a Switzerland-based specialty pharma player focused on the digestive system, shares his M&A principles and insights, their exciting recent acquisition of DIFICLIR™ from Astellas, and the company's recognition as a Great Place to Work® (GPTW) in Switzerland.

Thomas, when we last spoke to you in 2017, you had outlined two strategic priorities for the company: to find new assets that fit your strategy as a specialty pharma company working within the digestive system, and to find strategic partners for the US market. Can you quickly recap the highlights for Tillotts Pharma over the past few years and your progress on these two goals?

On the first topic, when we spoke in 2017, the last acquisition we had done was Entocort™ from AstraZeneca. Since then, we have had a team of five business development & licensing (BD&L) professionals solely dedicated to screening the global marketplace for acquisition possibilities. They are extremely proactive – they call investment banks, they call boutique firms, they call pharma companies and so – because Tillotts is not necessarily well-known to be at the top of potential buyers list when companies have assets they are looking for to sell. We have done extensive and deep due diligence on the assets available globally, in Europe and in Asia – hundreds

and hundreds of opportunities – but good opportunities that meet our internal criteria are rare and thus not too surprisingly, this has proven to be very challenging.

In our 2017 interview, I mentioned that we were looking for single products, product portfolios or even companies with approximately EUR 50 to EUR 150 million (USD 60 to USD 181 million) in sales p.a. within the specialty area or in hospital setting. Sometimes products were not a good strategic fit, the size of the acquisition would have been outside our scope, they were close to losing their patent protection or we found products we liked but they were not for sale – there were many reasons why we could not materialize on a transaction over the last years.

However, in November 2020, we were successful to acquire DIFICLIR™ (fidaxomicin) from Astellas for EUR 109 million (USD 131 million) for the regions of Europe, Middle East and Africa, as well as selected Commonwealth of Independent States (CIS) countries. DIFICLIR™ is a narrow-spectrum macrocyclic anti-bacterial agent and is indicated for the treatment of *Clostridioides difficile* infections (CDI), also known as *C. difficile*-associated diarrhea (CDAD) in adults and pediatric patients. Current annual revenues in Europe, Middle East, Africa and selected CIS are around EUR 30 million (USD 36.1 million) but since it is patent-protected, we believe that the product has excellent potential to grow to a significant size for us. This life-saving drug fits not only perfectly to our existing portfolio, but also with our geographic presence. The fact that Tillotts is part of Japanese Zeria Pharmaceuticals Group, and a commercial partnership already existed between Astellas and Zeria, obviously helped to build on the good and trustworthy relationship between the two companies.

Regarding our presence in the US, we are still searching for strategic partners. For the foreseeable future, we do not intend to establish our own affiliate in the US because of the significant resources needed. One of the strengths of Tillotts has always been to set the priorities right and to focus on what matters. As a mid-sized company, we cannot be present in all markets and have to make wise decisions when it comes to our strategic priorities.

Admittedly, it has been more difficult than expected to find the right strategic partner in the US, especially with our M&A strategy. We have looked at global opportunities that would have required a US presence. But the alignment of all the different aspects between Tillotts and the US company in the time frame needed to evaluate, negotiate and close such a deal is extremely difficult, since M&A transactions are very resource intensive and speedy processes. We have been fortunate that our previous two acquisitions – Entocort™ and DIFICLIR™ – have been for ex-US markets but if we see a global opportunity in the future, we will continue to search for the right strategic partner.

That being said, the advantage is that without US rights, the assets are much less expensive. In addition, since US sales are typically so much higher than in other regions, it is likely that the US partner would be the leading partner on such deals. They would acquire the asset and then we will have the ex-US rights as a second step. That obviously would be a different deal and we indeed were – and still are open – for such discussions.

With BD&L being so critical to Tillotts, what principles are you guided by when it comes to assessing assets?

Flexibility is fundamental and I mean this in different ways. I think everyone in the industry would agree, that there are few outstanding opportunities on the market – and those really good opportunities come with a high price-tag. We essentially follow our internal criteria and principals set for external growth and focus on strategic rather than on financial transactions. Our main interest is in assets accretive and in strategic fit with our existing product portfolio. The successful acquisition and integration of Entocort™ and DIFICLIR™ are the best proof that we can rely on our criteria also in the future.

Secondly, our portfolio is geared towards specialists, so we do not seek GP products. In addition, at this expansion stage of Tillotts, we are keen to move from a GI-based portfolio to a specialty product one. It is our plan to cover only few adjacent therapeutic areas with strategic fit. We need to focus and build critical mass, not stretch ourselves across different areas. We still maintain flexibility in terms of which new specialty therapeutic area we want to enter and the next asset we acquire might be outside of GI, thereby setting Tillotts' future strategic direction.

At the same time, the M&A space is becoming a lot more complicated. The interest rates have gone down, money is cheap, and opportunities are rare. Even five years ago, the multiples were very high. Ten years ago, the multiples paid were perhaps 2.5 times revenues but now we are looking at 3.5 to 4 times revenues for good M&A assets. That is expensive. It means that once you acquire the product, you have to ensure you exploit all possible synergies to recoup your investment. Thus, fast and smooth integration of your acquisition becomes key to deliver success as outlined in the business case that built the financial frame for your acquisition. For that – and speaking for a small to mid-sized pharma company – you need to mobilize all the resources in the entire company, especially each employee, to embrace all the changes that come with such acquisitions.

To exacerbate matters, we are working in very disruptive environments these days so your business model might not be as sustainable as you think. For instance, China is planning to implement significant price cuts to a wide variety of drugs. So if you bought an asset hoping to capitalize also in the Chinese market but then it gets hit by price cuts or other disruptive events, that is a huge setback. For this reason, I think acquisitions should be geographically as balanced as possible. If you acquire rights for just one market, you are much more exposed to risks.

Looking back, how significant has the Entocort™ acquisition been to your business over the past few years – and how significant do you expect the DIFICLIR™ acquisition to be?

I talked about the Catch-22 situation that growing SMEs face, where companies of our size typically did not yet have a full affiliate coverage across Europe to take on financially rewarding pan-European licensing or acquisition deals. Yet, without the availability of a sufficiently big product portfolio, you will not be able to expand your affiliate coverage. I said at one point, we had to be brave and break through one of these two barriers. The acquisition of Entocort™ was that bold decision and it has served us very well to accomplish this goal, namely not only pushing Top- and Bottom-Line up, but also allowing Tillotts to speed up its strategic plan, to expand its own presence in Europe. Entocort™ also helped us re-balance our portfolio and to decrease the dominance of Asacol™.

That being said, the performance of Asacol™ also reflects the success of our Life Cycle Management efforts. We recently rolled out a new patent-protected formulation, Asacol™ 1600mg, throughout Europe and globally. This success is also a double-edged sword since the product still continues to dominate our portfolio. Nevertheless, Life Cycle Management is critical for a company like Tillotts. My strong belief is that, unless the company has substantial financial capabilities because they did an IPO or are backed by venture capital or similar, it needs to be of a certain size to not only afford R&D expenses, but also to digest possible R&D failures.

For this reason, for small- to mid-sized pharma companies, M&A might be a much better way to build a portfolio quickly and with less risk. With the acquisition of assets, generating revenues, at least the product and the competitive landscape are known and above all income is guaranteed from day one. That being said, it is not always easy for smaller companies to build in-house M&A expertise – or maybe they are not that interested in it – but for Tillotts, we have robust M&A capabilities so we are in a strong position.

The Entocort™ deal back in 2015 was more “expensive” than we would have liked because we still worked – and therefore also shared the profit from Entocort™- with various distributors in markets where we were not yet present. To share profit with distributors obviously makes an acquisition less profitable and puts the offering company in a less competitive situation. With the very recent acquisition of DIFICLIR™, we were in a much stronger position to fully exploit the financial benefits of this deal. Most of the DIFICLIR™ revenues are currently generated in countries where Tillotts is already well established with its own affiliates, which also makes the integration much smoother. The remaining sales outside our existing affiliates will allow us to gain critical business. In summary, the acquisition of DIFICLIR™ does not only diversify our product portfolio further, but also increases our income already from 2021 onward. From a strategic perspective, the acquisition will enable us to expand our own presence with additional affiliates in 6 European countries over the months to come.

Furthermore, with assets being so expensive, we cannot justify only working in the markets where we have affiliates. We want to capitalize on all the markets available to us. We do have a very strong global network, from Europe to the Middle East as well as Asia. Tillotts is present in around 65 countries, either directly through an affiliate or through excellent marketing-partners. One of our newest partners is Menarini, with whom we will launch Asacol™ in China this year.

Beyond the financial numbers, however, having a pan-European presence is also crucial for the seller. Many of the assets are strongly associated with companies – for instance, DIFICLIR™ will still be known by physicians as an Astellas product for a while – and the seller also wants to see that the buyer will do the right thing and continue to make the product available to patients in all markets.

With the launch of DIFICLIR™, you will have to contend with this hot topic of product launches during the time of COVID-19. How do you anticipate this going? Is Tillotts ready when it comes to digitalization and such paradigm shifts?

With DIFICLIR™, we expect the product to be fully integrated latest by the end of this year, though we have been generating income since December 2020. As this is not the first asset we acquire, we fully understand the importance of a quick and efficient integration, and we have a clear plan of how to proceed.

We are actually in the midst of another product launch: our Asacol™ 1600mg tablet, which is as of today the tablet with the highest dose of mesalazine available on the market. Besides Asacol, we

are launching two more products, Tillhepo™ and Colpermin™ in a couple of markets too, so 2021 will be a very busy and also exciting year for our 320 employees.

Luckily, Tillotts had initiated digital marketing initiatives already before the COVID-19 outbreak and renewed and upgraded our IT infrastructure within the entire Tillotts group. This allowed us to efficiently communicate with our healthcare professionals (HCP) also during the various lock-down phases. That being said, the environment is still very challenging and despite webinars, digital promotional materials and social media being important pillars of our digital marketing campaigns, there is nothing that could replace personal contact.

In 2019, Tillotts was awarded the Great Place to Work® (GPTW) label. How would you characterize the value proposition of Tillotts for your employees, especially being based in Switzerland where the healthcare talent market is so competitive?

Especially during COVID-19, I think people started reevaluating their careers and challenging their work-life balance and the impact of the work they were doing. The reality is that managers often do not see the impact of their work at large pharma companies. They are not leaving their own footprints; they are much more executing the strategies of their bosses or the CEO. At Tillotts, this is very different, they have the space and also are encouraged to leave their footprints in the company. They can be entrepreneurs and for example build within a dedicated team a new affiliate from scratch. That is fascinating and rewarding work, and that is part of the value proposition we are proud to be able to offer to our employees.

Therefore, I am extremely pleased that as part of the 2020 GPTW® Award Ceremony, Tillotts was placed as the best small to mid-size pharma company in the important LifeSciences Hub of north-west Switzerland. Our HR team has done an excellent job in building and living our culture, which rewards performance and emphasizes transparency and appreciation.

Thomas, you have been with the company now for 25 years, including 14 years as CEO, which is quite rare because these days the mentality seems to be to build a company and sell it quickly, right? What more, looking forward, would you like to achieve for Tillotts?

It has been extremely exciting to stay with Tillotts for so long and together with a dedicated team, transform the business from a tiny company with 30 employees back in 1996 to one with over 300

employees, acting in 65 countries around the world. In 2009, we divested our company, which was owned by the former management, to our Asacol licensee in Japan, Zeria Pharmaceuticals. We were extremely fortunate with our new mother company, which provided us with great autonomy and trust to run the business according to our strategies and support us financially in all the acquisitions we did so far. This is also a reflection of the Japanese management style. Once you have built trust and proved your integrity with the Japanese upper management the relationship has a strong foundation. There is continuity. It is very different from being the CEO of an American or European company where often you are replaced after a half decade.

Frankly speaking, I do not want to change a winning horse! As a company, Tillotts has performed exceptionally well over the last decade. Our Vision 2030, which replaced Vision2020 last year, sets the direction for the next decade very clearly, allowing our managers to make the right strategic and operational decisions. I would like to see Tillotts with the volume and critical mass to do new things. We will strengthen our affiliate presence outside Europe. We will expand from gastroenterology into other specialty therapeutic areas. We will do so by combining organic growth, in-licensing, own R&D endeavours as well as M&A; here lies our expertise.

A final comment for our international audience?

I would like to stress that if companies want to build their M&A capabilities, it is critical to support and motivate the team because their jobs are not easy. Often, they have to inform the Board and management team that after the due diligence and further research, they do *not* recommend the deal. You must empower and trust the team to be able to assess the opportunities and say no when they have to. Tillotts went through five years without a successful acquisition despite our BD&L team working hard day in and out, and that requires self-motivation, discipline and maturity. Therefore, this is a process that needs to be done inhouse; external consultants can be very supportive and important in terms of additional capacity and expertise, but as externals it can be very difficult to recommend to *not* pursue an opportunity. I personally started in BD&L too, so I understand how frustrating and pressurizing this environment can be, especially if success is not around the corner. It all comes down to waiting for the right and best opportunity.

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