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PRESS RELEASE

60% of FDA approved medicines from 2011- 2020 originated in the United States.

One-third of all FDA approvals between 2011 and 2020 were developed by US based small companies with less than $500 mil in revenue.

5 December 2022

New research from the consultancy Vital Transformation (VT) has found that 60% of FDA approved medicines from 2011- 2020 originated in the United States. The FDA approved 363 new medicines over that time period, and the US was solely responsible for the origination of 223 of those medicines.

The study by Vital Transformation was an update of the often-cited 2010 Nature Reviews Drug Discovery publication by Robert Kneller. Broadly, since Kneller's publication, the US biopharma sector increased the total number of approved therapies that it originated from 118 to 223. Germany, the UK, and the EU broadly have seen declines in the number of therapies it originated during the same period. As well, the study also presents data showing that venture backed biopharmaceutical start ups in Asia, predominantly driven by China, now equal the annual total of the United States, with 93 start-ups. Europe was relatively flat, with 44 biopharma start-ups.

VT has also found that 55% of all therapies that the US originated were developed by small biopharma firms with less than $500 mil in annual revenue. Further, 45% were fully discovered by small biopharma firms on their own, without an academic or government transfer of IP. This data represents a profound shift of the global centers of innovation since the landmark publication of Harvard's Arthur Daemmrich who, in 2009, found that Europe produced in excess of 55% of the world's pharmaceutical products from 1970-1980.

VT's latest study outlines the unique ability of the US biopharma ecosystem to optimize development by the scale required by the rate of disease incidence, in that there appears to be a far greater exchange and transfer of IP between small and large biopharmaceutical firms after products are originated than has been previously observed and measured. While 102 new therapies originated in small US firms, a

substantial number, 91, were developed by large pharmecutical firms. However, when we see which type of organization applied for FDA product approval (i.e. and NDA or BLA for a product to enter the market) we see that fully 1/3rd of those therapies that originated in 'large' firms had been sublicensed to small biopharma firms, and roughly 1/5th of those assets developed by small firms had been licensed to large firms.

According to Vital Transformation's CEO, Duane Schulthess, "while the relationship between small firms and large firms is well known, whereby a large firm will partner and invest in smaller firms with promising assets at an early stage, the out-licensing of assets wholly developed by large firms to smaller firms is a far more frequent occurrence than has been previously quantified. When one looks at the total revenue and scale required in marketing these assets due to the number of patients who need to be treated, the answer becomes clear as to why this is the case."

In fact, VT's research shows quite clearly that the scale required to develop and market these assets by the number of patients to be treated appears to be the driver of the greater number of IP transfers than had previously been quantified.

According to VT's consulting economist, Dr. Harry P. Bowen, "we see a much higher frequency of orphan and rare diseases being developed and marketed by smaller biopharma companies. In contrast, assets requiring greater production scale and larger marketing and sales operations gravitate to the larger companies. These factors explain why revenues ultimately generated by the larger biopharmaceutical companies are two and one-half times greater than those generated by smaller firms."

This observation is further confirmed by the study's analysis of the number of US originated orphan and rare conditions, where 53% of all approved orphan therapies were originated by small biopharma firms. Further, 62% of all orphan therapies were marketed by small biopharma firms, as larger firms often transferred those assets targeting orphan and rare therapeutic areas to smaller firms.

According to Hans Sauer of the Biotechnology Innovation Organization, "This study casts a spotlight not only on the remarkable overall R&D productivity of US-based biopharmaceutical enterprises, but also on the interdependence of the various large and small, public, and private actors that contribute to this flexible ecosystem. While this system has enabled US-based enterprises to develop more new drugs than the rest of the world combined, we shouldn't take such successes for granted. It is critical that we maintain rational policies that enable enterprises to transfer assets, collaborate in their development, and raise the capital to bring investigational products to regulatory approval and market-readiness."

The full research pack and underlying data is available for download at www.vitaltransformation.com.
This study was funded and supported by BIO, Novartis, The US Chamber of Commerce, Pfizer, and Gilead.

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