Q&A on FDA's Requirements Related to Financial Disclosure by Clinical Investigators

What financial arrangements between clinical trial sponsors and clinical investigators must be disclosed in a drug, biologic or device marketing application?

In a marketing application, FDA requires that four types of financial arrangements be disclosed: (1) any financial arrangement between the sponsor and the investigator whereby the value of the compensation to the investigator for conducting the study could be influenced by the outcome of the study; (2) any significant payments of other sorts from the sponsor, such as a grant to fund ongoing research, compensation in the form of equipment, a retainer for ongoing consultation, or honoraria, which are greater than $25,000 in cumulative value and given to the investigator or the investigator's institution to support the investigator's activities, exclusive of the costs of conducting the study, for the duration of the study and for one year following the study's completion; (3) any proprietary interest in the tested product held by the investigator; and (4) any significant equity interest in the sponsor held by the investigator, which is any amount for a non-publicly traded company or an equity interest in a public company valued over $50,000 for the duration of the study and for one year following the study's completion.

How is a clinical investigator defined in the context of FDA financial disclosure regulations?

In FDA's financial disclosure regulations, the agency defines a clinical investigator as a listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator.

What does FDA look for with regard to financial interest?

FDA looks at several factors with regard to financial interest, including the size and nature of the disclosed financial interest, the steps taken to minimize the potential for bias, and the study design. For example, FDA will evaluate whether the study has been designed with multiple investigators (most without a disclosable interest), blinding, objective endpoints, or measurement of endpoints by someone other than the investigator. FDA may initiate audits of the data from the investigator at issue, request that the applicant submit further analyses of the data or conduct additional independent studies to confirm the results. The agency could also refuse to treat the study as providing data that can be the basis for an agency action. We recommend you contact your Goodwin life sciences or FDA lawyer for further explanation of the agency's financial disclosure regulations.

What has contributed to the rising cost of Directors and Officers (D&O) Liability Insurance for new public companies?

 Over the past year, the cost of obtaining D&O insurance for new public companies has increased substantially. Rates have increased from $50-60,000 per million dollars of coverage to over $150,000 per million dollars of coverage. Along with increased premiums, retention amounts have increased substantially (from $5 million to $10 million for smaller public companies up to $30 million for very large public companies). The increased cost of D&O insurance has been driven by the record level of securities class action filings over the last three years, as well as the increased settlement value of such actions (44% higher average settlement value in 2018 than the average of the past nine years according to Cornerstone Research). Further contributing to the increased cost is the U.S. Supreme Court's ruling in the 2018 case, *Cyan, Inc. v. Beaver County Employees Retirement Fund*, that state courts can hear securities claims under the Securities Act of 1933, creating additional uncertainty regarding the outcomes of such cases. These factors in turn have caused some carriers to limit (or entirely eliminate) underwriting D&O insurance for new public companies.

Given that securities class action suits are filed against companies in the life science industry more than any other industry, life sciences companies have been especially impacted by the increased cost of D&O insurance premiums, with rates continuing to rise materially on a monthly basis. One oncology company was given an initial premium estimate of $2.3 million for a June 2019 IPO closing, but ended up paying a premium of $4.3 million when its IPO closed in September 2019. Given these changes in the D&O insurance marketplace, we recommend that companies engage a D&O insurance broker early on in the IPO process to ensure that they will be able to obtain competitive and comprehensive coverage and to avoid last minute surprises when their boards of directors are being asked to approve such high-cost packages. We recommend you contact your Goodwin life sciences or corporate lawyer for further guidance on obtaining D&O insurance.

I want to engage a consultant to provide services on behalf of the company, but that consultant is a professor at an academic institution. Can I still do so?

 Yes. Many life sciences and biotech clients work with consultants that are associated with academic or research institutions. However, in considering whether to engage such a consultant, life sciences companies should be aware that the consultant will be subject to the intellectual property and conflict of interest policies of the associated institution. Most (if not all) academic or research institutions require their employees to assign ownership to the institution of any intellectual property (whether patentable or not) created by the employee either (1) in furtherance of the employee's responsibilities for the institution or (2) using university resources (e.g., labspace, funding, laptops, etc.).

When engaging a potential consultant associated with an institution, the institution will need to review the underlying consulting agreement before the consultant signs it. Be sure to build in time for this review. Usually the institutions will look to ensure the consulting agreement includes a reference to the university policies and an acknowledgement that the consultant is subject to those policies while providing services for the company.

After the consultant is engaged following completion of the institution's review of the consulting agreement, the consultant should ensure that any services provided for the company as a consultant are separated from any of his/her responsibilities for the institution or resources provided by the institution. This includes laptops, computers, iPads or other devices. Life sciences companies should ensure this separation is strictly adhered to. Otherwise, there is the potential for the institution to claim ownership over intellectual property created by the consultant, even if it was for or on behalf of the company.

There are certainly exceptions to institutional policies, so the above are not hard and fast rules. We would recommend always connecting with your Goodwin licensing or commercial counsel and discussing directly with the potential consultant and institution in each instance.

I want to license technology out of an academic or research institution. What kind of compensation will the institution typically look to receive?

 Academic or research institutions are at the core of early-stage innovation in the life sciences and biopharmaceutical industries. In order to gain access to the intellectual property generated or owned by those institutions, institutions typically offer to grant a license to its owned intellectual property to companies. In exchange for the license, institutions will look for consideration, which comes in a variety of forms. We can break down types of typical consideration into a few categories.

1. License Issue Fee: Institutions may ask for an upfront fee for the grant of the license. This is a one-time payment paid at the signing of the license.
2. Minimum Annual Royalties/Annual License Fees: Aside from the upfront fee, many institutions will ask for an annual "maintenance" fee. These can take the form of yearly lump sum payments, but can also sometimes be called "minimum annual royalties". If these payments are considered minimum annual royalties, then the yearly fee is creditable against any royalties owed to the institution that year.
3. Royalties: Institutions may ask for a percentage of the future sales of products that incorporate the intellectual property licensed. This comes in the form of on-going royalty payments. Typically, for most institutions, these are in the single-digits, but depend on the scope and breadth of the license.
4. Development/Commercial Milestones: Institutions may ask for lump sum payments based on the achievement of certain developmental or commercial milestones by the company. For example, if a product that incorporates the intellectual property licensed from the institution receives FDA approval, the institution may ask for a lump sum payment upon such achievement.
5. Sublicensing Income: Institutions like to ask for what we call "sublicense income". Through sublicense income, the institution is entitled to a percentage of the consideration the company receives from a sublicensee, if the company sublicenses the institutions intellectual property to a third party. The percentage varies and usually decreases over time, but is typically in the single-digits to low double-digits.
6. Patent Costs: If the company is taking an exclusive license, the institution will typically want the company to cover the costs of prosecuting any patents being licensed, those both already incurred and to be incurred in the future. In exchange, typically the company will have input in the future prosecution of the patents.
7. Equity: Depending on the relationship of the institution and the company, some institutions may request equity in the company in exchange for the license grant.

The amount and frequency of the above categories will vary from license to license, and will depend on the scope and breadth of the license (e.g., exclusive v. non-exclusive, limited geography v. worldwide, narrow field v. all fields, etc.). There also may be consideration institutions will ask for, other than the above. We recommend connecting with your Goodwin licensing or commercial counsel to discuss what might be typical for the scope of license you intend to enter into.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: Mergers and Acquisitions

 On Wednesday, January 15, 2020, during the J.P. Morgan Healthcare conference, Goodwin and KPMG held their initial all-day Symposium at the St. Regis hotel in San Francisco. The Symposium was composed of five separate "bursts" entitled (i) New Frontiers in Digital Diagnostics and MedTech, (ii) Europe Unleashed, (iii) Knowing the Best IPO Strategy, (iv) Trends in Biopharma and (v) Mergers and Acquisitions. Stéphane Bancel, the Chief Executive Officer of Moderna Therapeutics, provided the keynote address.

Burst Five consisted of a panel entitled "*The Brave New World of Antitrust in Life Sciences M&A.*" This panel was moderated by **Stuart Cable** of Goodwin and consisted of **Lisa Haddad** and Andrea Murino of Goodwin. In this panel, participants provided their insights regarding recent antitrust activity in the life sciences M&A sector. Overall antitrust merger investigations are up under the Trump administration, with a total of 29 investigations in 2019. In addition, the average duration of significant investigations continues to increase, with an average of 12.6 months for the first three quarters of 2019 as compared to 9.8 months for the same period in 2018. Foreign regulatory authorities also continue to increase their focus on proposed mergers, including through working collaboratively with U.S. agencies. Antitrust concerns with respect to life science transactions, especially in hot pharma markets, such as gene therapy, are high.

Key takeaways from Burst Five were as follows:

1. ***Stay apprised of the state of antitrust merger review, as new developments may make a given transaction more risky than expected.*** Antitrust merger review is constantly changing, particularly as administrations change. Recent FTC decisions in life sciences M&A transactions suggest that the FTC has started to look at the entirety of a company's product pipeline (including drugs in development as well as approved drugs) to determine if a given transaction raises anti-trust concerns. For example, as a condition to the BMS/Celgene merger, BMS was required to divest Otzela, a product for the treatment of psoriasis, marketed by Celgene. The FTC argued that this divestiture was required to incentivize BMS to continue to develop its own product candidate for the treatment of psoriasis. This was the case even though there is guarantee that BMS's developmental product would ever be successfully developed or reach the market.
2. ***Seek guidance from experienced antitrust counsel early in the process to evaluate regulatory risks associated with a proposed transaction and to develop an antitrust filing strategy.*** Given the regular changes in antitrust law, it is important to seek the counsel of experienced antitrust counsel early-on in the M&A process. Experienced counsel can help

companies assess the risk profile of a given transaction and help you develop a comprehensive antitrust filing strategy. The risk profile of a given M&A transaction will also inform the provisions to be included in the Merger Agreement and other transaction documents.

3. ***Given increased antitrust review timelines, make sure Merger Agreement contains proper protections for the seller.*** Given that antitrust review times have been increasing, it is important that Merger Agreements for transactions that are likely to be subject to extensive antitrust review contain the proper protections to avoid having the buyer just walk away from the seller. For example, sellers should consider strong covenants regarding the efforts that must be taken to obtain regulatory approval, an end date that allows for extension if there is a regulatory delay, and reverse termination fee payable to the seller if the buyer wants out of the agreement.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: Knowing the Best IPO Strategy

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Burst Three consisted of four parts. In the first part, Amit Sinha from Goldman Sachs provided a summary overview of the U.S. IPO market for biotech in 2019 and provided thoughts on the U.S. IPO market for 2020. Amit noted that biotech issuances remained near record levels in 2019, and while 2019 IPO volume was down in comparison to 2018, company valuations remained higher. In addition, pricing of biotech IPOs in 2019 remained mixed. Numerous macro factors, such as the 2020 presidential election and continuing effect of executed tariffs, are expected to drive macro sentiment in 2020, but the overall sentiment is that the pace of IPOs will continue in 2020, with many companies seeking to go public in the first half of 2020.

The second part of Burst Three was a panel entitled "*Traditional U.S. IPO Route: The Two Minute Drill to Complete a Successful IPO in the First Six Months of the Year.*" This panel was moderated by **Janet Lehman** from KPMG and consisted of **Tom Koncsics** from KPMG, **Michael Bison** from Goodwin, Jack Cassel from Nasdaq and Amit Sinha from Goldman Sachs. In this panel, participants provided their advice regarding things for companies to consider if they want to go public in the near term.

The third part of Burst Three was a panel entitled "*Hong Kong IPO: Seizing Opportunities in a New Emerging Market for Biotech IPO.*" This panel was moderated by **Wendy Pan** from Goodwin and consisted of **Irene Chu** from KPMG, Michael Chan from the Hong Kong Exchanges and Clearing Limited (HKEX) and Bin Li from Lake Bleu Capital. In this panel, participants provided an update on the Hong Kong IPO market and provided advice for biotech companies seeking to list on the Hong Kong Exchange. Participants noted that since their new listing regime launched in 2018, 15 biotech companies listed on the main board by 2019, raising HK$48.6 billion in total, and amongst these, eight were pre-revenue biotech firms. The Hong Kong Exchange hopes to continue to expand the types of listed biotech companies in the future.

The final part of Burst Three was a panel entitled "*Alternatives to U.S. IPO: Reverse Mergers and Direct Listings.*" This panel was moderated by **Deepa Rich** from Goodwin and consisted of **Gerry Schemidt** from KPMG, Mitchell H. Gold from Alpine Immune Sciences and David Snyder from Exicure. In this panel, participants provided their insight regarding going public through the reverse merger process. Overall panelists had the sentiment that we are likely to see more reverse mergers in the future given the number of public companies that have gone public through the traditional route.

Key takeaways from Burst Three were as follows:

1. ***Regardless of the strategy chosen for reaching the public markets, companies need to engage in various preparatory actions to ensure they are properly prepared, and therefore companies should engage with appropriate experts (legal, financial and stock exchange) early on in the process.*** Panelists stressed the importance of companies engaging experts, including legal and financial as early in the process of going public as possible in order to help them prepare for an efficient process. For example, in the traditional IPO process, legal experts can help the company understand timing for the various items that need to come together before a company goes public, while financial experts can help prepare the necessary audited financial statements for the registration statement. In a reverse merger process, engaging bankers early in the process can be useful in helping the company put together an attractive merger proposal. In all cases, the securities exchanges themselves can be helpful in providing the prospective public companies with resources to help the companies navigate the markets and listing compliance.
2. ***Feedback with respect to the new biotech chapter of the Hong Kong Exchange has been positive, but companies need to understand that some challenges remain.*** Panelists noted that although the feedback on the new biotech chapter has been overwhelming positive, challenges to listing on the Hong Kong Exchange still remain. Panelists noted that certain aspects of the ecosystem need to grow further. For example, more bankers and investors that are knowledgeable in biotech are still needed. In addition, there is a need to better inform potential companies seeking to list on the Exchange of the differing disclose standards as compared to the disclosure standards in the United States.
3. ***A reverse merger into an existing public company or a public company shell might be the best path to the public market for some companies, but the reverse merger process is unlikely to be cheaper than the traditional IPO route and is unlikely to be a true liquidity event.*** Panelists noted that a reverse merger may be the best path into the public market for some companies, for example, for companies whose capital structures do not allow them to go down the traditional IPO path, or for companies who are presented with an attractive proposal to merge into a failed existing public company. Panelists were also quick to note, however, that reverse mergers should not be viewed as a true liquidity event, because following or in connection with the reverse merger, a company needs to run a financing process. Therefore, panelists stressed that the reverse merger should be viewed as the

beginning of the long process on the road to success.