Biotechnology Innovation Organization

THE BIOTECHNOLOGY ECOSYSTEM: BY THE NUMBERS

As *The Economist* magazine has noted, "Creating new drugs through biotechnology is at the risky end of a business in which superhuman stamina and bottomless pockets are minimum requirements."[1] Here are key numbers to understanding the biopharmaceutical innovation ecosystem and its pricing dynamics:

70% of innovative clinical programs are being led by small companies, which rely heavily on venture capitalists, angel investors or partnerships with larger pharmaceutical companies to provide the enormous amounts of private capital required to fund these challenging and incredibly risky endeavors.[2]

90% of clinical programs ultimately fail to lead to an FDA approval; in fact, the success rate of clinical trials can be even less, particularly in areas like Alzheimer's and cancer.[3]

92% of biopharmaceutical companies are unprofitable at any given time.[4]

10–15 Years is the average time it takes to secure FDA approval of a new medicine, from initial discovery of a potential new molecule or approach, through pre-clinical and clinical programs, through the FDA regulatory and approval processes.[5]

$2.6 Billion is the average cost to develop and secure approval of a new medicine, taking into account all the trial and error and research failures along the way, and the cost of capital; this figure has skyrocketed in recent years, doubling since just 2003.[6]

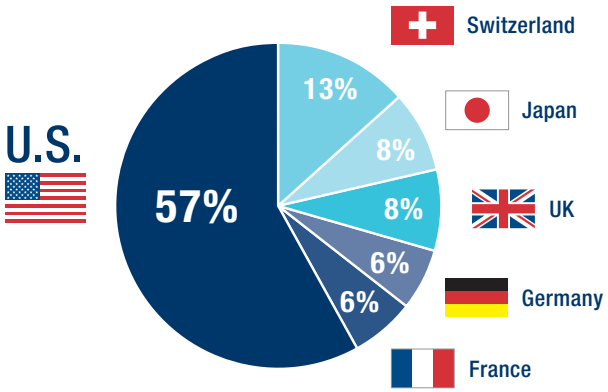
36th is where the biopharmaceutical industry ranks among domestic industries in terms of return on equity, despite the popular media narrative of excessive drug industry profits.[7]

89% of prescriptions in the US are for lower-cost generic copies of once-branded pharmaceuticals.[8]

2017: A BREAKTHROUGH YEAR

- **More than 50** novel drugs approved in 2017, the most in the past two decades.
- **First** approved cell-based gene therapy that modifies a patient's own blood cells to help the immune system attack an aggressive form of leukemia in children and young adults.
- **Breakthrough** CAR-T therapy approved for lymphoma in adults.
- **First** gene therapy approved in the US that targets a disease caused by a specific gene mutation that results in blindness in children.

THE U.S. PRODUCES MORE NEW DRUGS THAN THE REST OF THE WORLD COMBINED



Percentages do not add up to 100% due to rounding.

Source: Milken Institute; Xconomy, "Which Countries Excel in Creating New Drugs? It's Complicated" 2014; Kneller, Nature Biotechnology, 2012

[1] The Economist, February 15, 2014

[2] Emerging Therapeutic Company Investment and Deal Trends 2007–2016, BIO Industry Analysis, 2017.

[3] Clinical Development Success Rates 2006–2015, BIO Industry Analysis, 2016; for example, since 1998, 123 medicines in development for Alzheimer's have not made it through clinical trials, while only 4 have been approved — resulting in a 97% failure rate. See PhRMA, Researching Alzheimer's Medicines: Setbacks and Stepping Stones, Summer 2015.

[4] Factset, BIO Industry Analysis.

[5] DiMasi J., Grabowski, H., Hansen, R. Innovation in the Pharmaceutical Industry: New estimates of R&D Costs. Journal of Health Economics, 2016.

[6] Ibid.

[7] Factset, BIO Industry Analysis.

[8] Association for Accessible Medicines. Generic Drug Access & Savings in the U.S. (2016).