Morgan Lewis

Biotechnology Mergers & Acquisitions

Emilio Ragosa, Esq.
Andrew P. Gilbert, Esq.

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Special Issues for Public Companies

- Disclosure issues for public companies raised by collaborations and mergers in the biotech industry.

Assumptions

- Transaction between public small cap biotechnology company and large pharmaceutical company
  - **Merger**
    Negotiated acquisition by large pharmaceutical company of biotech company
  - **Collaboration**
    License and Development Agreement covering biotech company's compound; biotech company remains as '34 Act reporting company

Disclosure During Deal Life Cycle

I. Pre-Negotiation Period (Bid period)
II. Negotiation Period
III. Signing of Definitive Transaction Documents
IV. Closing
V. Post-Closing – ongoing Disclosure Requirements ("Post Collaboration")

I. Pre-Negotiation Period

- Primary Goals of the Parties
  1) Prevent misappropriation of proprietary information
  2) Ensure confidentiality of negotiations – existence and status of potential deal
  3) Prevent insider trading
  4) Prevent trading in target company stock
  5) Enable sufficient information flow in due diligence process to facilitate expression of intent to proceed and provide initial valuation range

I. Pre-Negotiation Period

1. Non-Disclosure Agreement

   Key terms:

   - Mutual confidentiality and non-use obligations
   - Standstill

I. Pre-Negotiation Period

2. Letter of Intent - Collaboration Context
   - Binding versus non-binding (unsigned term sheets) (a binding letter of intent would likely be disclosed)
   - No-shop / exclusivity provisions
   - Economics
   - Milestones / conditions

I. Pre-Negotiation Period

3. Bid Letter – Merger Context
   - Economics
   - Deal structure
   - Conditions/financing contingencies
   - Early disclosure of deal may limit public company's ability to negotiate deal

II. Negotiation Period – Merger Context

- Federal securities laws generally do not mandate disclosure of material developments
  - General Disclosure Rule
    - Parties generally agree that there is no disclosure event until execution of definitive agreement
    - Close trading window
    - No comment policy must be maintained
    - Timing issues regarding routine public statements (earning announcements, periodic filings, clinical development updates)

II. Negotiation Period – Merger Context

- Exceptions to general rule:
  - Form 8-K required under “new” rules; certain disclosure is mandated
  - Duty to update if previously disclosed information becomes materially incorrect; may have PSLRA safe harbor available
  - Rumors trigger need for market response; unusual trading activity; press speculation; questions from third parties (clinical trial investigators, CRO’s)
  - Stock exchange inquiry response
  - Delaware case law – Basic v. Levinson legacy (Alessi v. Beracha)

II. Negotiation Period – SOX Issues

- General effect on M&A transactions
  - Public target
    - ’34 Act filings by target should provide greater comfort to acquirer due to ongoing disclosure compliance
    - Processes need to be thoroughly diligenced
  - Private target
    - Less likely to have compliant processes in place (not subject to SOX) (however, public acquirers often require private target to have complied with certain provisions of SOX prior to closing)
    - Post-closing integration typically a greater concern, compliance plan needs to be developed by acquiror typically by signing of merger agreement
    - Significant expenses to ramp up compliance often necessary

II. Negotiation Period – SOX Issues

- Diligence Issues
  - Use of current audit firm for transaction-related non-audit services
    - Certain services are prohibited (e.g., appraisal and valuation services; non-audit “expert” services)
    - Others (e.g., accounting and tax diligence) require pre-approval by Audit Committee and disclosure
      - NOTE: Some institutional stockholders withhold votes for Audit Committee members that approve such additional services

II. Negotiation Period – SOX Issues

- Diligence issues (continued)
  - Process
    - Documentary diligence
    - Interviews/access
    - Key areas include disclosure controls and procedures (404), internal controls, SOX certification processes and management loans

II. Negotiation Period – SOX Issues

- Negotiation Issues
  - Representations and warranties
    - Enhanced reps re:, for example, financial condition, SEC filings, internal controls, off balance sheet arrangements and whistleblower issues
  - Covenants
    - Target obligations to remediate and/or, if applicable, provide post-closing support
  - Closing conditions
    - Tension between “material adverse effect concept” and stricter standards of SOX compliance
    - SOX issues included in MAE? Material weaknesses?
    - Indemnification
    - Expense provisions

II. Negotiation Period – Collaboration Context

- Specific deal points regarding on-going disclosure obligations
  - Collaboration agreement must address disclosure provisions on a post-closing basis
  - Provisions to reach agreement on disclosure of material developments
  - Both companies must retain unilateral right to disclose material events despite fact that there may not be agreement on disclosure
  - Need to reach agreement on scope of confidential treatment application relating to the collaboration agreement

III. Disclosure Following Execution of Definitive Transaction Documents – M&A

- Regulation M-A permits free communication to stockholders; provided the written communications pertaining to the transaction:
  - Filed with the SEC on the day of first use
  - Contain bold legend stating that investors should read all relevant documents (prospectus/merger proxy) when they are available
  - Contain all required participant information in the case of proxy solicitation materials

III. Disclosure Following Execution of Definitive Transaction Documents

- Timing – Form 8-K to be filed within four (4) business days
- Use of Form 8-K as solicitation material – check box to satisfy Reg M-A requirements under Rule 425, 14-12, 14d-2(2) and 13c-4(c) (as applicable)
- Item 1.01 – Entry into Material Definitive Agreement
  - Mandatory filing obligation
  - Applies to material, non-ordinary course agreements and material amendments
  - Description of material terms and parties is required
  - Agreement need not be filed as an Exhibit to the 8-K; can be deferred until next '34 Act filing to allow time to file Confidential Treatment Application
- Item 1.02 – Termination of Material Definitive Agreement
- Item 2.01 – Completion of Acquisition or Disposition of Assets

III. Disclosure Following Execution of Definitive Transaction Documents

Form 8-K (continued)

- 3.02 – Unregistered Sales of Securities
  - Upon agreement to issue 1% of class of equity securities
  - Integrate with other issuances since last 3.02 8-K or ’34 Act report
  - Private placement transactions
- 3.03 – Material Modification of Rights of Security Holders
  - Any charter or bylaw amendments
  - Any amendments to rights plan/poison pill
- 5.01 – Changes in Control of Registrant
- 5.02 – Appointment of New Principal Officers or Directors
- 9.01 – Exhibits
  - Press Release
  - Merger Agreement
  - Development Agreement (of other material collaboration agreements)

III. Disclosure Following Execution of Definitive Transaction Documents

- Post announcement shareholder communication materials
  - Merger prospectus/proxy disclosures
    - Form S-4
      - Filed in connection with stock for stock acquisitions (mergers and tender offers of public companies)
      - Two purposes of Form S-4:
        - » The registration statement and prospectus of the acquiror who will be issuing stock to shareholders of the target in the transaction
        - » The proxy statement for shareholders of the target to solicit their votes in favor of the transaction

III. Disclosure Following Execution of Definitive Transaction Documents

- Schedule 14A
  - Filed by the party soliciting proxies to approve the merger
  - In a cash merger, this would be the primary filing made by the parties
  - In a stock merger, the Schedule 14A disclosure requirements are integrated as part of the disclosure requirements of the Form S-4 and the disclosure document is one integrated document referred to as the proxy statement/prospectus.

III. Disclosure Following Execution of Definitive Transaction Documents

- Merger Proxy – Unbundling of Proposals
  - Separate proposals required
    - Shareholders are otherwise voting on the related merger or acquisition transaction
    - The same or comparable provisions were not previously part of the charter or bylaws of the voting shareholders' company
    - The provisions were not previously part of the charter or bylaws of the public acquiring company
    - State law, securities exchange listing standards or the company's charter or bylaws would require shareholder approval of the provisions if they were to be considered outside of the merger or acquisition transaction
    - The provisions are material

III. Disclosure Following Execution of Definitive Transaction Documents

- Merger Proxy – Unbundling of Proposals
  - Examples of corporate governance/control-oriented proposals requiring separate proposals
    - Classifying the board of directors
    - Limiting the removal of directors
    - Adopting supermajority voting provisions
    - Delaying the annual meeting of shareholders for more than one year
    - Eliminating shareholders' ability to act by written consent
    - Changing minimum quorum requirements for shareholder actions

III. Disclosure Following Execution of Definitive Transaction Documents

- Examples NOT requiring separate proposals
  - Adopting, or changing, a shareholder rights plan (since shareholder approval of such plans is typically not required)
  - Bylaw changes that may be adopted by the board of directors
  - Changing the corporate name
  - Restating the charter
  - Other technical changes (i.e., resulting from anti-dilution provisions)

III. Disclosure Following Execution of Definitive Transaction Documents

- The SEC review process
  - Form S-4 and Schedule 14A are filed with the SEC in preliminary form
    - When the SEC reviews a merger, whether consideration is cash or stock, the SEC will generally respond to the filing of an S-4 or Schedule 14A with comments within 30 days
    - Once the parties have amended the filing and cleared SEC comments, (and the SEC, in the case of an S-4, has declared the registration statement effective), the target can send the final proxy statement/prospectus to its shareholders

III. Disclosure Following Execution of Definitive Transaction Documents

- Disclosure to Stockholders
  - The background of the transaction
  - The terms of the transaction; consideration for stockholders
  - Fairness determination and analysis by financial advisor
  - Appraisal rights
  - Projections and forecasts provided to the other party
- Disclosure to Third Parties (Required Consents)
  - Change of control/constructive assignment provisions
    - Reasons for deal
    - Impact on parties

III. Disclosure Following Execution of Definitive Transaction Documents

- Securities Act Issues for Acquiror if Issuing Shares to Target's Stockholders
  - Registration of Securities under Form S-4
  - Section 3(a) (10) exemption of 1933 Act
  - Section 4(2) exemption (Regulation D safe harbor)
  - Rule 145

IV. At Closing/M&A and Collaboration Context

- Press Release
- Form 8-K
- Confidential Treatment Application
  - Trade secrets
  - Confidential commercial or financial information
  - Balance against disclosure of material information for investors

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

- Need Accurate and Timely Disclosures
  - Disclosure of the status of FDA proceedings for drugs and other products in the development pipeline is an especially sensitive area for biotechnology companies.
  - FDA approval proceedings are lengthy and complicated.

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

- Extreme care required for biotech companies to accurately and timely describe the status of the FDA approval process for material drug discoveries and product development.
- Failure to do so can result in:
  - Liability for the company and others under securities antifraud rules
  - Exposure to charges of insider trading by individuals and
  - Violations of Regulation FD for impermissible selective disclosure

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

- Complying with Regulation FD
  - Regulation FD prohibits a public company from disclosing material nonpublic information about the company to market professionals and holders of the company's securities who could be expected to trade on that information, without disclosing that information to the public generally
- Response to investor demands
  - Companies feel pressure to have proactive disclosure about early stage drug development and preliminary clinical trial results

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

Disclosure Pressure Points for Issuers

- Achievement and failures in clinical trials
- Risks associated with clinical trial design
- Prospects for FDA/European regulatory approval
- Scientific literature from third parties
- Differing expert opinions
- Serious adverse effects
- Warning of regulatory action by FDA (“warning letters”)
- Freedom to operate issues
- Comparisons to competitors’ products

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

Disclosure Tips

- Avoid disclosing positive partial or preliminary results from clinical trials without disclosing how those trials related to the company's overall development program.
  - What was trial designed to show?
  - Was statistical analysis of data conducted?
  - What was role of company and collaborators in trial?
  - Prevent potential erroneous conclusions by third parties

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

- Avoid selective disclosure information on FDA process without considering:
  - If selective disclosure is intentional, then the company must make the public disclosure simultaneously
  - If the selective disclosure is unintentional, then the company must make the public disclosure promptly
  - The method selected for public disclosure must be reasonably designed to effect broad dissemination
  - SEC uses a “materiality by hindsight” analysis to determine violations of Regulation FD often based on price and volume movements of the company’s stock
  - Be careful of indirect disclosures by researchers and experts working on company’s behalf

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

- Conform statements made to the FDA and statements made in press releases and SEC filings
  - FDA and SEC will review for accuracy and whether statements mislead public
  - Reduce the “spin” placed on results of trials or discussions with the FDA

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

- Minimize Risks from Disclosure Obligations
  - Create internal procedures and process to detect and report disclosure problems
    - Establish standard practices and procedures for public disclosure of material developments that warrant prompt public notice
    - Form disclosure committee that meets regularly and document meetings
  - Devote sufficient preparation and review time to public statements; create proper “tone at the top”
    - Internal team, senior management and counsel should have sufficient time to prepare and review a public statement prior to its release
    - Do not allow public communication to be released before all relevant parties have completed review and are comfortable with the disclosure

V. Post-Closing Period – Ongoing disclosure requirements for biotech companies

- Frequent consultation with internal and external experts and counsel
  - FDA, IP and SEC experts
  - Securities and regulatory counsel
  - Senior managers overseeing development programs and regulatory affairs
- CEOs and CFOs should not certify the adequacy of internal controls in SEC filings without existence and implementation of disclosure and insider trading programs

Presenters

Emilio Ragosa
(Partner, Princeton office)
609.919.6633
eragosa@morganlewis.com

Andrew P. Gilbert
(Partner, Princeton office)
609.919.6603
agilbert@morganlewis.com