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M&A ACADEMY

What Makes Life Sciences Transactions Different

Tony Chan, Jacqueline Berman and Janice Logan, Ph.D.

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What Is Driving Life Sciences M&A?

- M&A activity slowed towards the end of 2019:
  - Market jitters, trade conflict, and recession concerns saw many acquirers on the sidelines
  - Smaller companies seeking to develop and commercialize products independently
  - Uncertainty around drug pricing, health care expenditures, and market accessibility continued
  - $198 billion sales at risk due to patent expiries

Source: *Deloitte 2020 Life Sciences Outlook United States*

Impact of COVID-19 on M&A Activity

- Deal activity last week was just $12.5B, the lowest weekly total since April 2009
- Overall value of deals in the first quarter fell 28 percent from a year ago to $698B, the weakest Q1 period since 2016
- US M&A activity dropped 51 per cent to $253B
- Cross-border activity fell 17 percent from a year ago to $204B
- Private equity driven M&A rose 5 percent to $107B
- Expectation that M&A activity will bounce back

Source: Dealmaking grinds to a halt on coronavirus impact, *Financial Times*, March 31, 2020

What Are The Significant Life Sciences Market Trends?

- Pharmaceutical Drug and Disease Trends: Worldwide prescription drug spend expected to have a positive CAGR of 6.9 percent with sales expected to reach **$1.18 trillion by 2024**
- Orphan Drugs: By 2024, the **orphan drugs sector** is expected to double the CAGR of non-orphan drugs
- Cell and Gene Therapies: Large pharma companies are increasingly focused on cell and gene therapies, with an emphasis in oncology and rare diseases
- Med-tech: Projected to grow at a 5.4 percent CAGR through 2025. The market is expanding at a relatively faster pace in emerging markets and overseas.

Source: *Deloitte 2020 Life Sciences Outlook United States*

What Are The Significant Life Sciences Market Trends?

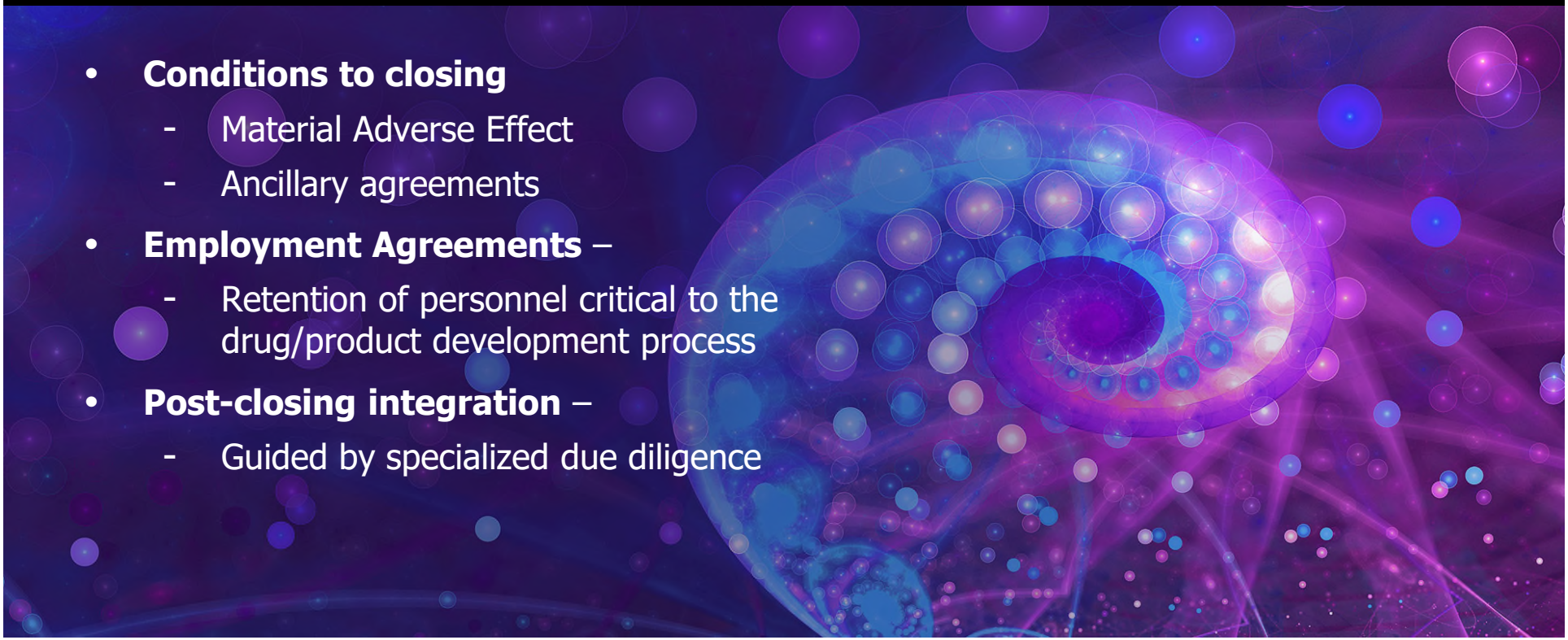
- Accelerating approvals through **Breakthrough Therapy Designations** and **Fast Track Designations** is trending upward
- The AI segment is predicted to increase from **$198.3 million** to **$3.88 billion** between 2018 and 2025. Many AI startups are focusing on repurposing existing drugs or generating novel drug candidates
- Pharma companies are partnering with **AI startups**, and tech giants are making advancements in biochemistry; in 2019, life sciences companies announced deals to acquire over 40 technology companies

Source: *Deloitte 2020 Life Sciences Outlook United States*

What Is Different About Life Sciences M & A?

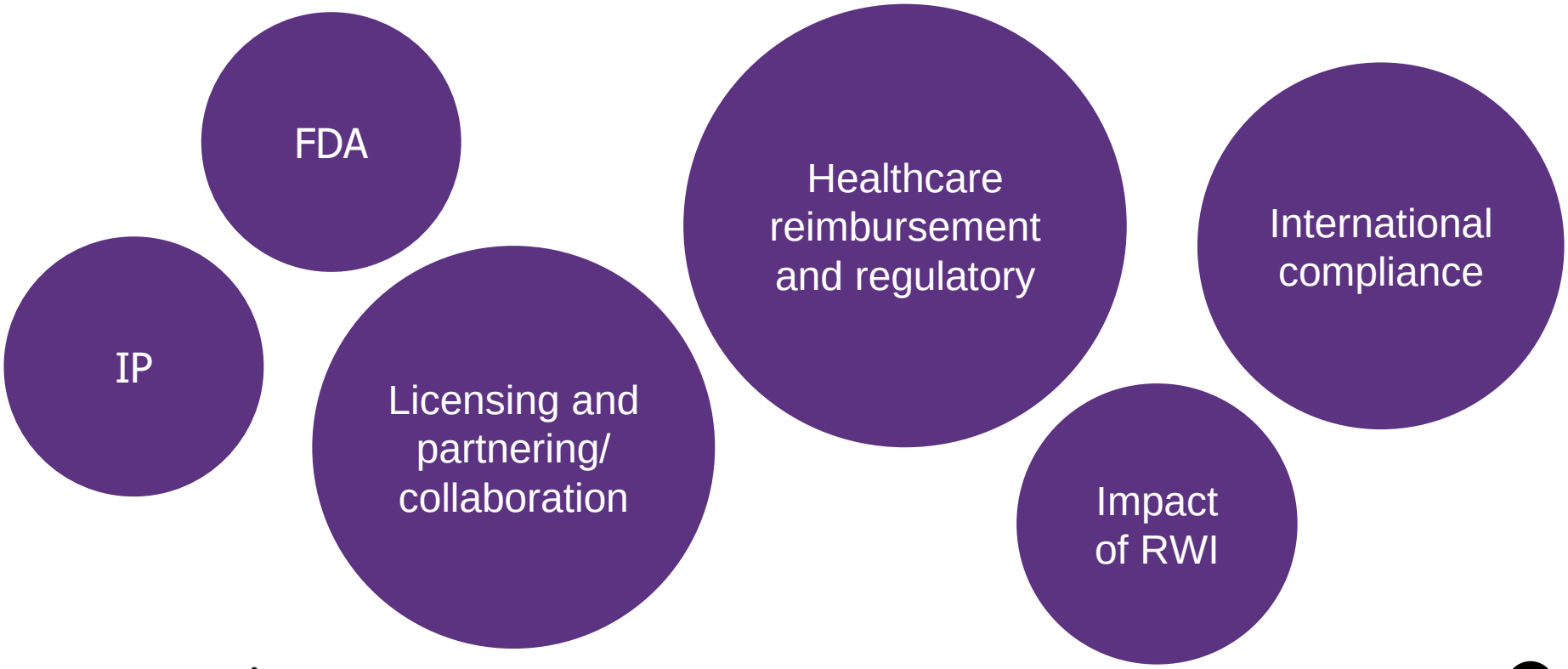
- **Specialized Due Diligence** –
  - IP
  - Licensing
  - Partnering/collaboration
  - Government grants/rights
  - FDA/health regulatory
  - Contracts
- **Earn-outs** and **CVRs**
  - Regulatory or commercial milestones
  - Bridge valuation gaps
- **Specialized Contract Provisions**:
  - Representations, warranties, covenants and indemnities

What Is Different About Life Sciences M & A?



- **Conditions to closing**
  - Material Adverse Effect
  - Ancillary agreements
- **Employment Agreements** –
  - Retention of personnel critical to the drug/product development process
- **Post-closing integration** –
  - Guided by specialized due diligence

What Are the Key Areas of Specialized Due Diligence?



FDA Due Diligence: Issues to Consider – Determining the Scope

- What is being acquired?
  - Specific products or the entire company
- What is material to the transaction?
  - Will dictate where to focus
- What stage are the products?
  - Pre-market
  - Post-market
- Following closing, how will the company be operated?

FDA Due Diligence:
Issues to Consider – Cross Cutting Issues

- Regulatory Correspondence (*e.g.,* meetings, letters, submission, summaries)
- Enforcement Actions (*e.g.,* warning and untitled letters, import alerts)
- Manufacturing (*e.g.,* cGMP compliance, recalls)
- Product Life Cycle (*e.g.,* exclusivity, additional uses/indications)
- Competition (*e.g.,* similar products, blocking products, follow-on products)
- Contractual Agreements (*e.g.,* partners, licensees, licensors, contractors/service providers)
- Overall regulatory landscape

FDA Due Diligence: Issues to Consider – Premarket Products

- Do the company's strategy and timeline align with FDA's?
- Scientific Assessment-Preclinical and Clinical Trials
  - Safety and efficacy results (*e.g.*, AEs/toxicities, preclinical indicators, clinical endpoints)
  - Study design (*e.g.*, scientific validity, consistency with FDA expectations)
  - Third-party reviewer comments (*e.g.*, IRBs, DSMBs)
- Regulatory Compliance (*e.g.*, GCPs/GLPs, clinicaltrials.gov)
- Application strategies
  - Application, specialized, and expedited pathways
  - Device strategies (*e.g.*, drug-device combinations, IVDs)
  - Application impediments (*e.g.*, patent certifications, citizen petitions)
  - Controlled substance scheduling designations
- Voucher opportunities

FDA Due Diligence: Issues to Consider – Marketed Products

- Basis for marketing
- Labeling (*e.g.*, restrictions, off-label risks)
- Safety/Efficacy
  - Robust pharmacovigilance system
  - Identified serious issues
- Promotional practices
- Post-approval Obligations (*e.g.*, REMS, Phase IV studies, controlled substances)
- Licensing/Registration Requirements
  - FDA, DEA, State licenses/registrations
  - License transfers

New Developments

- Over the last year there have been MANY changes in the regulatory M&A and legal landscape
- Companies may seek earlier stage products, which raises diligence challenges (but also opportunity)
- Cell and gene therapies are still the "hot ticket"
  - But, this is an evolving and somewhat uncertain area
  - E.g., FDA's new policy on the interpretation of orphan drug provisions for gene therapy products
- Increasing use of representation and warranty insurance, necessitating increased documentation of diligence efforts.
- Impact of COVID-19 and CARES Act

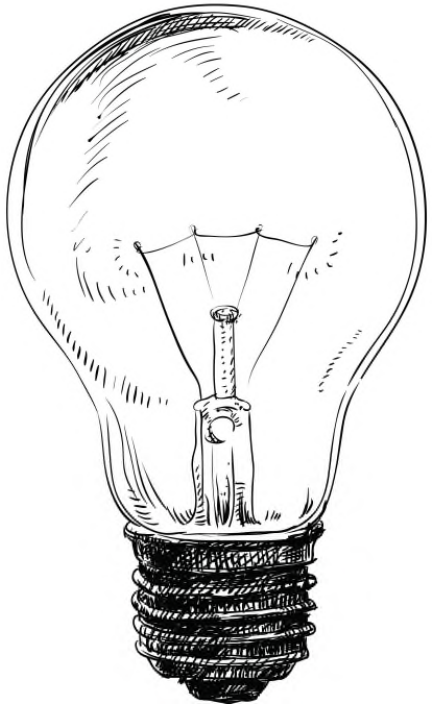
What Are the Key IP Due Diligence Issues?

- With early-stage biotechs, IP and key people may be only real assets

Ownership and right to use key platform technology

What Are the Key IP Due Diligence Issues?

- Strength of IP
- Availability of potential workarounds (e.g., biosimilars, generics, off-label sales)
- Evaluation of IP in relevant market jurisdictions (US, EP, Asia)
- Freedom to operate (FTO)
- Actual or threatened claims
  - Litigiousness of competitors
- Evaluation of IP portfolio under changing legal standards
- Impact of FDA and regulatory regimes



Changing Legal Standards

- Unenforceability of patents after *Therasense* (2011)
  - Based on Litigation Misconduct (2017)
  - Based on Patent Attorney's Business Misconduct (2018)
  - Based on Specific intent to withhold a prior offer for sale information from the patent office (2020)
- "Patentable Subject Matter" § 101 issues
- "Written Description" § 112 issues

"Patentable Subject Matter" § 101 issues

- ***Mayo v. Prometheus* (2012)**
  - Diagnostic method reciting ["law of nature" + "well-known, routine, conventional"] steps is not a patent-eligible matter
  - Patentable subject matter requires "**something more**"
- ***Association for Molecular Pathology v. Myriad* (2013)**
  - Removal of introns (cDNA) represents "something more" and is patent-eligible
  - An "isolated" sequence (DNA, RNA, protein) is not necessarily patentable subject matter
- ***Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015)**, ***cert denied***
  - Because the recited steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful.
- **Diagnostics, bioinformatics, methods all at risk**

"Written Description" § 112 issues

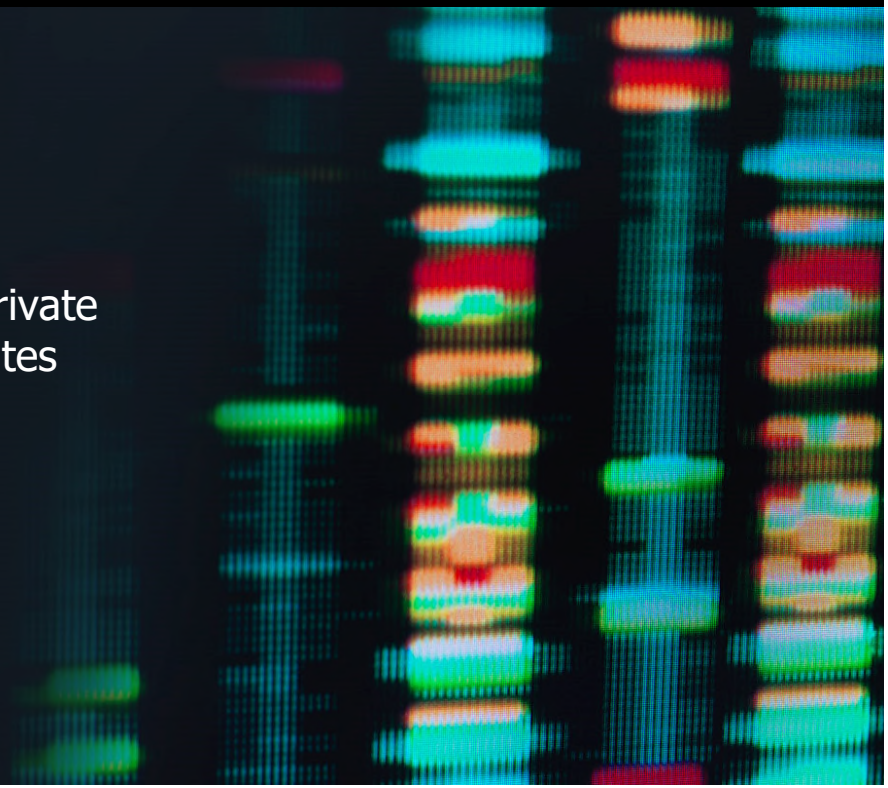
- 35 U.S.C. § 112, paragraph 1 requires that a patent specification must contain a written description of the invention
- New antibody applications are still having difficulties satisfying written description requirements.
  - Specification must disclose "a representative number of species falling within the scope of the genus *or* structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus. "*Amgen v. Sanofi*, 872 F. 3d 1367 (Fed. Cir. 2017), *cert denied.*

Contingent Consideration Structures

- To bridge valuation gaps with respect to products in development, earn-outs in private deals or contingent value rights in public deals are often included to compensate sellers, including:
  - Escrows
  - Deferred Purchase Price
  - Earn-Outs
  - Royalties
  - Regulatory Milestones
  - Sales Milestones
  - Contingent M&A

Common Issues Relating to Contingent Consideration

- Definition of Milestones
- Duration of Payments
- Determination and Disputes
  - Significant value can be deferred, and in private deals earn-outs are a large source of disputes
- Enforcement and Monitoring
- Commercially Reasonable Efforts
- Acceleration and Liquidated Damages
- Renegotiation of Milestones



Representation and Warranties; Covenants

- Representations and Warranties
  - Covering the key due diligence areas
  - Creates legal protection through conditions to closing (public deals) or indemnities for breach that survive closing (private deals)
  - Requires disclosure that helps with post-closing integration
- Delayed Sign and Close:
  - Signing and public announcement (public company deals)
  - Closing following receipt of required regulatory approvals
- Pre-closing covenants
  - Regulate ongoing regulatory, clinical, product development and other activities that could materially affect the business

Conditions to Closing

- Specialized Conditions to Closing
  - Potential issues between signing and closing, such as failure of clinical trials, product recalls, or termination of material license or collaboration agreements.
- Ancillary Agreements
  - Common IP, which may require cross-licensing within a defined field
  - Sharing or referencing of clinical data or clinical material/cell banks with respect to separate development activities
  - Transition services for supply, manufacturing, laboratory, personnel, accounting, and other back-office functions and other non-transferred resources
  - Noncompetition agreements to define the respective fields of development and commercialization
- MAE

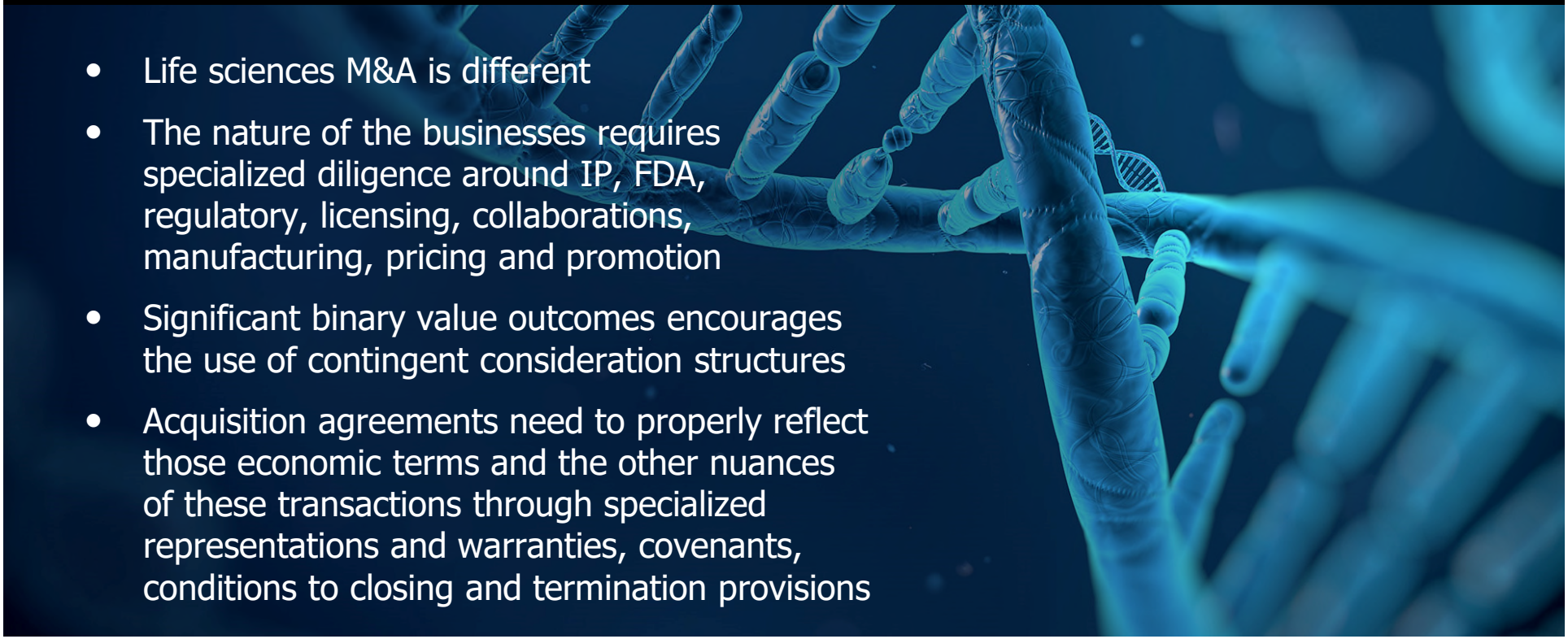
Key Contributors

- Identify key employees/consultants/inventors for assets being acquired
- Ensure retention through employment and retention agreements and appropriate incentive compensation packages
- Ensure that all IP developed has been properly assigned to the company and that non-patented trade secrets have been properly protected
- Consider non-solicitation and noncompetition provisions in employment and retention agreements, recognizing enforceability issues in certain jurisdictions

Post-Closing Integration

- Due diligence and Disclosure Schedules
  - Guide to developing an integration plan and start planning process before integration
  - Subject to antitrust and other regulatory reasons that prevent any actual integration or joint operation pre-closing
- Business teams develop integration plans beginning with day-1 activities and clear lines of authority and communication
- Poor integration planning can impede clinical trials and other aspects of the drug development process or undermine revenue from licensed products

Key Takeaways from This Session



- Life sciences M&A 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
- Acquisition agreements 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

Biography

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Jacqueline R. Berman advises companies on US Food and Drug Administration (FDA) regulatory, compliance, and enforcement issues, as well as clinical trials and FDA-regulated product development programs. She also counsels clients on the safety, labeling, and reporting requirements for consumer products under the laws enforced by the US Consumer Product Safety Commission (CPSC), the Federal Trade Commission (FTC), and related state enforcement agencies. Jacqueline's clients include pharmaceutical, device, biologic, dietary supplement, and food/food additive manufacturers.

Biography

Tony Chan
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Tony Chan has more than 15 years of experience advising companies on mergers and acquisitions (M&A), private equity, growth equity, and venture capital transactions, as well as on corporate governance, emerging company representation, and corporate finance. Tony's clients include strategic buyers and sellers as well as financial sponsors and their portfolio companies in the life sciences, investment management, technology, and video game sectors. He also regularly advises on complex international and cross-border matters.

Biography

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Janice Logan brings an extensive science and engineering background to her intellectual property law practice, focusing primarily on biotechnology, chemistry, and materials engineering matters. She guides clients through complex patent procurement and patent litigation matters, and handles patent portfolio management and development. She also manages due diligence for intellectual property asset transactions. Janice is fluent in Korean and Japanese.

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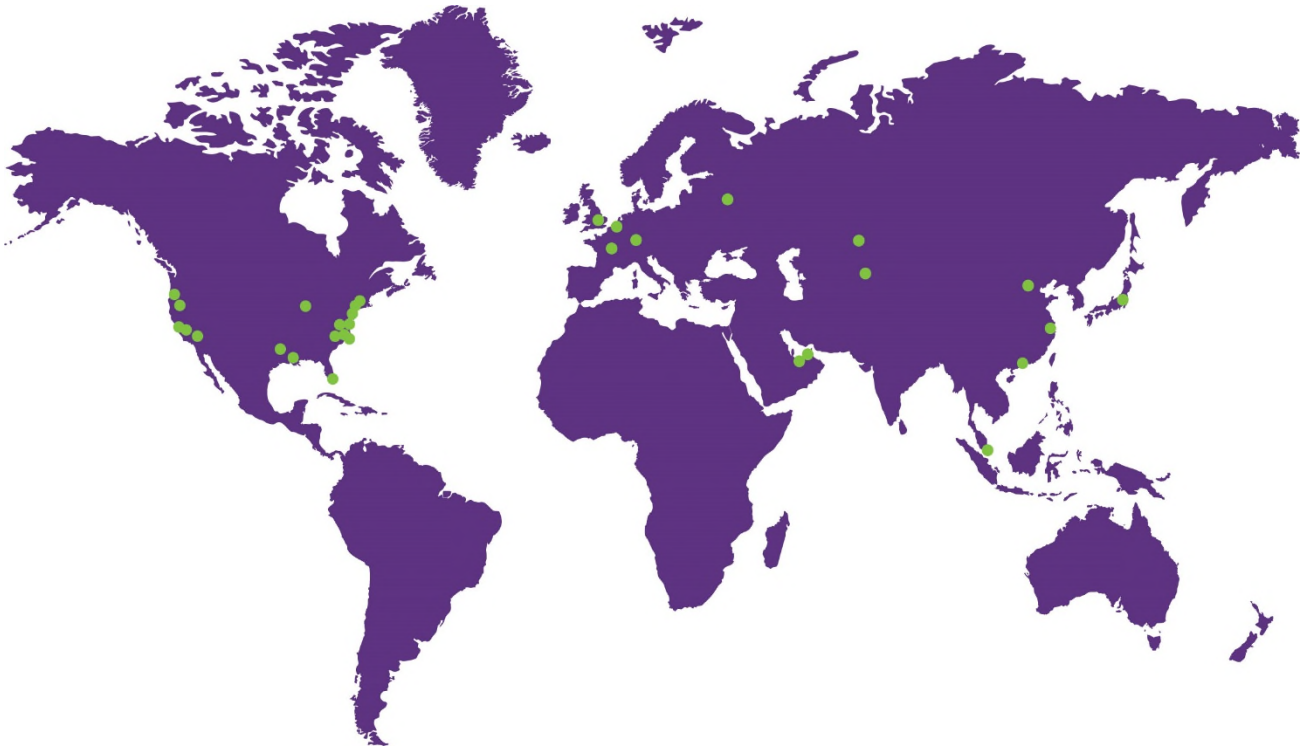

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