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M&A Considerations Across the Ever-Changing Life Sciences Landscape

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What Is Driving Life Sciences M&A?

- Life sciences M&A activity totaled US$159b in 2020, with one deal accounting for ¼ of the annual life sciences M&A spend, down from US$306b in 2019, reaching one of the lowest levels since 2014.
- M&A activity volume has remained consistent with 2019, however the deal value has dropped in 2020 and 2021:
  - High valuations and strong public markets (including SPACs) likely led acquirers to focus on smaller bolt-on deals.
  - Growth gaps could also create drive deals depending on clinical trial delays or sales slow-downs that have been caused by the pandemic.
  - With interest rates low, many medtechs increased their leverage, signaling an active 2021.

Source: *EY How the Pandemic has Changed the Rules for Life Sciences Deals*

Impact of COVID-19 on M&A Activity

- Executives are taking a wait-and-see approach to dealmaking in 2021, after the life sciences sector was one of the more active ones in in 2020.
- Only 43% of executives said that they expect their company to actively pursue M&A in the next 12 months.
- 2/3 life sciences companies said they canceled or failed to complete a planned acquisition in the past 12 months, most frequently citing disagreement on price or valuation as the reason.
- The volume of M&A deals increased significantly in the second half of 2020, an increase of 25% relative to the first half of the year and 14% up on the second half of 2019.
- In the Asia-Pacific region, deal volume for medical devices, biotech and pharma increased by 35%, 75% and 36%, respectively compared to the first half of 2020.

Source: EY *Life Sciences Executives Taking Longer-View Look at M&A Strategy*
PwC *Global M&A Industry Trends in Health Industries*

What Are The Significant Life Sciences Market Trends?

- Cell and Gene Therapy
- Mixing and Matching Technologies (AI/ML)
- Virtual Health
- Med-tech
- Growing Investments in Reshoring
- "Bolt On" Acquisitions
- Novel Regulatory Pathways

Source: Grand View Research *Life Science Analytics Market Size, Share & Trends Analysis Report By Component, By Type (Reporting, Descriptive, Predictive, Prescriptive), By Application, By Delivery, By End-user, By Region, And Segment Forecasts, 2020 – 2027 Deloitte 2021 Global Life Sciences Outlook*

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

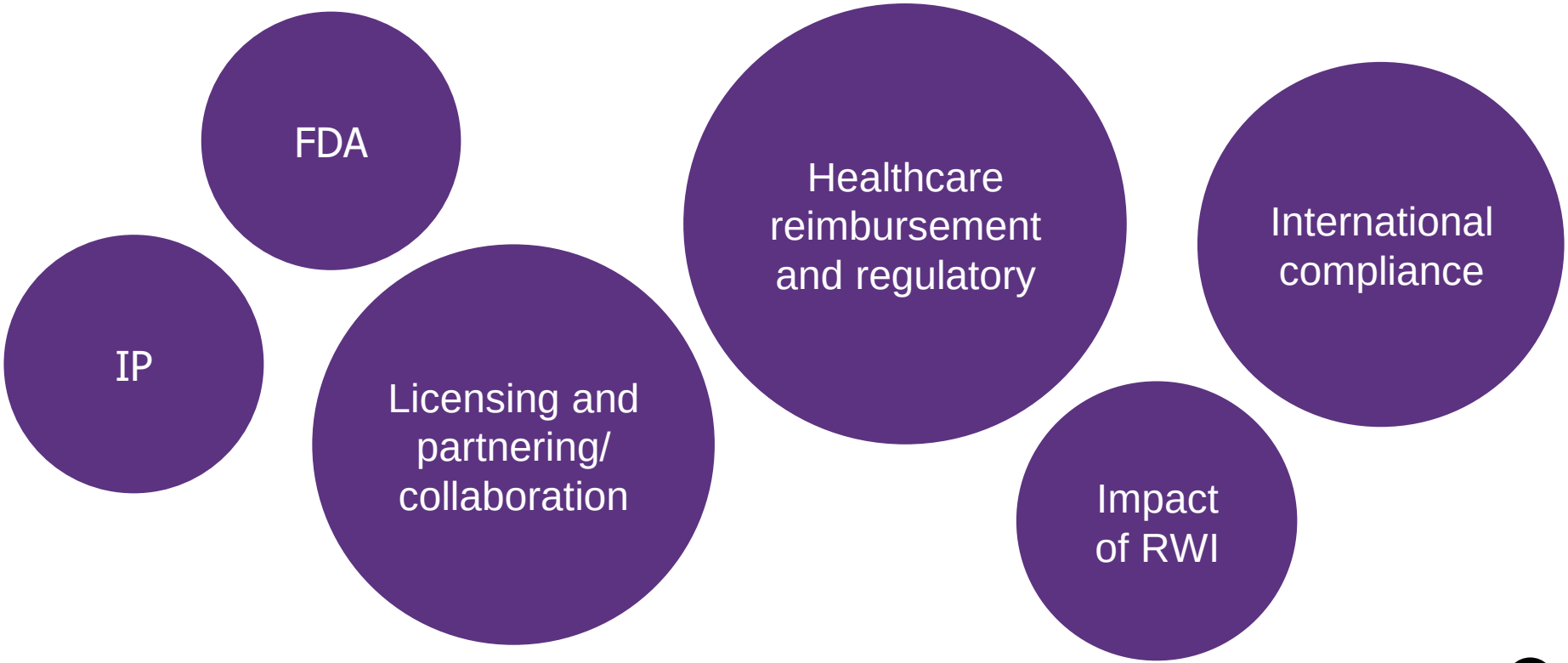
What Is Different About Life Sciences M & A?

- **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

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 Areas of Specialized Due Diligence?



What Are the Key IP Due Diligence Issues?

Ownership and right to use key platform technology

Intellectual Property Ownership

- Confirming proper assignment of IP by employees / consultants
- Proprietary Information and Invention Agreements (PIAA) / Consulting Agreements
- Company policies
- Confidentiality Agreements (CDA / NDAs)
- Patent filings (including provisional applications)
- Third Party IP Assignment

Licensed Intellectual Property

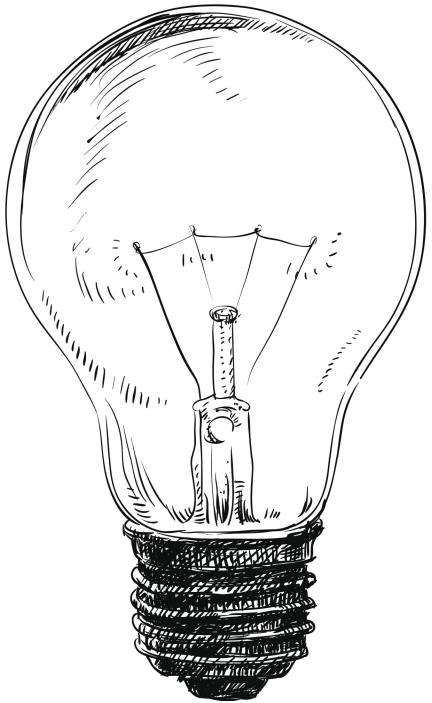
- Both In-Licenses and Out-Licenses
- Scope of Rights Granted
  - Scope of IP
  - Subject of License
  - Field of Use
  - Territory
- Restrictions
  - Exclusivity / Non-Competes
- Obligations
  - Options / ROFN / ROLMO
  - Prosecution / Maintenance / Enforcement / Defense Rights

Government Restrictions and Reserved Rights

- Bayh Dole Act (35 USC §§200-212) - Inventions arising from federally funded research in the US
- Non-Profit Entities / Universities
  - Requirements to comply with tax-exempt status
  - Facilities financed via tax free bonds
  - Internal policies
  - Balance of Academic Freedom vs. Preserving Value of New Technology
- State / Local Restrictions

Additional Key IP Due Diligence Issues

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

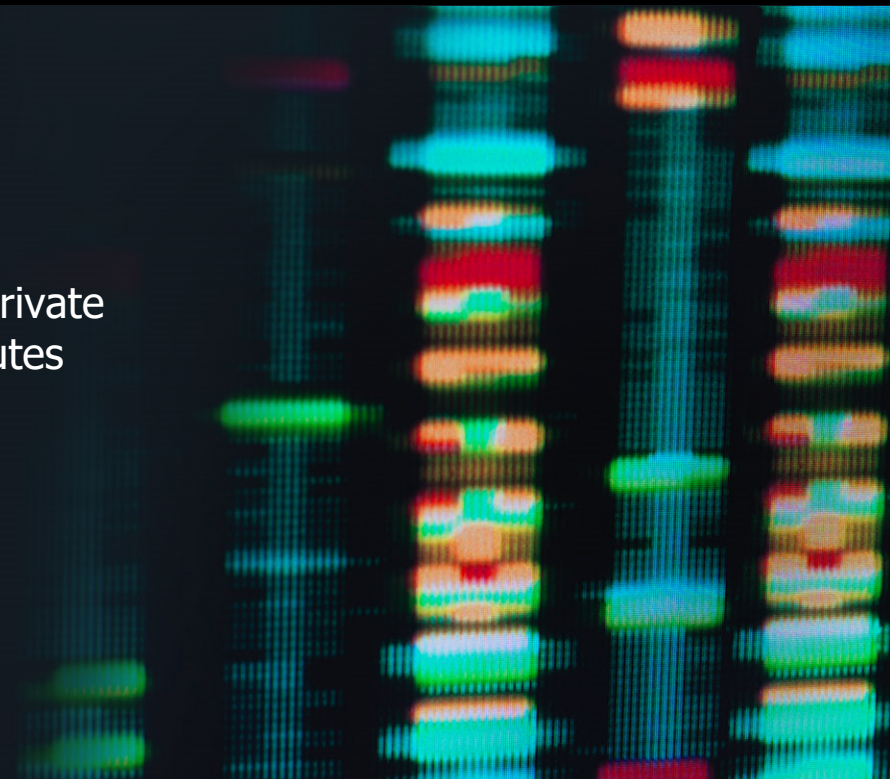


Contingent Consideration Structures

- 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

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Tony serves as an adjunct professor at Georgetown Law School where he has taught Takeovers, Mergers and Acquisitions since 2015. He is also involved in the community, serving on the boards of the Arlington Arts Center, the Asian Pacific American Bar Association of DC, and the Harvard Law School Association of DC.

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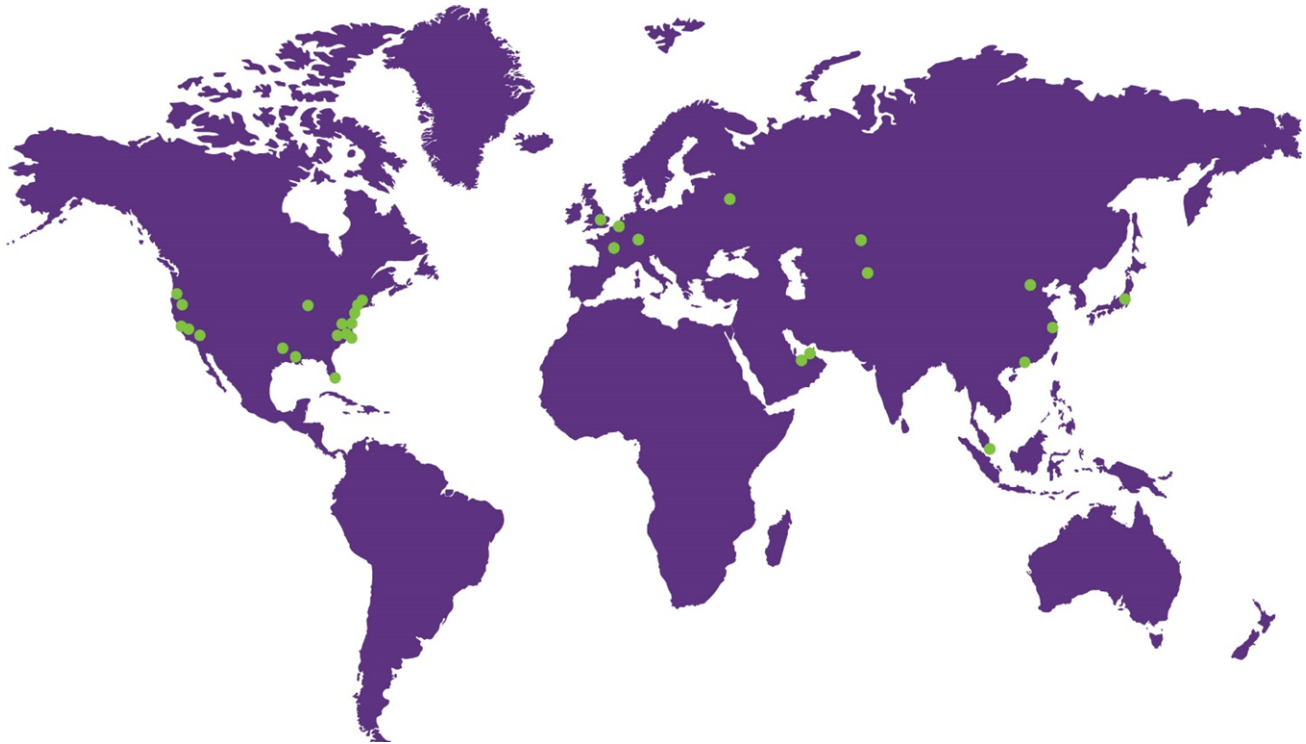

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