The Art of the Deal
Licensing Trends in Orphan Drugs

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Orphan diseases have gotten much attention in recent years, offering hope to those affected by these rare diseases. According to the National Institutes of Health, there are more than 6,800 rare diseases and collectively they impact an estimated 25 million people in the US alone. When regulatory agencies incentivized drug development for these small patient populations, Pharma stood up and took notice. Less competition, market exclusivity and fast track development quickly translated into a lucrative market for the industry.

Since Pharma discovered the considerable revenue potential of developing orphan drugs, there has been a surge in their development. Since 2009, the FDA granted orphan designations to well over 1000 drugs, a 50% increase from the previous 5 years. And just as with all drug development, licensing agreements have become an interesting factor in the evolution of the orphan drug market. However, not unlike other licensing deals, the volume of those involving orphan designated drugs has stagnated over the past few years and has even fallen off a bit. But the deal structures are quite different, and orphan drug licenses have even taken on a unique trend in terms of value and royalties.

**Deal Values**

Average licensing values in Pharma dropped considerably since 2009 and haven’t rebounded just yet, but those involving orphan drugs followed a different path. Their values continue to surpass other drug deals since the shift began in 2010. This trend clearly represents the significant impact these drugs currently have on the industry.
Royalty Rates

Over the past 5 years, royalty rates for orphan drugs remained much lower than those for other drugs. However, since 2011 there has been a noticeable uptick in the number of deals with a royalty component in the orphan space, especially in 2013.

While other licensing agreements are trending downward with respect to incorporating royalty payments, the lure of large returns on investment from orphan drugs is reflecting in the patterns of royalty terms.

Phase II has proven to be the sweet spot for in-licensing orphan drugs when royalty rates are relatively low. In the last 5 years, 20% of orphan deals took place at this point, compared to about half that for other deals.

Traditionally, royalty rates increase linearly as costly development progresses and the approval process draws near. However, due to the expedited review process granted to orphan drugs, the time frame
from Phase III to market is often shorter. We saw royalty rates more than double at Phase III when the value of orphan drugs is at a premium.

Despite the overall lackluster deal activity in Pharma over the past 5 years, an interesting trend is emerging with orphan drugs. Growth in the orphan sector continues to accelerate as Pharma seizes the cost-saving benefits of a fast-tracked review process, and freedom from generic competition orphan drugs offer. Notable players such as Swedish Orphan Biovitrum AB, Astellas, Novartis and Sanofi are just some of the many companies to take advantage of the regulatory and commercial benefits of in-licensing orphan drugs. The allure is driving up deal values and opening up new royalty streams at a rapid pace.

Trends in licensing values and royalty rates for orphan drugs were analyzed using Medtrack®, a leading provider of pharmaceutical and commercial intelligence. Medtrack’s platform follows nearly 34,000 biopharmaceutical companies, 130,000 ethical and generic drugs and over 100,000 deals including partnerships, mergers, acquisitions, venture financings, public offerings and private placements for both private and public companies worldwide.

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