The Royalty Rate Report 2011

A Comprehensive Assessment of Valuation in the Pharmaceutical Sector

A Report by the Consultants and Advisors at PharmaVentures

Edited by
Heather Cartwright and **Nigel Borshell**

Foreword by **Dr Fintan Walton**

PharmaVentures
Experts in deals and alliances

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Foreword

As always, this 2011 edition of our report is written with you as a deal maker in mind.

Our industry continues to undergo change and the past four years this change has been considerable. It was imperative therefore for us to research and survey those active in deal making and ask what impact there has been on deal terms and royalties for them. I think you will find the results very interesting.

Deal making and licensing is what we do at PharmaVentures, and working with our international clients we experience the real issues at first hand, especially when it comes to valuing and structuring licensing agreements. We understand the problems and frustrations that both large and small companies have when they are doing deals. This latest edition sets out to discuss and address these issues with you as a deal maker in mind.

This 2011 edition of the report is the most comprehensive on this subject ever produced and sets out to give you a full insight into determining deal values and royalties, and the huge impact that these terms can have on deals and their ultimate survival. Nigel Borshell, a Director at PharmaVentures, is the main author, and has written it in an entertaining and readable format without losing sight of the tremendous importance of the subject. Like its predecessors, the report draws on the significant wealth of information, experience and thought leadership from inside PharmaVentures.

There are a lot of myths about valuation, and many traps that individuals can fall into when structuring deals, and this report aims to provide you with more knowledge and confidence in approaching these critically important activities.

The report also draws on extensive data and analysis from within our proprietary PharmaDeals® v4 intelligence resource which is used and relied upon by all the major players in deal making within our sector.

Meanwhile, we are sure that you will get a significant return in your investment from this new report.

Dr Fintan Walton
Chief Executive
PharmaVentures

Preface

PharmaVentures has published earlier reports on royalty rates in the pharmaceutical industry: in 2005, 2006, 2007, 2009 and 2010. The Royalty Rate Report 2011 comprises a thorough update including a major new survey, revised figures, tables and several new royalty rate case studies. The Report represents a cornucopia of information about the history of royalties, how they are determined/calculated, insight into recent royalty trends and structuring as well as current royalty thinking.

The Royalty Rate Report 2011 is an essential weapon in the armoury of everyone directly or indirectly involved in royalty rates, value determination, deal structuring, deal negotiation or otherwise concerned with maximising the value of pharmaceutical product and technology transactions. For example, for the budding young licensing executive the Report provides a basis for formulating value, understanding how value is split between licensor and licensee and deriving sensible licensing terms. And for the licensing veteran, if you become stuck in negotiations regarding suitable terms for a transaction, the Report can serve to broaden your perspectives on alternative royalty structures and on other financial terms and conditions that you might not have considered hitherto, thus helping you to reopen discussions and conclude a satisfactory deal. Hence the Report is an indispensable tool for both the novice and the experienced alike.

Moreover, understanding historical and current trends in royalty rates may become increasingly important in today's geopolitical climate. There is increasing concern about the ever rising cost of healthcare including the high cost of many proprietary medicines. Any significant downward pressure on pharmaceutical pricing and reimbursement may well have a knock-on effect on company profits and hence royalty rates and other deal components that licensors and licensees can agree. Understanding royalty rate trends and alternative structures may thus become even more important to maximising the value of pharmaceutical transactions.

The Royalty Rate Report 2011 is thus an essential resource for everyone working in the pharmaceutical sector.

Introduction

Three Lessons on Royalties You Must Not Ignore

1 Deal making is as much an art as it is a science. If you are tempted to flip through these pages to find the bar charts and data tables holding the 'standard' royalty rates that you need to define your own deal term limits and expectations, then go right ahead. However, if you invest your time in absorbing the content of the report, you will come away with a better understanding of what royalties are, and how and why they are inextricably linked with overall deal value. Context is everything. Without a full understanding of the value in your product and of other contributions to deal value, you cannot determine a suitable royalty rate, no matter how many tables you read.

2 Deal making is as much about 'what you can live with' as it is about meeting specific industry norms. If either one party feels – or both parties feel – that the terms set out do not meet expectations, then there is no rosy future, even if the terms that you propose meet the industry norms. Only by an in-depth analysis of a programme's value, and of the split of that value among deal components (upfront payments, development milestones, sales milestones, royalties) will you be able to answer that 'what can I live with' question. 'Living with' involves envisioning the future in both the short and long term. Can we afford it? It could seem like a blindingly good deal long term from a business development perspective, but the short-term impact on the licensee's bottom line or the company cash flow from the CFO's (and shareholders') perspective might just be the deal breaker.

3 The third lesson is that there is more to be gained through effective knowledge-backed negotiation skills than there is from reading tables of royalty data or calculating value on a spreadsheet. Beyond the obvious impact of prevailing market conditions, actual value is fundamentally a function of a product's net present value enhanced by a licensee's strategic need for that product. Understanding the estimated 'actual' value that a product may have does not automatically translate into knowing how big a share of it you will get. That share comes from a skill-based activity called negotiation, and, unsurprisingly, it is a professional activity that is built on information, not on anecdote.

Royalties, Why Such a Focus?

Over the past 30 years, the pharmaceutical industry has changed out of all recognition. What we take for granted today would seem alien to pharma executives of earlier times. Pipeline productivity, or the lack of it, has become the single greatest driving force in corporate strategic planning. Survival is all about maintaining progress. Without the next big winner waiting in that pipeline, pharma companies are merely carrying today's blockbuster as a giant millstone around their necks. Being successful now is no longer enough: tomorrow is what counts to investors and shareholders alike. That unproductive pipeline can no longer be relied upon to create the follow-on products, and with the demise of branding in pharmaceuticals, today's products are dead in the water once the generic assault is launched upon looming patent expiry. Thirty years ago, drug companies had their 'war chests', their sales 'force' action plans and their marketing 'campaigns', but business philosophy was a-changing. Management speak began to adopt sporting metaphors to define and generate corporate success. Management 'teams', sales 'teams', 'teamwork' and 'team players' populated the burgeoning pharmaceutical industry. Today, the sports metaphor persists, but now the 'players' might be more accurately defined as being the drugs in the pipeline and on the market.

In this context, a company without collaborative strength has no strength at all, regardless of the past achievements of its personnel 'teams'. Just as the successful professional sports clubs have recognised that their own youth programmes and junior team scouts can no longer meet their needs, and that outsourcing the best current and (potential) players through high-value high-cost transactions is the only way to maintain success, so the pharmaceutical industry has similarly looked externally to find the products and technologies that will create the blockbusters or high-value niche products that will complement – or even supplant – its current successes.

Deals have become big business, and with the inherent uncertainties in the pharma development pipeline, deal structures need to reflect a sharing of risk and reward. The typical components of a product licensing deal all show elements of that risk and reward. Upfront money demonstrates the degree of exclusivity, and often reflects an urgency of financial 'need' in one or both parties; milestone payments reflect the achievement in overcoming significant hurdles in the development pipeline as major chunks of value are added to the product; and, eventually, market success is reflected in the royalty component. Upfront money is ephemeral – here today, gone tomorrow – and development milestone payments are the

performance bonuses for the increase in potential; but the royalties are the lasting pension, the annuity reward for the licensor's past achievement (and the enduring testament on the licensee's annual profit and loss statement). Long after the headline deal value has faded from the front page, the royalty flow for those that make it to market will live on.

In 1996, atorvastatin (CI-981, Warner-Lambert) was in Phase III trials for moderate-to-severe hypercholesterolaemia. Warner-Lambert reported that analysts were forecasting peak annual sales of the drug at US$1.5 B. Imagine a deal proposition based on this forecast, and with a 9% royalty rate. One of the negotiators might have said 'Make it 10% and we have a deal'.[1] Peak sales came in at US$12.9 B in 2007, and that 1% sweetener would have been worth an extra US$129 M to the licensor in that year. OK, so Pfizer's Lipitor® (as atorvastatin is better known) is a special case, but many of today's deals are for Phase II drugs for which a 5% royalty rate is common – in fact, many rates are in the double-digit range, as you will discover in this report. The hope is that many of these drugs will achieve blockbuster status. At US$1 B a year in sales, that 5% is worth US$50 M for every year that the US$1 B sales level is maintained: not an upfront payment, not a milestone, but a year-on-year stream. Deals are definitely big business, and royalties are definitely a big deal! For late development phase candidates, licensing deal royalties can typically comprise 50–80% of the expected Net Present Value (NPV) of the deal from the licensor's perspective: the highest value – but often the lowest visibility profile – in deal-making public relations.

Overview of the Report

The Royalty Rate Report 2011: A Comprehensive Assessment of Valuation in the Pharmaceutical Sector covers new ground in the analysis and interpretation of royalty information. It introduces methods for calculating useful financial data that are missing from the public domain, but are essential for deal makers in benchmarking, and in determining deal value and its relationship with eventual royalty streams.

Chapter 1 deals with the history of royalties, its relevance to the biotech/pharma arena and the psychology of royalty structures.

In Chapter 2, topics of thought leadership are covered. These include the concept of 'effective royalties' as an aid in the analysis of deal structures, royalty issues in biotechnology, a critique of the oft-quoted 25% rule of

[1] Hyperlipidaemia Therapy: Advances and Commercial Opportunities; Connect Pharma reports (1996).

thumb and its relevance – or lack of relevance – in pharmaceutical deals, and key opinion leader thoughts on the public disclosure of royalty rates.

Chapter 3 covers the practical aspects of royalty calculation, with a focus on benchmarking and expected Net Present Value (eNPV) skills.[2] These tools will give deal makers a complete understanding of the value intrinsic to their products, and of the relationship between royalties and other deal components.

Market data and current trends are covered in Chapter 4, which looks at actual royalty rates by indication, product type and phase of development. The emerging area of royalty monetisation is covered in detail, along with an analysis of the utility cost of that process.

Chapter 5 looks at current thinking on royalty rates. It starts with a review of the royalties literature, and goes on to investigate the results of pharma royalty market surveys from a critical perspective.

Chapter 6 presents and discusses the results of a survey of industry executives conducted by PharmaVentures in 2011 in order to uncover up-to-date information on royalty rates from active deal-makers and their attitudes and expectations with regard to deal making.

The comprehensive Addendum includes the full summary of the PharmaVentures 2007 market audit, and a listing of royalty reporting deals between 2004 and March 2011.

And throughout the report, you will find case histories, deal analysis and opinion leader comment, all relating to the quest for better and more usable royalty data.

Effective Royalties

Throughout this report, we will be using the concept of 'effective royalties' to analyse and explain various deal scenarios. Royalties are often viewed in isolation from other factors related to intellectual property (IP) licensing. Too much time (and too much energy) is spent searching for meaning within what little royalty evidence exists in the public domain. The truth is more complex than the superficiality of royalty values alone. Without insight into the value of other deal components, such as upfront payments or milestone payments, two seemingly similar royalty percentages may be seen as indicative of a trend or average when, in reality, they are components of

[2] Expected Net Present Value (eNPV) is widely used in capital budgeting and investment decision making. It means the current worth of future cash flows as discounted backwards with an industry-standard rate of return (or cost of capital), adjusted for the risks that the project faces.

deals which might have vastly dissimilar values and structures aside from this one coincidental component.

'Effective royalty' is a value concept that allows all those other deal components to be factored into a valuation, which is then expressed as a single component: a royalty. The effective royalty rate answers the question: if there were no other structural components included in this deal, what would the royalty be? In other words, what is the size of the royalty if all the value due to the licensor were incorporated into it? For deal makers, this can be very valuable, as it allows benchmarking and comparison without the confusion caused by the complexity of reported deal structures.

Effective royalty becomes a theoretical starting point for the value return to an IP licensor, as a function of (future) sales. If all deals were based on marketed products with flat sales, and all licensors sought a regularised cash flow from their licensees' sales revenues, with no upfront lump sum licence fee, then royalty data alone would be comparable. Furthermore, if expressed as a percentage of sales, royalty data would reflect the true shares of value. Knowledge of that profit margin would allow estimation of the share of value between the licensor, via royalty (thus answering the oft-posed question – 'As licensor what can I expect to get?'), and the licensee, via margin minus that royalty (so answering the licensee's equivalent question – 'After paying appropriate royalties, what benefit will the deal bring to my business?').

Deals are rarely as straightforward as that, however. More likely there will be complications with regard to product status. In the years pre-launch: at which clinical development stage is the product? And in the commercial years post-launch: at which stage is the product in the life cycle? Then there will be lump sum deal components (upfront payments, development milestone payments, equity investments, sales milestones), all of which will attempt to confound the derivation of value and the share of it between the parties. The estimation of value is, therefore, a key element in understanding effective royalty and, thereafter, actual royalty rates. In our experience, value in the biotech/pharmaceutical field is best derived by a discounted cash flow methodology (what is tomorrow's money worth today?) incorporating decision tree analysis (what are the chances or risks of reaching specific points of progress on the road to that future flow of tomorrow's money?). When project or product financial data are forecast, then expressed as today's value (NPV), we can consolidate all these data into one single figure, the eNPV. This subject is covered in greater detail in Chapter 3.

Value Calculation

Familiarity with eNPV calculation and utility will be of major advantage in maximising the use of this report, and in extrapolating the lessons learned into future deal analysis.

By combining our 'effective royalty' and 'eNPV' approaches, we can simplify complex deal structures, and we can assess the impact of those lump sum payments (one-off value payments, such as milestones) on the royalty rate (the regularised or repeat-value payments).

The Visualisation of Deals

Here, we will show three types of deal structures diagrammatically.

Our first diagram (*Figure 1.1*) visualises the outputs from eNPV/effective royalty calculations.

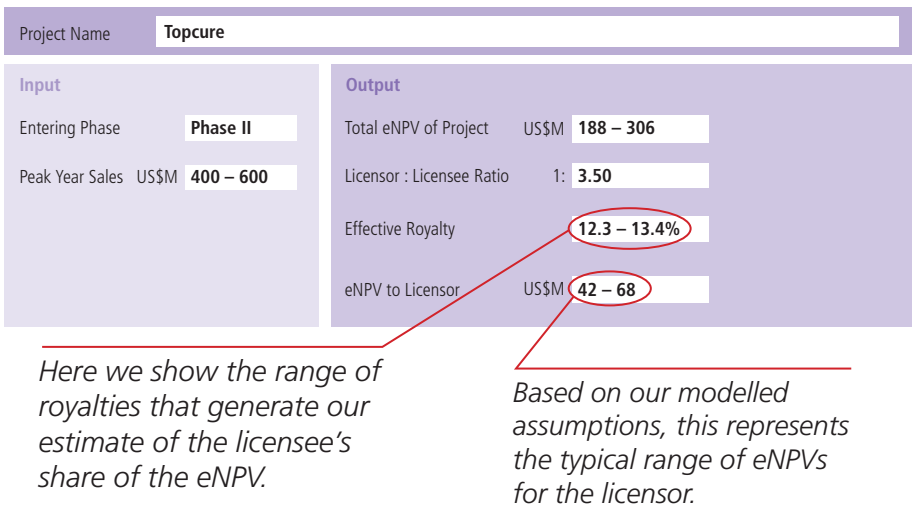

Figure 1.1 – Effective royalty calculation (scenario A).

Figure 1.2 shows an alternative structure for deals where upfront and milestone payments exist, and demonstrates their impact on royalties, thus producing an 'adjusted' royalty.

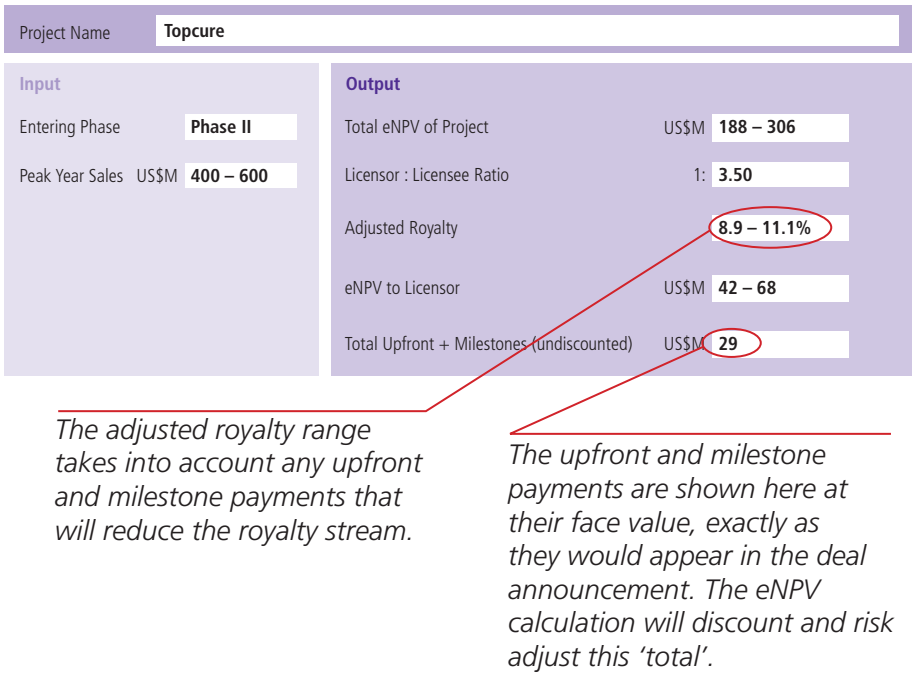

Figure 1.2 – Adjusted royalty calculation (scenario B).

Figure 1.3 provides a third visual summary for a more complex analysis that uses many more specific variables (which are either taken from available data, or modelled/estimated). The diagram depicts the same two scenarios of effective royalty (scenario A) and adjusted royalty (scenario B).

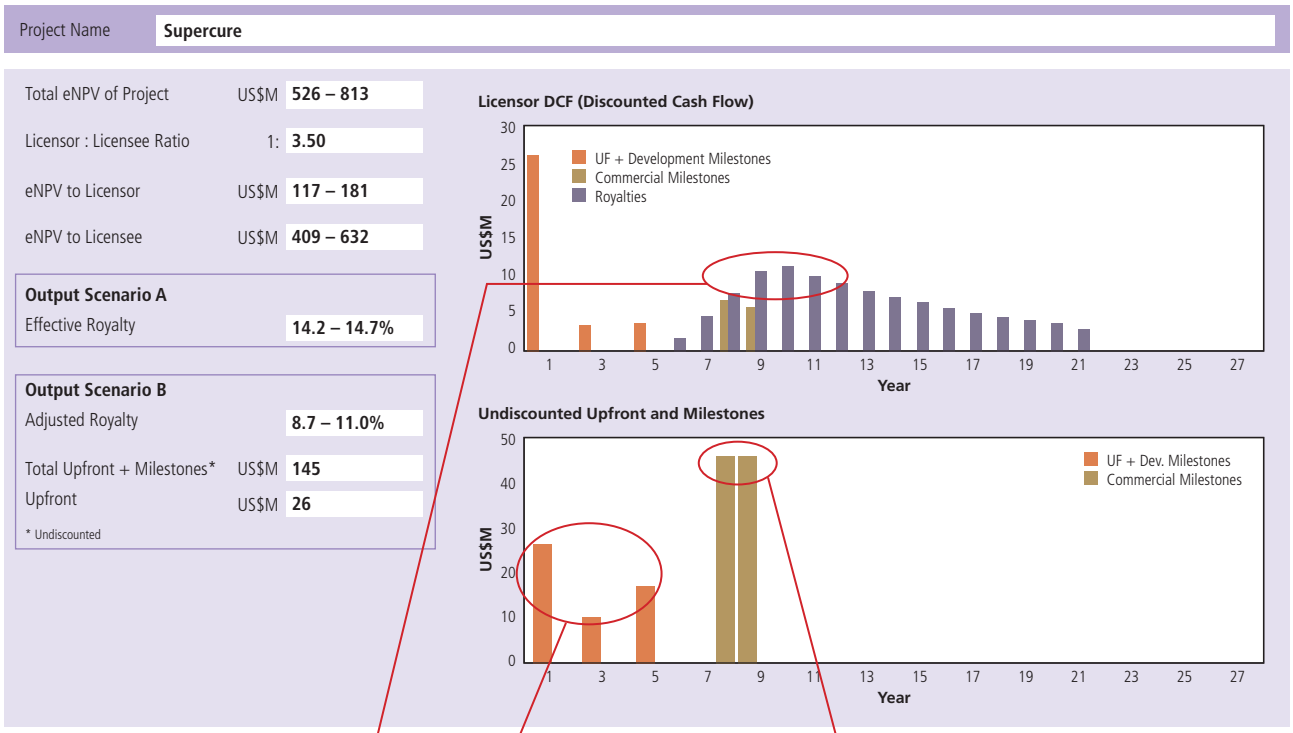

Figure 1.3 – Royalty scenario comparison.

Peak year for sales (corresponding here to risk-adjusted and discounted royalties) are taken from analyst data or, if no data are available, an estimate is based on industry averages adjusted for new indication and territorial factors.

Upfront and development milestones are modelled from industry-average time-scales adjusted, where appropriate, for therapy area and drug form if data are available.

Commercial milestones are modelled in the year corresponding to the sales level 'targets' announced in the deal, or estimated from typical incremental break points if not declared publicly.

When viewing these summaries, it should be remembered at all times that the use of eNPV calculations including decision tree analysis is a valuable comparative method, but does not relate to a future reality, only to our present estimate of value. An analogy might be to value two different sized piles of lottery tickets before the draw, either based on the totals of their face value, or, more accurately, based on total payout divided by ticket numbers; the future reality after the draw will change those values significantly – most will be worthless, while some will have far greater value than their initial price. However, before the draw, the value assessment is based on the best possible available information.