R&D Risk-Sharing Collaborations
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Clarus at a Glance

- Specialist life sciences investor group
  - Offices in Boston & San Francisco

- $1.2B under management; currently investing out of $700MM Fund II
  - 39 portfolio companies & investments since 2006
  - 100% focused on therapeutics and medical technologies

- Team has deep drug development & operating expertise
  - > 110 investments; > 20 approved drugs representing $35B in annual sales

- Active investor; company- and management team builder
  - We lead or co-lead almost all of our deals

- Track record of successful pharma spinouts and R&D partnerships

- Global industry network
Industry Trends: Big Squeeze on R&D

- $120B of branded drug sales being lost to patent expiry between 2011 – 2016
- New compounds entering late-stage pipeline increased from 35 in 2010-11 to 78 in 2011-12\(^1\)
- Cost and complexity of later stage trials increasing

Pharma R&D budgets and resources under intense pressure

As a result, most Pharma now have more NPV+, late-stage programs than they can develop themselves

Industry Trends: Pharma Externalizing Late-Stage R&D Risk Via 50:50 Collaborations

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<tr>
<th>Lead compound</th>
<th>Indication (stage)</th>
<th>Originator</th>
<th>Collaborator</th>
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<tbody>
<tr>
<td>Brodalumab</td>
<td>Psoriasis (ph 3)</td>
<td>AMGEN</td>
<td>AstraZeneca</td>
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<tr>
<td>Dapaglifozin</td>
<td>Diabetes (ph 3)</td>
<td>AstraZeneca</td>
<td>Bristol-Myers Squibb</td>
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<td>Sirukumab</td>
<td>RA (ph 3)</td>
<td>Johnson &amp; Johnson</td>
<td>gsk GlaxoSmithKline</td>
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<td>Empagliflozin</td>
<td>Diabetes (ph 3)</td>
<td>Lilly</td>
<td>Boehringer Ingelheim</td>
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<td>Dolutegravir</td>
<td>HIV (ph 3)</td>
<td>Viiv Healthcare</td>
<td>Shionogi</td>
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Industry Trends: Drug Development Becoming Increasingly “Virtual”

June 10, 2010. Today, with biotech IPOs virtually nonexistent and development costs rising through the roof, the math simply doesn’t work for the old model of venture-backed biotech. In response, VCs are now experimenting with new “virtual R&D” models for drug development. The goal is to get to clinical proof of concept (generally the trigger for an acquisition by “big pharma”) as efficiently as possibly by building a lean development team around each drug and outsourcing as much of the development as possible. Instead of building a large team with a large cash burn, build as small a team as possible and outsource almost everything. This allows the company to pay for headcount and resources only as needed…

“With the venture contraction of 2011, the asset-centric, virtual model became lauded as the way to develop a product without breaking the bank. A number of biotechs have jumped on that strategy – Boston Biocom LLC, Flexion Therapeutics and BioPontis Alliance LLC, to name a few – along with venture capital groups. CMEA Capital launched Velocity Pharmaceutical Development, a virtual firm aimed at in-licensing drug candidates to advance them to proof of concept before selling them off, while Atlas Ventures launched Atlas Venture Development Corp. to move assets via virtual development.”
Clarus Solution: R&D Risk-Sharing Collaborations

Established governance models

Pressing need to externalize R&D

Pharma R&D resource constraints

Licensing / peer-to-peer deals

Emerging business models

“Virtualizing” drug development

R&D Risk-Sharing Partnerships

Clarus has closed six deals in past 36 months
Overview of Model Structure

- Clarus forms a Devco that is staffed by core team of expert drug developers

- Devco enters into collaboration(s) with Pharma to co-develop one or more of Pharma’s assets through mutually agreed milestones

- Devco funds and conducts the development activities and owns all data and other assets newly generated in or as part of the development collaboration

- Governance consistent w/ peer-to-peer collaboration
  - Development plan, budget & success criteria negotiated between Pharma & Devco
  - Joint Development Committee (50:50) between Pharma and Devco oversees all material development decisions; joint agreement required for any key decisions
  - Pharma can provide services to Devco on arm’s length terms (i.e. as CRO/CMO)

- Upon attainment of pre-agreed success milestone, Pharma is contractually obligated to acquire Devco business for pre-agreed consideration

- Pharma has no obligation if the success milestone is not met
Clarus Has Closed Six R&D Risk-Sharing Collaborations in the Past Three Years

- Clarus and our partners have committed > $480M to date
- 4 deals with Pfizer
  - Two Phase 3 programs to support additional indications for already-approved oncology drugs
  - Two pivotal programs to support initial approvals
- 1 deal with Eisai
  - Pivotal program for thyroid cancer drug
- 1 deal with a European pharma partner
  - Phase 3 programs to support up to three additional indications for already-approved drug

First two deals have already achieved positive clinical read-outs
Key Questions

- Does Pharma consolidate the Devco?

- What are the P&L implications for Pharma during the collaboration?

- If the success milestone is achieved, how does Pharma account for the payments?
Summary of Financial Reporting Implications for Pharma

- During the collaboration period, Pharma does not consolidate Devco, nor would it typically recognize any contingent liability associated with the collaboration.

- If success milestone is achieved, success payment(s) would be capitalized and amortized over expected useful life of product.

- No P&L impact if success milestone not achieved.

- Level of disclosure depends on materiality of transaction.
Highlights of US GAAP Analysis

- Although Pharma’s collaboration agreement with Devco may represent a variable interest, Pharma is not the “primary beneficiary” of Devco and thus would not consolidate Devco
  - Pharma does not control the decisions that most significantly affect Devco’s economic performance (FAS 167)

- The collaboration is a “joint operation” between Pharma and Devco, and would be accounted for by Pharma and Devco using “proportionate accounting”
  - Pharma owns no equity of Devco
  - If Devco owns all of the JO assets and funds 100% of the JO expenses, then Devco would consolidate 100% of the JO P&L and B/S

- Since Devco constitutes a “business”, acquisition of Devco by Pharma would be accounted for in accordance with the business combination rules (ASC 805)
  - IPRD would be capitalized at FMV at time of change of control

- No “day 1” liability or P&L impact to Pharma as long as Pharma believes that it would be paying at or below FMV for Devco business if success criteria attained
  - Commitment to acquire Devco business is an executory contract that is not onerous, but pharma must monitor for impairment
  - No embedded derivatives
  - FAS 68-compliant structure
FAS 68 Analysis of R&D Risk-Sharing Collaboration

- An entity only recognizes a liability associated with repayment of funds provided by another party for R&D expense if the entity is obligated to repay any of the R&D funds regardless of the outcome of the R&D activity. (SFAS 68, para 5)

- Under the Clarus model structure, all payments are contingent upon R&D outcomes. Pharma has no obligation to repay any of the funds “regardless of the outcome of the R&D activity”.

- Thus, it is not “probable” that Pharma will have to repay any of the funds regardless of the outcome of the R&D. (SFAS 68, para 7)

- Transfer of financial risk is substantive and genuine.
FAS 68 & Risk Transfer

- Drug development is inherently risky, unpredictable and uncertain. Even in the late stages, there are no “sure bets”.
  - Many examples of surprising late-stage clinical failures
  - Industry-wide success rate for Phase 3 averages only ~50-75%, depending on indication*
  - Avg regulatory success rate ~85-90%*
  - Avg success rate for supplemental indications only ~50%**
  - Presumably for these reasons, US GAAP and IFRS do not deem technical feasibility to have been established for an internal development program until approval.

** Pharmaceutical Benchmarking Forum 2011
Applicable IFRS Principles

- **Consolidation**
  - IFRS 10, 11 & 12
  - Who controls the “relevant activities”?  
    - Very similar analysis to VIE rules, so why should the outcome be any different than under US GAAP?

- **P&L impact during collaboration**
  - IAS 37 (Contingent liabilities)
  - IAS 32 (Financial instruments)

- **How are success payments accounted for**
  - IAS 38 (Acquisition of Intangible Assets)
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