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25 Considerations in Preparing for an IPO for Healthcare + Life Sciences Companies

1. Experienced advisors

Choose experienced advisors, including lawyers, auditors and financial consultants (if necessary), and get them involved early. Advisors who work routinely with the SEC and investment bankers and each other will help proactively identify key issues, expedite the transaction and avoid the pitfalls that can delay offerings, create disclosure issues and cloud the process. Efficiency and execution are critical. If you are looking for experienced advisors, we have a few suggestions.

2. Investment bankers

Identify prospective investment bankers and leading analysts in your market space. Consider the appropriate number and mix of lead bankers for your IPO who will work well with and complement each other, and which ones can “get the deal sold,” especially if market conditions become less favorable. Pick lead bankers who understand your business and can tell your story with the same passion and insight of management. Pick co-managers with analysts who have leading positions in your sector and who believe in your business model and/or therapeutic approach.

3. Financial statements and auditors

Make sure your audited financial statements are close to final. You will only need two full years of audited financial statements in your SEC filings if you qualify as an “emerging growth company,” although occasionally some companies still elect to include three years. If you have switched auditors during that period, consult with both

firms, as your current firm may need to re-audit prior years. Consider when your quarterly interim financial statements will become available and understand the impact this will have on the timing of your SEC filings and overall IPO process. The FAST Act allows you to delay or omit submission of financial statements for certain interim periods, but be sure to keep your finance team and auditors prepared to have the most recent quarter reviewed. For certain issuers whose financial performance is critical, such as many med device, diagnostic and medtech companies, approximately two years of unaudited quarterly results may also be desired. Ensure that your audit firm is properly “independent” from your company under PCAOB and SEC rules. Do not hire employees of your audit firm without first understanding whether that may compromise the firm’s independence. Understand what relationships there may be between your auditors and your officers and directors, including whether the firm has provided any tax services to your officers.

4. Acquisitions or dispositions

Completing a significant acquisition or disposition during an IPO process can have a significant impact on your timing. Material disclosures may be required for transactions completed within the past two years, even for incomplete but contemplated transactions. While the SEC has been increasingly willing to grant relief in certain situations, depending on the “significance” of an acquisition under accounting and disclosure rules, additional financial statements, including pro forma financial statements and separate audited financial statements related to the acquired businesses, may be

required, which can require significant additional work and greatly slow down your IPO.

5. Accounting issues

Identify any sensitive issues or fine-line determinations in your significant accounting policies and practices. Discuss these with your audit team and make sure they discuss them with their “national office.” The SEC’s “hot issues” are constantly evolving, often unpredictably and without formal notice. Make sure your lawyers and auditors are active in the IPO market and have a strong sense of these issues as they evolve. Consider whether a potential accounting issue should be discussed or even pre-cleared with the Office of the Chief Accountant, as this can be an efficient way to settle a potential disclosure issue before commencing the IPO process in earnest.

6. Cheap stock

After a few years of lesser general scrutiny in this area, an SEC hot issue that has come back around on a number of recent IPOs is the “cheap stock” analysis – whether sufficient historical charges have been taken for stock options and other equity grants. Most companies within a couple of years of an IPO are, rightly, getting contemporaneous third-party valuations in connection with making equity grants to service providers, but even if those valuations comply with Section 409A of the Internal Revenue Code, they do not necessarily satisfy the SEC in its review of whether issuers took appropriate accounting charges for earlier grants. Work closely with your auditors and counsel to time third-party valuations, especially as they relate to grants made within a year of the IPO. Make sure your valuation firm is looking at the same comparable companies as those used by your potential investment banks. As you get closer to an IPO, you are likely to change valuation methodologies, moving to a “PWERM” method that takes into account the probability of an IPO and generally results in an increase in valuation. Analyze this issue early on and keep a close eye on your valuation discussions with your investment bankers to determine whether your ultimate IPO valuation could create any cheap stock concerns with respect to recent equity grants. In certain instances, consider whether proactively taking certain retrospective stock-based compensation accounting charges would be prudent.

7. Clinical and regulatory newsflow

Capital raising in the healthcare sector is often centered around clinical and regulatory milestones. Investors are often reticent to invest into the “overhang” of a key data readout or regulatory interaction, but at the same time want to ensure that there are sufficient value-creating catalysts in the near to medium term to drive stock price appreciation. Carefully consider how your planned IPO fits into your overall clinical and regulatory timeline to both better execute on the IPO and support favorable post-IPO performance. For companies that are or may become privy to material cuts of data, such as those with ongoing open label trials, special care must often be taken to pick an IPO window that appropriately corresponds with the data in hand. Moreover, for some companies, clinical results of other companies or institutions must also be carefully monitored and evaluated. Also, consider the impact of any scientific conferences or medical journal publications relative to disclosure of data in your registration statement – embargo policies may prevent you from presenting or publishing data that has already been disclosed, including in the context of a registration statement for an IPO.

8. Strategic collaborations

At the time of pricing of your IPO, your registration statement must contain disclosure on all matters material to the business. Collaboration and licensing arrangements are often material to healthcare companies and can take a significant amount of time to negotiate and complete. To the extent that a material strategic transaction becomes probable, but is not yet “ripe” for disclosure, the IPO process may need to be delayed until that deal is either completed and disclosed or abandoned. To avoid such delays, consider building in a “drop dead” date in your IPO timeline following which your corporate development team no longer pursues business development transactions until the IPO is complete.

9. Insider support, cross-over rounds and TTW meetings

Building a strong base of indications of interest from institutional investors prior to IPO launch has become critical to the success of many healthcare IPOs. Much of this support often comes from the pre-IPO investors who know your company best. In preparation for your IPO,

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consider whether your existing investors have the “dry powder” and desire to participate in an IPO. If not, consider whether a “cross-over” round aimed at investors who invest in both private and public securities might help bolster the company’s balance sheet, serve as a marker of validation and de-risk an IPO. For many healthcare companies, especially those not already backed by leading healthcare investors, cross-over rounds are a necessary prerequisite to an IPO. In addition, the testing-the-waters process under the JOBS Act is a key means of assessing interest from new investors prior to publicly launching an offering, and testing-the-waters strategy and timing should be carefully considered with your investment bankers. Bear in mind that the process of assessing investor interest in an IPO or in a private financing taking place in close proximity to an IPO is highly regulated, and violations of applicable securities laws could delay your IPO process and result in other penalties. Accordingly, counsel should be closely consulted with respect to all such interactions.

10. Lock-up agreements and trading restrictions

The vast majority of companies have a 180-day IPO lock-up period, and investment bankers expect substantially all or all stockholders and equityholders to sign lock-up agreements prior to the IPO to create stability in the trading market. Understand what equity awards will vest or settle during this period and consider whether the company will have enough funds on hand to cover withholding taxes associated with those awards. Withholding considerations may impact the provisions under your lock-up agreement and will need to be carefully coordinated with the investment bankers. Similarly, be mindful of your planned black-out periods in connection with your reporting timelines as a public company and how that might affect the expiration of the lock-up period and settlement of equity awards. Also consider whether certain holders will be granted unique lock-up carve-outs or preferential lock-up rights like “pro rata release rights,” and assess the ramifications of granting such rights.

11. Public communications

Concerns over “gun-jumping” continue to be a critical focus of the SEC. Discuss with counsel the rules that will govern your public communications during the IPO

process. Standardize public communications to establish a track record and develop consistent processes for external communications, including review of press releases by outside counsel and fact-checking all of your public statements before they go out. Beware of media interviews and public appearances in which a potential IPO is discussed – not just by management but by directors and insider stockholders as well, particularly where you do not control the timing of publication. Participation in industry conferences, particularly those hosted by investment banks, should be carefully choreographed during the IPO process.

12. FDA review

The FDA routinely reviews registration statements for many healthcare companies and may even provide comments to the SEC staff assigned to review your registration statement. Since “safe” or “effective” are conclusions of law that the FDA makes when approving regulated products, the FDA (acting via the SEC) will often object to pre-commercial companies making statements that imply their investigational products are safe or effective. While the FDA will not object to descriptions of what was actually observed in clinical trials, including on parameters such as “tolerability” and “clinical activity,” care should be taken to avoid conclusory statements that imply safety or efficacy. Further, alignment between your regulatory filings and IPO disclosure is critical given that the FDA may be reviewing both. Careful consideration should also be given to disclosures that characterize discussions with the FDA, including development and regulatory review risks memorialized in correspondence with the FDA.

13. Management team

Build out your senior management team, as necessary, to operate as a public company. Also consider key hires in areas such as financial reporting and investor relations. Run background checks on new significant hires to avoid surprises during the IPO process. Consider whether newer members of the team, particular those executives who will be interfacing with public investors, have been with the company for a sufficient amount of time to truly understand the company’s business, development strategy and commercial approach to convey the company’s story to investors. For certain non-US companies in particular,

hiring a US-based chief financial officer with experience on Wall Street can be important when looking to list in the United States.

14. Board and committees

Reassess the composition of your board of directors and board committees to identify any changes necessary to satisfy applicable exchange listing and SEC requirements. Seek out directors with diverse backgrounds and skills who can help you build a public company and contribute in a meaningful way to the company's culture, as well as support and challenge the management team. We believe strongly that diversity, including gender, ethnic, sexual orientation and neuro-diversity, creates a stronger board and a healthier company. Understand the requirements for independent directors and the transition rules that will apply after your IPO. Recruiting capable directors can take time, so start early. As you recruit directors, if applicable, also consider what skills will become valuable as you advance development of your product candidates, including, for example, when it makes sense to supplement clinical expertise with commercial experience.

15. Corporate governance

It is never too soon to begin to act like a public company. Focus early on corporate governance appropriate for a public company and develop a culture of compliance. Transitioning a lean organization focused on drug discovery and development to a heavily regulated public company takes time and effort, and the example should be set at the top. Work with counsel to adopt state-of-the-art corporate policies and codes of conduct. Consider strategies to ease the transition, such as mock earnings calls, closing your quarters on public company timelines and holding public company committee meetings. If you share key financial or clinical data broadly within the company, consider a strategy to begin to limit this disclosure, so that post-IPO you are limiting the number of potential insiders subject to trading blackout. Taking the time during the IPO process to train both management and employees on the important aspects of corporate governance, from insider trading to external communications, will make the transition to a public company much easier following the IPO.

16. Stock structure

Although still relatively rare for healthcare companies, consider whether you want a dual or multi-class structure depending on pre-IPO stockholder constituencies and long-term ownership desires. Multi-class structures can create stability for visionary leaders and long-term strategies but can come with costs. Talk to your lead bankers about investor sentiment regarding dual or multi-class structures ahead of the IPO process and any implications for marketing your IPO, including with respect to potential valuation. You should also discuss this issue with your legal advisors as adopting a dual or multi-class structure will have negative implications with respect to stockholder advocacy groups and the ability for your company to be included in certain trading indices.

17. Executive compensation

Consider engaging a compensation consultant to assist in analyzing compensation practices, including equity and non-equity incentives, comparison to peer companies and potential reactions from public investors, stockholder activists and proxy advisory services, such as Glass Lewis and ISS. Begin to develop a compensation structure appropriate for a public company, including a process for board compensation. Talk to your legal advisors about adopting public company equity plans that will meet the future needs of the business. Changing or adopting new compensation practices after being public can be decidedly more difficult. Finally, bear in mind that any loans from the company to executives or directors must be repaid before your first public filing with the SEC during the IPO process.

18. Internal controls and SOX compliance

Discuss with your advisors any "material weaknesses" or "significant deficiencies" in your internal financial controls and understand their impact on your SEC review. Be prepared to discuss these forthrightly with your investment bankers and their counsel, and to disclose them publicly. Even if there have been resource constraints or other problems in the past, investors want to see that you have a plan of remediation and path to strengthening your financial controls in the future. Similarly, understand the transition period over which you will need to become

compliant with the internal controls testing required by Section 404 of the Sarbanes-Oxley Act. Consider engaging an accounting consultancy firm now to assist with such compliance.

19. Cybersecurity and data privacy

Cybersecurity and data privacy have become an area of increased focus both for the SEC and investment banks. The SEC recently provided guidance on specific cybersecurity-related disclosure obligations, stressing the importance of maintaining comprehensive policies and procedures related to cybersecurity matters and highlighting the responsibility of boards for oversight on cybersecurity risk. At the same time, a flurry of high-profile data breaches and the passage of comprehensive laws related to data privacy, protection and security in a number of jurisdictions have lowered investment banks' risk thresholds and increased their due diligence processes around cyber/data/privacy issues. In light of this increased scrutiny, consult with counsel early in the process to ensure that you have policies and procedures in place that are appropriate for your company's scale and stage of development, as well as the nature of the data assets that you hold and the jurisdictions in which you operate. To the extent that you hold or receive sensitive data (e.g., personally identifiable information or personal health information) and are subject to laws or regulations governing the use of such data (e.g., HIPAA), extra care should be taken in this regard. Also be prepared to discuss any cyber or data security breaches with the investment banks and their counsel, including any completed and planned remediation measures, and understand that all such matters may require disclosure in your registration statement.

20. Selecting a stock exchange

Understand the benefits of the alternative stock exchanges, such as NASDAQ, NYSE, AIM in London and the Hong Kong Stock Exchange. Different exchanges offer different advantages and non-concentric investing audiences. This can be particularly important for healthcare companies. Dual-listed companies create additional complexities that need to be carefully considered. Analyze the listing standards of your preferred market to ensure that you will qualify to list there and that those standards match your corporate governance goals.

21. Corporate documents

Understand the provisions of your current charter, bylaws and other corporate documents as they relate to an IPO. Who has registration rights? Are any special approvals required from stockholders or third parties? Will your preferred stock automatically convert upon an IPO? Are all stockholders and other equityholders required to sign 180-day "lock-up" agreements with your investment bankers, and are any holders expecting special IPO lock-up rights based on their Investor Rights Agreement? Make sure that your capitalization records accurately reflect all stock issuances, transfers and cancellations, as well as option and warrant issuances, exercises and cancellations. Your lawyers are often required to give a capitalization opinion in connection with an IPO, and they will need to be able to rely on detailed and accurate records in order to do so.

22. Due diligence

The investment bankers and their counsel will conduct extensive due diligence on your company, including a thorough review of your minute books, capitalization records, material agreements, etc. Anticipate what materials the investment bankers and their counsel will want to review and begin organizing these documents to expedite the due diligence process. Failure to do so could result in avoidable delays to your offering. Establish an online data room for the delivery of due diligence materials, and get materials posted early. Pay particular attention to privacy and security risks and OFAC and FCPA compliance, each of which are closely scrutinized by the investment bankers and their internal and external counsel and are viewed as critical risks to the business for most investors. In addition, if applicable, investment bankers will likely want to speak with key opinion leaders who understand your products or product candidates and disease areas, as well as other key third parties, such as collaborators, manufacturers or customers. You will generally have the opportunity to suggest third parties for the investment banks to speak with and should ensure that you are selecting individuals who have good familiarity with and a favorable view of your programs and strategy. In addition, the IPO will include an extensive factual backup process for various claims made in your registration statement. Compiling appropriate backup ahead of time can greatly facilitate the IPO process.

23. Investigations or disputes

Analyze any past, pending or threatened investigations or disputes, and assess the disclosure requirements that may apply to them. In extreme circumstances, material investigations or litigation could potentially delay or derail the IPO. Also consider the impact that filing for an IPO may have on your negotiating position in these situations. Litigants will often be less likely to settle for a reasonable amount if they know the company is in the IPO process. If you are thinking of initiating a dispute with another party, consider its likely effect on the IPO. This is an area of particular focus for investment banks.

24. Material agreement determinations and confidential treatment

SEC rules will require you to publicly file material agreements, including material collaboration and license agreements. Determine which agreements will likely be required to be filed and review these agreements for confidentiality provisions that will need to be waived by the counterparty. Also, determine which terms, if any, of these agreements would be competitively harmful if disclosed. Discuss with your counsel the process of obtaining confidential treatment for these provisions in connection with your IPO, and provide your collaborators with an opportunity to review and comment on any proposed redactions. The SEC has recently adopted rules providing deference to companies in making these determinations as to what provisions may be redacted, but the rules regarding eligibility for confidential treatment have not changed, and the SEC may still comment on redactions that it deems to be inappropriate. Getting this right requires careful analysis and can take some time.

25. Director and officer liability insurance

The exposure to liability is significantly greater for directors and officers of public companies than it is for private companies. A private company D&O insurance policy will not be appropriate once the company is public. Post-IPO securities litigation is rampant, particularly amongst many healthcare companies, and insurance premiums have never been higher. Choose an experienced D&O insurance broker and coordinate with the broker early in

the process to ensure that your officers and directors are adequately protected – and understand the sticker shock associated with today's D&O insurance policies for public companies.

This fact sheet is intended as a general introduction to the transaction process and is not intended to provide legal advice as to any specific transaction; it will not be deemed to create an attorney/client relationship between Cooley LLP and the reader and you may not rely upon any of the statements contained herein for purposes of any specific transaction. Each transaction is unique, and will involve complex legal issues that can only be properly analyzed by an attorney who is retained by you to provide you with legal advice specific to the facts and circumstances pertaining to that transaction. © Cooley LLP.