

How to read deals

Press releases announcing license agreements in life science in general disclose little information on how much money flows from the in-licensing to the out-licensing company. Usually, the amount of the upfront payment and the total sum of potential milestones – if all are triggered – are disclosed. In some cases the companies also mention whether the royalty payments are one or two digits high. As an outsider it is not trivial to get an understanding of how these deals are financially structured. Nevertheless, having an idea about the deal terms is essential when valuing a company that depends on its license revenues or when benchmarking an own deal.

Avance presented an analysis of early-stage deal terms in its December 2007 newsletter. The displayed milestone weights offer a particularly interesting insight in the way deals are structured (Fig. 1).

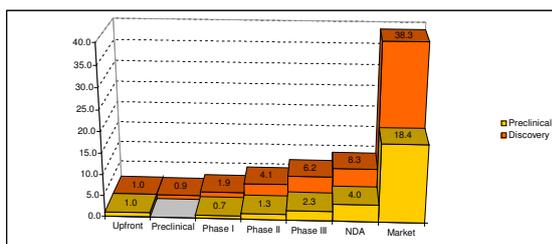


Figure 1: Milestone weights

These milestone weights allow extrapolating the size of future milestones knowing the upfront payment. If in a preclinical deal the upfront payment has been stated with USD 4 Mio, then this would mean that the NDA milestone would amount to four times the upfront payment, i.e. USD 16 Mio. In theory, all milestones should sum up to the total amount of

potential milestones as announced in the press release. For a preclinical deal this would mean that the total amount of potential milestones should be $0.7+1.3+2.3+4.0+18.4=26.7$ times the upfront payment. Often these numbers do not match exactly. First, the displayed milestone weights represent an industry average. Second, companies tend to artificially increase the launch milestones, and to some lesser degree also the approval milestones. They add significant milestones for the approval of a second or third indication, even if such an extension is unlikely. Of course, this increases the milestone figure excessively and makes it somewhat less representative. In some deals backup molecules are included which double the potential amount of milestones to be paid.

Another method to reach an impressive headline is to include sales related milestones. The in-licensing company must pay a milestone payment if it exceeded for the first time e.g. USD 200 Mio sales on a cumulative (or sometimes annual) basis. These payments are linked to well-defined goals, i.e. sales figures. But in fact the figures are royalties disguised as milestones, which help increasing the total milestone figures.

We will now see how we can apply the knowledge of these milestone weights to a press release of a deal.

“Jerusalem, Israel, and Lund, Sweden, June 14, 2004: TEVA AND ACTIVE BIOTECH ANNOUNCE AGREEMENT FOR LAQUINIMOD POTENTIAL ORAL THERAPY FOR MULTIPLE SCLEROSIS.

(...)

Teva has agreed to make an upfront payment of 5 million USD to Active Biotech and to conduct and fund the further clinical development of laquinimod. The contract between the two companies also calls for Teva to make payments to Active Biotech upon the achievement of various milestones, which include sales targets. If such milestones were all to be met, payments to Active Biotech would aggregate to 92 million USD. Active Biotech will also receive tiered double-digit royalties on sales of the product, once marketed. (...) (source: www.activebiotech.com)

In addition to the USD 5 Mio Active Biotech receives another USD 87 Mio if all milestones will be reached. Laquinimod was in phase II at the time of licensing.

If we assume the weights displayed in figure 1 and assume the phase II milestone to be an upfront payment, then the subsequent milestones are weighted as displayed in table 1. The data sets for preclinical and discovery deals are slightly different, we can therefore derive two sets of milestone weights; but they remain pretty similar:

Table 1: Milestone weights for phase II

Dataset	Discovery	Preclinical
Upfront	1.0	1.0
Phase III	1.5	1.7
NDA	2.0	3.0
Launch	9.3	13.8
TOTAL	13.8	19.5

In the press release the ratio upfront/total milestones is $5/92 = 1/17.4$. Applying more or less the weighting

arising from the preclinical dataset we therefore obtain the following deal structure for the TEVA-Active Biotech deal:

Table 2: Forecasted milestones

Milestones	Calculation	USD Mio
Upfront	5*1.0	5.0
Phase III	5*1.7	8.5
NDA	5*3.0	15.0
Launch	remainder	63.5
TOTAL	92.0	92.0

In 2007 Teva initiated the phase III:

"...net sales for the corresponding period in the preceding year included an initial milestone payment of SEK 51.2 M from Teva Pharmaceutical Industries (Teva) relating to laquinimod..." (source: *Active Biotech, year-end report, January-December 2007*)

Active Biotech received another milestone of about USD 10 Mio upon reaching phase III. This is pretty much in line with the predictions from table 2. We can slightly adjust the milestones predictions, because we now also know the phase III milestone. We can also assume that the launch milestone will be about USD 30 Mio (distributed over different geographical areas) and the rest will be paid upon reaching sales targets. To our experience launch milestones are only excessively larger than the previous milestones if several indications or commercial milestones are involved. We can expect that the milestones figure of USD 92 Mio is not artificially blown up because no company mentioned any other indication than multiple sclerosis. Excluding other indications we assume that about half of the remaining

milestones, i.e. USD 32 Mio, will be paid as launch milestones. The new, revised deal forecast is presented in table 3.

Table 3: Forecasted milestones (2)

Milestones	USD Mio
Upfront	5
Phase III	10
NDA	15
Launch	30
Sales Milestones	32
TOTAL	92

We still do not know the royalty structure. The royalties are said to be double-digit. In order to divine the royalty rate (disregarding the tiered structure for a moment) we refer to the companies' press releases that stated the multiple sclerosis market to be 4.2 bio in 2004 with TEVA being a major player commercialising Copaxone® with 2003 annual sales of USD 720 Mio (in 2007 TEVA reported Copaxone® sales of USD 1,713 Mio, excluding Sanofi-Aventis' Copaxone® sales). We can therefore assume that Laquinimod will reach blockbuster status, above all because of its oral administration. Assuming USD 1 billion sales and 15% royalties we get a 67%-33% value share between TEVA and Active Biotech (calculated at 12% discount rate). If the sales potential is USD 2 billion then the value share becomes 77%-23%. A phase 2 deal is said to have a value share between 25% and 35% percent, depending on the industry standard. A tiered royalty structure of 15% up to maybe 20% seems therefore realistic.

In review USD 5 Mio upfront seem little for a potential blockbuster drug. One reason is certainly the low success rates for CNS drugs in phase II, which reduce

the value of such compounds significantly. A second reason might have been Active Biotech's will to retain as much upside as possible, putting more weight to sales milestones and royalties.

This method of estimating future deal terms is essential when valuing companies whose revenues stem essentially from license agreements. For an analyst it is virtually impossible to value such a company without having an idea of the deal terms. The outlined method should serve as a guideline to divine such deal terms.