Healthcare M&A 2021

Contributing editors
Jason Zemmel, Philippa Chatterton and Charlotte Beston

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Getting The Deal Through

Publisher
Tom Barnes
tom.barnes@lbresearch.com

Subscriptions
Claire Bagnall
claire.bagnall@lbresearch.com

Senior business development manager
Adam Sargent
adam.sargent@gettingthedealthrough.com

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

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Andreas Rötheli, Stephan Erni, Sevan Antreasyan and Federico Trabaldo Togna

Lenz & Staehelin

TRANSACTIONAL ISSUES

Structures

1 What is the typical structure of a healthcare-related business combination in your jurisdiction?

The Swiss healthcare market is composed of a rich variety of companies in terms of size, organisation, development stage (research and development (R&D) and revenue-generating companies) and activities (drug products, medical devices, pharma and biotechnology). Many types of structures are used for healthcare-related business combinations. The choice of one type over another will mainly depend on the nature of the companies involved in the combination, as well as on the scope of the contemplated transaction.

Where the target is a company at an early stage of development (eg, companies at pre-clinical stage or undertaking clinical trials in Phase 1), the business combination will usually take the form of a minority equity investment in the target by one or more larger companies or financial investors. The investors will subscribe for new shares in the target in the context of a capital increase decided at the shareholders' meeting of the target or by its board of directors, based on a pre-existing authorisation of the shareholders' meeting. The new shares will generally benefit from preferences as regards dividend distributions and liquidation proceeds, which will also apply in the context of an exit. In the context of the transaction, the shareholders' meeting of the target will generally elect a representative of the lead investor or investors to the board of directors, whereas other investors may be entitled to appoint observers to the board. Depending on the cash burn rate of the target, various financing rounds will be completed before an exit is implemented with, at each new financing round, the creation of a new class of shares with financial preferences over the previously issued shares.

Where the acquirer is interested in acquiring an entire business (eg, companies undertaking clinical trials in Phase 2 or 3 or revenue-generating companies), the combination will most often be structured as a purchase of the entire share capital of the target. On the contrary, if the acquirer intends to acquire part of the business (eg, activities relating to a specific drug product or divestment of an entire business unit by the seller), the combination will most often occur through an asset transfer to the acquirer (or in two steps: asset transfer to a newly formed subsidiary of the seller; and sale of the shares in such new subsidiary to the acquirer). If the asset transfer is governed by the Swiss Merger Act (SMA), it occurs by operation of law at the time of the registration of the transfer in the relevant commercial register. The transfer agreement and its enclosures are, in this case, filed with the commercial registry and publicly available. On the contrary, if the SMA is specifically excluded by the parties, each asset within the scope of the combination has to be transferred individually. These transfers enable the preservation of confidentiality about the transaction as no filing is completed with public authorities. The choice of one type of transfer over the other mainly depends on the nature and quantity of the assets that are to be transferred, as well as the confidentiality requirements of the parties.

In addition, other types of transactions or contracts are used (and may involve aspects of business combinations). For example, if the combination relates to a drug product in early development (ie, not yet approved by regulatory authorities), the parties may in a first step cooperate to further the development under a licence and development agreement. Such agreements may involve the acquisition of shares of the company developing the drug product upon reaching certain milestones.

Timeline

2 How long do healthcare business combinations usually take, and what factors tend to be most significant in determining the timing to completion?

The time required to complete a healthcare-related business combination will depend on various factors such as the complexity of the combination or the conditions precedent to closing agreed upon by the parties. An equity investment will most often take less time to carry out than a share purchase, which in turn will be less burdensome than an asset transfer. The completion of a combination will generally require two to six months.

Representations and warranties

3 What are the typical representations and warranties made by a seller in healthcare business combinations? What areas would be covered in more detail compared with a more general business combination?

Sellers make extensive representations and warranties in the areas of intellectual property (IP) rights and compliance with regulations governing the healthcare industry.

With respect to IP rights, sellers usually agree to represent that:

- the sold business, as it is contemplated to be conducted in the future, especially with respect to the commercialisation of drug products under development, will not breach third parties' IP rights; and
- the seller has implemented reasonable measures to protect IP rights and trades secrets material to the sold business.

Such measures will typically consist in the entry into employment agreements with employees and confidentiality agreements with third parties, which provide for an automatic transfer to the company of IP rights developed by each employee or third party while performing their activities in favour of the seller.

With respect to regulatory matters, sellers usually represent that:

- clinical trials relating to drug products or medical devices within the scope of the combination have been carried out in compliance with applicable regulations, with a specific focus on data protection regulations; and

- the development of these products or devices has been made in compliance with professional standards applicable to the pharmaceutical industry such as the Good Laboratory Practice, Good Clinical Practice and Good Manufacturing Practice.

If the combination relates to biosimilar or generic products, sellers also frequently represent that, except as for specific disclosures made to the buyer or general development risks for products under development, there are no circumstances that are reasonably expected to prevent the successful development of such products and filings with the relevant regulatory authorities (ie, the Food and Drug Administration or European Medicines Agency). Owing to recent changes in the European regulatory framework governing medical devices that will be fully effective as from May 2020 (and May 2022 as regards in vitro medical devices), sellers of businesses developing or manufacturing medical devices agree to represent that the medical devices within the scope of the combination, as well as, more generally, the target company, comply with these new regulations. If this is not the case at the time of the combination, buyers generally agree that the sellers' representation in this respect be limited to a confirmation that all measures required to comply with the new European regulations before the end of the relevant transitional period have been or are in the process of being implemented.

On the contrary, in the context of combinations in the biosimilar or generic industry, sellers most often refuse to make any representation or warranty for the documentation relating to the strategy on freedom to operate.

Representations and warranties given in the context of equity investments generally have a narrower coverage than those given with respect to outright acquisitions, considering that equity investors do not take control over the target and that targets are at an earlier stage of development.

Due diligence

4 | Describe the legal due diligence required in healthcare business combinations. What specialists are typically involved? What searches would typically be carried out?

The legal due diligence mainly focuses on contracts (licence, IP assignment, R&D, consultancy, distribution, etc), IP rights ownership and validity, regulatory aspects, confidentiality, data protection and business practices.

Owing to a recent extension of the perimeter of the criminal offence of bribery in the private sector in Swiss criminal law, certain commercial practices of companies having extended business relationships with medical professionals (eg, incentives paid to medical professionals and certain form of sponsorship) may be at risk of being unlawful. Consequently, the scope of the legal due diligence often encompasses a review of the business practices of the target with particular attention on these recent legislative developments.

Risk exposure

5 | If due diligence is not correctly undertaken, what specific healthcare risks might buyers inherit?

The risks associated with undiscovered legal issues will often materialise in exposure to civil or administrative liabilities (eg, patent or data protection related litigations), but also criminal proceedings (eg, criminal liability of the company for bribery in the private sector).

Specific diligence issues

6 | How do buyers typically approach specific material diligence issues in healthcare business combinations?

The buyer generally requires that material issues identified during the due diligence process be addressed and solved by the seller prior to the completion of the combination. If the seller cannot entirely remedy such issues prior to closing or if the corrective measures implemented prior to closing are not, by nature, sufficient to exclude the exposure of the buyer, specific indemnities are included in the transactional agreement. In the context of equity investment, the indemnification usually takes the form of the issuance of new shares (at nominal value) to the indemnified investor, rather than a cash payment.

Conditions before completion

7 | What types of pre-closing conditions are most common in healthcare business combinations?

The buyer will often require that employees material to the business, such as management and scientific teams, and key counterparties (eg, material licensors, R&D partners or manufacturers) confirm that they will not oppose the transfer of their relationship to the buyer (for asset transfers) or terminate their agreement with the sold company (for other types of transactions).

If the seller undertakes to continue providing services to the buyer after closing, the parties generally include, as a pre-closing condition, the entry into the relevant service agreements (eg, transitional service agreement or clinical studies, regulatory, safety and submission support services agreement). For equity investments, the entry into a shareholders' agreement among the shareholders of the target, containing customary investors' protective provisions (eg, investors' consent for specific decisions) and transfer restrictions (eg, tag and drag along rights) is a standard condition precedent to closing.

Pre-closing covenants

8 | What sector-specific covenants are usually included to cover the period between agreement and completion in healthcare business combinations?

It is typical for the parties to covenant that best efforts will be used in collecting waivers for change of control termination rights or negotiating the split of agreements not exclusively relating to the transferred business (eg, a master service agreement with SoWs relating to drug products that are transferred and other products that are not transferred to the buyer).

Sellers may also covenant to involve buyers in filings that have to be completed with regulatory authorities between signing and closing, subject to gun-jumping restrictions.

The implementation of measures aimed at remedying issues identified during the due diligence process are also typical sellers' pre-closing covenants.

W&I insurance

9 | What specific provisions are commonly seen in warranty and indemnity insurance policies for healthcare business combinations compared with general business combinations?

Although insurance companies offer W&I insurance coverage in a variety of business combinations, namely when private equity sponsors are involved, Swiss M&A practice does not yet foresee W&I insurance in healthcare business combinations as an obvious solution for a better allocation of risks.

Specific documentation

10 Is there any sector-specific documentation typically used in healthcare business combinations? Does this differ depending on the structure of the transaction?

In the context of asset transfers, the assets pertaining to the transferred business have to be transferred by the seller to the buyer. Where regulatory authorisations and IP rights are transferred, specific filings with regulatory authorities (eg, the Food and Drug Administration (FDA), European Medicines Agency (EMA) or Swissmedic) or administrative bodies (eg, IP offices) have to be undertaken to register the relevant transfers. For this purpose, the parties execute separate documents, such as assignment declarations or forms, to avoid filing the entire contractual documentation. On the contrary, in business combinations structured as share transfers, there is no particular documentation that needs to be established.

Post-completion undertakings

11 Which post-completion undertakings are common in healthcare business combinations? Which undertakings are common?

Buyers often desire to secure that sellers will not, in the future, be involved in businesses carrying out activities in the same field as the transferred business. Accordingly, sellers most often accept to be bound by a non-compete undertaking, limited to the field in which the transferred business is active and for a certain period. Sellers frequently undertake not to solicit employees of the buyer after closing, which is also generally limited to a certain period. If the seller only transfers part of its activities, the buyer may also be bound by a non-solicitation undertaking with terms similar to the undertaking of the seller.

REGULATION

Laws and regulations

12 What are some of the primary laws and regulations governing or implicated in healthcare-related business combinations? Are healthcare assets subject to specific regulation that would be material in a typical transaction? Is law and regulation of healthcare national or subnational?

Whereas the Swiss legislative framework does not contain specific regulations governing the transactional aspects of healthcare-related business combinations, Switzerland has a comprehensive regulatory framework governing the activities carried out by healthcare companies that has to be taken into account in the context of healthcare-related business combinations. Most of these regulations are enacted at the level of the Swiss federal state. Nevertheless, in specific areas of the pharmaceutical industry, the federal legislator delegates to the Swiss cantons certain legislative competences, which may be exclusive (ie, cantonal regulation excluding federal regulation) or complementary (ie, cantonal regulation complementing federal regulation). Accordingly, Swiss cantons have, inter alia, the exclusive competence to regulate public hospitals or health institutions, whereas a complementary competence of the cantons exists in relation to the authorisation to practise medical professions.

The main rules governing the healthcare industry in Switzerland are as follows:

- the Swiss Federal Act on Medicinal Products and Medical Devices (TPA), which provides for a general regulatory framework applicable to medical products and medical devices;
- the Swiss Federal Ordinances on Drug Products, on Authorisations in the Field of Drug Products and on Requirements relating to Marketing Authorisations of Drug Products, which implement the provisions of the TPA relating to drug products and regulate in detail the process and requirements for the various authorisations applicable to drug products (eg, marketing authorisation, manufacturing authorisation, import or export authorisation);
- the Swiss Federal Medical Devices Ordinance (MedDO), which implements the provisions of the TPA relating to medical devices and regulates in detail the conditions for market launch and conformity assessment of medical devices;
- the Swiss Federal Act on Medical Professions and its implementation ordinances and cantonal regulations, which regulate the medical professions and set forth the conditions for practicing these professions;
- the Swiss Federal Act on Research involving Human Beings (HRA) and the Swiss Federal Ordinance on Clinical Trials in Human Research (ClinO), which regulate the undertaking of clinical trials on human beings; and
- the Swiss Federal Act on Narcotics and Psychotropic Substances (NPSA), which governs, inter alia, the use of narcotics and psychotropic substances in the healthcare industry; the NPSA was recently revised, introducing a new provision (article 8a) that enables the Swiss Federal Office of Public Health to authorise scientific pilot tests related to the use of cannabis products.

Owing to a recent strengthening of the European regulation governing medical devices, the Swiss legislative framework applicable to this field is in the process of being entirely revised to comply with the new European provisions. These amendments essentially relate to the TPA and HRA, as well as the MedDO and ClinO, and have entered into effect at the end of 2020 (for medical devices) and will enter into effect in 2022 (for in vitro medical devices). Until 26 May 2021, the Mutual Recognition Agreement between Switzerland and the EU allowed for facilitated trade of medical devices between these jurisdictions, in particular by enabling Swiss/EU medical devices companies to carry out conformity assessments for the EU/Swiss market in accordance with the technical regulations applicable in their jurisdiction and to place the products on the market of the other jurisdiction without further controls. At the time of this writing, this Mutual Recognition Agreement has not been extended – meaning that Switzerland will be considered, as of 26 May 2021, as a third country for the purposes of the EU Medical Device Regulation – and a transitional solution (eg, allowing a Swiss medical devices company to place medical devices in the EU without the need to designate an authorised representative) has not yet been confirmed.

Consents, notification and filings

13 What regulatory and third-party consents, notifications and filings are typically required for a healthcare business combination?

The structure of a combination is an important element to determine whether regulatory and third-party consents, notifications and filings are required to complete a transaction.

In the context of share purchases, the completion of the transaction does not result in a change in the identity of the holder of the regulatory approvals or authorisations. Accordingly, other than the collection of third-party consents under change of control provisions contained in certain agreements, no specific filing or notification has to be completed as a result of the combination.

Where the combination is structured as an asset transfer, regulatory authorisations or approvals pertaining to the transferred business (eg, sponsorship for clinical trials and marketing authorisations) have to be transferred to the buyer, the approval of the relevant regulatory authorities being required to complete such action. The acquirer will

thus file an administrative form requiring the transfer of the relevant authorisation or approval, generally with Swissmedic, to which it will enclose an assignment declaration signed by the seller. It is worth mentioning that, under the TPA, marketing authorisations will only be issued if, inter alia, the applicant holds, at the time of the issuance, the required operations-related authorisations (eg, authorisation to manufacture, import or trade) and meets the quality control requirements. As the conditions required for the issuance of a marketing authorisation have to be fulfilled at any time, Swissmedic will only approve the transfer of a marketing authorisation if, together with the other conditions being fulfilled, the buyer holds the required operations-related authorisations. It should be further noted that, although the sponsorship will, at the end of the process, be taken over by the buyer, there will be no formal transfer of sponsorship, but rather the issuance by Swissmedic of a new authorisation in favour of the buyer. The taking over of the clinical trial by the new sponsor will also have to be approved by the relevant cantonal ethics committee, which is also competent to authorise the undertaking of clinical trials, and study subjects will be informed of such change. Finally, operations-related authorisations cannot be transferred and the issuance of new authorisations has to be requested by the buyer.

Ownership restrictions

14 | Are there any restrictions on the types of entities or individuals that can wholly or partly own healthcare businesses in your jurisdiction?

Whereas such restrictions exist in the aviation or banking industries, Swiss legislation does not contain any specific restriction on the types of entities or nationality of individuals that can wholly or partly own healthcare businesses in Switzerland.

Directors

15 | Are there any restrictions on who can be director of healthcare businesses in your jurisdiction?

No specific restrictions on who can be a director of a healthcare business are contained in Swiss law. That being said, directors are under a general obligation to carry out their function as director with care, which requires them to benefit from a sufficient knowledge of the industry and have a professional background enabling them to comply with this requirement.

Operating outside the home jurisdiction

16 | What domestic regulatory issues might arise for a company based in your jurisdiction operating healthcare businesses in other jurisdictions?

A healthcare company based in Switzerland but operating outside of Switzerland will have to comply with Swiss regulations as regards the activities it carries out in Switzerland and with the foreign legislation with respect to the activities completed abroad. In this respect, Swiss companies commercialising drug products outside of Switzerland have to obtain a specific authorisation from Swissmedic. For example, a company manufacturing drug products in Switzerland and exporting them to the European market will need to obtain a manufacturing authorisation and a specific authorisation to commercialise the drug products abroad from Swissmedic, as well as the appropriate marketing authorisation from the European Medicines Agency.

Failing the extension of the Mutual Recognition Agreement between the EU and Switzerland by 26 May 2021 (or a potential transitional solution), Swiss companies active in the medical devices sector will need to comply with the EU Medical Device Regulation applicable to third country companies.

Cross-border acquirers

17 | What domestic regulatory issues arise when the acquirers of healthcare businesses are based outside the jurisdiction?

In transactions structured as share purchases, the change of ownership in the shares of the acquired company does not have specific consequences in healthcare combinations, as compared to share purchases in other industries.

If the combination is structured as an asset transfer, the authorisations pertaining to the business will have to be transferred, where possible, to the buyer. In this respect, the acquirer has to consider, inter alia, the following limitations imposed by Swiss regulations:

- under the TPA, the holder of a marketing authorisation is required to have a registered address, registered office or a branch office in Switzerland; and
- under the ClinO, the sponsor of a clinical trial is required to have a registered address or be represented in Switzerland.

The parties may deal with these limitations in two different ways. If the parties decide to implement a clean cut at completion, the buyer generally sets up an affiliate in Switzerland prior to closing, which will take over the sponsorship of clinical trials and to which the relevant marketing authorisations will be transferred. Alternatively, the seller may agree to remain holder of certain marketing authorisations and sponsor of certain clinical trials for the benefit of the buyer, in which case the parties will govern their relationship with respect thereto in a separate service agreement.

Competition and merger control

18 | What specific competition or merger control issues may arise in healthcare business combinations?

There are no specific competition or merger control issues in the context of healthcare business combinations; however, merger control in Switzerland is based on turnover (except for insurance companies, banks and financial intermediaries). Two relatively high thresholds must be met in the business year prior to the combination:

- the concerned undertakings have reported an aggregate worldwide turnover of 2 billion Swiss francs or an aggregate turnover in Switzerland of 500 million Swiss francs; and
- at least two of the concerned undertakings have reported individually a turnover in Switzerland of 100 million Swiss francs.

In addition, a combination involving an undertaking that has been determined by the Swiss Competition Commission to be dominant on its market will, in principle, be subject to merger control, even if the thresholds are not met.

State and private healthcare combinations

19 | Are there any differences for healthcare business combinations if the transaction relates solely to businesses servicing private clients rather than state-funded clients?

Businesses servicing state-funded clients may be subject to some specific regulations or public procurement requirements. These would typically be part of the due diligence undertaken by the buyer.

FINANCING AND VALUATION

Financing

20 How do buyers typically finance healthcare-related business combinations?

The manner in which a combination is financed mainly depends on three factors: the liquidity available to the buyer, the type of transaction and the transaction value. When the combination is structured as an equity investment, the acquirer will pay the subscription price for the issuance of shares entirely through directly available cash. For other types of transactions, a financial investor will generally finance, to the maximum extent possible, the combination through the taking out of loans for ensuring the highest return on equity for the investors. Where the buyer is an industrial partner, it will generally focus on the synergies created through the combination rather than on the manner, in itself, in which the combination is financed. In such cases, a larger part of the purchase price may be paid through funds immediately available to the buyer or shares issued by the buyer.

Security

21 Describe the typical security structures in healthcare business combinations, including confirmation of any registration or notary fees in respect of the security documents.

The Swiss M&A market does not foresee specific security structures tailor-made for healthcare business combinations. However, in Swiss transactions, if the seller is an individual or a company with a limited financial strength, a portion of the purchase price (generally up to 20 per cent) is commonly deposited in escrow with a Swiss bank to cover possible indemnification claims of the buyer. This amount will be released in favour of the seller after the expiry of a period of 12 to 36 months (which generally corresponds to statute of limitation of the representations and warranties set forth in the contractual documents) if the buyer has not brought any such claim against the seller during this period.

Financial assistance

22 Are there any financial assistance rules that arise in healthcare business combinations?

There are no specific financial assistance rules in Switzerland that arise in healthcare business combinations.

Price and consideration

23 What pricing and consideration structures are typical in healthcare business combinations?

Where the target company generates revenues (eg, manufacturing and commercialising of drug products or medical devices), the pricing and consideration structures follow classical rules applied in other sectors of the industry.

If the target company is a R&D-focused company and does not generate revenues from its ordinary business activities at the time of the combination, the price mechanism will most often be structured with a first instalment being paid on closing and earn-out related payments becoming due upon the achievement of certain development, regulatory and commercial milestones relating to the products under development.

Typical milestones for drug products are the first patient dosing in a clinical trial, validation of the filing for a marketing authorisation by regulatory authorities, grant of marketing authorisation for a drug product by regulatory authorities, and first commercial sale (potentially differentiating between various indications) of the product on the market. The regulatory authorities generally comprise the European Medicines Agency and the the Food and Drug Administration. These types of combinations also typically foresee sales-related earn-outs after market launch.

Other payments may also be agreed upon in relation to development milestones, which vary depending on the concerned product and the development stage.

Enterprise value

24 How are healthcare-related businesses typically valued?

The valuation of a healthcare-related business carrying out revenue-generating activities follows the methods applied in other sectors (eg, discounted cash flow or multiple of EBITDA methods).

For R&D-focused healthcare businesses that do not generate revenues at the time of the combination, the typical valuation methods are the net present value and the risk adjusted net present value. Both methods use a discounted cash flow approach, which incorporates the expected net cash flows generated by the business, a discount rate for the development risks related to the products in development and the number of years in development and on the market for each product.

TAX

Typical issues in combinations

25 What are some of the typical tax issues in healthcare business combinations and to what extent do these typically drive structuring considerations? Are there certain considerations that stem from the tax status of a target?

One of the typical tax issues arising in healthcare business combinations relates to the valuation of IP rights in the context of transfer pricing between related companies. Whereas valuation of IP rights does not have any adverse tax effect in case of share purchase, as no change occurs in the ownership of the IP rights, the situation is different in the context of asset transfers. As there are no specific transfer pricing regulations under Swiss tax law, tax authorities may consider that a transaction between related parties does not satisfy the arm's-length principle. Therefore, part of the payment will be qualified as a constructive dividend, which will trigger tax adjustments and penalties. Furthermore, if, in the course of a tax assessment, the valuation of the IP cannot be properly determined (eg, because of inappropriate documentation), the taxable base is estimated at the discretion of the tax authorities.

The taxation of equity options granted to employees will typically also be a topic of concern in the context of R&D-focused healthcare business acquisitions structured by way of share purchases. Indeed, depending on how the equity incentive plan has been implemented, the exercise or cash-settlement of the employees' options in the framework of the transaction may influence the tax value of the options.

These issues will generally be taken into account in setting the consideration paid to the seller and addressed in the contractual documents, rather than have an actual impact on the structure of the combination (eg, choice between an asset transfer and a share purchase). It is also a common practice to seek tax authorities' written approval prior to entering into a transaction or setting-up an incentive plan. Rulings are available for almost every aspect of taxation. They are, in principle, valid as long as the facts set out in the ruling request remain true and correct and there is no change in law.

Furthermore, the Swiss tax framework has been recently revised to comply with international accepted standards. One of the main drivers of this change consisted in abolishing special Swiss tax regimes.

However, to maintain the attractiveness of the Swiss tax system, the tax revision was, inter alia, associated with the introduction of new measures particularly favourable to R&D-focused companies through the adoption of a 'patent box', pursuant to which specific intangible property income may be subject to reduced taxation under certain circumstances, and a 'super deduction' for R&D expenses made in Switzerland.

Tax risks for healthcare businesses

26 What are the typical tax risks that are associated with healthcare businesses? What measures are normally taken to mitigate those typical tax risks in healthcare business combinations?

Other than risks relating to the valuation of IP rights in the context of transfer pricing between related companies and to the taxation of equity options granted to employees, which are typical to healthcare-related transactions, the tax risks relating to combinations in this area are similar to those arising in transactions completed in other sectors of the industry (eg, tax neutrality of the restructuring or transaction, tax adjustments for the past years, tax compliance). These risks will be allocated between the parties in the transactional documents through classical tax representations and warranties or specific tax indemnities. It should, however, be noted that tax risks associated with R&D-focused companies (mainly corporate and withholding income tax) are generally limited to the extent that they do not generate revenues.

PUBLIC RELATIONS AND GOVERNMENT POLICY

Public relations

27 How do the parties address the wider public relations issues in healthcare business combinations?

In Swiss transactions, the public relations of the acquired business after closing are not commonly addressed by the parties in the transaction documents. They are generally limited to agreeing on the manner in which the transaction itself is presented to the public, typically by including press releases in the contractual documents.

Policy

28 How do parties address the wider political issues in healthcare business combinations?

Due to its pragmatic and consensus-oriented political environment, Switzerland is considered to be a stable country with limited political changes. Accordingly, the Swiss political situation is not a matter of concern in the context of healthcare business combinations and is not specifically addressed by the parties in the transaction documents.

With respect to changes in the regulatory framework, the parties generally adopt the following mechanism: if a legislative change has already been enacted at the time of the combination (but has not necessarily entered into force), the parties agree that the acquired business should be compliant with this new regulation at the time of completion or, if this cannot be completed by closing, that the measures required for such purpose are under implementation prior to closing.

The buyer generally bears the risks and costs associated with future changes to policy, government or regulatory framework applicable to the acquired business.

LENZ & STAEHELIN

Andreas Rötheli
andreas.roetheli@lenzstaehelin.com

Stephan Erni
stephan.erni@lenzstaehelin.com

Sevan Antreasyan
sevan.antreasyan@lenzstaehelin.com

Federico Trabaldo Togna
federico.trabaldotogna@lenzstaehelin.com

Route de Chêne 30
1211 Geneva 6
Switzerland
Tel: +41 58 450 70 00
Fax: +41 58 450 70 01

Brandschenkestrasse 24
8027 Zurich
Switzerland
Tel: +41 58 450 80 00
Fax: +41 58 450 80 01

www.lenzstaehelin.com

UPDATE AND TRENDS

Recent developments

29 What are the current trends, and what developments are expected in healthcare business combinations in your jurisdiction in the coming year?

The initial effects of the covid-19 pandemic affected the number and value of M&A deals carried out in Switzerland in 2020, which were lower as compared to 2019. That said, despite this initial reaction, 2020 revealed itself as a record year from a financing perspective for the Swiss healthcare market: in total, Swiss biotech companies managed to raise, in their financing activities, approximatively 4.3 billion Swiss francs (against 1.2 billion Swiss francs raised in 2019).

Investors targeting assets located in Switzerland continue to benefit from its diversity of healthcare companies composed, inter alia, of young R&D-focused start-ups generally emerging near to the Swiss Federal Institutes of Technology in Lausanne or Zurich, well-established revenue-generating SMEs located all over the Swiss territory that already develop and manufacture drug products and medical devices, as well as fully integrated pharmaceutical companies (FIPCOs) mainly established in the area of Basel and the Lake Geneva region.

The covid-19 pandemic has already increased public–private investments in companies developing diagnostic platforms, vaccines or drug product candidates focused on covid-19. Also, both FIPCOs and growth companies have followed the trend by investing massive amounts in the development or manufacturing of covid-19 related products, be it medical devices (eg, self-diagnostic tests), drug products or vaccines (eg, contract manufacturing activities). With governmental lockdowns that were repeatedly set up and removed, this pandemic

has made 2020 a year full of challenges for a large part of the Swiss healthcare industry: delays in recruitment of patients for clinical trials, longer regulatory authorisation processes and higher competition in access to financing are those that come to mind first. Nevertheless, the Swiss healthcare landscape remains remarkable in its diversity and the vitality of its R&D activities. Over the next years, Switzerland is expected to remain an inescapable hub for healthcare M&A owing to the following three drivers: continued investments in R&D-focused companies through equity investments or exit strategies, consolidation on the SMEs market and refocusing of FIPCOs on their core activities through large divestments from their non-core business units.

Coronavirus

30 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

As opposed to other jurisdictions, where export restrictions may have been decided on certain medical products or devices as a result of the pandemic, the Swiss government did not implement any initiative specifically focusing on the healthcare industry. The measures that have been enacted in Switzerland are rather general measures aimed at helping companies affected by the pandemic to survive throughout this hard period. These measures include, for example, an access to state guaranteed loan facilities for companies in dire need of working capital and an easier access to furlough scheme. These measures have largely benefited Swiss companies, regardless of their size, activities sector or location.

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