

Trends and Developments

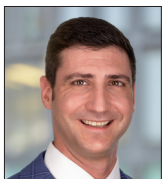
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Loyens & Loeff

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and Switzerland provide its clients with a team of experts who have a thorough understanding of their businesses. Additionally, Loyens & Loeff has a dedicated and multidisciplinary life sciences & healthcare team working closely with venture capital funds, private equity and strategic investors.

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Deal Activity and Market Insights *Deal activity in 2023*

In general, M&A activity in Switzerland has seen an overall decrease in 2023. However, M&A activity in the Swiss healthcare sector has remained strong and increased in 2023 compared to the previous year, both in terms of number of deals and value.

Private equity and venture capital investors have been particularly active in healthcare M&A. In 2023, more than 50% of the M&A deals in the Swiss healthcare industry involved either private equity or venture capital investors. Whereas in the past, private equity investors mainly focused on healthcare service providers, their focus shifted in 2023 towards investments in pharmaceutical and medtech companies. In contrast, venture capital investors continued to focus on the Swiss biotech sector. Beside private equity and venture capital, larger pharmaceutical companies were heavily involved in the Swiss M&A market: the three Swiss pharmaceutical companies Roche, Novartis and Lonza were involved in almost half of the ten largest M&A deals by value in the Swiss healthcare industry.

Multifaceted healthcare industry in Switzerland

The Swiss healthcare industry consists of a wide variety of companies in terms of sectors, size, stage of development, activities and organisational structure. Healthcare targets range from early-stage start-ups, through numerous small and mid-market companies, to large, fully integrated pharmaceutical companies. This variety of targets results in high diversity in terms of deal structuring, including in terms of scope of due diligence, sophistication of deal documentation, compensation (including, increasingly, earn-out provisions), governance and protection.

Investments in early-stage start-ups are usually minority equity investments in which new preferred shares are issued through a capital increase. It is common to thereby grant to the new investors preferential rights with respect to dividend and liquidation proceeds, anti-dilution protection, and information and governance rights.

In certain sectors, in particular pharmaceuticals, biotech and medtech, early-stage financing may be secured by entering into development and licensing agreements with pharmaceutical companies and later exiting by sale to private

equity or strategic investors. Where only certain products are targeted by an investor's interest, asset deals by way of carve-out may be implemented.

Outlook

Besides the overall slowdown of the economic growth in Switzerland, 2023 has been marked by numerous challenges, including high inflation, rising interest rates, the strength of the Swiss franc, turbulence in the financial sector and ongoing wars. However, with an increase in the number and value of deals compared to 2022, M&A activity in the Swiss healthcare industry remains strong. The outlook for M&A activity in the Swiss healthcare industry through 2024 remains positive. An increase in transaction activity is expected assuming more certainty with respect to the economy and regulatory landscape.

Key Drivers in Swiss Healthcare M&A

Digitalisation

The use of new technologies is a key driver of M&A activity in the Swiss healthcare industry. Digitalisation and the emerging new fields of applications of artificial intelligence (AI) are driving companies to acquire respective capabilities.

Between 2018 and 2023, almost half of the Swiss transactions by healthcare providers were directly or indirectly linked to digitalisation. Diagnostic labs, medical suppliers and technology companies in the field of ophthalmology were particularly targeted. Additionally, it is recognisable that hospitals are trying to achieve digital innovation through M&A transactions, eg, in the area of healthcare ICT. This enables hospitals to meet current challenges such as budget restraints and staff shortages. Potential applications include remote patient monitoring and care, but innovation may also be required for

an efficient use of newly introduced electronic patient records.

Large pharmaceutical companies have recognised possible applications of AI to accelerate innovation and transform drug discovery and development. Pharmaceutical companies still appear to be focusing on collaborations and partnerships to assess the potential of AI applications rather than acquiring or building in-house capabilities. In fact, the proportion of M&A activity related to expanding AI capabilities in drug discovery is still relatively small, but has increased in recent years. Increased experience and confidence in the use of AI is likely to have additional positive impact on M&A activity in the healthcare sector.

Investments in R&D-focused companies

R&D plays an important role in the healthcare industry. A well-balanced R&D pipeline with respect to new drugs and medtech products is essential for companies' long-term success. It is therefore not surprising that M&A activity is often driven by investments in R&D-focused companies, especially in Switzerland, where many attractive R&D-focused companies are available as potential targets.

With the renowned Federal Institutes of Technology in Zurich (ETH) and Lausanne (EPFL), Switzerland is home to many start-ups in the biotech and medtech sectors. The ETH has traditionally been very strong in the fields of biotech and pharmaceuticals. In 2023 alone, eight start-ups in these fields were founded as ETH spin-offs. Spin-offs with ETH, EPFL or other Swiss universities are usually subject to specific contractual arrangements with such academic institutions and these institutions may hold equity or have rights to acquire equity in spin-offs.

A particular feature of M&A transactions involving R&D-focused companies is the widespread use of earn-out clauses, especially when the companies are at a relatively early stage. The earn-out is usually a performance-related, variable purchase price component, which is paid in addition to a fixed base price. The performance indicators can be defined by the parties. Financial performance indicators, such as net income or operating cash-flow, are frequently used. This way, the earn-out depends on actually generated revenues and can thus compensate for uncertainties with regard to future returns.

Portfolio optimisation

In the last few years, there was a recognisable tendency for fully integrated pharmaceutical companies to focus on their core business and to divest non-core assets. For example, Novartis has completed its spin-off of its generics and biosimilars business Sandoz in 2023 as part of its strategy to fully focus on its core competencies in the field of innovative medicines. The proceeds from these divestments will then be used for the expansion of the core business, eg, through respective M&A transactions. Large pharmaceutical and life science companies are expected to continue following this strategy in the years to come.

Regulatory and Other Developments

Swiss adaption to the European regulation governing medical devices

Since the Mutual Recognition Agreement between the European Union (EU) and Switzerland was not updated in 2021, Switzerland is now considered a “third country” under the EU regulations. Thus, Swiss registrations/authorisations are not recognised in the EU any more, and vice versa. The Swiss Federal Council tried to mitigate the negative consequences of this non-recognition by aligning the Swiss legisla-

tion on medical devices and in vitro diagnostics with the European Union Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) and imposing certain additional measures. For example, medical devices with an EU conformity assessment (CE marking) are unilaterally recognised in Switzerland. These legislative developments may be relevant to M&A activity in the field of medical devices. For example, if a non-European company acquires a Swiss manufacturer of medical devices with the respective authorisation(s) under Swiss law, this does not suffice for the target to be recognised as manufacturer or distributor in the EU. The appointment of an authorised representative or other authorisations may be necessary under EU regulation for such purpose. Generally, Swiss medtech companies have addressed this topic in a timely manner and implemented the measures required to be compliant under EU law.

Revision of the Swiss Data Protection Act

On 1 September 2023, the new Swiss Data Protection Act (revDPA) came into force. The aim of the revDPA was, on the one hand, to modernise Swiss data protection law and, on the other hand, to bring it into line with EU law, in particular with the EU General Data Protection Regulation (GDPR). Companies that were already compliant with GDPR had only minimal adaptations to implement under the revDPA. The revDPA may be relevant in the context of Swiss healthcare M&A if the business of a target company involves processing of Swiss personal data or generally processing personal data in Switzerland. It is noted that the transfer and processing of personal data in the context of a due diligence exercise may trigger obligations and restrictions under the revDPA.

Failure to comply with the revDPA may result in criminal sanctions against the individuals involved.

EU Artificial Intelligence Act (EU AI Act)

Artificial Intelligence (AI) is making its way into the healthcare sector, in particular in the area of pharmaceuticals where AI is used in research and development, including for better processing of large amounts of data and quicker evaluation of different combinations of active ingredients. In medical treatment, AI increasingly comes into use in medical devices, either as standalone software or integrated into hardware components.

On 8 December 2023, the EU Commission published a draft of the AI Act, the first-ever legal framework on AI that aims to provide AI developers, deployers and users with clear requirements and obligations regarding specific uses of AI. Like the GDPR, the AI Act will have an extraterritorial reach and will not only be applicable to a Swiss company that makes an AI system available in the EU market but will also apply if the output generated by the AI system of a Swiss company is used in the EU. Once it is formally adopted, it is expected to be fully applicable after two years.

There is currently no specific AI systems regulation in the Swiss legal system. On 22 November 2023, the Federal Council has instructed the Federal Department of the Environment, Transport, Energy and Communications to prepare a report on the possible regulatory approaches to AI systems for Switzerland that are particularly compatible with the EU AI Act and the Council of Europe's AI Convention, which should create the basis to issue a concrete mandate for an AI regulatory proposal in 2025.

Foreign direct investment screening

Currently, Switzerland does not have any general foreign direct investment (FDI) screening mechanisms in place. However, certain regulatory requirements apply to certain industries and sectors, for example, banking and real estate. Several additional business activities require a governmental licence, and the licensing conditions include specific requirements regarding foreign investors. Examples of such business activities are aviation, telecom, radio and television, and nuclear energy.

Mid December 2023, the Federal Council adopted the dispatch on a new Investment Screening Act. Under the new draft legislation, investment screening is intended to only apply when a foreign state-controlled investor takes over a domestic company that operates in a particularly critical area, such as health infrastructure. This means that the takeover of Swiss hospitals and companies active in the research, development, production or production or distribution of medical products, devices or other equipment by a foreign state-controlled investor would need an approval subject to reaching certain turnover thresholds. The proposal is still subject to the approval of the Swiss parliament.