

Life Sciences M&A: Myths vs. Facts

Mergers and acquisitions (M&A) are unique in promoting a more innovative and competitive American life sciences industry. It is important to understand the reality of how M&A works as a critical pathway for life sciences companies to “pass the baton” along the long and costly journey to bring new treatments to patients.

MYTH 1

The life sciences industry is consolidated.

America’s life sciences industry is unique given the competitive dynamics that exist across companies of all sizes, each aiming to find a new, better way to treat disease. **More than 2,300 biopharmaceutical companies are headquartered in the U.S.,¹ and hundreds more start every year.²** Altogether, America’s life sciences ecosystem employs over two million people and operates out of more than **120,000 business establishments in all 50 states.³**

The U.S. life sciences industry is among the most competitive globally, in large part due to longstanding bipartisan innovation policies—such as the Hatch-Waxman Act,⁴ Orphan Drug Act⁵ and 21st Century Cures Act.⁶ Together with these policies, life sciences M&A has fostered an ecosystem where early-stage innovation is incentivized, fueling a constant pipeline of newer and more advanced approaches to help treat and cure many serious diseases.

With more than **8,000 potential new treatments and cures on the horizon** across dozens of disease areas,⁷ this pipeline translates into direct competition for finding the best approach to treat a disease.

MYTH 2

M&A decreases innovation.

The journey to bring scientific discoveries to patients is long and risky, and most companies are unable navigate the process alone. On average, it **costs \$2.6 billion and takes 10-15 years** to bring a new treatment to patients.⁸ Life sciences M&A is fundamentally about improving companies’ chances of successfully completing this journey to bring new breakthroughs to patients. M&A allows companies to specialize in what they do best, and partner when it makes sense.

Experts, including the American Bar Association⁹ and Congressional Budget Office,¹⁰ have acknowledged that M&A can help life sciences companies overcome these difficulties.

Unlike many other industries, about **80 percent of biopharmaceutical companies operate without a profit.¹¹** External investment, including venture capital, plays a unique, central role to advancing promising early-stage innovations through the development pipeline. M&A incentivizes this investment, creating the potential for investors to recover their investment while offsetting the risks of early-stage research and development.



We need to increase antitrust enforcement in the life sciences.

M&A activity across the life sciences benefits patients by serving a unique and fundamental role in advancing innovation across the ecosystem. Balanced competition policies have fostered life sciences innovation, while supporting patient access to therapies, for decades.

The unique role of M&A in the life sciences has been reaffirmed by our courts and other leading experts for decades. The Congressional Budget Office has acknowledged that, **“In making [an] acquisition, a large company might bring a drug to market more quickly than the small company could have or might distribute it more widely.”**¹⁰ **Smaller, early-stage life sciences companies have asserted that mergers “simply mark a turning point in the natural evolution of the drug development process.”**¹²

Drastic antitrust policy shifts have introduced new uncertainty and risk to an already high-stakes process for America’s life science ecosystem. The Federal Trade Commission (FTC) and Department of Justice (DOJ)’s antitrust agenda has risked deterring M&A broadly and indiscriminately, putting new treatments and cures for patients at risk. **Policymakers must acknowledge the importance of balanced policies that reflect the unique competitive dynamics in the highly innovative American life sciences industry.**

¹ Citeline. 2023. Pharma R&D Annual Review April 2023. https://images.intelligence.informa.com/Web/InformaUKLimited/%7B1e2824e9-0137-4cb4-9ef5-b8643c2243cc%7D_13575_Citeline_R_D_White_Paper_V6.pdf.

² Booth, B. 2022. Life Sci VC. <https://lifescivc.com/2022/04/biotechs-january-chill-big-drop-in-new-startups/>; Armstrong, A. 2022. We have achieved peak biotech formation. It's time for 'musical chairs.' FierceBiotech. <https://www.fiercebiotech.com/biotech/too-many-biotechs-musical-chairs-startup-funding-venture-capital>.

³ TEConomy, CSBA and BIO. The U.S. Bioscience Industry: Fostering Innovation and Driving America's Economy Forward 2022. https://go.bio.org/rs/490-EHZ-999/images/TEconomy_BIO_2022_Report.pdf

⁴ Hatch-Waxman Letters. U.S. Food and Drug Administration. Updated February 2022. <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters>.

⁵ Orphan Drug Act – Relevant Excerpts. U.S. Food and Drug Administration. Updated March 2018. <https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/orphan-drug-act-relevant-excerpts>.

⁶ 21st Century Cures Act. H.R. 34. 114th Congress (2016). <https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf>.

⁷ PhRMA. In the Pipeline. <https://phrma.org/en/Scientific-Innovation/In-The-Pipeline>.

⁸ DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. "Innovation in the pharmaceutical industry: new estimates of R&D costs." Journal of Health Economics 47 (2016): 20-33.

⁹ Comments of The American Bar Association Antitrust Law Section in Response To The Multilateral Pharmaceutical Merger Task Force's Request For Public Comment, Project No. P212900. June 2021.

¹⁰ Congressional Budget Office. Research and Development in the Pharmaceutical Industry. April 2021. <https://www.cbo.gov/publication/57126>.

¹¹ Rottgen, R. Biotech Valuation Idiosyncrasies and Best Practices. <https://www.toptal.com/finance/valuation/biotech-valuation>.

¹² Spark Therapeutics. Comments Re: Pharmaceutical Task Force, Project No. P212900. June 2021.