that independently of the study sponsor the phase I/IIa trials will cost EUR mio all together. They are estimated to last over full years. She assumes that the success rate for a cancer phase I/IIa trial corresponds to published phase I cancer success rates. According to cancer success rates she estimates phase I/IIa trials to be successful in 64% of all cases. Phase IIb trials would then take three years at a cost of EUR 10 mio and with a success rate of 42%. Phase III trials last another three years at a cost of EUR 68 mio and a success rate of 69%. Finally, approval phase will take another 12 months at EUR 2 mio with approval 85% of all cases.

Once BT-100 gets approval, Mrs. Business Developer estimates the drug to achieve peak sales of EUR 300 mio worldwide if commercialised by Midpharm. She calculated the number by comparing the properties of BT-100 to the current market leader for the treatment of Glioblastoma, Temodar, which had sales of 703 US$ mio in 2006, taking into account that BT-100 probably will only be a second line treatment. Accounting for the lack of marketing experience she estimates the drug only to achieve EUR 250 mio if marketed by Bio-Tec. In both cases, EUR 50 mio launch costs and an operating margin of 70% (i.e. Cost of goods and marketing and sales account for 30% of net sales) need to be considered. Mrs. Business Developer also thinks that Midpharm can achieve peak sales faster than Bio-Tec. This is displayed in the different sales ramps she uses for the calculation. The sales of BT-100 will be protected by patents for 14 years after launch. Furthermore, Mrs. Business Developer estimates the Glioblastoma market not to grow and the volatility of sales for real options analysis to be 30%.

License contracts

	Phase I deal	Phase II deal	Phase III deal
Upfront	1	1	1
1st dose phase II	1	-	
1st dose phase III	2	1	-
NDA	3	2	1
Approval	4	3	2
Royalties	4%-15%	8%-20%	10%-30%
Value share	25%-75%	35%-65%	50%-50%

A phase II deal (closed after phase I results) usually displays a value share of 35%-65% for licensor and licensee. Upfront and milestone payments are set in a way that their relative size behave like the indicated weights. The approval milestone therefore is three times the size of the upfront payment. These rules can however be modified according to the preferences of the contract partners.

For the calculation Mrs. Business Developer also needs to know the cost of capital of both companies. In the last financing round 2 months ago Bio-Tec was valued at a cost of capital of 18%, and since then no significant event happened. Midpharm is a publicly traded company and analysts use 13% as its cost of capital.

For the calculation of license contracts Mrs. Business Developer consults industry reports and databases and finds that in general, the deals are arranged such that in phase III licensor and licensee each get 50% of the project value (calculated at the licensee's cost of capital) For phase II deals this value share shifts to 35%-65% for licensor and licensee. For a phase I deal finally, the value share is 25%-75%.

Milestone payments are typically increasing and royalties range from 10%-30% for a phase III deal and from 8%-20% for a phase II deal, and from 4%-15% for a phase I deal.

Mrs. Business Developer feels now sufficiently equipped to value the various options.

Commercialisation

The graph displays the different sales curves as percentage of peak sales for Midpharm and Bio-Tec. Midpharm is expected to achieve peak sales of EUR 300 mio, Bio-Tec of EUR 250 mio. Both companies need to spend EUR 50 mio to launch the drug. Operating expenses amount to 10% COGS and 20% marketing and sales, which results in an operating margin of 70%.

Task

1. Value BT-100 as if Bio-Tec will ultimately commercialise the project
2. Find reasonable deal terms for a phase II deal
3. Find reasonable deal terms for an immediate phase I deal
4. Design a counteroffer to Medpharm
5. What do you propose Dr. CEO to do?

Use the attached file Bio-Tec.xls to perform the calculations. Calculation instructions can be found in the article Villiger and Bogdan, " Getting real about valuations in biotech", Nature Biotechnology, April 2005.

For questions concerning the case you can reach the authors at ralph.villiger@avance.ch, or boris.bogdan@avance.ch.