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M&A Considerations Across the Evolving Life Sciences Sector

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March 21, 2023

Overview

2022 in Review

What Makes Life Sciences Deals Different?

Trends in Dealmaking

Lessons Learned

Market Trends in M&A Life Sciences space for 2022 and Forecast for 2023

Overview: M&A and Life Sciences in 2022

- M&A investment for 2022 YTD has fallen 53% compared to the full year of 2021. In all, 117 deals were signed, a 27% decline compared with 2021

- 2022 is the lowest dealmaking year by value for the life sciences sector since 2017, with only $105 billion in M&A deals completed by November 2022

- Q4 2022 significantly lifted the overall deal value for the sector, with Johnson & Johnson's US$16.6 billion acquisition of Abiomed

Source: 2023 EY M&A Firepower report, Biomedtracker

Overview: M&A and Life Sciences in 2022

- In the biopharma sector deal value fell 42% compared with 2021, with Pfizer's acquisition of Biohaven the single largest deal prior to December 2022
- At the end of November 2022, the biopharma industry alone held more than US $1.4 trillion in Firepower: an 11% increase on 2021
- Alliances remain a significant focus for biopharma and companies' M&A

Figure 2: Total biopharma M&A value and volume, 2014-2022 YTD

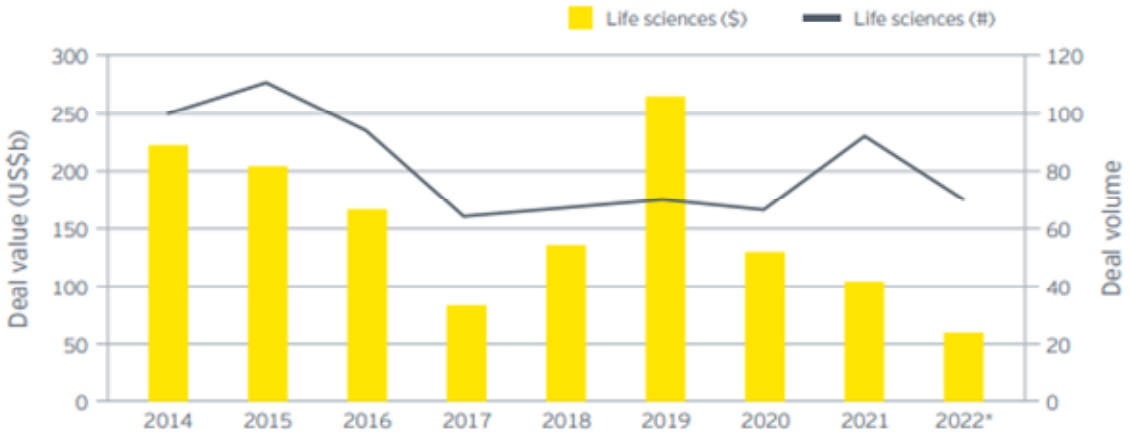


Figure 4: Biopharma strategic alliance investment, 2014-2022*

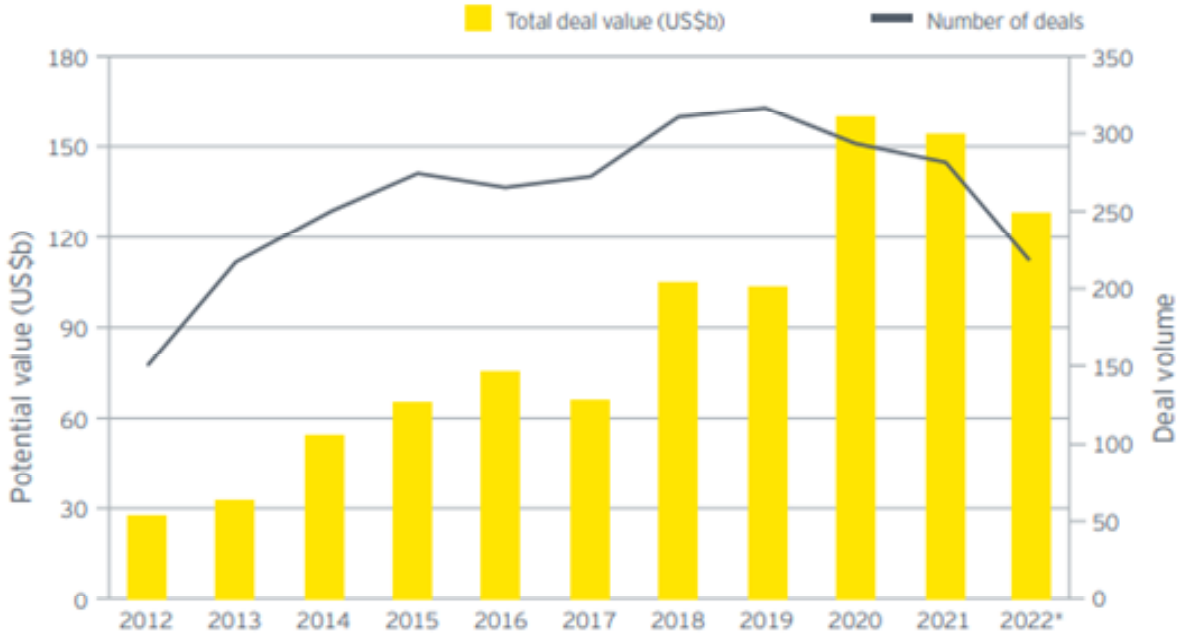
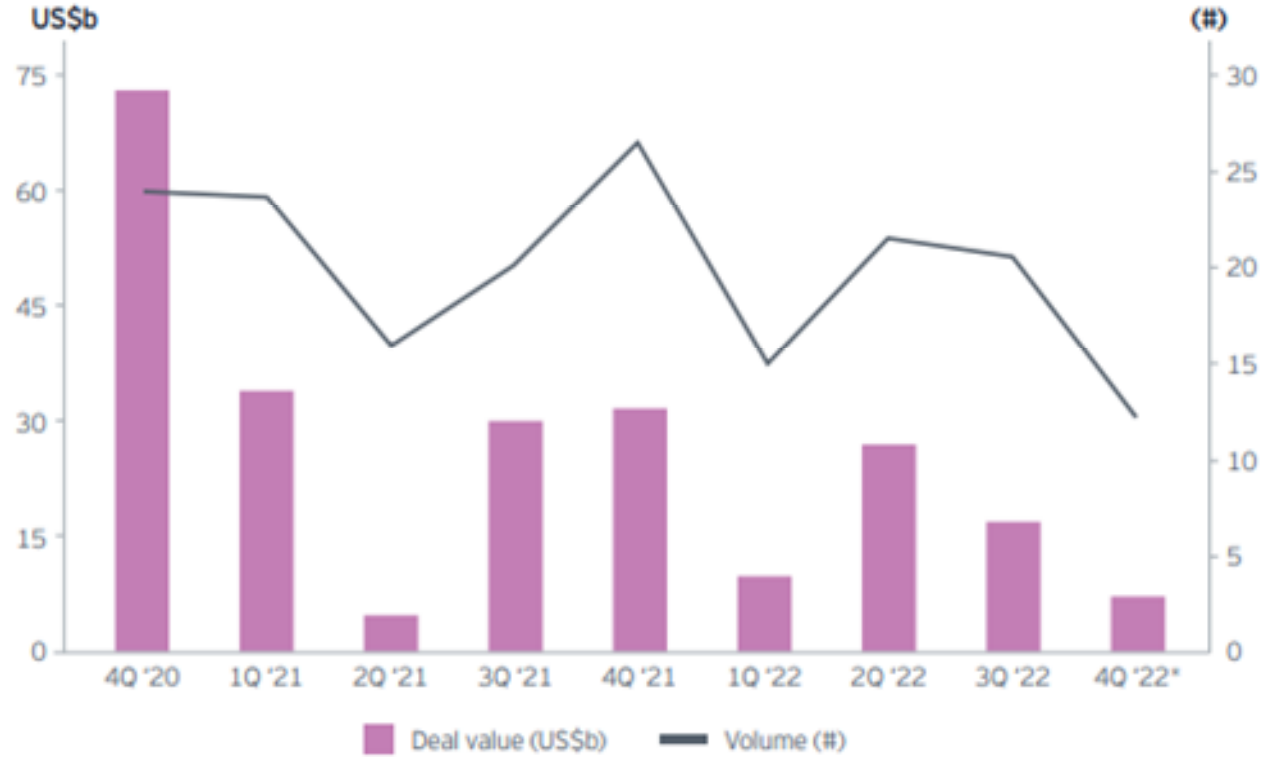


Figure 3: Biopharma quarterly M&A deal value and volume trends



What to expect in 2023

- Q1 of 2023 has been quite active so far, with several significant deals announced:
  - **Takeda/Nimbus** – Takeda acquires Nimbus Therapeutics' TYK2 Program Subsidiary, $4 billion deal value, $6 billion including milestone payments
  - **AstraZeneca/CinCor Pharma** – AstraZeneca acquires CinCor Pharma, $1.3 billion deal value, $1.8 billion including milestone payments
  - **Chiesi/Amryt Pharma** – Chiesi acquires Amryt Pharma, $1.25 billion deal value, $1.48 billion including milestone payments
  - **Pfizer/Seagen** – Pfizer acquires Seagen, $43 billion deal value

- In 2023 we expect M&A to more closely resemble prior years with a total deal value in the $225 billion to $275 billion range across all subsectors

- Continue to expect that deals in the $5 billion to $15 billion range will be the market sweet spot but see the potential for one or more deals in the $20 billion to $40 billion range before year-end

Source: PwC Pharmaceutical & Life Sciences deals outlook 2023

The Future of Life Sciences Deals – Industry Specialization

- 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.
  - Deep industry knowledge by practioners, regardless of transaction structure.
- 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

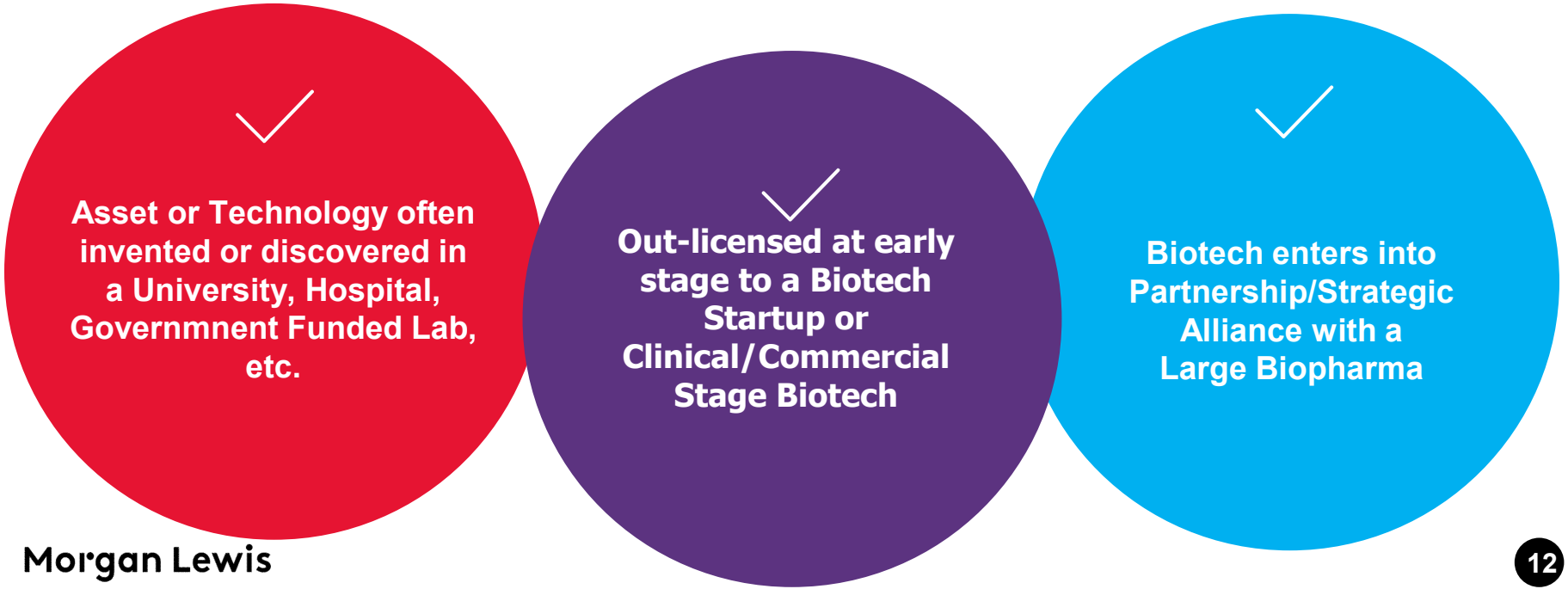

UNIQUE NATURE OF ASSETS OF LIFE SCIENCES COMPANIES
UNIQUE INDUSTRY ECOSYSTEM
FUNDAMENTAL DIFFERENCE in WHAT MAKES LIFE SCIENCES DEALS DIFFERENT

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?

Lifecycle of a Pharmaceutical Product Ownership/Financial Obligations



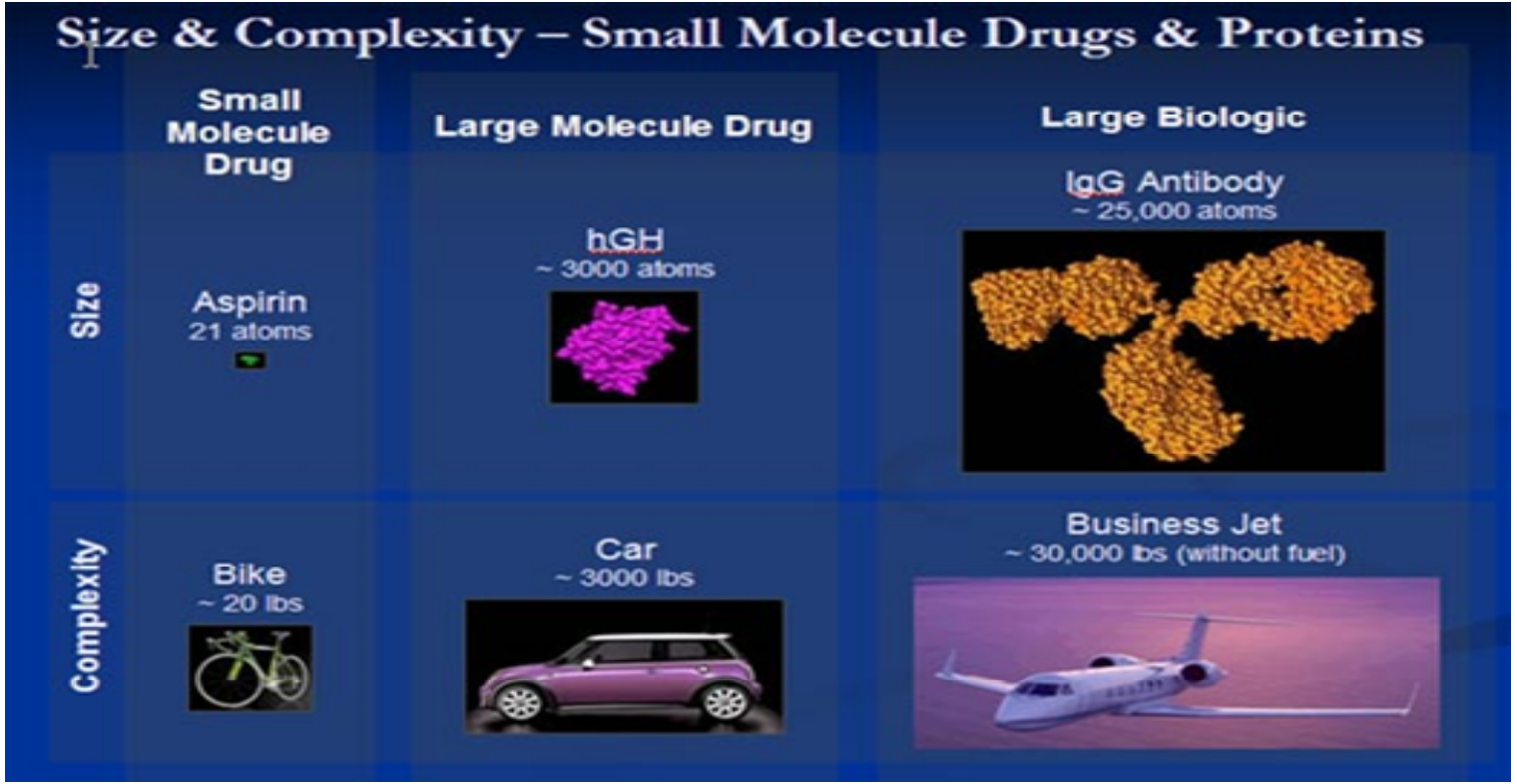
What Makes Life Sciences Different: The Asset Lifecycle

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

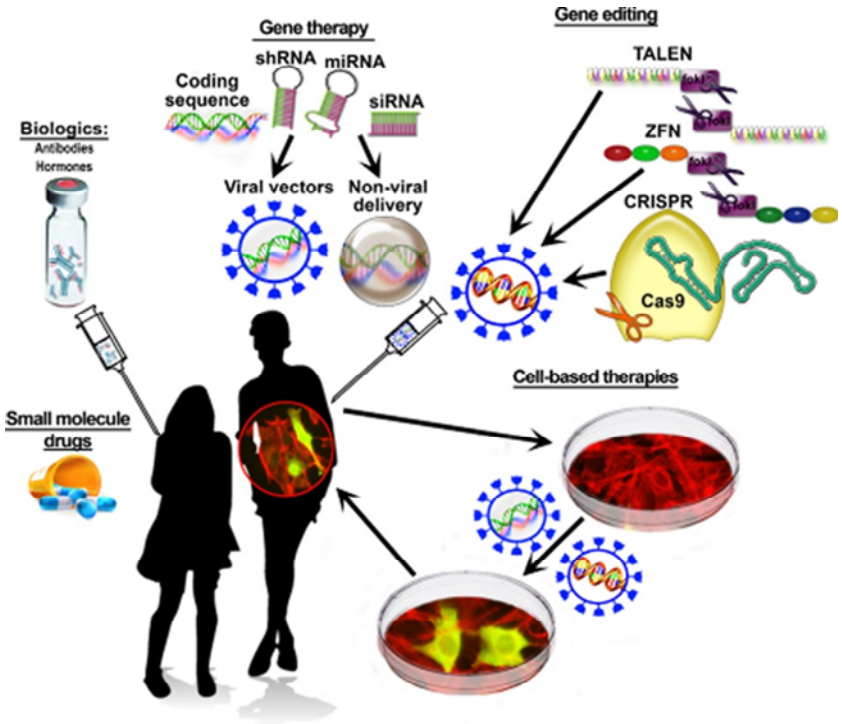
- Fundamentally different from other industries
  - Lifecycle of an asset through the ecosystem = complex due diligence and upstream obligations that flow down to buyer/licensor
    - Traditional patent/IP due diligence
    - **Corporate due diligence of upstream agreements is critical** (SEC filings 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

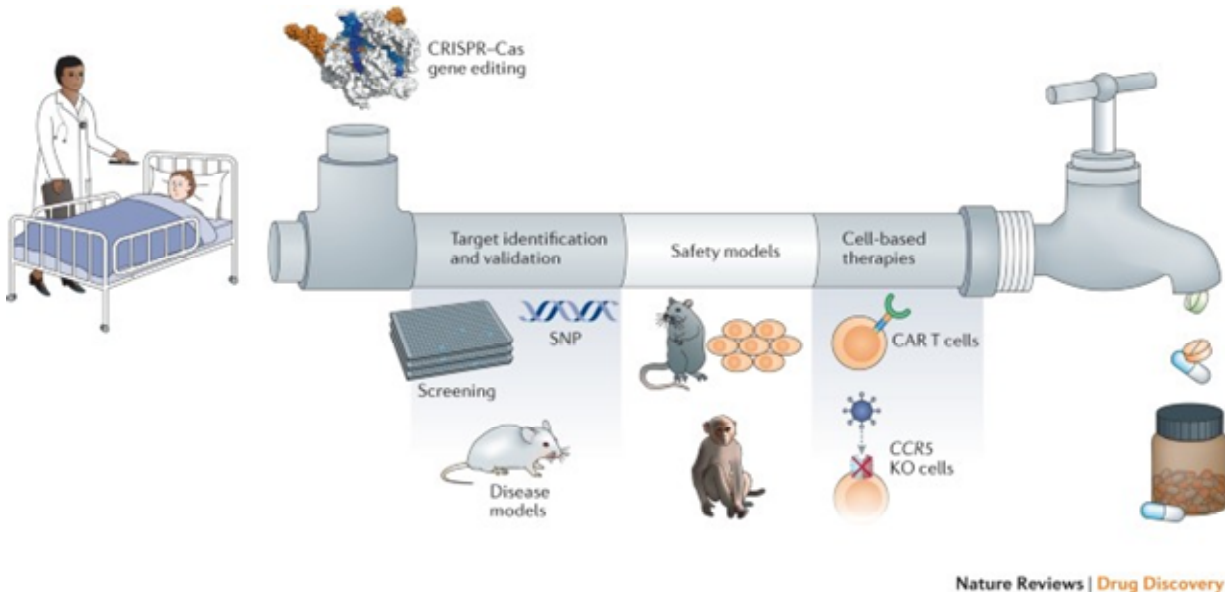


Source: AZBIO – Small Molecules, Large Biologics and the Biosimilar Debate


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

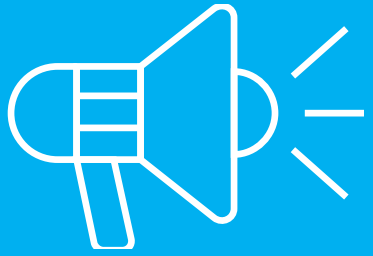
Source: FDA

CRISPR Modalities



Unique Factors that Affect the Dealmaking in Industry

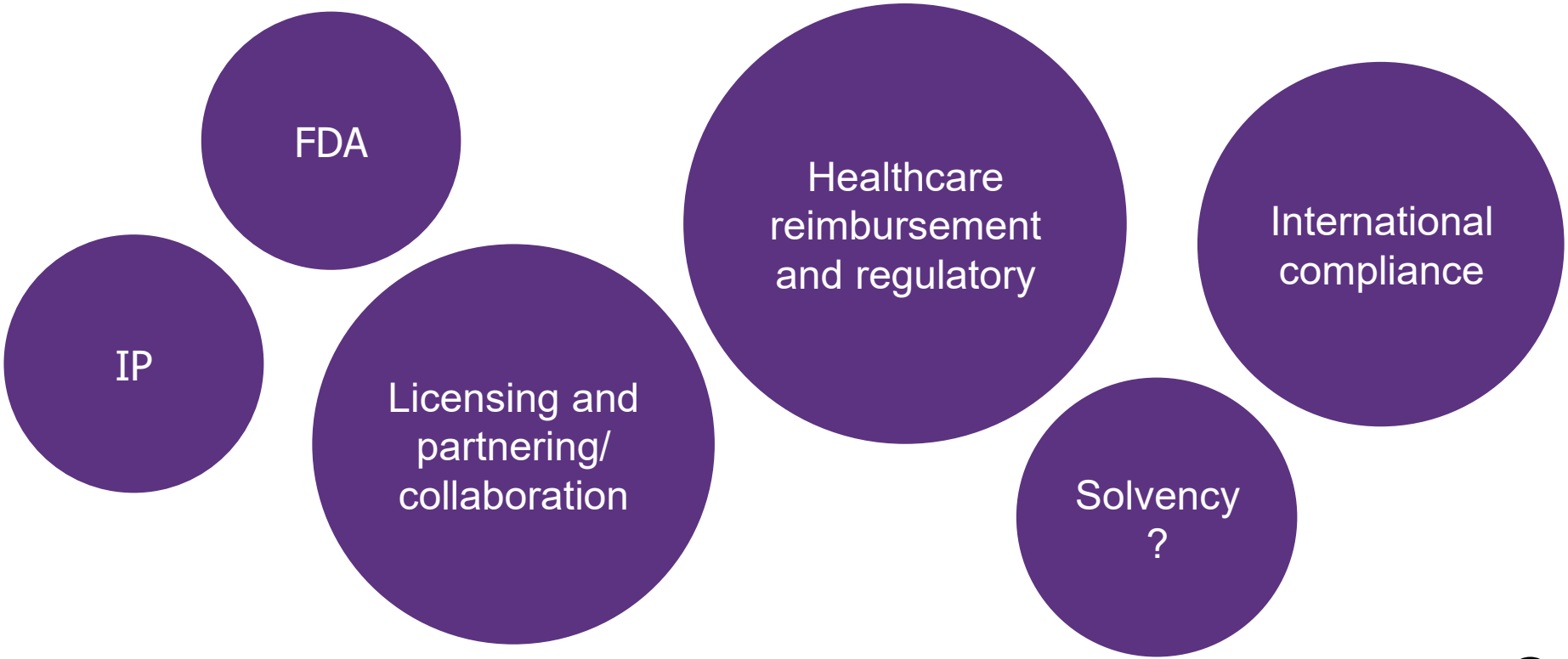
Specialized Due Diligence



Science/IP
Industry Knowledge

Economics
Valuations Challenging

What Makes Life Sciences Deals Different? Specialized Due Diligence.



Specialized Diligence

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

Other Bespoke obligations

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

What Makes Dealmaking Different? 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.
  - ***Trend***: Seeing an increase in Licensors requesting firm diligence obligations (anti-shelving)

Economics: Bridging Valuation Gaps

- Earnouts are commonly used in private target transactions as a way to bridge valuation gaps.
- When the target is public, the tools that are traditionally used to bridge valuation gaps are slightly different.
- Two types of deal structures that are intended to address this issue and that are becoming more common in public healthcare transactions:
  - **Spin-off mergers:** The target company separates some of its assets into a separate company and distributes the shares of this company to its shareholders. After the spin-off is completed, the spun off company ("SpinCo") then merges with a third-party buyer
  - **Contingent value rights (CVRs):** Essentially the public company version of an earnout (the right of the target company's shareholders to receive payments if and when milestones are achieved)

Source: Businesss Law Today

Spin-Off Mergers (And Their Complications)

- Spin-off mergers may be used to move certain assets and liabilities into a new company in connection with an anticipated sale (e.g. to move a target company's clinical stage products into a new vehicle but **not** the target company's early-stage products)
- This can be helpful from a valuation perspective because it allows the ultimate owner of pharma/biotech assets to separate those assets that are difficult to value from those that are more concrete
- For reasons that will become clear shortly, spin-off mergers are more common in private target deals as opposed to public target deals
- The first public company spin-off merger in the pharma industry was Johnson & Johnson's acquisition of Actelion (announced 2017)—Actelion spun off its pre-clinical drug and early-stage clinical development assets into a separate company, followed by a spin-off merger with a US pharma company

Source: Businesss Law Today

Spin-Off Mergers continued

- Complications of a public-target spin-off merger:
  - SpinCo must be set up as a stand-alone public company. This means: (1) the filing of a new registration statement with the SEC that includes IPO-level disclosures of the business that is being spun-off and audited financial statements; (2) SpinCo must have sufficient funding (which could be challenging depending on the assets moving across); and (3) SpinCo must have a stand-alone management team that can help SpinCo succeed (which may be tricky if, for example, the scientific team that developed the assets is staying with the parent)
  - Even if the above is attainable, there are oftentimes remaining interdependencies between SpinCo and the parent company that have to be contracted around including, by way of example, transition services agreements, contract manufacturing agreements, IP licenses, and data sharing protocols
  - If otherwise doable, this tends to take a lot of time

Cotingent Value Rights (CVRs)

- CVRs serve the same purpose as an earnout in a private transaction—namely a value bridge given that the sellers only receive additional consideration if events that are likely to, or do, result in additional revenue for the buyer are achieved. This can be particularly helpful in the pharma space since the value of a drug, for example, can change drastically depending on the ability to achieve a major development or milestone
- How do CVRs vary from a traditional private earnout?
  - A CVR itself may be deemed a security that must be registered with the SEC. To avoid this, CVRs typically are not transferable (a necessary feature to avoid registration)
  - Distinct from a private company, in the public company context, the publicly traded entity generally doesn't know who all of its underlying shareholders are. As a result, the CVR agreement has to include mechanics about who the rights agent has to pay and how subsequent payments will be made

Source: Business Law Today

CVRs continued

- Although useful in bridging value, CVRs are subject to many of the same considerations as traditional earnouts:
  - Because CVRs generally shift what would otherwise be guaranteed consideration into contingent consideration, you tend to see more CVRs as the market shifts from a seller's market to a buyer's market.
    - Not surprisingly, 2022 had more public CVR deals than the previous two years combined.
  - As is the case with earnouts, CVRs typically contain a hotly negotiated covenant that spells out what the buyer does, and does not, have to do in order to achieve the payment triggers (the "Efforts Clause"). The Efforts Clause can take time to negotiate and, regardless of what it says, compliance is ripe for litigation.

Source: Business Law Today

CVRs continued (Managing Litigation Risk)

- As a buyer, there are a few things that can be done to mitigate litigation risk:
  - Push for no Efforts Clause at all. If that proves impossible, ensure that the Efforts Clause, and the underlying milestones, are as objective as possible
  - Specify that CVR holders can enforce their rights only through the rights agent under the CVR and not individually
  - Specify that only a minimum percentage of CVR holders (30% - majority) can have the rights agent bring claims for breach of the Efforts Clause
  - Reduce the relative size of the CVR—the larger the CVR payments are relative to the maximum purchase price, the more likely people are to care about achievement.
  - Payment Milestones should be as clearly defined and objectively determinable as possible to avoid disputes as to whether milestone was met.

Trends to Watch in 2023

What We're Seeing…..

Bankrupcy/Solvency – Financial Due Diligence

Antitrust/Anti-Competition and IRA/Pricing

US/China Impacts/CFIUS

Partner's Enforcing Diligence/CRE Obligations

Bankruptcy/Solvency Concerns

Financial Health of Partner

Will Partner be Solvent?

Jurisdictional Issues

Where are IP Assets located?
Are they used as collateral?
What bankruptcy laws apply?

Structure Transaction to de-risk

- Collaborations/Drug Development takes many Years… increased awareness of bankruptcy/solvency risks.
- Creative de-risking strategies… (ownership, advance triggers, waivers on liens, etc.)

Efforts/Diligence/CRE Trends

Key Area of negotiation

Time Based diligence obligations

Gated Development Plans with specific targets/funding obligations

Strong pushback by buyers/licensees

De-prioritization in Research Collaborations

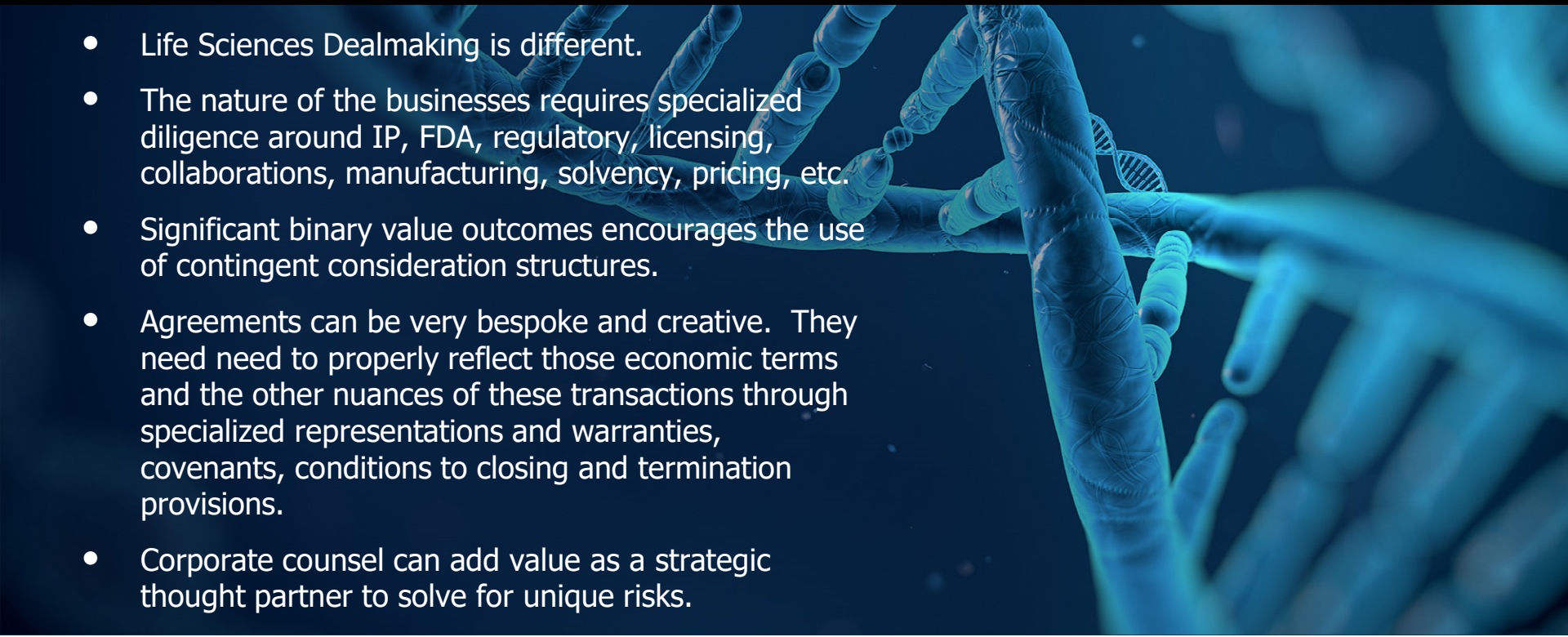
Renewed Focus on Remedies – special enforcement provisions, arbitration, etc.

Trends to Watch in Life Sciences Dealmaking

- CFIUS/Government Regulations on US-China transactions
  - F-Star approval well-received by markets
  - Increased deal activity?
- Impact of Inflation Reduction Act on pharmaceutical pricing
  - Big Unknown
  - Starting to see bespoke provisions in deals to address downstream pricing impacts.
    - Royalty Step-downs
    - Net Sales Definitions

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, solvency, pricing, etc.
- 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 the 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 of 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.
- If a significant percentage of the consideration is downstream (CVRs, Earnouts, Milestones) – ensure triggers clearly defined.

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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.

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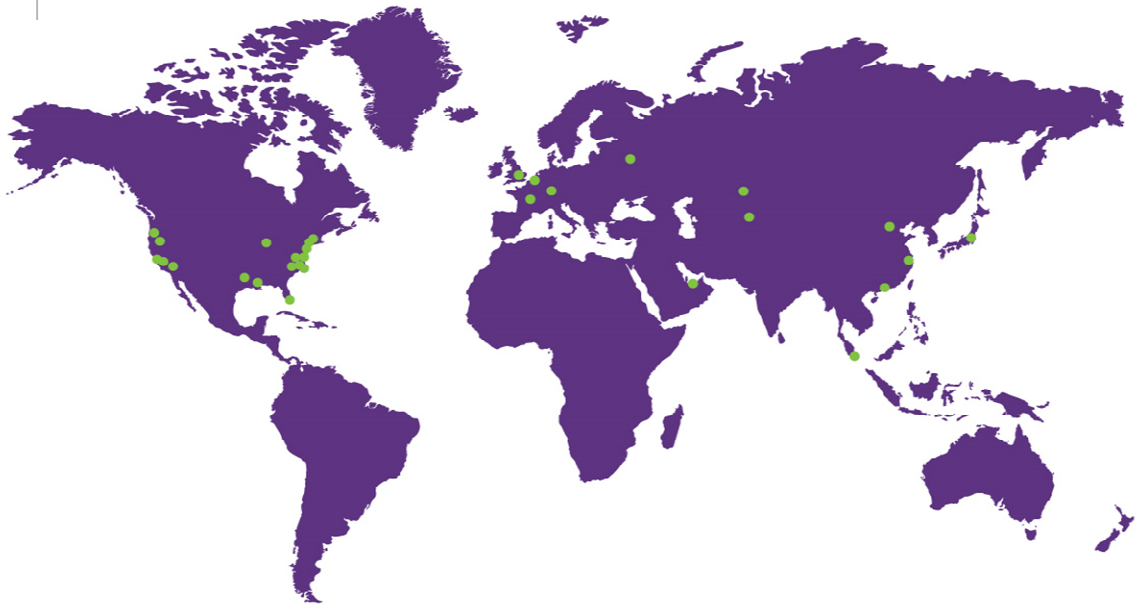

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