

White Paper

EMD Millipore Emerging Biotech Executive Summit: *Your Connection to Success*

EMD Millipore hosted its first annual Emerging Biotech Executive Summit: Your Connection to Success, on June 15, 2015. The goal of the event was to establish an open dialog within the biotech community as well as provide networking and insight from executives in alliance management, in-licensing and venture funding, to help companies advance their molecules and bring lifesaving drugs to market.

The purpose of this white paper is to provide key takeaways from the meeting, highlighting perspectives on early stage investments and partnerships as well as how to build value, credibility and recognition to your company's clinical stage products or services.

Dr. Udit Batra, President and CEO of EMD Millipore, reinforced the company's commitment to the Emerging Biotech community during his opening presentation at the summit. Panelists included leaders from the Biopharmaceutical Business of Merck KGaA, Darmstadt, Germany: Dr. Susan Herbert, Executive VP, Head of Global Business Development & Alliance Management; Dr. Joern Peter Halle, Head of External Innovation; Philippe Lopes-Fernandes, Sr. VP, Head of Global Licensing & Business Development; Roel Bulthuis, Managing Director at MS Ventures; Dr. Erica Shane, VP Process Development, Novavax, Inc.; William Newell, CEO, Sutro Biopharma, Inc; and Dr. Peter Watler, CTO, Coherus BioSciences.

Dr. Ruta Waghmare, Director, Emerging Biotechnology at EMD Millipore welcomed the attendees and Dr. Susanne Andreae, Head of Strategy and President's Office, EMD Millipore, provided closing remarks. Dr. Johnathan Freeman, Senior Vice President, Head of Portfolio Management, from the Biopharmaceutical Business of Merck KGaA, and Dr. Ruta Waghmare moderated the panel sessions.

Introduction

Despite the fact that both drug discovery and development improvements are seen year upon year, the process of taking a biotech molecule from discovery to commercialization continues to be complex and challenging.

Fortunately, based on the pipeline of molecules, the future is bright. At EMD Millipore, we have a simple thesis: Emerging biotech companies are a critical component and source of innovation, helping to bring groundbreaking drug products to market. Taking a look at the pharma industry's R&D pipeline (Figure 1), it is evident that the number of potential molecules coming out of emerging biotech companies is increasing each year.

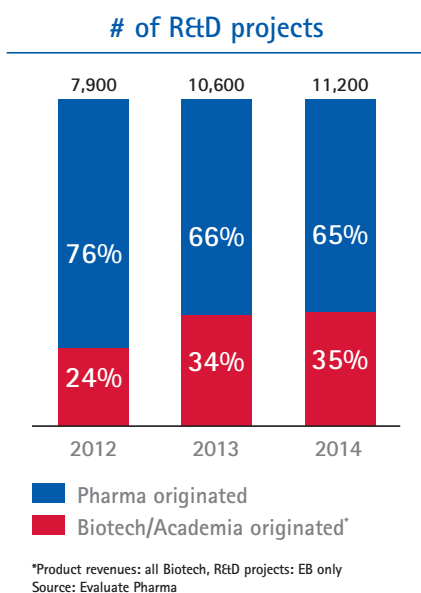


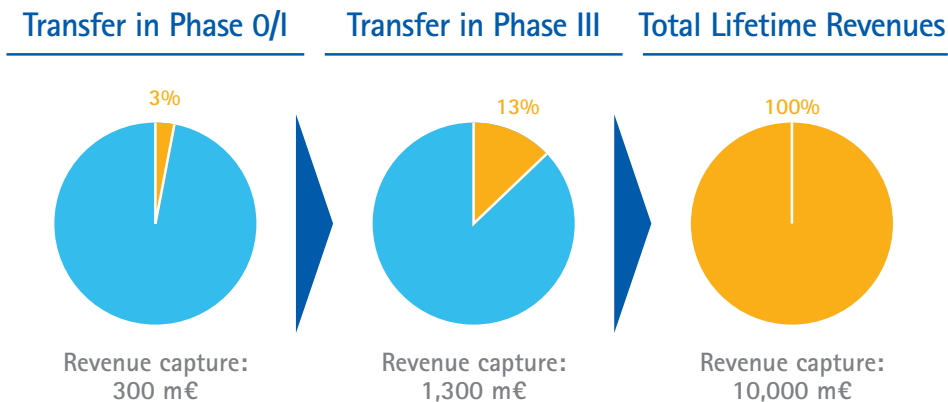
Figure 1. Innovation is increasingly originated from Biotech companies

With an abundance of biotech originated products, these companies are at the forefront of exciting science that will transform the way we look at developing new drugs.

And yet, the question that arises is: Why are emerging biotech companies not capturing a higher share of the molecule value?

Figure 2 tells a compelling story. It's a simple model based on assumptions that if a company launches a blockbuster drug molecule it would receive 100% of the cumulative revenue (in this example 10B€). However, if the company transfers the molecule in Phase I or earlier, one can assume the company will see 100MM€ upfront and 2% royalties, or 300MM€. And if the company transfers the drug candidate in Phase III after de-risking then it can potentially capture approximately 13% or 300MM€ upfront and 10% royalties. This still leaves almost 87% of the value to someone else. While it seems evident that emerging biotech companies would benefit more by keeping their molecule and bring it to market themselves, there are reasons why many decide to transfer their molecules early. In many cases, emerging biotech companies have neither the funds to further develop their molecules nor the capabilities or experience to complete clinical development and product launch.

It is clear that if an emerging biotech company were to form a strategic partnership in the early phase of development, versus transferring the molecule, they would be able to keep a much larger share of the profits later. Emerging Biotechs can often avoid capital expenditure and staffing costs by instead outsourcing to EMD Millipore. EMD Millipore brings value to emerging biotech companies with its the services and expertise to propel molecules to the next clinical stage.



Note: non risk-adjusted; 100% = Cumulated lifetime revenues of an example molecule with 1 bn€ peak sales

Figure 2. Emerging biotech opportunity: Capture a higher share of the molecule value.

Perspectives on Early Stage Investments and Partnerships

It is imperative to understand that large pharmaceutical companies invest by creating a portfolio with future potential assets. Ideally, companies like to invest at the phase where they can add the most value, which in this case, is often at the time of company creation. By investing at the seed stage, pharma companies can be a key player in laying the foundation of the biotech's organization—being heavily involved in building the team and forming the strategy.

Much of this comes down to respect and trust. Emerging biotech companies need to “trust that their partner is truly invested in the success of the asset, because for them, the asset is the company. Trust that a large pharma won't bail at the first sign of trouble and move on to the next thing.”¹

In the end, it is about remaining agnostic as to where assets originate. The goal is to let the best compound win and move forward. By partnering, emerging biotech and pharma companies can share the risks and rewards together.

Building value, credibility and recognition on your road to clinic

In order to get large companies to invest and partner with emerging biotech companies, there are several key strategies that emerging biotech companies should employ. With the goal of transitioning from surviving to thriving, partners can be a powerful resource. Collaborations and partnerships not only build value in relationships, but also help advance product candidates and raise capital.

First, emerging biotech companies need to choose their strength and identify the sweet spot of their technology—what is the differentiating factor of this technology in the industry? It's also critical to form a strong management team that is well versed and highly skilled. Emerging biotech companies should seek top talent as they build their organizations. Pharma companies

looking to partner with emerging biotech firms want to see that the founding scientists are willing to take roles that fit them best and then form a new team with the knowledge and know-how to bring this company to the top.

An additional key factor in getting a company to thrive is building strong relationships with vendors. Client/vendor partnerships are critical as they have access to the top suppliers, state-of-the-art facilities and are unencumbered by legacy manufacturing facilities and high overhead costs. Vendors know their product lines and are eager to help emerging biotech companies find solutions for their specific set of challenges. As a result, emerging biotech companies can work more effectively and determine what technology is most beneficial.

Conclusion

Key takeaways

- Small companies require the right strategy to be successful
 - Not every great idea will work in the clinic or be an easy product to develop
- Use the vendors and partners
 - Small companies have limited manpower
 - Leverage the expertise of vendors rather than building in-house
- Some ideas are too expensive to develop alone
 - Large scales of operation may require partners
 - Be open to partnering or selling a promising product that has a long development timeline
- Never let a crisis/public awareness go to waste
 - Ebola (NewLinks Genetics Corporation)
 - H7N9 (Novavax, Inc.)
- Always plan for success
 - See the vision and drive for it

The biotech industry is currently undergoing a tremendous boom, with capital flowing in and an increasing number of drug approvals.² It's important to realize how critical emerging biotech firms are to ensuring the drug market continues to experience this fast-paced growth. By having a solid strategy and partnering at the right time, emerging biotech companies can expect to thrive, helping more potential molecules make their way through the pipeline.

Partnering with EMD Millipore

As the life science business of Merck KGaA of Darmstadt, Germany, EMD Millipore is motivated by solving the toughest problems in life science. The needs of emerging biotech companies are not foreign to us. We are dedicated to helping you advance your molecule by providing a range of products, services and programs.

Comprised of three business areas—Bioscience, Lab Solutions and Process Solutions, we serve as a strategic partner for scientists, engineers and researchers with a portfolio of more than 60,000 products. We offer a broad spectrum of proven tools and technologies for research and analytical laboratories, together with performance solutions innovations, dedicated to helping our customers succeed in the research, development and production of biotechnology and pharmaceutical drug therapies.

We provide Provantage® Services; an end to end capability that spans the entire development and production value chain. We work with clients who want to develop a process but either don't have capacity internally or increasingly don't want to invest in building capabilities for making clinical batches. Our facilities include a GMP facility in France where we design and develop a process with you, work on the analytical methods and validation, file the dossier and supply the clinical materials. Finally, we help transfer this process to a manufacturing facility.

What's more, we are fully committed to launching programs to help emerging biotech companies develop their molecules, via programs such as the 2014 Emerging Biotech grant program. NGM Biopharmaceuticals was the recipient, in which they were awarded products and services from EMD Millipore.

References

1. Seaton, Daniel. "Sanofi's Chris Viehbacher: Trust, Respect Key in Pharma-Biotech Partnerships," Biotech Now. February 11, 2014. <http://www.biotech-now.org/events/2014/02/sanofis-chris-viehbacher-trust-respect-key-in-pharma-biotech-partnerships>
2. Pollack, Andrew. "Riding High, Biotech Firms Remain Wary," New York Times. January 18, 2015. http://www.nytimes.com/2015/01/19/technology/riding-high-biotech-firms-remain-wary.html?_r=0



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