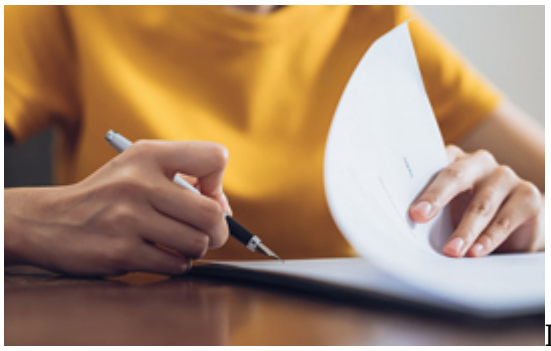
Hedging COVID-19 Pandemic Risks in M&A: PPP Loans

 During the COVID-19 pandemic, M&A counsel and their respective life science clients have attempted to navigate the new normal of an unprecedented situation.[1] In addition to impacts on due diligence, material adverse effects clauses, termination provisions, contingent payment mechanics and representations, warranties and covenants, potential acquirers have also had to hedge specialized risk associated with target companies engaged in the Paycheck Protection Program ("PPP").

Financially healthy life science companies have often been cautious of being associated with PPP loans during the COVID-19 pandemic, especially with the increased scrutiny surrounding the "necessity" analysis by the U.S. Small Business Administration ("SBA") and, in the case of public companies, the disclosure requirements to shareholders. Consequently, target companies with outstanding PPP loans have been required to address potential risks. Prominent means to hedge such risks include the use of escrow funds and covenants obligating target companies to seek forgiveness of some or all of a PPP loan. In fast-paced transactions, targets may not be able to apply and receive forgiveness prior to the transaction's closing and thus, forgiveness as a closing condition is improbable. In such situations parties may opt to set-up an escrow account in an amount equal to the PPP loan forgiveness amount and, if negotiated, the out-of-pocket costs borne by the sellers related to the forgiveness application. Relatedly, among other things, sellers may also be required to indemnify acquirer(s) indemnitees from any losses arising from a target company's obligation to repay any portion of the PPP loan that is outstanding as of the transaction's closing, to the extent it is not forgiven. The combination of a separate and dedicated escrow account, along with a covenant to eliminate PPP loans and indemnification for related losses, can provide acquirers of life sciences companies (which are typically bigger and often do not meet the requirements for PPP loans) with some level of comfort with respect to the potential effects of PPP loans on their other operations.

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[1] For an overview of the impact of COVID-19 on M&A see **client alert**

Down Rounds 101

 Private life sciences companies looking to raise funds in the current environment might face the prospect of a "down-round" – a financing round at a lower pre-money valuation than the post-money valuation in prior round(s). "Down-rounds" raise various risks and considerations for both companies and investors.

"Down-rounds" affect both ownership percentage and value of shares, and typically trigger antidilution protections, which would increase the conversion price/ratio such that existing investors would receive more Common Stock for each share of Preferred Stock, based on the formula in the company's Certificate of Incorporation.[1] Companies should carefully calculate and evaluate the effects of "down-rounds" on their capitalization and related thresholds for various requisite approvals. Following "down-round" financing, the conversion prices should be reset to reflect any adjustments.

Companies can encourage existing investors to participate (and, potentially, avoid "down-round") by offering senior preference (ahead of prior liquidation preferences), adding a multiple liquidation preference (e.g. 2x instead of 1x), and/or introducing mechanics that would further dilute non-participating investors or even convert Preferred Stock of such investors to Common Stock, such as pay-to-play, cram down (by stock splits or conversion ratio modifications) or pull up (by converting the outstanding preferred stock of participating investors to the new preferred stock).

Careful consideration should be given to fiduciary duties of controlling stockholders and of directors, in particular those representing existing investors who participate in a "down-round," since "Interested party" transactions are not afforded the benefit of the business judgment rule, and may face liability for such financings under the "entire fairness" standard. Due process matters, and adopting practices (to the extent possible) can mitigate potential risks. Customary and advisable practices include a board committee of disinterested directors, consent of a super-majority of the stockholders, offering all stockholders the right to participate in the financing through a rights offering, soliciting outside investors and obtaining a third-party valuation or fairness opinion.[2]

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[1] Customary protections include: (i) full ratchet, which resets the conversion price to the price of new securities and is unfavorable to founders and, consequently, is rare; (ii) narrow based weighted average, which takes into account the share price and number of the new securities, the original issue price of existing shares and the number of outstanding shares, and counts fewer shares as outstanding; and (iii) broad based weighted average, which is the same as narrow based weighted average, but counts more shares as outstanding and is therefore less favorable to investors and results a smaller increase in conversion rates.

[2] For an overview of good practices see client alert **https://www.goodwinlaw.com/publications/2020/04/04_28-dilutive-down-round-financings-in-the-us**.

Life Science Companies Participate in Convertible Bond Surge

Life science companies have been among the biggest users of convertible debt financing in the first half of 2020. As highlighted in our recent **Client Insight article**, life science, technology and other traditional high-yield debt issuers were the biggest participants in the record issuance of convertible bonds. Through June 30, 2020, U.S. companies raised over $64 billion in 114 convertible bond offerings with most of the surge occurring in the second quarter. May 2020 saw a record $20.7 billion of convertible debt issued. The previous record monthly high for convertible issuance was $19.2 billion in May 2001.

The strength of the convertible bond market was due in part to high share price volatility in equity markets and wide credit spreads above comparable U.S. Treasuries in debt markets. These market conditions make convertible debt an attractive source of capital versus equity follow-ons and high-yield debt offerings. One notable life science transaction in the first half of 2020 was BridgeBio Pharma Inc.'s (BBIO) pricing of an upsized $550 million (from $375 million) convertible debt offering that featured a 2.50% coupon. Additionally, BBIO entered into capped call transactions to raise the effective conversion prices of the notes and hedge risk of equity dilution upon conversion. The strength of the convertible debt market enabled BBIO and other life science companies to raise capital at attractive levels. In the first half of 2020, the average coupon rate for all convertible debt offerings was 1.25% with an average conversion premium of 37%.

Given that share price volatility and credit spreads are still at historically high levels, convertible bond offerings are expected to remain a popular source of financing for life science issuers in the second half of 2020.

Think Your Drug is Safe and Effective? Not So, Says the SEC

 For life sciences companies who are or are looking to become publicly traded in the U.S., one of the most frequent comments that we see from the SEC as part of their review process is the following:

You make several assertions regarding the safety and efficacy of certain of your product candidates. Safety and efficacy determinations are solely within the authority of the FDA (or applicable foreign regulators). Please revise these statements to remove statements/inferences that your product candidates are safe and/or effective. We will not object to a discussion of whether your product candidates were well-tolerated or discussion of whether trial endpoints were met.

Given the frequency with which verbiage such as “safety data” or “efficacy data” is used among drug developers, investors and even the FDA itself, this position by the SEC often catches companies by surprise. However, the SEC has consistently taken the view that such references are not appropriate in companies’ SEC disclosures. Importantly, even oblique references to “safety” or “efficacy” (for instance, forward-looking statements regarding the expected safety profile of a product candidate) will often draw an SEC comment.

Fortunately, there are typically relatively straightforward ways to resolve this comment. For instance, rather than referring to a drug’s efficacy, companies can instead refer to whether it met trial endpoints or demonstrated activity. Similarly, in lieu of referring to a drug’s safety, companies can refer to its tolerability or its adverse event profile observed to date.

While this topic is typically a point of emphasis in the IPO process, we often find that companies become less vigilant about avoiding “safety” and “efficacy” references in their subsequent Exchange Act periodic reports (not to mention their press releases and investor presentations). However, we frequently see this comment come up in SEC reviews of public company periodic reports, and proactively steering away from references to “safety” and “efficacy” can be a useful way to remove some low-hanging fruit that might otherwise draw an SEC comment.

UK Government Announces ‘Future Fund’ Financing Package for Start-Up Technology and Life Sciences Companies

 The UK Government has announced a new fund that provides financing to UK start-ups and scale-ups in the form of a convertible loan which is invested directly by the Government. For further detail on the fund please see: https://www.gov.uk/guidance/future-fund.

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Update: U.S. Health and Human Services Clarifies Broad Eligibility of Providers for Payments Under $30 Billion CARES Act Healthcare Provider Relief Fund

 As discussed in Goodwin's prior Client Alert, on April 10, 2020, the U.S. Department of Health and Human Services (HHS) began disbursing $30 billion to Medicare providers and suppliers under the Public Health and Social Services Emergency Fund (PHSS Emergency Fund). HHS is requiring providers to agree to certain terms and conditions or return the payments. A number of the terms and conditions created some confusion as to whether providers who have not provided services directly related to COVID-19 may keep the payments. HHS has now clarified that providers may keep payments distributed under the PHSS Emergency Fund regardless of whether they have or will provide services directly related to COVID-19.

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Key Considerations for U.S. Public Company

Compensation Committees in Light of COVID-19

 As the COVID-19 pandemic continues to unfold, U.S. public company compensation committees face unique challenges as they focus on retaining and appropriately incentivizing employees while evaluating the impact of the pandemic on the company. This client alert provides a high-level overview of some key issues that compensation committees should be focusing on in this environment.

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U.S. CARES Act Supply Shortage Provisions: What Drug and Device Manufacturers Need to Know

 On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act in response to the U.S. COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public discussion and concern over the availability and accessibility of critical medical devices, such as ventilators, and the pandemic has highlighted gaps in the U.S. Food and Drug Administration's (FDA's) authorities regarding medical product shortages. FDA has been able to collect information on drug shortages and take steps to help prevent or mitigate such shortages under authorities set forth in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). However, FDA had not, until now, had equivalent authority with regard to shortages of critical devices. Among the many provisions of the CARES Act ("the Act") are amendments and additions to the Federal Food, Drug, and Cosmetic Act (FDCA) that give FDA the ability to effectively address such shortages. Additionally, the Act enhances FDA's existing authority with respect to drug shortage measures. Below, we have highlighted the key provisions in these areas under the new law.

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CMS Expands Availability of Advances on Medicare Reimbursement; U.S. CARES Act Increases Medicare Reimbursement Rates

 In response to the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) announced on Saturday March 28, 2020, that it is expanding its Medicare Accelerated and Advance Payment Program (AAPP) to allow nearly all Medicare providers and suppliers to receive advances on future Medicare reimbursement. To provide further relief to healthcare providers and suppliers, the Coronavirus Aid, Relief, and Economic Security U.S. Cares Act (CARES Act), which was signed into law on March 27, 2020, eliminates from May 1, 2020, through December 31, 2020 the 2% sequestration-mandated reductions to Medicare reimbursement. We review these developments in greater detail below.

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Collaboration, License and other Commercial Agreements: Key Considerations for Life Sciences Companies in the Age of COVID-19

 The COVID-19 pandemic is continuing to cause major global disruption to the activities of development stage and other life sciences companies due to, among other factors, limited or no access to clinical trial sites, reduced supply levels for active

pharmaceutical ingredients or other key materials needed to make drug candidates or medical devices, and the inability of personnel to access laboratory and other specialized work spaces.

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