

Recent Trends in Specialty Pharma Business Model

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Abstract: *The recent rise of specialty pharma is attributed to its flexible, versatile, and open business model while the traditional big pharma is facing a challenging time with patent cliff, generic threat, and low research and development (R&D) productivity. These multinational pharmaceutical companies, facing a difficult time, have been systematically externalizing R&D and some even establish their own corporate venture capital so as to diversify with more shots on goal, with the hope of achieving a higher success rate in their compound pipeline. Biologics and clinical Phase II proof-of-concept (POC) compounds are the preferred licensing and collaboration targets. Biologics enjoys a high success rate with a low generic biosimilar threat, while the need is high for clinical Phase II POC compounds, due to its high attrition/low success rate. Repurposing of big pharma leftover compounds is a popular strategy but with limitations. Most old compounds come with baggage either in lackluster clinical performance or short in patent life. Orphan drugs is another area which has gained popularity in recent years. The shorter and less costly regulatory pathway provides incentives, especially for smaller specialty pharma. However, clinical studies on orphan drugs require a large network of clinical operations in many countries in order to recruit enough patients. Big pharma is also working on orphan drugs starting with a small indication, with the hope of expanding the indication into a blockbuster status. Specialty medicine, including orphan drugs, has become the growth engine in the pharmaceutical industry worldwide. Big pharma is also keen on in-licensing technology or projects from specialty pharma to extend product life cycles, in order to protect their blockbuster drug franchises. Ample opportunities exist for smaller players, even in the emerging countries, to collaborate with multinational pharmaceutical companies provided that the technology platforms or specialty medicinal products are what the big pharma wants. The understanding of intellectual properties and international drug regulations are the key for specialty pharma to have a workable strategy for product registration worldwide.*

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