GIBSON DUNN

March 30, 2020

COVID-19 AND LIFE SCIENCES COMPANIES – 10 ACTIONS TO CONSIDER

To Our Clients and Friends:

The COVID-19 outbreak has caused major disruptions in global economies, including in particular to life sciences companies that are conducting clinical trials and manufacturing and marketing pharmaceutical products. The following ten actions are among those that life sciences companies may wish to consider in light of current events:

SEC Disclosures	-	Update disclosures regarding clinical trials
	-	Update (or suspend) earnings guidance
Material Contracts	-	Review in-licenses and collaboration agreements
	-	Review debt covenants
Governance and Operations	-	Consider virtual annual meetings for 2020
	-	Revisit succession and contingency plans
	-	Be prepared to (re)assess status as an "essential business"
	-	If financially stressed, acknowledge broader fiduciary duties
Finance and M&A	-	Assess alternate sources of capital and risk-sharing arrangements
	-	Consider the need for a poison pill

Discussion

SEC Disclosures

Update disclosures regarding clinical trials. In light of the expected impact of the pandemic on clinical trials, many companies are suspending the commencement of clinical trials, pausing ongoing trials and/or modifying study protocols.[1] Even if trials remain ongoing, there may be significant delays, dropouts and a greater number of adverse events (even if unrelated to the study drug). For studies that are now expected to be completed with fewer patients, the statistical power of the study will be reduced and may increase the likelihood that an otherwise successful study will be unable to demonstrate a statistically significant benefit. As a result of these considerations, we are seeing many companies update disclosures regarding timelines for commencement and anticipated completion, as well as updating risk

factors and forward-looking statement disclosures regarding clinical trials. For one example of such an update, the March 23, 2020 announcement from Eli Lilly suspending their clinical trials can be found here.

Update (or suspend) earnings guidance. For companies with marketed pharmaceutical products, many sales representatives are currently unable to access physicians and the expected impact in sales will be hard to project. Additionally, supply-chain disruptions may lead to drug shortages. In this environment, companies are considering updating or simply suspending revenue and earnings guidance until there is greater clarity on current events. For companies that last provided guidance prior to the spread of the pandemic in the United States, we expect to see an increased trend in suspending earnings guidance as Q1 results are announced starting in April.

Material Contracts

Review in-licenses and collaboration agreements. Certain foundational in-licenses and collaboration agreements may have "diligence" milestones relating to the development and commercialization of drugs and drug candidates, which, if not satisfied, may result in reduction or loss of rights for licensor or licensee. Additionally, other contracts with third parties (*e.g.*, CROs) may also have performance-based milestones that could be in jeopardy of not being met. In light of potential extended delays in the ability to operate in the ordinary course, consideration should be given to any such performance requirements and whether force majeure or similar clauses can be invoked to excuse any missed deadlines. (Gibson Dunn checklist and flowchart on force majeure clauses can be found here)

Review debt covenants. Companies with debt facilities may have various financial and non-financial covenants that could be impacted by decreased revenue or liquidity. Companies should consider the impact of these covenants on operations and public disclosures and begin forbearance discussions with lenders as soon as a potential issue is apparent. For those companies planning to access a small business SBA-backed loan under the CARES Act (described below), consideration should also be given to covenants that limit additional indebtedness; lenders should be willing to accommodate requests for waivers given the forgivable nature of these loans.

Additionally, venture debt facilities frequently provide for the ability of borrowers to draw down on the facility in tranches as certain milestones are met within given timeframes. If applicable, borrowers should assess whether COVID-related disruptions will make the timely achievement of such milestones unlikely or impossible. Depending on the expected impact of these disruptions, companies may wish to negotiate for extensions and liquidity disclosures in SEC filings may need to be updated.

Governance and Operations

Consider virtual annual meetings for 2020. The COVID outbreak comes at annual meeting and proxy season time for companies with a December 31 fiscal year end. Given the shelter-in-place orders and limits on gatherings of large groups, companies should consider making annual meetings "virtual." For companies that have already mailed proxy statements, consideration should be given to changing to virtual meetings, while being certain to comply with the notice requirements under state law. In moving to a virtual meeting, companies should consider how they will handle shareholder questions and

engagement. Companies should also expect that providers of virtual meeting platforms, such as Broadridge, may be overwhelmed with requests, which means that: (i) there may be no capacity to host the virtual meeting on a desired date, and (ii) it may take longer than normal to have the necessary infrastructure set up to host a meeting online.

Revisit succession and contingency plans. In light of the risk of a senior member of management falling ill, Boards should be certain that they have contingency plans in place for management succession. Additionally, Companies should consider the possibility of not being able to convene a quorum of the Board of Directors. Delaware law permits the inclusion of an "emergency" provision in the corporate bylaws, which allows for the conduct of business with less than a quorum present. Boards should also consider the formation of an Executive Committee (with delineated powers of the Board), with alternate members in the event that one member is unable to serve.

Be prepared to (re)assess status as an "essential business." As shelter-in-place orders are expanding and possible stricter quarantine orders are considered, life sciences companies should be prepared to (re)assess the status of their operations as "essential" businesses. Many of the shelter-in-place orders issued so far have specifically identified healthcare-related companies as "essential," including biotechnology, pharmaceutical and diagnostic companies. However, not all orders have had this degree of clarity and stricter orders may be forthcoming, which could further limit permissible business activities. To the extent that companies are manufacturing and distributing marketed products, these operations will undoubtedly continue to be permitted. However, for other activities not related to supplying pharmaceutical products (and unrelated to COVID research and development), contingency plans should be considered.

If financially stressed, acknowledge broader fiduciary duties. For a solvent corporation, the board of directors acts as a fiduciary for the benefit of stockholders. However, for a company that is insolvent or in the zone of insolvency, the duties of the board shift to run the enterprise for the benefit of all stakeholders (which includes creditors). In this rapidly evolving environment, boards of directors should be mindful of the financial position of the corporation and to whom duties are owed. Companies should also document due consideration of these expanded duties, if applicable.

Finance and M&A

Assess alternate sources of capital and risk-sharing arrangements. For companies looking to strengthen their balance sheets, the capital markets to be too choppy for equity financings. In this environment, companies should consider alternate sources of capital, including forgivable SBA-guaranteed loans provided for under the newly adopted CARES Act, as well as royalty-based financing (whether selling rights to existing royalty streams or selling a "synthetic royalty" on sales of an approved or to-be-marketed product). Additionally, companies with clinical programs may wish to consider collaboration arrangements where a third party assumes the performance of late-stage clinical trials and absorbs a portion of their costs (and risks) in return for shared upside.

For companies that may be considering arrangements that involve partnering or collaborating with a competitor, the FTC and DOJ have announced that they will be issuing guidance on collaborations that

will be permitted during the pandemic. (Gibson Dunn client alert on the FTC/DOJ guidance can be found here)

Consider the need for a poison pill. With depressed share prices, many companies are concerned about being undervalued and a possible hostile takeover threat. In response, many companies are adopting short-term COVID pills, often with terms between 6-12 months. Goldman Sachs reports that these are being widely adopted, which suggests that the expected criticism from proxy advisory firms such as ISS may be blunted if the pills are short-term in nature. At a minimum, companies should consider maintaining a poison pill "on the shelf" so that it can be quickly deployed if a hostile threat emerges. (Gibson Dunn client alert on the adoption of COVID poison pills can be found here)

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[1] Recognizing the impact of COVID-19 on clinical trials, the National Institutes of Health and the U.S. Food and Drug Administration recently released guidance regarding the conduct of clinical trials during the COVID-19 pandemic. This guidance included accommodations for patient visits and changes in protocols. The NIH guidance can be found here and the FDA guidance can be found here.

Gibson Dunn's lawyers are available to assist with any questions you may have regarding developments related to the COVID-19 outbreak. For additional information, please visit the Gibson Dunn COVID-19 Resource Center or contact any member of the firm's Life Sciences Practice, including the following:

Michael Bopp | CARES Act SBA Loan Program
(+1 202.955.8256 | MBopp@gibsondunn.com)

Eduardo Gallardo | Shareholder Activism; M&A
(+1 212.351.3847 | EGallardo@gibsondunn.com)

Robert Klyman | Bankruptcy and Restructuring
(+1 213.229.7562 | RKlyman@gibsondunn.com)

Marian Lee | FDA and Healthcare
(+1 202.887.3732 | MJLee@gibsondunn.com)

Ryan Murr | SEC Reporting, Capital Markets and M&A
(+1 415.393.8373 | RMurr@gibsondunn.com)

Karen Spindler | Licensing & Collaborations, M&A and Royalty Financing
(+1 415.393.8298 | KSpindler@gibsondunn.com)