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Client Alert Commentary

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5 Tips for Navigating PIPEs in the European Life Sciences Sector

The challenging funding environment will likely prompt small- and mid-cap listed life sciences companies to seek financing through private investments in public equity.

Key Points:

- Traditional PIPEs involve sales of common stock, while structured PIPEs use convertible instruments. Combinations of common stock with convertible instruments and/or warrants are also possible.
- There is currently significant variation in terms and structures for European life sciences PIPEs across jurisdictions and among companies in the same sub-sectors.
- Understanding the regulatory landscape as well as the research, development, and (eventual) commercialization status of products in scope is essential to successfully structure and execute PIPEs and require appropriate due diligence.
- Conditions are ripe for a more consolidated PIPE market practice to develop, particularly given the SPAC experience and the emergence of experienced healthcare financial investors.

Small- and mid-cap life sciences companies typically draw upon two major fundraising sources: licensing and collaboration agreements (which have the potential to provide funding without dilution) and equity injections. While equity injections can involve contributions-in-kind from strategic partners, they more commonly take the form of private investments in public equity (PIPEs) by financial or strategic partners.

Historically, traditional PIPEs for listed companies have been conducted on an accelerated bookbuild (ABB) basis without a prospectus, with a book constructed from orders by institutional investors through the intermediation of a placement agent. PIPE ABBs can be announced with minimum allocations to one or more lead investors (subject to potential scale-back rights by the company). Outside of ABBs, traditional PIPEs can also be executed bilaterally through block trades directly with the investors, although for primary transactions, this approach is more common with strategic investors. Structured PIPEs are almost always executed through bilateral, direct placements with the investors, given the more bespoke nature of the instrument(s).

Listed companies and investors should consider the following points when looking to execute traditional and structured PIPEs in the second half of 2023 and beyond.

1. Standing Authorizations

Company law in most European jurisdictions grants preemptive subscription rights to existing shareholders in the event of a capital increase, which protects them against dilution. Company law does, however, permit shareholders to approve derogations, which can authorize capital increases without preemptive subscription rights, subject to certain limitations (either imposed by law or by market practice). The most common derogations permit capital increases at a set maximum percentage of share capital, placements to a defined category or categories of investors, and usually set a maximum discount to the prevailing share price or volume weighted average price (VWAP). Many of these authorizations are renewed from time to time, and they often provide discretion to the board of directors or the management board to negotiate and finalize a traditional or structured PIPE.

- In France, the typical standing authorizations are: (1) placements limited to qualified investors for up to 20% of the share capital, with a maximum issue price discount of 10% to the VWAP of the three trading days prior to the offer period; and (2) a placement limited to a special category not restricted by law as to amount, with the maximum percentage of share capital varying from company to company, from 20% to 60%, typically with a certain pricing floor. In this second category, PIPEs are limited to strategic partners of the company and/or investment funds (or similar) that have a track record of investing in the life sciences sector (or similarly defined), plus investment services intermediaries that can underwrite a placement to investors satisfying such conditions. These authorizations are typically sought every two years and granted to the board of directors.

- In Germany, company law permits stock corporations to seek standing authorizations from shareholders for capital increases that can be executed without preemptive subscription rights for up to 10% of the share capital, at a price discount that is not materially below the prevailing stock exchange price of the company's shares. These authorizations are typically sought every five years and granted to the management board, though the capital increase remains subject to the approval of the supervisory board. German stock corporations typically do not have other standing authorizations for capital increases without preemptive subscription rights that could be used for PIPEs; therefore, for a larger PIPE, shareholders would need to pass a specific resolution. Such resolution, however, would be subject to shareholder contestation rights, which could delay the implementation of the PIPE.

The significant variation across jurisdictions and among companies in the same sub-sectors is relevant to investors and issuers as it sets the tone for the negotiation of either a traditional or structured PIPE. If a standing authorization is already in place, it can easily facilitate a PIPE without the need for shareholder approval.

2. Governance Implications

Structures vary considerably in the market, making it difficult to generalize when governance rights are concerned. However, PIPE investors can access governance rights in the right circumstances, depending on the size and strategic rationale of the PIPE.

- In France, the bylaws of a company set a maximum number of board members. However, the board that is seated often has fewer members, meaning that the board can provisionally appoint an additional member in connection with a PIPE transaction. Such appointee would then be subject to a shareholder vote at the next general assembly.

- In Germany, governance rights are less common in PIPEs, in particular if they are conducted as ABBs. This is largely due to differences in market practice and the provisions of German stock

corporate law. Depending on the shareholder structure of the company, agreements with existing shareholders providing governance rights, vetoes, or similar may be obtained in parallel, subject to vetting merger control and "acting in concert" considerations.

Obtaining board representation may not be relevant for all PIPEs. Notably, obtaining such representation requires in-depth analysis of the applicable corporate governance code, listing rules, and company law as well as considerations regarding the regulation of inside information.

3. Deal Terms

In keeping with the nascent European life sciences PIPE market, documentary deal terms vary from transaction to transaction. A traditional PIPE executed via an ABB does not involve binding agreements executed between the lead investor(s) and the issuer; rather, the issuer signs a placement or, depending on the jurisdiction, subscription agreement with the banks that run the bookbuilding exercise. In cases where a lead investor provides an undertaking to subscribe and receives a preferential allocation undertaking, specific procedures covering topics that are uniquely germane to the capital raise may be included by way of disclosure rights (i.e., information received and to be disclosed concurrently with the ABB in the same or a separate press release).

In a traditional or structured PIPE that is bilaterally negotiated, the nature of the public company issuer limits representations and warranties further than what would be typical in a purely private transaction. Nonetheless, depending on the jurisdiction, fundamental representations and warranties may be provided regarding, among other things:

- authorization to issue;
- rights attaching to the shares;
- absence of inside information;
- securities laws;
- capitalization;
- compliance with laws;
- sufficient working capital; and
- regulatory matters, licenses, and intellectual property (as appropriate for the issuer's situation).

In certain jurisdictions, for example Germany, company law limits the scope of representations and warranties that can be given to a future shareholder, which is an important consideration in negotiations.

Lockup agreements by the company, which may also extend to certain existing shareholders, board members, and key officers may be appropriate in ABBs (such lockups benefit the placement agents and are waivable in their discretion). They may also be given in the context of bilateral PIPEs, depending on the circumstances.

Information that is classified as "inside information" (within the meaning of the Market Abuse Regulation) and shared with the investor must be divulged on a "wall-crossed" basis pursuant to a non-disclosure agreement. Specific provisions should govern the disclosure of such information upon launch (or abandonment) of the PIPE to permit an investor to be "cleansed."

Companies should take special care to determine the points that would be relevant for the PIPE and consider the ways in which an investor may cover them, either through due diligence or public disclosures.

4. Retail Not to Be Left Out

The COVID-19 pandemic brought renewed focus on the healthcare and life sciences sector by retail investors. A PIPE by its very nature is dilutive, and one of the trends observed in some European jurisdictions in recent months is the tendency of companies to seek to structure a retail offering alongside a private placement as a means of offering existing shareholders the possibility to participate in the new fundraising. This approach would only be appropriate for traditional PIPEs in which the instrument is fungible common stock. Various platforms have proliferated that permit retail investors to participate in an ABB, up to the limit by which capital raises are exempt from the prospectus requirements (currently €8 million, though the proposed Listing Act would raise this to €12 million), as prescribed by the Prospectus Regulation.

Recent transactions have shown that companies can raise up to €5 million in the context of an ABB, from 2,000 to 3,000 individual investors. While this amount may not seem to be particularly material, it can enhance the execution of a PIPE through investor engagement and support liquidity.

5. Product Diligence and Regulatory Aspects

A PIPE is typically executed in the context of a specific project that the company is seeking to finance, such as new product candidate research and development, pivotal clinical studies to support marketing authorization applications, certifications, or specific collaborations. Navigating and understanding the regulatory landscape applicable in the jurisdictions where the company has a significant presence or exposure, which usually include both the US and the EU, is therefore paramount for an investor to correctly price a PIPE. This will become even more relevant as the EU regulatory framework is currently undergoing a major legislative overhaul, significantly reforming the landscape for medicinal products as well as medical devices and in vitro diagnostics.

As a result of the stringent requirements imposed by the new EU Medical Devices Regulation, medtech companies are currently under high scrutiny as to whether they will be able to develop, launch, or continue marketing medical devices in the EU. Although some companies may benefit from the (recently revised) transitional periods and remain on track to bring their products into compliance with the new regime, others may not be able to obtain their certification in due course and therefore seek to implement business strategies to mitigate these delays and to avoid delayed launch or discontinuation of their products in the EU. As such information is not publicly available, conducting tailored regulatory due diligence is essential. PIPEs for medtech companies may therefore be expected to include disclosures on the relevant steps to comply with (or transition towards) the relevant regulations.

In the pharmaceutical sector, investors in a PIPE would also be interested in the development milestones, timetable, and outcome of ongoing and upcoming pivotal clinical trials and the forecast of eventual product commercialization and available regulatory data protection for such products — some of which may be significantly impacted by the proposed revision of the EU pharmaceutical legislation. These are all areas that would be of interest to the investors in a PIPE, and which would typically not be available with any granularity from public sources without a diligence exercise.

For bilateral PIPEs, parties should carefully align on the diligence procedures and public disclosure that will precede and accompany the PIPE execution. PIPEs conducted via ABBs have a lower scope for such procedures, although an anchor investor may expect to receive such information prior to making an undertaking to subscribe. Typically, once diligence procedures have taken place, press releases can facilitate updates of this nature, but a significant new factor that is relevant to the company may require

an update of the company's Universal Registration Document (URD) or an ad hoc disclosure if the issuer does not prepare a URD.

Conclusion

PIPEs, whether conducted via ABBs or through bilaterally negotiated transactions, will likely become an increasing component of listed European companies' capital stack. The structural drivers include a difficult public fundraising environment for small- and mid-cap companies in growth areas (such as technology and life sciences), the exponential growth of pools of private capital (whether dedicated to life sciences, technology, or ESG matters), and the need for listed companies to maintain diverse sources of funding to increase their resilience. While this Client Alert focuses on healthcare and life sciences, many of the considerations discussed herein can also be applicable (with some adaptation) to PIPEs by financial and strategic investors in, among other areas, technology, real estate, and new media.

If you have questions about this Client Alert, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

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