



Swiss Biotech Report 2019

Table of contents

Editorial	4
Shaping change	5
Open up science!	6
Working together towards innovation	8
The future is now: Strategic direction of biotechnet	10
Trends in biotechnology: Visualizing Swiss innovation through patent landscape analysis	11
Swiss biotech hub exploits opportunities offered by a changing healthcare landscape	14
Swiss biotech: Building windmills not walls	16
Roivant Sciences: Reinventing what a large pharma company of the future might look like	18
Hero and bogeyman: The public face of leadership after an IPO	20
Swiss Biotech Success Stories demonstrate the power and potential of Swiss biotech	23
Year in review: Selection of events in 2018	27
Swiss biotech in 2018: Facts & figures	31

Editorial



The theme of this year's Swiss Biotech Report is 'shaping change'. Biotechnology is one of many areas where change is happening fast, revolutionizing the way we help to heal, fuel, and feed the world. It is an exciting time but – alongside the opportunities to do new and exciting things – the speed and scope of change is of a magnitude that creates enormous challenges. Rapid change can cause anxiety, which in turn leads to resistance. That is why it is so important for us to communicate effectively and enable understanding across society.

A key aim of this report therefore is to explain and demonstrate how all stakeholders in the Swiss biotechnology industry are working together to plan and deliver the best possible outcomes. Business and academia are coming together to innovate, not just in terms of technologies, but also in terms of research and business practices.

Switzerland does have a highly qualified workforce, a stable economic and political system, and a good network comprising research institutes, companies, and government institutions. This enables the country to perform at the highest level and across all aspects of the industry; from new treatments to novel business models and particularly in 'red biotech' (health and medicine).

This gives us confidence that, with everyone working together, we can shape change positively. In this report you will gain insights into how this is happening today and take away ideas and inspiration to shape further change tomorrow.

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

Guy Parmelin
Federal Councillor of the Swiss Confederation

Shaping change

Swiss biotech is extraordinarily vibrant and these are exciting times, some might say too exciting. As industry commentator DrugPatentWatch puts it, "the way human beings are being medicated is witnessing a change that closely resembles what the internet has done so far to change our lives". And the internet is not just changing our lives but also the very way in which we do business.

It is a fact of nature that with the passage of time everything is subject to change. As we grow and learn so we change and adapt to changes in our environment. This is true not just for individuals but also for societies, nations and organizations. Just look at our industry. New, life-saving drugs are coming on to the market and investment in biotech is strong. At the same we are grappling with a host of new issues and concerns around biotechnology and we have similar new and evolving challenges at an industry level. Even the things that we create are transformed and changed through their lifecycle.

Change is not only constant but it is also happening very fast. This speed of change, and the shortened lifecycles it generates, create enormous challenges which we have to engage with.

Survive and grow

To maintain our status or position in the hierarchy of things, we cannot rely on old routines; falsely believing that if we do the same today as we did yesterday we can maintain our status quo. As an industry we have to be ready to change often in response to the constantly changing social, regulatory, geopolitical, ecological, economic and technological environment.

*"To improve is to change;
to be perfect is to change often."*

Winston Churchill

At the same time we must also recognize that rapid change and shorter life cycles are creating feelings of insecurity and powerlessness in society. And without a clear and positive vision of what future societies will be like, this sense of helplessness can become resistance to change. To change, we need to see why it is important and where it will lead us to.

Power to adapt

To respond effectively to change, we first have to realize that it is happening and then we need to understand what difference it is making. Switzerland is too small a country to shape the world on its own but we do have the power to adapt to change by setting our own standards and rules.

Constant vigilance and regular benchmarking can identify where ground has been lost and where measures to adapt must be taken. This comparison or competitive analysis with the outside world has to be matched up with the expectations, convictions and visions within the country.

The fragmented and federalist system of Switzerland has always guaranteed that the political will to change was balanced with expectations and convictions from the base. This might be a slow system for change management, but tries to keep everyone onboard which is important. On top of this, Switzerland realized early on that providing the best possible education to its people provided the best possible foundation for reacting to change and proactively shaping the new world.

Shaping the future

Change can be, and has been, seen as an opportunity to learn, grow and to create and shape a better future. However, to shape the future one requires a vision and strategy, as well as sufficient time to get there. In addition the impact of measures and the reaction to change have to be known.

On a global scale, the task seems enormous and the required competences are numerous. Professionals from all branches of science are needed to interact with society and government to define goals and visions. On a smaller scale, the way forward seems easier when all stakeholders are involved in jointly formulating a desirable future based on shared principles.

Enabling change

Stephen Sherwin, former chairman of BIO, describes biotechnology as "a horizontal technology used in a variety of industry segments to help heal, fuel and feed the world". Such a dynamic industry sector needs stakeholders to come together to plan and deliver a best possible future. The contributors to the Swiss Biotech Report represent the Swiss biotech ecosystem.

Our funding agencies Swiss National Science Foundation and Innosuisse influence the direction of basic and applied research with their funding instruments and regulations. The industry associations scienceindustries and Swiss Biotech Association interact with policy makers to improve framework conditions and with academia such as biotechnet Switzerland to maintain joint R&D in Switzerland. The critical analyses of our innovation potential by the Swiss Federal Institute of Intellectual Property and the industry statistics by EY help us to benchmark with global biotech. Switzerland Global Enterprise supports the industry by communicating the benefits and USPs of Switzerland as a business location and SIX provides the financial platform to grow and prosper.

Authors: Cathy Kroll & Jonathan Buckley

Open up science!



Florian Fisch
Science Editor
Swiss National Science Foundation

Research funded by the public should be, as far as possible, publicly accessible and free of charge. The Swiss National Science Foundation (SNSF) is committed to the global project of open science.

Access, reproducibility and speed

It was a shock back in 2011, when two pharmaceutical companies published that they were unable to replicate biomedical studies. Only in fewer than half of the cases, were the results consistent with the original publication. The Reproducibility Project: Cancer Biology has since tried to replicate high profile studies but with mixed success. Up until the end of 2018, only five out of twelve replication studies could reproduce important parts of the original publication. The lack of reproducibility in research has since become a major discussion topic in the scientific community, and in other disciplines such as psychology.

This has led to calls for more open science and the SNSF has implemented its own policies (see box). Open science means that the detailed methods as well as the raw data, should be accessible so that everybody is able to judge the results based on the full knowledge of the original experiments. **Open research data** should help the community reach higher standards.

Not only that, the sharing of all the information on experiments should also help to speed up innovation. No time wasted searching for the correct conditions, materials and analysis protocol: Everything is available online. No need to contact researchers of the original paper to obtain more information, hoping that they respond promptly (if at all!). New methods of text and data mining can be used: Algorithms analyse the research data of many studies in parallel.

Open science is also more trustworthy. This is advantageous at a time when influential political interest groups and certain media are increasingly questioning scientific knowledge. Even within the scientific community, the transparency can further scrutiny by colleagues and therefore results in a more thought-through research process from the beginning.

A second pillar of open science is to ensure **open access** (meaning free and digital) to scientific publications – especially for research that has been funded with taxpayers' money. Even if only a few non-science people are ever going to read scientific articles, they should have the right to read the results of their investment if they wish. Public accountability is an important

factor for convincing politicians to invest more public funds in education and research.

If publications are not freely accessible, the public pays twice for scientific results. First, they fund the research project and then they are charged to see the results. In addition, the price of a single article is usually prohibitively high. For scientists in rich research institutions of wealthy countries, this is usually not a barrier because their library has already paid the subscription fee. In poorer research institutions of low-income countries, the prices result in a large part of the scientific community being excluded from fresh results.

Transparency can go much further than open research data and open access to publications. **Open lab books** ensure that all research activities become transparent. **Open source software and hardware** helps replication efforts while **open peer review** could ensure more constructive feedback. **Pre-registration** discloses changes of end point while **open grant review** could yield more feedback and much more (see graphic). Such changes cannot be implemented through new policies alone. They require a huge cultural shift within the science community. Where the advantages are big enough, the SNSF wants to move forward together with the community of researchers.

The SNSF sets timeframes

Open access: By 2020 all publications from research projects financed by the SNSF will be published in a freely accessible form, including books. In 2018 this was already the case for half of the articles and books.

There are two possibilities: The gold road consists in publishing directly in an open access journal or book; the SNSF covers the cost for publishing. The green road to open access allows researchers to publish their article behind a paywall first, then they have to place them in a public database after six months (twelve for books).

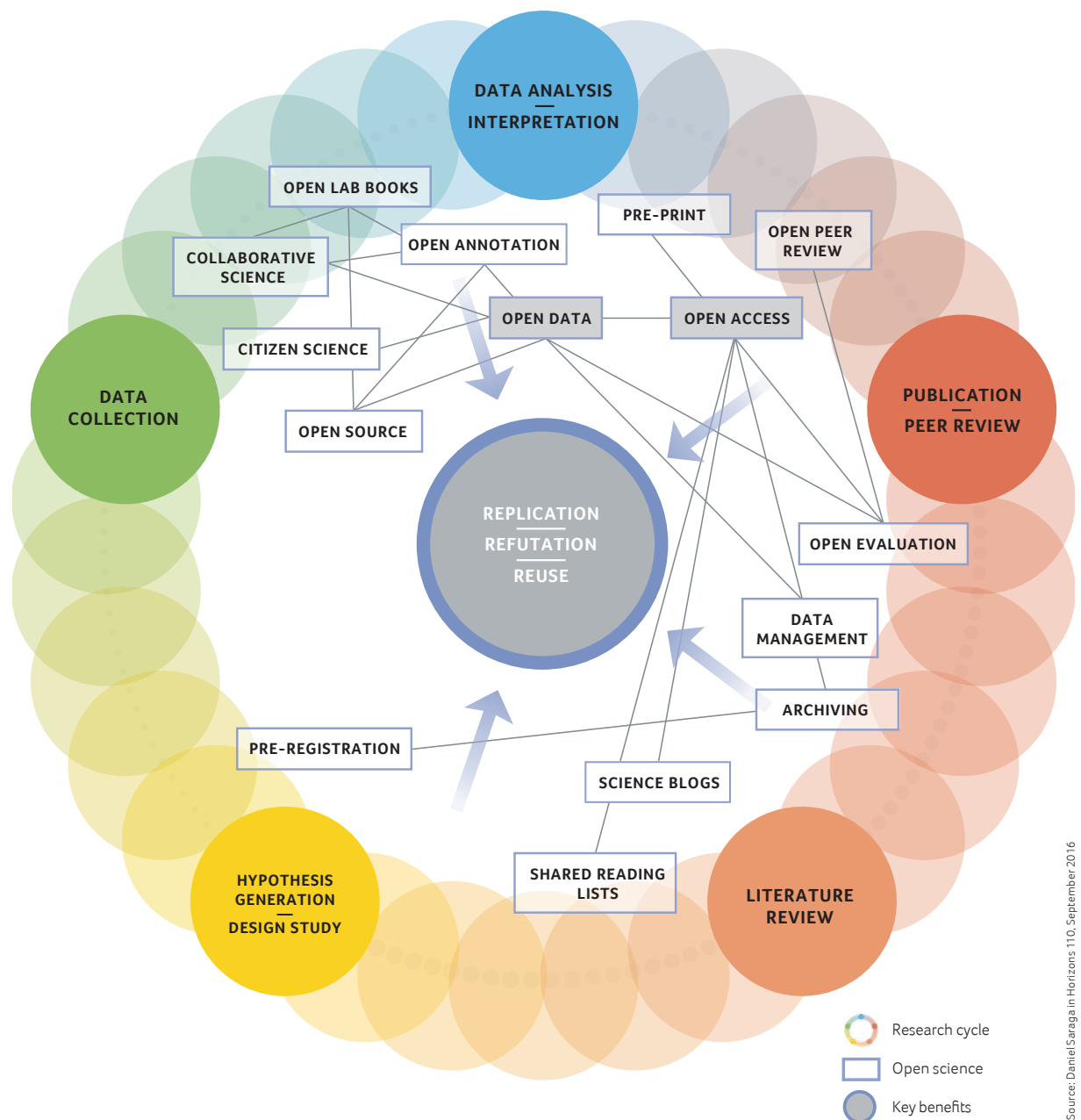
The strategy goes hand in hand with Swiss and European policy. Swiss higher education institutions decided that all publicly funded publications must be freely accessible by 2024. The SNSF also supports the 'European Plan S' but has not yet signed up, continuing to pursue its own 'Open Access Policy 2020'. The SNSF wants to walk the path to open access together with the community.

Open research data: The first step is for scientist to plan how they will organise their data and make it accessible to everyone: a data management plan. This facilitates handling, publishing and archiving the research results in a useful way. Since 2017, researchers have to include a data management plan in their funding application for most of the SNSF schemes. The SNSF pays up to CHF 10,000 for the additional work required. The first experiences have been generally positive.

Constant dialogue: The SNSF is discussing with researchers and coordinating with international funding institutions, Swiss higher education institutions, the State Secretariat for Education, Research and Innovation and Swiss politicians to further the transparency of science.

References:

- Horizons 110, September 2016, "Open up, science!", www.horizons-mag.ch/category/feature/open-science/
- SNSF open science policy, www.snf.ch/en/researchinFocus/dossiers/open-science/



Source: Daniel Saragat in Horizons 110, September 2016

The elements of open science: Grassroots movements have created a plethora of new concepts.

Funding excellent research

The Swiss National Science Foundation (SNSF) is the most important agency promoting scientific research in Switzerland. As mandated by the Swiss Federal Government, the SNSF supports research in all scientific disciplines, from philosophy and biology to the nanosciences and medicine. The best applicants are funded to the tune of over CHF 900 million each year. The SNSF supports over 6,000 projects involving more than 16,000 researchers annually. www.snsf.ch

Working together towards innovation



Annalise Eggimann
CEO
Innosuisse

The Zurich-based company InSphero has successfully completed a joint project with the University of Applied Sciences and Arts Northwestern Switzerland, School of Life Sciences (School of Life Sciences FHNW) to develop a 3D organ-on-a-chip assay that can predict the metabolic stability of pharmaceutical drugs. The year-long project was part-funded by Innosuisse, the Swiss Innovation Agency and the study culminated in partnerships being forged with major pharmaceutical companies.

A true success story

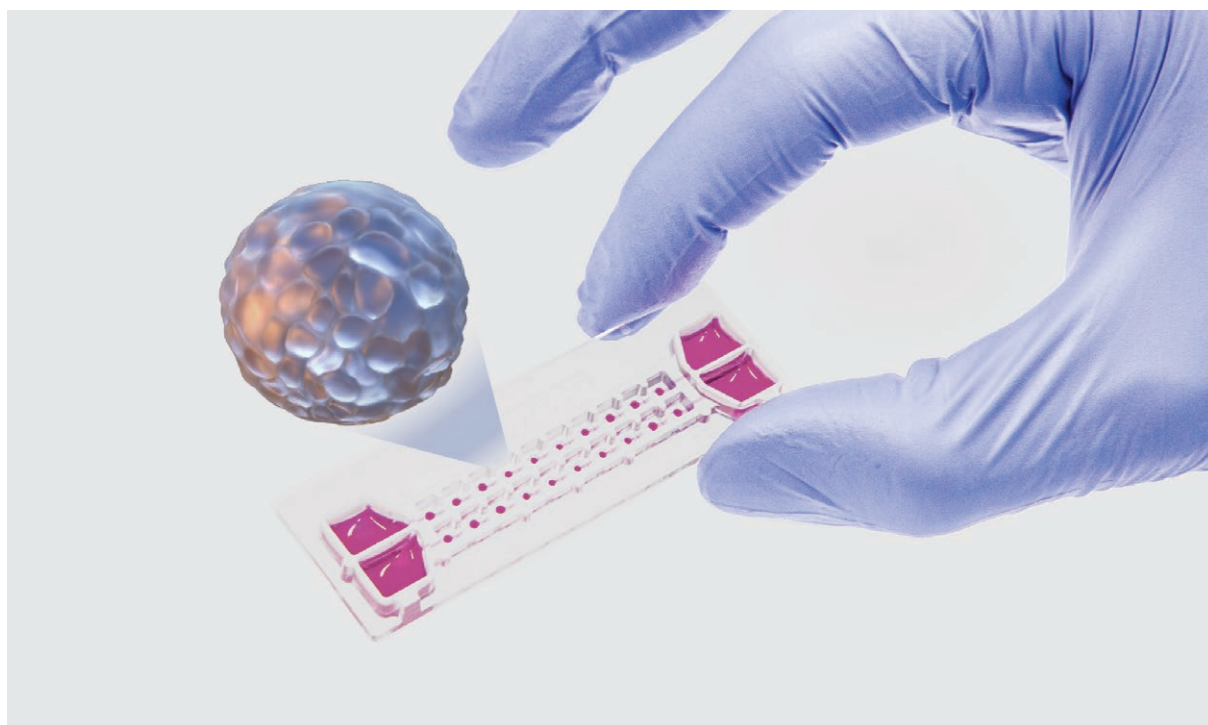
Not all innovative schemes and ideas, however inspired, end up as a success story. Finding the path to success requires a multitude of factors to come together and sourcing funding or potential partners forms an integral part of this process. The Zurich-based company InSphero, a specialist in 3D tissue-based assay solutions, set off on its journey in 2017. Its project was to reproduce a system that closely mirrored the workings of the liver in order to observe how the metabolism breaks down drugs. And only one year later, the work was done and the results were on the table.

Nothing happened by chance. Rather, it was down to the determination of a team of highly motivated and resourceful entrepreneurs with a welcome boost from Innosuisse, the Swiss Innovation Agency. Of particular importance was the assistance (see box) that Innosuisse provides in facilitating joint innovation projects between companies and research institutions. Working with Innosuisse was ideal for InSphero.

“We had to conduct a lot of experiments to prove that our system was viable, which takes considerable work and resources. This required external support. We thought that Innosuisse would be the perfect partner to get this project completed, from the initial model to the final product.”

Dr Olivier Frey, Head of Technologies and Platforms, InSphero

Having already benefited on other projects from the expertise of School of Life Sciences FHNW – and more specifically from the knowledge of Dr Laura Suter-Dick, Professor of Molecular Toxicology, and her research team – the SME applied to Innosuisse for funding to carry out the study.



© InSphero AG

InSphero 3D organ-on-a-chip assay

It was not just the innovative approach, but also the potential for generating value for the economy and society, that were key to the project funding application being accepted. “We have to be able to create new drugs to treat any new disease that emerges,” says Dr Suter-Dick. “And studies need to be done to understand how long a substance remains stable in the human body and therefore how many times it can be given to a patient. The system proposed by InSphero makes it possible to reproduce what goes on in the body using an in vitro technology – in other words, without having to test anything on animals, for example.”

On the back of a positive evaluation, the project quickly took shape. “The decision-making process doesn’t take long, which is a benefit when getting a study off the ground,” says an enthusiastic Dr Frey.

Dr Suter-Dick agrees: “I am a firm believer in Innosuisse’s funding model. The opportunities it offers are a great help to SME. I don’t think you will find anything like this anywhere else – there won’t be many other countries offering this kind of support.”

The project was brought to a successful conclusion in October 2018, one year after its launch. “The initial studies were quite tech-heavy and took us a bit longer than expected. But what matters in the end is that results have been achieved and that the data collected can be used,” says Dr Frey. “We are currently working on obtaining even more validations by conducting even more experiments. With the data we have in our hands, we have already been able to approach clients and some major pharmaceutical companies are testing our product. Once the necessary tests have been done, the idea is to standardise it.”

The InSphero 3D organ-on-a-chip assay is a great example of successful project execution. It demonstrates how productive working together can be and how in so doing, the potential for forging future partnerships is increased. “We’ve maintained some good contacts at InSphero and are exploring the idea of collaborating on a new project and asking Innosuisse for its support once again,” Dr Suter-Dick concurs.

“Without the financial support from Innosuisse, we wouldn’t have been able to finish this project. I don’t believe that a small company like InSphero could have funded the kind of scientific research that we did. It’s not always easy for small outfits like ours to do exploratory research, and I think Innosuisse is the perfect way to go about this.”

Dr Olivier Frey, Head of Technologies and Platforms, InSphero



Salvatore Mannino, School of Life Sciences FHNW, at work on a cell bench

© School of Life Sciences FHNW

The provision of funding for innovation projects is Innosuisse’s most important support instrument. Partners from industry and research join forces to implement clearly defined innovation projects. Innosuisse covers up to half the project costs, paying the salaries of the researchers involved in the project with the companies funding the other half.

Throughout Switzerland, Innosuisse Innovation Mentors offer their services for free to enable companies to find the right research partners and work with them to write their funding application. Meanwhile, National Themed Networks (NTNs) facilitate meetings between researchers and entrepreneurs from a specific field of innovation.

Start-ups can also enjoy professional support in the form of coaching. Innosuisse provides companies with vouchers allowing them to select their own partners from a pool of accredited coaches as well as offering a range of courses and training modules for anyone looking to start up their own company in this way. www.innosuisse.ch

The future is now:

Strategic direction of biotechnet



Prof. Laura Suter-Dick
President biotechnet Switzerland,
University of Applied Sciences Northwestern
Switzerland, School of Life Sciences (FHNW)

The biotechnology sector includes a wide array of technologies and applications, with a significant share of Swiss players. Under the umbrella of NTN Swiss Biotech, biotechnet Switzerland together with the Swiss Biotech Association (SBA) has been instrumental in generating private-public partnerships to support the biotechnology area.

The speed of scientific and technical development as well as the continuous position of Switzerland as a key player in biotechnology make the ties between industrial and research partners still necessary, if not indispensable. Thus, the dissolution of NTN Swiss Biotech in the fall of 2018 represents the end of a formalized union but is definitely not the end of the joint efforts of SBA and biotechnet to foster interactions between Swiss biotech stakeholders. 2018 was an important year for biotechnet Switzerland. On the one hand, we were deeply devoted to fulfilling the commitments linked with the financial support by Innosuisse (former CTI). On the other hand, we were devising a strategy allowing us to play our role in the years to come. With this in mind, we continued our relationship with SBA, jointly formulating a Memorandum of Understanding that outlines common areas of interest.

biotechnet started prioritizing specific fields of interest, sponsoring and promoting focused events addressing key biotechnological developments in Switzerland. One of the highlights was the formal initiation of the Translational and Clinical Bio-Manufacturing (TCBM) platform in May 2018, as a natural evolution of the former Regenerative Medicine platform.

Now the focus has been sharpened and the platform, jointly led by Prof. Eliane Müller (SCRM & University of Bern) and Prof. Steffen Zeissberger (Wyss Zurich), has capitalized on synergies between five organizations from Swiss universities and university hospitals, that use and operate cleanrooms (including bio-manufacturing) for translational clinical applications. In a related topic, the Tissue Engineering for Drug Discovery platform (TEDD), led by Prof. Michael Raghunath (ZHAW), continued its successful trajectory promoting scientific events as well as visits

to industrial partners. In a field soon to face new regulations, the In Vitro Diagnostics platform jointly led by Prof. Marc Pfeifer (HES-SO) and Dr Dieter Ulrich (CSEM) organized the second very successful Point of Care (POC) Symposium in October.

The Personalized Medicine platform led by Dr Silke Schneider (University of Zurich/ETHZ) organized a conference entitled 'Personalized Health Technologies and Translational Research' in Zurich (June 2018). biotechnet also strives to increase the international visibility of Swiss biotechnology. Hence, the Bioresources platform led by Prof. Philippe Corvini (FHNW) made it possible for biotechnet and SBA to chair a session at the 'European Conference in Biotechnology' in July 2018 in Geneva. It also promoted the very successful 'International Symposium on Persistent Toxicant Substances' in November 2018 in Muttentz. In the platform Biocatalysis and Biosynthesis Prof. Rebecca Buller (ZHAW) organized a second CCBO (Competence Center for Biocatalysis) Symposium; a meeting that provides a platform for scientific knowledge transfer and dialogue. Addressing a key societal and health issue, the Antibiotics platform led by Prof. Markus Seeger (University of Zurich) chaired a session in Basel Life 2018 entitled 'Antibiotics Brought by NTN Swiss Biotech', a topic that met the interest of the pharmaceutical industry and academia alike.

There is no future without education. Hence, biotechnet has been promoting biotechnology skills for nearly 20 years. In 2018, biotechnet supported the realization of the 'XIII Summer School on Advanced Biotechnology' with the Università degli Studi di Palermo. In a more tailor-made approach, with the platform Training for Pharma/Biotech Prof. Daniel Gygax (FHNW) promotes interactions between the industrial sector and the directors of universities of applied sciences in the area of life sciences, to ensure that Switzerland remains a top choice for the biotech industry requiring specialized staff.

Albeit the need for some refocusing and definition of specific fields of academic and industrial interest, biotechnet remains committed to closely interacting with SBA and the Swiss biotech industry. With its collection of competencies and enhanced networking, biotechnet strives to identify niches that may lead to larger research programs with the end goal of technology transfer and industrial commercialization. The future has just begun.

biotechnet Switzerland is a network of universities of applied sciences, universities and research and technology organizations. It comprises 10 full members and a large number of associated and platform members in each of the thematic platforms. As such, it provides an excellent means to channel access to a wide variety of competencies in biotechnology to support biotech industry. For further details or to join the network, please visit www.biotechnet.ch.

Trends in biotechnology: Visualizing Swiss innovation through patent landscape analysis



Christian Moser
Swiss Federal Institute
of Intellectual Property

This year's patent analysis builds on the work presented in the Swiss Biotech Report 2018 and drills deeper into specific biotechnology subsets, including the red (health and medicine), white (industrial) and green (agriculture) biotech categories, as well as established and emerging biotechnology subsets.

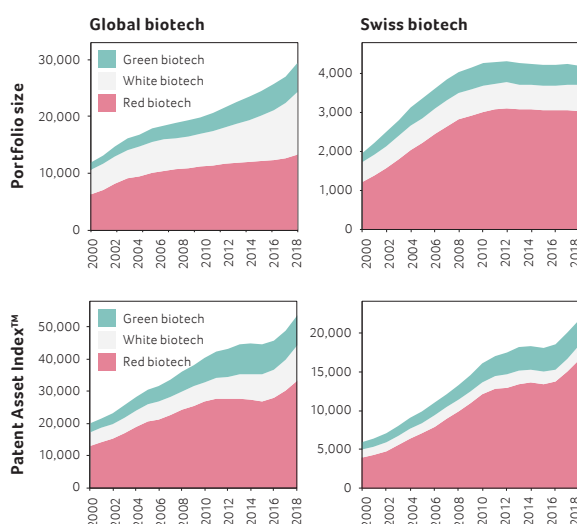
The biotechnology sector includes a wide array of technologies and applications, and is subject to continuous change, driven by innovation. Patent landscape analyses can visualize these developments from various perspectives, such as technology, geography, or ownership, or combinations thereof.

A quantitative and qualitative comparison of the global biotech patents with those invented in Switzerland reveals the strengths and weaknesses of the Swiss biotech community in the different subsets. With a share of 1.3% of the global biotech patent portfolio accounting for 4% of the global portfolio value, Switzerland is a small but high-quality player in biotech.

A particular strength of Swiss biotech is in the red biotech sector and medicine, and most prominently in the field of antibodies and cytokines. Swiss inventors have been involved in the initial phase of emerging technologies, such as probiotics, CAR cells (cells engineered to display chimeric antigen receptors), or genome editing (i.e. CRISPR/Cas, TALEN, ZNF). Other emerging technology fields such as nanotechnology, digital health, sequencing, or bioinformatics are examples of technology fields which feature a low share of patents invented in Switzerland.

Green, white and red biotech portfolio size from 2000 to 2018

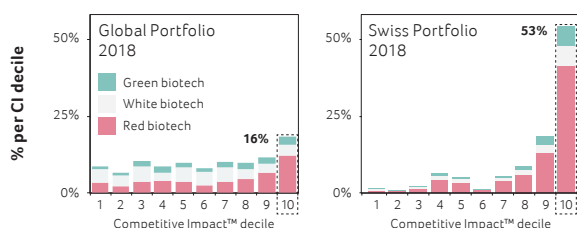
Based on their patent classification, the biotech patents can be categorized in three major application fields: health and medicine (red biotech), industrial (white biotech) and agriculture (green biotech) applications. Biotech patents not assignable to any of the three categories account for less than 3% in both portfolios.



Red biotech represents the largest subset in both portfolios, in particular among the patents invented in Switzerland (2018: 45% of global and 66% of Swiss). On the global scale, the total number of patents has grown substantially during the past decade, in particular in white biotech, which has caught up with red biotech. This trend is not detectable at all in the Swiss industrial biotech portfolio, which has neither grown in size nor changed in proportions during the past decade.

Even though the global and the Swiss portfolios are very distinct with regard to the development of the portfolio size, their value growth profile measured by Patent Asset Index™ (PAI) is strikingly similar, except for the higher proportion of red biotech in the Swiss portfolio. The red biotech sector shows a significant increase in the Patent Asset Index™ in the past three years for both the global and the Swiss portfolio. The same pattern is evident in several subsets related to red biotech, such as antibodies, vaccines, cytokines, gene editing, and CAR cells.

Competitive Impact profiles in 2018



The very distinct Competitive Impact™ (CI) decile profiles of the global and the Swiss biotech patents explain the discrepancy between growth profiles for portfolio size and PAI. The global portfolio spreads widely across all 10 deciles, and only 16% of the global portfolio belongs to the highest CI decile 10, also referred to as 'world-class patents' (highlighted by frame in the graph). Within global biotech only red biotech displays a slight shift towards the higher CI classes. In contrast, the Swiss portfolio – in red, white and green biotech – concentrates mostly in the high CI deciles, with 53% in qualifying as world-class patents.

Note: The qualitative parameters Competitive Impact™ for individual patent families and Patent Asset Index™ for the cumulative value of a given portfolio allow for a more differentiated analysis beyond purely quantitative statistics. The biotech patents and the red/white/green biotech subsets were defined exclusively based on the international patent classification (IPC) and corresponding cooperative patent classification (CPC) using the PatentSight platform.

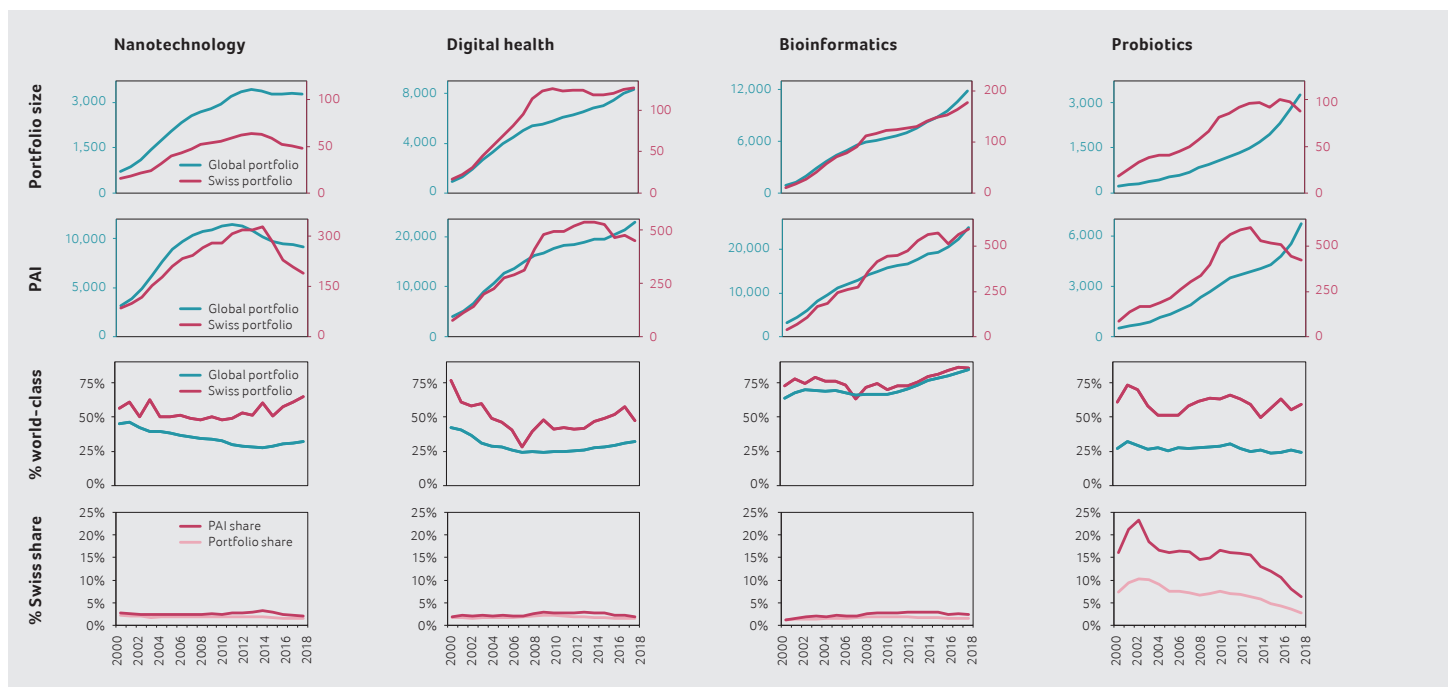
Examples of established biotechnology subsets

Subsets with a substantial patent portfolio size of over 1,000 existing in the year 2000 were defined as 'established biotech'. As a reference, the graphs on the left represent the entire global biotech portfolio. For each subset, the three top graphs provide the key indicators plotted over the past 18 years, i.e. portfolio size, PAI, and share of 'world-class patents' (top CI decile 10), both for the global subsets



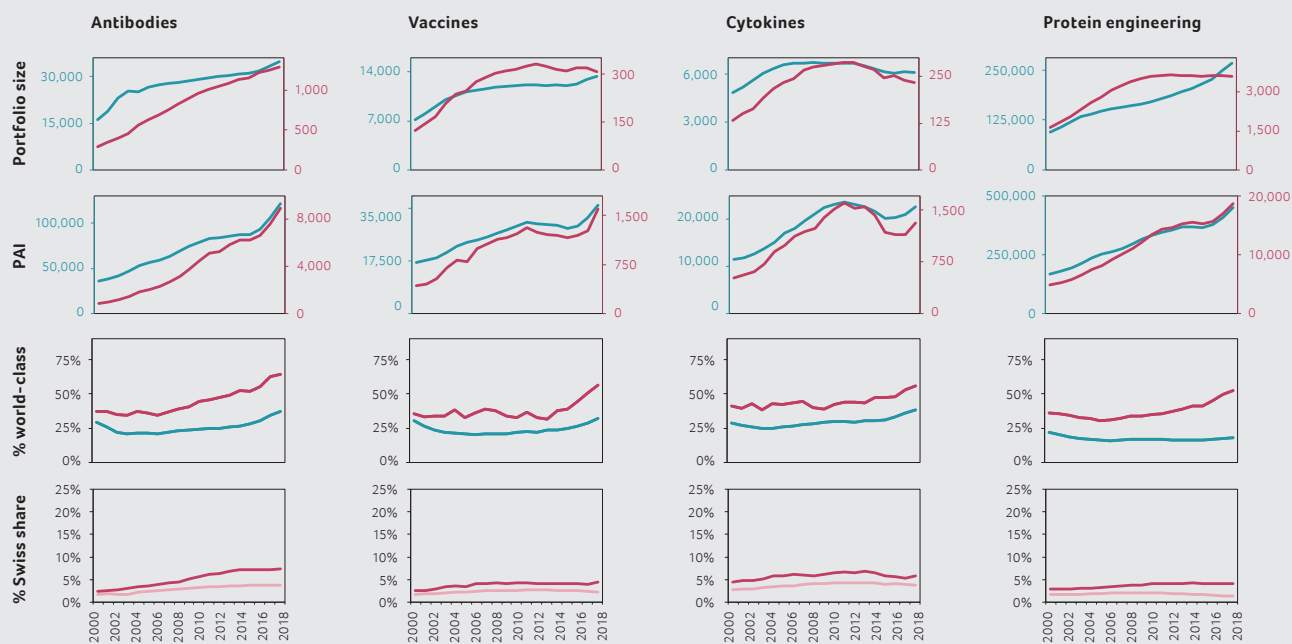
Examples of emerging biotechnology subsets

Emerging technologies are here defined as novel fields within biotechnology, which have evolved from small or non-existent portfolios in the year 2000, often with exceptionally high growth rates. The graphs show the same parameters as displayed in the graphs before.



Note: The subsets for emerging technologies were generated by more complex filters including keywords as well as IPC/CPC classification from different databases (Epodoc, WPI, PatentSight), and evaluated with the software PatentSight (www.patentsight.com).

(in petrol green) and for the patents invented in Switzerland (in red). In the two upper graph rows, the left y-axis represents the global portfolio, and the right y-axis refers to the Swiss portfolio. The bottom graph row shows the share of the Swiss patents within the global portfolio, with regard to portfolio size and to PAI.



The Swiss Federal Institute of Intellectual Property is the official government body for intellectual property rights in Switzerland and is responsible for examining, granting and administering these rights. The Institute's services also include training courses on various aspects of intellectual property and tailor-made searches for trademarks and patent information, including strategic patent analyses involving patent quality parameters. For further information visit www.ige.ch.

Swiss biotech hub exploits opportunities offered by a changing healthcare landscape



Michael Altorfer
CEO
Swiss Biotech Association

Globally, investments in the biotech sector are soaring. The ever increasing and aging global population, together with a wide range of unmet medical needs and new technologies that offer more targeted treatment options, are creating global business opportunities that attract ever more players.

Switzerland has established one of the strongest, most densely populated and comprehensive biotech hubs in the world. However, the growth in number of competitors suggests that this leading position may increasingly be challenged. Continuous innovation in science, business and financing models, together with a clear focus on patients' needs, are vital to retain a leading position and develop valuable and effective biotechnology products, diagnostics and novel medicines.

We take a closer look at the way in which the Swiss biotech industry is evolving and exploits opportunities offered by four key industry trends:

1. Structural change in the pharma industry offers opportunities for the biotech companies
2. Innovative financing models provide leverage
3. Investors push for effective management structures
4. Artificial intelligence enables more targeted and effective therapies

Structural change opportunities

As global pharma companies continue to adjust and optimize their business model, more and more elements of the integrated value chain are outsourced. Contract research organizations play an ever more important role in research, clinical trials and manufacturing. Even in drug distribution big pharma companies are increasingly open to out-licensing their products if they can identify a partner that is more effective in certain indications or has a better connection to selected patient groups.

Increasingly, pharma companies rely on external innovation provided by biotech companies. They in turn optimize their business models to handle the inherent risks associated with developing new technologies and medicines. Service providers and contract research or manufacturing organizations are also ready to assume development risk. They team up with investors that support them in financing innovation, clinical trials or the build-up of production sites. In return these investors, together with the biotech companies and service providers, participate in the upside when a joint product development is completed successfully.

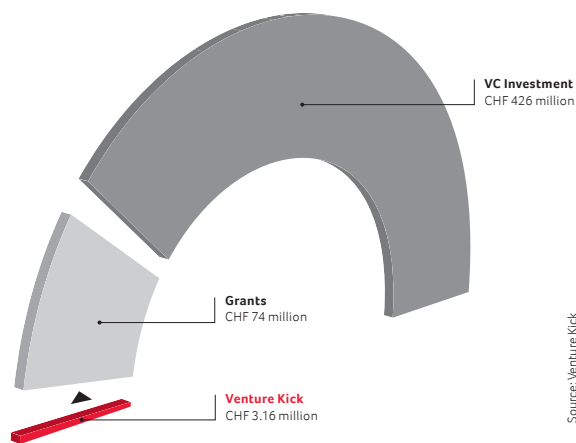
Some of these models have been developed only recently and it is therefore too early to assess whether they will all be successful and prevail but overall the trend is clear. The pharma companies distance themselves from managing the entire value chain, and from carrying the entire development risk on their own. They rely on partners to de-risk the projects and in return these partners participate in the success. The end result is an increase in specialized parties combining their efforts in developing, producing and distributing new medicine. As all of them share risk and reward. They are incentivized to work together effectively and to assess, sooner rather than later, whether a project is viable or not.

Innovative financing models

Financing biotech companies is inherently associated with a significant attrition risk. Less than 1% of research projects lead to a successful product launch and the development of a new medicine typically requires intense R&D efforts for in excess of 10 years. Furthermore, such projects normally require many sequential financing rounds and the biotech companies need to be able to raise several hundreds of million US dollars (and often > USD 1 billion) if they want to develop their products on their own.

To grow and prosper these companies need to combine sound science with an experienced management team and the ability to effectively finance development. In this context time is money. As soon as patents are filed, the clock is ticking and any delay inevitably results in a shorter period of market exclusivity. Seamless and effective financing is thus an essential element of a successful biotech hub.

Switzerland has been successful in attracting venture capital in this sector (more than USD 1.5 billion new funds were made available to Swiss biotech companies in 2018 alone). Nevertheless, all too often companies have lost time with preparing and implementing financing rounds and some have struggled to get started despite attractive and promising scientific rationales.



Since 2007 Venture Kick invested CHF 3.16 million in 48 Swiss biotech start-ups. This amount was amplified 159 fold by grants and VC investments.

To address these issues, Switzerland has invested in innovative financing models. These include different types of capital sources (non-dilutive, philanthropic, angel investors, venture capitalists, etc.) and marketing platforms (private networks, crowd funding, ICOs, small and large public markets).

Various organizations combine their efforts to promote and finance start-up companies (including e.g. >>venture>>, Venturelab and Venture Kick). Their initial investments have proven to be particularly effective: Since 2007, Venture Kick has invested more than CHF 3 million in 48 Swiss biotech companies and this initial seed money was amplified more than 150 fold by subsequent grants and venture capital investments.

Effective management structures

Next to the efforts to access capital in a timely manner and on favourable terms, companies are increasingly establishing innovative organizational structures to gain time and reduce capital needs. Thanks to leading universities, innovative hospitals and a traditionally strong pharma sector, Switzerland has been a rich source of new technologies, sound science and opportunities to apply scientific findings to address medical needs and benefit patients. The good reputation and efforts of these organizations means that business opportunities have attracted the required financial resources. However, strong growth in the Swiss biotech industry creates the risk of a shortage of dedicated entrepreneurs and management teams that can effectively manage all these opportunities.

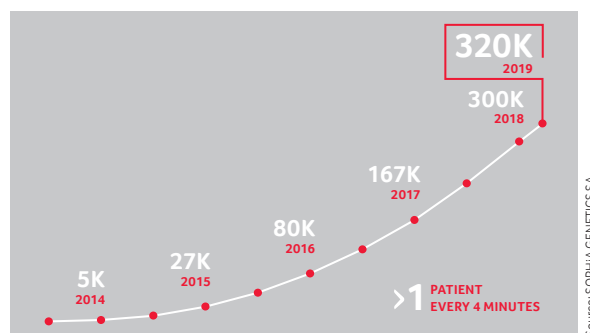
Given this situation, investors are pushing for highly effective management structures. The goal is to reduce research costs by running virtual companies and increase the chances of individual projects by establishing highly skilled and specialized management teams. Consequently, specialized investors assemble their own management teams and operate in virtual company settings (e.g. Versant Ventures, Medixi Ventures) or exploit synergies by running several companies under one roof (Roivant Sciences).

In return, the investors are willing to provide very solid financial reserves (e.g. Vir, Roivant Sciences), in some cases exceeding USD 1 billion, to ensure that successful projects will be fully funded and thus eliminate the need for sequential financing rounds. Such significant financial commitments will only be granted if the investors have full trust in the management team to indeed eliminate projects that do not meet expectations as early as possible.

Faster and more precise with artificial intelligence

Artificial intelligence (AI) powers more and more smart clinical trials and enables highly targeted therapies. Genomic and imaging data are particularly useful for new AI-driven analytical applications as they both represent valuable sources of information to support patient diagnosis, prognosis and monitoring. Thereby AI is used to identify those molecular biomarkers, which are essential for the development of targeted therapies, making treatments more personalized to individual patients. This smart diagnostic tool seeks to identify specific molecular signatures to provide the right treatment to the right patient at the right time.

As these data collections grow they become ever more powerful. SOPHiA GENETICS, one of the leading companies in this field, has helped diagnose more than 320,000 cancer patients so far, almost twice as many as by the end of 2017. An ever increasing number of hospitals from around the globe use their platform to collect and share data and thus all their patients benefit from this joint effort. AI can thereby contribute to reducing the costs and timelines of clinical trials while at the same time enabling much more precise and effective therapies.



SOPHiA GENETICS has supported the diagnosis of over 320,000 patients worldwide so far and the data collection is rapidly expanding.

The continuous optimization and adaptation of business models, access to funding for early stage projects, effective management structures and the opportunities created by AI bear the potential to further accelerate the growth and value contribution of the Swiss biotech hub. But constant innovation will remain an ongoing obligation in the context of increasing global competition, healthcare cost challenges and the objective to provide ever more targeted and effective therapies.

Founded in 1998, the Swiss Biotech Association represents the interests of the Swiss biotech industry. To support its members in a competitive market, the Swiss Biotech Association works to secure favorable framework conditions and facilitate access to talents, novel technologies and financial resources. To strengthen and promote the Swiss biotech industry, the Swiss Biotech Association collaborates with numerous partners and life science clusters globally under the brand Swiss Biotech™. For more information visit www.swissbiotech.org.

Swiss biotech: Building windmills not walls



Jan Lucht,
scienceindustries

Breakthroughs, scientific or medical, can transform industries, especially in an environment as dynamic as biotech. To take full advantage of the opportunities, you have to be prepared, and you must have the flexibility to change established procedures, business models and regulatory frameworks.

Around 500 BC, Heraclitus declared, “the only thing that is constant is change”. Outcomes of change very much depend on how one deals with them and whether the focus is on potential threats or the opportunities: “When the wind of change blows, some build walls while others build windmills” (Chinese proverb). It takes courage, determination and a long-term strategy to take full advantage of change and build ‘windmills’ instead of ‘walls’.

Cell-based immunotherapy challenges

Biotechnology has been highly successful in providing new treatments for serious health conditions and for improving patients’ quality of life. For 2019, it is predicted that eight of the top ten best-selling pharma compounds worldwide will be biotech products. Most of them are monoclonal antibodies for cancer therapy. While the availability of these has allowed great progress in the treatment of specific tumors, the effectiveness of antibody therapy for other types of cancer is limited.

Very recently, a completely new class of treatments for neoplastic diseases became available: cell-based immunotherapy, and specifically chimeric antigen receptor T-cell (CAR-T) therapy. This new approach to cancer treatment has a huge medical potential but also presents a variety of challenges for pharma companies. Regulations, the production process and delivering the treatment to patients, all require major changes to established practices. This is illustrated by Kymriah®, a groundbreaking, novel cancer therapy developed by Novartis.

Immunotherapy harnesses the body’s own defense systems to combat cancer. For CAR-T therapy, some of the patient’s T-cells are removed, genetically modified in the lab (to be able to recognize and attack the patient’s tumor), multiplied, and then re-infused into the patient. The results have been remarkable: many seriously ill patients have improved dramatically with their cancer going into remission or disappearing. This is a breakthrough for the treatment of serious, life-threatening diseases, where previously there were only very limited treatment options.

Much of the ground-breaking work for CAR-T cell therapy was done at the University of Pennsylvania. In 2012, Novartis partnered with UPenn and pushed on to make the therapy available to patients as soon as possible. Very positive results from clinical

studies and a good collaboration with regulatory agencies helped guide the treatment through the authorization process, even though this was a treatment with no direct precedent.

In August 2017, Novartis obtained first-in class authorization in the US for Kymriah®, the CAR-T based therapy for treatment of B-cell acute lymphoblastic leukemia in young patients. The indication was subsequently expanded to include diffuse large B-cell lymphoma in adults. Marketing authorization for the EU and Switzerland followed in 2018.

The CAR-T cells are prepared individually for each patient using a highly technical process requiring expertise and specialized equipment. The treatment of the patients takes place in dedicated medical centers. This meant that new manufacturing and supply chain systems that deviated significantly from those used for traditional off-the-shelf drugs had to be set up. Kymriah® is unlike a classical pill that can be produced in large numbers at a few sites and much more like a very personalized service.

The labor-intensive preparation of each individual patient’s CAR-T cells, the complex cooperation involved, and the small number of patients with an indication for Kymriah® treatment, means that the costs of the single infusion required for the treatment appears to be very high – especially when compared with the single doses of more traditional drugs that are given repeatedly over a longer course of time. This has led to discussions about the pricing of short-time treatments, including cell-based immunotherapies that result in long-lasting or permanent benefit.

In comparison to traditional approaches like stem-cell transplantation from a matching donor, the highly efficient and potentially curative CAR-T treatment is cost-effective. In the long run, pharma companies and the healthcare system will have to find a new approach to compensation. This would also take into account the value of a given treatment for the patient and might include outcome-based pricing models where payment is linked to the success of a therapy.

For healthcare biotechnology companies, the medical breakthrough of CAR-T cancer therapy required many changes including authorization, business model, logistics and healthcare financing. The continuing willingness of all actors to change established practices and adapt them to new developments will play an important part in realizing the huge potential of immunotherapy to transform cancer care.

Novartis is currently expanding its network of production sites in Europe, including a CHF 90 million investment in Switzerland to build an ultramodern production site for innovative cell and gene therapies in Stein (AG), with a potential of up to 450 highly qualified jobs. The first batches of Kymriah® from Stein will likely be available in 2020.

Changes to genome editing regulations

Recently developed tools for genome editing, like CRISPR/Cas9, have given a boost to research and product development in all sectors of the biotech industry. Applications are wide-ranging: improvement of production strains for industrial biotechnology, more resistant and sustainable crop plants in agricultural biotechnology, and new cures for disease and the production of optimized active compounds in healthcare biotechnology. However, the regulatory framework has not kept pace with the rapid scientific progress.

The European Commission has been aware of these developments for over a decade but has repeatedly postponed adapting the quarter-century old EU regulations governing genetic engineering techniques. This lack of action resulted in the controversial decision by the European Court of Justice in the summer of 2018. Based on the antiquated EU regulations, it classified all organisms resulting from genome editing, irrespective of the introduced changes, as 'genetically modified organisms' (GMO) and thereby subjected them to strict authorization and labeling requirements. This decision means that for the EU, genome editing has been removed from the toolbox in some biotechnology sectors like plant breeding, and research and development has been paralyzed for years to come.

In Switzerland, the government realized the need for action and in November 2018 announced a plan to adapt the regulatory framework to the newly available technologies. Genetic changes in organisms should be classified according to different risk levels, with different requirements. This opens the possibility

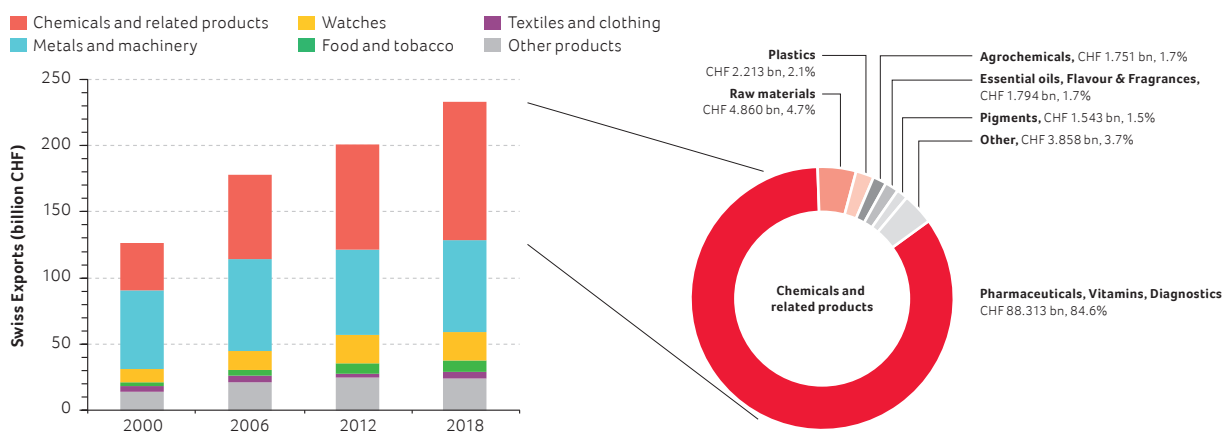
for the development of flexible, proportionate, and science-based, future-proof rules for genetic engineering technologies in Switzerland. Here, a willingness to change the regulation will benefit the Swiss biotech sector in general and could also give an impulse to the gridlocked situation in the rest of Europe.

Major contribution to Swiss exports

Favorable framework conditions in Switzerland, including a highly qualified workforce, a stable economic and political system and a good network comprising research institutes, companies and government institutions have supported strong economic development. In 2018, exports from the Swiss chemistry, pharma and life sciences sector, including biotech products, reached a record high of CHF 104.3 billion.

This sector's share of total exports has steadily increased from 28% in 2000 to 45% in 2018. Since 2009, it has been Switzerland's largest export industry (see figure below). Swiss exports from all sectors have increased by 84% since the year 2000 to reach CHF 233.1 billion in 2018. Over the same period, the contribution of the life sciences subsector (pharmaceuticals, vitamins and diagnostics, with a significant proportion of biopharmaceuticals and biotech products) quadrupled from CHF 22.1 billion to CHF 88.3 billion. This demonstrates the strong dynamics of the life sciences sector.

Compared to the previous year, the life science sector exports grew by 5% and now contribute 85% of the total exports of the chemistry, pharma and life sciences industry, and 38% of the total Swiss exports.



Swiss export statistics according to industry sector demonstrate the lead of the chemistry, pharma and biotech industry (scienceindustries/Federal Customs Administration 2019)

scienceindustries – the Swiss Business Association Chemistry Pharma Life Sciences

scienceindustries supports some 250 member companies: fostering an innovation-friendly environment in Switzerland, creating a competitive production and business framework, enabling attractive market conditions, and facilitating worldwide market access. For more information visit www.scienceindustries.ch.

Roivant Sciences: Reinventing what a large pharma company of the future might look like



Sascha Bucher
Head Basel Roivant Pharma and
Head of Global Transactions



Interviewed by:
Sirpa Tsimal
Director Investment Promotion
Switzerland Global Enterprise

Roivant Sciences was founded in New York by a young investor and entrepreneur, Vivek Ramaswamy. In 2016, the company opened its global headquarters in Basel, Switzerland. Sascha Bucher, Head Basel Roivant Pharma and Head of Global Transactions, talks with Switzerland Global Enterprise about his company's game-changing business model and why Basel is the perfect place to be.

What did Roivant find in Basel that it didn't have in New York? What were the key factors in your company's decision to select Switzerland as a new location?

We selected Basel on account of the city's deep and diverse talent pool and its central location in the heart of Europe. Basel is home to two of the world's largest pharmaceutical companies – Novartis and Roche – but it also serves as a regional headquarters for many other pharma companies and is a leading hub for many smaller biotech and medical device companies.

“Having operations in Basel makes it easy for us to hire experts across the entire biopharma value chain, from academic and industrial research to CMC (chemistry, manufacturing and controls) and formulation to clinical development and commercial operations.”

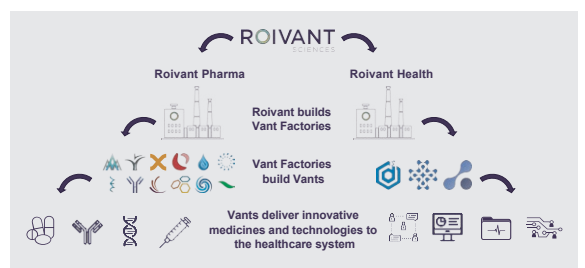
Basel has been a hub for the life sciences and complex manufacturing for a very long time. It dates back to the arrival of Huguenot refugees in the sixteenth century. They established Basel's silk ribbon industry and laid the foundation for the city's export-oriented chemical and pharmaceutical industries.

I should also note that the regional authorities for the canton of Basel-Stadt and the team at BaselArea.swiss (investment and innovation promotion of the Basel region) make it very easy for companies to establish operations in the city and plug into existing networks for partnerships and recruiting.

Roivant's philosophy is game-changing in terms of talent acquisition and financing: With Axovant you've had the biggest biotech IPO in US history; with Myovant you've had the largest biotech IPO in 2016; and the USD 1 billion invested in Roivant by Softbank was the largest VC funding in Europe in 2017. What is the key to your success?

We hire top drug developers from within biopharma, but we also look outside the industry for fresh perspectives. We recruit top talent from tech, finance, academia, and other sectors. We see the catalytic combination of industry expertise with ideas from outside biopharma as a key element of our culture.

We have a unique decentralized model that is intended to better align the incentives of individuals working on development programs, and that model allows for greater flexibility in how we finance R&D. This brings down the total cost of capital. We are also always open to new opportunities. For example, we established a company in China called Sinovant which is focused on partnering with Western biopharma companies to develop innovative medicines in China. In a little over a year of operations, it has already built one of the leading pipelines for late-stage therapies in China.



Roivant's new model

Big Pharma is changing: Old business models no longer work and new players are entering the scene. Where do you see Roivant in this changing environment?

We see ourselves as reinventing what a large pharma company of the future might look like. Instead of a single and centralized organization, we are building the 'Alphabet of Healthcare'; a decentralized family of companies working to improve the process of developing and delivering medicines to patients. Each of those companies in our ecosystem benefits from being a part of that broader family backed by Roivant.

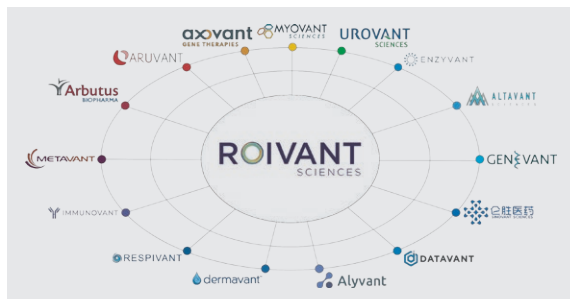
Other companies have adopted similar models, such as BridgeBio which is focused on developing therapies for rare diseases, and we see this as a positive trend. Some large pharma companies have tried to decentralize elements of their operations, but we believe it will prove more difficult to retrofit existing companies instead of starting from scratch.

What will you focus on next? Which therapeutic areas have the potential to become the next members of your Vant family?

Roivant's business model involves building nimble, entrepreneurial biotech and healthcare technology companies with a unique approach to sourcing talent, aligning incentives, and deploying technology to drive greater efficiency in R&D and commercialization.

“We are open to all modalities and therapeutic areas: if we see value for patients, we are interested.”

Our pipeline today includes small molecule pills being developed for the treatment of urological, cardiometabolic, pulmonary, and women's health conditions; topical ointments for inflammatory skin diseases; subcutaneous monoclonal antibodies for autoimmune diseases; gene therapies for neurological and hematological diseases; enzyme replacement and regenerative therapies for ultra-rare diseases; drug-device combinations for respiratory conditions, and potential RNA-based therapeutics.



The Roivant family of companies

That is just a selection of what we are working on today. We see potential near-term opportunities in anti-infectives and oncology, and there is no inherent limit to the number of potential Vants we intend to build so I expect that in time our pipeline will eventually include therapies in most, if not all, therapeutic areas.

New technologies are also entering the world of healthcare. Artificial intelligence and blockchain are currently on everybody's mind. What is your take on that?

They are largely buzzwords when it comes to healthcare today. What is far more important is collecting and joining healthcare datasets between and within institutions. We believe that is the rate-limiting step to unlocking insights which improve human health and that is the thesis of Datavant. Datavant works with data owners and users across the healthcare industry to ensure that health data can be safely and appropriately linked to power analytics and applications, while safeguarding individual patient privacy.

In our view, Switzerland with its impressive talent base and openness to new ideas has positioned itself well to adapt those new technologies.

What would be your advice for growing biotech companies that are expanding to Europe?

We have had a very positive experience and we would strongly encourage them to consider Basel.

“Basel is an ideal location for a growing biotech company and Switzerland is a very welcoming place for business to be conducted.”

In terms of challenges, it may sound mundane but it is very important to have a thorough plan in place to ensure communication across offices in multiple time zones, including investments in videoconferencing technology.

Switzerland Global Enterprise (S-GE) works all over the world to support entrepreneurs and promote Switzerland as a business location. In its role as a center of excellence for internationalization, its mission is to help clients develop new potential for their international business and to strengthen Switzerland as an economic hub. S-GE, with a global network of experience advisers and experts, is a strong and trusted partner for its clients, the cantons and the Swiss government. For more information, visit www.s-ge.com, www.s-ge.com/invest-biotech

Hero and bogeyman: The public face of leadership after an IPO



Christian Fehr
Relationship Manager
Primary Markets, SIX

With an IPO, not only the company but also the leadership team goes public; in particular the Chairman, the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO). Interest in the company and the behavior of the management gains a new dimension in terms of public attention. This is why it is so important to take a close look at corporate governance and related topics regarding public relations and establish guidelines and measures that are conducive to the successful management of a company at an early stage.

Alongside the technical aspects of corporate governance – mechanisms, processes and relations with which companies are managed and controlled – there are a number of specific challenges for the leadership team, particularly when it comes to public companies, which are related to corporate governance but have no precise boundaries. Top managers often become the screen on which a multitude of expectations, both within and outside the company, are projected. How to deal with it? Is it possible to escape from the media and the public? Or should you get involved, fully aware of the fine line between hero and bogeyman?

Due to the increased need for transparency, the leaders of a public company are the focal point for public interest. A certain inviolability, which was considered a given in earlier times, is nowadays critically questioned. Currently, of particular interest to the public and especially the press, are remuneration models and the associated expectations regarding social responsibility. For example, it is very difficult to understand how, when employees are laid off, the bonus-pool allocated to top management can simultaneously increase.

Merging of personal and professional

In the age of social media, information is received and shared much faster and more easily. A good example is the use of twitter to comment and share views on experience. The challenge here is to craft communications so that information is correctly received and understood thereby avoiding a maelstrom of bad press and possibly more serious consequences for the individual or organization. For example, customers no longer write a private letter of complaint to a company but instead make public their dissatisfaction with a product or service on twitter. Complicating the situation further is the fact that such information may be true but could also be fake. Success is all about coping with these communications in an effective and timely manner.

Another challenge is that reporting for professional reasons has widened its remit and now encompasses increased interest

in (and expectations of) the behavior of individuals in a private capacity. The CEO in particular needs to be acutely aware of public expectations regardless of whether these are business-relevant activities or private concerns, or to what extent this may or may not be justified. There is now a clear expectation on people in such positions. A CEO must set an example within his or her company and also in public. A modest appearance and/or social commitment may be recognized in the form of a benevolent public response.



Interview with

Giacomo Di Nepi
CEO
Polyphor

Have the requirements and your own expectations of a leader changed since becoming CEO of a listed company, or during the IPO process itself?

I think that a few things have changed, mainly with regards to the requirements of a listed company, but possibly less than what could be the case for other companies going through a similar process. The fact that we already had more than 500 shareholders before the IPO helped us a lot when it came to having a somewhat smooth transition. For instance, this meant that we were familiar with AGMs (Annual General Meetings), results' teleconferences and business progress updates and the provision of equal and transparent information to all shareholders.

Also, the 'ethics of performance' have not changed: we need to deliver on our targets, provide a collaborative work environment to succeed as a team and push the organization towards ambitious but achievable goals. And, most importantly, we need to deliver innovative new medicines that provide substantial benefit for patients in need as this is the ultimate mission of our company.

What has changed as a public company are the regulatory requirements with which we must comply with. This increases the sensitivity of our corporate communication and has an impact on our investor relations strategy; this must be more explicit and elaborated and requires a proper allocation of management time and attention.

What has changed for you when you evaluate your leadership style before and after the IPO?

This question you had better asked my colleagues... seriously now, I didn't change my leadership style. As I mentioned before, we had already implemented our performance management system and our values as a private company. This of course hasn't changed during the IPO process. The one thing however that I am reminding everyone over and over again is the need to give equal and transparent information to all shareholders and

therefore the need to be very careful in what we say externally. This was true also before but now the need is even greater.

Were you aware of the leadership challenges post IPO, and how did you prepare e.g. trainings, studies?

Most of my professional experience has been in public companies so I already knew what would be awaiting me. My last experience with InterMune, as General Manager Europe, was of particular importance. Europe has been 'the story' for almost three years as Esbriet, our product for idiopathic pulmonary fibrosis was launched in Europe before the US. Europe was the 'beta test' for the expected launch in the US, which happened a few years later. I learned there how to provide factual, equal and transparent information while 'telling the story'. Paraphrasing the motto of a well-known agency, giving 'the truth well told'. What is specific to the biotech sector, including Polyphor, is that we have to deal with small companies in a high-stake business and therefore many more things may be material information. For example, a change in a single research or clinical program would be non-material for a Novartis or a Roche, but it would be very much for us.

This further increases my and our whole organization's responsibility, when it comes to how we deal with information. One week after the IPO we conducted a training with the whole organization, explaining what it means to be a public company. I took this opportunity to provide some practical examples and I'm planning to do a 'second shot' of training this year. It's based

on a principle similar to a vaccination, where you really want to have a full, continuous and extended coverage. As we say in marketing language, 'repetition is the mother of retention!'.

In retrospect, would you do something different and if so, what?

The IPO process is very intense and extremely time-consuming, which can be very challenging for a small organization. It is almost unavoidable that some of the operations and the organization get a bit neglected. Therefore, I think it is very important to plan for a full immersion period after the IPO to make sure all the operations and the organization get the necessary attention and make sure that responsibilities, timelines, and deliverables for each project are clear and properly tackled. In other words... don't think that after the IPO you can get some rest. Wrong assumption!

Do you have any recommendations for CEOs of future listed companies?

Probably the usual recommendations! Make sure that the equity story and the value creation potential is well documented, clear and understandable. Make sure, test it again and again, and adapt where needed. Get a top team, internally as well as externally, to be well prepared for what will come. Learn quickly to manage the different stakeholders involved and be prepared to hold your nerve because until the end, you do not know what will be the real result. But, as we know, biotech is not for the faint of heart, so... we were well trained!

Ad Hoc Publicity

In the context of ad hoc publicity, the obligation to disclose information relates to potentially price-sensitive facts that have arisen in the sphere of activity of a listed company and are not in the public domain. The following parties must be informed as a bare minimum:

- SIX Exchange Regulation,
- two electronic news providers (e.g. Reuters and Bloomberg),
- two major Swiss daily newspapers and
- notification on request (push notification).

Examples of price-sensitive facts are:

- Significant changes in profits, profit collapses and profit warnings
- Mergers and acquisitions
- Restructuring
- Takeover offers
- Staff changes in the board of directors and the executive committee

§ Directive on Ad hoc Publicity:

www.six-exchange-regulation.com/dam/downloads/regulation/admission-manual/directives/06_17-DAH_en.pdf

🗉 The legal basis and further information can be found at the following address:

www.six-exchange-regulation.com/adhoc_publicity

✉ You can send ad hoc notices to us simply and efficiently by e-mail to adhoc@six-group.com

The impact of public statements by management on share prices



Marcus Balogh
Topic Leader Financial Services/Blockchain
Farner Consulting AG

Interviews and other public statements issued by the management of a company can have a significant impact on the share price. That is why there is a comprehensive set of rules in place as to how companies must correctly communicate key information. In Switzerland, these are contained in the 'Directive on Ad hoc Publicity'. These guidelines apply to all types of potentially price-relevant information. They ensure that events that may significantly impact a company's share price are communicated in the same fair and transparent way to all interested stakeholders. And obviously, certain statements made by management can also be directly relevant to the share price.

But this specific instance of management communication, with its well-regulated guidelines, is just one side of the coin. The other relates to the question of what long-term impact public statements – that is to say, those that are not containing immediate price sensitive information – can have on the company's share price. From our perspective, management statements should help achieve a company's strategic objectives in exactly the way as all other communication measures. This means that management communication helps create and maintain a positive (and in an ideal case, mutually inspiring) relationship with various stakeholders, as well as boosting a company's reputation over the long term.

In this respect, management statements should be considered as a strategic tool, which should be used both internally and externally. We fully understand why companies are tempted to focus their resources on purely tactical communication measures at times. But communication departments and management must always bear in mind that the different messages sent

by the various corporate representatives should do more than just coexist nicely. In this regard, obtaining an external expert perspective can often prove critical to success as external consultants with a broad and international experience help avoid the 'tunnel vision' that is so easy to develop when one is deeply embedded in a corporate environment.

Of course, it is possible to send board members to speak in front of stakeholder groups without providing them with a deeper understanding of their role in their corporate communications framework and a set of strategic key messages, trusting them to 'say the right thing'. But given the significant impact that management statements can have on how companies are perceived by the general public and their investor community, we always recommend combining this healthy trust in board members' abilities with a pragmatic communication strategy, customized to the needs of each individual member of management.

SIX

SIX operates and develops infrastructure services in the Securities & Exchanges, Payments and Financial Information business with the aim of raising efficiency, quality and innovative capacity across the entire value chain of the Swiss financial center.

In the Securities & Exchanges business, SIX offers its customers in Switzerland and around the world a comprehensive range of exchange services from listing, trading and post-trade solutions, from a single source. SIX operates one of the most important European stock exchanges. It offers outstanding liquidity in trading of Swiss and foreign securities and connects companies from around the world with international investors and trading participants. As a self-regulated exchange, it is able to provide particularly market-friendly conditions for listing and trading in equities, bonds, ETFs, ETPs, mutual funds and structured products.

www.six-swiss-exchange.com

Swiss Biotech Success Stories demonstrate the power and potential of Swiss biotech

'Swiss Biotech Success Stories' recognizes valuable accomplishments and honors those who have made important and sustainable contributions to the biotech industry in Switzerland. The award is presented each year at the Swiss Biotech Day and reflects the diversity and achievements of this innovative industry.

Switzerland is one of the world's leading biotech hubs and attracts many foreign companies, specialists and investors. It provides over 50,000 jobs and together with the pharmaceutical and chemical industries, makes up more than 40% of Swiss exports.

The Swiss Biotech Success Stories initiative was launched to make the impact of this industry more visible. Selected success stories are showcased to illustrate how Swiss biotech companies help patients, improve health care worldwide, and make a valuable and significant contribution to the Swiss and global economy.

Laureates are individuals or groups who have earned extraordinary merits. Success is broadly defined as scientific, translational, medical or commercial, together with other aspects that have a positive impact on the biotech and life science ecosystem and society in Switzerland and beyond.

12 Success Categories

- ☆ Completed achievement with lasting impact
- ☆ Scientific breakthrough
- ☆ New technology
- ☆ Strong impact on society
- ☆ Product approval and sustainable revenues
- ☆ Important IP, innovative deal-making, acquisition
- ☆ Involvement of one or more Swiss citizens
- ☆ Swiss-based company / institution
- ☆ Creation of jobs in Switzerland
- ☆ Other aspect with a direct link to Switzerland
- ☆ Enabler for the biotech industry
- ☆ Swissness: Think global, made in Switzerland

"It is essential to share with the public the importance and success factors of biotech companies and ensure that decision-makers understand what it takes for the industry to develop and remain competitive," says Michael Altorfer, CEO of the Swiss Biotech Association. "At the same time, young talent should be inspired and motivated to take a closer look at the great variety of career profiles in biotech. As a successful and booming economic sector, the biotech industry depends on many passionate, visionary and well-trained up-and-coming talent."

An independent jury of experts



Luca Bolliger
President of the jury,
Vice president
Swiss Biotech Association,
VP Corporate
Licensing Recordati



Patrick Aebischer
President Emeritus EPFL,
professor, serial entrepreneur



Martine Clozel
Co-founder, CSO
Actelion and Idorsia



Gabrielle Gache
President Swiss Healthcare
Licensing Group,
Head Strategy and BD&L OM Pharma



Ulrich Geilinger
Head of Private Equity
HBM Partners



Robert Lussi
Branch Manager
Mirabaud Basel



Birgit Voigt
Business journalist
NZZ am Sonntag



Jürg Zürcher
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Swiss biotech companies – Biogen, Roche Glycart, Okairos, Selexis and Vifor Fresenius Medical Care Renal Pharma – were honored for their great achievements by an independent jury at the Swiss Biotech Day 2018.



Source: www.biogen-solothurn.ch

Biogen's biologics manufacturing facility in Switzerland

SUCCESS CATEGORIES

- ★ Completed achievement with lasting impact
- ★ Scientific breakthrough
- ★ New technology
- ★ Strong impact on society
- ★ Product approval and sustainable revenues
- ★ Involvement of one or more Swiss citizens
- ★ Swiss-based company / institution
- ★ Creation of jobs in Switzerland
- ★ Enabler for the biotech industry
- ★ Swissness: Think global, made in Switzerland

Founded in Geneva in 1978, Biogen is a true biotech pioneer, bringing innovative therapies to people living with severe neurological diseases all around the world.

Today one of the world's largest biotech company with over 7,000 employees, the breadth of expertise across the company's founders, scientific advisors, and co-workers, as well as its original investors, has helped shape much of the development of the global biotech industry. Notable industry leaders include Nobel Prize laureates, Walter Gilbert and Phil Sharp, as well as Charles Weissmann and André Muller. Each has had a significant impact on the development and success of Biogen.

In 1982, the company moved its headquarters to Boston and in 1983 launched its IPO on the NASDAQ stock exchange. Despite the move, Biogen maintained close Swiss links. In 2003, Biogen merged with Idec Pharmaceuticals and the following year the company returned to Switzerland, establishing its international headquarters in Zug in 2004. In 2006 it acquired Swiss company Fumapharm, having licensed one of its most important products, Tecfidera, a fumaric acid ester used to treat relapsing forms of multiple sclerosis.

Today, Biogen's R&D efforts focus on devastating neurological diseases. The company has a next-generation biologic manufacturing facility under construction in Luterbach. This is forecast to create up to 600 new Swiss jobs and drive unrivalled, innovative scientific research.



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The birth place of GAZYVA

SUCCESS CATEGORIES

- ★ Completed achievement with lasting impact
- ★ New technology
- ★ Product approval and sustainable revenues
- ★ Important IP, innovative deal-making, acquisition
- ★ Involvement of one or more Swiss citizens
- ★ Swiss-based company / institution
- ★ Creation of jobs in Switzerland
- ★ Swissness: Think global, made in Switzerland

Glycart Biotechnology was founded in 2001 as a spin-off from the ETH Zürich. Its founders had big ambitions, but little did they realise just how quickly the business would rise up through the ranks. A successful, independent Swiss biotech company, it was eventually acquired by Roche in July 2005 for CHF 235 million.

The acquisition of Glycart by Roche secured 'big pharma' access to the biotech's innovative proprietary GlycoMAb technology and to its GlycoMAb-enhanced drug candidates, in particular GA101. GlycoMAb is a fully developed platform to modify the carbohydrate component (glyco-engineer) of therapeutic antibodies increasing their biological activity. GA101 (now known as obinutuzumab, GAZYVA, GAZYVARO) is a 3rd generation, humanized and glycoengineered type II CD20 antibody. Since 2005, Roche Glycart has made considerable progress. It first worked with Roche, Genentech and Chugai Pharmaceuticals for the clinical development of GAZYVA, which became in 2013 the first ever drug granted approval by the FDA under the Breakthrough Therapy designation regime.

Now 14 years later, Roche Glycart has grown within the Roche Group increasing its number of employees from 29 to over 180, all based in Schlieren-Zürich, where it has become the Roche Innovation Center Zurich (RICZ), part of the Pharma Research & Early Development (pRED) organization of Roche. RICZ is a Roche center of excellence for cancer immunotherapy and protein engineering R&D, with numerous new drug candidates in clinical development, including Roche's new generation of T-cell bispecific antibodies and targeted immunomodulators.



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Okairos team at the time of spin-off

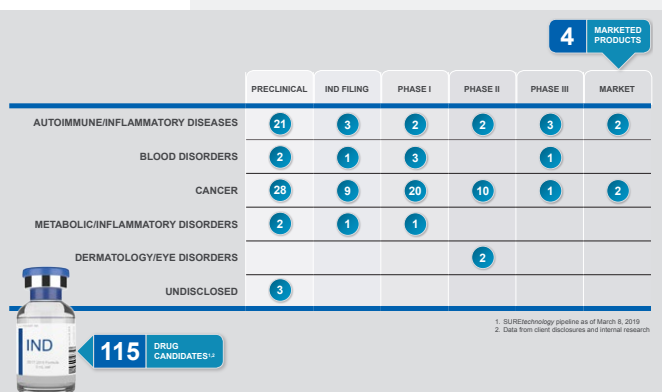
SUCCESS CATEGORIES

- ★ New technology
- ★ Important IP, innovative deal-making, acquisition
- ★ Swiss-based company / institution
- ★ Other aspect with a direct link to Switzerland

Okairos was founded in 2007 as a spin-out from Merck Laboratories' Research Centre in Rome. It was led by Riccardo Cortese and Alfredo Nicosia and co-founding investors, Life Science Partners and BioMedInvest. Early on, the company moved its headquarters to Basel, Switzerland to benefit from the innovation-friendly Swiss environment. This decision was backed by initial investors, represented by Markus Hosang and Joachim Rothe.

The move was crucial to attracting well-connected industry leaders and specialists in the field, such as Thomas Szucs and Bill Burns. It also set the company on an impressive trajectory towards pioneering T-cell based vaccines for major infectious diseases including malaria, as well as cancer. The company made exceptional progress and within two years could demonstrate that a T-cell targeting adenoviral-vector-based vaccine was not only safe in healthy volunteers but also protective in volunteers challenged with an attenuated malaria strain.

In 2010 Okairos gained Versant Ventures and the Boehringer Ingelheim Venture Fund as additional investors. This financing was used to conduct preclinical and clinical studies in difficult-to-treat viral infections, including hepatitis C virus (HCV), respiratory syncytial virus (RSV), influenza and Ebola virus. Three years later in May 2013 – just six years since the inception of Okairos – the company was acquired by GSK for EUR 250 million in cash. In that year, this was the record cash deal for a European Biotech company.



Drug development programs utilizing Selexis' cell lines and technology

SUCCESS CATEGORIES

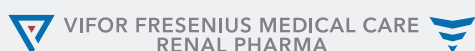
- ★ New technology
- ★ Product approval and sustainable revenues
- ★ Important IP, innovative deal-making, acquisition
- ★ Involvement of one or more Swiss citizens
- ★ Swiss-based company/institution
- ★ Creation of jobs in Switzerland
- ★ Enabler for the biotech industry
- ★ Swissness: Think global, made in Switzerland

Selexis was founded by Igor Fisch PhD and Professor Nicolas Mermod and launched as an academic spin-out from the University of Lausanne. Now based in Geneva, the company is a scientific pioneer and global leader in mammalian cell line generation.

At the time of the company's launch in 2001, average cell line development took more than a year and a half and the cells produced up to 1 gram/liter in a typical bioprocess. The introduction of the Selexis SUREtechnology Platform marked a real paradigm shift in biopharmaceutical drug development. By 2005, Selexis technology had reduced the mammalian cell line development time to just two months and boosted yield five-fold (up to 5 gram/liter).

Selexis, which is backed by Nobel Prize winner Sir Gregory Winter, has been granted more than 150 patents since 2001. More than 1,000 clonal research cell banks have been generated with the SUREtechnology platform in the areas of cancer, autoimmune/inflammatory diseases, blood disorders, metabolic disorders and dermatology/eye disorders.

In 2017, Selexis was acquired by the Japanese company JSR Corp. and integrated into its contract development and manufacturing division. Today the company boasts over 100 partners worldwide, more than 110 biologic drug development programs and four commercial products utilizing its cell lines and technologies. Selexis is a true Swiss success story. It has a history of empowering scientists and biopharmaceutical companies around the world to realise the full potential of their research and to improve the speed to market and economics for biologics and vaccines.



A unique set-up in the industry: with direct access to the world's largest network of dialysis clinics VFMCRP can bring innovative products and services to patients.

SUCCESS CATEGORIES

- ★ Completed achievement with lasting impact
- ★ Product approval and sustainable revenues
- ★ Important IP, innovative deal-making, acquisition
- ★ Involvement of one or more Swiss citizens
- ★ Swiss-based company/institution
- ★ Creation of jobs in Switzerland
- ★ Other aspect with a direct link to Switzerland
- ★ Enabler for the biotech industry
- ★ Swissness: Think global, made in Switzerland

For a long time, biotech companies have merged with pharma organisations to sell products effectively, to engage in global licensing deals, and/or to build in-house sales teams. Today, innovations based on a strategic partnership like the joint company Vifor Fresenius Medical Care Renal Pharma (VFMCRP) provide an attractive and valuable alternative to the traditional approach.

Born when Vifor Pharma, a niche player and global leader in iron therapy, teamed up with Fresenius Medical Care, the world's leading dialysis company, VFMCRP combines Vifor Pharma's expertise in pharmaceuticals with the skills and infrastructure of Fresenius Medical Care. This vertical integration allowed Fresenius to provide Vifor Pharma with a worldwide distribution platform and access to the majority of renal patients. Vifor Pharma used this to run effective clinical trials and develop a powerful sales platform to reach patients with renal diseases. In less than ten years, Vifor Pharma has established itself as a world leader in renal care. The successful market launch of Mircera[®] displaced the existing drugs – Aranesp and Epogen – within less than a year and reached 90% market share after just one-and-a-half years. This process transformed VFMCRP into a trusted partner for big pharma players, such as Pfizer and Roche, which have licensed some of their products to VFMCRP.

This incredible Swiss biotech success story means that patients with chronic kidney disease benefit from comprehensive care, as well as information and access to attractive clinical trials. Vifor Pharma meanwhile accelerates innovation of its renal care product portfolio and further strengthens its competitive advantage.

Year in review:

Selection of events in 2018

January 2018

Collaboration	Addex Therapeutics (ADXN)	Addex and Indivior signed strategic partnership to accelerated development of GABAB PAMs as addiction treatments.
Milestone achievement	Molecular Partners (MOLN)	Molecular Partners' collaboration partner Allergan exercised options for two DARPin® product candidates.
Negative study results	Axovant	Axovant announced negative results for Intepirdine in phase 2b HEADWAY and pilot phase 2 gait and balance studies.
Licensing deal	Basilea Pharmaceutica (BSLN)	Basilea announced completion of the license agreement extension with Pfizer for antifungal Cresemba® for China and Asia Pacific.
Licensing deal	Tillotts Pharma	Tillotts Pharma signed license agreement on antibody technology with Inven2.
Award	Polyphor	Polyphor has been selected by the Access to Medicine Foundation as one of the leading companies in the area of research and development against antimicrobial resistance as published in the 2018 Antimicrobial Resistance Benchmark.
Negative opinion	Santhera Pharmaceuticals (SANN)	Santhera received negative CHMP opinion on appeal for authorization of Raxone® in Duchenne Muscular Dystrophy.
Financing	Auris Medical (EARS)	Auris Medical announced pricing of USD 5.5 million registered direct offering.
Award	T3 Pharma	T3 Pharma selected for second stage of BaseLaunch accelerator program.

February 2018

Market access	Santhera Pharmaceuticals (SANN)	Santhera launches U.S. expanded access program with Idebenone for patients with Duchenne Muscular Dystrophy (DMD).
Financing	BB Pureos Bioventures	BB Pureos Bioventures will be investing in private, innovative drug development companies primarily located in Switzerland, the UK, the EU, Canada and the US.
Capacity expansion	INTEGRA Biosciences	Integra Biosciences will invest CHF 20 million in the next few years and increase its headquarters in Zizers by 150 percent.
Capacity expansion	Lonza (LONN)	Lonza to establish cell- and gene-therapy centers of excellence to accelerate growth.
Licensing deal	Polyphor/Santhera (SANN)	Polyphor entered worldwide exclusive license agreement with Santhera to develop and commercialize POL6014 in cystic fibrosis and other pulmonary diseases.
Milestone achievement	Molecular Partners (MOLN)	Molecular Partners' collaboration partner Allergan exercised the third option for a DARPin® product candidate in ophthalmology.
Financing	Santhera Pharmaceuticals (SANN)	Santhera announced that its share capital recorded in the commercial register was increased from 6,279,857 shares by 247,622 shares to 6,527,479 shares.
Orphan Drug Designation	GeNeuro (GNRO)	Geneuro received Orphan Drug Designation from the US FDA for GNBAC1 in chronic inflammatory demyelinating polyneuropathy (CIDP).
Study initiation	Basilea Pharmaceutica (BSLN)	Basilea reported clinical phase 3 study start with antibiotic ceftobiprole in skin infections under BARDA contract.

March 2018

Market access	Basilea Pharmaceutica (BSLN)	Basilea reported launch of antibiotic Zevtera (ceftobiprole) in Argentina by Grupo Biotoscana.
Capacity expansion	Glenmark Pharmaceutical	Glenmark Pharmaceutical to invest in new translational research group at Biopôle.
Financing	BioMedPartners	BioMedPartners closed their new healthcare venture fund BioMedInvest III at CHF 100 million.
Negative study results	Auris Medical (EARS)	Preliminary top-line data from the TACTT3 trial indicated that the study did not meet its primary efficacy endpoint in the Tinnitus Functional Score.
M&A	Prexton Therapeutics	Lundbeck to buy Prexton for phase 2 Parkinson's drug. Lundbeck is handing over EUR 100 million upfront and committing to up to EUR 805 million in milestones tied to clinical, regulatory and commercial successes.
Financing	Addex Therapeutics (ADXN)	Addex raised CHF 40 million in capital increase.
Financing	Auris Medical (EARS)	Auris regained compliance with Nasdaq's minimum bid price requirement.

April 2018

License application	NovImmune	Novimmune submitted a Biologics License Application to FDA seeking marketing approval for its lead compound, emapalumab (NI-0501), for the treatment of a life threatening disease in children.
Product launch	Basilea Pharmaceutica (BSLN)	Basilea reported launch of antibiotic Zevtera (ceftobiprole) in Canada by Avir Pharma.

Collaboration M&A	Relief Therapeutics (RLF) Baliopharm	Relief Therapeutics announced an in-licensing agreement with Genclis. Promethera Biosciences acquired Baliopharm to strengthen its therapeutic strategy in NASH with a unique TNF-R1 antibody drug candidate.
Capacity expansion	Selexis	Selexis strengthens cell line development services for partners with key strategic hires and investment in state-of-the-art laboratory equipment.
Collaboration	Roivant Sciences	Arbutus and Roivant launched Genevant Sciences with industry-leading platform to develop broad range of RNA therapeutics for genetic diseases.
Milestone achievement	Polyphor	Polyphor successfully completed Wellcome Trust collaboration for development of novel antibiotics against multi-drug resistant Gram-negative pathogens.
Licensing deal	Basilea Pharmaceutica (BSLN)	Basilea licensed late-stage oncology drug candidate derazantinib from ArQule.
Study results	Combinoxin	Positive results from first-in-man trial for the treatment of Pneumonia.
Collaboration	leadXpro/InterAx	New immune oncology drug molecules expected to result from leadxpro/Interax partnership.
Study initiation	Basilea Pharmaceutica (BSLN)	Basilea reported start of clinical phase 3 study in Japan by Asahi Kasei Pharma with antifungal isavuconazole.
Fast Track Designation	Polyphor	FDA grants Fast Track designation for Polyphor's immuno-oncology candidate balixa-fortide in combination with eribulin as third line therapy for metastatic breast cancer.
Development termination	ADC Therapeutics	ADC Therapeutics announced the termination of its ADCT-502 program targeting HER2 expressing solid tumors.
Facility expansion	Biopôle	Retraites Populaires and Biopôle unveil the SE-B building and StartLab, the first incubator dedicated to life sciences located in the Canton of Vaud.
May 2018		
Product approval	Novartis (NOVN)	Kymriah® (tisagenlecleucel), first-in-class CAR-T therapy from Novartis, received second FDA approval to treat appropriate r/r patients with large B-cell lymphoma.
Milestone achievement	Neurimmune/Biogen	Biogen and Neurimmune announced option exercise for the Alzheimer's disease investigational treatment Aducanumab triggering a one-time payment of USD 50 million.
Positive opinion	Auris Medical	Auris Medical received positive scientific advice from EMA on development plan and regulatory pathway for AM-111.
Financing	MEMO Therapeutics	Memo Therapeutics closed Series A2 financing round of CHF 5 million to advance its antibody discovery programs into preclinical and clinical development.
Financing	Polyneuron Pharmaceuticals	Polyneuron completed CHF 3 million seed financing.
IPO	Polyphor (POLN)	Polyphor priced its IPO at CHF 38 per share and lists on SIX.
Product launch	Basilea Pharmaceutica (BSLN)	Basilea reported launch of antibiotic Zevtera (ceftobiprole) in Saudi Arabia by Hikma Pharmaceuticals LLC.
Award	Selexis	Selexis named one of the "Best Companies to Work for in Switzerland 2018".
Joint venture	Biosynth	Joint venture NEMIS Technologies, formed by Biosynth and Ramot at Tel Aviv University develops rapid diagnostic tests for pathogenic bacteria in food safety and clinical applications.
License application	NovImmune	FDA accepted emapalumab Biologics License Application with priority review.
June 2018		
New drug application	Santhera Pharmaceuticals (SANN)	Santhera submitted NDA in South Korea for Raxone® for the treatment of LHON.
Financing	InSphero	InSphero received additional USD 10 million for organ-on-a-chip disease models.
M&A	Sophia Genetics	Sophia Genetics acquired the French-based tech company Interactive Biosoftware (IBS).
Collaboration	NovImmune	TG Therapeutics and Novimmune announced global agreement for development and commercialization of a novel anti-CD47/ anti-CD19 bispecific antibody.
Financing	CUTISS	Personalized skin startup Cutiss raised USD 7 million.
Positive opinion	Santhera Pharmaceuticals (SANN)	UK's MHRA renewed Early Access to Medicines Scheme Scientific Opinion for Santhera's Raxone® (idebenone) in Duchenne Muscular Dystrophy.
Licensing deal	GenKyoTex (GKTX)	Genkyotex expanded license agreement for Vaxicase platform with Serum Institute of India.
Financing	Inthera Biosciences	Inthera Bioscience secured EU 4.7 million in series A financing.
Financing	Roivant Sciences	Roivant announced creation of Roivant Pharma and Roivant Health and launch of Altavant.
Financing	NBE-Therapeutics	NBE-Therapeutics closed a CHF 20 million financing by Novo Holdings A/S.
Positive opinion	Novartis (NOVN)	Novartis received positive CHMP opinion for Kymriah® for treating two aggressive blood cancers, marking important medical advance for patients in Europe.

July 2018		
Collaboration	BC Platforms	BC Platforms and Tieto partnered to integrate genomic and clinical data management to advance precision medicine.
License application	Enzyvant	Enzyvant announced initiation of RVT-802 rolling Biologics License Application Submission for the treatment of complete DiGeorge anomaly.
Licensing deal	Axovant	Axovant announced global licensing agreement for AXO-AAV-OPMD program for treatment of oculopharyngeal muscular dystrophy with Benitec Biopharma.
Collaboration	Genevant Sciences	Biontech and Genevant Sciences sign strategic mRNA-focused partnership in rare diseases.
Financing	Idorsia (IDIA)	Idorsia completed the offering of new shares and the offering of convertible bonds thereby securing long-term funding for the development of its advancing pipeline.
Licensing deal	Dermavant	Roivant subsidiary Dermavant Sciences signs agreement with GSK to purchase rights to tapinarof.
IPO	ObsEva (OBSV)	Obseva started trading on the Swiss Stock Exchange.
Financing	Polyphor (POLN)	Polyphor announced listing of new shares related to the convertible loan facility agreement with the Wellcome Trust.
Financing	AC Immune (ACIU)	AC Immune announced price of USD 11.75 for offerings and issuance of up to 10 million common shares.
Milestone achievement	Basilea Pharmaceutica (BSLN)	Basilea reported receipt of milestone payment based on first Cresemba® approval in Latin America.
Study results	Molecular Partners (MOLN)	Allergan and Molecular Partners announced two positive phase 3 clinical trials for Abicipar pegol 8 and 12-week regimens for the treatment in patients with neovascular age-related macular degeneration.
Licensing deal	NovImmune	Sobi™ strengthened inflammation franchise by acquiring global rights for emapalumab from Novimmune.
Orphan Drug Designation	Asceneuron	Asceneuron's tau modifier received Orphan Drug Designation.
Financing	AC Immune (ACIU)	AC Immune announced successful closing of second subscription rights offering.
August 2018		
Award	Sophia Genetics	Sophia Genetics is Top Global Innovator of the Year.
Financing	Relief Therapeutics (RLF)	Relief Therapeutics announced a formal commitment by GEM Global Yield Fund LLC SCS to amend and prolong the Share Subscription Facility (SSF) currently in effect.
Collaboration	Glenmark Pharmaceutical	Harbour BioMed and Glenmark signed agreement to develop GBR 1302, a first-in-class bispecific antibody for treatment of HER2-positive cancers.
Financing	Therachon	Therachon completed a USD 60 million mezzanine financing led by Novo Holdings.
Study initiation	Basilea Pharmaceutica (BSLN)	Basilea started clinical phase 3 study with antibiotic ceftobiprole in Staphylococcus aureus bacteremia (SAB).
Product approval	Basilea Pharmaceutica (BSLN)	Basilea reported on first Cresemba® approval in MENA region.
Financing	GenKyoTex (GKTX)	Genkyotex secured an up to EU 7.5 million gross financing to further expand the development of its lead product.
MAA	NovImmune	Novimmune submitted Marketing Authorisation Application in Europe for its lead drug emapalumab.
Financing	ProteoMediX	Proteomedix raised CHF 5.2 million in financing round.
Financing	Lunaphore	Lunaphore closed a CHF 5.3 million Series B financing round.
September 2018		
Collaboration	Gene Predictis/ Synlab Suisse	Gene Predictis and Synlab Suisse announced strategic partnership to market genetic tests.
Financing	Polyphor (POLN)	Novo Holdings invested CHF 6.8 million in Polyphor to accelerate the development of novel antibiotics against multi-drug resistant Gram-negative pathogens.
Financing	Creoptix	CREOPTIX attracted Waters as corporate investor.
Financing	AMAL Therapeutics	Amal Therapeutics finalized EU 8 million (CHF 8.3 million) Series B round.
Financing	CRISPR Therapeutics (CRSP)	Crispr raised USD 200 million in a public follow-on offering
Licensing deal	Relief Therapeutics (RLF)	Relief Therapeutics announced an out-licensing agreement with H&H Group.
Divestment	GeNeuro (GNRO)	Geneuro regained worldwide rights ex US and Japan to GNBAC1 in multiple sclerosis from Servier.
Milestone achievement	Neurimmune	Neurimmune achieved milestone in collaboration with Ono Pharmaceutical.
Research grant	Addex Therapeutics (ADXN)	Addex received UKE 1.2 million funding for Human Drug and Brain Research from Wellcome Trust.

Facility expansion	Sophia Genetics	Sophia Genetics opened operations in Boston to meet the burgeoning demand across the United States.
Financing	TOLREMO Therapeutics	Tolremo Therapeutics completed an oversubscribed series A financing round of CHF 9.0 million.
Product development	Virometix	Virometix presented new generation of fully synthetic vaccines and immunotherapeutic drugs.
October 2018		
Study initiation	MaxiVAX	Maxivax's cancer immunotherapy entered phase 2 clinical trials.
M&A	Therachon	Therachon acquired Glypharma Therapeutic Inc. adding apraglutide to its portfolio. The transaction came on the heels of a USD 60 million mezzanine financing led by Novo Holdings.
Product development	CRISPR Therapeutics (CRSP)	Crispr and Vertex announced FDA lifted the clinical hold on the investigational New Drug Application for CTX001 for the treatment of sickle cell disease.
Positive opinion	Santhera Pharmaceuticals (SANN)	Santhera received positive opinion for Orphan Drug Designation in the EU for POL6014 in Cystic Fibrosis.
Patient enrollment	Myovant Sciences	Myovant Sciences announced completion of enrollment in phase 3 HERO trial of Relugolix in men with advanced prostate cancer.
M&A	Lonza (LONN)	Lonza acquired a controlling stake in Octane Biotech to further develop Cocoon™ autologous technology.
Study initiation	Inositec	Inositec to launch clinical studies for its drug against kidney-related issue.
November 2018		
Award	SunRegen Healthcare	BIO-Europe Copenhagen's Startup Slam Winner 2018: Sunregen Healthcare
Award	T3 Pharma	T3 Pharma won prestigious Falling Walls Venture Award for its bacterial cancer therapy.
Financing	AMAL Therapeutics	Amal Therapeutics finalized EU 29 million (CHF 33.2 million) Series B round.
Financing	Roivant Sciences	Roivant Sciences announced USD 200 million investment round.
Award	AC Immune (ACIU)	AC Immune awarded 3rd follow-up grant from The Michael J. Fox Foundation for first-in-human study of a Positron Emission Tomography (PET) Tracer for PD.
Research grant	BioVersys	Eurostars Funds IMPACT2 to establish a break-through translational AMR platform.
Patent expansion	MetrioPharm	MetrioPharm expanded patent protection for its lead compound to Canada.
Licensing deal	Roivant Sciences	Roivant Sciences and Intron Bio signed licensing deal for novel anti-superbugs biologic SAL200.
Licensing deal	Santhera Pharmaceuticals (SANN)	Santhera entered into agreement to acquire option from Idorsia for exclusive sub-license of first-in-class dissociative steroid Vamorolon.
Product approval	NovImmune	FDA approved Gamifant® (emapalumab), the first and only treatment for primary haemophagocytic lymphohistiocytosis (HLH).
Award	Polyphor (POLN)	Polyphor won the most important technology prize for innovation and technology transfer in Switzerland in the category "Innovation Leader".
Award	Lunaphore	Lunaphore won the most important technology prize for innovation and technology transfer in Switzerland in the category "startup".
December 2018		
Orphan Drug Designation	Therachon	The European Commission has granted Therachon an Orphan Drug Designation for apraglutide for the treatment of short bowel syndrome (SBS).
Orphan Drug Designation	Auris Medical (EARS)	Auris Medical announced acquisition of Orphan Drug Designation and secures rights to in-license additional patents related to betahistine.
Milestone achievement	Basilea Pharmaceutica (BSLN)	Continued strong Cresamba® (isavuconazole) U.S. sales performance triggers CHF 10 million milestone payment to Basilea.
Collaboration	AC Immune (ACIU)	AC Immune and Lilly announced license and collaboration agreement.
Financing	MetrioPharm	MetrioPharm closed financing round of CHF 20 million.
Licensing deal	Axovant	Axovant licensed investigational gene therapies for GM1 gangliosidosis, Tay-Sachs and Sandhoff Diseases from University of Massachusetts Medical School.
Proof of concept	Anergis	Mymetix and Anergis announced successful pre-clinical proof-of-concept study for birch pollen allergy.
Financing	Santhera Pharmaceuticals (SANN)	Santhera raised gross proceeds of CHF 23.5 million and secured acquisition of option to Vamorolone sub-license.
Financing	Cellestia Biotech	Cellestia raised CHF 20 million in Series A financing round.

Disclaimer: This information was selected and compiled on the basis of publicly available information only. We therefore cannot guarantee that all events are included in the above summary for 2018.

Swiss biotech in 2018:

Facts & figures



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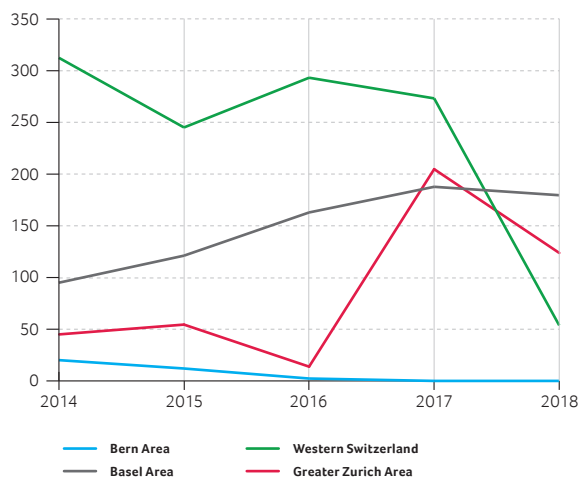
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In 2018, there were no mega deals to compare with the Actelion takeover by Johnson and Johnson in the year before, but the industry still delivered some extraordinary results. Globally the biotech industry got a lot of attention from investors and other life sciences companies. They were on the lookout for new, innovative drugs to address the still unmet demand for certain disease areas. This was to optimize their portfolios as well as react to the increasing influence of the digitization.

The IPO class of 2018 was playing in a league of its own with a total of 77 IPOs (2017: 58) which generated more than USD 7.2 billion in new capital. Some 58 US IPOs were able to harvest fresh money to the tune of approximately USD 6.3 billion (2017: 30 US IPOs with USD 2.8 billion). There were 19 European IPOs which generated USD 1.2 billion (2017: 28 European IPOs with USD 1.1 billion).

Swiss biotech landscape

The Swiss biotech industry generated revenues of CHF 4.0 billion, compared to CHF 3.8 billion in 2017. This result represents another milestone for the sector. Furthermore, the continuing R&D spending is a promise for future growth.



Distribution of private capital investments in the different Swiss regions (in CHF million)

Swiss biotech financing

Financing reported another good year, coming in just somewhat below the record year 2017 with a total CHF 1.62 billion in fresh money for the industry. However, 2018 was clearly a year that favored public financing (approx. CHF 1.26 billion), led by Idorsia with CHF 550 million in debt and equity financing, followed by CRISPR Therapeutics with two equity rounds totaling more than CHF 300 million of new capital.

Other public companies which were successfully using the 'cheap money' available were AC Immune with a follow-on financing in summer 2018 of almost CHF 120 million. And let us not forget the successful IPO of Polyphor from Allschwil in May 2018 at SIX. This IPO (harvesting CHF 155 million) was among the most successful European IPOs in the past year. Also, in summer 2018, Geneva-based ObsEva did another primary listing of its shares. This time at the Swiss Stock Exchange.

During Q1/2018, Bellevue Asset Management launched a new venture capital fund for qualified investors, called BB Pureos Bioventures, to seek capital to invest in young, innovative drug development companies in Switzerland and abroad. We will certainly hear more about this new financing vehicle in the future.

M&A and collaborations

It was not just on the financing front that the Swiss biotech sector recorded many successful events. In the area of collaborations, several successful new cooperations came into being in 2018. Among those were:

- Molecular Partners with Amgen to collaborate on immunoncology and with AstraZeneca to collaborate in ongoing oncology clinical study with MP0250 in EGFR-mutated NSCLC.



Distribution of public capital investments in the different Swiss regions (in CHF million)

- AC Immune with Wuxi Pharma to establish a strategic partnership and with Eli Lilly for a license and collaboration agreement
- Santhera Pharmaceuticals in-licensing from Polyphor in February 2018 and again from Idorsia in December 2018 to diversify the risk after the non-approval by EMA back in January 2018 in the re-filing for Raxone.
- CRISPR Therapeutics with ViaCyte to develop gene-edited stem cell-derived therapy for diabetes.
- Selexis announced various new deals with Hoba Therapeutics, Symphogen and Teneobio.
- Biogen and Neurimmune announced option exercise for the Alzheimer's disease investigational treatment Aducanumab.

On the M&A front, Geneva-based Prexton Therapeutics was acquired by Danish Lundbeck for an upfront payment of EUR 100 million and commitments of up to EUR 805 million. Sophia Genetics from Geneva was also active at the M&A front, by acquiring the French company IBS. Basel-based Therachon acquired at the end of Q3/2018 the Canadian biotech company GLyPharma, boosting its drug portfolio overnight into a phase II/III clinical development program. Shortly before Christmas 2018, their drug apraglutide got FDA orphan drug designation. Balio-pharm, a Basel-based biotech, was acquired by Promethera Biosciences thereby strengthening its therapeutic strategy.

Product development

The global industry saw record approvals by the FDA (59 compared to 46 in 2017) and a slight reduction in European approvals by EMA (84 compared to 92 in 2017). Swissmedic itself approved 31 innovative new drugs in 2018, one less than 2017.

NovImmune, through its collaboration partner SoBi from Sweden, got its drug Gamifani® (emapalumab) approved by the FDA in November 2018.

Furthermore, ObsEva launched several phase III trials of its lead compound (Nolasiban) and was already able to report some positive results.

Within their collaboration Allergan launched the redefined phase III trial of Abicipar from Molecular Partners. Idorsia progressed some of its clinical candidates further in the development and now has a portfolio of four phase III drugs.

Nevertheless, there were also some setbacks to be noted during 2018. As already mentioned, Santhera Pharmaceuticals didn't get the EMA approval for Raxone in the re-filing. Auris Medical reported negative phase III results for the TACTT 3 trial which caused additional pressure on the share price and market capitalization.

Several Swiss biotech companies received awards in 2018:

- Sophia Genetics was named the 'Top Global Innovator of the Year'.
- Polyphor won the Swiss Technology Award in the 'Innovation Leader' category.
- Lunaphore won the Swiss Technology Award in the 'Startup' category.
- T3 Pharma won the 'Falling Walls Venture Award'.
- SunRegen Healthcare was the 'Startup Slam Winner' at BIO-Europe 2018.

All of these awards are a clear indication of the strength of the Swiss biotech sector and reflect the progress made over the last few years.

About the global EY organization

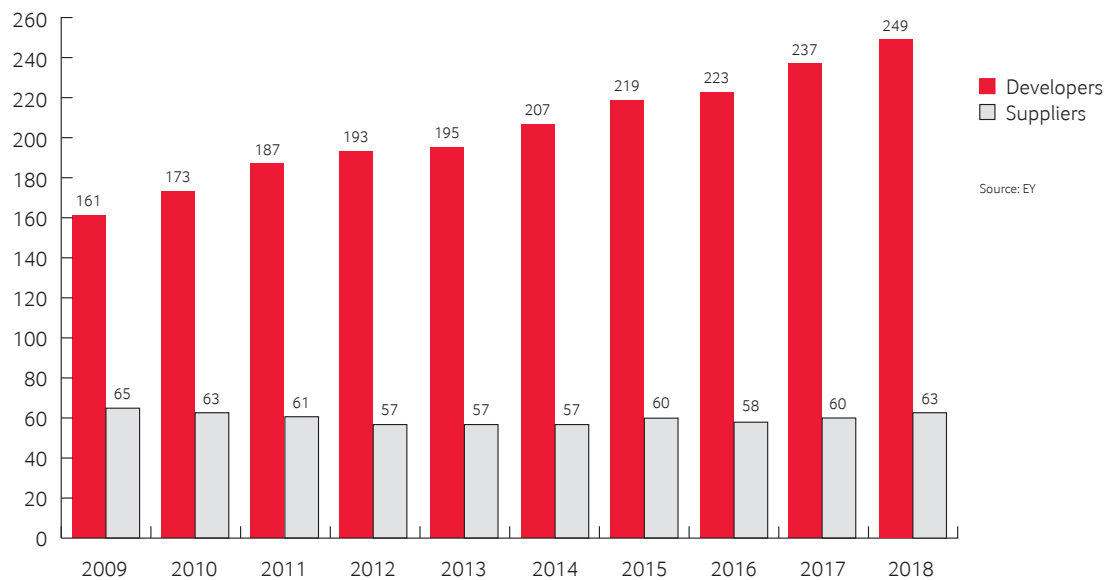
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About EY's Global Life Sciences Center

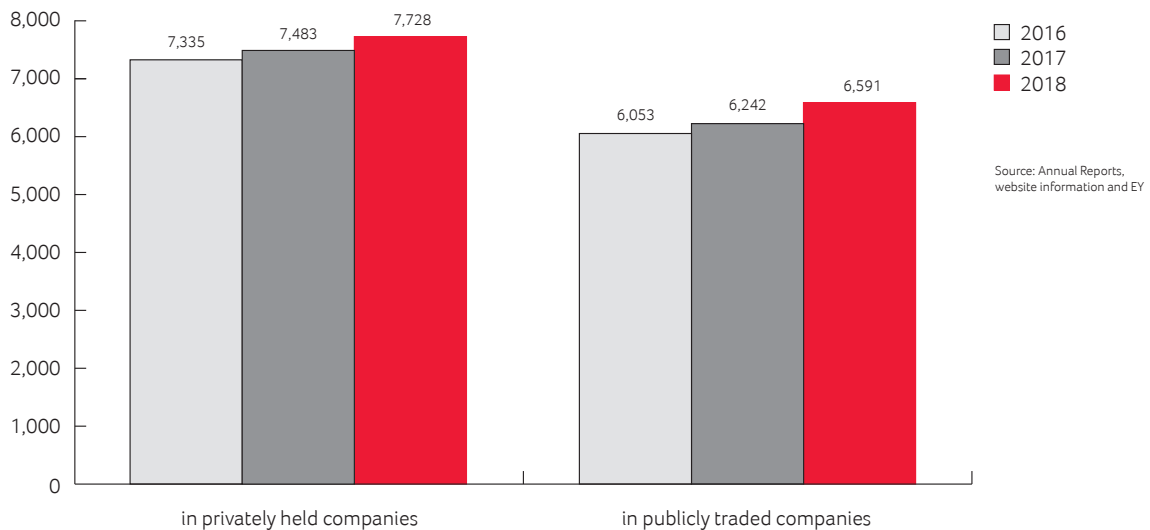
Life sciences companies – from emerging start-ups to multinational enterprises – face new challenges in a rapidly changing health care ecosystem. Payers and regulators are increasing scrutiny and accelerating the transition to value and outcomes. Big data and patient-empowering technologies are driving new approaches and enabling transparency and consumerism. These trends challenge every aspect of the life sciences business model, from R&D to marketing. EY's Global Life Sciences Sector brings together more than 7,000 sector-focused assurance, tax, transaction and advisory professionals to anticipate trends, identify implications and develop points of view on responding to critical issues. For more timely insights on the key business issues visit ey.com/lifesciences.

Facts & figures

Number of biotech companies in Switzerland



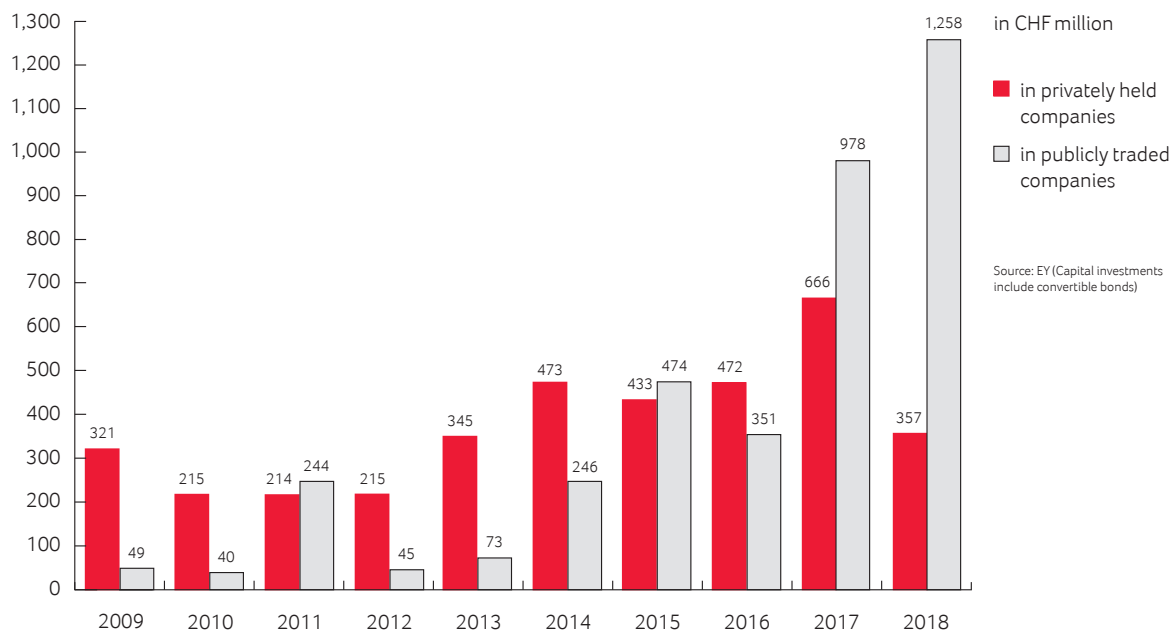
Number of employees



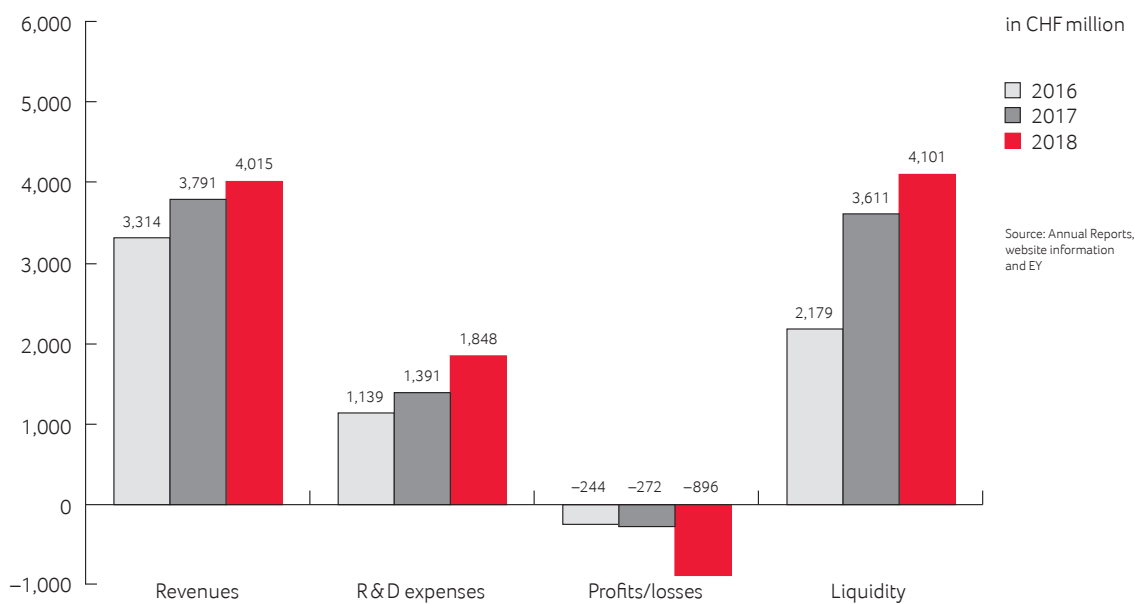
Notes

- The 2018 data in this table is based on information that was available up until March 2019 when this report was compiled. At this time, some of the companies had not yet disclosed their final financial figures for 2018. Therefore, some figures were carefully extrapolated on the basis of the latest interim data publicly available (e.g. Q3 2018).
- Selected financial figures for biotech activities of Lonza's business segment 'Pharma & Biotech Market Segment', which has been established as part of the reorganization at Lonza, are included for 2018. For the previous periods presented, Lonza's 'Bioscience' and 'Biological Manufacturing' are included based on actual figures publicly available or careful estimates. Lonza's 'Pharma & Biotech Market Segment' respectively 'Bioscience and Biological Manufacturing business sectors' are presented due to Lonza's transformation into a life sciences company and its inclusion into the ICB Biotech Sector and the SXI LIFE SCIENCES® and SXI Bio+Medtech® indices at the Swiss Stock Exchange.

Capital investment in Swiss biotech companies



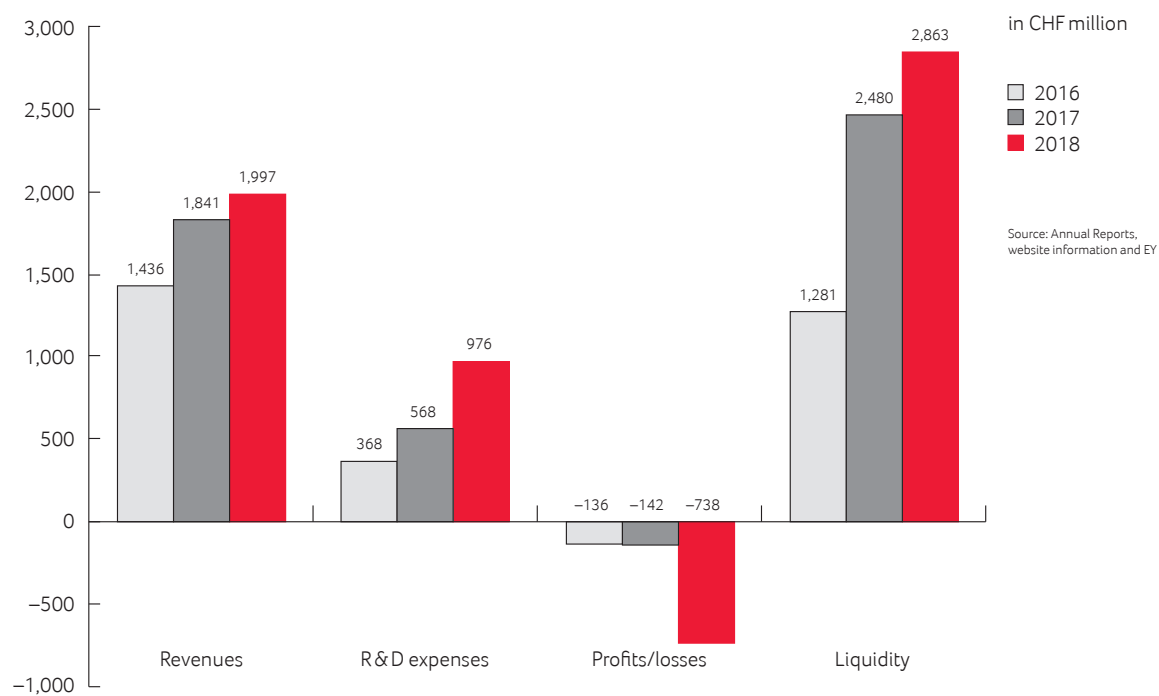
Total Swiss biotech companies



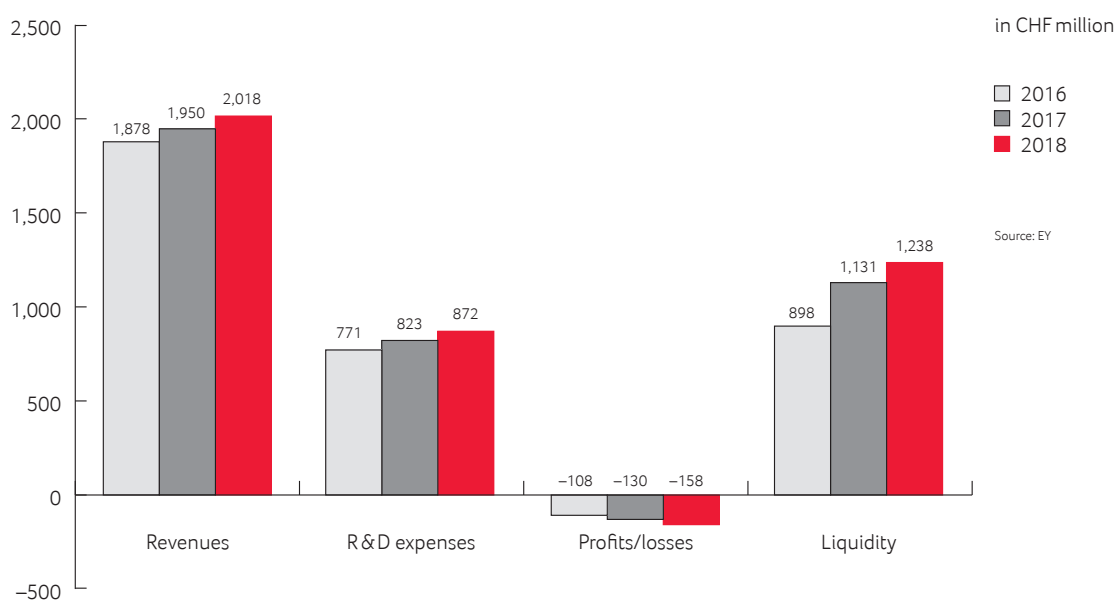
– As some privately held companies do not disclose financial figures, the figures above represent EY's best estimate.

– All figures are headquarter-counted and do not include data from pharma companies such as Novartis and Roche.

Publicly traded Swiss biotech companies



Privately held Swiss biotech companies



Impressum

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