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M&A ACADEMY

M&A Considerations Across the Evolving Life Sciences Sector

Suzanne Filippi and Laurie Burlingame

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Presenters

Suzanne Filippi

Laurie Burlingame

Morgan Lewis

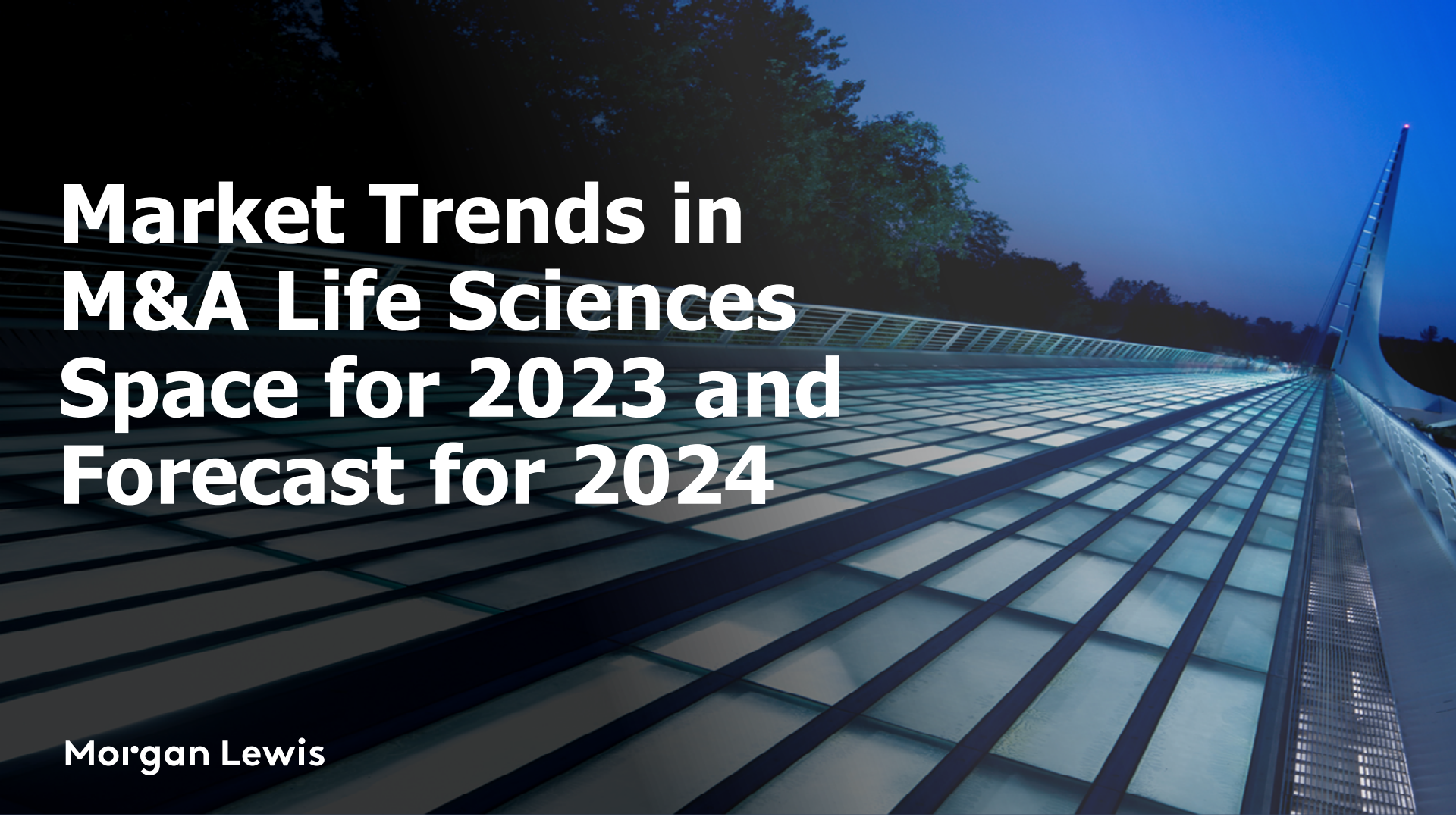
Overview

Market Trends and Forecasts

What Makes Life Sciences Deals Different?

Case Study of a Cross-Border Biotech Acquisition

Lessons Learned



Market Trends in M&A Life Sciences Space for 2023 and Forecast for 2024

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Life Sciences M&A in 2023

- Life sciences M&A spend rose to $191 billion in 2023, up 34% from 2022.
- In 2023, Big Pharma began to embrace big dealmaking once again, as numerous key products face the loss of patent protection in the next five years.
- 2023 was an active year for pharmaceuticals 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

Source: 2024 EY M&A Firepower report, Biomedtracker

MedTech M&A in 2023

- Inflation and high interest rates caused M&A activity in the medtech sector to be down for a second straight year in 2023, with a dearth of deals of greater than $1 billion being completed.
  - Most medtech deals that were completed were tuck-in acquisitions
- According to EY Firepower, only 46 medtech deals of greater than $100 million were completed as of December 10, 2023, for aggregate proceeds of $33.7 billion.
- Some of the more notable M&A deals of 2023 included:
  - Merger of Globus Medical with Nuvasive in a deal valued at $3.1 billion
  - Danaher's acquisition of AbCam in a deal valued at $5.7 billion
  - Thermo Fischer's acquisition of Olink in a deal valued at $3.1 billion
  - Boston Scientific announced acquisition of Axonics in a deal valued at $3.7 billion

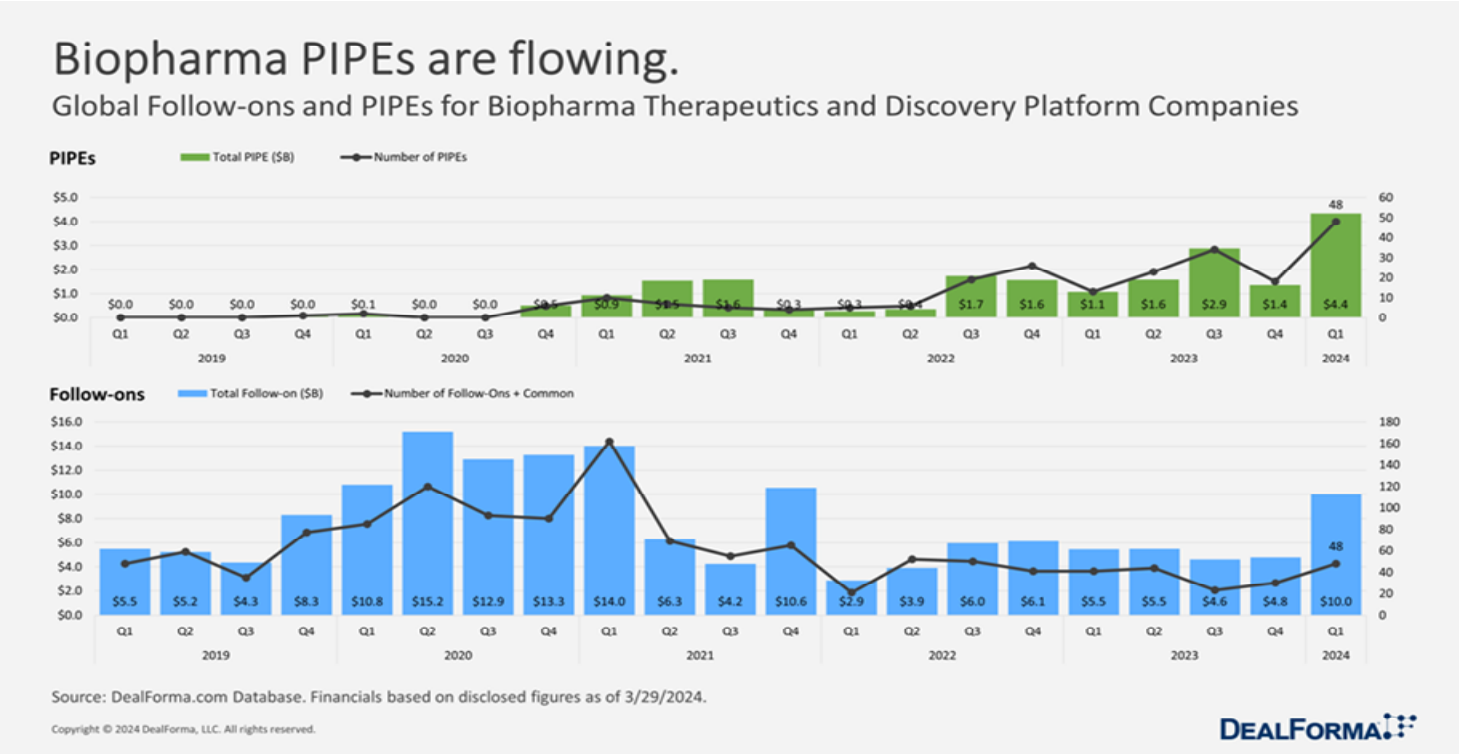
China-based Transactions

- In 2023, out-licensing deals in China exceeded in-licensing deals, indicative of a burgeoning innovative biotech scene that's attracting cross-region interest.
  - During this period Chinese biotechs executed 63 cross-region out-licensing deals in 2023, a record for the industry and an 80% increase compared to 2022.
  - In-licensing deals fell by 56% over the same period, from 59 to 26, the data show.
- As out-licensing deals have increased, so have the financial stakes. Total upfront payments to Chinese biotechs from out-licensing deals eclipsed $2.2 billion in 2023, more than doubling 2022. For comparison, back in 2019, Chinese biotechs collectively brought in $10 million in upfront payments from out-licensing deals.
- However, potential for current geopolitical conditions to hinder such transactions in 2024.

Biopharma Recovery

- PIPEs were open in Q1
  - 48 privately negotiated fundraisings of publicly traded companies totaling $4.4 billion
- Follow-ons are up
  - 48 deals accounting for $10 Billion
  - Most in a quarter since 2021
- IPOs are (mostly) positive
  - $3.9 billion in IPO money
- M&A slows after busy Q4
  - 26 deals total $19.4 billion after $60 billion Q4
- VC dollars match 2019
  - 306 total deals investing $12.4 billion into sector

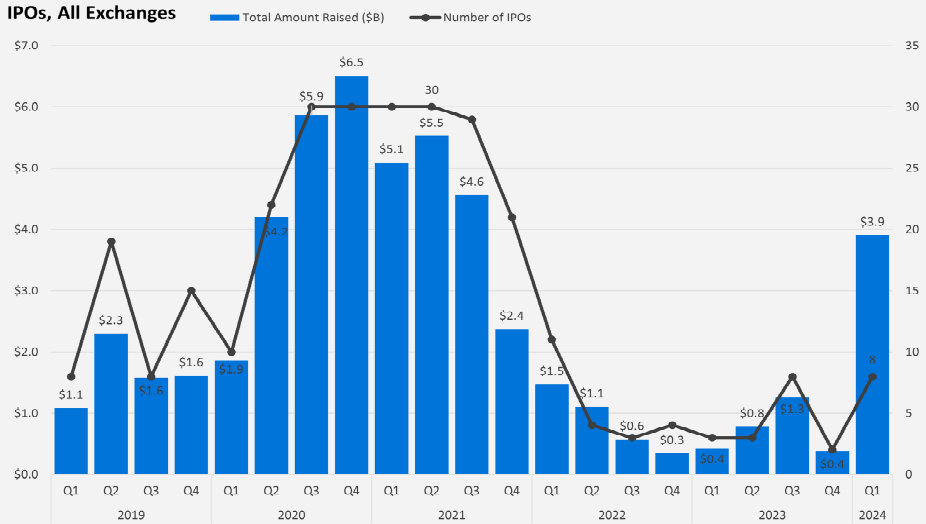
Story of Q1 2024 – Biopharma Pipes



IPOs rebound

Biopharma IPOs found an open window.

Global IPOs for Biopharma Therapeutics and Discovery Platform Companies



IPO – 2023	Q1 2024
16	8
Biopharma IPOs 2023 vs. 22 2022	Biopharma IPOs Q1 2024
$2.8 B	$3.9 B
Biopharma IPOs 2023 vs. $3.5 B 2022	Biopharma IPOs Q1 2024 Galderma $2.5 B

Source: DealForma.com Database. Completed IPOs over $15M on any exchange. Financials based on disclosed figures as of 3/29/2024.

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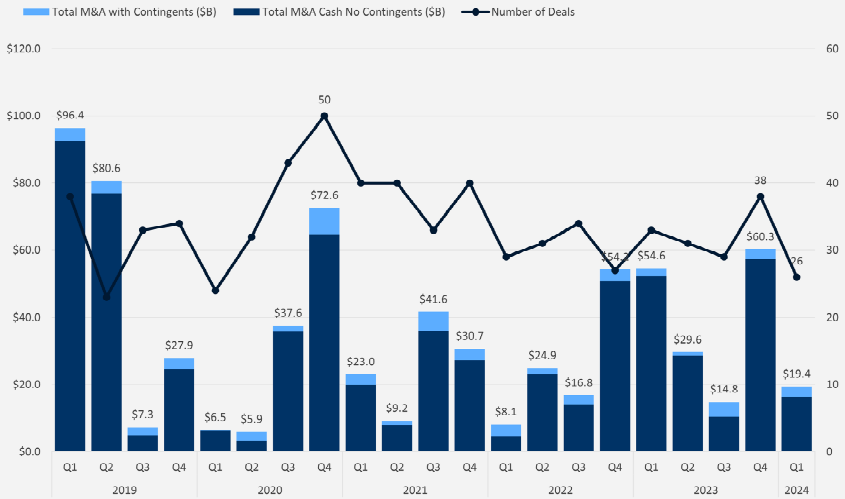
M&A Cools Off

Biopharma M&A is all about $1 billion to $2 billion deals.

M&A Deals by Biopharma Therapeutics and Discovery Platform Companies



M&A – FY 2023

131
M&A Deals 2023
vs. 121 2022

$158.9 B
Announced
Total M&A Value 2023
vs. $104.0 B 2022

Q1 2024

26
M&A Deals Q1 2024

$19.4 B
Announced
Total M&A Value Q1 2024

Source: DealForma.com Database. Biopharma buy side; Any company sell side. Financials based on disclosed figures as of 3/29/2024.

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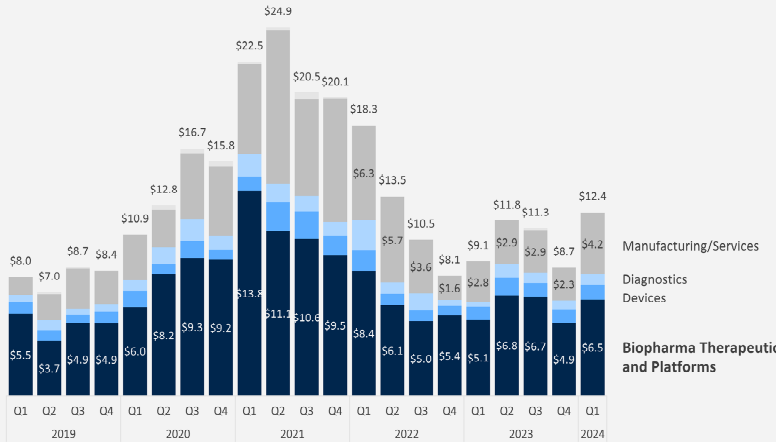
VC funds pace pre-pandemic levels

Venture dollars stacked higher in Q1 from a few mega rounds

Seed and Series Totals by Healthcare and Life Sciences Subsector ($B)



	Venture – FY 2023	Q1 2024
	1,176 Venture Rounds 2023 vs. 1,394 2022	306 Venture Rounds Q1 2024
	$40.8 B Total Venture 2023 vs. $50.3 B 2022	$12.4 B Total Venture Q1 2024
	$23.4 B **Biopharma** 2023 vs. $24.9 B 2022	$6.5 B **Biopharma** Q1 2024

Source: DealForma.com Database. Financials based on disclosed figures as of 3/29/2024.

DEALFORMA

Predictions for 2024

- Biopharma dealmaking will accelerate in 2024 and onwards, because the industry is now reaching the much-anticipated "patent cliff"
- Sector retains more than $1.37 trillion in available capital for M&A
- Priority should be targeting the right asset for future growth
- In 2024 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: 2024 EY M&A Firepower report, Biomedtracker

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?
Morgan Lewis

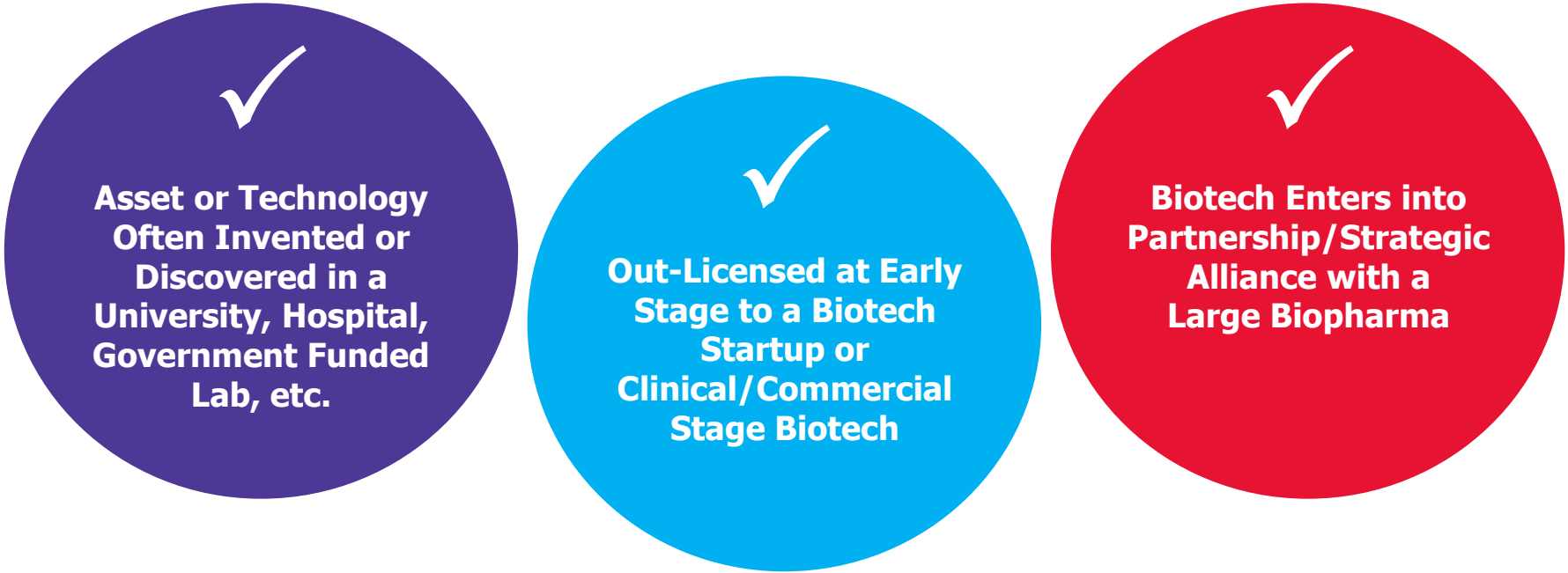

Unique Nature of Assets of Life Sciences Companies
Unique Industry Ecosystem
Fundamental Difference in What Makes Life Sciences Deals Different

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



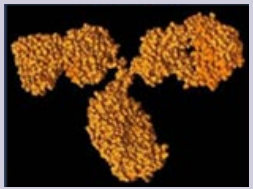
What Makes Life Sciences Different: The Asset Lifecycle

- 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

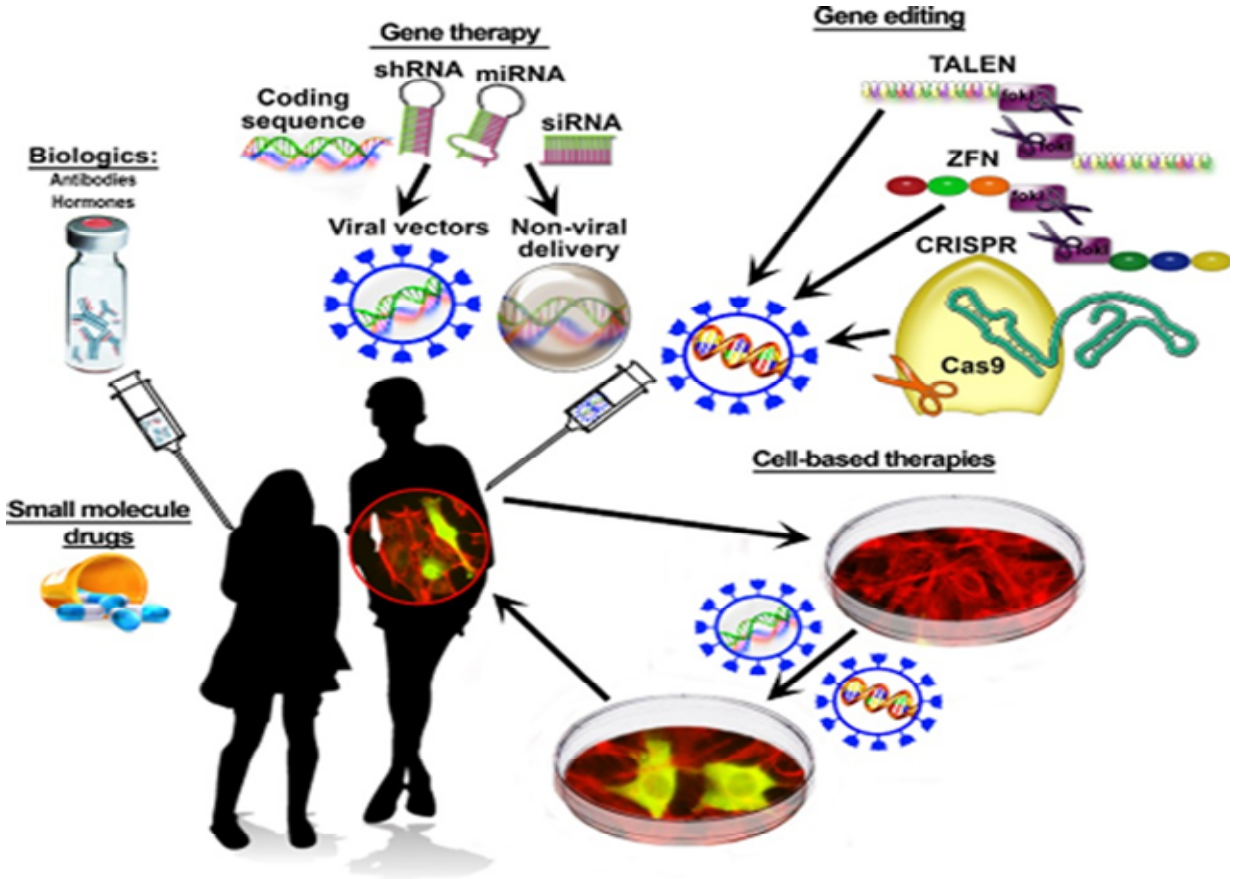
What Makes Life Sciences Different: The Science

- 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

Size and Complexity: Small Molecule Drugs and Proteins

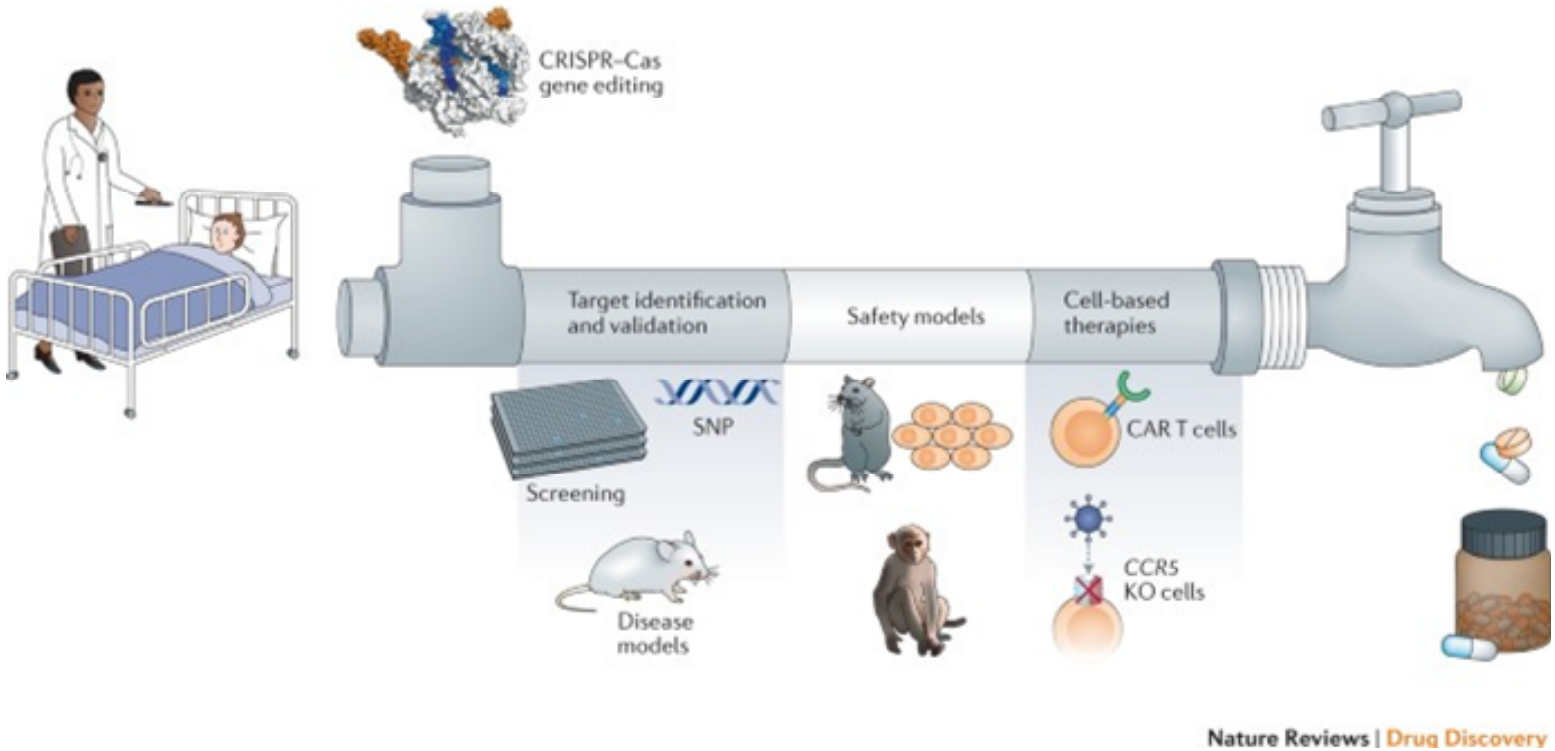
	Small Molecule Drug	Large Molecule Drug	Large Biologic
Size	Aspirin 21 Atoms 	hGH ~3,000 Atoms 	IgG Antibody ~25,000 Atoms 
Complexity	Bike ~20 lbs 	Car ~3,000 lbs 	Business Jet ~30,000 lbs (without Fuel) 

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


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

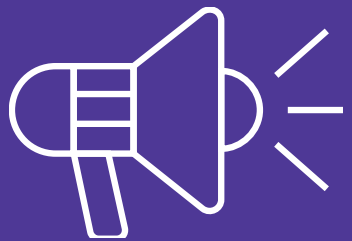
Source: FDA

CRISPR Modalities



Who Are the Key Players in the Life Sciences Ecosystem?

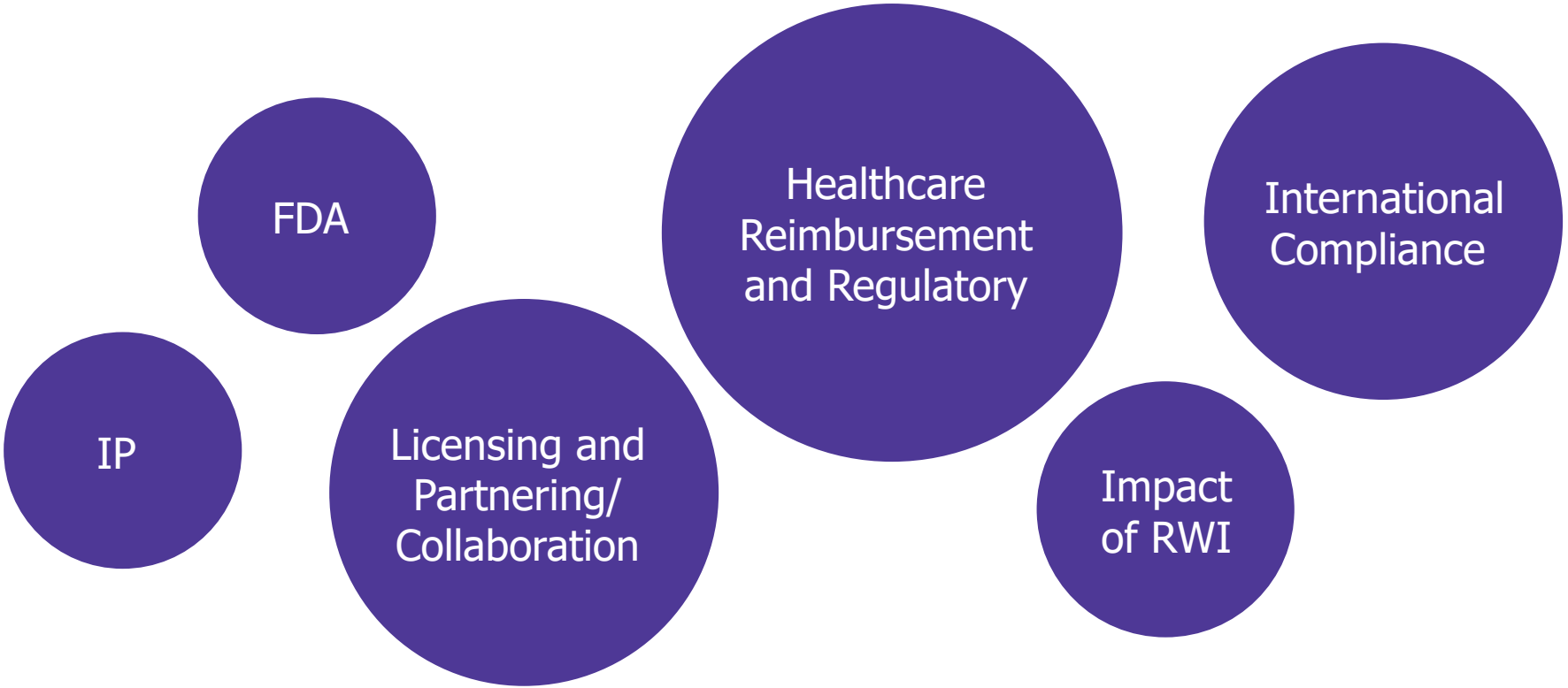
Specialized
Due Diligence



Science/ IP
Industry Knowledge

Economics
Valuation Challenging

What Makes Life Sciences Deals Different? Specialized Due Diligence



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)

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

Spin-Off Mergers (and Their Complications) (cont'd)

- 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

Contingent 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

Contingent Value Rights (CVRs) (cont'd)

- 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.

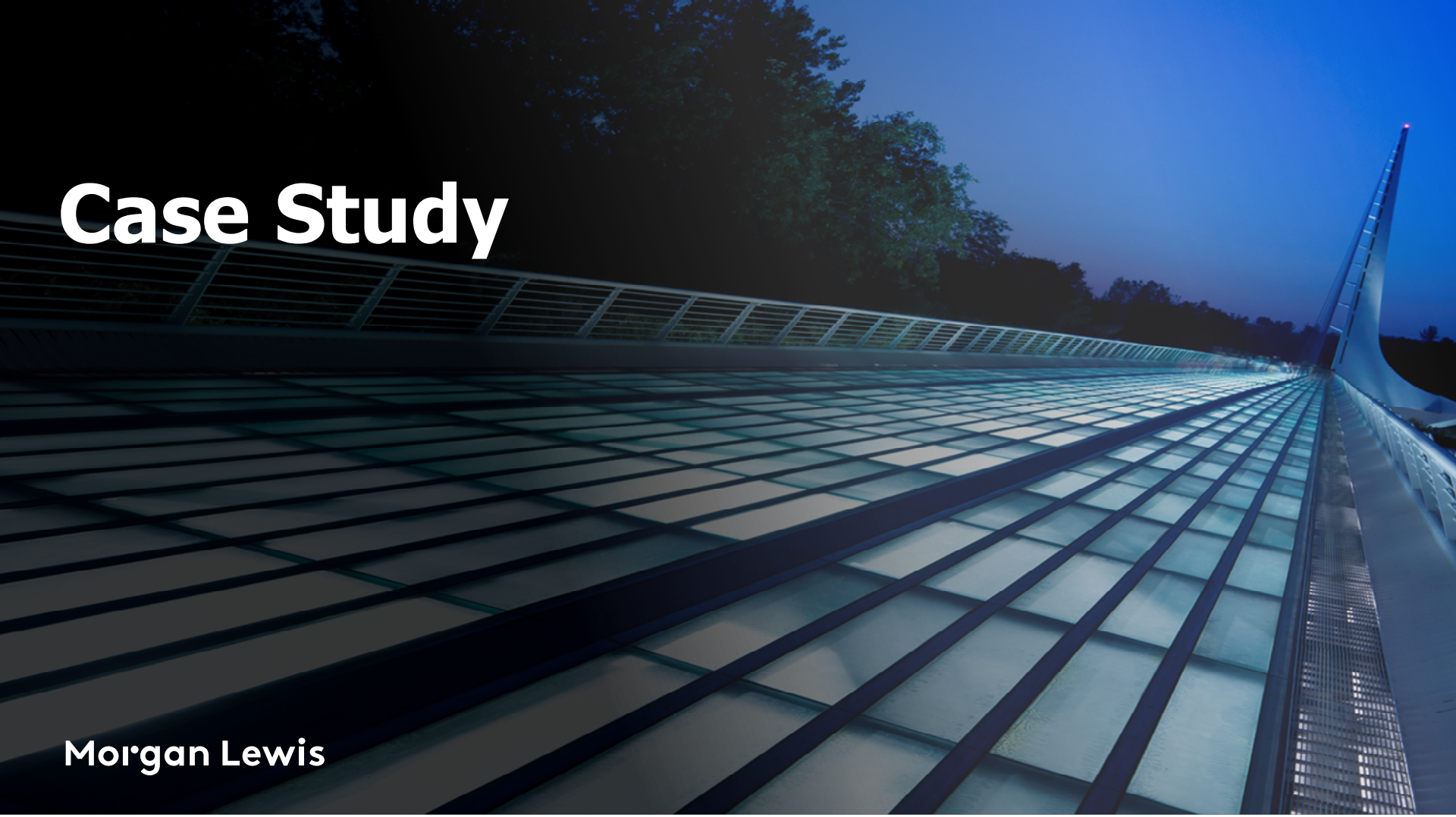
Source: Business Law Today

Contingent Value Rights (CVRs) (cont'd) (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.

Option to Acquire Deals

- If a potential Buyer does not have sufficient conviction in assets in a Target company, may enter into an option to acquire transaction, where Buyer funds certain activities of the Target in exchange for the right to acquire the Target once certain data has been generated and considered
- Buyer will typically require the Target to comply with numerous covenants to protect its option, including prohibitions on additional financings or other type of collaboration.
- Target want to ensure they have sufficient ability to purse alternative transaction if the Buyer elects not to exercise the option.


Case Study
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Case Study: Acquisition 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 Agreements that can poison a company's platform

Grant backs of Know-How/IP

Duty to share improvements upstream to competitors and unusual Change of Control provisions in Upstream Agreements that will get triggered by the deal.

Company Overview

Discovery stage product (Tox Studies Not Completed)

10 Employees, No Tangible Assets

Target resident in EU

Very Complex Upstream IP Landscape

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.


Trends to Watch
in 2024
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What We're Seeing.....

Bankruptcy/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
  - But increased geopolitical risk (BIOSECURE Act)
- 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

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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 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 (cont'd)

- 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 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 M&A and partnership deals in the Life Sciences industry, remember that your partner may not be your partner next year… plan accordingly.

Biography

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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.

Biography

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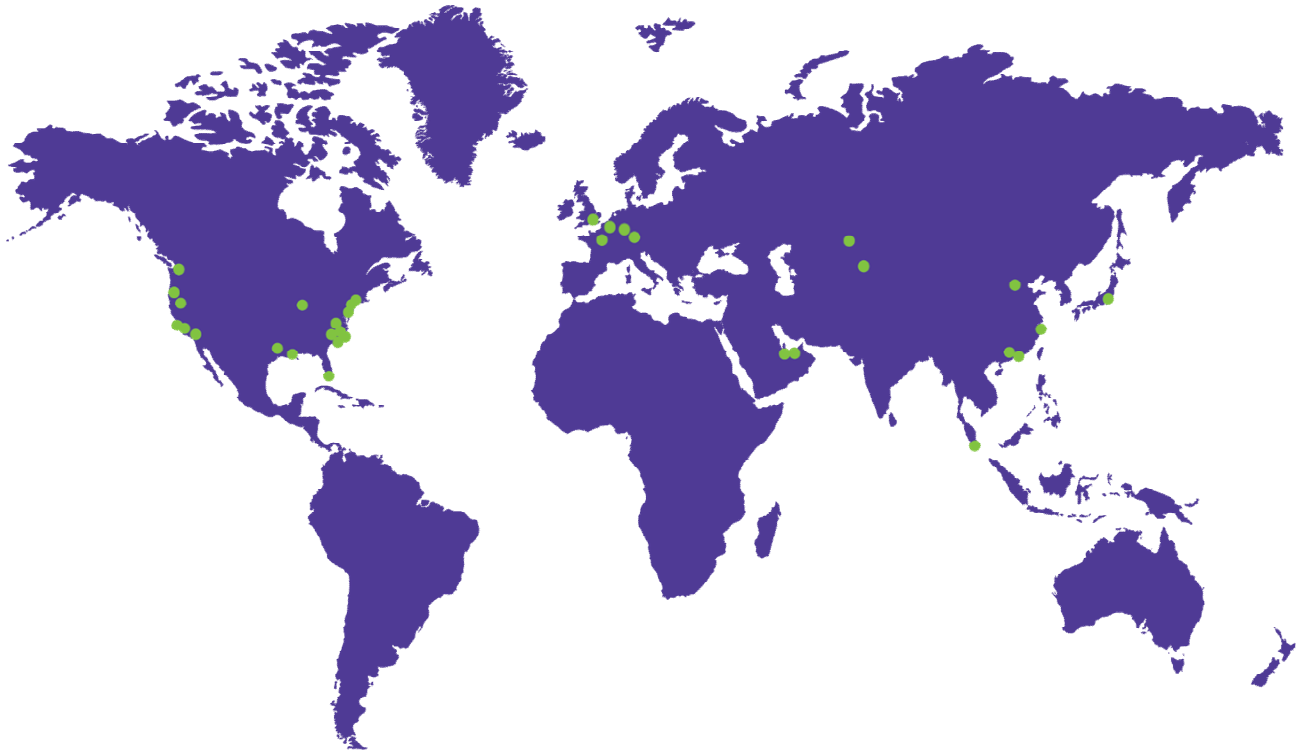
Laurie A. Burlingame has a diverse practice representing clients on a broad spectrum of transactions in the life sciences and technology industries, including initial and follow-on public offerings, venture capital financings, de-SPAC transactions, and mergers and acquisitions (M&A). She regularly serves as outside general counsel to clients, advising management teams and boards of directors on a variety of matters throughout the lifecycles of various companies, including formation and founder issues, licensing transactions, strategic collaborations, commercial transactions, corporate governance, disclosure requirements, and other general corporate matters.

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Abu Dhabi
Almaty
Astana
Beijing
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong
Houston
London
Los Angeles
Miami
Munich
New York
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Seattle
Shanghai
Shenzhen
Silicon Valley
Singapore
Tokyo
Washington, DC
Wilmington



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THANK YOU