Reducing complexity as a function of strategy

Roundtable moderators:

Andrea von Bartenwerffer,
Head Account Management,
Issuer Reslations, SIX Swiss Exchange AG

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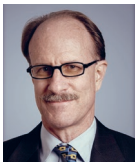
The call for clarity has never been louder because it is considered essential when it comes to making sense of complexity. Companies that master a structured approach to reduce complexity will unlock new opportunities and successfully manage the ever-growing list of regulations. Not only will they become more effective, they will also be better understood by the public and investors. SIX solicits the view of executives from listed companies and a corporate finance representative.

Roundtable participants:

Ronald Scott, CEO, Basilea Pharmaceutica (SIX: BSLN)



Dr. Chris Tanner, Head of Transactions Office and Head of Investor Relations, Cosmo Pharmaceuticals (SIX: COPN)

Stefan Weber, CEO, Newron (SIX: NWRN)

Marc Klingelfuss, Managing Director, Deputy Head of Corporate Finance, Bank Vontobel

SIX: **What does complexity mean to your company?**
Scott: Basilea is in the middle of rolling out two novel, innovative hospital products around the world. In key European markets, we are directly leading this project. There, the country-specific pricing and reimbursement structures and processes, with their national, regional and even local levels, add another level of complexity to market access as compared to the single US market.

Regarding innovation, the development of new therapies for unmet medical need in areas such as oncology and hospital anti-infectives, frequently requires the combining of different products. This increases the complexity in drug discovery and development but also provides opportunities, especially for smaller, fast-moving and flexible companies such as our own that have the relevant know-how.

Tanner: For Cosmo, complexity starts with every new employee. Hiring and retaining the right breed of employees is a major task for us as their integration potentially reduces or increases the complexity of our organization. Most of these specialists come from big pharma companies. The challenge is to balance the need to nurture the existing culture and the entrepreneurial spirit of the early days with the need to add new expertise as we grow into a full-scale company with processes in place for every task.

Weber: Newron develops innovative therapies for disorders of the central nervous system. Strategically, we focus our activities around both, the 'R' and the 'D' of R&D as well as the commercialization of drugs for rare diseases. So, we do not care ourselves for research or production, nor do we build in-house capacities for all disciplines in development such as pharmacology or toxicology. We fare better when we contract the best specialists and pay them by the hour. In our experience, the flexibility we gain is worth more than the associated risks and costs.

SIX: **What areas currently pose the most complex challenges for your company?**
Tanner: Cosmo's strategy is to build an integrated company that covers all aspects of drug development, production and commercialization. Experience taught us that dealing with these complexities internally is the best option for us. In the past, we partnered the development and commercial rights, thereby delegating the complexity, but we became dependent on our partners' commitment and capacity to master it.

Partnering means that you take an extremely complex decision now in the hope that it will turn out to be the right decision in the long run. We decided to go all the way by ourselves and add complexity step by step as we constantly learn and adapt to new challenges.

Weber: Newron focuses on orphan indications for three reasons: first, we only need one single pivotal trial for market approval; second, once approved, we can commercialize the products by our own organization; third, in the orphan space, you don't need a huge sales force to serve the markets.

If everything goes according to plan, we start shipping our first orphan product in Rett syndrome by the end of 2018 or early 2019. Our current prediction is that a specialized sales team of 25 to 35 medical liaison officers will suffice to do this in Europe and North America. However, making marketing and sales a core competence will put our ability to adapt and overcome new challenges to the test.

Scott: A current key focus for Basilea is to ensure that patients, who are outside our core European markets and the USA and in need of novel therapies, can gain access to our products as quickly as possible. There are different regulatory and legal requirements for the registration and commercialization of

drugs in each country. In order to effectively and efficiently access all of these markets, a local presence is required. In certain countries this may be mandatory in order to register and commercialize drugs.

SIX: **How do you reduce complexity in these areas and prevent complexity in others?**
Weber: With a staff of 24 employees, Newron has to stick to its core competences and source the rest. There is no reason why we should abandon this approach in the future even as we grow into a commercial company. We reduce complexity by focusing on key areas and become masters in whatever we do. Everything else is outsourced to partners with the expertise and a track record in a given specialty task. Our main challenge is to manage these interfaces. That's why project and relationship management is one of our core competences.

Scott: Basilea is working with a contract sales organization for our approved products in the core European markets. This allows us to leverage existing infrastructure without the need for us to expand our own infrastructure. In regions like Latin America, the Middle East and North Africa, we entered into partnerships with specialized regional partners who have an understanding of local regulations. They manage the registration process and the commercialization, which significantly reduces complexity on our side.

Another example of how we address the economic complexity is our contract with the US Biomedical Advanced Research and Development Authority (BARDA), under which we receive government funding for the phase III development of our antibiotic Ceftobiprole in the US. In oncology, we follow yet another approach to reduce complexity. We plan to partner our drug candidates in mid-to late stage development to specialists with the expertise to run global clinical studies in multiple tumor types. Focus is key in a highly regulated industry. It is critical to focus on one's strengths and to establish a structure that allows organizations to deliver value-driving milestones.

Tanner: Retaining full control over our assets is a cornerstone of Cosmo's strategy. We accept the associated increase in complexity as a trade-off. In 2012, we partnered our candidates in dermatology with a US company. We gained some financial flexibility and focused on the gastro-intestinal pipeline. However, two years later we terminated the collaboration.

Instead of re-integrating the dermatological business, we decided to transfer all assets into a separate, albeit fully-owned entity. The main reason was to reduce the complexities of running a company with two different pillars that had only little synergy but lots of differences such as markets, culture and people. In 2015, we took this separate company public under the name Cassiopea.

SIX: **Complexity and growth seem to be twins, particularly in the biopharmaceutical industry. Is complexity an inevitable companion of growth?**
Scott: Innovations that translate into improved treatments for patients, for instance in the oncology field, keep on raising the bar for providing significant medical benefits, preferably in a targeted fashion or ideally as personalized medicine. However, in many medical areas, the required combination of complementary treatment approaches to further improve patient outcome is adding complexity. On the other hand, our understanding of biology keeps on increasing and we thus have access to more tools to address the problem. This is why there are increasingly more R&D partnerships established even among the big pharmaceutical companies.

Weber: We opportunistically focus on our sub-class of non-toxic voltage gated sodium channel blockers and our expertise in reprofiling compounds in orphan indications. The group of ion channel blockers was originally discovered by our founders, and by repurposing them into indications other than epilepsy, we have managed to present unique mechanisms of action in Parkinson's disease, schizophrenia and pain indications.

The second pillar is the 'in-licensing' of compounds with a proven toxicity and safety. Sarizotan is such an example. Originally developed for Parkinson's disease, we now develop the compound in Rett syndrome, a rare debilitating genetic disorder of the brain. Because Sarizotan is safe, we can focus on efficacy and this saves money and time.

Tanner: Growth results in larger organizations and larger organizations require a division of labor to remain effective. The downside is that collaboration becomes more complex as frictions occur more frequently. In our industry, complexity increases exponentially if a company decides to build its own integrated biopharmaceutical business.

Most biotechs start with some research labs and a first major crossroad comes when a compound is ready to enter the clinic. Retaining an external CRO (contract research organization) or building your own development team has a tremendous impact on the complexity. The commercialization of a compound represents another major threshold: build your own sales force or partner the rights.

Klingelfuss: No doubt, the life science industry is extremely complex as it deals with life itself in its countless variations. Even for a non-industry practitioner it is clear that every aspect of drug development, production and commercialization is heavily regulated with more legislation looming. In this context growth can imply further complexity and there are many different ways to manage it effectively. There seems to be no one-size-fits-it-all solution to reduce complexity. The approaches

companies opt for are rather a reflection of their strategy, people and resources.

The complexities of raising capital for growth can also be addressed through different sources: going public is just one of the alternatives available to biotech companies. They are used to dealing with complexity and operating within a regulated environment, which facilitates the adoption of the additional requirements that go with becoming a listed company. With regard to minimizing complexity, SIX Swiss Exchange offers a straight-forward regulatory framework, helping companies to become and stay public with as little effort as possible.

SIX: **The preparation for an IPO is considered to be a first major exercise to reduce complexity. What was your experience?**
Weber: Who wouldn't agree that housekeeping is a permanent task? In practice, urgent matters and daily routine tend to stimulate quick solutions. This holds true for Newron, too. In the run up to our going public, we abolished the organically grown structures and replaced habit with written processes. We abandoned the different classes of shares, introduced formal checks and balances and much more. The effort was well worth it and resulted in a lean, transparent and hence more efficient company.

Tanner: The first clean-up campaign at Cosmo was undertaken when professional investors came on board. The IPO brought additional tasks particularly in public reporting. The pressure to explain our business and how our activities fit into the strategy, results in the continuous re-evaluation of certain projects, in particular non-core activities with no near-term inflection points. The spin-off Dermatos, which we IPO'ed in 2015 at SIX Swiss Exchange under the new name Cassiopea, is the result of such considerations.

Scott: Basilea went public in Switzerland back in 2004. The listing requirements and reporting obligations have been evolving in the interest of increasing transparency – which is good for companies and investors. As an issuer, the existence of a critical mass of peer companies on the listing platform is helpful, as it typically leads to investors being more familiar and comfortable with the complexity entailed in the biopharmaceutical business.

Klingelfuss: When preparing for an IPO, the task of phrasing an attractive and compelling investment case for sector-specialist as well as generalist investors forces the organization to find ways to reduce the complexity. When the management team phrases its equity story, it has to focus on key messages relevant to potential investors and their investment decision. At this stage it becomes clear that it needs to take into account that the focus of specialist and generalist investors differs.

SIX: **Some say a transatlantic listing might offer many opportunities. However, this comes with a significant increase in complexity. What is your view?**
Tanner: A listing on a foreign exchange, and in particular in the USA, results in a significant increase in regulatory and reporting complexities. Companies need additional staff for financial reporting and permanent legal assistance from external lawyers. In my view, such a listing abroad can easily turn into a risky and expensive endeavor.

Every company is different and so is their appetite for risks. For some, the larger pool of institutional investors might justify a listing in the USA. Also, US investors are usually more open and risk seeking. For Cosmo and Cassiopea, the pros and cons remain in favor of a SIX listing and I don't expect this will change in the near future.

Scott: It is true that a transatlantic or even dual listing may add complexity. For instance through different or additional reporting obligations, overlapping and longer trading hours or different liquidity on the different trading platforms. This would have to be appropriately managed and requires employees in the US. On the other hand, there may also be benefits related to such a listing, in particular for companies in our industry. These may include enhanced visibility and analyst coverage, increased liquidity, a larger number of peers, and access to capital to fund growth.

Weber: The question is how to attract US investors by becoming relevant money-wise, since they are key for a higher market capitalization for every biotech company. An estimated two thirds of investments originate in the USA and approximately half of these are available for overseas investment targets.

When Newron prepared for the IPO, the odds for success were clearly in favor of the SIX. However, there is no guarantee for a steady flow of US funds for European biotech companies. That is why we regularly weigh the costs of financial reporting and regulatory compliance versus the benefits of access to the largest investment pool in our industry.

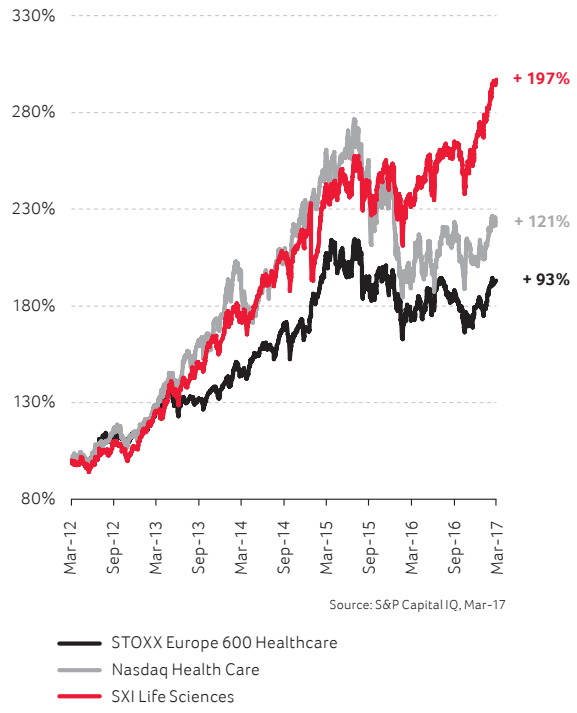
Klingelfuss: A number of European biotech companies, including a few Swiss ones, have considered a listing overseas. This is not a new trend. In the USA, there is a considerably larger pool of specialist investors with a bigger risk appetite for early stage biotech companies than in Europe. However, there is also a much larger number of listed biotech companies available to these specialist US investors. They tend to vote with their feet if the performance of the company does not meet their high expectations.

It is important to note, that many institutional US investors can also invest in an IPO on SIX Swiss Exchange, if the offering includes a private placement under Rule 144A of the US Securities Act. Adding such a 144A tranche will incur additional, though limited, costs and preparation work for the company.

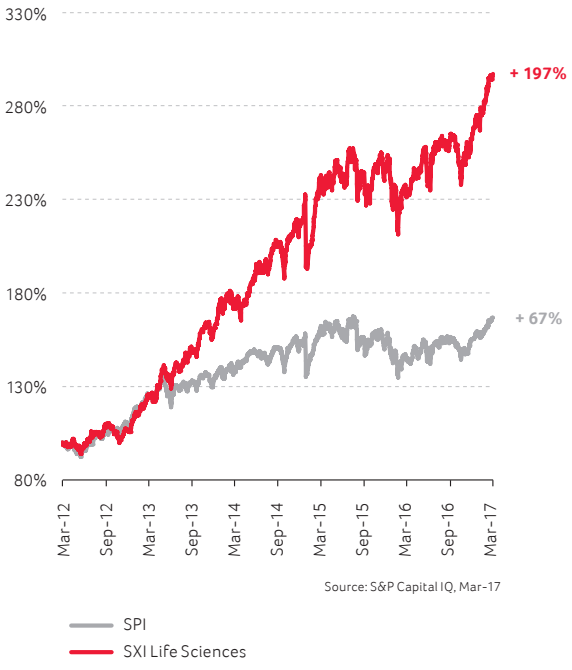
There are additional incentives for early stage biotech companies to list in the USA like the 2012 JOBS (Jumpstart Our Business Startups) Act. But as going public has a long-lasting impact, it is well worth looking at the increase in complexity that a European company faces in the USA. Sooner or later, companies need to be compliant with Sarbanes-Oxley, meaning that, when they reach a certain market cap or maturity, the more complex US regulations will need to be fulfilled.

In certain cases extra staff, designated to the US market, will be required. Overall a transatlantic listing brings more complexity that needs to be properly assessed.

SIX Swiss Exchange listed life science companies outperform their peers



SXI Life Science Indices performance comparison



SXI Life Science Index performance vs. SPI

SIX Swiss Exchange

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The roundtable was organized by Thomas Staffelbach of TS Kommunikation, a specialized PR and IR consultancy for biotech companies.