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Maximizing Royalty Rate Opportunities in Pharma Licensing:

Analysis of Average Royalty Rates in Pharma by Phase and Therapy Area

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Royalty payments are an essential component of most pharmaceutical deals. Along with upfront payments and milestones, companies are rewarded for surpassing certain developmental hurdles. A properly structured deal will achieve a balance among these financial payment types. This begs the question of what is the proper royalty rate to be paid to the product owner or originator. In order to address this, an analysis of historical royalty rates in the pharmaceutical sector was assembled using Medtrack ®'s Royalty Analyzer. Medtrack®, a leading provider of pharmaceutical and commercial intelligence information, follows nearly 32,000 pharmaceutical, biotechnology and medical device companies, 124,000 drugs (including generics) spanning 2,100 indications, and 105,000 deals including partnerships, mergers, acquisitions, venture financings, public offerings and private placements for both private and public companies worldwide. The findings of the analysis are discussed in the body of the report herein.

The pharma spectrum is quite broad, encompassing numerous therapeutic areas and phases of development. In order to accurately surmise the appropriate royalty rate for a future partnership or acquisition, it is necessary to further subdivide the industry into several distinct therapeutic areas and phases. This analysis examines 14 major therapy areas and six distinct phases of development. As expected, the data varies among therapy area and phase at deal signing.

The first part of the analysis examines the royalty rates paid by phase of development at deal signing over the last five years. Medtrack data includes deals with products signed from preclinical through marketed phase (approved phase was excluded due to statistical insignificance of the data). As expected, deals signed with products at the preclinical phase of development, received the lowest percentage royalty rate, with an average rate of 8.0%. Deals reviewed at this phase of development had royalty rates ranging from a low of 1% to a high of 25%. Some of the outliers received drastically different royalty rates due to a number of factors including therapeutic category (which will be discussed in more detail below) and uniqueness of product offering/value proposition. An example reflecting this was the June 2012 partnership deal between Intrexon and Oragenics for infectious diseases – bacterial infections.

This transaction received a royalty rate of 25% of the gross quarterly profits derived from the sale of products developed from the channel collaboration agreement. The seemingly high royalty percent is most likely partly attributed to the fact that the rate is paid on gross profit and not on revenue, requiring the company to pay a higher percentage as cost of goods would already be deducted from the revenue.

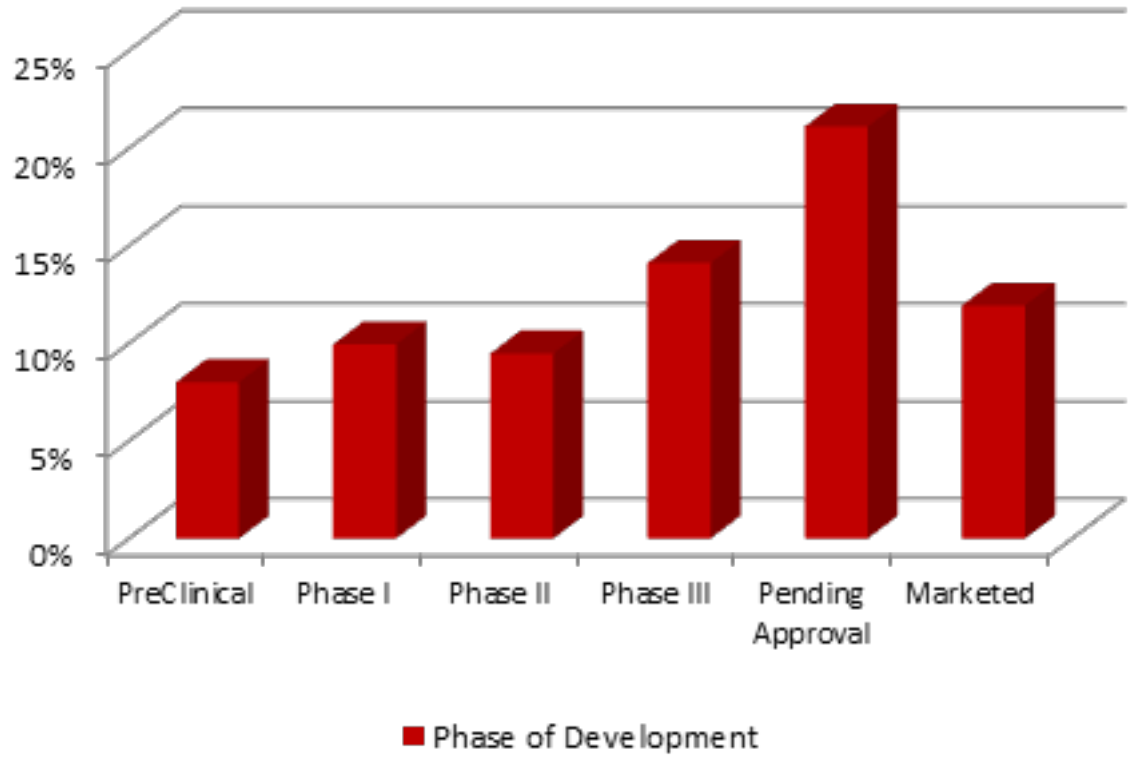
Those deals with products in development phases I, II and III received mean royalty rates of 10%, 9.5% and 14.1%, respectively. One would expect higher royalty rates as products advance through phase of development, as the company developing the product requires greater compensation for their cost outlay and development work to date. Furthermore, as products advance through development, there is an implied belief that the percent chance of approval is greater, making the products theoretically more attractive to potential licensors.

All data analyzed in phases I through III showed high levels of statistical significance. It is interesting to note that the average royalty for phase II at 9.5% was slightly lower than the average for phase I of 10%. Once again we will examine these underlying causes further in our analysis of therapy areas below.

One reason for the higher royalty percentage average in phase I is the outlier deal in October 2011 between Bayer and Onyx for Regorafenib, an oral multikinase inhibitor of angiogenic, stromal and oncogenic receptor tyrosine kinases (TK) currently being investigated in clinical trials for its potential to treat patients with various tumor types as an investigational agent. On the other end of the spectrum was the March 2009 deal between Globe Laboratories and Kedem Pharmaceuticals for X-Excite, which licensed a new drug formulation for male sexual enhancement, which clocked in at a low of 2% royalty on net sales.

Those deals involving products that were pending approval received mean royalty rates of an astonishing 21.1% and marketed products received an average royalty of a more moderate 12%. Perhaps potential licensors prefer to enter into deals at the pending approval phase due to the high potential for future short-term approval and the prospective of a steady stream of yet to be realized future revenue once approved. This is in contrast to products that are already marketed, where some of the revenue has already been realized and the market may already be somewhat saturated.

Royalty Rates by Phase at Deal Signing - Last 5 Years*



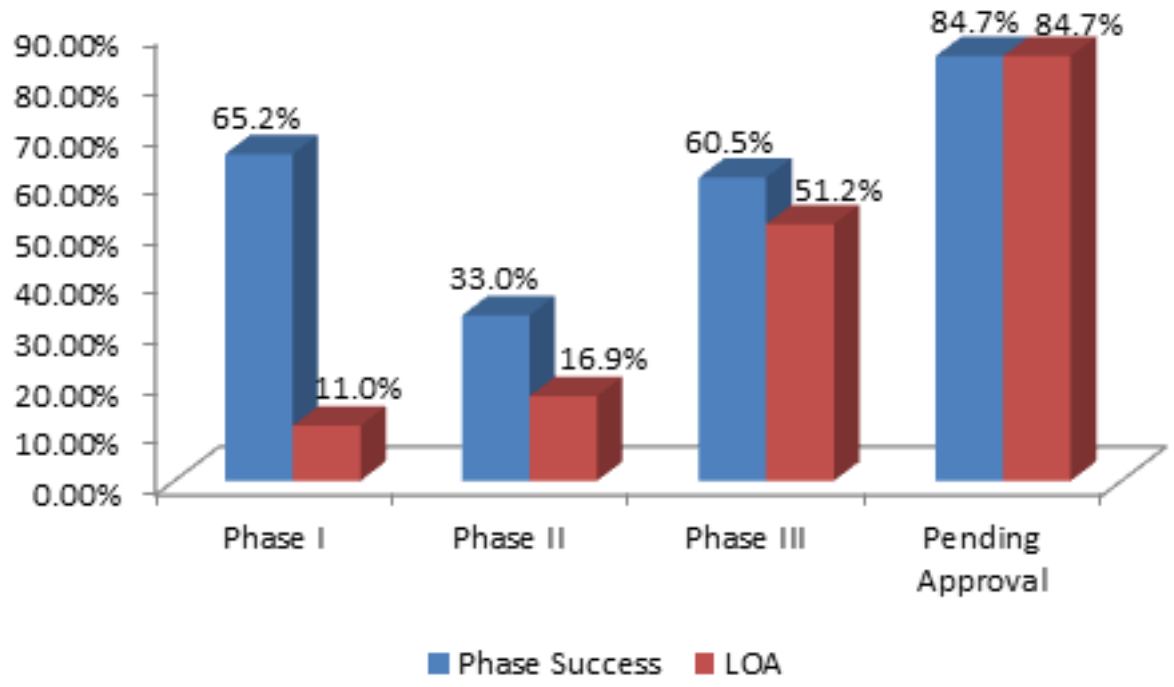
*Excludes approved phase due to statistical insignificance

ROYALTY RATE DISTRIBUTION BY PHASE AT DEAL SIGNING						
Trial Phase	0-5%	5-10%	10-15%	15-20%	20-25%	>25%
Discontinued	10	7	6	1	3	2
Suspended	2	1	NA	NA	NA	NA
Research	3	1	1	1	NA	NA
PreClinical	27	13	4	3	1	1
Phase I	16	16	14	5	NA	NA
Phase II	26	19	16	10	1	1
Phase III	11	12	8	10	4	1
Pending Approval	1	2	3	3	2	4
Approved	NA	1	NA	NA	1	1
Marketed	19	15	14	14	6	5
Post Marketing	NA	3	NA	1	2	2

***Some deals may be counted more than once due to their royalty rate crossing over into more than one royalty % range**

Medtrack's sister product, BioMedTracker, analyzes the overall success rates and likelihood of approval "LOA" for drugs at various phases from Phase I through pending approval. The analysis involves data from over 1,000 companies, both public and private, U.S. and international, and examines the time horizon from January 1, 2003 through December 31 2012. The results show an average likelihood of approval of 11.0% in Phase I, 16.9% in Phase 2, a much higher 51.2% in Phase 3 and an even greater 84.7% likelihood of approval in the pending approval phase.

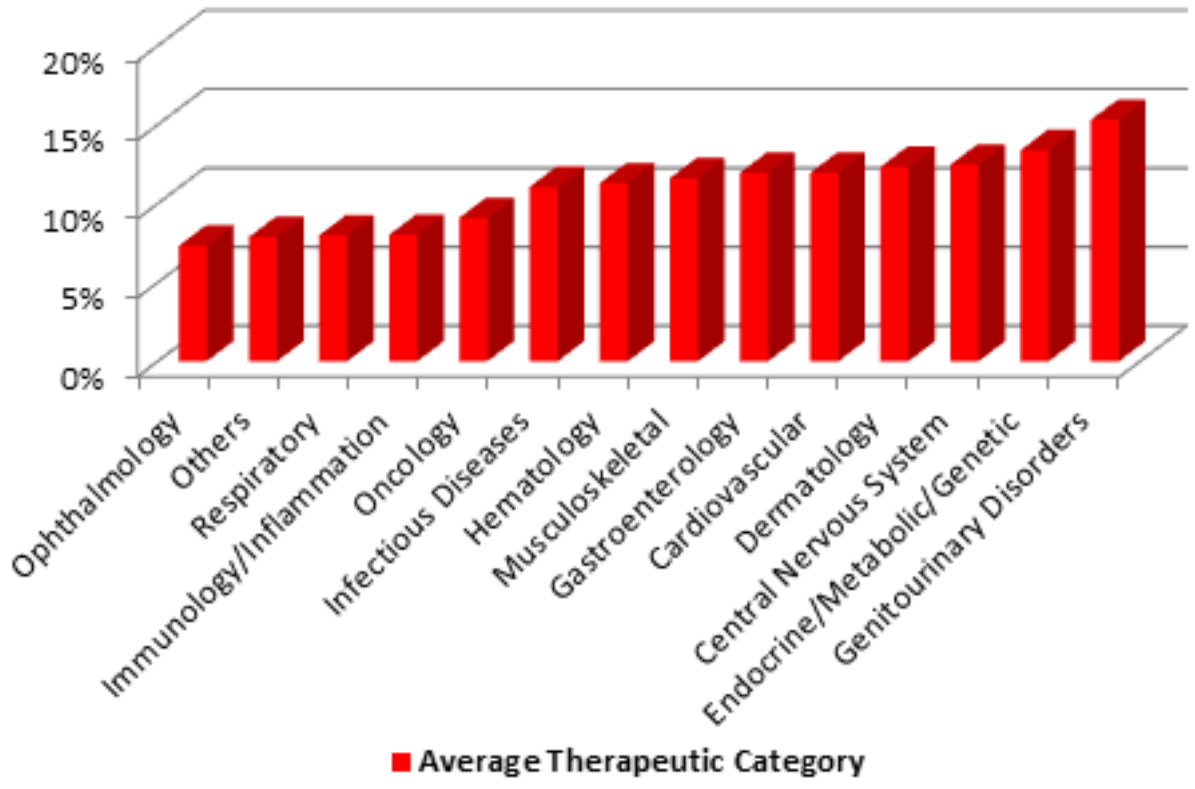
This data correlates positively with the royalty rates received by phase below, as a higher likelihood of approval generally demands a greater royalty rate be paid out. Additionally, the chart below shows the percentage of drugs that advance to the next phase, denoted by the bar "phase success." As one would expect, there is a large gap between the phase success and LOA in phase I and as products advance in development, this gap narrows until the pending approval phase, where the numbers converge.



While the royalty analysis by phase is somewhat telling, it is necessary to take a deeper dive into the inner workings of royalty rates. To do so, Medtrack reviewed nearly 400 deals and segmented them by unique therapy area. The therapy areas, displayed on the chart below, range from ophthalmology to genitourinary. The mean royalty rates ranged from a low of 7.3% for ophthalmology to a peak of 15.3% for deals involving genitourinary disorders. While there were some outliers in the dataset, these statistics speak to how specific therapy areas demand premium rates, while other therapy areas receive relative discounts.

This data must be analyzed in conjunction with the phase at deal signing data, as ophthalmology deals in the sample were generally signed at phase II which could also be partly responsible for the lower relative royalty rates. In contrast, most of the genitourinary deals were signed at either phase III, pending approval or marketed phases. Perhaps this is cause alone to reflect the higher royalty rates.

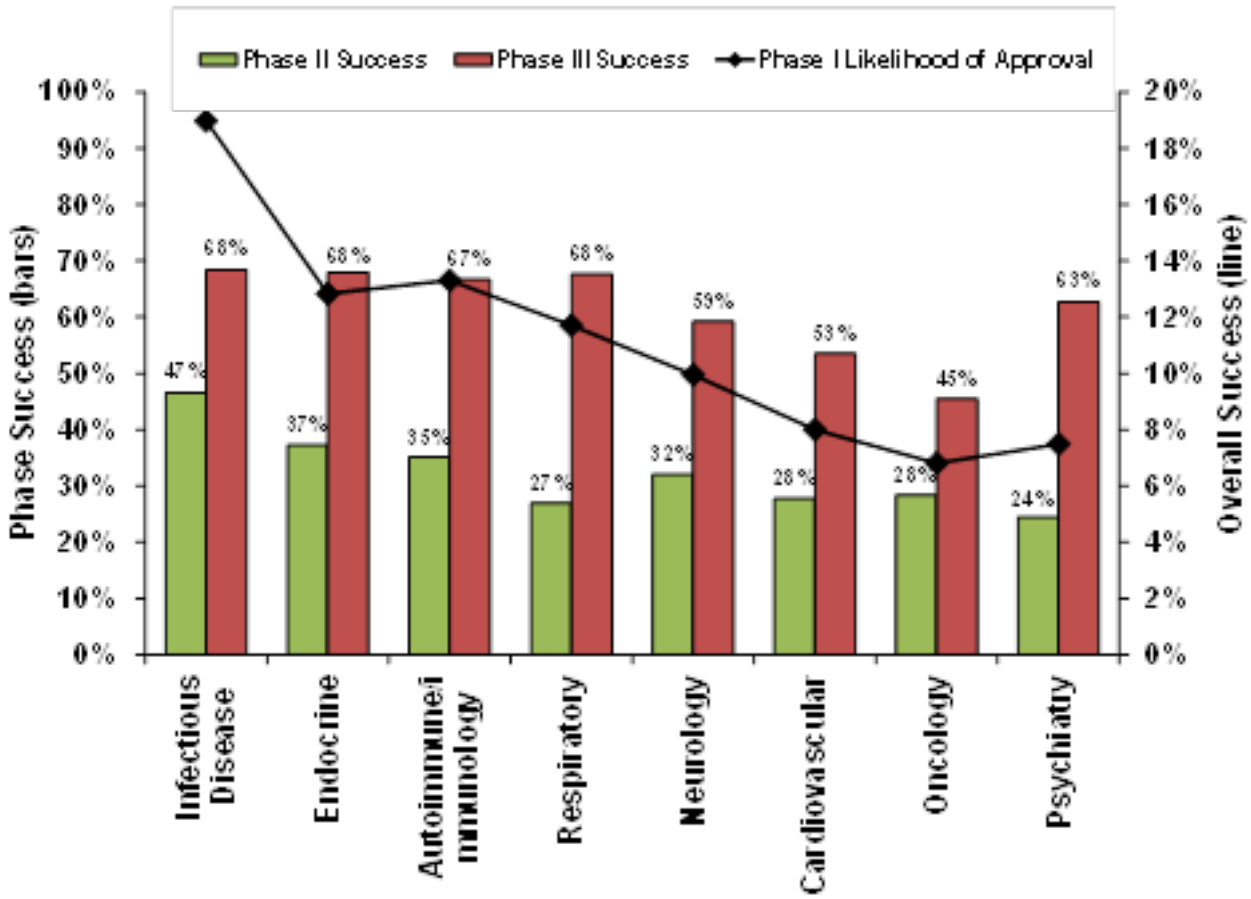
Royalty Rates by Therapy Area - Last 5 Years



ROYALTY RATE DISTRIBUTION BY THERAPEUTIC CATEGORY

Therapeutic Category	0-5%	5-10%	10-15%	15-20%	20-25%	>25%	Total
Cardiovascular	5	6	5	3	NA	2	21
Central Nervous System	13	14	10	9	3	4	53
Dermatology	7	1	3	3	NA	2	16
Endocrine, Metabolic and Genetic Disorders	15	9	2	2	2	7	37
Gastroenterology	10	3	6	6	3	NA	28
Genitourinary Disorders	7	3	7	4	3	3	27
Hematology	7	4	5	2	3	1	22
Immunology and Inflammation	9	8	4	1	NA	1	23
Infectious Diseases	13	10	10	3	4	1	41
Musculoskeletal	3	3	3	NA	NA	1	10
Oncology	36	25	14	10	2	NA	87
Ophthalmology	3	1	1	NA	1	NA	6
Others	4	3	NA	1	NA	NA	8
Respiratory	5	1	2	2	NA	NA	10

The following analysis, which is based on data from BioMedTracker, shows how the phase I likelihood of approval in a given therapy area correlates with the Phase II and Phase III overall success of the drug. (The therapeutic categories below reflect the BioMedTracker industry taxonomy which may vary slightly from Medtrack.)



This further begs the question as to why certain therapeutic areas generally enter into royalty deals at earlier phases of development than others. Are there a set of unique underlying factors that would cause this to be true or is one therapy area in greater demand than the others based on current market conditions and saturation? All of these suppositions can be answered using the power of the Medtrack database and tailored to your company's individual needs.

Perhaps your company is exploring entering into a licensing deal and you want to know the most appropriate phase of development to sign the deal at in order to guarantee the greatest royalty stream. Perhaps you are a potential licensor and want to make a competitive bid for a deal without overpaying or overestimating a royalty rate paid to a licensee. Whatever your need, Medtrack is here to assist. For further information or to receive a complimentary demo of the newly released OneView product offering, please go to www.medtrack.com.

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