Case Study: Bio-Tec's lead compound

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General

Bio-Tec is a young biotech company, founded six years ago by Dr. CEO. Dr. CEO, while still working as a postdoc at the university, discovered a new method to identify a special class of molecules that act on the central nervous system. Dr. CEO, supported by the tech transfer office, spun-out his technology from the university. In exchange, the university now holds 5% of Bio-Tec's shares.

The technology allows Bio-Tec to identify drug candidates acting on the CNS. At the moment, Bio-Tec holds a promising pipeline of three projects, two of them already being studies in clinical trials. In addition, several other leads are still in discovery, and the company expects to be able to put each year one compound into regulatory preclinical phase. The company currently has EUR 16 mio cash at hand, which should be sufficient to take BT-100 to proof of concept in man, i.e. end of phase IIa, BT - 101 through phase I, and apply for an IND for BT-102 within the next 24 months.

Pipeline of Bio-Tec

Project	Phase	Indication
BT-100	Phase I/IIa	Glioblastoma
BT-101	Phase I	Parkinson
BT-102	Preclinical	Not disclosed

In addition, we can expect that Bio-Tec can generate each year a new preclinical project.

Strategy

Bio-Tec's most advanced project, BT-100, has just entered phase I/IIa trials. Dr. CEO assumes that after having shown proof of concept in man after this phase I/IIa study, the optimal time has come to partner the compound with a pharmaceutical company. Dr. CEO acknowledges that large-scale clinical trials are not Bio-Tec's core competence and assumes that a large pharmaceutical company is better placed to conduct a phase III trial. Also, Dr. CEO believes that the commercialisation of BT-100 requires an enormous effort and a set-up of a large sales department within Bio-Tec. A license deal would be beneficial to the company in three ways:

1. A license deal would provide Bio-Tec with valuable cash, potentially avoiding further dilution of existing investors.

2. A license deal allows Bio-Tec to securitize a part of BT-100's value, mitigating the risk of phase II & III failure or non-approval.

3. License deals often mean that renowned industry players approve the concept of the drug, which has a value enhancing effect on the whole company.

Midpharm enters the scene

On an industry conference Mrs. Business Developer from Bio-Tec got approached by Midpharm, a mid-sized pharmaceutical company specialised in the cancer market. Midpharm has shown interest in licensing BT-100. After having exchanged confidential disclosure agreements Midpharm started a due diligence of BT-100's preclinical results and of the current phase I/IIa setup. Mrs. Business Developer then received a letter from Midpharm, saying that they seriously consider in-licensing BT-

100. Attached Midpharm sent a term sheet where they offered to license BT-100. The main points of the term sheet are displayed in the table below:

Midpharm exclusively in-licenses worldwide rights for BT-100 under the following financial terms:

Milestone payments	In EUR mio
Upfront (cash)	1
1st dose phase IIb	1
1st dose phase III	3
Submitting NDA	5
Marketing approval	6

In addition, Midpharm pays 4% of net sales as royalties to Bio-Tec.

Mrs. Business Developer immediately heads for Dr. CEO's office, presenting him the term sheet.

Evaluating the options

Dr. CEO took a look at the term sheet and commented that these terms will hardly please Bio-Tec's investors. On the other hand it seems pretty clear that this term sheet is meant as a low-balled starting point for negotiations. Although Dr. CEO has not considered licensing BT-100 right now, this might be an attractive way to take the company forward. Especially because Dr. CEO considers that the core competence of the company is not in cancer, but in CNS. He could therefore use the cash to bring the company's core project BT-102 forward. Dr. CEO decides to consider Midpharm's term sheet and asks Mrs. Business Developer to provide him with the necessary analysis to respond to Midpharm. In particular, Dr. CEO wants to know:

1. What is BT-100 worth if Bio-Tec decides to commercialise it on its own?

2. What can Bio-Tec expect to achieve in a license contract after positive phase II data (phase III deal)?

3. What deal terms would be reasonable for a phase I/IIa deal?

4. What deal terms should Bio-Tec get to reach a similar result to a phase IIb deal?

5. What counteroffer should Bio-Tec make?

6. Are there other reasonable options?

Market research

Mrs. Business Developer immediately starts working on these six questions. First, she establishes the data for the clinical trials, including development costs, timelines, and success rates. Mrs. Business Developer assumes

Clinical development data

	Phase I/IIa	Phase IIb	Phase III	Approval
Costs	4	10	68	2
Duration	2	2	3	1
Success rates	64%	42%	69%	85%

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.

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