TOP OF MIND ISSUES FOR GLOBAL LIFE SCIENCES COMPANIES IN THE ERA OF COVID-19

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About Goodwin's Global Life Sciences Capability

The Life Sciences industry continues to rapidly evolve in the era of COVID-19 with new innovations in areas ranging from vaccine development to diagnostic testing, and advancements in medical equipment, systems and protocols to treat patients.

We recognize movement in the market and empower our life sciences clients to:

Achieve advancements in accessibility and affordability across the life sciences vertical

Adapt business strategies to support novel and changing patient needs

Establish and maintain increasing demands in regulatory compliance, while pushing for innovation (e.g., leniency around telemedicine laws)

Support innovative investments by guiding on financings and executing on strategic collaborations and licensing agreements

HOW WE FIT IN:

- Leveraging our lifecyle practice expertise
- Understanding of increased investment focus in this vertical
- Experience in all aspects of the life sciences sector
- Accomplished FDA and EMA services
- Critical Regulatory Guidance
- Global IP, Litigation and Licensing/Collaboration expertise
- Representative experience in all sectors from Big Pharma to Biotechs, as well as Generic and Biosimilar sectors
- Strong knowledge of the global market

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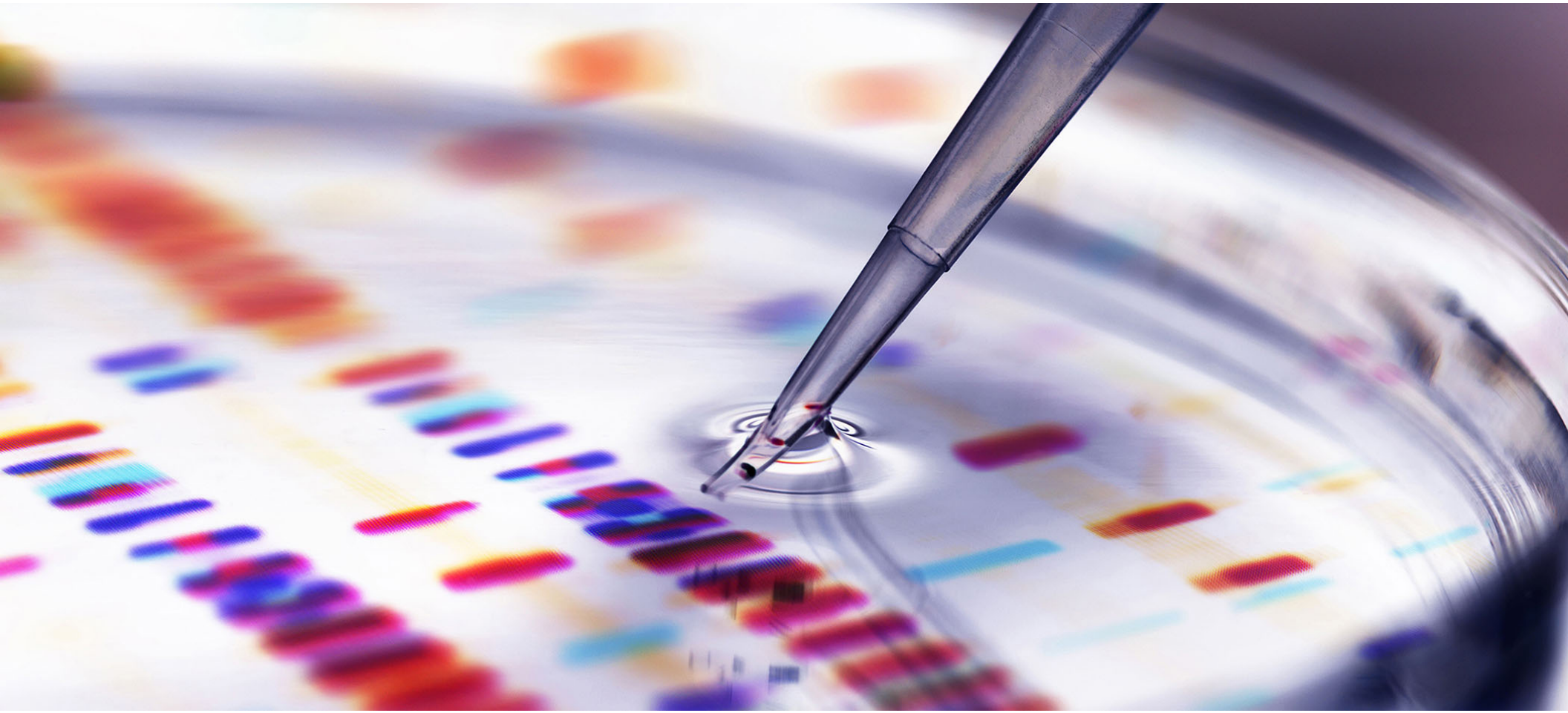
Agenda

- FDA and EMA Regulatory Guidance
- IP Developments
- Global Employee Retention Issues
- Challenges to Existing Collaboration, License and Commercial Arrangements
- Global Trends in Private and Public Capital Markets
- A Perspective on the Current and Coming Private and Public M&A Markets
- Questions?

U.S. FDA Regulatory Developments and Innovations



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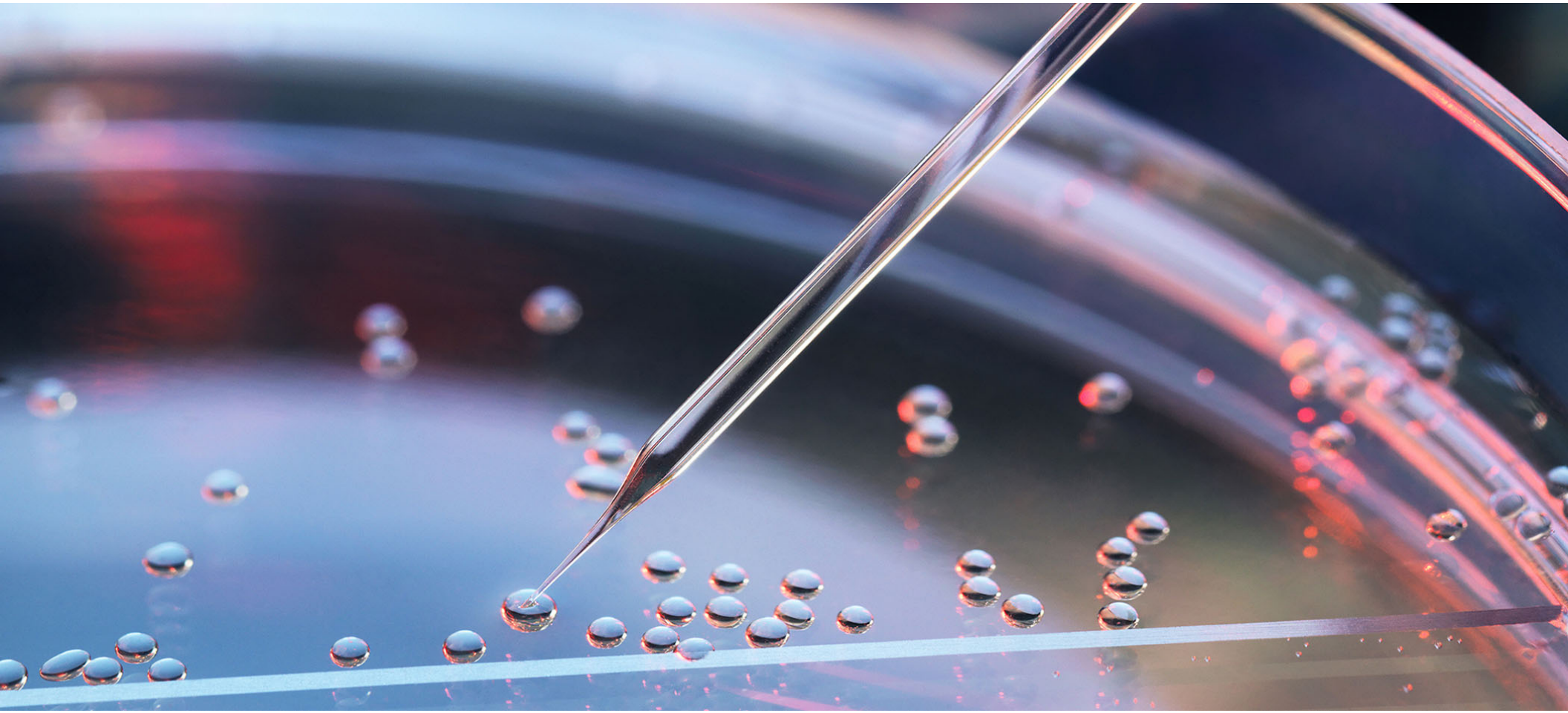
Clinical-Stage Companies and Programs

- March 2020: FDA Guidance on Conducting Clinical Trials during the COVID-19 pandemic
- Institutional Review Board site-adopted COVID-19 policies
- Expanded Access offerings and compassionate/emergency use INDs
- Clinical supply interruptions or delays
- Practical Implications:
  - Inventory clinical program status & consider redesign, postponement, or pause
  - Statistical analysis plans & keeping datasets intact
  - Informed consent updates and protocol amendments
  - Safety reporting (treatment withdrawal, COVID-19 impacted patients)
  - Virtual patient assessments
  - Virtual site monitoring & GCP oversight
  - Minimizing protocol deviations
  - Recordkeeping
  - FDA advisory committee meetings
  - PDUFA date delays
  - Informing future trial design (e.g., fewer study sites, lower-risk geographies)

Commercial-Stage Companies and Programs

- Commercial supply interruptions or delays
  - Reporting shortages to FDA
- Routine FDA surveillance inspections – on hold
  - Foreign: “mission critical” inspections on case-by-case basis only (March 10)
  - Domestic: “for cause” and “mission critical” inspections only (March 18)
    - March 25th – One public U.S. company reported FDA had completed a pre-approval inspection
- Label updates
  - New safety information or warnings/precautions/contraindications on marketed products
- Enforcement for product marketing claims
- Managing compliant product promotion
  - Robust U.S. healthcare compliance programs
- Managing external Medical Information/Medical Affairs communications
  - Solicited vs. unsolicited off-label inquiries
  - False Claims Act exposure
  - Government investigations
- Concern over possible invocation in US of Defense Production Act to divert production capability to the government to make materials needed to address COVID-19

EMA Regulatory Developments and Innovations



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Clinical-Stage Companies and Programs

- March 27, 2020: EMA Guidance on the Management of Clinical Trials during the pandemic. Key points:
  - Only strictly necessary visits at trial sites – virtual assessments instead
  - Temporary trial halts; suspending or slowing recruitment
  - Where sites need to be closed, doing so safely
  - Initiation of new sites not expected unless no other solution exists for current participants
  - Overall well-being and best interests of trial participants are paramount
  - Implement measures which prioritize subject safety and data validity – with safety prevailing if there is a conflict between the two
  - Frequent reassessment of risks required by sponsors and investigators
  - Alternative procedures required to obtain informed consent in COVID-19 trials as physical consent cannot leave the isolation room (e.g. oral consent with independent witness present)
  - Updating of consent for ongoing trials
  - Changes to distribution of IMP – local laws apply for direct to participant supply
  - Remote source data verification challenges
  - Fast track, free scientific advice on COVID-19 related trials
- April 2020: Implications of COVID-19 on methodological aspects of ongoing trials – currently out for consultation

Commercial-Stage Companies and Programs

- April 10, 2020: EMA Q&A on regulatory expectations for medicines during the pandemic –
  - Extensions of MA renewal deadlines
  - Application of the 3 year sunset clause – exemption requests on public health grounds
  - Swift implementation of supply chain changes – ECMP (exceptional change management process) is available to MAHs of crucial medicines for COVID-19
  - Quality variations to accommodate significant increases in manufacturing capacity to meet EU demand for patients
  - Labelling exemptions to facilitate movement of crucial COVID-19 medicines within the EU to deal with shortages in certain countries
- Exemptions to the medical device and PPE regulations
- National regulators have issued guidance too, such as the UK's MHRA:
  - Exemptions to the medical devices regulations during the pandemic
  - Desk-based inspections rather than on-site inspections and audits
  - Electronic systems for approving pharmaceutical lifecycle and GLP studies
  - Flexibility in relation to Good Distribution Practice for wholesalers

IP Developments

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IP Developments

- Proceedings before the USPTO: Beware of statutory deadlines, know which deadlines may be extended because of COVID-19
    - Important statutory deadlines include non-provisional patent applications that claim priority to, e.g., a foreign priority application
    - PTAB has been liberal in offering virus-related extensions for non-statutory IPR, PGR deadlines
- Proceedings before US Federal Courts: The deadlines for many patent and other IP litigation matters have been delayed or courts are using remote means for depositions, hearings, and trials
    - Expect delays in litigation timelines, including postponement of discovery deadlines
    - District courts doing hearings and some trials remotely
    - Practices vary widely among courts and judges
    - Federal Circuit and Supreme Court doing oral arguments remotely
    - PTAB judges are accustomed to working and hearing oral arguments remotely, so few delays
    - Bonus: judges have had more time to write opinions so are issuing them somewhat more quickly/clearing backlogs
- Some recent questions:
    - Does patent “safe harbor” apply to making/using patented subject matter for submission of an Emergency Use Authorization application to FDA?
    - Are injunctions against patent infringement for COVID-19 treatments, medical supplies available?

IP Developments

- Non-profits, academic institutions and certain businesses are creating patent pools and databases to facilitate patent sharing for COVID-19 technology
    - WHO: voluntary pool to collect patent rights, regulatory test data, and other information that could be shared for developing drugs, vaccines, and diagnostics
    - Open COVID-19 Pledge: permits companies to provide medical supplies without risk of patent infringement litigation
    - Stanford, Harvard and MIT: “COVID-19 Technology Access Framework” to provide “rapidly executable non-exclusive royalty free licenses”
    - “The Medicines Patent Pool” (U.N.-sponsored) publicly available repository of patent data
- Patent owners have mixed approaches in handling IP rights for COVID-19 treatments/tests
    - AbbVie suspended enforcement of global patent rights on all formulations of the HIV medication, KALETRA (lopinavir/ritonavir), being evaluated to treat COVID-19
    - Gilead Sciences stopped granting patients emergency access to remdesivir under compassionate use, except for pregnant women and children under 18 with severe COVID-19
    - Labrador Diagnostics sued the diagnostics business BioFire and its parent company BioMérieux in Delaware, accusing them of infringing two Theranos patents for their COVID-19 tests
- Good reasons for biopharma innovators to act cautiously when enforcing U.S. IP rights: U.S. government may trigger compulsory licenses or “march in rights” in public health emergency

Global Employee Retention Issues

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COVID Impact on Non-Essential Employees

- Most countries have imposed mandatory quarantine measures for non-essential business or workers
  - Many countries have modified rules allowing employers mandate that employees required to stay at home to take their annual leave entitlement
  - Other jurisdictions are issuing new rights to paid sick leave due to COVID-19 illness, government mandated quarantine, or caring for a sick family member
  - Many countries have quickly set up programs that subsidize employee wages or employer burdens of retaining a workforce that is unable to return to work
- For employees that are able to work remotely, maintaining productivity requires a balance of morale building and accountability
- Employers are being asked to be more understanding of distractions at home (e.g., childcare responsibilities due to closure of schools, difficulty securing goods, limited internet connectivity)
- For non-essential personnel who are not permitted to leave their homes and are unable to work remotely, employers are facing difficult decisions including furloughs, terminations, or pay reductions

Avoid Disruption of Worker Productivity Requires Care

- Depending on the jurisdiction, where essential workers are permitted to work on-site, employers must still comply with rigid protocols around protecting workers at the worksite (e.g., social distancing and providing protective equipment)
  - Re-configure work spaces to allow for social distancing
  - Modifying work hours or days of work to reduce number of employees at the worksite without reducing productivity
  - Modification of terms and conditions of employment may require working with a works council or union
- Increased employee pushback and protests where work conditions feel unsafe
- Employers need to immediately start formulating a return-to-work plan for when quarantine restrictions ease
  - Testing (temperature, antibody, infection)
  - Employee illness (privacy, applicable disability laws, pay status)
  - Commuting and entry protocols
  - Complying with local health directives
  - Consider maintaining remote work for some

Challenges to Existing Collaboration, License and Commercial Arrangements

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Issues to Consider for Existing Collaboration, License and Commercial Arrangements

- **Assess Mitigating Steps.**
  - Anticipate issues that might arise under existing collaboration, license and commercial agreements
  - Consider reviewing with collaboration partners existing and novel technologies to find virtual ways to continue to focus on and advance clinical development activities
- **Review Existing Agreements.**
  - Review with counsel existing agreements to understand force majeure clauses or commercially reasonable efforts standards
  - Might your or your partner's obligations be excused or might there be a need to propose new contracts or amendments to address the current pandemic
- **Impossibility versus Force Majeure.**
  - Understand the difference between impossibility and force majeure concepts in existing contracts
  - Each can potentially excuse or delay performance
  - It must be recognized that the application of these standards is very fact specific and depends on the contract's language and governing law

Issues to Consider for Existing Collaboration, License and Commercial Arrangements

- **Review CRE Provisions and Document Communications.**
  - Disputes related to commercially reasonable efforts (CRE) clauses and related standards agreed to by life sciences companies in their collaboration agreements should be reviewed carefully
  - The pandemic may be used by collaboration and commercial partners to shift priorities whether it is related to the pandemic or not, so expect it will be increasingly difficult to use the CRE clause as a lever to get a counterparty to act
- **Arbitrations and Courts.**
  - Access to courts and arbitrations has never been more limited
  - Expect delays and difficulties in moving commercial dispute matters through courts and arbitration panels
  - Negotiating leverage will be affected
- **The Law Evolves in Extreme Times.**
  - Extreme times such as these, which have also arisen in the past around 9/11 and the financial crisis often, lead to significant changes in the law

Global Trends in Private and Public Capital Markets

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Global Trends in Private and Public Capital Markets

- **Market overview:**
  - Slow down in seed and earlier stage venture financings, but have not yet observed many re-priced venture rounds, and more mature private life sciences companies are still attracting venture investments; some open rounds are even getting oversubscribed
  - Increased interest by early and growth stage investors in companies that can treat or retool to address COVID-19
  - Increased interest in alternative financing structures like PIPES, ATMs and royalty monetizations
  - Since March, there has been a modest re-opening of the equity capital markets with 17 follow-ons and convertible offerings.
    - 8 of the 9 follow-on offerings have been confidentially marketed, converts accounted for 44% of deals; on average stock has traded well after the deal
- **Life Sciences IPOs:**
  - 2 life sciences US IPOs: Zentalis (April 2, 2020) and Keros (April 7, 2020) IPOs priced at the high end of their price ranges and have traded well with both having exercised their overallotment or green shoe options
  - Hitgen is 4th biotech listing on Shanghai Stock Exchange (SSE) STAR (Chinese equivalent of Nasdaq)
    - IPO priced at 20.52 RMB. On first day of trading (April 16), stock closed at 47.08, up 129%.
  - Junshi Biosciences (HKEX: 1877), also pursuing dual-listing on SSE STAR
  - 10 IPOs so far this year and the majority of them are trading well
  - There are 8 life sciences IPOs that have flipped public and are evaluating launch options from what we can tell
  - No new IPO filings seen, so expect next few weeks to be light from an IPO perspective

Global Trends in Private and Public Capital Markets

- **Life sciences follow-on offerings:**
  - There were 5 life sciences follow-on offerings that priced last week, 2 in early April and only 5 in all of March, following a relatively robust February
  - During March and April there were 5 convertible note offerings.
- **Increased governmental oversight:**
  - CFIUS being employed to protect sensitive businesses from being controlled or influenced by foreign countries
  - EU Foreign Direct Investment powers being expanded, with an emphasis on protecting European life sciences companies from being controlled by ex-EU countries

A Perspective on the Current and Coming Private and Public M&A Markets

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COVID-19 Impact on Early Stage Deals and M&A "Pipeline"

- For early-stage deals, chilling deal environment and logistical obstacles
  - In-person meetings and social interactions help develop trust and repertoire among business teams, which is essential early in the transaction process
  - Very difficult to conduct diligence and inspect properties/assets remotely
  - Many buyers taking a "wait and see" approach to potential M&A deals
- For the deal "pipeline" in the life sciences industry, preliminary discussions are on hold for many would-be buyers or sellers
  - Most strategic deals trace their origin to in-person meetings among senior management at conferences, dinners and other events, which are not occurring
  - "Big Pharma" has been reallocating its resources in light of COVID-19
  - However, opportunities remain for both opportunistic and financial buyers that can take advantage of depressed asset prices
- For deals that have not yet priced, very challenging environment
  - We are seeing a general disconnect between buyers and sellers on valuations
  - For transactions with publicly-traded securities, volatility makes pricing especially difficult
- For deals that have already priced but have not yet been signed/announced, tension on price and underlying assumptions
  - When valuations employ financial approaches such as discounted cash flow analyses, EBITDA multiples, etc., the underlying inputs and assumptions are being revisited

Uncertainty For Deals That Have Been Announced But Have Not Closed

- For deals that have already signed, generally a sprint to closing…
  - Deals that involve debt financing subject to risk such financing becomes unavailable
  - For strategic deals, rush to integrate businesses as soon as possible
  - For deals involving stock as consideration, concern that further decline in market prices could cause the target's stockholders to vote down the deal
- …however, we are seeing exceptions in certain circumstances
  - For deals under review by regulatory authorities, some logistical delays
    - For example, the Federal Trade Commission (antitrust regulator), has paused its administrative proceedings, which could lead to delays in deal closings
  - For some buyers, uneasiness over COVID-19 giving them second thoughts
    - Some have sought to delay closing, which has resulted in a big increase in deal litigation by sellers seeking to compel the closing
    - Some buyers are looking to closing conditions to evaluate whether they can get out of, or renegotiate, a deal
      - Renewed emphasis on Material Adverse Effect clauses in light of the COVID-19 pandemic
  - For some sellers in transactions where the buyer is using its stock for consideration, tension over whether the seller's stockholders will approve the deal in light of declines in market prices of the buyer's stock
    - Some buyers and sellers are seeking to address this by negotiating changes to the transaction to increase deal certainty

Questions?

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