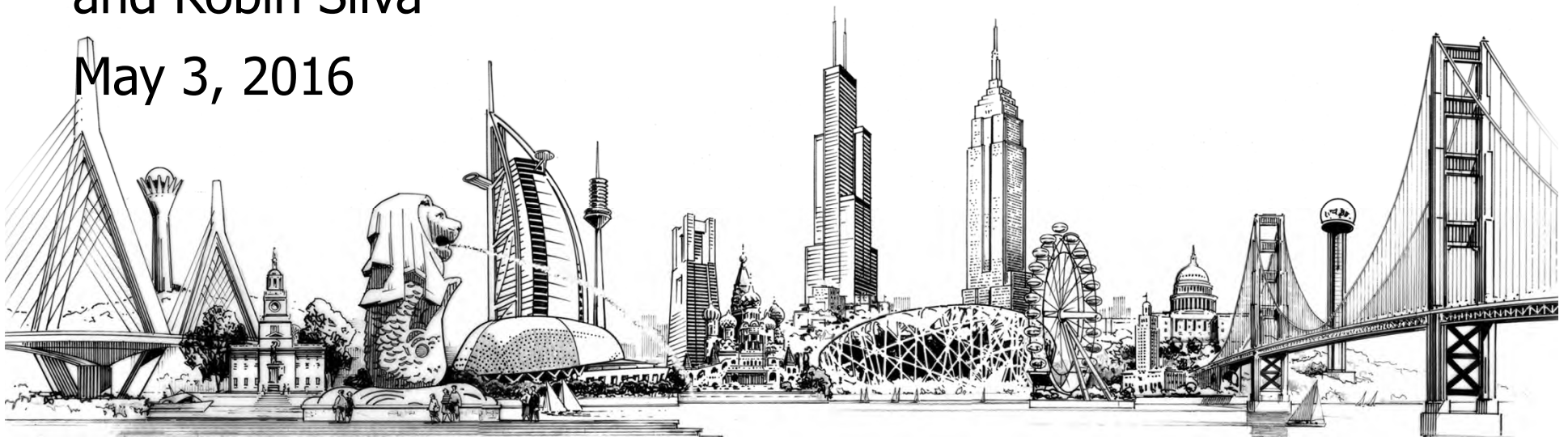


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LIFE SCIENCES M & A TRENDS AND SPECIAL ISSUES

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May 3, 2016



1. What Is Driving The Increased Activity in Life Sciences M & A?

- Economic factors and the regulatory environment are the most important considerations when companies evaluate new markets.
- Competitive pressures, as well as the desire to diversify their portfolios, are the strongest motivators for companies embarking on M & A.
- For almost half of the pharmaceutical companies, patent expirations are a motivation behind M & A activity.
- Tax considerations (e.g., inversions to the extent not shut down by recent Treasury regulations) are an important driver of M & A activity.
- The North American life sciences and healthcare market remains the primary investment destination, followed by the Asia-Pacific region.
- 70% of larger companies anticipate M & A activity in the next three years.
- In addition to M & A, an increase in various forms of collaboration are anticipated, particularly in the pharma sector, to help spread risk.

Source: *Deloitte M & A Trends in Life Sciences and Health Care*, September 2014

2. What Are The Significant Life Sciences Market Trends?

- Market reconfiguration and consolidation: expiring patents, shorter product life cycles, formulary coverage challenges, changing commercial practices, growth in new markets and value-based reimbursements, increased activity in emerging markets, biopharmaceutical and med-tech, increased activity among healthcare providers, health plans and downstream subsectors changing customer profiles (B2B instead of B2C).
- Pricing pressures: Affordable Care Act reforms include shortened regulatory pathway for biosimilars and generic versions of off-patent biotech drugs. More focus on curtailing anti competitive practices (e.g., pay-for-delay practices).
- Health reform and the shift to value: Life sciences industry will increasingly need to show a product's clinical, safety, and economic impact (e.g., comparative effectiveness to better communicate value proposition).
- R & D productivity: To combat declining R & D productivity, life sciences companies will need to increase efficiency, reduce costs, and maximize value of investments.
- Disruptive technologies: Digital technology and patient empowerment, mobile health/telemedicine, 3D device printing.
- Risk regulation and compliance: Product safety issues, security and privacy breaches, IP disputes, whistleblower complaints, FCPA exposure, disclosure of financial interests, greater demand for product data.

Source: *Deloitte 2015 Life Sciences Outlook* United States

2. What Are The Significant Life Sciences Market Trends (cont.)?

- With 45 drugs approved in the United States in 2015, the highest level in over a decade, there is an optimism in terms of R & D that may contribute to enhanced M & A activity.
- The shutdown in the US IPO market from December 2015 to February 2016 and slow reopening thereafter could negatively affect M & A activity.
- There is a growing movement within larger life sciences companies to act like venture capitalists and seek to lock in promising technologies as early as possible.
- Life sciences companies will need to develop a competency in both buying new assets and selling noncore assets. Antitrust considerations may lead to the disposition of certain assets following larger M & A.

Source: *PWC Pharmaceutical and Life Sciences Deals Insights Quarterly Q4 2015*

3. What Are Key Findings Of Life Sciences M & A Studies?

- Earn-outs – Particularly common and large in life sciences deals.
- Time to exit – The median time from founding to exit is 7 years and less than 50% of earn-out dollars are tied to milestones projected by sellers at closing to be achieved, if at all, within 4 years of the acquisition.
- Investor returns – No consistent multiple of returns on equity capital, either in upfront payments or in total potential returns including earn-outs.
- Milestone achievement – Of milestones due or projected to be due by sellers at closing to have been achieved by now, one-third to one-half of milestone dollars have been achieved and paid.
- Intellectual property (IP) indemnification – IP representations survive longer but are subject to the general liability cap more often in life sciences deals.
- Disputes – Disputes regarding earn-outs remain common and complex, arising in 29% of deals. Renegotiations are increasingly common, arising in 17% of deals.

Source: 2012 *SRS Life Sciences M & A Study* and 2015 Update

4. What Is Different About Life Sciences M & A?

- Specialized due diligence (IP, licensing and partnering/collaboration, government grants/rights, FDA/health regulatory and international compliance, including FCPA) depending upon the stage of development.
- Specialized representations, warranties, preclosing covenants and indemnities (private deals) that tie into due diligence issues.
- Special conditions of closing and MAE definitions that tie into due diligence issues and/or regulatory or commercial milestones.
- Frequent use of earn-outs (private deals) or contingent value rights (public deals) tied to regulatory and commercial milestones/milestone payments to bridge valuation gaps.
- In asset or carve-out transactions (as opposed to acquisition of entire company), need for ancillary documents relating to common IP, sharing or referencing of regulatory data, clinical development material/cell banks, transition services, noncompetition.
- Employment/retention agreements for personnel are critical to the drug/product development process.
- Postclosing integration to be guided by specialized due diligence; corporate cultural differences (biotech vs pharma); development team and product sales force integration issues.
- Collaboration/licensing agreements are distinct from M & A and are not covered here, as they have their own set of issues.

5. What Are the Key Areas of Specialized Due Diligence?

- IP
- Licensing and partnering/collaboration
- Government grants/rights
- FDA/Health regulatory
- International compliance

6. 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
 - Rights to inventions of employees/consultants – confirming proper assignment (including provisional applications) and assessing IP “leakage” risk
 - Scope of in-licensed and out-licensed rights, definition of products, territories
- IP 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); need for third-party licenses
 - Patent cliff issues and barriers to entry (e.g., regulatory exclusivity/evidence of anticompetitive conduct (e.g., “pay to delay”))
 - Rights of US Government to IP under Bayh-Dole or other funding agreements
 - Actual or threatened claims
 - Litigiousness of competitors
 - Evaluation of IP portfolio under changing legal standards (see next slide)

Changing Legal Standards

- Changing legal standards: United States
 - New post-America Invents Act (AIA) changes rules about what is prior art
 - AIA enacted Inter Partes Reviews (IPRs)
 - Alternative to or in addition to district court litigation to attack validity of issued patents
 - Easier to invalidate patents in an IPR
 - Evaluation of breadth of claims: remedial action or attack competitors
 - “Patentable Subject Matter” § 101 issues
 - Diagnostics, bioinformatics, methods all at risk
 - “Written Description” § 112 issues
 - Of particular concern in the antibody space
- Changing legal standards: EP
 - New European Unitary Patent and Unified Patent Court coming soon
 - Awareness issues; desire to “opt out”
 - Inventive step issues in antibodies

7. What Are the Key Licensing and Partnering/Collaboration Due Diligence Issues?

- Key terms for both in-licensing and out-licensing, as well as any partnering/collaboration agreements.
- Compliance with terms, particularly any payment, funding, and/or diligence obligations.
- Noncompetition and nonsolicitation provisions.
- Potential revenue from regulatory and sales milestones/potential liabilities for same.
- Change of control/antiassignment provisions.
- Effect on ownership or right to use IP, whether separately owned or jointly developed.
- Actual or threatened claims or termination.
- Forward-thinking considerations: agreements on deciding Patent Term Extension (PTE) in United States, Supplemental Protection Certificates (SPCs) in United States, which party can decide to “opt out” of new European Unified Patent Court.
 - Important for “platform” companies with more than one licensee.

8. What Are Key Government Contract, Grant And Rights Due Diligence Issues?

- Government contracts, grants and/or funding can create special contractual and regulatory compliance obligations with risks of fines, penalties, and debarment for noncompliance.
- In asset transactions, the assignment of government contracts requires compliance with the novation process.
- Government grants/funding create rights in the government rights to IP under the Bayh-Dole Act
 - Private parties need to comply with notification and prosecution requirements to obtain ownership of subject inventions – failure to comply results in ownership by government.
 - Government retains fully-paid, non-transferable, non-exclusive license in perpetuity to subject inventions.
 - Government has “march in” rights if subject inventions not practiced or for health/safety reasons – not invoked to date.
 - Manufacturing substantially in the US is required absent waiver.
- Government contracts/grants/funding may limit scope of use and rights in data.

9. FDA/Healthcare Due Diligence: Issues to Consider

- Are the target's products pre- or postmarket? The product stage will impact the scope of the due diligence.
- For all products (pre- or postmarket) diligence should cover:
 - Regulatory communications (e.g., meetings, letters, submissions)
 - Product enforcement actions (e.g., warning and untitled letters, import alerts)
 - Manufacturing
 - Are the products manufactured in accordance with cGMPs and other manufacturing requirements (inspections, internal audits, internal metrics)?
 - Potential product life cycle
 - What exclusivity does/may the product have and what does the exclusivity protect?
 - Agreements
 - Is the company adequately protected from regulatory risk in its agreements?

10. FDA/Healthcare Due Diligence: Issues to Consider – Premarket Products

- Preclinical trials
 - Are there any significant adverse safety signals and is there a preliminary indication of efficacy?
 - Were the studies conducted in accordance with GLPs?
- Clinical trials
 - Were any material adverse events or other safety effects found?
 - Were efficacy endpoints met with statistical significance?
 - Were the trials designed in accordance with FDA requirements and recommendations?
 - Were the studies conducted in accordance with GCPs?
 - Have third-party reviewers (e.g., IRBs, DSMBs) expressed concerns pertaining to the studies?
 - Are the trials registered with clinicaltrials.gov and are the results properly reported?
- Premarket promotion
 - Has the company made promotional statements concerning investigational products that could subject it to FDA enforcement action?
- Kinds of applications
 - What applications are planned?
 - Are there any impediments to the applications that may increase the risk of delay of approval/marketing (e.g., patent certifications for ANDA and 505(b)(2) applications)?

11. FDA/Healthcare Due Diligence: Issues to Consider – Marketed Products

- Labeling
 - Are there any significant restrictions on the use of the product that would limit the available market? Are there off-label use risks?
- Safety/Efficacy
 - Does the company have a robust pharmacovigilance system and has it identified any serious issues?
- Postapproval Obligations
 - Are products subject to postapproval obligations that may increase the cost of doing business or that may restrict the potential market (e.g., REMS, Phase IV studies, controlled substances)?
- Licensing/Registration Requirements
 - Have the company and all contractors (e.g., CMOs, distributors) obtained all required registrations and licenses for the conduct of the business? Do they need to be transferred or renewed?
- Healthcare Considerations
 - Are there coverage and reimbursement-related challenges? Effective Medicaid contracts?
 - Are there any potential HIPAA issues? Data breaches?

12. What Are The Key International Compliance Due Diligence Issues?

- If the company has any international operations, compliance with FCPA, export control, and sanctions issues need to be addressed.
- Foreign doctors are often considered “foreign governmental officials” for purposes of the FCPA, and the pharmaceutical industry has been an area of focus for FCPA enforcement cases for payments made to foreign doctors or certain charitable activities connected with foreign government officials.
- Regulatory issues ex United States are different, and the potential liabilities associated with noncompliance are different.
- Certain technologies (e.g., biodefense and select agents) are regulated for export control purposes and exports are deemed to have been made with non-US persons working in US laboratories with access to such technologies.
- Heightened scrutiny required for certain markets (e.g., China).

13. What Are The Specialized Representation, Warranty and Preclosing Covenants and Indemnities?

- The acquisition agreement will contain detailed representations and warranties covering the key due diligence areas discussed above, which serves two purposes: (1) creates legal protection through conditions to closing (public deals) or indemnities for breach that survive closing (private deals) and (2) requires disclosure that helps with postclosing integration.
- Many deals are subject to two steps: (1) signing and public announcement (public company deals) and (2) closing following receipt of required regulatory approvals (e.g. HSR, SEC) and the gap between the two can in certain cases last 3 months or longer.
- Special conditions of closing or material adverse change clauses may be included to address potential issues between signing and closing, such as failure of clinical trials, product recalls, or termination of material license or collaboration agreements.
- Special preclosing covenants will regulate ongoing regulatory, clinical, product development and other activities that could materially affect the business.
- 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 for subsequent successful regulatory and commercial milestones; significant value can be deferred, and in private deals earn-outs are a large source of disputes.

14. What Are Special Considerations for Asset or Carve-Out Transactions?

- In asset or carve-out transactions (as opposed to acquisitions of the entire company), there is often a need for ancillary agreements relating to the following:
 - 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 nontransferred resources.
 - Noncompetition agreements to define the respective fields of development and commercialization.

15. What Are Special Considerations for Key Employees?

- Identify key employees/consultants/inventors for assets being acquired.
- Ensure retention through employment and retention agreements and appropriate incentive compensation packages; recognize cultural issues in retention (“biotech” vs “pharma”).
- Ensure that all IP developed by key employees/consultants/inventors has been properly assigned to the company and that nonpatented trade secrets have been properly protected; minimize risk of any IP “leakage”.
- Consider nonsolicitation and noncompetition provisions in employment and retention agreements, recognizing enforceability issues in certain jurisdictions.

16. What Are Special Considerations for Postclosing Integration?

- Use due diligence issues and disclosure schedule to acquisition agreement as a guide to developing an integration plan and start planning process before integration; there may be antitrust and other regulatory reasons that prevent any actual integration or joint operation pre-closing.
- Have substantive business teams (e.g., HR, legal, sales and marketing, manufacturing, procurement, regulatory, quality) develop subintegration plans beginning with day-1 activities and clear lines of authority/communication.
- Poor integration planning can impede clinical trials and other aspects of the drug development process or undermine revenue from licensed products.

Biography



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Carl Valenstein focuses his practice on domestic and international corporate and securities matters, mergers and acquisitions, project development, and transactional finance. He counsels extensively in the life science, telecom/electronics, and maritime industries, and he has worked broadly in Latin America, the Caribbean, Europe, Africa, Asia and the Middle East.



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Kathleen M. Sanzo centers her practice on regulatory and compliance issues connected to products regulated by the US Food and Drug Administration (FDA). She leads and counsels clients on matters relating to prescription, OTC drug, and biotechnology products clinical testing; food, dietary supplement, and cosmetic product manufacture, approval, marketing, and distribution; device promotion and labeling issues; food, drug, and device compliance matters; and all consumer product issues regulated by the US Consumer Product Safety Commission (CPSC) and state enforcement agencies.



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