

Untying the Invisible Hand of Biomedical R&D

Private Session at Milken Global Conference

Tuesday, April 30, 2019

Background and Session Goal

A tighter reimbursement environment has heightened a need for efficiency and resulted in pipeline cuts as biopharmaceutical R&D organizations pursue greater specialization. Some cuts include compounds and drugs with promising science but lower strategic relevance, at least in the context of their current owners' strategies/portfolios. These are potential therapies that could go on to benefit patients, but instead go undeveloped.

The Milken Institute has launched the “Biomedical Innovation Incubator” to create a more dynamic market for biomedical innovation by advancing novel business, research, transaction, and financing models. The Incubator is co-led by two centers of the Milken Institute—FasterCures and the Center for Financial Markets—blending its expertise in biomedical innovation and finance.

The work of the Incubator will be to help organizations that are focused on this goal identify common obstacles and potential solutions, share best practices, and shape policies that support a more vibrant environment for investment.

As part of the launch of the Incubator, the Milken Institute hosted a private session during the Milken Global Conference with the goal of identifying priority areas of focus.

Overall Takeaways

1. Development of promising compounds and drugs is being discontinued for business reasons; there are few incentives for biopharmaceutical companies to externalize these assets.
2. Unlocking discontinued assets will require addressing barriers within biopharmaceutical companies: operational challenges; lack of information; and cultural barriers.
3. Capital is plentiful but mechanisms to match assets to funders are lacking.
4. Current clinical trial infrastructure and uncertain reimbursement pathways are limiting factors to drug development.
5. Multiple efforts to address these issues exist but they are silo-ed or are not being integrated from other sectors; the Incubator is well-positioned to shepherd solutions.

Challenges in Resuscitating Assets

Operational challenges within biopharmaceutical companies include a lack of:

- Resources to catalogue project information to prep assets for their next owner
- Positive cost-benefit rationale for externalization activities (e.g., cost of preparing externalization are viewed as higher than what can be gained from such deals)
- Timely approach to return the IP of a discontinued asset to originating biotechs (or others) that may have interest/resources to keep progressing the asset

Cultural challenges within biopharma companies include:

- Perception that job is to bring assets in, not let assets out
- Executive mindset: “I would rather have 100% of something on the shelf than 20% of a blockbuster that somebody else develops”
- Pressure from Wall Street analysts discourages out-licensing/divestiture of assets

Lack of information on discontinued assets

- Data/information on the asset is often lost or buried
- Development teams for discontinued assets have often moved on, limiting due diligence efforts
- Transparency on the reason for discontinuation is often not provided, leading the marketplace to guess and often inappropriately tainting the asset

Inefficient matching of capital to assets

- Mostly done via word of mouth
- Discrete stakeholders (VC, nonprofit, government, big pharma, biotechs, etc.) are not as fully acquainted with each other’s resources, limiting their ability to partner/strike deals/collaborate
- Capital is available but often blocked from seeing assets where it could be applied

Recommended Action Items

Support biopharmaceutical companies in institutionalizing an approach to externalization

- Develop a common industry vocabulary that describes assets
- Establish criteria to help companies identify assets suitable for externalization
- Promote an approach to capturing data/information on an asset as part of routine project close-out activities
- Encourage mechanisms by which discontinuation decisions are disclosed

Encourage more transparency of:

- Decision making about asset discontinuation
- New drug applications rejected by FDA
- Unanalyzed/raw data generated during drug development

Promote culture of asset externalization within biopharmaceutical companies to enable resuscitation of deprioritized assets

- Help companies change the failure/loss mindset to an opportunity mindset
- Encourage companies to return IP to originator
- Convene investment community to gain their support in encouraging more partnership/divestiture of biotech/pharma assets

Leverage management consultants, who have a privileged view across industry, to develop a market map illustrating potential alternative pathways for resuscitated assets

- Identify databases of available assets and opportunities to create interoperability and drive data liquidity
- Create typology of potential funding partners, including nonprofits/social enterprises that serve within a sector that could develop capacity to lift assets out of biopharma

Establish investment pools or financing instruments to mobilize funds toward areas of need

Work with FDA to assess opportunity to evolve risk/regulatory paradigm leading to costly and time intensive trials

Next Steps

Looking ahead, the Milken Institute is planning the following activities for 2019 to move the Incubator forward:

- Conduct targeted outreach and public affairs campaign to build awareness of these challenges
- Create case studies to feature the work of organizations tackling the challenges and to glean learnings from their experience
- Develop a program roadmap and chart the work streams
- Identify members of working group and sub-committees

Contact Us

We welcome your input on this document and your engagement in the Incubator. Please contact us with your comments and questions:

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