



# Exploring Under the Surface: Yielding Higher Value From Life Science Transactions

**NASDAQ OMX**

**FOLEY**  
FOLEY & LARDNER LLP

# Managing the Due Diligence Process: Keys for Success

**R. Brian McCaslin**  
**Foley & Lardner LLP**

# Matt Bastardi

## Covidien

# Stages of Diligence

## Initial Analysis

- Market Assessment
- Product Assessment
- Customer Assessment
- Preliminary IP Review
- Initial Financial forecast / valuation



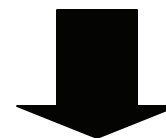
- Small, focused team until the appropriate functional expert (R&D; IP)
- 1-2 Months to complete
- Enough Detail so you are not surprised during “formal due diligence”

## Letter of Intent



## Formal Due Diligence

- In depth review of all functional areas (sales; marketing; operations; IT; Legal; etc)
- Validate “Initial Analysis” findings
- Integration Planning



- Comprehensive team comprised of functional leaders
- 1 Month to complete

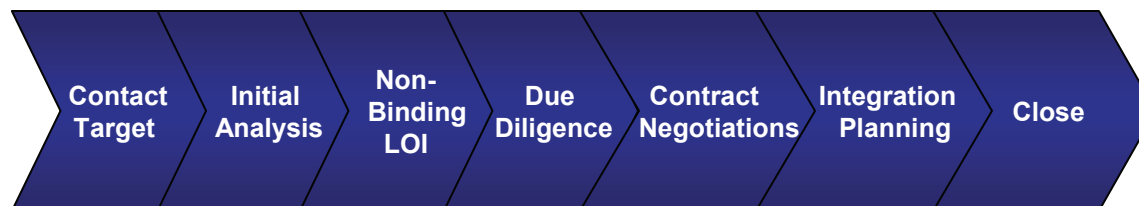


## Due Diligence Team

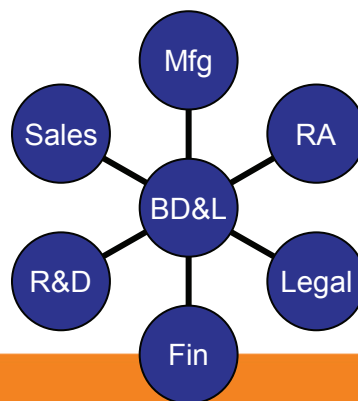
- Due diligence team should be comprised of the functional leaders that will own these activities post acquisition closing
  - VP / Director Sales
  - VP / Director Marketing \*
  - VP / Director R&D \*
  - VP / Director Operations
  - VP / Director Regulatory \*
  - VP / Director Human Resources
  - VP / Director IT
  - Legal – Commercial (*internal or external*)
  - Legal – IP (*internal or external*) \*
  - Finance (*internal or external*)
  - Integration Lead
- Diligence Team should be led by Business Development, but should also include a “Deal Champion”

# Common Due Diligence Mistakes

- Managed as a Linear Process



- Functions are in silos with individual checklists
- Key points of value are not well understood by entire due diligence team
  - Lack of interdependence / common perspective results in mistakes (gaps), hurried approach, bottleneck with BD&L

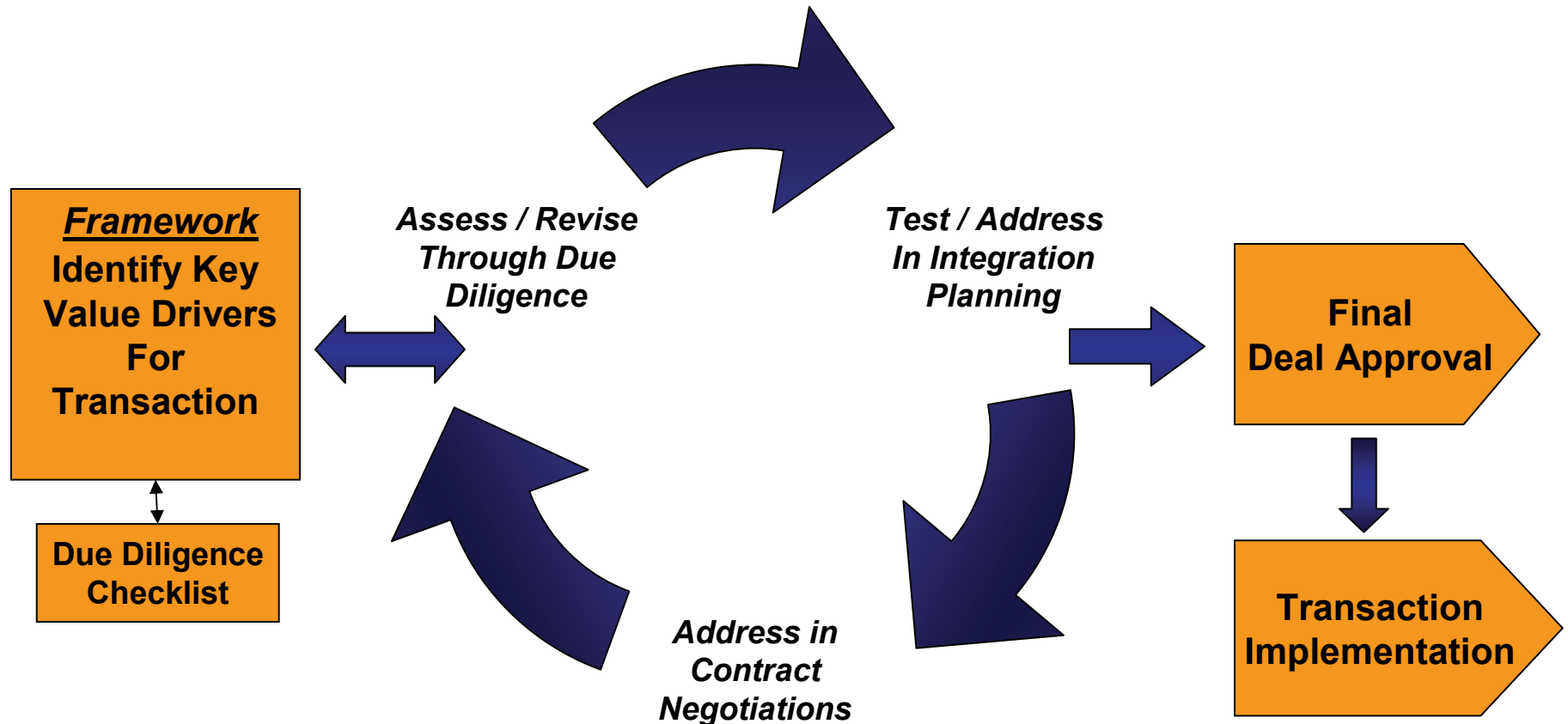


# Due Diligence Process – Best Practice

Pre Due Diligence

Due Diligence / Negotiations

Final Approvals / Closing





# Due Diligence - Using Key Value Drivers

- Clearly Identify the Key Value Drivers for the Transaction (KVDs)
  - Use KVDs to provide a unifying framework to the Transaction Process (Due Diligence, Integration Planning, Contract Negotiations, Deal Presentations)
- Key Value Drivers are communicated to the entire due diligence team
  - KVDs are used to break-down silos through the due diligence process
    - Goal is for functions to work interdependently through overarching objectives
  - Assists the lawyers with drafting and negotiating the definitive agreements
- KVDs are Tested and Revised Throughout the Deal
  - Testing and revision of KVDs helps avoid linear due diligence process

## Generic Example

### Pre-Due Diligence

#### Pre-Due Diligence Value Drivers

- Growing Base Business W/ High Gross Margins
- Disruptive Next Generation Technology
- Proprietary IP Position
- Stock Deal – No Surprises

Purchase Price –  
All Cash

### Due Diligence / Negotiations

#### Key Due Diligence Findings

- High Gross Margins Not Sustainable Long Term
- Next Gen Technology Not Compelling
- Contingent Liability a Major Concern

### Final Approvals / Closing

#### Post-Due Diligence Value Drivers

- Growing Base Business W/ High Gross Margins
- Disruptive Next Generation Technology
- Proprietary IP Position
- Stock Deal – No Surprises

Purchase Price –  
Declined to Bid

# Due Diligence Deliverables

- **Detailed Due Diligence reports by function**
  - Reports should include: complete review of relevant functional activities / operations; risks and opportunities; targets and milestones to achieve; integration plan
  - Utilize due diligence check-lists for each function
- **Complete financial projections**
- **Functional team members “sign up” to achieve plan**
  - Sales targets; costs targets; integration plans; etc.
- **ALL risks & liabilities are identified and evaluated**
- **Go / No Go Decision**

# Integration Planning

- **Ineffective integration of target companies destroys value**
- **Detailed integration plan should be developed in conjunction with due diligence activities**
- **Integration Lead should be identified upfront and be an integral part of the due diligence team**
- **Functional team members create their integration plans**
- **Integration activities should start before deal closing**

# Due Diligence Keys to Success

- **Be comprehensive in diligence activities, but focus efforts on Key Value Drivers and Major Issues**
- **Be respectful when placing demands on target company**
  - Buyer should assign one point of contact to funnel all information requests through
- **Make sure integration is integral part of the due diligence**
- **Don't forget about people issues**
- **Time kills deals – be thorough, but move fast**
- **Don't be afraid to walk**



# **Lisa Alexander**

Novartis Institutes for Biomedical Research  
Novartis Vaccines & Diagnostics

- General Parameters
  - Type and scope of deal
  - Timelines and value of deal
- How to Move IP Diligence Process
- Diligence Issues
  - What types of IP issues to consider?
  - Communications with client and other party.

- Type and size of deal
  - Merger/acquisition: many or few products/technologies
    - Need to prioritize
  - Product acquisition/collaboration
  - Platform acquisition/collaboration
  - Geography: Global or limited territory

- Size of target
  - How big is the target? Public or private?
    - Public or private company: will determine how much information is publicly available.
    - Reliability of information.
  - Identify highest priorities: key products, key technology, key geographic areas.
  - Timelines and size can limit your ability to analyze all products/platforms; consider outside counsel.

- Communications with client:
  - Business people need to bring patents and IP into the loop as early as possible!
    - It can take weeks or even months to do a thorough diligence, depending on the number of products/technologies and their complexities
  - IP specialist to needs to have open communication with business/corporate development to stay abreast of changing priorities



- IP also needs communication with research scientists, clinical development, and process/development.
  - These people are critical to understanding the scope of the FTO results and strength of IP portfolio.
  - Diligence process and interactions with these groups are iterative.

- Communication with other party
  - Be careful of waiving attorney-client privilege!
    - If deal goes through, you could be stuck with waiver.
    - Mixed authority on value of side agreements to protect privilege during diligence.
  - Other party can provide lists of issued and pending patent applications, relevant agreements, assignments, etc.

- Beginning and moving IP diligence forward:  
Acquirer's side
  - Obtain basic information on the target from business people including confidential and public presentations, 10-Ks and press releases (if public company)
  - Identify key products and technologies, i.e., value drivers
  - Obtain preliminary search results on target's patent IP portfolio and FTO



**Exploring Under the Surface:**  
Yielding Higher Value From Life Science Transactions



- Focus diligence on key value drivers
- Start obtaining relevant information from research, clinical development and technical operations/manufacturing as they go forward with their diligence.
- Your IP diligence will be iterative as you identify and resolve new issues.
- Keep communicating with internal clients.
- Written privileged IP diligence report?

- IP Diligence Issues
  - Types of IP in the deal
    - Patent and Non-Patent
  - Freedom to operate
  - Transfer of rights and license agreements



- Types of IP
  - Patent Portfolio
  - Trade Secrets (know-how, proprietary technology, databases, programs, algorithms, ongoing R&D)
  - Regulatory filings and data exclusivity
  - Trademarks, copyrights
  - Licenses to the above
- In some cases, non-patent IP can be a value driver.

- Patent Portfolio: Issued patents and pending applications
  - Scope and strength of claims? Is the scope reasonable in view of the prior art and product coverage?
  - Ongoing litigation, interferences, oppositions? Potential for those?
  - Obligations to third parties?
  - Inventorship correct?
  - Which countries has the patent/application been filed?
  - Term extensions, SPCs, and Orange Book listings (where appropriate)

- Freedom to Operate Issues.
  - Have a good search done: US, EP, Japan, other key geographies patents/applications as well as competitive intelligence.
  - PAIR and EPO file history review?

- Non-patent IP
  - In technology deals, know-how and trade secrets can have as high or higher value than patents.
  - Likewise for regulatory filings and data exclusivity. Make sure that the other side can provide access to those.
  - Data exclusivity varies from country to country.
    - In the US, does not apply to biologics, at least for now.
    - For small molecules, it can be critical to protect against generic competition.

- What if target has acquired IP from a third party? Then review agreements:
  - Ability of target to transfer rights
  - Diligence on the value of those rights
  - Costs of transfer or rights (royalties/milestones)
  - Change of control issues for target or third party?
  - Termination conditions
  - Third party obligations

**James Burnes**  
Credit Suisse Securities LLC