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: Trends in Biopharma

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Burst Four consisted of a panel entitled "*Evaluating and Partnering New Technologies and Emerging Business Models.*" This panel was moderated by **Kingsley Taft** from Goodwin, **Jeffrey Stoll** from KPMG and Nicholas Pullen from Bristol-Myers Squibb. In this panel, participants provided their insights regarding active deal sectors in biotech and issues to consider with respect to deal structure.

Key takeaways from Burst Four were as follows:

1. ***Platform technology deals in areas involving gene therapy, mRNA and immuo-oncology have been active, but some concern persists that companies in certain areas are over-valued, potentially decreasing the overall number of deals that have been made.*** Although many areas of biotech have actively been generating deals, the number large deals announced in the run-up to JP Morgan appeared to be less than in the prior year. The panelists suggested that the decreased number of deals may be a function of the high valuations that have been placed on biotech companies, noting the premium acquisition price that Roche paid for Spark as an example.
2. ***Given the complexities associated with certain platform technologies, such as gene therapy, many pharma partners prefer partnering deals as opposed to outright acquisitions for platform companies.*** Panelists suggested that pharma companies are more

likely to favor a partnership structure over an acquisition structure when it comes to early-stage platform technologies in biotechnology. The reason for this is that the platform technology is likely to need a great deal of additional investment in numerous areas, including manufacturing, before the emergence of a product candidate that the pharma company is willing to develop on its own. In addition, it is very difficult for a pharma company to put a valuation on an early-platform company, but things become easier when the platform actually starts to generate potentially marketable products.

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

 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 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.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: Europe Unleashed

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Burst Two consisted of two parts. The first was a panel entitled "*The Evolving Landscape for Growth-Stage Venture Funding in Europe*." This panel was moderated by **Sophie McGrath** from Goodwin, and consisted of Francesco De Ruberti from Medicxi and Dirk Kersten from Forbion. In this panel, participants provided their insights regarding the status of growth-stage venture financing in Europe and provided some comparisons between growth-stage investing in Europe versus in the United States.

The second part of Burst Two was a panel entitled "*Maximizing Returns through Structured M&As.*" This panel was moderated by **Graham Defries** from Goodwin and consisted of Erik van den Berg from AM-Pharma, Geert-Jan Mulder from Forbion, Maarten de Jong from Moelis & Company and Andy Stephenson from KPMG. In this panel, participants provided their advice and perspectives regarding structured M&A deals, such as option to acquire deals.

Key takeaways from Burst Two were as follows:

1. ***Different investors have differing views of what constitutes the growth equity phase, therefore, it is important for companies to understand the requirements of different investors to determine which investors are the best fit.*** Panelists noted that companies should be aware that different funds have differing perspectives regarding what constitutes a growth-stage company for purposes of growth-stage investing. For example, one of the panelists noted that his fund considered a growth-stage company as one that is receiving its first private financing round before a major event, such as a pharma partnership or a liquidity transaction. The other panelist noted that his fund considered a company with an asset in Phase 2b/3 development as a growth-stage company. Companies should understand these differences so that they are able to properly target investors.
2. ***Syndication of financing rounds is essential for growth stage biotech companies given their high capital requirements.*** Panelists noted that European investors must develop a syndicate in order to properly fund growth-stage biotech companies, given the high capital needs of these companies. Typically, investors tend to syndicate with other investors that are

of similar or larger size, as they want to ensure that sufficient capital will be available when needed.

3. ***European biotech companies tend to raise less money than U.S. biotech companies, as European investors tend to tie raises to a company's forecast over a specified period of time.*** Panelists noted that European investors typically invest a smaller amount of money in any given round than their U.S. counterparts, representing a difference in funding strategy. European investors only like to invest as much as is required by a company's forecast, where U.S. investors are typically willing to invest more than is needed, although they often do so in tranches. Panelists also noted that European biotechs tend to be smaller than their U.S. counterparts and have lower operating costs.
4. ***Structured M&A deals are a good sources of financing for a company, but many of these deals do not result in an actual acquisition, therefore, companies that enter into these deals need to be prepared.*** Panelist noted that structured M&A transactions, such as options to acquire, can provide companies with a solid fundraising source, but companies must be cognizant that many challenges exist with these deals. For example, in most option to acquire deals, the optioned company is prohibited from engaging in certain actions without the prior consent of the potential buyer. The optioned company should keep these prohibitions as light as possible to avoid cumbersome intrusion by the potential buyer. In addition, many option deals do not end with the optioned company being acquired by the potential buyer or being acquired on the terms originally agreed to. This could leave the optioned company in a bad position, such as, without additional funding, and having to agree to a new, less desirable deal with the buyer. In addition, other potential buyers might view the company as tainted, wondering why the original buyer backed out of the deal.
5. ***In structuring option deals, goal is to maximize upfront payment given the uncertainty in option deals and decreased likelihood that later milestones will be paid out.*** Given the uncertainty associated with option to acquire deals, panelists suggested that an optioned company seek as large an upfront payment as possible to avoid the potential of leaving money on the table. In addition, even if an acquisition of the optioned company does take place, outlets such as SRS have reported that approximately only 30% of milestones associated with a deal end up being paid out.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: New Frontiers in Digital Diagnostics and MedTech

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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 One consisted of three parts. Roger Cohen from Goodwin provided an overview of the current state of the healthcare sector and regulations. During this session, Roger provided an overview of the FDA's definition of a medical device subject to FDA regulation, highlighting whether digital technologies would be encompassed within such definition. In addition, Roger reviewed other key federal and state laws of importance to companies involved in the digital healthcare space – including privacy laws such as HIPPA – and state laws regarding the corporate practice of medicine.

The second part of Burst One was a panel entitled "*New Frontiers in MedTech Space on the Global Stage: What are the Challenges in IP, Regulatory and Commercial*?" This panel was moderated by **Kristin Ciriello Pothier** from KPMG, and consisted of **Nicholas Mitrokostas** from Goodwin, Stefan Scherer from GlaxoSmithKline, Joseph Zaccaria from TrialSpark and Reena L. Pande from AbleTo. In this panel, participants provided their perspectives regarding the numerous challenges associated with bringing new medical technology to market, including as it relates to intellectual property, regulatory approvals, reimbursement and commercialization.

The final part of Burst One was a panel entitled "*Issues Facing Therapeutic Companies Using ML and AI in Drug Discovery Methods.*" This panel was moderated by **Danielle Lauzon** from Goodwin and consisted of David Berry from Flagship Pioneering, and Dan Housman from Graticule and Courage Therapeutics. In this panel, participants provided their insights regarding how artificial intelligence, or AI, and machine learning, or ML, is used in the drug development process, and debated what type of input data is necessary for AI and ML to be truly useful in the drug development process.

Key takeaways from Burst One were as follows:

1. ***MedTech, digital diagnostic and health IT companies should seek guidance from experienced counsel as early on in the process as possible as laws and regulations are numerous and complicated.*** Various panel members noted that one of the biggest mistakes that companies in the evolving medtech, digital diagnostics and health IT spaces make is failure to consider the numerous, complicated laws and regulations that may apply to their technologies. Therefore, they highly recommended obtaining experienced lawyers early in the company lifecycle to avoid potential missteps. For example, determining whether certain medical software will be regulated as a medical device by the FDA is very fact intensive and requires input from an experienced regulatory specialist as there are dire consequences for making the wrong determination. In addition, it is important to note that these laws and regulations are constantly evolving, therefore, something that may be permissible today may not be permissible in the future. Experienced counsel can keep you up-to-date on pending developments that might affect your company.
2. ***In many areas, the law has not kept pace with the speed of technological innovations; therefore, a great deal of gray space remains.*** Panelists noted that legal issues facing companies in rapidly-evolving sectors may not have a clear answer as the law has not kept pace with the speed of technological innovations. For example, in patent law, folks have had to consider whether a computer should be deemed the investor of the output from certain AI processes.
3. ***In order for new technologies in areas such as medtech, healthcare IT and digital diagnostics to become successful on a large scale, there is a need to balance the innovative mindset with the entrenched mindset and there must be an openness to collaboration both internally and externally.*** Many panelists cautioned that in order for

new innovations in medtech, digital diagnostics and healthcare IT to be accepted by the current healthcare system, it will require a great deal of cooperation between the innovators and the entrenched players. Therefore, panelists advised that companies developing new technologies in these areas should seek to involve more entrenched players into their decision-making and development process as early as possible, and to seek returns on a smaller scale before seeking returns on a larger scale in order to build credibility.

4. ***AI has a great deal of promise in drug development, but questions remain regarding (i) how to obtain a sufficient amount of data for useful predictions, and (ii) the quality of the data that is used to arrive at predictions.*** Panelists noted that AI can be used throughout the drug development lifecycle, from assisting with target selection to helping predict the patient population that is most likely to respond to a product candidate. However, a panelist cautioned that the hype associated with AI should be toned down, as AI has yet to provide many of the promised benefits. Furthermore, there are many differing positions regarding the type of quality of data needed for AI to be truly useful in the drug development process.