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]

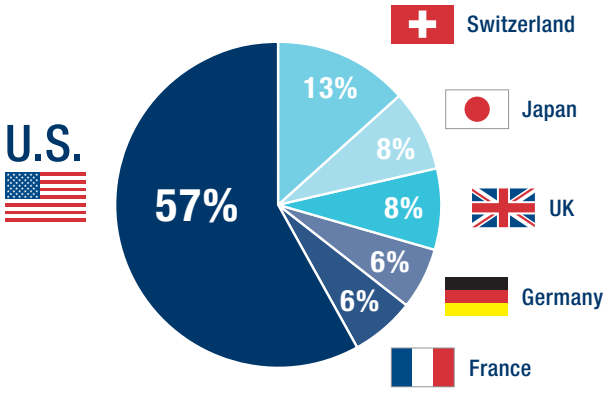
36th is where the biopharmaceutical industry ranks among domestic industries in terms of return on equity, despite the popular media narrative of excessive drug industry profits.[7]

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

2018: A BREAKTHROUGH YEAR

- **59** novel drugs approved in 2018.
- Second consecutive year with **more than 50** novel drug approvals.
- **First-ever** approval of an RNA interference therapy, opening an entirely new class of treatments for patients with rare diseases.
- **16** new cancer therapies approved.
- **A new class** of drugs for migraine prevention.
- **First** new drug for endometriosis in over a decade.

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).