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CONSIDERATIONS FOR M&A AND STRATEGIC PARTNERSHIPS IN THE EVER-CHANGING LIFE SCIENCES LANDSCAPE

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Overview

Market Trends & Forecasts

What Makes Life Sciences Deals Different?

Case Study of a Cross-Border Biotech Acquisition

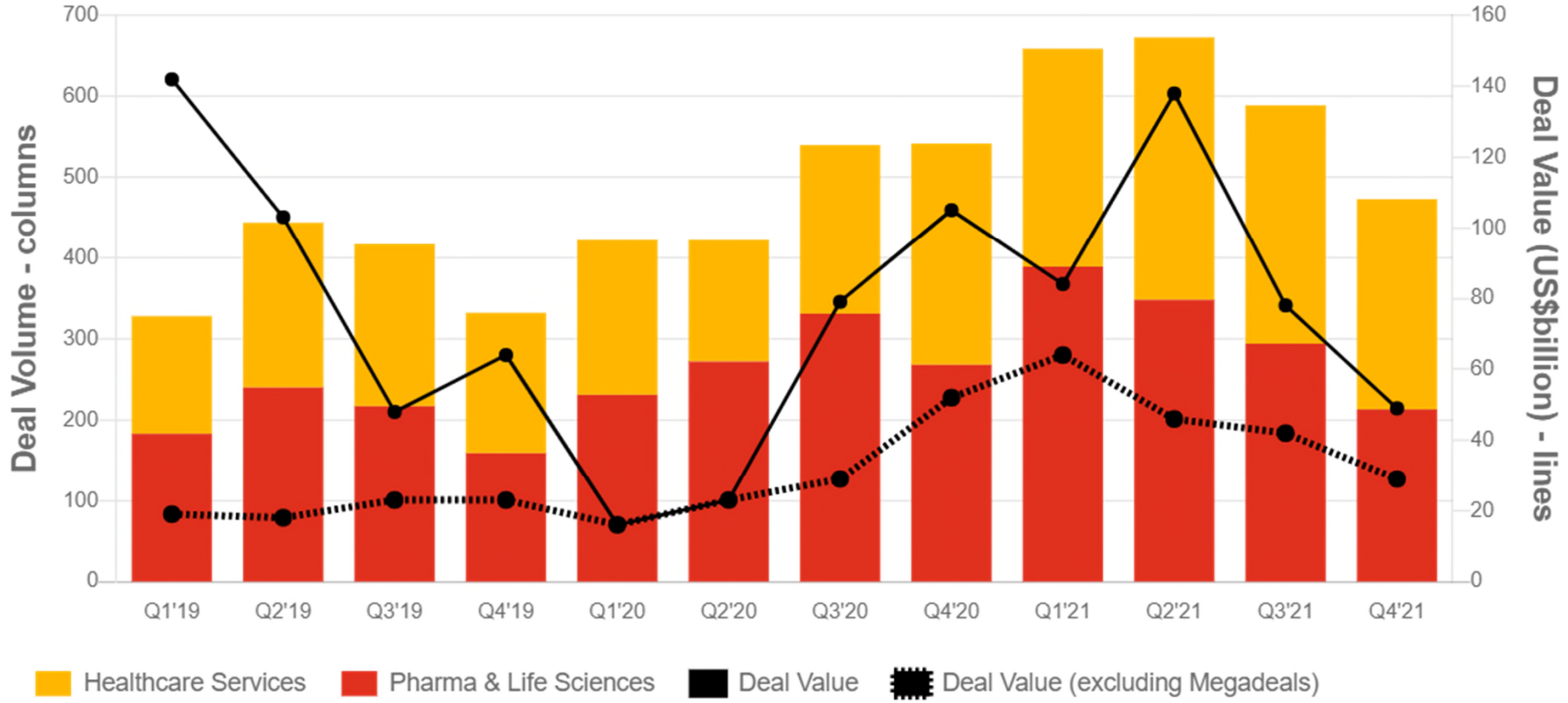
Lessons Learned

Market Trends in M&A and Partnership Space for 2021 and Forecast for 2022

What Drove Life Sciences M&A Activity in 2021?

- Global life sciences mergers and acquisitions (M&A) activity totaled US$219b in 2021, up from US$159b in 2020 – however, this was mainly driven by medtech deals (US$111b).
- Biopharma M&A activity, in contrast, dropped in 2021 to one of the lowest levels in a decade, totaling US$108b, down from US$128b in 2020 and US$261b in 2019. Largely driven by the lack of megadeals.
- 2021 was a volume story (52% increase in deal volume in 2021 vs. 2020 (370 announced M&A transactions). Smaller bolt-on transactions represented 88% of total deal volume.
- At the end of 2020, large Biopharmaceutical companies had approximately $1.7 Trillion of "Firepower," yet only 9% of biopharma's firepower was deployed on M&A in 2021, compared with 25% in 2019 and 12% in 2020.

Source: 2022 EY M&A Firepower report, Biomedtracker


Deal Volume - columns
Deal Value (US$billion) - lines
700
600
500
400
300
200
100
0
160
140
120
100
80
60
40
20
0
Q1'19
Q2'19
Q3'19
Q4'19
Q1'20
Q2'20
Q3'20
Q4'20
Q1'21
Q2'21
Q3'21
Q4'21
Healthcare Services
Pharma & Life Sciences
Deal Value
Deal Value (excluding Megadeals)

Source: EY

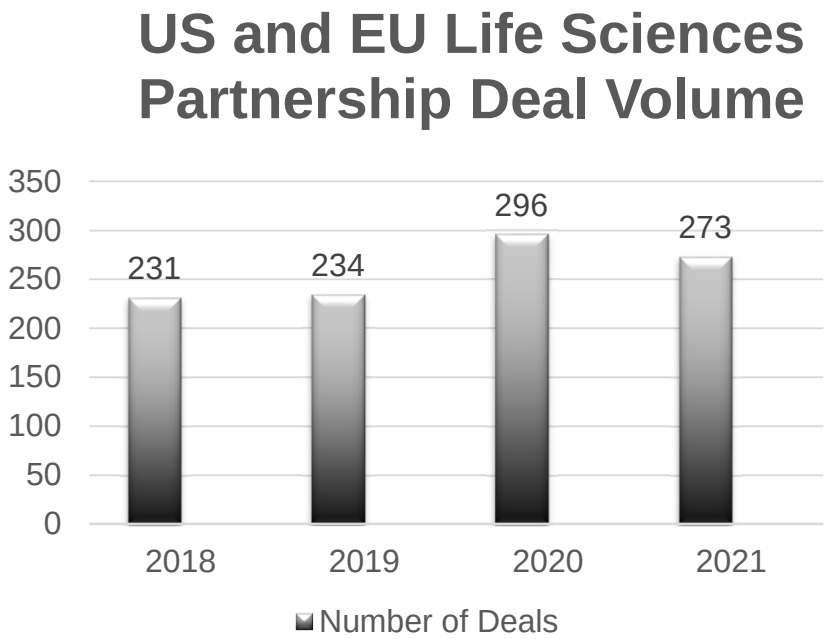
Market Forces in 2021 pushed Biopharmas away from M&A towards Partnerships

- Capital was still readily available in 2021. Last year, biopharmas raised more than US$80b in follow-on financing, venture funding and initial public offerings (IPOs), second only to the US$90b raised in 2020.
- SPACS: This capital for early- and growth-stage companies was further augmented by the expanding role of special purpose acquisition companies (SPACs), a trend that accelerated in 2021.
- This ready liquidity has given sellers multiple paths to value creation outside of M&A and increased expectations of the value of their assets. With little financial pressure to sell, these target biopharma companies were in a much stronger negotiating position and could demand high deal premiums, especially if their drugs belonged to new therapeutic classes or modalities.
- This translated into sky high premiums in 2021.
  - 62% premiums on average, jumping to 150% for cell therapy companies, 108% for next-generation antibody players and 94% for gene therapy startups.
  - Economics increasingly mirror partnership deals with pushed downstream in 2021 (share of M&A spending that's tied to future clinical and other milestones reached 8% in 2021)
- Biopharmas increasingly focused on partnerships and strategic alliances as a source for de-risked external innovation. Conservative with capital.

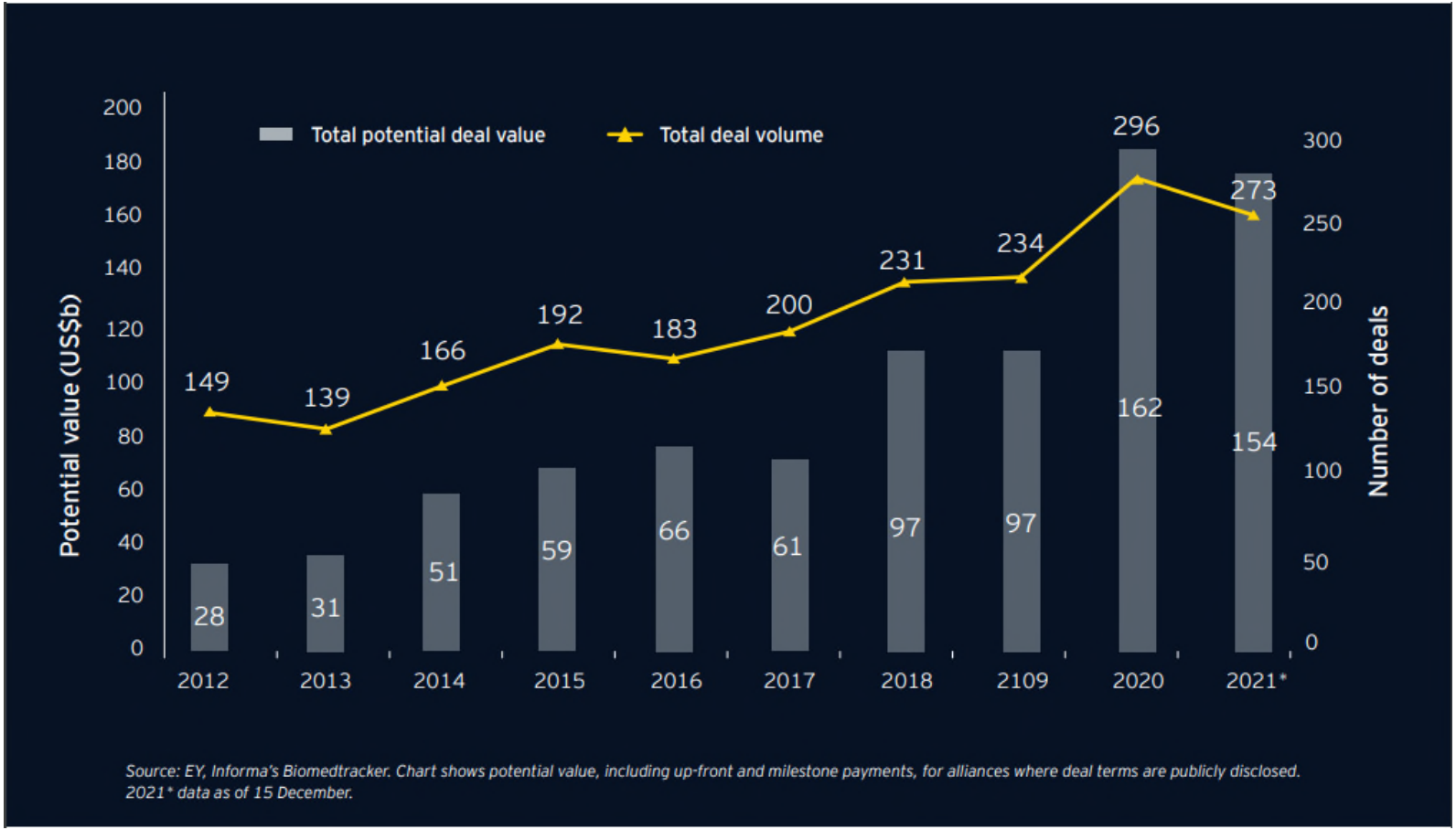
Source: 2022 EY M&A Firepower report

Partnership Deal Activity Holding Steady and Key Use for Firepower

- ***Since the beginning of 2020, major biopharmas have deployed roughly 1.5 times more firepower on alliances relative to M&A.***
- Partnership deal activity held steady in 2021, with biopharma companies prioritizing smaller partnerships with lower upfront payments after larger deals in 2020
- In 2020, biopharmas signed 38 alliances with upfront deal values greater than US$100m and four greater than US$1b.
- In contrast, in 2021, companies prioritized smaller deals with lower upfront values.
- Momentum around strategic partnerships expected to continue in 2022
  - Key areas to watch: Cell and gene therapies, antibody drug conjugates and RNA- and DNA-based medicines

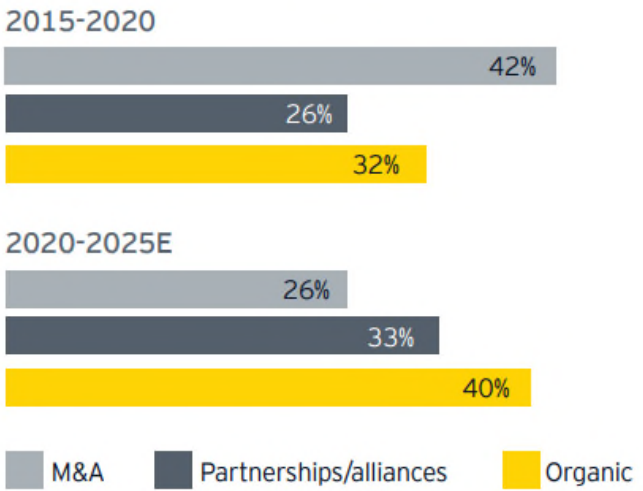


Source: 2022 EY M&A Firepower report, Biomedtracker

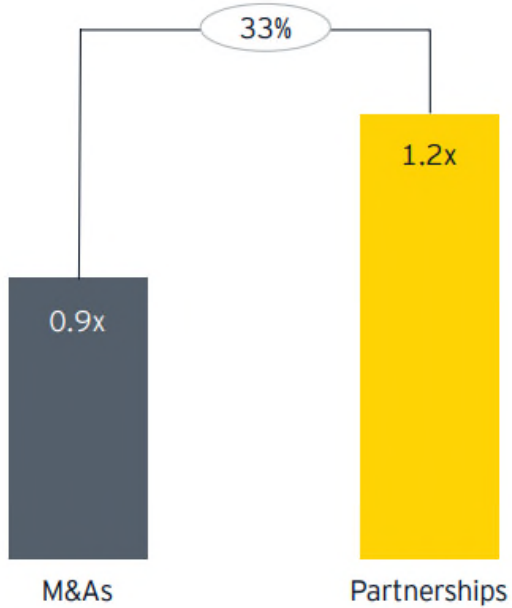


Source: EY, Informa's Biomedtracker. Chart shows potential value, including up-front and milestone payments, for alliances where deal terms are publicly disclosed. 2021 data as of 15 December.*

Figure 8. M&A and partnering relative contributions to projected growth 2015-2020, 2020-2025



Average ROI on M&A vs. partnering 2000-2015 (%)



Source: EY Analysis, Evaluate Pharma, Capital IQ. The top five therapy areas were identified for 25 biopharma companies. Products in each of these therapy areas were mapped according to their origin (organic or acquired via M&A or partnering). Market share gains were assessed using data from Evaluate Pharma. Returns on M&A and partnering calculated based on 5-year sales from all products obtained through dealmaking between 2000 and 2015 for this cohort of companies. Capital IQ and Evaluate Pharma were sources for M&A and alliance spending respectively.

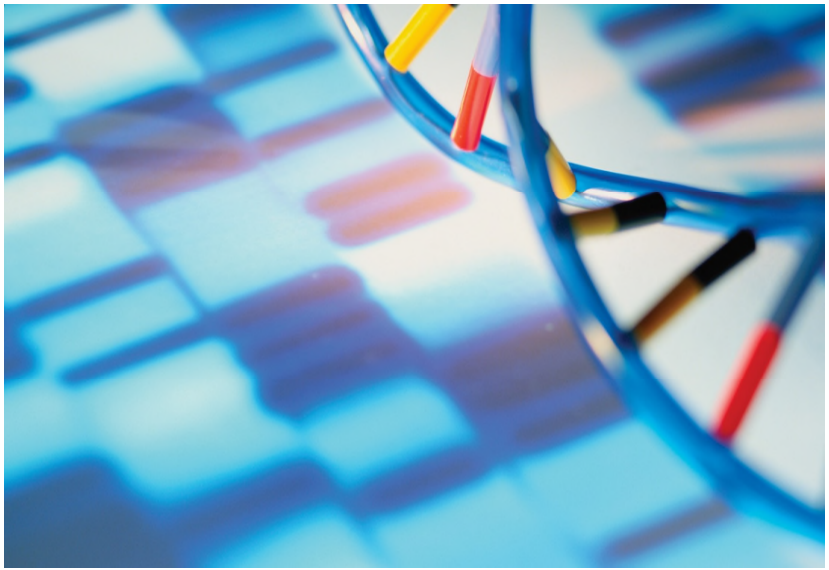
What is Expected for Life Sciences M&A in 2022?

- Potential for divestitures as large biopharmaceuticals continue the trend of focusing on core business strategy ("Divest to invest")
- Approaching patent cliffs and more favorable valuations
- The Bear outlook?
  - Pause on M&A due to geopolitical forces in Russia and China
  - Buyers remaining selective, conservative with capital.
  - Continued shifting of capital allocation away from M&A to alliances and strategic partnerships.
- Bullish outlook? M&A reaching $400 billion in 2022, driven by all subsectors
  - Could see 1 or 2 mega deals ($50 - $100 billion or more) given the continued need for transformative scale
  - Continued biotech acquisitions in the $5 billion to $15 billion range throughout the year as companies continue to try to fill potential gaps in 2024 to 2026 pipelines
  - With weaker sector performance in 2021, favorable valuations make public targets more attractive for acquisitions.
  - SPACs steady in the life sciences sector (as of November, 2021, there were more than 80 life sciences and health care SPACs looking for targets)
  - Biotechs that de-SPAC'd could become attractive acquisition targets

Source: PwC Pharmaceutical & life sciences: Deals 2022 outlook; Endpoints News Biotech Outlook 2022

Life Sciences Transactions and the SPAC Craze

- Life Sciences transactions were not excluded from the SPAC craze of 2020-2021
- After we will provide a little background on SPACs, we will discuss trends, current challenges and what the future may hold



What is a SPAC?

- A **S**pecial **P**urpose **A**cquisition **C**ompany is a blank check company formed for the purpose of effecting a business combination with one or more businesses
- SPACs are formed to raise capital in an IPO with the purpose of using the proceeds from the IPO to acquire an unspecified business after the IPO
- SPACs are formed by a Sponsor (typically a private equity fund, financial institution or group of investors)
  - The Sponsor makes an initial (pre-IPO) investment of $25,000 in exchange for "founder shares" typically referred to as the "Promote"
  - The Promote is a substantial portion of the SPAC's post-IPO equity
- Capital Structure
  - In its IPO, the SPAC typically issues equity that is structured to include one share of common stock and a warrant to purchase common stock
  - Simultaneously with the IPO, the Sponsor acquires additional units, shares or warrants in a private placement

Key Features of a SPAC

- The proceeds of the IPO are held in a trust account until released to fund the de-SPAC transaction
- A portion of the proceeds of the Sponsor's private placement investment is held outside of the Trust and is available to the SPAC for use in seeking a target for a business combination
- de-SPAC Transaction
  - Following the IPO, the SPAC will seek an opportunity to acquire an operating business (the "**Target**"). This is known as a "**de-SPAC**" or the "**Business Combination**"
  - It allows a private company to become a US public company outside of the typical IPO process
  - Additional PIPE Investors
  - Approvals and Trust Fund
    - The de-SPAC transaction requires approval from the SPAC's stockholders
    - The IPO investors have the option to convert their shares into a pro rata portion of the trust account and keep their warrants ("**Redemptions**")

SPAC Trends

- In general, 2021 was a record year for SPAC launches
  - The number of SPAC launches in 2021 was 613 which was a material increase from the 248 SPACs launched in 2020
- Consistent with the general trends, 2021 saw both, an increase in the number of SPACs launched with the goal of acquiring a Target that operates in the Life Sciences space and the number of Life Sciences de-SPAC transactions effectuated
- In April of 2021, the SEC announced a change in interpretation of accounting requirements applicable to most SPAC warrants. Thereafter, there has been a fair amount of direct and indirect guidance that the SEC intends to focus on SPACs in formulating new regulations
- This increased regulatory scrutiny, coupled with a tightening in the PIPE market and more "data" on the performance of earlier deals towards the end of the year, only temporarily reduced the number of SPAC launches within the year, but it did change the terms of such IPOs, the "nature" of many de-SPAC targets, and the relative attractiveness of effectuating a de-SPAC for many potential Targets.

What Do These Trends Mean Today?

- Change in Terms of SPAC IPOs
  - Increased warrant coverage
  - Decreased "runway" to effectuate the de-SPAC
  - Takeaway: The riskiness of SPACs is beginning to be priced into the marketplace
- Change in the "nature" of de-SPAC Targets
  - The number of de-SPAC transactions effectuated based solely on a "good idea" and projections decreased significantly
  - Most de-SPAC targets became late-stage post-profit companies with a real financial track record (which made justifying valuations with hard data easier)
- Change in the attractiveness of effectuating a de-SPAC for Targets
  - The PIPE market locking up resulted in insiders having to have more skin in the game, generally lower valuations and deals taking significantly longer to get done
  - Massive increases in Redemptions significantly impacted funding certainty

What Has This Meant for Life Sciences Transactions and What is it Likely to Mean Going Forward?

- Many of the earlier Life Sciences de-SPAC deals didn't pan out and ultimately ended up trading below $10
  - This general trend is why the terms of SPAC IPOs became more favorable to investors and why the PIPE market locked up
- Many of the earlier Life Sciences deals were early-stage pre-profit companies that, in retrospect, probably did not have enough positive clinical data to "prove" value and generally may not have been fully prepared for "life as a public company"
- With downward pressure on valuations, smaller PIPEs and higher Redemptions, an "average" de-SPAC transaction becomes less and less attractive to a Life Sciences company that has material capital needs
  - Cannot overlook the "cost" associated with being a public company
- What does this likely mean for the future?
  - The more attractive de-SPAC targets are likely to be later-stage Life Sciences companies
  - Because of increased risks, it is likely that fewer Life Sciences companies consider a de-SPAC their preferred means of financing (although there will be exceptions and hybrid deals that try to mitigate this risk)
  - A unique story that the market can buy into will be increasingly important

Hybrid Deals - The Future of Life Sciences Deals?

So what does this all mean?

- Market forces may affect transaction form, but innovation is necessary for the ecosystem.
- Transaction form vs. function (Partnerships vs. M&A): What's really driving dealmaking?
  - **Fundamental goal is to bridge valuation and de-risk the science**
  - "Scientific Renaissance" - the breakneck speed of innovation in this field, combined with inventors collaborating throughout the ecosystem and competing stakeholder interests means industry knowledge, transactional creativity and thought partnership is a must.
- Biopharmas BD and Corp Dev teams are becoming increasingly creative with deal structures, blending M&A transactions with Partnership and Co-Commercialization elements, along with spinoffs, options and other creative mechanisms to de-risk development.
  - Especially with new modalities and platform technologies (gene therapies, ADCs, immunotherapies, etc.).

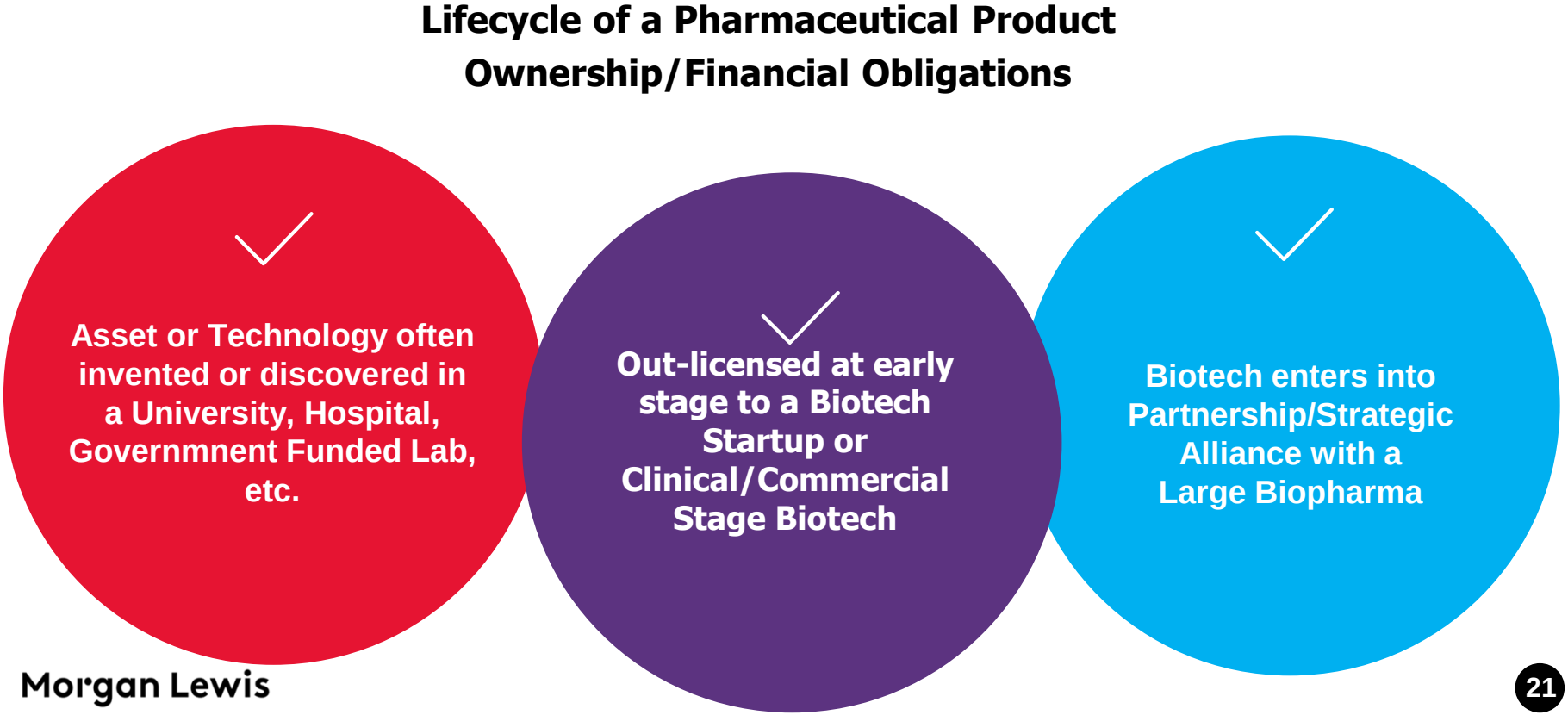
What Makes Life Sciences Deals Different


UNIQUE NATURE OF ASSETS OF LIFE SCIENCES COMPANIES
UNIQUE INDUSTRY ECOSYSTEM
FUNDAMENTAL DIFFERENCE in WHAT MAKES LIFE SCIENCES DEALS DIFFERENT

What Makes Life Sciences Different: Ecosystem

- The Ecosystem
  - Unique ecosystem of key players - interrelationships create a complex web of ownership issues, competing interests and priorities.
  - Academics/Hospitals >> Startups >> Biotechs >> Big Biopharma
    - "Upstream Agreement": A partnership agreement (license agreement, option agreement, research and collaboration agreements, co-commercialization and co-development agreement, etc.) with a third party pursuant to which a party in-licenses or otherwise maintains **control** of patents, know-how or other intellectual property rights. Unlike Merger Agreements or Stock Purchase Agreements, generally very bespoke and vary widely.
    - "Flow Down Obligations": A flow down clause is a contractual clause where a contracting party "flows down" contractual terms and conditions it has to another party in a separate contract. This can include the obligation to share clinical trial data or information related to IP improvements.

Who are the Key Players in the Life Sciences Ecosystem?



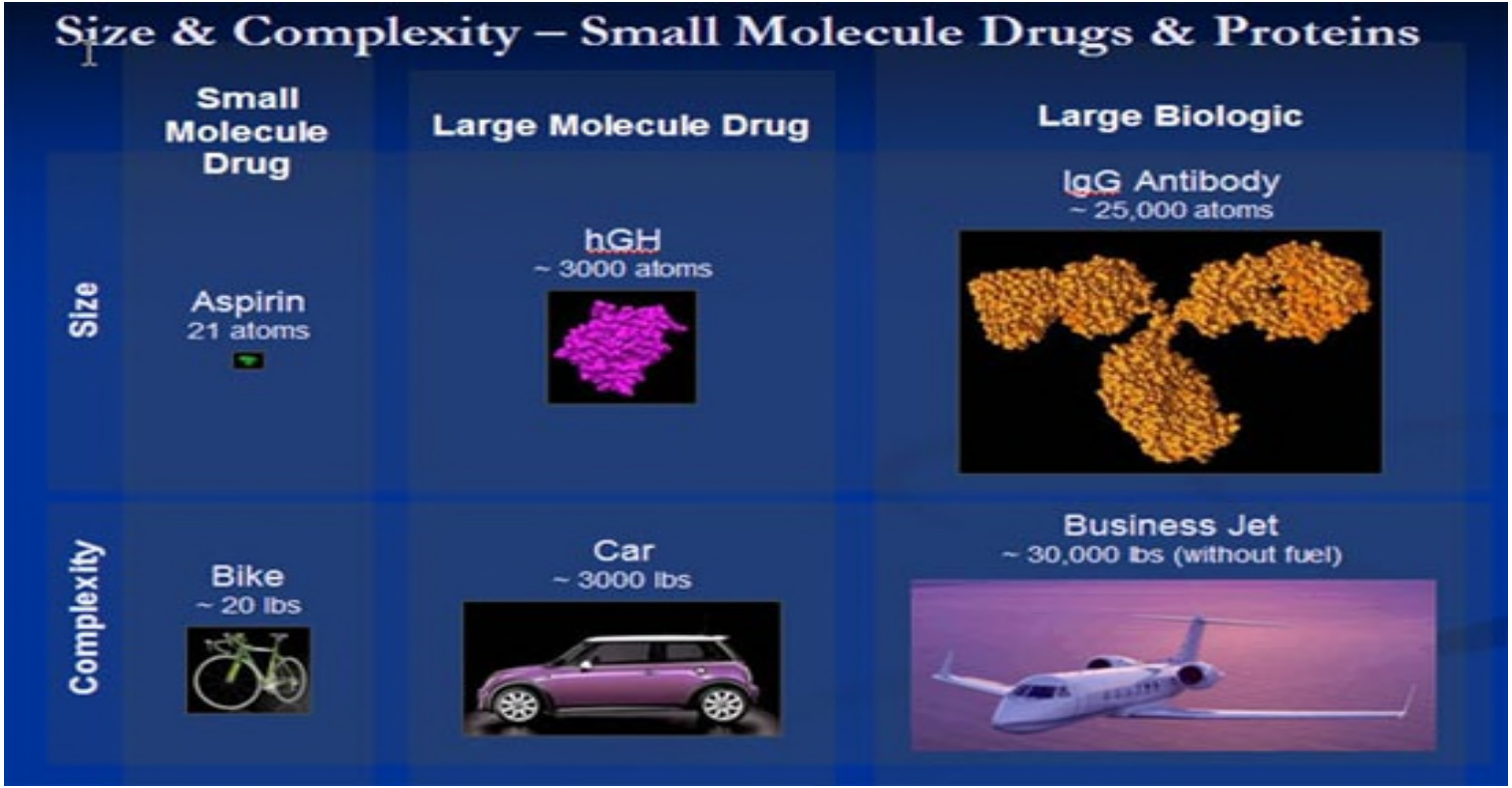
What Makes Life Sciences Different: The Asset Lifecycle

The Assets: Highly Differentiated, Technical Assets with Layers of Ownership Interests

- Fundamentally different from other industries
  - Lifecycle of an asset through the ecosystem = complex due diligence and upstream obligations that flow down to buyer/licensor
    - Traditional patent/IP due diligence
    - **Corporate due diligence of upstream agreements is critical** (SEC filings and public company due diligence often not sufficient - materiality thresholds and confidentiality mean upstream agreements often not filed or fully disclosed)
    - Given the amount of licensing and collaboration transactions and limited resources, many opportunities for mistakes ("poison pills").
      - "Poison Pill": In Life Sciences transactions, a clause or provision in an Upstream Agreement that creates a very broad obligation to share confidential information, inventions, future patents, improvements, know-how, etc. with an upstream licensor. Generally, these are focused upon when a biotech company is a target for acquisition. If the risk is too high or the upstream licensor won't renegotiate to limit these rights, the acquiror may walk from the deal rather than face future litigation or risk their platform.

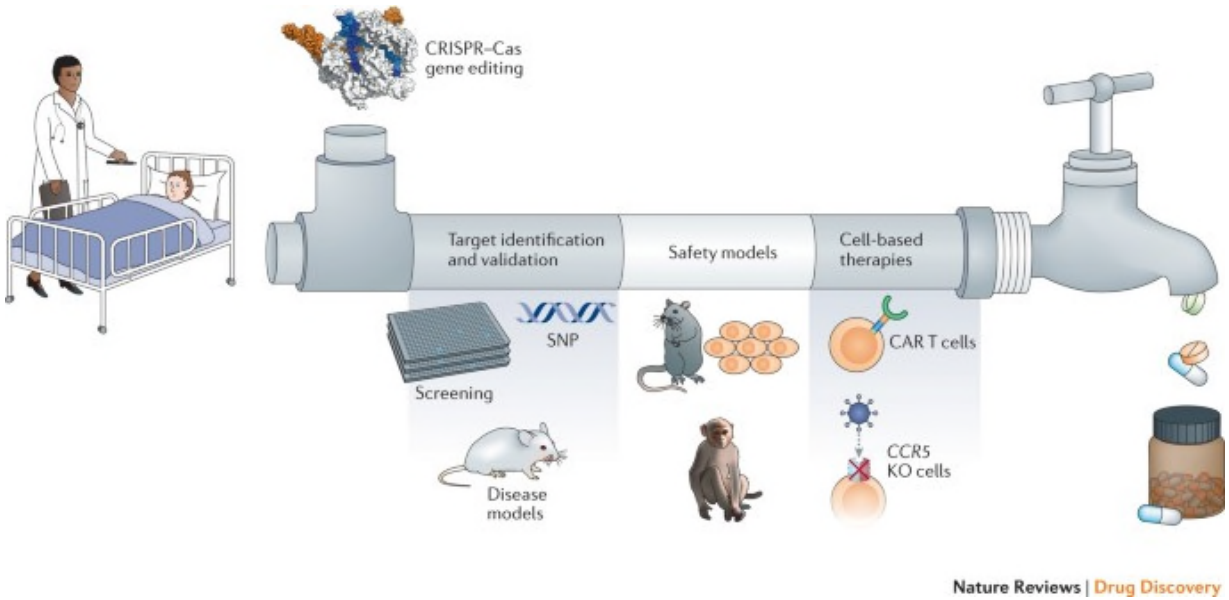
What Makes Life Sciences Different: The Science

- Phase of asset (Discovery, Phase I, Phase II, Phase III, etc.)
  - Earlier stage assets generally have lower valuations because of the cost and risk associated with clinical Development and Commercialization.
    - *"Development": the Development stage of a Drug product, from preclinical activities through Clinical Trials and the filing for Regulatory Approval of the product. Development Costs: the costs associated with Development, calculated on a Full-Time Equivalent and Out-of-Pocket Cost or other basis*
    - *"Commercialization: the marketing, promotion, sale and distribution of a pharmaceutical product. Strategy and key factors depend heavily on patient population and indication (e.g., oncology vs. dermatology).*
  - Phase III or Market assets = higher premiums, bigger upfronts and less risk.
- Type of modality or technology – it's critical to understand (or attempt to understand!) the SCIENCE.
  - The risks associated with a Gene Editing deal vs. small molecule deal are very different. Therefore, the constructs and mechanics corporate attorneys use to solve for those risks are very different, regardless of the form of the transaction.
    - E.g., Exclusivity clauses in small molecule deals vs. gene therapy.
  - Not uncommon to have 25 pages of scientific definitions whether it's a Partnership agreement or Stock Purchase Agreement



Source: AZBIO – Small Molecules, Large Biologics and the Biosimilar Debate

CRISPR Modalities

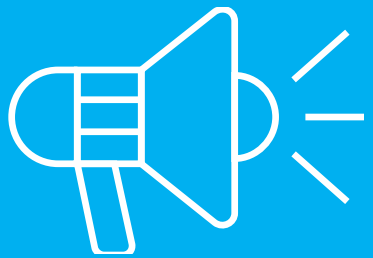


Economics

- Upfronts, Earnouts/Milestones, Royalties/Net Sales
  - Whether a partnership deal or a M&A deal, economics are often very similar and reflect the Research and Development stage of the Asset + expected market opportunity (Phase I, II, III)
- Generally, buyers/licensors seek to push economics downstream and sellers/licensees seek more upfront.
- Upstream financial obligations are critical to understand and model in M&A context as they will flow down to acquiror
- Sellers/Licensees will often seek enhanced diligence/CRE or anti-shelving protections.

Unique Factors that Affect the Industry

REPUTATION & COLLABORATION



Patient Considerations

Global Regulatory Factors

Case Study

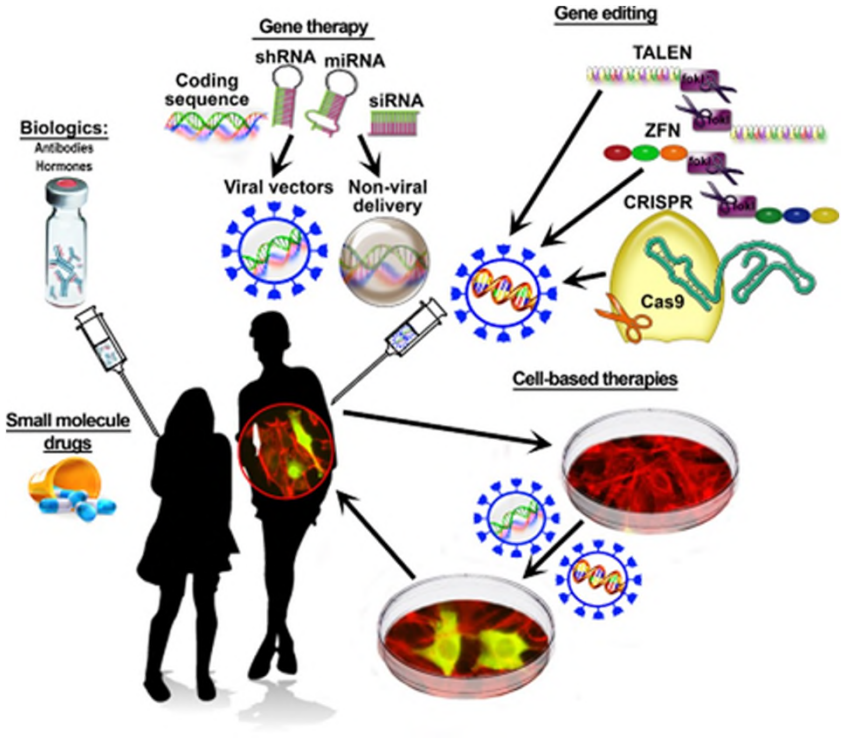
Company Overview

Discovery stage product (Tox Studies Not Completed)

10 Employees, No Tangible Assets

Target resident in EU

Very Complex Upstream IP Landscape


Gene therapy
shRNA
miRNA
Coding sequence
siRNA
Biologics:
Antibodies
Hormones
Viral vectors
Non-viral delivery
Gene editing
TALEN
ZFN
CRISPR
Cas9
Small molecule drugs
Cell-based therapies

Source: FDA

Case Study: Acquistion of an EU Startup by a US Biotech

Things to Watch Out For

If the entire value of the company is one or two intangible assets, important to make sure you know the company actually owns them

Also need to know any upstream obligations to previous owners/inventors because they will become YOUR upstream obligations.

Poison Pills

Provisions in Upstream Collabs that can poison a company's platform

Grant Backs of Know-How/IP

Duty to share Improvements upstream to competitors & unusual Change of Control provisions in Upstream agreements that will get triggered by the deal

Case Study

Regulatory Considerations

EUROPEAN FDI

CFIUS

Anti-competition/ FTC

FDI = Foreign Direct Investment = Heightened "CFIUS" rules in Germany, France and the UK

Case Study Notes

Creative Solutions to de-risk

Started FDI filing contemporaneously with negotiation of transaction

Successfully Negotiated a Side Letter with upstream licensor to limit grant-back obligations (with firewalls going forward)

Utilized "gatekeeper" consultants for highly confidential know-how and other information sharing

Bespoke Anti-Shelving/De-Prioritization Provisions

Collaboration – Employment Agreements, Non-Competes, etc.

Key Takeaways

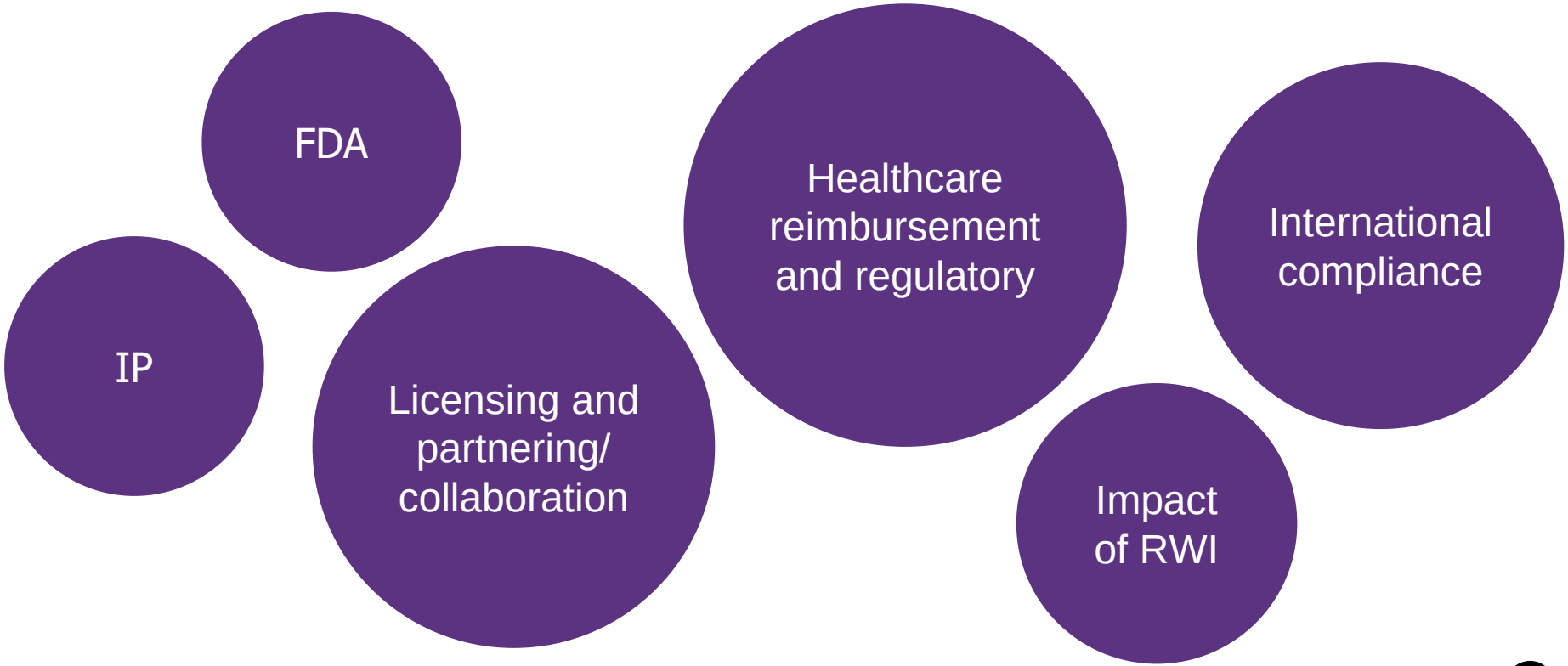
Key Takeaways from This Session

- Life Sciences Dealmaking is different
- The nature of the businesses requires specialized diligence around IP, FDA, regulatory, licensing, collaborations, manufacturing, pricing and promotion
- Significant binary value outcomes encourages the use of contingent consideration structures
- Agreements can be very bespoke and creative. They need need to properly reflect those economic terms and the other nuances of these transactions through specialized representations and warranties, covenants, conditions to closing and termination provisions.
- Corporate counsel can add value as a strategic thought partner to solve for unique risks.

Key Takeaways from This Session

- Where vast majority of value of a company is an intangible asset (patents, unique know-how that may only reside in a scientist's brain or lab notebooks), due diligence by industry experts is critical.
- Beware the poison pill – don't acquire a company that can poison your platform or create significant obligations that aren't worth the trouble.
- We may not be able to get the deal to zero-risk, but there are many creative mechanics we can utilize to de-risk as much as possible.
- Given the constant innovation and steady flow of of M&A and partnership deals in the Life Sciences industry, remember that your partner may not be your partner next year… plan accordingly.

What Are the Key Areas of Specialized Due Diligence?



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Suzanne Filippi exclusively focuses on US and global corporate transactions in the life sciences industry, representing both multinational pharmaceutical companies and public or private biotechnology companies. Drawing on her deep life sciences industry knowledge, Suzanne counsels clients in a wide range of corporate transactions, with an emphasis on complex license and collaboration agreements, co-commercialization/co-promotion matters, and mergers, acquisitions, and externalizations in the life sciences sector. She is recognized by clients for her collaborative energy, solutions-minded approach, and keen understanding of the unique, mission-focused nature of life sciences companies and their patient populations..

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Russell Franklin counsels global private and publicly held companies in connection with structuring, and effecting, complex strategic transactions. This includes structuring and negotiating mergers and acquisitions (M&A), minority investments, and joint venture transactions for strategic and financial clients including private equity firms. His practice also includes general stock and asset transactions, and purchases and sales resulting from bankruptcy and out-of-court restructurings. Russell is a member of the firm's SPAC Task Force and routinely counsels clients contemplating SPAC and de-SPAC transactions. His clients can be found in numerous industries including healthcare, life sciences, retail, financial services, and media.

Our Global Reach

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Europe
Latin America
Middle East
North America

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Dubai
Frankfurt
Hartford
Hong Kong*
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Miami
New York
Nur-Sultan
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Princeton
San Francisco
Shanghai*
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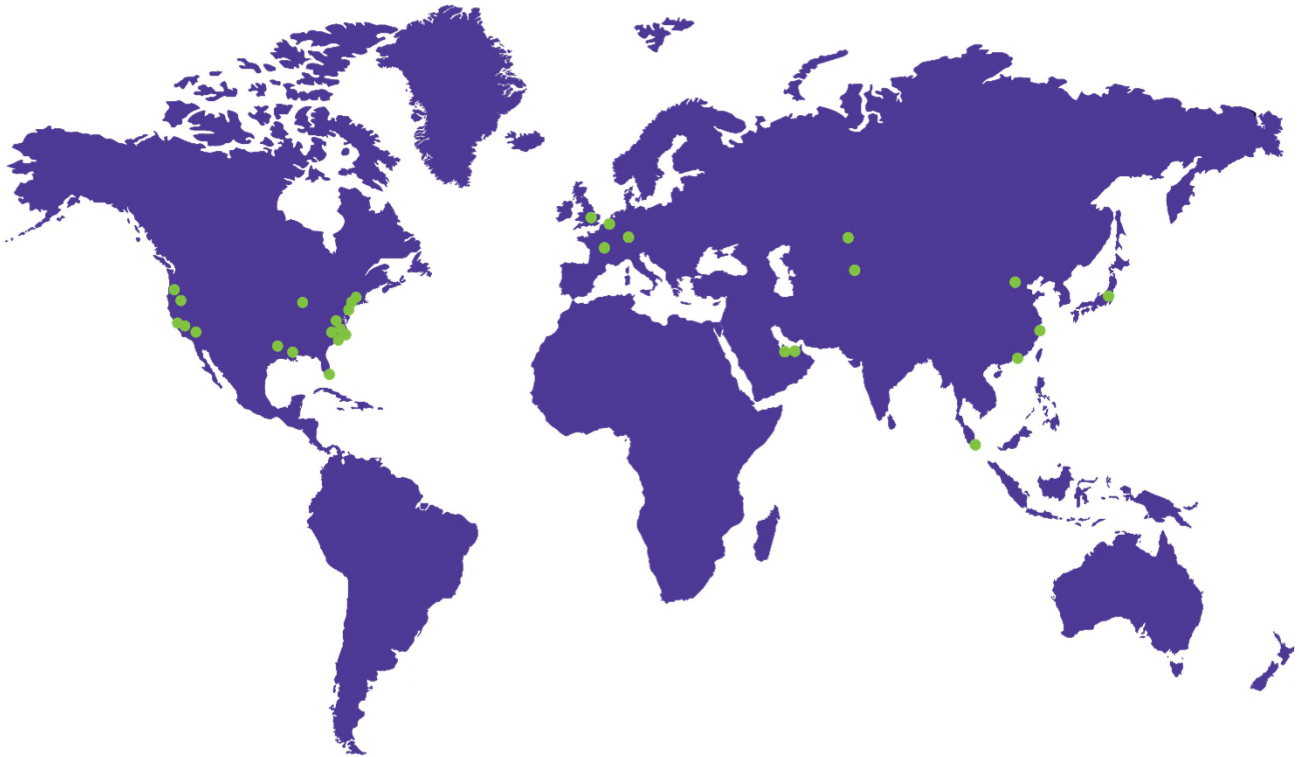
Tokyo
Washington, DC
Wilmington



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