

Return On Investments: Acquiring New Drug Products

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Initial steps to identify potential deals

- Initial assessment of overall investment strategy, e.g.,
 - Consider product category or disease state
 - Consider regulatory strategies – balance potential target patient populations with regulatory exclusivities for small populations
- Assessment of scientific literature for university research opportunities
- Assessing other companies' research programs
- Attendance at conferences
- Review of clinical trial databases

Structure and financing of potential deal

- Assess potential structure of a deal
 - Asset acquisition
 - Joint-development
 - Equity position in asset owner
- Financing
 - Cash
 - Stock of the acquirer
 - Debt issuance

Preliminary technical and commercial assessment of deal

- Understanding the status of research
 - Review of *in vitro* and *in vivo* data
 - Focus on toxicity and efficacy data
 - Likelihood of moving product into clinical development
- Understanding the potential market
 - Potential patient population
 - Competitors that service or may service that patient population
 - Efficacy of existing therapies

Detailed review – Regulatory and IP

- Assess regulatory strategy
 - Clinical trials required
 - Available regulatory exclusivities
 - Availability of priority review vouchers, e.g., rare pediatric, rare tropical diseases, medical countermeasures
 - Timing for approval
 - Clinical study design, potential approved label, IP considerations
- Assess IP strategy and competitive IP landscape
 - Company's IP filings
 - Ability to protect proposed product from generic/biosimilar competition
 - Ability to limit competition within patient population
 - Third-Party IP – any potential barriers to entry
- Assess geography of the deal –
 - acquiring worldwide rights versus country-specific rights

Detailed review – Financial and Management

- Assess financial aspects
 - Size of patient population
 - Percentage penetration expected
 - Reimbursement/third-party payer issues
 - Tax considerations
- Assess existing management
 - Existing management's involvement in product going forward
 - May affect deal structure
 - Acquirer takes over development of product
 - Existing management will remain involved

Detailed review – Exit strategy

- Assess exit strategy for investment
 - Monetize through subsequent sale of asset to another entity for commercialization
 - Monetize through IPO of company with asset
 - Monetize through commercialization of asset by acquiring entity
- Initial deal structure may affect the available exit strategies

Negotiating the terms of the acquisition

- Defining financial terms, lump sum purchase, milestone payments, ongoing royalty
- Product rights
 - Compounds
 - Disease states
- Geography
- Development responsibilities

Drafting and executing the deal documents

- Asset Purchase Agreement
- Merger agreement
- Equity offering
 - Prospectus
 - Regulatory submission
- IP agreements
 - Assignments
 - Licenses
- Collaboration or joint development

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