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Swiss Biotech Report 2024

Reliable partners beyond borders

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Reliable partners beyond borders

"In 2023, the Swiss biotech industry saw a record of CHF 7.3 billion in revenues recognized and was able to raise more than CHF 2 billion in capital investments - an increase of over 50% from 2022."

Frederik Schmachtenberg
EY Life Sciences

"The life sciences sector in Switzerland is four times as large as it was 25 years ago. Its innovative strength, diversified product portfolio and excellent international network provide financial stability at home and benefit our global partners abroad."

Jan Lucht
scienceindustries

"Swiss companies are spearheading international collaborations to make personalized healthcare a reality. Dynamic pursuit of alliances extends from research organizations to regulatory authorities."

Michael Altorfer
Swiss Biotech Association

"To address stakeholder demands, Switzerland has introduced reporting obligations on non-financial matters including sustainability. SIX Swiss Exchange can help its listed companies disclose the newly required information and improve transparency."

Fabian Gerber
SIX Swiss Exchange

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State Secretary
Helene Budliger Artieda
State Secretariat for
Economic Affairs
SECO

"The new agreement between Switzerland and the US on mutual recognition of GMP inspections will benefit life sciences companies in both countries."

Biotech sector as a reflection of Switzerland: locally grounded, globally connected

Of Switzerland's many strengths, one in particular stands out in times of multiple global crises: as a bastion of reliability, our country offers stability and predictability. This allows companies from small startups to major international players to focus on their core business, further develop their products and services, and pioneer ground-breaking innovations. The resulting ecosystems are mutually beneficial, often across sectors and borders. Switzerland's vibrant biotech industry with its close network of specialized companies, suppliers and research institutions is a prime example of this.

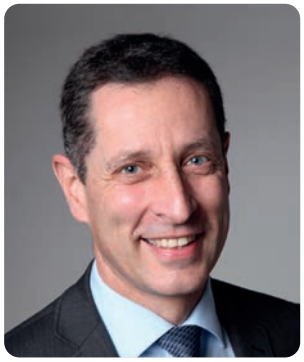
In the Federal Administration, we rely on local ecosystems to provide the Swiss economy with the best possible, needs-based support for businesses. As 'Team Switzerland' we want to open up additional business potential for companies and create added value through partnership-based cooperation between federal agencies, funding instruments and associations. We also work hard to develop international relations, foster joint initiatives and collaborations, and deliver an effective global healthcare system.

Our country is a reliable and competent partner beyond borders. This is particularly true in the life sciences sector, where cross-border cooperation is crucial for developing innovative products and technologies, as health crises such as COVID clearly demonstrate. The foreign trade policy framework is therefore of vital importance, and we continue to update and expand multilateral and bilateral trade agreements.

In July 2023, for example, the agreement between Switzerland and the US on the mutual recognition of inspections in relation to good manufacturing practice for medicinal products came into force. The agreement facilitates the trade in medicinal products between the two countries and reduces the administrative and financial burden for the life sciences industry. Switzerland is also committed to the reliable protection of intellectual property rights and their effective enforcement at international level, which is of crucial importance for sectors such as biotech with a high degree of research and development.

A rules-based system with international rights and obligations creates legal certainty, predictability and stability. This ensures that Switzerland remains an attractive location for value-added companies, which make a significant contribution to prosperity and employment. Even though there is a trend towards countries developing official industrial policies, based on strategic efforts to encourage economic growth, Switzerland continues to focus on ensuring the best possible framework conditions for companies that are based here. That way the economy can continue to write its own success stories – as the innovative and competitive biotech sector demonstrates.

Editorial Swiss Biotech Report 2024



Michael Altorfer
Chief Executive Officer,
Swiss Biotech Association

Reliable partners form the bedrock of international alliances and supply chains. Such alliances are particularly valuable and vulnerable at times of global crisis, as experienced during the COVID pandemic. Together with Switzerland's leading universities, hospitals, global CDMOs, and multinational pharma companies, Swiss biotech companies have established a vast network of international collaboration partners.

The World Intellectual Property Organization (WIPO) has placed Switzerland top of the Global Innovation Index for the past 13 consecutive years. Such innovation power is particularly valuable in the life sciences industry as it enables the development of effective new products and solutions which not only benefit one country but help to address global medical needs and advance the entire global healthcare system. Similarly, industrial biotech applications can address global challenges to provide more sustainable solutions which reduce the consumption of energy and natural resources.

Switzerland is also collaborating in regulatory alliances to streamline, facilitate and accelerate market access for innovative products. In just a few years, Swissmedic and its regulatory partners in the Access Consortium (see Swissmedic article, page 30), namely the UK, Canada, Australia and Singapore, have managed to combine their knowledge, resources and expertise to accelerate the approval of new drugs and streamline the regulatory framework for their combined markets in a way none of these countries could have done on their own. Such alliances must be based on trust, and on shared values and purpose, which help develop a mutually beneficial framework.

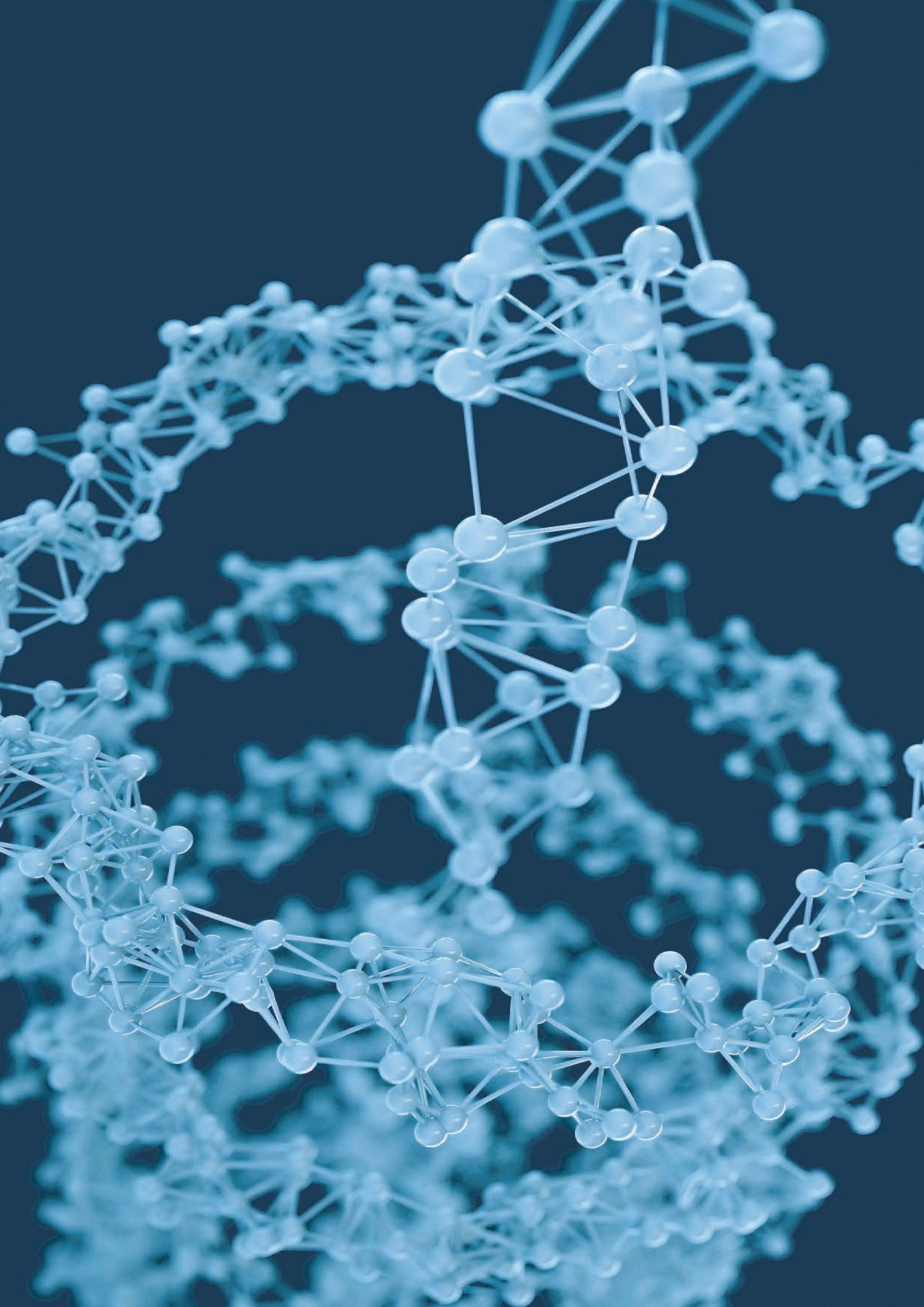
"With its R&D and manufacturing capacity far exceeding its own needs, Switzerland has established itself as a trusted partner in bilateral and multilateral alliances."

Ever since the vulnerability of some supply chains and alliances became evident during the COVID pandemic, a number of countries concluded that rather than collaborating, it is safer to rebuild capacity within their own borders. This led to more "protectionist" approaches, often financed with taxpayer funds and embedded in a strategic industrial policy approach. Such approaches may be functional for very large countries and alliances, but they often hamper international collaboration and distort global free markets.

In times of serious healthcare challenges each country will prioritize its own people; given its small population of only 9 million, Switzerland could be one of the first countries to offer its knowhow and resources to support other countries and engage in international alliances to develop effective global solutions. Experience has shown that connecting the smartest brains and most skilled specialists has led to significant innovative steps and world-class patents (see IPI article, page 18). Switzerland is interested in collaborating with all partners and emphasizes the importance of strong IP protection and free trade.

As outlined in the "Facts and figures" section (see page 8), Swiss biotech companies continue to attract capital investments of more than CHF 2 billion/year and invest close to CHF 2.5 billion in their R&D projects. On average, the companies spend about two thirds of these investments on external collaborations. This in turn means that last year Swiss biotech companies dedicated about CHF 1.6 billion to collaborations all over the world.

On behalf of all the partners of the Swiss Biotech Report 2024, I invite you to dive into the articles in this year's report that address the main topic of "Reliable partners beyond borders" from their different perspectives. They highlight how Switzerland is contributing to international alliances and innovation which serves a global purpose (see IPI article, page 18). This includes the power of facilitating a multicultural talent pool (SNSF, page 16, S-GE, page 44, and SBA, page 36), how stock exchanges can help listed companies realize the potential benefits of becoming more sustainable (SIX, page 40), and the power of biotechnology in developing sustainable solutions way beyond the field of drug development (scienceindustries, page 34, Biotechnet, page 22, and SATW, page 26).



Swiss biotech 2023: Facts & figures

Frederik Schmachtenberg

EY | Partner, Global Health Sciences & Wellness Lead for Financial Accounting Advisory Services

Helena Rosa

EY | Senior Manager, Global Health Sciences & Wellness, Audit Services

In 2023, the Swiss biotech industry saw a record of CHF 7.3 billion in revenues recognized and was able to raise more than CHF 2 billion in capital investments - an increase of over 50% from 2022.

During the course of 2023, the global biotech sector continued to suffer from developments that occurred over the past few years and some companies were even forced to stop operations. Especially in the United States, looking back, it became clear that several of the companies that went public through recent SPAC transactions were taken public too early in terms of their development stage.

In terms of biotech IPOs, the picture is mixed, with overall fewer IPOs happening, but this reduced count of IPOs raised more funds than in 2022. This is true both globally, where the IPO class of 2023 counted 18 IPOs (2022: 22) generating approximately USD 2.9 billion in funds (2022: USD 1.5 billion), as well as in the US with 16 IPOs (2022: 17) collecting a total of USD 2.6 billion (2022: USD 1.3 billion). The same is true for Europe, with only two biotech IPOs (2022: 5), raising USD 338 million (2022: USD 0.2 billion). Switzerland can be proud to have contributed one of these two European IPOs, as further detailed below.

Swiss biotech landscape

In 2023, the Swiss biotech industry saw new records in terms of revenues recognized (CHF 7.3 billion in 2023 compared to CHF 6.8 billion in 2022), whereas R&D investments slightly decreased (CHF 2.4 billion in 2023 compared to CHF 2.7 billion in 2022). Despite a slight decrease in R&D expenses, the number of FTEs working in Swiss R&D biotech companies remained almost unchanged in 2023 compared to 2022, which seems to indicate that, even when some companies have to restructure or reorganize, the highly qualified employees often find new opportunities with other companies in the sector.

Swiss biotech financing

Despite the above-mentioned challenges, the Swiss biotech industry was able to raise more than CHF 2 billion in 2023 (2022: CHF 1.3 billion), an increase by more than 50% in capital investments compared to 2022, with around CHF 1.4 billion collected by public companies and the remaining CHF 0.6 billion collected by private companies. Noema Pharma with CHF 103 million raised, and Alentis Therapeutics with CHF 94 million raised, were the two largest private company financing transactions in 2023.

PUBLIC COMPANIES	CHF MILLION
MoonLake Immunotherapeutics	415
Lonza	150
Oculis	134
Bachem	108
Idorsia	75
Total	**882**

Table 1: Major 2023 public financing transactions

PRIVATE COMPANIES	CHF MILLION
Noema Pharma	103
Alentis Therapeutics	94
Rejuveron	67
Nouscom	65
NewBiologix	45
Total	**374**

Table 2: Major 2023 private financing transactions

The only Swiss biotech company that went public in 2023 was Oculis, with a SPAC transaction on NASDAQ, which was initially started in late 2022 and successfully completed in March 2023, collecting gross proceeds of USD 104 million, plus a follow-on financing with another USD 40 million raised in May 2023.

Further, MoonLake Immunotherapeutics, one of the two Swiss biotech companies that went public in 2022, due to some positive clinical results in 2023, was able to gain additional funds from investors through a follow-on transaction as well as from a market-share program (totaling approximately CHF 415 million).

However, 2023 was also a difficult year for several companies, which led to the fact that some restructuring measures had to be initiated or, even worse, the going concern assumption was in question due to setbacks in clinical studies or insufficient funding. Selling of valuable assets (Evolva, Spexis), entering a reverse-merger transaction (Kinarus), or even taking the decision to stop operations (ObsEva) were some of the unfortunate implications.

In summary, while total capital investments in 2023 increased by more than 50% compared to 2022, it was not a high count of companies that benefited or, in other words, many companies unfortunately received very little or no funding. This is also evidenced by the fact that the average financing of the Top 5 financing transactions in 2023 increased by 42% for public biotech companies and by 44% for private biotech companies, compared to 2022.

In addition, or one could say as a result, with equity and debt markets still being more difficult to access for many companies, Swiss biotech companies continued to be agile in terms of finding alternative ways of financing (licensing, collaborations, but also monetization of assets transactions) which, in a similar way to 2022, provided non-dilutive financing also in 2023.

M&A and collaborations

Swiss companies were involved in several significant M&A transactions:

- Bruker acquired a majority stake in Biognosys
- Siegfried acquired a 95% stake in DiNAMIQS (subsidiary of Dinaqor) as a best-in-class development and manufacturing platform for cell and gene therapies
- Ironwood Pharma took over VectivBio for more than USD 1 billion
- Abiogen Pharma acquired 97.09% stake in EffRx Pharmaceuticals
- Idorsia sold its Asia Pacific (ex-China) operations to Sosei Heptares for a total consideration of CHF 400 million
- Pierre Fabre Laboratories purchased Vertical Bio and its innovative targeted therapy candidate for patients suffering from non-small cell lung cancer with MET alteration

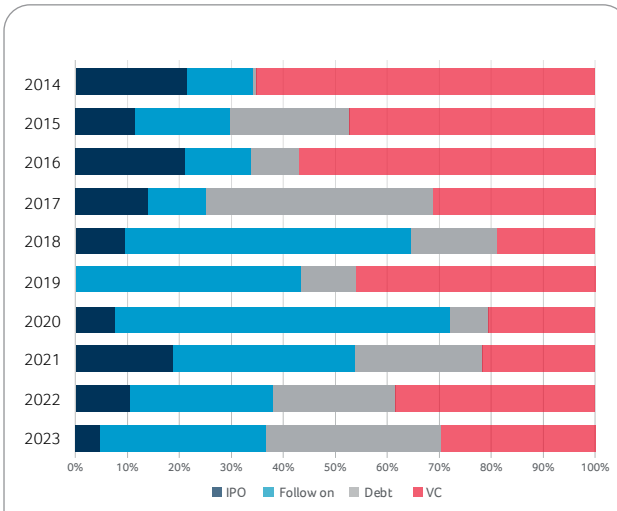


Figure 1: Biotech financing categories in Switzerland 2014 to 2023

- Boehringer Ingelheim acquired T3 Pharma for an amount of up to CHF 450 million
- Evolva and Lallemand closed the sale of Evolva AG to Danstar Ferment AG

At the same time, entering into new collaboration and licensing agreements was important for several Swiss biotech companies as some of those partnerships contained significant attractive financial components, which – as mentioned above – provided alternative ways of funding (alternatives to equity or debt financings, which continued to be more difficult to obtain in 2023). A selection of such collaboration and licensing transactions is shown below:

- EraCal and Nestle Health Science entered collaboration to develop new anti-obesity treatments
- STALICLA partnered with US National Institute on Drug Abuse for Phase III development of anti-cocaine drug mavoglurant
- CRISPR Therapeutics closed licensing deal with Vertex worth up to USD 330 million for hypoimmune cell therapy development
- Santhera closed exclusive North American license agreement with Catalyst Pharmaceuticals for vamorolone worth up to USD 231 million plus royalties
- Relief Therapeutics announced USD 46.5 million license agreement for OLPRUVA™ (ACER-001) for urea cycle disorders with Acer Therapeutics

Swiss biotech 2023: Facts & figures

CONTINUED

Product developments

In 2023, the industry saw a similarly high number of regulatory approvals compared to prior years, which is positive. More specifically, the EMA approved 77 new drugs in 2023 (2022: 89 new drugs) and the FDA approved 55 new drugs (compared to 37 in 2022).

Furthermore, among the new FDA approvals there were two new drugs developed by Swiss companies. Santhera Pharmaceuticals received approval for AGAMREE® (vamorolone) for the Treatment of Duchenne Muscular Dystrophy (DMD). Further, the FDA approved the CRISPR/Cas9 gene-edited treatment, co-developed by CRISPR Therapeutics and Vertex Pharmaceuticals, in sickle cell disease. Both drugs were afterwards also approved by European authorities.

The level of approvals by Swissmedic was slightly above prior year with a total of 49 new drugs (2022: 47).

Awards

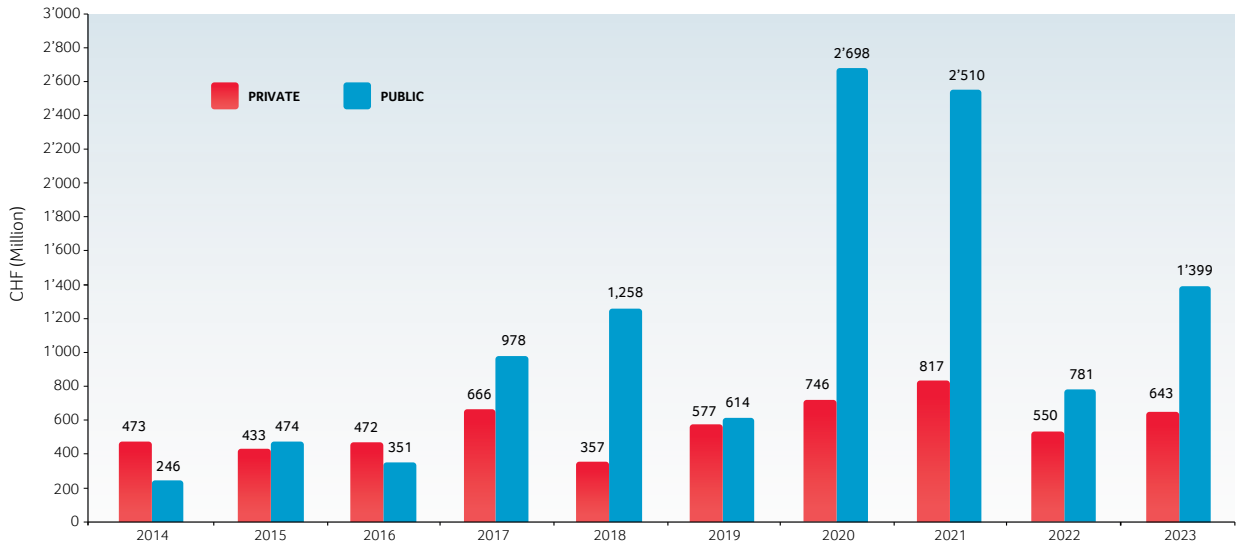
Several Swiss biotech companies also received various prestigious awards throughout 2023. Some of these awards included:

- 2023 Swiss Digital Innovation of the Year award for Tigen SA
- Luca Santarelli, CEO of VectivBio until June 2023 when VectivBio was acquired by Ironwood Pharma, received Entrepreneur of the Year (EoY) award in the category "Industry, High-Tech & Life Sciences"
- Jenny Prange and Deana Mohr, Co-founders of Muvon Therapeutics, share Swiss Female Innovator of the Year Award
- Top 100 Startup Awards: HAYA Therapeutics wins the first prize

Private & public Swiss biotech regional financing 2021-2023

Capital investments in Swiss biotech companies 2014 -2023

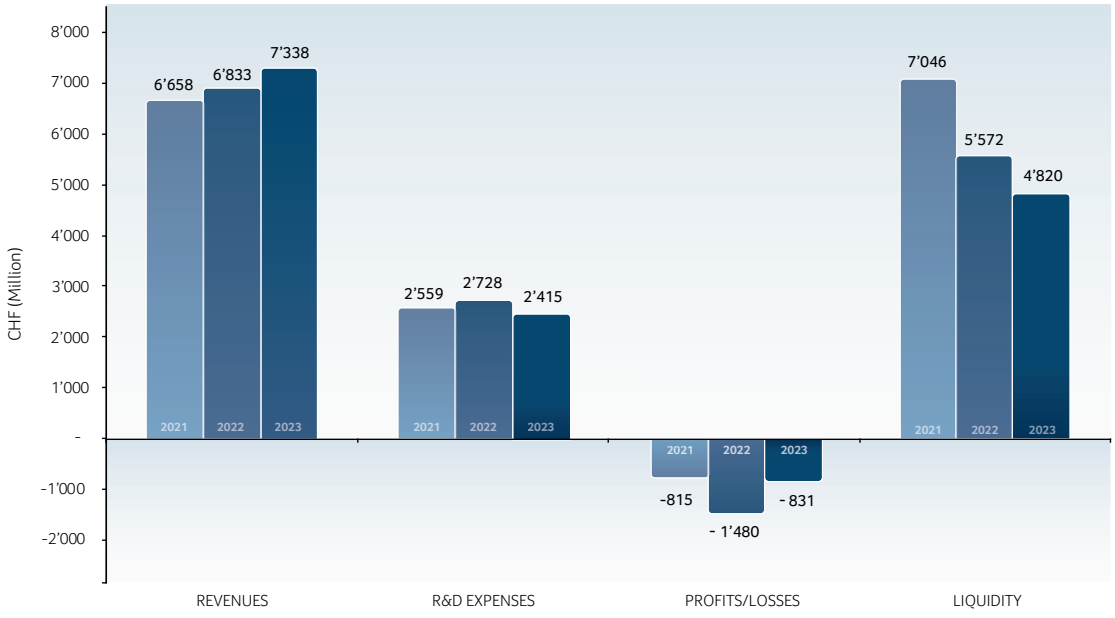
Private & Public Swiss Biotech Companies



Source: EY (Capital investments include convertible bonds)

Revenues, R&D expenses, profit/loss, liquidity 2021-2023

Total Swiss Biotech Companies



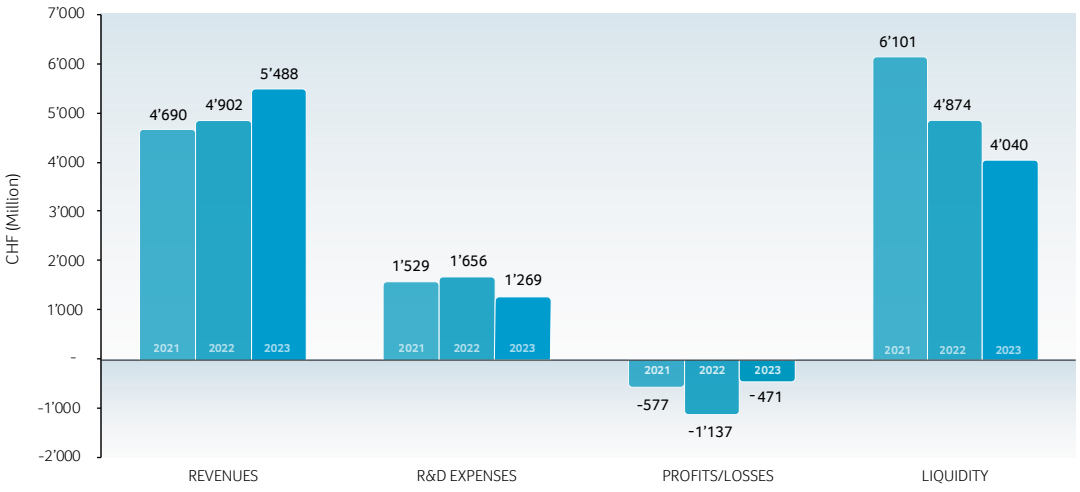
Source: Annual Reports, website information and EY

Note: The 2023 data in above tables is based on information that was available up until March 31, 2024. At this time, some of the companies had not yet disclosed their financial figures for 2023. Therefore some figures were carefully extrapolated on the basis of the latest interim data publicly available (i.e. Q3 or Q4 2023)

The year in charts

Revenues, R&D expenses, profit/loss, liquidity 2021-2023

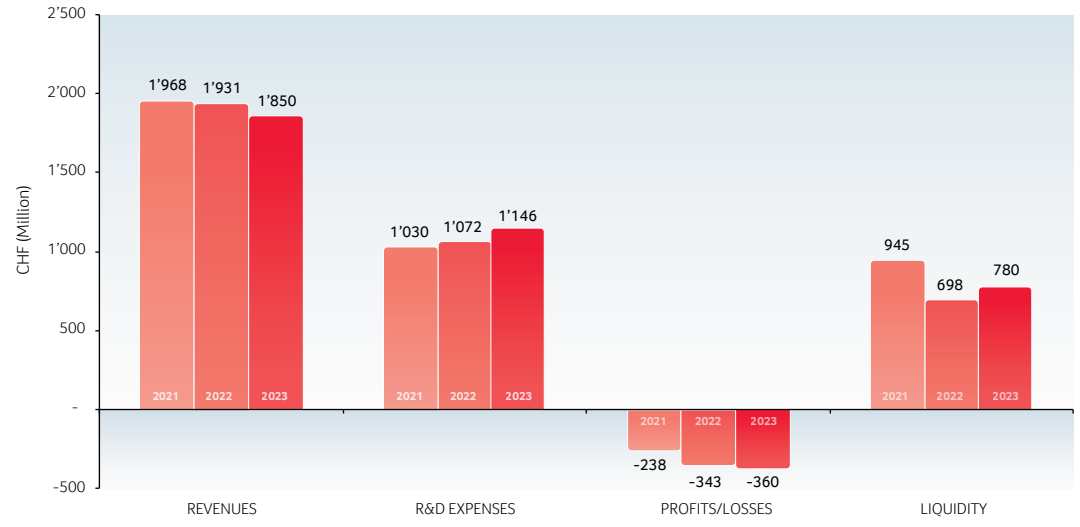
Public Swiss Biotech Companies



Source: Annual Reports, website information and EY

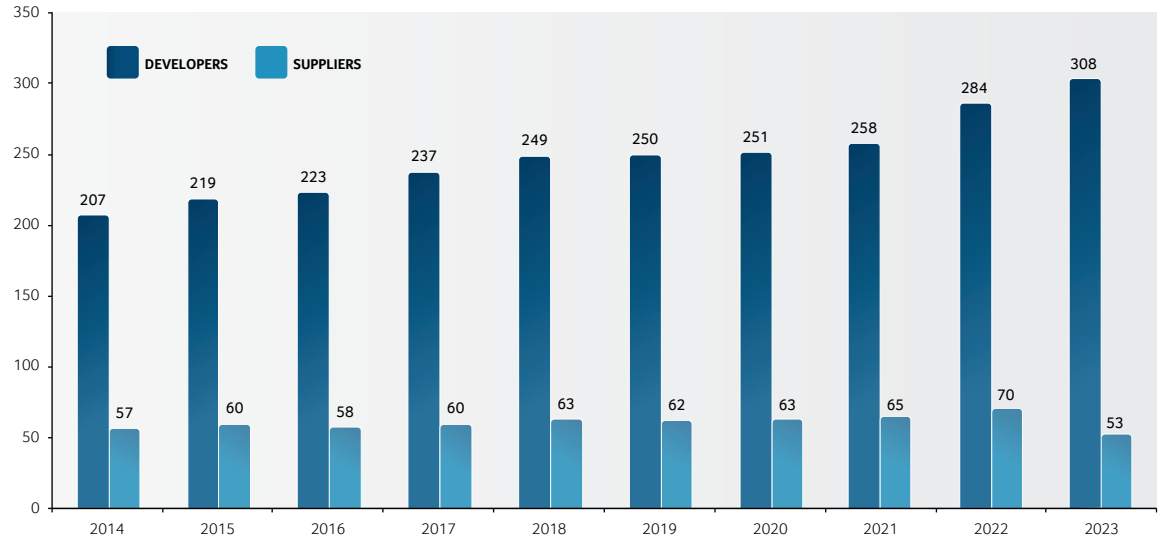
Revenues, R&D expenses, profit/loss, liquidity 2021-2023

Private Swiss Biotech Companies



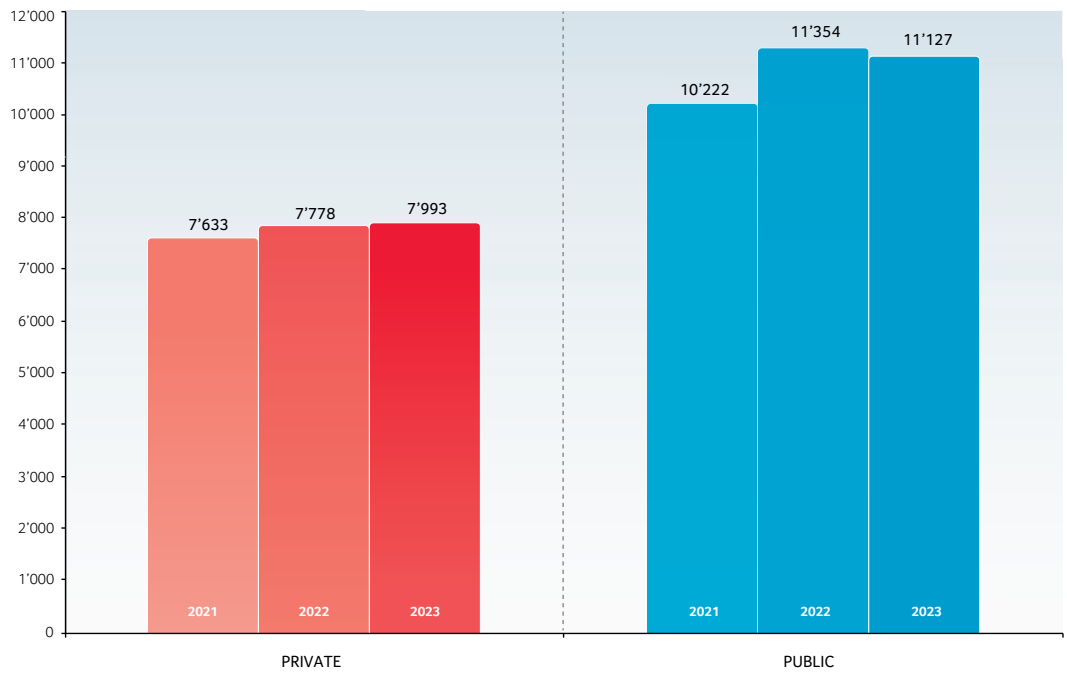
Source: Swiss Biotech Association, EY (incl. estimates and extrapolations based on prior year figures)

Number of biotech companies in Switzerland 2014-2023



Source: Swiss Biotech Association, website information and EY

Number of Swiss biotech employees 2021-2023



Source: Annual Reports, website information and EY

The life sciences sector as a reliable pillar of the Swiss economy

scienceINDUSTRIES
SWITZERLAND

Jan Lucht

scienceindustries | Head Biotechnology

The life sciences sector (pharmaceuticals, vitamins and diagnostics) is Switzerland's largest export industry. In 2023, it accounted for 38.5% of total Swiss exports and contributed CHF 105.5 billion to the foreign export trade.

The uncertain geopolitical situation, high raw material and energy prices and the strong Swiss franc characterized the economic environment in 2023 and had a negative impact on trade. Quarterly Swiss exports fluctuated, and the annual total fell by 1.2% to CHF 274.3 billion. While the life sciences sector recorded real export growth of 5.2%, nominal exports (adjusted for inflation and currency effects) fell by 3.8%. The sector was particularly affected by a decline in medicines exports (-8.5%).

In contrast, the immunologicals sub-segment, which includes biotech products such as monoclonal antibody therapeutics and vaccines, was only marginally affected. With an export value of CHF 47.1 billion (-1.4%), it contributed a significant share to the total Swiss exports in 2023. Growth in the other immunologicals categories more than compensated for the decrease of CHF 2.4 billion in human vaccine exports compared to the previous year in the wake of the COVID crisis. The growth of the immunologicals sub-segment has been remarkably dynamic: in 2023, exports were > 30 times greater than twenty-five years ago.

The life sciences sector has been a solid pillar of the Swiss economy and foreign trade for decades. In 2013 it took the lead as the largest export industry. It has shown remarkable resilience, continuing to grow even during the peak year of the COVID pandemic in 2020, when exports almost universally slumped. While exports from all other sectors combined grew by 81% in the twenty-five years from 1999 to 2023, the contribution of the life sciences sector grew by 400% over the same period (see Figure 1). The innovative strength, diversified product portfolio and the excellent international network of the Swiss life sciences industry provide financial stability at home and benefit its global partners abroad.

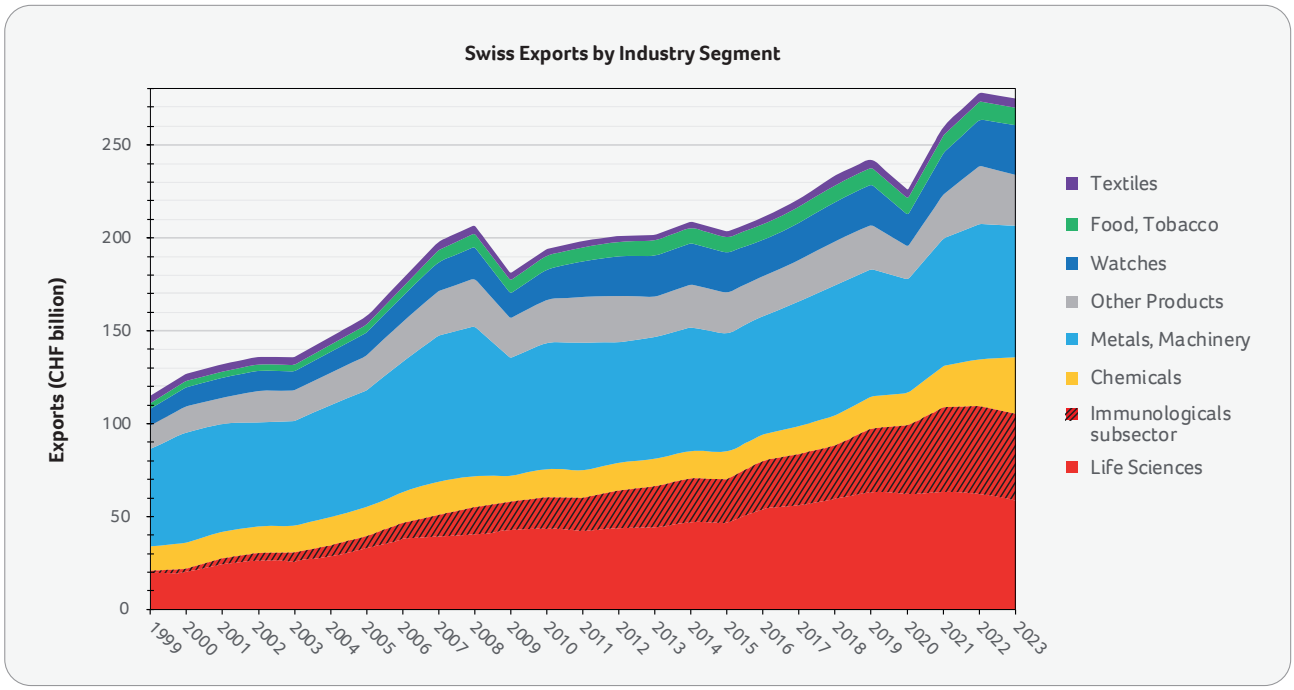
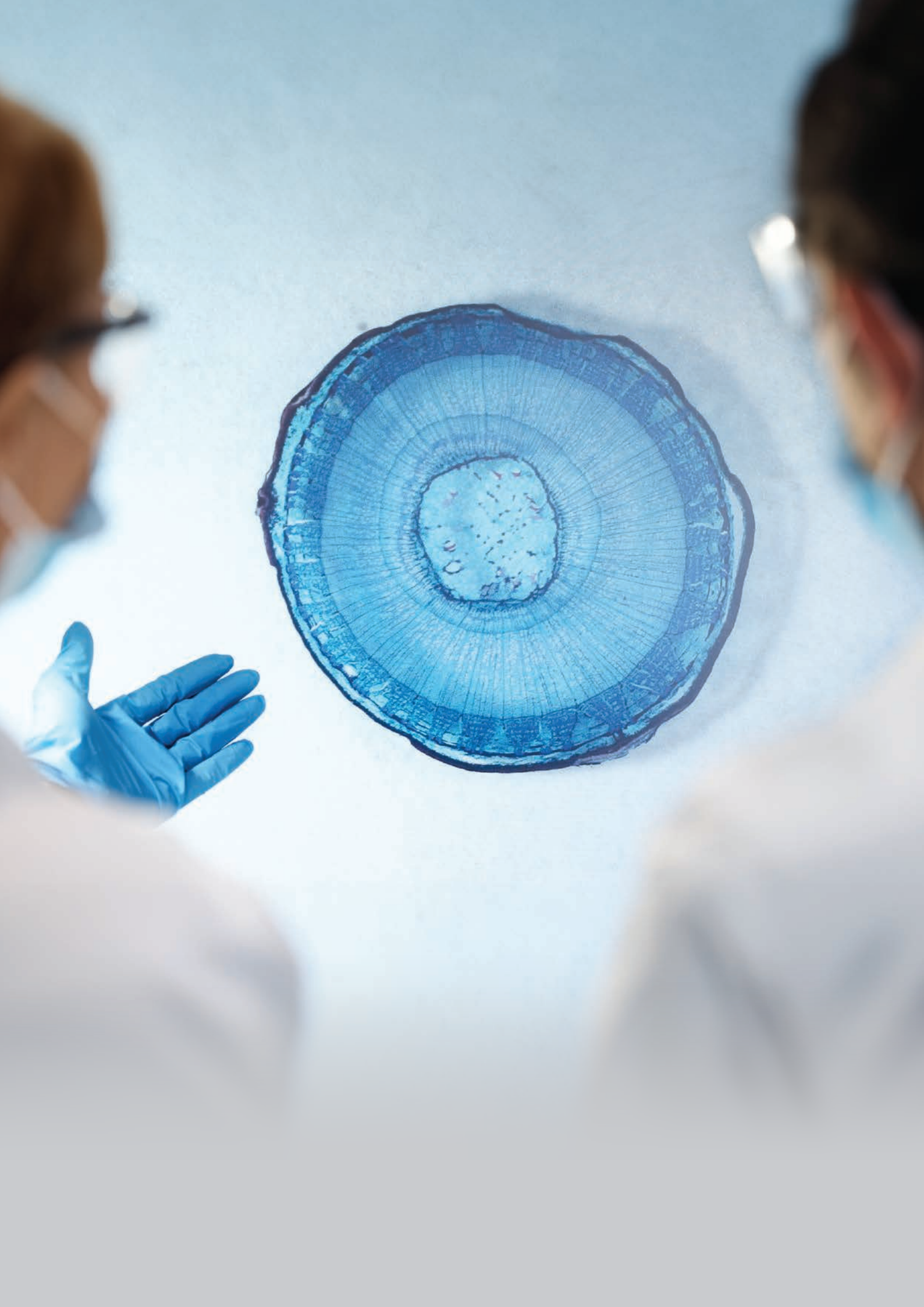


Figure 1: Annual Swiss exports according to industry sector demonstrate the increasing importance of the life sciences industries (pharmaceuticals, vitamins and diagnostics). This sector alone contributed 38.5% to the total Swiss exports in 2023 (Data: scienceindustries/Federal Customs Administration 2024, Swiss IMPEX database).



Switzerland has a vibrant scientific research industry and a culture of innovation

Florian Fisch

Swiss National Science Foundation | Science editor

ETH Zurich bioethics professor Effy Vayena has experience collaborating across many different cultures. She talks about the value of cooperation and the international role of Swiss researchers.

Multicultural expert in health data policy

Greek-Swiss dual citizen Effy Vayena studied the history of medicine and bioethics in Greece, the UK, the USA and Switzerland. After completing her doctoral degree in the history of science at the University of Minnesota, she worked in a research position at the WHO in Geneva. She assumed the role of assistant professor at the University of Zurich in 2015, funded by the SNSF professorship program. Dr. Vayena is now professor of bioethics at ETH Zurich, with her work supported by continued grants from the SNSF.

Effy Vayena

FF: *Professor Vayena, you grew up in Greece, and completed your doctoral degree on the history of medicine in the United States. What brought you to Switzerland?*

EV: Searching for a postdoctoral position, I discovered a relevant research program at the WHO. I moved to Geneva, initially for one year, but in the end spent seven years working at the WHO. I then returned to academia, at the University of Zurich where I conducted research in the area of bioethics and health policy.

FF: *Today you successfully lead an international research program called Health Data Governance and Value Creation. What is its overall goal?*

EV: In this program we study responsible access to health data for research purposes. The project began before artificial intelligence became an everyday term. Keep in mind that health data are even more sensitive than other personal information. The process we developed for ethical data access extends to the use of health data collected outside of hospitals and clinical medical records. Using this type of data quickly becomes an international matter, with health-related apps often developed in a different country, and health data stored in yet another.

FF: *Therefore, it makes sense to collaborate with researchers from other countries?*

EV: Exactly. We are a consortium of individuals and groups in Switzerland and Singapore, and we collaborate with teams throughout Europe. It is vital to include the unique perspective of each country and combine the strengths of various disciplines. Science is competitive and collaborative at the same time.

FF: *What are the advantages of working in consortia?*

EV: The funding of a consortium allows for a broader strategy, with individuals and institutions assembled to think about the same problem. There are also many consortia purely within Switzerland. Consortia can be as simple as two co-principal investigators, and often include non-academic partners such as companies or individuals working in government.

FF: *You know different working cultures firsthand. How do they influence teamwork?*

EV: I try to work with people I think I can collaborate with well, so clearly there is a selection bias in my experience. Of course, each culture is distinct, and culture also varies by research institution. Germany, South Africa, and the United States have different administrative requirements, ways of organizing meetings, and institutional hierarchies. We must ensure that partners from the Global South are included in scientific collaboration.

FF: *Is Switzerland a good country for research collaboration?*

EV: Working here, I may be biased, but in my experience Switzerland is a very good country for collaboration. There is a rich research culture, and Swiss society values science. Administration is concise and lean without unnecessary paperwork, which is a big asset. Switzerland is also an attractive partner in terms of infrastructure. There is a vibrant scientific research industry and a culture of innovation. If you look at various metrics, from university rankings to innovation indices, Switzerland continuously features in the top league. Achieving this takes time and cannot just be created overnight. Of course, it varies according to the area of research. And especially concerning data access, Switzerland still has a few challenges to overcome.

FF: *You are talking about health data. Switzerland does not have a biobank with a cohort of 500,000 people like the UK, or access to all individual health records like Denmark. We still work with PDF files.*

EV: We indeed have some way to go. However this has been recognized, and there is a strong commitment to improving access to health data. The first task of the Swiss Personalized Health Network, for example, was to enable data access from university hospitals. As each hospital records and annotates information differently, this required a great deal of work. On the other hand, it is difficult to compete with the UK and Denmark when it comes to data access, as they have very different healthcare systems from Switzerland. These systems allowed more centralized collection of data from early on.

FF: *Are Swiss researchers forced to collaborate because of our geographical situation?*

EV: For any science-oriented society, it is essential to look beyond our borders and collaborate. The neighboring countries are also strong in science and innovation. Our unique political system is an enormous asset, helping to shape society's opinions and actions. Flexibility and agility are two advantages of being a small country, and these attributes are valuable for scientific collaboration.

FF: *Let's talk about Horizon Europe, the largest research program in the world. While some parts of the program are still open to Swiss researchers, they are currently excluded from important areas. Do you feel the consequences during your work?*

EV: Switzerland has been the beneficiary of the work of the Horizon Europe initiative. Not only in terms of funding, but more so the significant effects of competition and collaboration. Having a similar level of expertise, but lacking the ability to participate as an equal partner, results in a poor dynamic for cooperation. We researchers are hopeful to re-enter the initiative.

Swiss basic research depends on international collaboration

European Research Framework Program Horizon Europe is the world's biggest research funding scheme. Switzerland has been excluded from important parts of the program for the second time since June 2021. A swift renewed association is necessary to avoid damaging the Swiss research landscape further. Still, the SNSF supports the participation in the areas of the European program that are still available and supports other international collaboration possibilities.

A selection of SNSF funding schemes:

- **Scientific Exchanges:** invite colleagues from abroad or host events in Switzerland
- **COST Actions and Projects:** networking activities and collaborations with researchers from COST member countries
- **Mobility grants for PhD students and postdocs:** support early-career researchers to perform research abroad
- **Weave/Lead Agency:** financing of joint projects across borders between two or three countries where agreements exist
- **SOR4D:** mixed-consortia with researchers from the least developed, low and lower-income countries
- **SPIRIT:** two to four research groups across borders with development assistance recipient countries

A selection of other international collaborations available to Swiss researchers:

- **Bio-Based Industries:** partnership between the EU and biotech industry
- **Innovative Medicines Initiative:** partnership between the EU and healthcare industry associations
- **EMBL:** collaboration around the European molecular research laboratory in Heidelberg
- **Human Frontier Science Program:** funding for European basic research in life sciences
- **ESRF:** European synchrotron light source in Grenoble for x-ray related collaboration
- **CERN:** nuclear physicists from around the world meet at the European particle physics collaboration in Geneva
- **Euratom:** the EU's European nuclear energy program also funds European research
- **ESO:** European astronomical research in Chile is where astronomical research from Europe coalesces

Switzerland's ability to attract international partners continues to strengthen its role as a global hub for biotech inventions

Christian Moser Nikles
Swiss Federal Institute of Intellectual Property | Patent Expert

David Rees
Swiss Federal Institute of Intellectual Property | Patent Expert

Biotechnology is a key industry in Switzerland, generating a large number of patented inventions. These are often coauthored with colleagues from international organizations and have a global impact. At the same time, an even larger number of biotech patents from around the world is in force in Switzerland. The present analysis provides a snapshot of the statistics for 2023, covering both aspects. It shows how deeply embedded Switzerland is in the global network of biotechnology innovation and supply, and how the country's attractiveness as a partner and a startup location is a vital factor in its success.

Switzerland: an attractive international partner

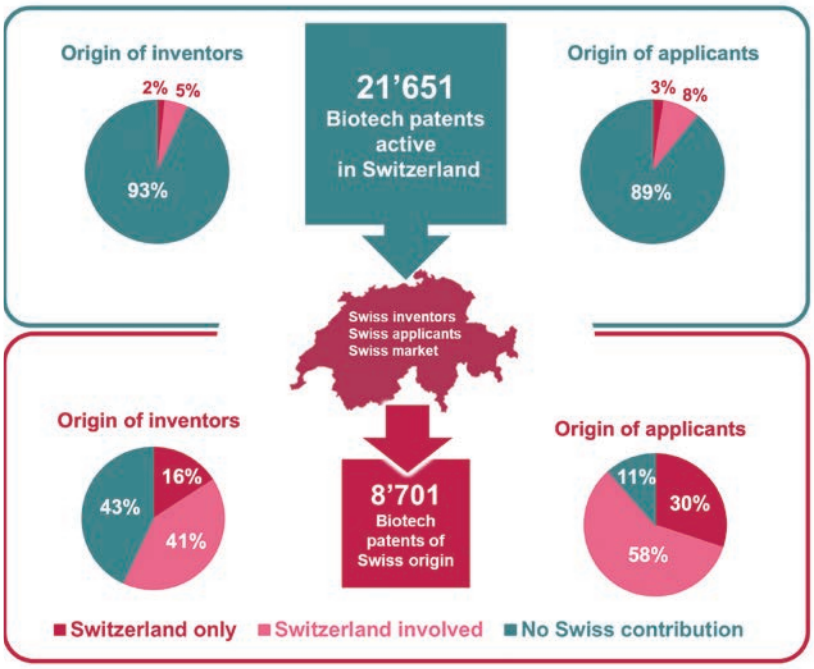


Figure 1: Origin of biotech patents active in Switzerland

A total of 21'651 biotech patent families are currently active in Switzerland, i.e., granted and in force. This is 2.5 times the number of 8'701 active biotech patents of Swiss origin, invented or owned by a Swiss resident.

The vast majority, 88% of the patents active in Switzerland are not of Swiss origin, neither invented nor owned by residents of Switzerland.

The 8'701 patents of Swiss origin comprise about 5'000 patents naming inventors resident in Switzerland, and 7'700 patents filed by applicants from Switzerland, with considerable overlap.

In fact, most of the patents list several inventors and applicants, often from different countries, thereby resulting in significant overlaps in all analyses presented in this article.

Purely Swiss patents, with both inventors and applicants exclusively from Switzerland, account for only 11% of the patents of Swiss origin. The majority of the portfolio involves co-inventors and/or co-applicants from outside Switzerland, emphasizing the strong international links of both the Swiss industry and the Swiss academic research community. Notably, more than 40% of the patents of Swiss origin do not list any Swiss inventors, but they have been filed by a Swiss applicant.

Origin of biotech patents active in Switzerland

The 21'651 biotech patents active in Switzerland include all patents granted and in force in Switzerland. This does not include the 78'000 currently pending international applications in the biotech sector, filed under the Patent Cooperation Treaty (PCT) or the European Patent Convention (EPC). These pending applications were excluded here, because they would inflate the numbers across the board and mask the differences between the countries. At this point in time, it remains unclear how many of these pending applications will be validated in Switzerland sometime in the future.

The USA is the dominant origin of patents active in Switzerland, both in terms of inventors and applicants, followed by Germany and France. The top five countries of origin, including Switzerland, account for two-thirds of all patents active in Switzerland.

Patents of Swiss origin account for 12% of the patents currently active in Switzerland.

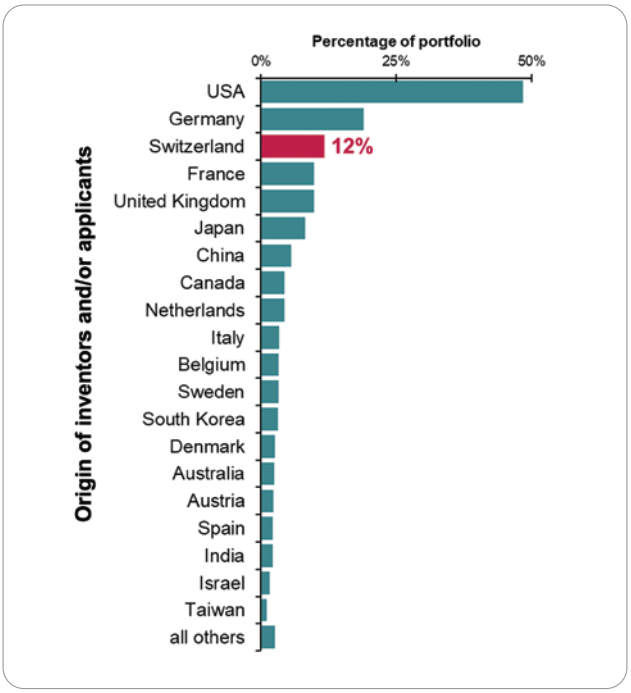


Figure 2: Origin of biotech patents active in Switzerland

Territories protected by biotech patents of Swiss origin

The 8'701 biotech patents of Swiss origin, i.e., those assigned to a Swiss inventor or applicant, are active in many countries around the world. In contrast to the previous section, this portfolio does also include the pending international applications filed under PCT or EPC.

Almost 80% of the patents of Swiss origin are active in the United States, and half of them are also validated in Japan and China.

Only 29% of patents of Swiss origin are currently in force in Switzerland. However, the pending international applications (PCT or EPC), accounting for 46% of the portfolio, still have the potential for validation in Switzerland, or any other European country.

For the non-European states, this additional coverage is limited to the 11% pending PCT applications.

"A full third of the patents of Swiss origin are definitely not targeting the Swiss market. Over 80% of these patents are active in the United States."

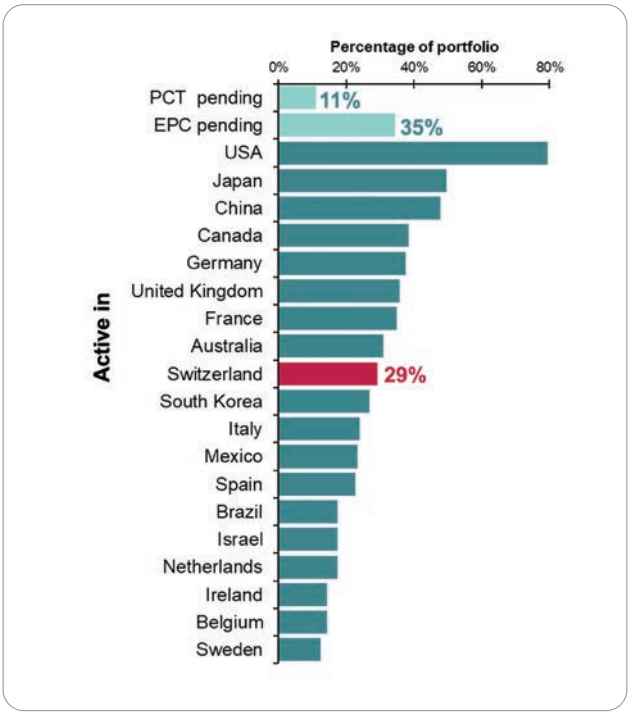


Figure 3: Territories protected by biotech patents of Swiss origin

Switzerland's ability to attract international partners continues to strengthen its role as a global hub for biotech inventions

Patent density: the global view

Active patents per country include all patents that are pending or in force in a given country, also known as patent density. Figure 4 shows the ten countries with the highest number of active biotech patents in their territory. Again, the 78'000 pending international applications under PCT or EPC are excluded to avoid masking differences between countries.

China has the highest number of active biotech patents in its territory. Nearly 60% of the currently 450'000 active biotech patents worldwide are active in China, followed by the United States (32%), Japan (17%), and South Korea (14%).

The active patents in the top four countries include a significant proportion of domestic patents filed only in the respective country concerned, and with no effect in any other country. In China, 76% of all active patents are domestic. Taken together, two thirds of the biotech patents worldwide are domestic patents, and active in a single country only.

In contrast, the countries on ranks five to ten have hardly any domestic patents.

Switzerland ranks 10th and is still within the top ten countries worldwide, even though Switzerland represents a much smaller market than the top nine economies.

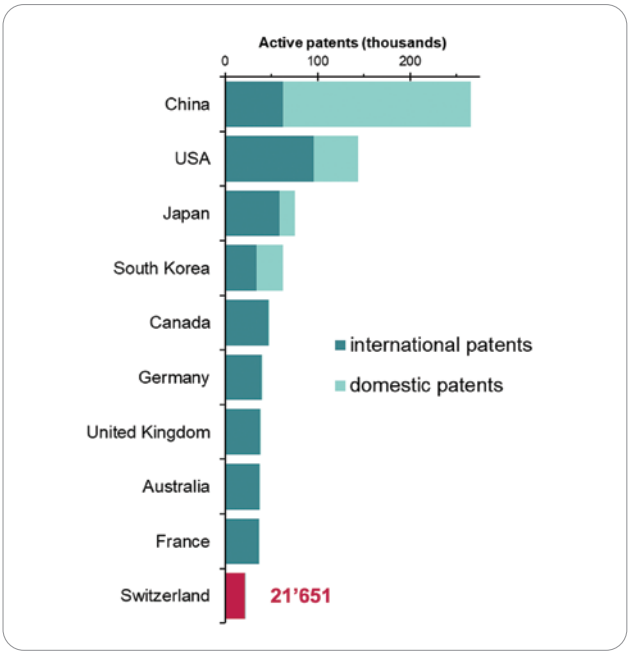


Figure 4: Active biotech patents per country

Patent output: the global view

The patent output of a given country of origin is defined as the sum of all patents either assigned to an applicant from that country or invented by a resident of that country. Currently, approximately 450'000 biotech patents are active worldwide, including all pending international applications.

China and the United States also dominate in terms of biotech patent output, followed by South Korea and Japan. These top four countries together account for almost 90% of all active biotech patents. The same four countries also have a significant proportion of domestic patents, active only in their own territory. More than 90% of the patents originating from China are domestic patents, as are 38% of the patents originating from the US.

In contrast, the six next ranked countries generate very few domestic patents. Almost all biotech patents of European origin are filed as PCT or EPC applications and thus, are international patents.

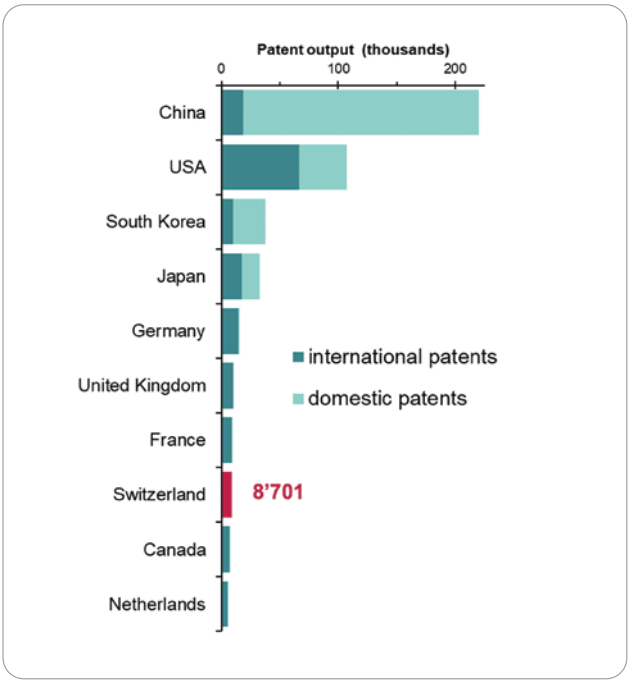


Figure 5: Biotech patent output per country

Conclusions

Biotechnology inventions provide solutions to global problems and address global markets. Accordingly, one would expect biotech patents to be filed and validated in multiple countries.

However, it turns out that this is only true for one third of the biotech patents worldwide. Two thirds are validated exclusively in a single country, in one of the home markets of the four dominant countries of origin; these are China and the US, followed by Japan and South Korea. This dominance applies not only in terms of innovation, as measured by patent output. It is equally evident from a market perspective, as reflected in the number of patents active in each country.

Despite its small size, Switzerland ranks among the top ten countries in terms of both the output of patents and patent density. However, it should be emphasized that biotech inventions of Swiss origin are mainly the result of international collaboration, as discussed in the 2023 edition of the Swiss Biotech Report.

In general, three main reasons motivate patent owners to validate a patent in a particular country:

- **protection of the home market by the patent holder resident in that country**
- **the country is an attractive market worth protecting**
- **serious competitors are located in the country**

Obviously, the Swiss territory is worth protecting for patent owners from all over the world. This is because Switzerland is an important source of biotech inventions and is home to key players in the global biotech industry.

> *"In terms of patent output, Switzerland ranks eighth in the world. Notably, domestic patents account for less than 0.2% of the portfolio of Swiss origin."*

Methodology and definitions

Biotechnology patents were identified according to the **World Intellectual Property Organization (WIPO) technology field definition**, based on patent classifications.

The term patents in this article refers to active patent families. Active patent families are defined as patent families with at least one family member granted and in force, or pending at a given time point. For the data presented here, this time point is 7 December, 2023.

A patent family includes all patents worldwide that are based upon the same common technological content, referring to the same original priority application.

International applications are patents filed under the **Patent Cooperation Treaty (PCT)** or under the **European Patent Convention (EPC)**. PCT applications are administered by the WIPO, EPC applications by the European Patent Office (EPO).

A portfolio refers to a collection of patents, for example all biotech patents active in Switzerland.

The data was generated by PatentSight, a commercial patent database and analysis software.

Applied research organizations offer sustainable solutions for biotech research

Laura Suter-Dick
Biotechnet | President

Sonia Thomson
Biotechnet | Communications

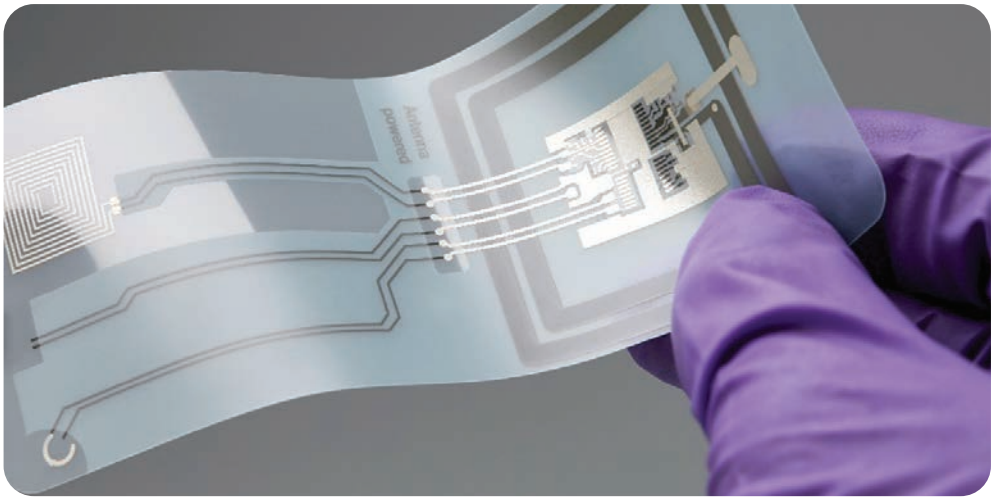
Switzerland's applied research organizations are trusted partners for national and international R&D projects. Collaborators count on our research excellence, high-quality infrastructure, and young talents. Increasingly, their needs and expectations involve sustainable development. As an association of applied research organizations, Biotechnet Switzerland is actively involved in addressing sustainability and working towards global environmental targets.

Biotechnet's members conduct specialized research into green technologies such as bioremediation, biocatalysis, and bioenergy, and organize scientific conferences on these topics. We also raise awareness of best practices for durable biotech research, helping our members discover new tools and strategies to improve ways of working in the lab, reduce plastic waste, and limit their carbon footprint. Several research groups affiliated with Biotechnet actively promote the replacement of animal studies, which is arguably an important step towards sustainability in biotech research.

Exemplary projects in sustainable biotechnology

With Swiss and international partners, Biotechnet's members are developing sustainable diagnostic tests, biomanufacturing processes, biopolymer components, personal care products, and technologies for recycling plastic packaging.

Point-of-care diagnostic tests have revolutionized healthcare by providing rapid and convenient results to both healthcare providers and patients. However, it is crucial to address their environmental impact, as most test kits and cartridges are designed for single use, contributing to plastic and electronic waste. In collaboration with international and national partners, CSEM is pioneering durable technologies for in vitro diagnostic tests and dedicated electronics. Eco-friendly batteries, wireless power management and compostable and biodegradable material will reduce the



CSEM is working on revolutionary all-in-one demonstration of sustainable flexible disposable sensing solutions including eco-friendly substrates, inks and sensing layers

carbon footprint of IVD tests. CSEM is also developing cutting-edge green biochemical sensors to offer unparalleled sensitivity and specificity for body fluid monitoring, bringing new possibilities for more sustainable point-of-care diagnostics tools and personalized medicine. These innovations are being developed within the industry-driven EU projects EECONE and SUSTRONIC.

Biopharmaceuticals are a cornerstone of biotech and pharma but the highly complex production processes pose a burden to the environment. Thomas Villiger at the School of Life Sciences (FHNW) is collaborating with Vienna University of Technology, the University of Chemistry and Technology, Prague, and Merck Serono SA to increase sustainability in biomanufacturing. Together, they developed a bleed recycling technology that allows cell culture medium to be reused while increasing yield in perfusion processes by 20%. Increasing yields remains the most effective way to reduce the material and energy required in biopharmaceutical production.

Enzymes as biocatalysts have a lower environmental impact than chemical catalysts and can support the development of more sustainable processes. The team around Rebecca Buller at the ZHAW has made major progress in identifying biocatalytic processes. They recently published exciting data on the synthesis of anthocyanins, a plant pigment with several uses in the cosmetic and food industry. Also, scientists from the FHNW are involved in several European projects focused on using enzymes to improve sustainability. In FuturEnzyme, the Shahgaldian and Corvini groups at the FHNW are applying enzyme supramolecular engineering to lipases and esterases to make them suitable for manufacturing processes in laundry, personal care, and textile products.

In the area of biopolymers, HES-SO successfully completed the SNSF project BIOPLATE with Chulalongkorn University, Bangkok and the Fraunhofer Institute for Manufacturing Engineering and Automation/Electroplating, Stuttgart. Manfred Zinn's team at HES-SO Valais converted syngas into bacterial biomass and the biopolymer poly(3-hydroxybutyrate) (PHB), a 3D-printable material suitable for electroless metal plating.

Nanobiocatalyst developed by the FHNW in the FuturEnzyme project

The finished parts are used in the automotive industry for dials, knobs, and other components. The project provides an excellent alternative to the more toxic metal coating of petrol-based polymers.

In addition to improving production processes, it is also key to address waste generation, degradation and recycling. FHNW is participating in the EU Terminus project aimed at improving plastic packaging recycling. The Corvini group is working on an embedded enzyme that helps delaminate multilayer packaging so that its individual components can be recycled, addressing a major global issue.

> *"Innovative contributions from research organizations within Biotechnet are enabling more sustainable biotechnology to support the Swiss and international economy while considering the health of our planet."*

Thematic platform-driven networking fostering synergies inside and outside of Biotechnet

Next to technological progress, networking and scientific exchanges are key to the promotion of the change of mindset required for the implementation of more sustainable approaches. Biotechnet hosted five events in 2023-2024 that featured a strong emphasis on sustainability.

Three thematic platforms organized specialized scientific conferences, bringing together national and international participants:

- Biocatalysis uses enzymes to perform chemical transformations on organic compounds. It's a practical and environmentally friendly alternative to chemical synthesis. The **4th annual CCBIO Symposium** held at the ZHAW focused on this technology.
- Bioremediation relies on natural processes and microorganisms to remove contaminants without causing harm to delicate ecosystems. The 3rd edition of **Bioremid** held at the FHNW brought together European stakeholders around this topic.
- Sustainable use of antibiotics remains a challenge, especially in low- and middle-income countries. The **Indo-Swiss Antimicrobial Resistance Innovation Dialogue** brought experts from India and Switzerland together to tackle this challenge.

Undoubtedly, education plays a key role in sustainable solutions for the future. Biotechnet organizes an annual summer school and an annual meet-up, which provide a broader forum for networking and exploring key topics identified each year.

- The XVII **Summer School on Advanced Biotechnology** in Palermo featured four sessions dedicated to biotechnology advances in food, green energy, and the environment.
- The **Biotechnet Meet-Up** was held in January 2024 on the topic of Sustainability in Biotech, providing participants with concrete suggestions to improve their lab practices.

Conclusion

It is clear that sustainability is and will remain a relevant topic that will influence our everyday lives and affect technological developments and the economy. In this context, biotechnology plays a double role, as it can profit from optimized, novel methodologies and processes to become more sustainable and can also deliver means to achieve sustainable solutions to specific problems. Applied research organizations can be good partners for industry when developing sustainable solutions (see scienceindustries article, page 34) and Biotechnet members support companies in devising optimized processes and protocols for manufacturing and research, as well as in finding biotechnological solutions for issues such as recycling. However, there is still a long way to go and much to be done to achieve a more sustainable biotechnology.
So, how do we help you biotech in a sustainable manner?


CO2

Building trusted alliances across borders in times of limited resources

Hans-Peter Meyer

Swiss Academy of Engineering Sciences SATW | Head, Working Group Biotechnology

Unprecedented recent shortages in generic drugs and fine chemicals are putting lives at risk. It is clear that a comprehensive Europe-wide strategy is needed, encompassing diversified procurement networks, mandatory stockpiles, and collaborative partnerships. Only by working across borders and deploying biotechnological and technological solutions will Europe be able to achieve secure supply chains. Swiss organizations could play a pivotal role in supporting and facilitating connections.

The end of plenty?

Over the past two decades, China has been responsible for half of the growth of the world chemical market, and in 2017 it accounted for nearly 40% of global chemical industry revenue.[1] Limited availability of generics, chemicals, chips, plastic, metals, wood and other products at certain times in recent years has had significant repercussions around the world. For example, at times, up to 600 drugs such as propofol (muscle relaxant for intubation), fentanyl (painkiller) or synthocinone (induction of labor) were almost impossible to obtain in Switzerland and, in the case of synthocinone, veterinary products were reformulated for human use.[2]

Population growth, diminishing access to arable land, finite natural resources and political unrest paint a picture of a world grappling with escalating scarcity of supply. The imperative transition from reliance on oil to a sustainable economy, which will require substantial investment, is likely to exacerbate current problems. Nevertheless, amid these challenges, there exist innovative biotechnological and other technological solutions—some readily deployable and others in conceptual stages—that hold the potential to address these pressing issues.

Defossilization will bring new challenges to the chemical industry

Globally, our collective oil consumption stands at approximately 90 million barrels daily. To put this into perspective, Switzerland alone imported a staggering 22'000 tons of crude oil and its derivatives each day during 2021. Defossilization in the energy sector may be a financial feat, but the necessary methods, technologies and solutions such as photovoltaics, wind, geothermal energy and possibly also new nuclear reactor concepts are already available.

90% of chemicals, from high volume primary chemicals to fine chemicals, are made from oil and gas, and the chemical industry is responsible for 14% of global oil and 8% of natural gas consumption worldwide, with the remainder coming from coal and biomass. Moreover, the use of fossil sources for chemistry is increasing in relative and absolute terms, and by 2050, oil demand related to the consumption of plastics could exceed that of road passenger transport. Replacing oil, gas or coal as a raw material for all these products will be a major challenge as the chemical industry has only three options:

- **improved efficiency and recycling**
- **bio-based raw materials**
- **carbon capture and utilization**

Chemistry stands at the beginning of countless value chains, forming the bedrock of many industries through its diverse array of products. Within this realm, biotechnology emerges as a pivotal force, poised to facilitate the deliberate revitalization of chemical processes by enhancing efficiency and cost-effectiveness.

It will be imperative to accelerate the integration of biotechnological solutions and adopt a mindset that encourages thinking chemically while acting biocatalytically. With the organic chemical toolbox at its limit as E-Factors reach unacceptable levels (Figure 1) and increasing structural, chiral, and functional complexity, novel synthetic approaches are needed to address these challenges.

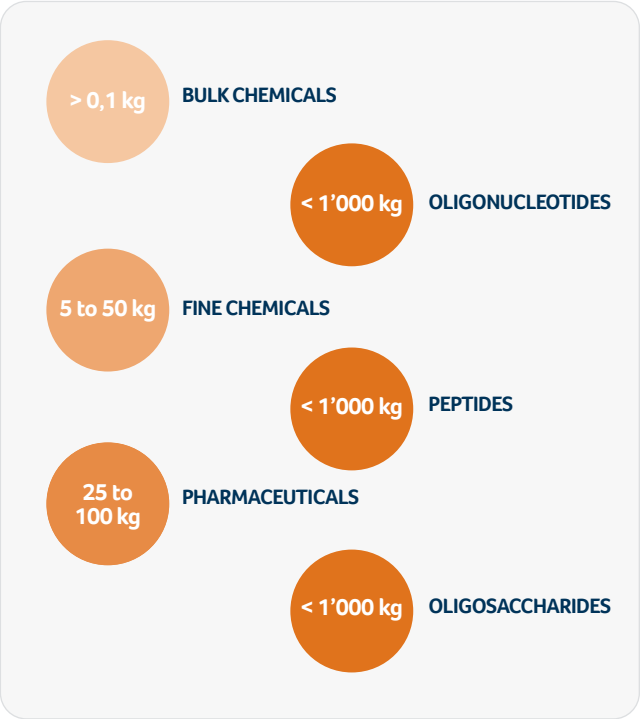


Figure 1: Waste generated per kg of product produced in the chemical industry (E-Factor)

Malthusian crunch and the need to cooperate

There is also a need to strike a balance between the exponential growth of information and the linear growth of useful information. This requires fostering creativity beyond the confines of laboratories and factories, inventiveness in how we collaborate, and the exploration of novel approaches to form and sustain collaborative groups. The Swiss Biotech Report 2022 highlighted blockchain as a radically innovative option with the potential to contribute significantly to the sustained success of the biotech sector. The proposition of a groundbreaking Decentralized Autonomous Organization (DAO), whereby transactions and program rules are securely recorded on a blockchain, has the potential to greatly facilitate essential collaborations.

> *"In the 1980s, approximately 80% of active pharmaceutical ingredients (APIs) for products consumed in the European Union were produced within its borders. Today, this proportion has dwindled to less than 20%, with over 45% of APIs by volume coming from China.[3]"*

Reliable Swiss partners beyond borders

Switzerland's leading position as an innovator carries a responsibility to actively engage in service and collaboration with the global community (see scienceindustries article Page 34). Furthermore, the Swiss chemical and pharmaceutical sector consistently ranks within the top three on the "Global Industry Competitiveness Index". Despite the lesser-known status of Swiss biotech companies operating beyond the biopharmaceutical sphere, here is a curated selection of potential partners worth considering:

- **Inofea**, **Insite** and **lock and key bioscences** are partners for innovative enzyme solutions, enzyme immobilization or expression of toxic or difficult to express enzymes and proteins.
- **Rheiazymes**, enzymatic recycling with a focus on polyamide-elastane (PA/EA) blends, and a circular YARN-TO-YARN® ecosystem.
- **Redbiotec** provides a microorganism-based platform designed for the high-yield expression of proteins and small molecules.
- **Bacthera** is a Chr Hansen-Lonza joint venture for live biotherapeutic bacterial products, particularly fastidious strict anaerobes.
- **Arxada**, the former Lonza Special Ingredients division, has an over 30 years' experience in industrial biotechnology with a large state of the art fermentation site in Kouřim (CZ).
- **Sandoz** is a global leader in off-patent medicines with the last remaining integrated antibiotics production chain in the western hemisphere.
- **Clariant** developed a process (sunliquid®) for converting straw to advanced biofuels.
- **Cell Culture Technologies**, the **Swiss Biotech Center** and **Scinora** all have competence in serum-free defined media and in cultivation and cryopreservation techniques. These competences are required for cell-based meat, seafood or dairy products.

Building trusted alliances across borders in times of limited resources

- **Cultivated Biosciences** elaborated a yeast based dairy cream replacement.
- **Geneva based Planetary** has a manufacturing platform for fermentation-based microbial and fungal novel food products.
- For more than two decades **ABAC** has employed the process of baker's yeast fermentation combined with plant-based raw materials to manufacture a diverse range of products serving nutritional, cosmetic, enological, and animal feed applications.
- Since the early 1970s **Bioengineering** has created a fermentation system for laboratory, piloting and manufacturing purposes.
- **Infors** and **Kbiotech** provide cutting-edge bioprocess equipment and bioprocess software tailored for fermentation and cellular applications.
- **Neocarbons** specializes in the development of LED photobioreactor systems designed for efficient phototrophic manufacturing.
- With a rich history spanning three decades, **Securecell** has excelled in the continuous advancement of bioprocessing solutions, software, and monitoring devices.

First contacts

It is worth noting that numerous Swiss universities are actively engaged in the biotechnology field. Organizations such as **Biotechnet Switzerland**, the non-profit competence hub **Swiss Biotech Center** and the **Swiss Industrial Biocatalysis Consortium (SIBC)**, play a pivotal role in supporting and facilitating connections. They can offer resources and facilities for those taking their initial steps towards product development. For any inquiries related to biotechnology, the **Swiss Biotech Association** is a valuable point of contact that you should consider reaching out to: www.swissbiotech.org

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Improving global access to innovative medicines through international collaboration and harmonization

Jörg Schläpfer

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Julia Djonova

Swissmedic | Head of the Advanced Therapy Medicinal Products (ATMP) department

Regulation of medicinal products and medical devices is vital to ensure the safety, efficacy and quality of products. Stable and predictable regulations and international collaboration between regulators and biotechnology companies allow breakthrough technologies and therapies to be deployed quickly and effectively, ensuring that patients can access the best possible care. Switzerland is part of the Access Consortium which recognizes the urgent need for harmonization of the evolving international regulatory framework in order to facilitate decision-making and accelerate the introduction of innovative products.

The ever more rapid pace of change in medicine, science and technology and the complexity of innovative products pose challenges for regulators, ranging from different product classifications and legal requirements to the ability to make decisions when assessment criteria are not well defined. Although the overriding priority of regulators is to protect patients and enhance public health, an authorization decision for breakthrough therapies, such as advanced therapy medicinal products (ATMPs), is often made before all the usual data is available. The implementation of any new model must always take account of patient safety, even if the medical need is high.

Benefits of collaboration, convergence and regulatory reliance

The need to address various risks so that the safety and efficacy of innovative products can be adequately assessed is widely accepted.[1] Minimizing risks relies on close collaboration between regulators, manufacturers, marketing authorization holders, experts in fields such as nanotechnology, biotechnology, pharmacogenomics, and healthcare professionals and patients.

Rapid approval of an innovative product, similar therapies, platforms or processes can only be achieved through flexible procedures and the sharing of information between regulators. This may include the classification of products, clinical trial results, market authorization assessment criteria and decisions, plus the exchange of post-marketing information and use of data from registries.

The COVID pandemic highlighted how challenging it can be for applicants to meet the different technical requirements in their respective countries, and the difficulties for regulators to accept documents that did not meet specific local requirements. Fast yet responsible regulatory decisions were the result of an unprecedented exchange of knowledge and agreements on specific approval requirements between authorities and stakeholders. This international cooperation enabled the establishment of common criteria for approving mRNA-based vaccines.

Although there is currently no binding framework at either national or international level, collaboration between regulators could help to provide developers with harmonized international requirements. Specific guidelines are now being developed, for example, within the framework of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Coalition of Medicines Regulatory Authorities (ICMRA), the Conference of Drug Regulatory Authorities (ICDRA) or the International Pharmaceutical Regulators Programme (IPRP), of which Swissmedic is a member.[2]

Swissmedic's cooperation with international organizations/initiatives

Harmonization of standards and scientific principles or procedures in different national legislations can bring many benefits, such as reducing animal testing or avoiding unnecessary duplication of clinical trials in humans without compromising safety and efficacy. This is particularly important for rare diseases, which require highly harmonized regulation as reliable data is difficult to collect and results are difficult to confirm.[3]

One instrument that will become increasingly important in the near future is the ability to use Real World Evidence (RWE) data. Decisions for most approved ATMPs or orphan drugs are based on non-randomized single-arm clinical trials, but have

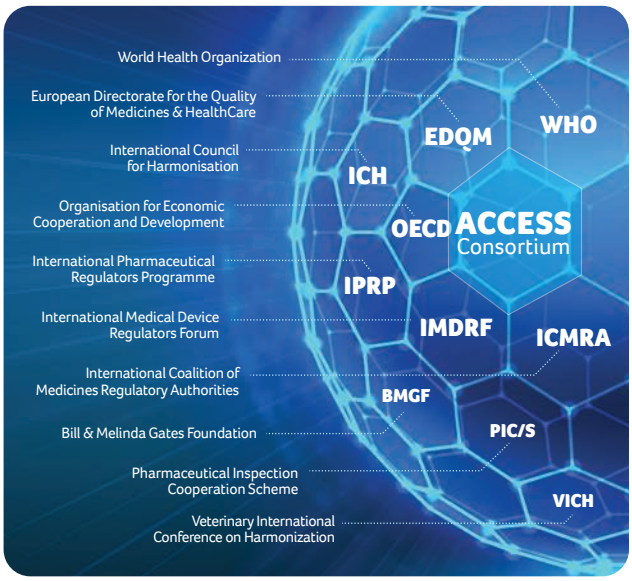

Figure 1: Swissmedic is actively involved in multilateral cooperation with international organizations or initiatives in the entire spectrum of therapeutic products regulation (www.swissmedic.ch/international)

post-marketing observational studies as a prerequisite. National legislation should be harmonized to take account of RWE, and the possibility of sharing and incorporating data from this source or the use of AI should be considered.

Rethinking traditional approaches to life sciences regulation

In recent years, numerous innovative products have been made available to patients, particularly in the fields of oncology, genetic or metabolic diseases. There has been rapid development of "personalized" therapies that aim to improve the stratification and timing of healthcare by using biomarkers at the level of molecular pathways, genetics, proteomics, and metabolomics.[4]

> *"In order to provide sufficient support for researchers and meet the expectations of the public, Switzerland has set itself the goal of promoting the early market launch of innovative medicinal products and establishing Switzerland as a research and business location by 2026, with federal measures to promote biomedical research and technology."*

As the regulatory and supervisory authority for therapeutic products, Swissmedic is aware that patient-centered medicine requires a new level of collaboration between industry, academia, patients, regulators, and reimbursement institutions. Initial measures have been implemented by expanding scientific advice with a regulatory and scientific focus. Swissmedic also operates an Innovation Office, which is present on site in the most important centers and at events to encourage active exchange of information on innovative products so that solutions can be found.

Current Swiss legislation already allows for rapid approval, such as fast-track assessment or conditional approval (e.g. post-authorization safety and efficacy studies). However, innovative medicinal products face numerous technological, scientific, ethical, and regulatory challenges, and the task is made more challenging by the lack of clinical standards and guidelines for data management, analysis and interpretation or a common understanding of alternative animal models for toxicology. It is important that collaboration is strengthened not only between national authorities but also at the international level.

> *"Switzerland is in the process of updating its legislation on ATMPs so that therapies can be authorized more quickly. In addition, new regulatory models are being explored, such as the recognition of real-world data as supporting evidence[5], flexible clinical trial designs (e.g. validated surrogate endpoints) or decentralized trials."*

Regulatory harmonization in practice: the Access Consortium

The Access Consortium is a coalition of regulatory authorities which face similar challenges. It was renamed from the previous Australia-Canada-Singapore-Switzerland Consortium (ACSS) in October 2020, with the introduction of the UK. The new name reflects the group's main objective of providing patients with timely access to high-quality, safe and effective therapeutic products in member countries.

The group recognizes the urgent need for an integrated approach, including criteria for the evaluation of new trends such as preclinical biostatistical models, new manufacturing platforms, and the use of unified e-health data systems. Its objective is to promote interdisciplinary scientific discussions on innovative therapeutic concepts and technologies, to encourage harmonization of the evolving international regulatory framework for the evaluation of ATMP applications, and to develop future synergies for work-sharing. The experience gained will facilitate harmonized decision-making and accelerate the market introduction of innovative products.[6]

> *"The Access Consortium offers common pipeline meetings, product assessments (work sharing) and meets on a regular basis to exchange information on issues and challenges such as harmonization guidelines to better align the regulatory systems and reduce unnecessary duplication and differences. In June 2023, a dedicated Access ATMP Working Group was established. As there are different legal provisions and definitions for ATMPs, a comprehensive exchange is crucial."*

Swift access to innovative medicines tailored to patients' needs

On the one hand, patients urgently need life-saving medicines; on the other hand, knowledge about the short- and long-term efficacy and safety of a product that has not yet been fully tested before or after approval, can only be built up through a constant exchange of information between all stakeholders involved. Only when life sciences companies have durable, predictable yet flexible regulations in place, can breakthrough technologies and new generation treatments be introduced and distributed worldwide for the benefit of patients. The need to share data within an international framework has taken on an important dimension in view of the special aspects of innovative products.

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2 WHO, Regulatory convergence & networks (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks)

3 Data Analysis and Real-World Interrogation Network (DARWIN EU®)

4 Personalised medicine EU Health Ministers in their Council conclusions on personalised medicine for patients

5 Swissmedic position paper on the use of real-world evidence (https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/positionspapier-verwendung-real-world-evidence.html)

6 Concept paper for ACCESS CONSORTIUM ATMP working group

Swiss life sciences industry and global value networks

Jan Lucht

scienceindustries | Head Biotechnology

Global supply networks must be strengthened and made more resilient in order to ensure an uninterrupted supply of essential medicines and everyday goods. Swiss life sciences companies contribute to this on several levels, from investments in R&D to international cooperation and sustainable production for global markets. Improvements in Switzerland's framework conditions could further support this role.

Recent events such as the COVID pandemic and the Russia-Ukraine war have reminded us that an unlimited, reliable supply of goods is an illusion (see also SATW article, page 26). Global supply chains can be easily disrupted by many and often unpredictable factors, which makes it all the more important to transform fragile supply chains into more resilient supply networks. This requires cooperation between many partners across international borders.

Biotechnology and biomanufacturing are playing an increasing role in the production of goods ranging from life-saving innovative medicines and vaccines, to bio-based fine chemicals and consumer products, to food and ingredients. As a result, life sciences are becoming an indispensable part of global supply networks. With its thriving biotech and life sciences ecosystem, Switzerland is a reliable partner on many levels.

Swiss scientists and entrepreneurs, and the international collaborations of which they are a part, contribute to global supply security from pioneering basic research at its excellent academic institutions, to the development of innovations in creative startup companies, to research and development and the global supply of goods by established industries. This is illustrated by some examples from scienceindustries member companies.

Biopharmaceuticals

Biotechnology provides important health benefits to society by enabling innovative therapies for serious diseases. Biotech medicines, including biopharmaceuticals and cell and gene therapies, already account for more than 30% of the global pharmaceutical market and are growing much faster than traditional small molecule drugs. Switzerland is supporting this increasing demand with major investments in healthcare biotech R&D (see Facts & figures, page 8), as well as biomanufacturing infrastructure.

The need for foresight and courage in strategic investment decisions is shown by the Biogen example. Founded in Geneva in 1978, the company has its international headquarters in Switzerland. In 2016, it began construction of a USD1.5 billion state-of-the-art biologics manufacturing facility in Luterbach, near Solothurn in north-west Switzerland, while the development of potential drug candidates for production there was still ongoing.

Operations began in 2021, but a first biologic manufactured at the site for a neurodegenerative disease failed to meet market expectations. In July 2023, the breakthrough Alzheimer's drug Leqembi®, developed by Biogen and Eisai (JP), received FDA approval. Biogen is ramping up production at Luterbach, initially the world's only manufacturing site, to meet expected high demand.

Sustainable flavors

The availability and security of supply of natural raw materials can be greatly affected by external circumstances. Nootkatone, a natural flavor compound derived from grapefruit, is a case in point. Widely used in food and beverages, nootkatone is traditionally obtained by extraction from grapefruit peel or by biochemical conversion of citrus extracts. However, plant pathogens and weather extremes can have negative impacts on the availability and quality of the raw materials, leading to price and supply volatility.

To provide an alternative, reliable natural source of nootkatone, Givaudan, a global leader in the taste and wellbeing industry headquartered in Switzerland, partnered with US-based Manus Bio, a specialist in next-generation industrial biomanufacturing. By combining Givaudan's analytical, flavor and processing expertise with Manus Bio's advanced strain development capabilities, a fermentation process was developed to produce

BioNootkatone, a breakthrough ingredient from Givaudan, answers market demand for sustainable, natural, clean-label citrus flavour without the cost and supply volatility of traditional citrus extracts

nootkatone from sugar, independent of citrus raw materials. The resulting BioNootkatone has a superior taste profile with woody, citrus and peely notes and is reportedly the most cost-effective and sustainable natural nootkatone on the market.

In addition to increased supply security, BioNootkatone offers reduced greenhouse gas emissions compared to citrus-based compounds. The compound will be produced and marketed in partnership between the two companies to meet global demand.

Bio-based vitamin A

Vitamin A is an essential nutrient in food and animal feed. It supports the immune and digestive systems and contributes to good health. Traditionally, it has been synthesized from petrochemicals. To reduce dependence on fossil fuels while increasing the sustainability of the production process, Swiss-based dsm-firmenich has developed a breakthrough bio-based fermentation approach to produce vitamin A.

It is derived from an adapted yeast strain developed through pioneering research at the company's US R&D facilities that uses renewable, locally sourced carbon resources as a feedstock. The process has been refined through global collaboration at six dsm-firmenich facilities in the US, the Netherlands, Germany and Switzerland. It has significant environmental advantages over traditional chemical synthesis, including reduced carbon footprint and waste generation.

While the initial application of bio-based vitamin A is as a potent anti-aging ingredient in environmentally conscious cosmetic products, it has the potential to revolutionize vitamin A production worldwide, including for human and animal health applications. In addition to offering greater sustainability, the biomanufacturing process requires less complex infrastructure than traditional chemical synthesis. This could facilitate decentralized production at multiple sites close to markets, contributing to a robust global vitamin A supply network.

Necessary framework conditions

Although Switzerland is a strong and reliable partner in the global supply network for life sciences products, improvements in the framework conditions would help to maintain and expand its position. Some current supply problems, such as recurrent shortages of some medicines, could also be addressed. Further diversification of production within the life sciences industry would strengthen the resilience of supply networks and reduce dependency on single factors.

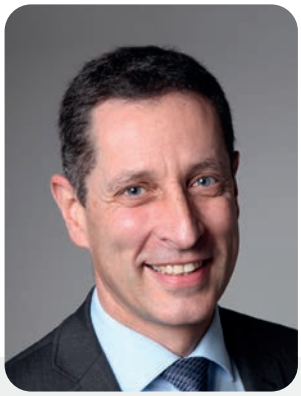
This could be achieved, for example, by broadening the technological base. Innovative research in both academia and industry could drive the development of new applications, the use of alternative raw materials, and technologies to support decentralized applications and local production. At the same time, regulatory frameworks should be kept up to date with scientific progress, e.g. for new genomic techniques such as genome editing for all applications, and for ATMPs (see discussion of the Access Consortium, Swissmedic article, page 30). In this context, it is relevant that both the US (2023) and the EU (2024) have announced biotech and biomanufacturing initiatives - Switzerland should not lag behind.

Full participation in the EU's Horizon Europe program would strengthen international research cooperation. Support for international trade, including appropriate conditions for tariffs and intellectual property, is another prerequisite for Switzerland to fulfill its obligations in global supply networks. Last but not least, good framework conditions for the Swiss life sciences industry will also enable a shift towards an even more sustainable economy.

Tradition of openness and collaboration provides impetus for Switzerland's role as a leading global life sciences partner

Michael Altorfer

Swiss Biotech Association | CEO



Marta Gehring

Swiss Biotech Association | Special projects

Switzerland remains a steadfast driver of crucial scientific discoveries which support global healthcare innovation across many therapeutic areas and stages of product development, including diseases which have a major impact in the developing world. For over a decade Switzerland has ranked top in both the Global Innovation Index and INSEAD's Global Talent Index, but much of its success can be attributed to international partnerships and collaborations.

Pioneering Swiss contributions to global healthcare innovation

With a multitude of ventures and companies contributing to the evolution of international healthcare, Switzerland is a fertile ground for innovation. The Spiez Laboratory, a cutting-edge BSL-3 biosecurity lab in the Bern area, exemplifies this commitment. Analyzing the initial strains of COVID-19, the laboratory provided vital information which could be applied worldwide. Meanwhile, Geneva's European Organization for Nuclear Research (CERN) has played a pivotal role in advancing critical medical imaging technologies, including the development of positron emission tomography (PET).

Tecan's laboratory automation solutions, Genedata's bioinformatics solutions, Molecular Partners' DARPins technology, Amazentis' innovations in mitochondrial health, CRISPR technology developed by CRISPR Therapeutics, and engineered cell line technology for gene therapies by NewBiologix are just a few examples of Swiss-driven advancements. Through active engagement in precision medicine initiatives, Swiss companies are also spearheading international collaborations to make personalized healthcare a reality.

In the area of biotech patents, Switzerland has the highest market coverage, i.e. number of countries for which protection has been obtained and their relative market importance, as well as an exceptionally high "technology relevance". A crucial factor in this success is that more than two-thirds of Swiss-based inventions involve co-authorships with colleagues worldwide, fostering a global scientific approach that enhances research impact (see IPI article, page 18).

Switzerland's leadership also extends beyond cutting-edge therapeutics. The nation actively promotes research and development of drugs relevant to the developing world. Collaborative efforts involving Swiss state and private players have resulted in the development of a malaria prevention drug suitable for pregnant women, a tuberculosis therapeutic, and a treatment for African trypanosomiasis (sleeping sickness). To ensure global access, the Swiss Agency for Development and Cooperation (SDC) supports quality approval procedures in partner countries and facilitates low-cost access to these life-saving drugs.[1] This holistic approach reflects Switzerland's commitment to bridging global health disparities.

Dynamic pursuit of international alliances extends across the value chain from research to regulatory authorities

Through its integral role in EUREKA, a global public network for international cooperation in R&D and innovation, Switzerland helps to shape the future of healthcare. Swiss organizations participating in EUREKA projects gain eligibility for funding through various network initiatives:

- **Eurostars empowers Swiss SMEs to lead international project consortia, receiving national and EU funding to realize their innovations**
- **EUREKA Clusters are industry-led international communities which focus on strategic technologies, including advanced manufacturing**
- **Globalstars facilitates R&D projects beyond the EUREKA network**

All three of these initiatives are generously funded by Switzerland.

Simultaneously, Switzerland's regulatory landscape is evolving through strategic collaborations, notably with the FDA, marking a significant expansion of influence, particularly in the pivotal manufacturing sector. The partnership encompasses a Mutual Recognition Agreement (MRA) between Swissmedic and the FDA, a transformative pact effective since July 2023, specifically covering Good Manufacturing Practice (GMP).[2] This agreement validates inspections conducted by each other's regulatory authorities, alleviating the regulatory burden for Swiss manufacturers operating in the US, and for US multinationals with manufacturing operations in Switzerland.

Swissmedic's engagement extends beyond manufacturing to include collaborative efforts to accelerate the approval of therapeutics, showcasing Switzerland's proactive role in global initiatives. Notably, its involvement in the FDA Oncology Center of Excellence's (OCE) Project Orbis since 2019 underscores the country's commitment to expediting regulatory reviews of cancer treatments. Switzerland's adeptness in keeping pace with the FDA review process distinguishes it among member countries.[3]

Furthermore, Switzerland is a key player in the Access Consortium (see Swissmedic article, page 30) alongside Canada, Singapore, the UK, and Australia, and was one of the first members to approve a new monoclonal antibody (faricimab) for wet AMD and diabetic macular edema (DME) within a remarkably brief review period of 212 days in 2022.

Engagement with partners via robust international supply chains and integrated solutions

Switzerland's industrial strength is reinforced by international collaboration and the close proximity of customers.

Lonza, headquartered in Visp and Basel, exemplifies this approach, with a global footprint extending across more than 30 sites spanning five continents, from Antwerp in Belgium, to Wellington in New Zealand. Specialized Lonza sites are strategically located worldwide, focusing on bioavailability enhancement in Bend, Ohio; mammalian cell lines in Guangzhou, China; in vitro immune assays in Cambridge, Massachusetts; and upstream development in Singapore.

In Schwyz, **Kühne & Nagel**, a global leader in distribution, operates a specialized life sciences distribution arm. With pharmaceutical hubs strategically positioned in Europe, Asia, the Middle East, Africa, and the Americas, the company recently assumed the distribution responsibilities for the Moderna-SARS-CoV-2 vaccine.

Siegfried Holdings, based in Canton Aargau, has this year announced substantial investments, up to CHF100 million in the development and manufacturing of viral vectors for cell and gene therapies and to construct a new large-scale production plant for drug substances. This initiative complements Siegfried's existing "network of sites" which includes the US, Malta, China, Germany, France, and Spain.[4]

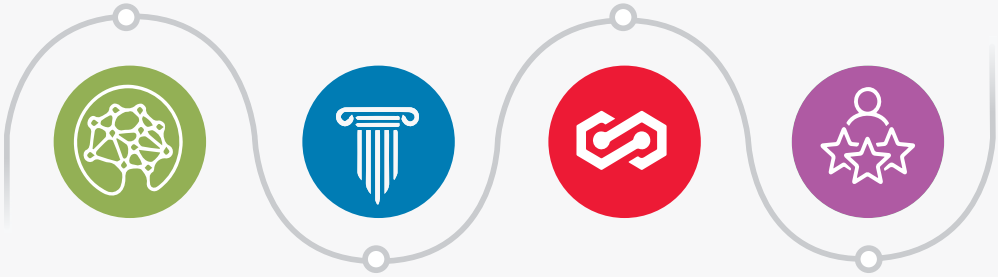
"This strategic expansion underscores Switzerland's commitment to maintaining a leading position in the global landscape of biopharma and life sciences manufacturing."

1. RESEARCH & INNOVATION

Pioneering Swiss contributions to global healthcare innovation

3. SUPPLY CHAINS

Engagement with partners via robust international supply chains and integrated solutions



2. ALLIANCES AND REGULATORY

Dynamic pursuit of international alliances extends across the value chain from research to regulatory authorities

4. PEOPLE & TALENTS

Pivotal role of Switzerland's diverse and dynamic talent hub

Pivotal role of Switzerland's diverse and dynamic talent hub

Switzerland benefits from an exceptionally varied and versatile talent pool, thanks to the way the country has developed its policies and education system. The country works closely with the European Union within the framework of the Swiss-EU Bilateral Agreement on the Free Movement of Persons (AFMP) and has adopted the EU's system of mutual recognition of professional qualifications. Nationals from non-EU states are entitled to apply for recognition of their foreign qualifications, and companies are able to tap talent from neighboring countries, with 1 in 5 workers crossing daily into Switzerland for work.

The Times Higher Education World University Rankings shows that Switzerland boasts five of the top 100 universities in life sciences and medicine, and two in the top 100 for natural sciences.[5] These universities help to provide a pool of highly skilled professionals who have attained advanced qualifications in areas such as pharmaceuticals, biotechnology, and medical sciences. They also attract global talent, and many of their graduates choose to pursue their careers in Switzerland.

International talent and its role in the economy and the life sciences sector[6]

39% of all company founders

50% of all startup founders and **78%** of all "unicorn" founders

37% of all inventors (based on patent applications)

Life sciences sector

44% of employees in general

70% R&D

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3 https://pink.citeline.com/PS149096/Swiss-To-Introduce-Parallel-HTA--Regulatory-Submissions-More-Transparent-Decisions
4 Siegfried media release https://www.siegfried.ch/2032/
5 https://www.timeshighereducation.com/world-university-rankings/2023/subject-ranking/life-sciences?page=1#
6 https://www.avenir-suisse.ch/en/publication/innovation-without-borders/

How SIX Swiss Exchange's position as the leading European biotech exchange can help achieve global sustainability goals

Fabian Gerber

SIX Swiss Exchange AG | Senior Relationship Manager Primary Markets

Switzerland's capital-rich investor base, strong financial system and leading industry know-how support the country's vibrant biotech ecosystem, enabling companies to efficiently raise capital with a view to driving scientific discovery through to market launch. This benefits both local startups and global players in the life sciences sector. New requirements for sustainability reporting and increased transparency on non-financial matters will necessitate additional effort but will also offer new opportunities and address stakeholder demands.

The healthcare industry accounts for around one-third of the total market capitalization of all SIX Swiss Exchange-listed companies. The high concentration of pharma, biotech and medtech companies in Switzerland is no coincidence. Longstanding interaction between the well-established Swiss companies in the sector and Switzerland's financial institutions have helped foster a fruitful environment that sustains not only domestic investor knowledge, but also attracts international attention.

The two sector indices SXI Life Sciences® and SXI Bio+Medtech® enhance the industry's visibility in the financial market and have a positive impact on liquidity. Figure 1 highlights the size of the SIX Swiss Exchange healthcare sector compared to other European exchanges.

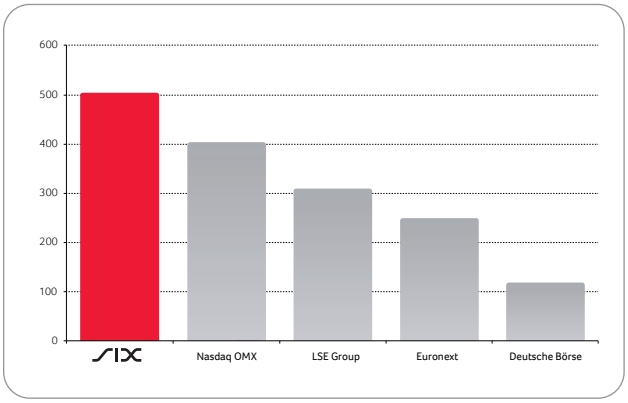


Figure 1: Free float market capitalization in the healthcare industry as per year-end 2023 (in EUR billion)

Environmental, Social and Governance (ESG) is here to stay

The topic of "sustainable business", often equated with the term ESG, has become firmly established on global political agendas in recent years. Many agree that climate targets will not be achieved without concrete measures and that doing nothing will result in irreversible environmental damage. In view of the new legal requirements, many companies, whose contribution to fulfilling these goals will be essential, aim to become more transparent on ESG.

Stakeholders of biotech companies are increasingly engaging directly and indirectly to demand more sustainable business development and good corporate citizenship. While companies from other sectors must focus on "E" for Environmental in ESG due to their high Scope 1 emissions (direct greenhouse emissions, e.g. those resulting from fuel combustion in boilers, vehicles, etc.), biotech companies are faced with increased reporting requirements and the need for transparency with regard to social metrics (e.g. patient and employee safety, ethical business practices, animal testing, responsible R&D, safety in clinical trials, etc.).

New reporting requirements

To keep up with international developments, including EU legislation, Switzerland has introduced reporting obligations on non-financial matters.

Most importantly, on 1 January 2023, the new Articles 964a to 964c of the Swiss Code of Obligations came into force. This means that affected companies are now required to publish a sustainability report. The new legislation applies to:

- public-interest entities (as defined by the Auditor Oversight Act), i.e., FINMA-regulated financial institutions, listed Swiss companies[1], and issuers of bonds[2]
- companies that have at least 500 full-time employees in two consecutive financial years on a consolidated basis (i.e., including all controlled companies[3]; and exceed at least one of the following in two consecutive financial years: (i) a balance sheet total assets of CHF 20 million, or (ii) a turnover of CHF 40 million

How SIX Swiss Exchange-listed companies have coped with ESG so far

A survey of 496 CFOs and IR officers [4] from SIX-listed companies conducted in August 2023 showed that over 80% of companies are either ready or at least well advanced in terms of preparing a sustainability report to fulfill the regulatory requirements. The picture is somewhat different for climate reporting, where only 8% say that they are ready and almost 50% say they have still a lot of work to do.

Companies mentioned the preparation of relevant data and information management as the biggest challenges, necessitating additional resources, such as internal control systems. In 33% of the companies, at least one employee works specifically in the area of sustainability, and 46% stated that they had nominated at least three employees (both part- and full-time employees) to be responsible for this purpose.

Many respondents said that their sustainability report had simplified communication with stakeholders and generally strengthened their perception as ESG leaders or had given them the opportunity to position themselves accordingly vis-à-vis stakeholders. Companies which had previously voluntarily prepared a sustainability report in accordance with an internationally recognized standard stated that this had resulted in an increase in ESG rating coverage, and improvement in their ESG ratings and analyst forecasts. Most of these companies said that they had so far been motivated to produce such a report as it was requested from their stakeholders, who demanded more transparency.

There is also a positive, albeit less pronounced, trend towards an increase in the number and type of investors ("sustainability-driven" investors), whereas a positive correlation between the cost of capital and the preparation of a sustainability report was only observed to a limited extent (see Figure 2).

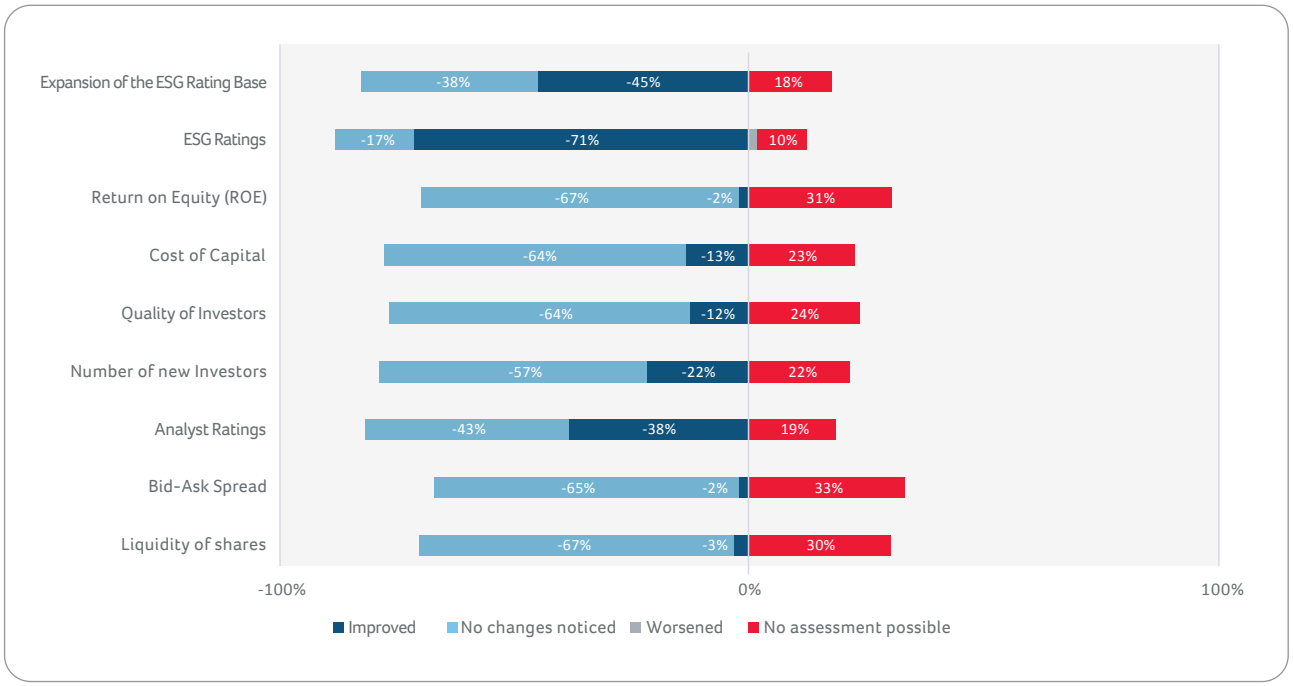


Figure 2: Observed impact of sustainability reporting on capital-market activities Source SIX (Survey, August 2023)

How SIX supports its listed companies

Stock exchanges such as SIX Swiss Exchange can augment sustainability transparency for investors by helping listed companies disclose non-financial information.

Since 1 July 2017, a provision has been in force that enables voluntary sustainability reporting for companies listed on SIX Swiss Exchange (so called "opting-in"), which will also be maintained after the entry into force of the law[5] beyond 2023. By means of an "opting in", issuers have the possibility to inform the market participants and the stock exchange regulator that they will prepare a sustainability report in accordance with an internationally recognized standard. To date, around 50 SIX Swiss Exchange-listed companies have chosen to opt in and cited as reasons the additional visibility and credibility due to the alignment with SIX-requirements. Figure 3 highlights further key initiatives and activities of SIX in supporting its issuers:

Initiative / Activity	Solution
1 Flagging of sustainable bonds with a positive sustainability contribution	https://www.six-group.com/en/products-services/the-swiss-stock-exchange/market-data/bonds/sustainable-bonds.html
2 SIX Sustainability Handbook	https://www.six-group.com/dam/download/the-swiss-stock-exchange/listing/equity/services-for-equity-issuers/sustainability-handbook-en.pdf
3 Creation of new **SIX ESG equity indices** (SPI ESG Index, SPI Gender Equality Index, etc.)	https://www.six-group.com/en/products-services/the-swiss-stock-exchange/market-data/indices/esg-indices.html
4 Dedicated **training sessions** in the area of sustainability and climate reporting for issuers	Best in Class Sessions, Workshops[6]
5 SIX collaboration with UZH for new education program	https://www.finance-weiterbildung.uzh.ch/en/programs/cas/cas-stakeholder-management-and-stewardship.html?utm_source=six&utm_medium=generisch
6 ESG Data Hub	https://www.six-group.com/en/products-services/financial-information/esg-data/esg-data-hub.html

Figure 3: SIX key initiatives to support sustainability

Source: SIX

References

1 The term "listed" is not limited to Swiss stock exchanges but is also applied to companies that are listed on a foreign stock exchange.

2 It is not a prerequisite that bonds are listed in order to fall under this provision.

3 Art. 963 para. 2 defines "control" as a legal entity that controls another company if it: (I) directly or indirectly holds the majority of votes in the supreme governing body, (II) directly or indirectly has the right to appoint or remove the majority of the members of the supreme management or administrative body; or (III) can exercise a controlling influence on the basis of the articles of association, the foundation deed, a contract or comparable instruments.

4 With 150 people completing the survey, the response rate was 30.2%.

5 Articles 964a to 964c of the Swiss Code of Obligations.

6 In cooperation with UNSSEi.


E
Environmental
S
Social
G
Governance
100%
Group 1
Group 2
Group 3
Group 4
100
75
50
25
0
A
B
C
D

How BeiGene drives global cancer treatment access

Sirpa Tsimal

Switzerland Global Enterprise | Director Investment Promotion

From its European headquarters in Basel, Switzerland, BeiGene strategically collaborates with stakeholders worldwide to advance oncology research and development. It is commercially present in 40 countries and runs its clinical trials in over 45 countries.

Sirpa Tsimal talks with Gerwin Winter and Jan-Henrik Terwey of BeiGene about the company's global mission of making cancer treatments more accessible and affordable.

Gerwin Winter
Head of Europe

Jan-Henrik Terwey
VP Medical Affairs Europe

Briefly, describe what BeiGene does

BeiGene is a global biotechnology company committed to developing new cancer medicines that are more accessible and affordable to far more patients around the world.

With more than 10'000 employees worldwide working on five continents, it has one of the largest oncology research teams in the industry with ~1'100 scientists, driving a treatment pipeline that covers 80% of the world's cancers by incidence. 30% of its clinical trials have involved European participants across a range of countries in the continent, of which 16 have been pivotal.

Our fundamental belief is that patients deserve access to high-quality, innovative, and impactful medicines. Cancer has no borders, and so, as a global company, we seek to ensure our therapies are accessible to as many eligible patients as possible. Our collaborative approach to pricing and reimbursement requirements has resulted in rapid patient access, often faster than industry averages.

Could you tell us about the history of BeiGene and when it established its presence in Basel?

BeiGene was founded in 2010 by an American entrepreneur, John V. Oyler, and a preeminent Chinese-American scholar-scientist, Xiaodong Wang, with the mission to build the first, next-generation global biotechnology company by addressing the two biggest challenges in cancer treatment: access to medicines and affordability. They combined their scientific knowledge, entrepreneurial mindset, and shared passion for fighting cancer to create a global company that would play a significant role in how cancer is treated.

With more than 40 offices worldwide, Basel, Beijing and Cambridge, Massachusetts are its administrative locations. BeiGene has been operating out of Basel since 2019, and officially inaugurated its offices in 2022 to serve as the company's European HQ.

Why did BeiGene choose Switzerland as European HQ location?

When we decided to open our European office, we had to make two decisions: first the choice of country, then the choice of canton/state. Switzerland was the ideal candidate from the beginning.

Switzerland has an excellent reputation as one of the most competitive business locations in the world. It offers stable political, social, economic, and financial conditions. In addition, Switzerland has long been recognized as the most innovative country in the world, with the best access to talent.

The presence of renowned research institutes and pioneering work being done by organizations like the Swiss Group for Clinical Cancer Research (SAKK) shows us that Switzerland is at the forefront of translating science from the lab to the clinic. Moreover, the geographical location in the heart of Europe offers Switzerland a unique framework to benefit from synergies on a national and international level, such as a highly qualified workforce, strategic access to the European market, and excellent networking opportunities.

We chose Basel for our European HQ as it has a well-established pharmaceutical industry and is home to a very strong biotech industry. At BeiGene, we value the power of collaboration. The existence of more than a thousand different research groups in Basel is proof of its vibrant, collaborative ecosystem. As a rapidly growing company, we wanted to be where talent is. Switzerland acts like a magnet to qualified workers from abroad and retains the talent it grows, and Basel is no exception. It has an experienced talent pool, with more than thirty thousand exceptionally skilled people.

What is your growth strategy for Switzerland and internationally?

BeiGene is at an inflection point for our business and will look to build on our foundation in 2024, which we expect to be an exciting and transformational year. We are already an innovative oncology leader in hematology and are rapidly becoming a leader in solid tumors. We have one of the largest oncology R&D teams and most compelling pipelines, with more than fifty potential medicines. The company's global revenue is already one of the top 10 for innovative therapies in hematological malignancies.

Switzerland supplies BRUKINSA, a Bruton's Tyrosine Kinase (BTK) inhibitor and BeiGene's flagship product, which won the prestigious "Prix Galien Suisse" 2023, to all major commercial markets. BeiGene's solid tumor medicine, TEVIMBRA, is currently under review by Swissmedic.

At BeiGene we take pride in our ability to attract and expand our global teams to meet our ever-evolving needs. We have more than 10'000 colleagues worldwide. Since 2022, Europe's headcount has tripled to reach 600 colleagues by the end of 2023 including approximately 250 colleagues in Switzerland.

As a leading oncology R&D innovator, what do you think of the Swiss research community?

Switzerland is home to a globally unique life sciences cluster. In addition to large chemical and pharmaceutical firms, this encompasses a concentrated network of medtech, biotech, and nanotech companies. In comparison to other top international locations, the Swiss life sciences industry has the highest work productivity. It comes as no surprise that chemical and pharmaceutical products make up more than half of Switzerland's most important exports.

Switzerland features world-renowned academic institutions developing cutting-research in oncology, through the work of its associated cancer centers, such as the Department of Oncology in the University Hospital of Zurich, the Swiss Cancer Center Basel, part of the University Hospital Basel, the Swiss Institute for Experimental Cancer Research located at the Swiss Federal Institute of Technology in Lausanne, just to name a few and in no particular order. These and other research centers and their faculties play a critical role in advancing the understanding of cancer biology and developing novel cancer treatments.

Switzerland consistently invests a significant portion of its GDP in research and development, both public and private. Moreover, it's a country that has robust intellectual property protection laws, an important incentive for companies to invest in R&D, without significant concerns of infringement.

BeiGene Switzerland receiving the prestigious Prix Galien in the Cancer category in 2023 for its self-developed BTK inhibitor BRUKINSA®

What is your experience collaborating in life sciences ecosystems beyond borders?

Our fundamental belief is that patients deserve access to high-quality, innovative, and impactful medicines. "Cancer has no borders. Neither do we." is our motto. As a global company, we seek to ensure our therapies are accessible to as many eligible patients as possible around the world. Our efforts to close existing health equity gaps require multi-stakeholder collaboration, namely among industry, academia, and government. By working together, we can reduce health inequities and improve the health and wellbeing of millions of patients globally.

We support healthcare industry efforts and government policies that advance science, enhance medical innovation, and work to build health equality for patients around the world. Our collaboration with a multitude of healthcare players extends from the very beginning of the development process until medicines are made available to patients. As an example, we engage with cancer communities around the world to gain insights to bring the patient voice into what we do, from clinical trials to patient-centered outcomes research but also to inform disease education and awareness efforts.

We have a solid innovative portfolio validated by clinical results, global approvals but also major external collaborations, such as Novartis, Bristol Myers Squibb, Seagen, Leap Therapeutics, to name just a few of the more than 20 industry collaborations. Our partners share our patient-centric vision and our unwavering commitment to transformational science.

> *"Switzerland is synonymous with high quality, innovation, and stability. Its willingness to support companies in doing business is unmatched. In Switzerland, industry, academia, civil society, and the government are action-driven and committed to facing challenges together and making the best of opportunities that arise. It's a small but powerful country, catalyzed by strong networking, top talent, and excellent connections with the rest of Europe and the world."*

How will cancer treatment develop in the future?

As the world's population ages, the number of people being diagnosed with cancer is expected to increase. Over 35 million new cancer cases are predicted in 2050, a 77% increase from the estimated 20 million cases in 2022.[1]

Overall, the future of cancer treatment is likely to involve increasingly complex and individualized combination therapies aimed at improving outcomes, reducing side effects, and ultimately achieving better long-term control of the disease. Collaboration among researchers, clinicians, pharmaceutical companies, and patients will be crucial in driving these advancements forward.

Reference

1 https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services

Switzerland is incubating the next global innovations

Daniel Chancellor

Citeline | Thought Leadership and Consulting Director

Switzerland sits in a unique position. No other country possesses its concentration of biopharmaceutical capabilities across the entire value chain, from drug discovery through to commercialization. Its high innovative output and low domestic demand mean that continued success depends on an outlook that embraces international collaboration. Swiss biotechs are therefore the ideal partner, both for accessing innovation and providing the platform to make a global contribution.

Translating scientific excellence into attractive biotechnology businesses

For the 13th year in a row, Switzerland has finished top of the UN Intellectual Property Organization (WIPO) Global Innovation Index, this time edging out Sweden, the US, the UK, and Singapore.[1] This ranking is built upon the country's ability to translate its inputs – investment, universities, and skilled workforce – into world-leading outputs such as intellectual property, manufacturing, exports, and brand value.

This is particularly the case in the biotechnology industry, where there is also the analogy of translating novel science into investible, commercially viable startups. While Switzerland has its fair share of leading academic institutions, and attracts impressive levels of funding on a per capita basis, it is the quality of its biotech output that is world-leading.

Since 2020, private and public Swiss biotech companies have raised a total of approximately CHF10 billion in debt and equity financing, (see EY article, page 8). Furthermore, partnering deals have generated an additional approximately CHF3 billion in upfront or licensing payments over the same time period.[2] The therapies and technologies being developed by Swiss firms are clearly attractive investment propositions, both for local and global investors.

Furthermore, the local infrastructure also strongly encourages international innovators to consider Switzerland as the base to begin a biotechnology business. An analysis of domestic biotech and medtech startups shows that 56% of founders hold a foreign passport. This sentiment was expressed by Juha Yrjänheikki, Chief Executive Officer of Basel-based biotech Aurealis, which spun out of Finland in order to capitalize on the Swiss ecosystem.[3]

> *"Moving the headquarters to Switzerland really allowed us to tap into richer business development, funding and partnership opportunities."*

Discovering the next generation of therapies

The fruits of this investment can be seen in the R&D pipeline of domestic biopharmas. Swiss companies currently have a collective pipeline of around 1'200 assets, spanning preclinical development through to lifecycle management for approved drugs.[4] This collective footprint is among the largest in Europe, and importantly two thirds of these drugs are Swiss discoveries. Another third have been licensed from international sources, harnessing the infrastructure, funding, and expertise within Switzerland to further progress towards patients.

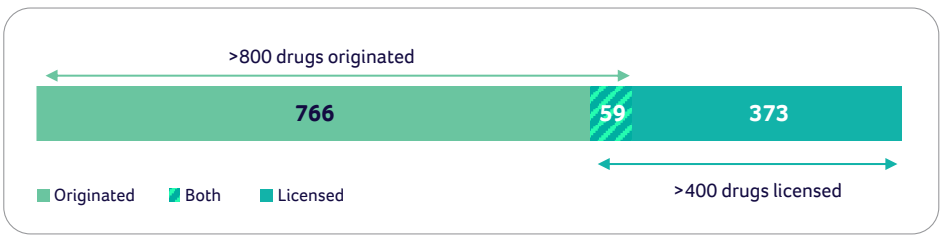


Figure 1: Swiss biopharma R&D pipeline (Source: Citeline, Pharmaprojects, December 2023)

Large emphasis on unmet need and innovation

Within the pipeline, there is a keen focus on areas of particular unmet need, market opportunity, and novel science. The three major therapeutic areas under investigation are oncology, neurology, and metabolic, all of which are major drivers of industry growth. These are particularly well aligned with advances in multi-omics technologies, digital biomarkers, and the transformational effect of GLP-1 agonists.

This combines with an increasing emphasis on sophisticated biological drug classes. Almost half of drugs under development by Swiss companies are biologics, and this share rises further when looking at assets originated in Switzerland. Monoclonal antibodies remain a major focus for industry R&D (~25%), although cellular- and nucleic acid-based therapies continue to gain prominence (~5% each). In particular, Zug-based CRISPR Therapeutics gained global recognition after the approval of Casgevy, the first successful drug to employ gene editing technology. Casgevy works by altering a patient's own hematopoietic stem cells to increase production of fetal hemoglobin, thus improving the lives of patients with sickle cell disease and beta thalassemia. Exemplifying the Swiss approach of collaborating beyond borders, CRISPR is partnered with Vertex to commercialize Casgevy internationally.

Although not strictly biological in definition, Switzerland is also building a heritage in the next generation of chemical-based drugs such as RNA therapies and protein degraders. Both Novartis and Roche are heavily investing through partnerships, while domestic biotechs such as Versameb and GlycoEra are building foundational platforms to advance these novel classes.

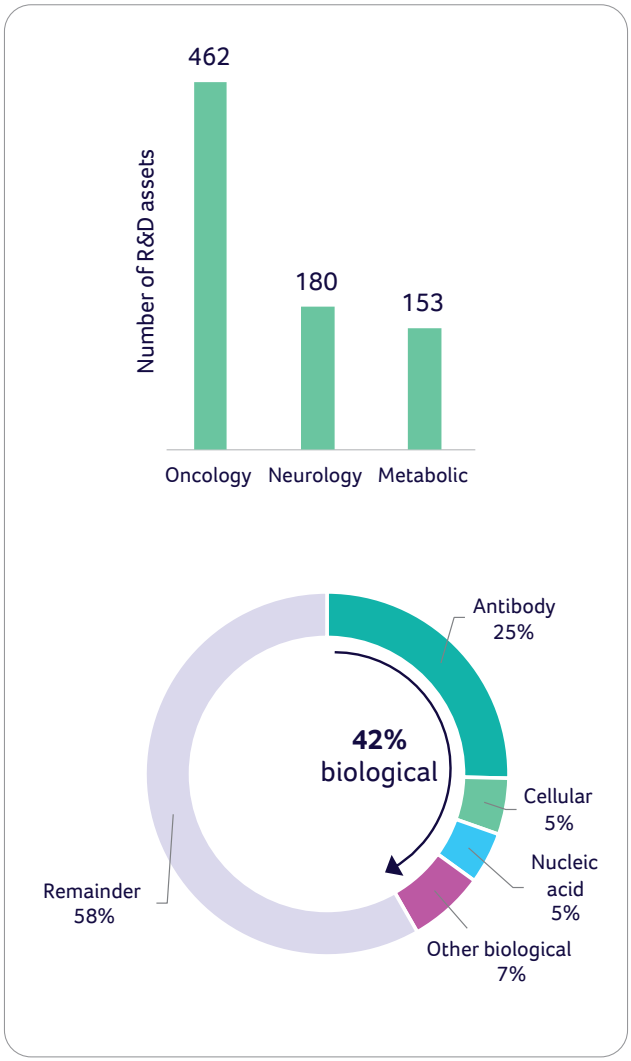


Figure 2: Distribution of R&D assets by therapy area and class (Source: Citeline, Pharmaprojects, December 2023)

Biotechs are collaborating internationally

The relationship between CRISPR and Vertex is very typical. Many of the 800 pipeline assets originated by Swiss companies are either partnered, or will become available for licensing, in order to achieve an international reach. Since 2020, Swiss biotechs have completed 150 out-licensing or R&D alliance deals, featuring partners from across North America (39%), Europe (33%), and Asia (25%).[5] The distribution is relatively even, indicating the readiness of Swiss firms to partner and export innovation across all borders.

Similarly, Swiss companies have signed a further 150 in-licensing deals over the same time period. Two thirds of these involve either Roche or Novartis, and the cross section of these partnerships shows the strong influence of the United States in shaping global R&D trends. Switzerland is an important gateway into Europe for US biotechs, while local innovations are in global demand.

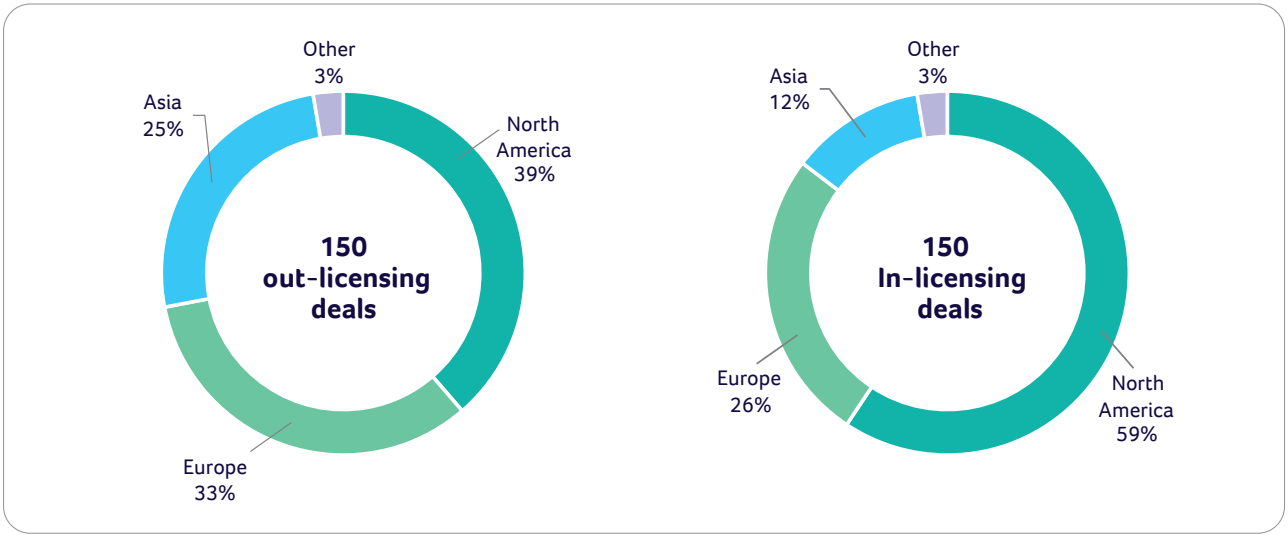


Figure 3: Partnership universe for Swiss biotechs (Source: Citeline, Biomedtracker, December 2023)

Commercialization through the Swiss gateway

Many companies choose Switzerland not only on the strength of its scientific translation, but also as a base for commercialization. Through the presence of Novartis and Roche, two of the pharmaceutical industry's giants, there is an abundance of experience in developing and launching novel pharmaceuticals. These two companies consistently launch multiple new active substances (NAS) each year, accounting for a majority of activity within the Swiss industry.[6]

This creates a large talent base and alumni network, which then attracts many multinational companies to choose Switzerland as a base for commercial operations. Jiangsu Hengrui and Moderna are two recent examples of rapidly growing biotechs that have established European headquarters in Basel.[7]

Amit Munshi, the former CEO of Arena Pharmaceuticals – a US-based company with a strong Zug base, before being acquired by Pfizer – explained this dynamic in the 2023 Swiss Biotech Report.[8] "Over the years, I have set up Swiss hubs for three of my companies. The decision to do so was driven by a desire for operational excellence." Other prominent biotech examples in the Greater Zurich Area include Alnylam, which carries a USD 20 billion+ valuation, and The Medicines Company, which was acquired by Novartis in 2020 for USD 10 billion.

Producing for a global audience

Completing the pharmaceutical value chain, Switzerland is also renowned as a manufacturing partner. As well as being home to Lonza, the global market leader by revenue, the wider ecosystem contains 65 CDMOs.[9,10]

According to data collected by EFPIA, Switzerland has the largest manufacturing footprint in Europe, producing EUR 60 billion of pharmaceuticals in 2021.[11] With a domestic market value of just EUR 6 billion, approximately 90% of Switzerland's output therefore serves a global audience. In reality, this figure is much higher for many newer, more sophisticated drugs, including those that may have been discovered and developed locally.

Swiss capabilities in biologics and precision medicine will ensure that its CDMOs remain essential partners to the pharmaceutical industry for decades to come. Speaking at the 2023 Swiss Biotech Day, Hanns-Christian Mahler, CEO of Basel-based ten23, described the opportunity ahead.[12]

> *"With the general trend in healthcare towards more personalized medicines, encompassing a diversity of therapeutic modalities and patient stratification requiring separate batches, demand is still present."*

References

1 WIPO (2023) Global Innovation Index 2023

2 Citeline (2023) Biomedtracker

3 Citeline (2023) Swiss R&D Innovation: A Tale Of Two Firms Developing Cell Therapies For Wounds

4 Citeline (2023) Pharmaprojects

5 Citeline (2023) Biomedtracker

6 Citeline (2023) Pharmaprojects

7 Citeline (2023) From Hengrui To Moderna: Why More Biotech Companies Are Creating Swiss Hubs

8 Swiss Biotech Association (2023) Investing in Switzerland: Arena Pharmaceuticals - a global biopharmaceutical company benefiting from a presence in Switzerland

9 Genetic Engineering and Biotechnology News (2023) Top 10 Contract Development and Manufacturing Organizations

10 Swiss Biotech Association (2023) The Swiss Biotech Directory

11 EFPIA (2023) The Pharmaceutical Industry in Figures

12 Citeline (2023) Ex-Roche Executive Mahler On Past, Present And Future Of Swiss CDMOs

Celebrating and honoring outstanding contributions to the industry

The Swiss Biotech Success Stories Awards are presented each year at Swiss Biotech Day to honor those who have made important and sustainable contributions to the biotech industry in Switzerland. The awards reflect the diversity and achievements of this innovative sector.

Switzerland is one of the world's leading biotech hubs and attracts many foreign companies, specialists and investors. It provides over 50'000 jobs in R&D biotech companies and specialized biotech suppliers and advisors; And, together with the pharmaceutical and chemical industries, it accounts for almost half of Swiss exports. To make the industry's impact more visible, the Swiss Biotech Success Stories initiative was launched in 2018. Selected success stories are showcased to illustrate how Swiss biotech companies help patients, improve healthcare worldwide, and make a valuable and significant contribution to the Swiss and global economy.

Laureates are individuals or groups of extraordinary merit in scientific, translational, medical or commercial fields, that have a positive impact on the biotech and life sciences industry and society 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.*
>
> *"Young talent should be inspired and motivated to take a closer look at the great variety of career profiles in biotech."*
>
> **Michael Altorfer**, CEO
> Swiss Biotech Association

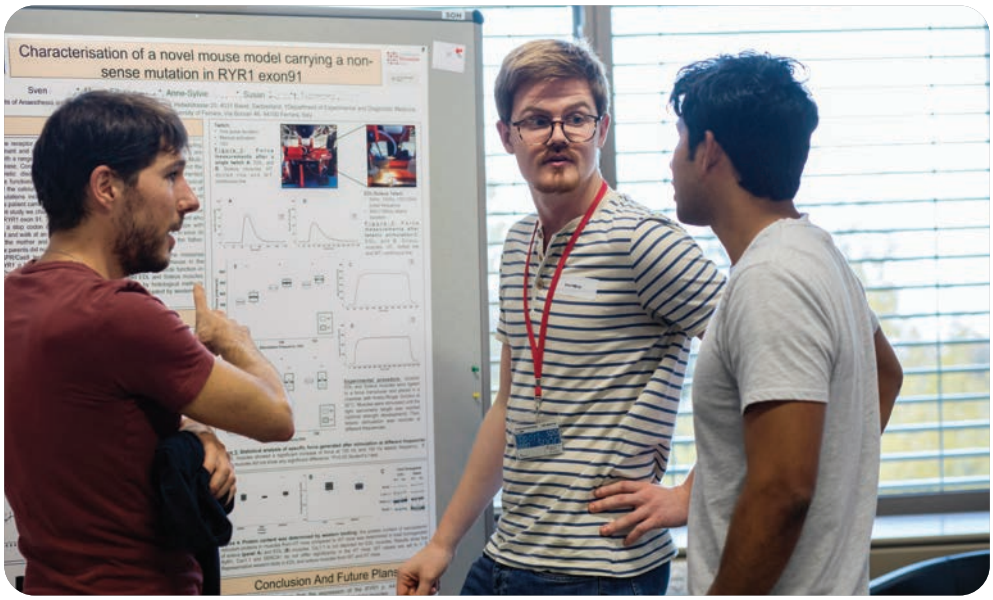
12 success categories

- 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

This year's winners of the Swiss Biotech Success Stories Awards are Hans-Peter Strebel and the FSRMM, a Swiss foundation for research into muscle diseases. They are prime examples of Swiss-based institutions and outstanding personalities addressing major global challenges.

Swiss Biotech Success Stories award winner 2024

A Swiss foundation supporting R&D for the treatment of neuromuscular diseases since 1985



Imagine that you are the parents of two sons who have difficulties running and playing football with their friends. After seeing many doctors, both children are diagnosed with a genetic, progressive neuromuscular disease. Medical understanding of this disease is rudimentary; there are many variants, no available therapies and the prognosis is often fatal.

This is what happened to Jacques and Monique Rognon in the early 80s. After an initial period of despair and helplessness, they decided to promote research on neuromuscular diseases. In 1985, together with two patient organizations, they created the "Fondation Suisse de Recherche sur les Maladies Musculaires" (FSRMM) and from then on devoted all their energy to fundraising.

Since its inception, FSRMM has raised in excess of CHF 30 million and funded more than 200 research projects at Swiss universities and hospitals. These projects range from basic research to clinical applications, with a particular focus on supporting young researchers to establish their own neuromuscular research projects. FSRMM also contributes to patient registries, supports seven Swiss reference centers that care for the patients and help their parents, sponsors the European Neuromuscular Centre, a forum that brings scientists together to discuss specific neuromuscular diseases, and organizes a biannual, three-day meeting for Swiss researchers. Finally, FSRMM has provided seed funding to two startup companies. Clinical trials are underway and the first compounds have now been approved in the US and Europe.

fsrmm
fondation suisse de recherche sur les maladies musculaires
fondazione svizzera per la ricerca sulle malattie muscolari
schweiz. stiftung für die erforschung der muskelkrankheiten

"Over the last 40 years, remarkable progress has been made in the understanding of rare diseases and neuromuscular diseases in particular. FSRMM occupies a prominent position in this niche area in Switzerland. As a private complement to public research funding, its objective remains unchanged: to advance research and give hope to those affected."

Alain Pfulg, President of the FSRMM

Swiss Biotech Success Stories award winner 2024

Dr. Hans-Peter Strebel

Dr. Hans-Peter Strebel founded Fumapharm AG with three other scientists in 1983. This was the start of more than 40 years of successful research leading to the development of Tecfidera, a disease modifying therapy for relapsing multiple sclerosis (MS) which has so far benefitted more than 600,000 patients worldwide.

The story began with approval from the German drug regulatory authority in 1994 for Fumaderm, an oral medication for the treatment of psoriasis. Fumapharm subsequently invested significant time and resources researching the mechanisms of action of individual components of the drug, which led to the discovery that one of the active ingredients, dimethylfumarate, could also be used to treat MS. In 2003, an intensive collaboration began with Biogen Idec, aiming to develop dimethylfumarate as a potential medication for MS. Biogen Idec contributed its expertise in the clinical development and approval of medications.

In 2013, after years of intensive, global clinical studies, Tecfidera® received approval from regulatory authorities in countries worldwide, including the FDA. Tecfidera was approved as an oral therapy option for patients with relapsing forms of MS and has since proved to be highly effective at reducing relapses and disease progression. Due to its efficacy, safety, and convenient oral administration, Tecfidera has become an important component of the treatment spectrum for MS patients, and represents a significant advancement in the treatment of relapsing forms of the disease.

Independent jury of experts

Luca Bolliger

President of the jury

Vice President Swiss Biotech Association

Patrick Aebischer

Entrepreneur

Former President of EPFL

Stefanie Flückiger-Mangual

CEO and Co-Founder

Tolremo

Gabrielle Gache

Head of Business Development (EMEA)

Santen Pharmaceuticals

Seraina Gross

Business Journalist

Handelszeitung

Chandra P. Leo

Investment Advisor Private Equity HBM Partners

Daniela Marino

CEO and Co-Founder

Cutiss

Jürg Zürcher

Independent biotechnology leader and expert

Thomas Staffelbach

Secretary of the jury

TS Kommunikation

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Swiss Biotech Association

Hall of fame 2019 - 2023

Headquartered in Allschwil, Actelion is part of the Johnson & Johnson Family of Companies. Its groundbreaking research and medicines have been a key contributor to improve the lives of people affected by pulmonary hypertension, and have made Actelion an industry leader in this area.

Bachem is a leading manufacturer of peptides and oligonucleotides. The company has grown over 50% in the last five years and now offers more than 5'500 different biologically active peptides amino acid derivatives and oligonucleotides. Its investment plans call for the investment of over USD 400 million to continue to pursue its growth strategy.

Basilea Pharmaceutica is a leader in novel antibiotics and antifungals. Since its listing in 2004 (SIX: BSLN), Basilea has launched two anti-infective treatments: Cresemba® (isavuconazole) for invasive fungal infections and Zevtera® (ceftobiprole), an antibiotic for severe hospital bacterial infections.

Biogen in Baar is a leading biotechnology company that pioneers innovative science and delivers new medicines to transform patient's lives. A broad portfolio of medicines to treat multiple sclerosis, the first approved treatment for spinal muscular atrophy and the state-of-the-art biologics manufacturing facility in Luterbach are proof of Biogen's pioneering approach.

Family-owned Debiopharm from Lausanne, identifies high-potential compounds in oncology and for the treatment of bacterial infections. They are tested in clinical development and licensed to business partners globally. Over a million patients benefit from their therapies every year.

ESBATech, now a Novartis company, is recognized for its pioneering role in developing single-chain antibody fragments for ophthalmic indications. The most advanced product from the ESBATech platform received marked approval by the FDA in October 2019 and shortly thereafter in all major markets.

Hall of fame 2019 - 2023

Etienne Jornod, Swiss entrepreneur, was Executive Chairman of the Vifor-Galenica Group delivering 25 consecutive double-digit net profit growth, supporting millions of patients and creating thousands of jobs. In 2020, he acquired OM Pharma with friends, aiming to create a unique biopharmaceutical company based on bacteria lysates expertise.

Genedata, global market leader for software solutions that digitalize data-rich and complex bio-pharmaceutical R&D processes, enables an R&D revolution driven by precision medicines and artificial intelligence approaches. It helps the industry to deliver innovative biotherapeutics, vaccines and cell & gene therapies faster.

The Schlieren-based company is an integral part of Roche Pharmaceutical Research and Early Development since 2005, and a pioneer in antibody engineering in cancer immunotherapy. Its antibody glycosylation technology increases immune-mediated cancer cell killing and builds the basis for improved cancer medicines.

Helsinn, an important employer in Ticino, has a broad portfolio of marketed cancer care products and a deep development pipeline. It has built significant R&D and manufacturing capacities, also advances patient care and supports healthcare innovation with its investment fund.

Humabs BioMed, subsidiary of Vir Biotechnology, uses its immunologic expertise and cutting-edge technology to combat infectious diseases and other serious conditions. It is a pioneer in the discovery, engineering, and development of human monoclonal antibodies, which have helped transform the infectious disease landscape and have been crucial for fighting diseases such as Ebola and COVID-19.

Lonza is one of the world's largest healthcare manufacturing organizations, serving pharmaceutical, biotech and nutritional markets. Lonza's work enables its customers to develop and commercialize their therapeutic discoveries, allowing their patients to benefit from life-saving and life-enhancing treatments.

Founded by the renowned immunologist, Professor Bernard Mach MD PhD, privately-owned Novimmune is a leading light in the discovery and development of fully-human, antibody-based drugs used to fight autoimmune and inflammatory diseases and cancer.

Hall of fame 2019 - 2023

Fully integrated into GlaxoSmithKline since 2013, Okairos from Basel developed innovative T-cell based vaccines for major infectious diseases such as malaria, hepatitis C, HIV, and Ebola. Its novel replication-incompetent adenovirus vectors could enable the development of important new vaccines and offer immunizations against illnesses that lack vaccines.

The advanced technologies in protein expression by Selexis provide biotech and pharmaceutical companies a rapid, stable, and cost-effective solution for the production of recombinant proteins. Nearly a hundred drug candidates in clinical development and three commercial products utilize the technologies of the Plan-les-Ouates-based company.

SOPHiA GENETICS generates clinically actionable insights and improved patient outcomes from a global data-sharing network. It democratizes data-driven medicine globally through a cloud-based, decentralized SaaS platform, empowering shared insights among clinicians and researchers, and aiming for equal access to knowledge and improved clinical outcomes.

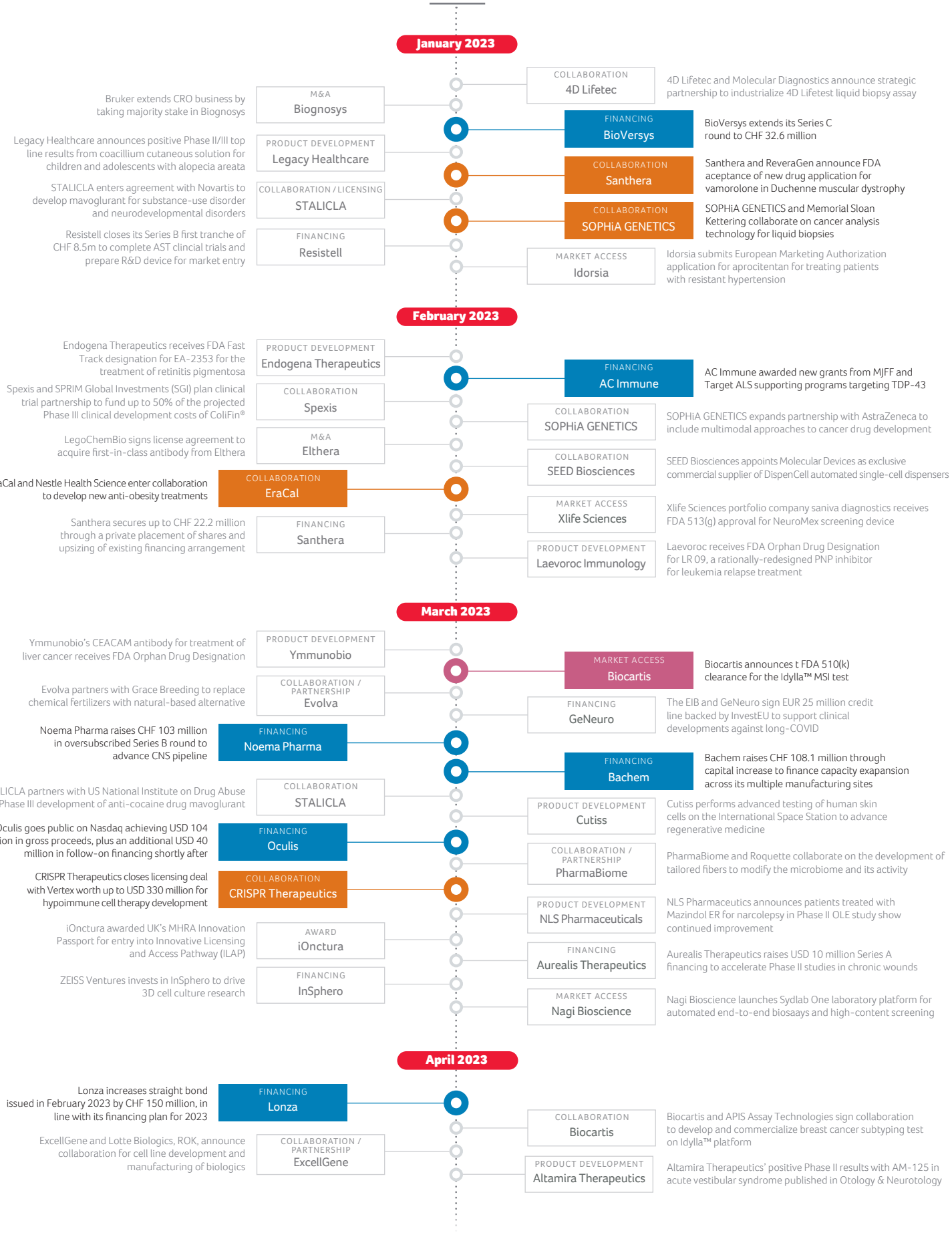
The trio of foundations has been supporting biotech startups with great success for more than 10 years, thereby making a significant contribution to the growth of the Swiss biotech industry. They share the nomination for the Swiss Biotech Success Stories Award.

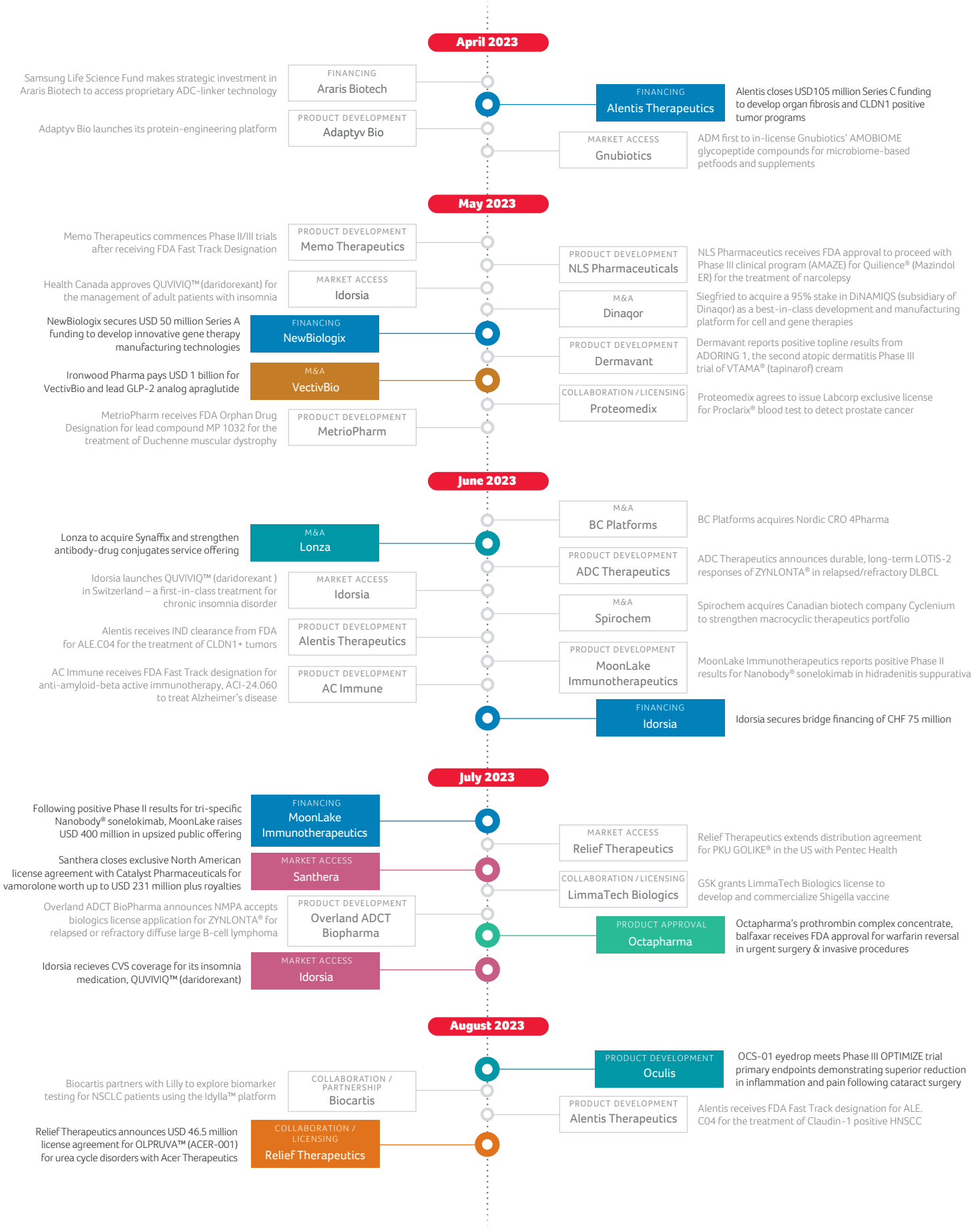
This transformational joint venture provides Vifor Pharma direct access to dialysis patients, facilitating the product distribution and recruitment for clinical development. It transformed the company from Glattbrugg rapidly into a global nephrology corporation. Such vertical integration is a role model for the convergence of different life sciences sectors.

Werner Arber, Swiss microbiologist and geneticist, won the 1978 Nobel Prize in Physiology or Medicine for his discovery of restriction endonucleases. His groundbreaking research in the field of molecular genetics was instrumental in the development of biotechnology.

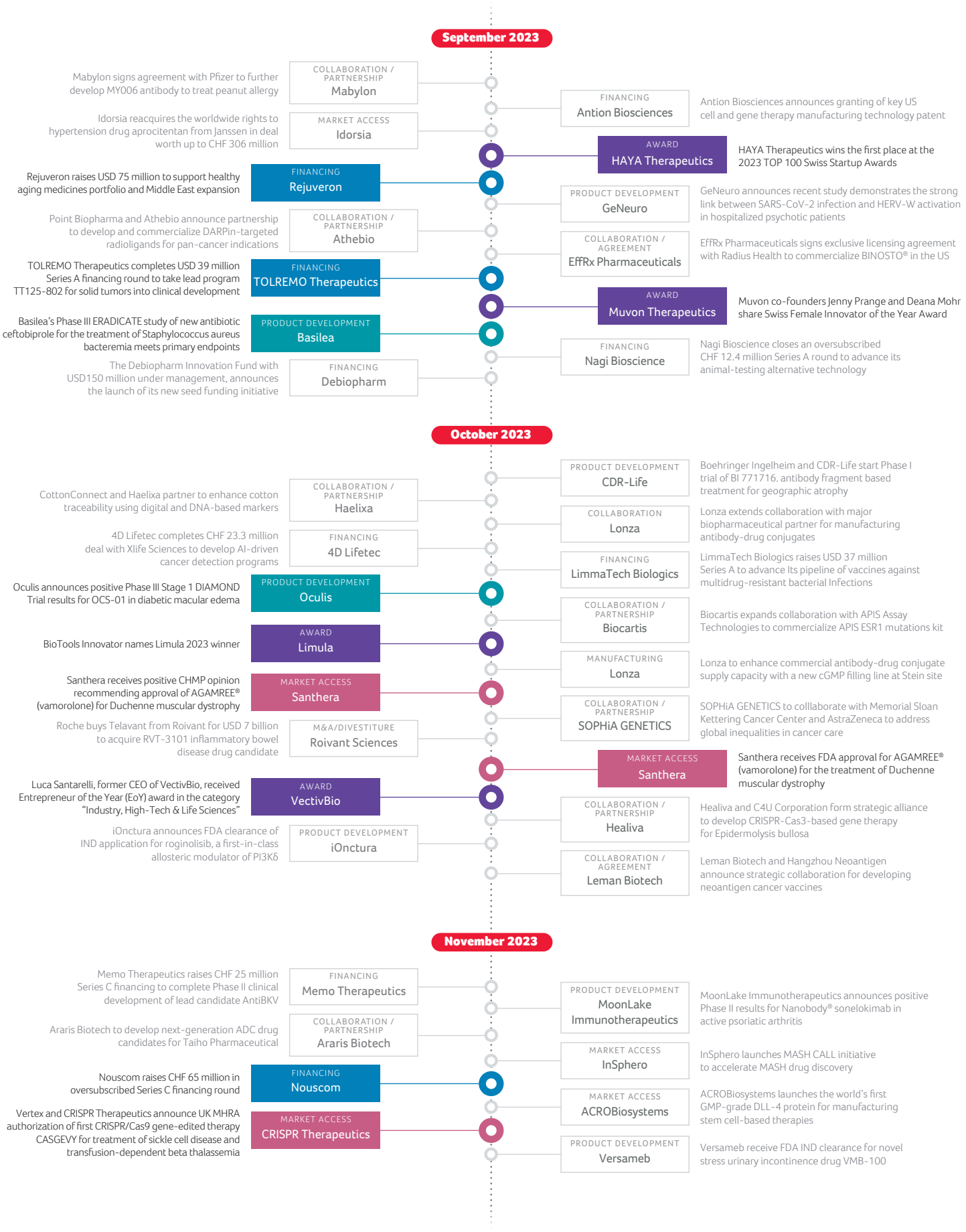
Find more info at swissbiotech.org/success-stories

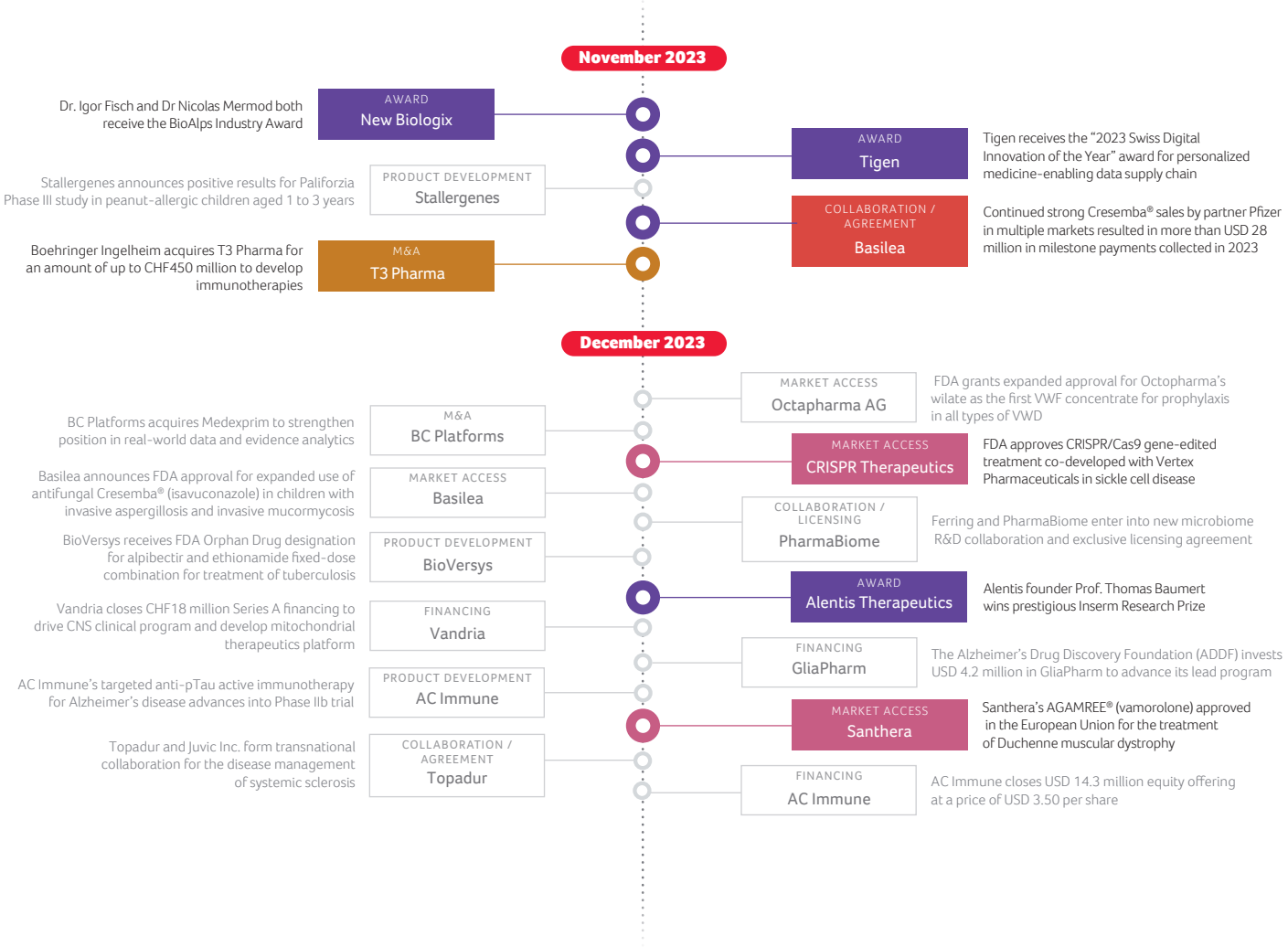
Swiss biotech events of 2023




April 2023
Samsung Life Science Fund makes strategic investment in Araris Biotech to access proprietary ADC-linker technology
FINANCING
Araris Biotech
Adaptyv Bio launches its protein-engineering platform
PRODUCT DEVELOPMENT
Adaptyv Bio
FINANCING
Alentis Therapeutics
Alentis closes USD105 million Series C funding to develop organ fibrosis and CLDN1 positive tumor programs
MARKET ACCESS
Gnubiotics
ADM first to in-license Gnubiotics' AMOBIOME glycopeptide compounds for microbiome-based petfoods and supplements
May 2023
Memo Therapeutics commences Phase II/III trials after receiving FDA Fast Track Designation
PRODUCT DEVELOPMENT
Memo Therapeutics
Health Canada approves QUVIVIQ™ (daridorexant) for the management of adult patients with insomnia
MARKET ACCESS
Idorsia
NewBiologix secures USD 50 million Series A funding to develop innovative gene therapy manufacturing technologies
FINANCING
NewBiologix
Ironwood Pharma pays USD 1 billion for VectivBio and lead GLP-2 analog apraglutide
M&A
VectivBio
MetrioPharm receives FDA Orphan Drug Designation for lead compound MP 1032 for the treatment of Duchenne muscular dystrophy
PRODUCT DEVELOPMENT
MetrioPharm
PRODUCT DEVELOPMENT
NLS Pharmaceuticals
NLS Pharmaceutics receives FDA approval to proceed with Phase III clinical program (AMAZE) for Quilience® (Mazindol ER) for the treatment of narcolepsy
M&A
Dinaqor
Siegfried to acquire a 95% stake in DiNAMIQS (subsidiary of Dinaqor) as a best-in-class development and manufacturing platform for cell and gene therapies
PRODUCT DEVELOPMENT
Dermavant
Dermavant reports positive topline results from ADORING 1, the second atopic dermatitis Phase III trial of VTAMA® (tapinarof) cream
COLLABORATION / LICENSING
Proteomedix
Proteomedix agrees to issue Labcorp exclusive license for Proclarix® blood test to detect prostate cancer
June 2023
Lonza to acquire Synaffix and strengthen antibody-drug conjugates service offering
M&A
Lonza
Idorsia launches QUVIVIQ™ (daridorexant) in Switzerland – a first-in-class treatment for chronic insomnia disorder
MARKET ACCESS
Idorsia
Alentis receives IND clearance from FDA for ALE.C04 for the treatment of CLDN1+ tumors
PRODUCT DEVELOPMENT
Alentis Therapeutics
AC Immune receives FDA Fast Track designation for anti-amyloid-beta active immunotherapy, ACI-24.060 to treat Alzheimer's disease
PRODUCT DEVELOPMENT
AC Immune
M&A
BC Platforms
BC Platforms acquires Nordic CRO 4Pharma
PRODUCT DEVELOPMENT
ADC Therapeutics
ADC Therapeutics announces durable, long-term LOTIS-2 responses of ZYNLONTA® in relapsed/refractory DLBCL
M&A
Spirochem
Spirochem acquires Canadian biotech company Cyclenium to strengthen macrocyclic therapeutics portfolio
PRODUCT DEVELOPMENT
MoonLake Immunotherapeutics
MoonLake Immunotherapeutics reports positive Phase II results for Nanobody® sonelokimab in hidradenitis suppurativa
FINANCING
Idorsia
Idorsia secures bridge financing of CHF 75 million
July 2023
Following positive Phase II results for tri-specific Nanobody® sonelokimab, MoonLake raises USD 400 million in upsized public offering
FINANCING
MoonLake Immunotherapeutics
Santhera closes exclusive North American license agreement with Catalyst Pharmaceuticals for vamorolone worth up to USD 231 million plus royalties
MARKET ACCESS
Santhera
Overland ADCT BioPharma announces NMPA accepts biologics license application for ZYNLONTA® for relapsed or refractory diffuse large B-cell lymphoma
PRODUCT DEVELOPMENT
Overland ADCT Biopharma
Idorsia recieves CVS coverage for its insomnia medication, QUVIVIQ™ (daridorexant)
MARKET ACCESS
Idorsia
MARKET ACCESS
Relief Therapeutics
Relief Therapeutics extends distribution agreement for PKU GOLIKE® in the US with Pentec Health
COLLABORATION / LICENSING
LimmaTech Biologics
GSK grants LimmaTech Biologics license to develop and commercialize Shigella vaccine
PRODUCT APPROVAL
Octapharma
Octapharma's prothrombin complex concentrate, balfaxar receives FDA approval for warfarin reversal in urgent surgery & invasive procedures
August 2023
Biocartis partners with Lilly to explore biomarker testing for NSCLC patients using the Idylla™ platform
COLLABORATION / PARTNERSHIP
Biocartis
Relief Therapeutics announces USD 46.5 million license agreement for OLPRUVA™ (ACER-001) for urea cycle disorders with Acer Therapeutics
COLLABORATION / LICENSING
Relief Therapeutics
PRODUCT DEVELOPMENT
Oculis
OCS-01 eyedrop meets Phase III OPTIMIZE trial primary endpoints demonstrating superior reduction in inflammation and pain following cataract surgery
PRODUCT DEVELOPMENT
Alentis Therapeutics
Alentis receives FDA Fast Track designation for ALE.C04 for the treatment of Claudin-1 positive HNSCC

Swiss biotech events of 2023





Please note that the above presented information is only a selection of publicly available information. We therefore cannot guarantee that all events are included in the above summary for 2023.

Contributors' profiles

Swiss Biotech Association
The Swiss Biotech Association has represented the interests of the Swiss biotech industry since 1998. 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 also collaborates with numerous partners and life science clusters globally under the brand Swiss Biotech™.
www.swissbiotech.org

EY
EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. Our Global Life Sciences Sector brings together a worldwide network of 23'000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.
www.ey.com/lifesciences

scienceindustries
scienceindustries is the Swiss business association of chemistry, pharma and life sciences. It supports around 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.
www.scienceindustries.ch

Swiss National Science Foundation
The Swiss National Science Foundation (SNSF) is Switzerland's foremost research funding agency. In accordance with its government mandate, the SNSF supports scientific research in all disciplines, from physics to medicine to sociology. Each year the best new projects are awarded around CHF 1 billion in total based on rigorous evaluation processes. The SNSF supported around 5'700 projects involving 21'000 researchers at year-end 2023.
www.snsf.ch

Swiss Federal Institute of Intellectual Property
The Swiss Federal Institute of Intellectual Property (IPI) is the federal center of competence for patents, trademarks, geographical indications, design, and copyright. Individuals and companies can register their inventions and creations with the IPI to protect them from being copied. In addition to this, the IPI informs the public about the IP rights system of protection. It also fulfils a political mandate in all areas of intellectual property in that it prepares legislation, advises the federal authorities, and represents Switzerland within international organizations and vis-à-vis other countries.
www.ige.ch

Biotechnet Switzerland
Biotechnet Switzerland helps industry access high-caliber competences in biotechnology from Swiss universities of applied sciences, universities, and research and technology organizations. Industrial partners including small, medium and large enterprises can rely on our proven expertise and outstanding infrastructure to support innovative research & development projects. We are also a premium partner to address continuing education needs.
www.biotechnet.ch

Swiss Academy of Engineering Sciences SATW
SATW is a network of engineering experts contributing to the progress and competitiveness of the Swiss economy. Positioning Switzerland in a leading role is one of the key goals of the academy, and we work to identify promising technologies and assemble the best experts to foster innovation. SATW is also the leading Swiss organization for encouraging young women to pursue a career in a technical field.
www.satw.ch

Swissmedic
Swissmedic, the Swiss Agency for Therapeutic Products, is the Swiss authority for the authorization and monitoring of therapeutic products (medicinal products and medical devices). The Agency is attached to the Federal Department of Home Affairs, is independently organized and managed, and has its own budget. Statements made in the Swiss Biotech Report represent the view of Swissmedic from the regulatory perspective.
www.swissmedic.ch

SIX
SIX Swiss Exchange operated by SIX, is the leading European exchange for companies from the Life Sciences sector, offering Swiss and international clients a comprehensive range of exchange services - listing, trading and post-trade solutions - from a single source. It is the fourth largest incumbent exchange in Europe in terms of both free float market capitalization and trading volume. With Sparks - the equity segment for small and medium-sized companies - the Swiss stock exchange is also the ideal place to list when it comes to growing your SME.
www.six-swiss-exchange.com

Switzerland Global Enterprise
Switzerland Global Enterprise (S-GE) is mandated by the Swiss government for export and investment promotion. In its role as a center of excellence for internationalization, its mission is to help Swiss SMEs develop new potential for their international business and to strengthen Switzerland as an economic hub. S-GE assists foreign companies in evaluating Switzerland as a business and technology location, and together with its cantonal partners helps companies during the entire site selection and incorporation process.
www.s-ge.com

Guest Contributor – Citeline
Citeline (a Norstella Company) powers a full suite of complementary business intelligence offerings to meet the evolving needs of health science professionals to accelerate the connection of treatments to patients and patients to treatments. Our global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts and more.
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The contributors have been listed in order of appearance in this report

"Advances in biotechnology require innovative approaches from regulators, ensuring that new instruments such as international work-sharing procedures and the use of AI or Real World Evidence (RWE) data, generate benefits for patients."

Jörg Schläpfer
Swissmedic

"Switzerland's attractiveness as a partner and as a business location is a key factor in its success. Despite its small size, Switzerland ranks eighth in the world in terms of patent output."

Christian Moser Nikles
Swiss Federal Institute of Intellectual Property

"Only by working across borders and deploying biotechnological and technological solutions will Europe be able to achieve secure supply chains. Swiss organizations could play a pivotal role in supporting and facilitating connections."

Hans-Peter Meyer
SATW

"Innovative contributions from research organizations within Biotechnet are enabling more sustainable biotechnology to support the Swiss and international economy while considering the health of our planet."

Laura Suter-Dick
Biotechnet

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