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Merck & Company: Evaluating a Drug Licensing Opportunity

Rich Kender, Vice President of Financial Evaluation & Analysis at Merck, was working with his team to decide whether his company should license Davanrik, a new drug with the potential to treat both depression and obesity. The small pharmaceutical concern that developed the drug, LAB Pharmaceuticals, lacked the resources to complete the lengthy approval process, manufacture the compound, and market the drug. LAB had approached Merck with an offer to license the compound. Under this agreement, Merck would be responsible for the approval of Davanrik, its manufacture, and its marketing. The company would pay LAB an initial fee, a royalty on all sales, and make additional payments as Davanrik completed each stage of the approval process.

Merck

In 2000, Merck & Co., Inc. was a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of human and animal health products, directly and through its joint ventures, and provides pharmaceutical benefit management services (PBM) through Merck-Medco Managed Care. Since 1995, Merck had launched 15 new products including Vioxx™ for the treatment of osteoarthritis, Fosamax™ for the treatment of osteoporosis and Singulair™ for treating asthma. The Company earned $5.9 billion on 1999 sales[1] of $32.7 billion, about a 20% increase from 1998. **Exhibits 1** and **2** contain Merck's Income Statement and Balance Sheet.

A handful of Merck's most popular drugs, Vasotec™, Mevacor™, Prinivil™, and Pepcid™, generated $5.7 billion in worldwide sales. The patents for these drugs, however, would expire by 2002[2]. Once the patents expired, Merck anticipated that the sales of these drugs would decline substantially as generic substitutes became available. The only way to counter the loss of sales from drugs going off patent was to develop new drugs and constantly refresh the company's portfolio. The company develops new compounds primarily through internal research, but complements this

[1] Including $15.2 Billion in Medco (PBM) sales.

[2] Deutsche Bank Equity Analyst Report, January 2000.

David Krieger (MBA '00) and Professor Richard S. Ruback prepared this case. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

through initiatives with biotechnology companies to ensure Merck is on the leading edge of select therapeutic categories.

Davanrik

LAB Pharmaceuticals originally developed Davanrik to treat depression. Antidepressant drugs work by affecting certain parts of the central nervous system. Various receptors in the human brain, when stimulated or blocked, create or inhibit various moods. The serotonin system controls nervousness, depression, insomnia, hunger, sexual dysfunction, nausea, and headaches. Through a combination of chemical compounds, the receptors in this system of cells can be stimulated or blocked to treat a patient with one or more of the given symptoms[3]. Davanrik seemed not only to stimulate the receptor that promotes antidepression, but also to block the receptor that causes hunger.

At the time of LAB's offer, Davanrik was in pre-clinical development, ready to enter the three-phase clinical approval process required for pharmaceuticals in the United States. In Phase I, the drug is given to a small number of healthy volunteers to test for safety. This usually takes about 1½ years. In Phase II, a larger number of patients are tested to determine if the drug is effective in treating a certain condition and to measure potential side effects. This usually takes about 2½ years. Finally, in Phase III, a large number of patients are tested for safety and efficacy. This phase takes about 3 years to complete. **Exhibit 3** summarizes the FDA approval process.

LAB Pharmaceuticals specializes in developing compounds for the treatment of neurological disorders. While the company was only 15 years old and though it had a few drugs in Phase II and Phase III testing, none had successfully completed the FDA approval process. In fact, the FDA had recently denied approval of another of LAB's compounds that had completed all three phases of clinical testing; LAB's stock price fell by over 30% in response to this decision. As a result, LAB was hesitant to issue additional equity to finance the testing of Davanrik and was seeking a larger pharmaceutical company to license the drug and provide LAB with some much-needed cash. The licensee would design, administer, and fund the clinical testing of the compound, its manufacturing and its marketing. The licensor, LAB, would receive an initial payment followed by additional payments as Davanrik completes each clinical testing phase. LAB would also receive a royalty on the eventual sales of Davanrik.

Davanrik's Potential Cash Flows

Rich Kender assembled a team to evaluate the potential profitability of Davanrik. Senior researchers evaluated scientific aspects of the compound, and marketers evaluated the market size, potential competition, and requirements to successfully launch the drug. Meanwhile, manufacturing managers determined the capital required to produce the drug, and people in Kender's own department built a financial analysis of the licensing decision.

The evaluation team determined the costs and likelihood of completing each stage of the FDA approval process along with a forecast of profitability of the drug if it successfully completed the approval process. Overall, the approval process was expected to consume about seven years. LAB obtained a patent on the product which is estimated to have a remaining life, including all possible

[3] From The Merck Manual of Diagnosis and Therapy, Section 15, Chapter 189 (Mood Disorders).

extensions, of 17 years. Therefore, the product would have a 10 year period of exclusivity, beginning in 7 years.

Phase I Davanrik would be administered to 20-80 healthy people to determine if the drug was safe enough to continue into the efficacy stages of clinical testing. Phase I would take two years to complete. It was expected to cost $30 million, including an initial $5 million fee to LAB for licensing the drug. There was a 60% chance that Davanrik would successfully complete Phase I.

Phase II In this phase, Davanrik would be given to 100 – 300 patient volunteers to determine its efficacy for treating depression and/or weight loss and to document any side effects. To complete the efficacy tests, Davanrik would have to demonstrate a statistically significant impact on patients suffering from depression, obesity, or both. The Merck team estimated a 10% probability that Phase II would show that Davanrik would be efficacious for depression only, a 15% probability for weight loss only, and a 5% probability that it would be efficacious for both depression and weight loss at the same time.[4] Like Phase I, Phase II would require two years of clinical testing to complete. Phase II was expected to cost $40 million, including a $2.5 million licensing milestone payment to LAB.[5]

Phase III In Phase III, Davanrik would be administered to 1000-5000 volunteers to determine safety and efficacy in long term use. Because of the number of volunteers and nature of testing, this was the most costly of the phases and was expected to take three years to complete. The costs and probabilities of success depended on the outcome from Phase II. If Davanrik was effective for only depression, Phase III trials would cost $200 million including a $20 million payment to LAB, and have an 85% chance of success. If it were effective for weight loss only, it would cost $150 million (including a $10 million LAB payment), and have a 75% chance of success. If, however, it was efficacious for both weight loss and depression, more specialized trials would be required to determine efficacy for the dual indication. The total cost of the Phase III clinical tests for the two separate indications together with the dual indication was expected to be $500 million, including a $40 million licensing payment to LAB, and had a 70% chance of successful outcome. Under this scenario, there was a 15% chance of a successful outcome for depression only, and a 5% chance of a successful outcome for weight loss only. The probability of complete failure of the dual indications or either separate indication was only 10%.

Davanrik had substantial potential profits, especially if it was effective both as a treatment for depression and weight loss. If the drug were approved only for the treatment of depression, it would cost $250 million to launch, and had a commercialization present value of $1.2 billion.[6] If Davanrik were only approved for weight loss, it would cost $100 million to launch, and would have a PV of $345 million. However, if Merck could launch the product with claims for both indications, it would cost $400 million to launch and have a PV of $2.25 billion.

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[4] According to the FDA, a pharmaceutical must prove dual indications in addition to proving each indication separately if it wants to be able to claim therapeutic effects for people suffering from both disorders.

[5] All cash flows are expressed as after-tax present values discounted to time zero, including capital expenditures.

[6] This PV was calculated as the after-tax present value of 10 years worth of cash flows from the drug discounted back to today. It was believed that after 10 years, the drug had very little value to the company since it would be off its patent by then (and thus a terminal value of zero was used in the calculation).

Exhibit 1 Consolidated Statement of Income & Retained Earnings

	Year Ended December 31,		
	1999	**1998**	**1997**
Sales	32,714.0	26,898.2	23,636.9
Costs, Expenses, and Other			
Materials and production	17,534.2	13,925.4	11,790.3
Marketing and administrative	5,199.9	4,511.4	4,299.2
Research and development	2,068.3	1,821.1	1,683.7
Acquired research	51.1	1,039.5	0
Equity income from affiliates	(762.0)	(884.3)	(727.9)
Gains on sales of businesses	0	(2,147.7)	(213.4)
Other (income) expense, net	3.0	499.7	342.7
	24,094.5	18,765.1	17,174.6
Income Before Taxes	8,619.5	8,133.1	6,462.3
Taxes on Income	2,729.0	2,884.9	1,848.2
Net Income	5,890.5	5,248.2	4,614.1
Basic Earnings per Common Share	2.51	2.21	1.92
Earnings per Common Share Assuming Dilution	2.45	2.15	1.87
Retained Earnings Balance, January 1	20,186.7	17,291.5	14,772.2
Net Income	5,890.5	5,248.2	4,614.1
Common Stock Dividends Declared	(2,629.3)	(2,353.0)	(2,094.8)
Retained Earnings Balance, December 31	23,447.9	20,186.7	17,291.5

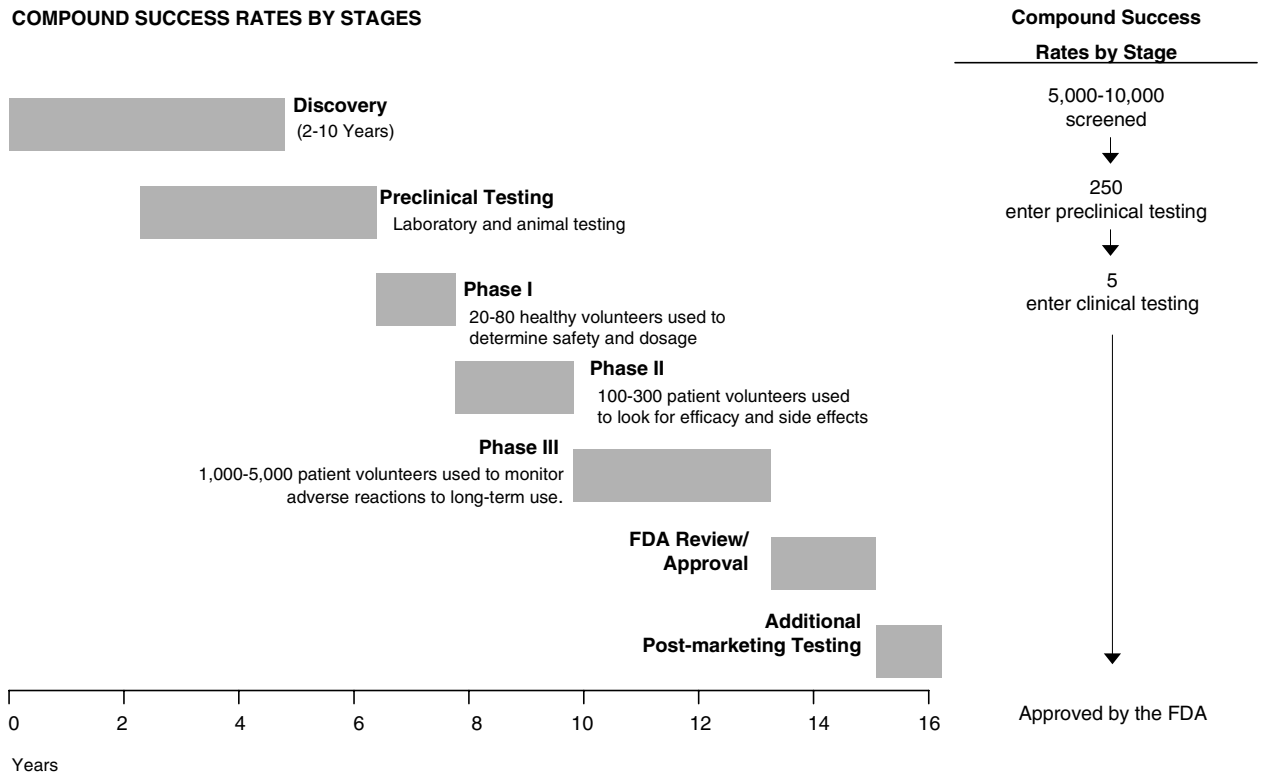
Source: 1999 Merck & Co. Annual Report.

Exhibit 2 Consolidated Balance Sheet

	Year Ended December 31,	
	1999	1998
Assets		
Current Assets		
Cash and cash equivalents	2,021.9	2,606.2
Short-term investments	1,180.5	749.5
Accounts receivable	4,089.0	3,374.1
Inventories	2846.9	2,623.9
Prepaid expenses and taxes	1,120.9	874.8
Total current assets	11,259.2	10,228.5
Investments	4,761.5	3,607.7
Property, Plant and Equipment (at cost)		
Land & Buildings	4,725.0	3,892.8
Machinery, equipment and office furnishings	7,385.7	6,211.7
Construction in progress	2,236.3	1,782.1
	14,347.0	11,886.6
Less allowance for depreciation	4,670.3	4,042.8
	9,676.7	7,843.8
Goodwill and Other Intangibles	7,584.2	8,287.2
Other Assets	2,353.3	1,886.2
	35,634.9	31,853.4
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable and accrued liabilities	4,158.7	3,682.1
Loans payable and current portion of long-term debt	2,859.0	624.2
Income tax payable	1,064.1	1,125.1
Dividends payable	677.0	637.4
Total current liabilities	8,758.8	6,068.8
Long-Term Debt	3,143.9	3,220.8
Deferred Income Taxes and Noncurrent Liabilities	7,030.1	6,057.0
Minority Interests	3,460.5	3,705.0
Stockholder's Equity		
Common Stock	29.7	29.7
Other Paid-in capital	5,920.5	5,614.5
Retained earnings	23,447.9	20,186.7
Accumulated Other Comprehensive Income (loss)	8.1	(21.3)
	29,406.2	25,809.6
Less treasury stock, at cost	16,164.6	13,007.8
Total stockholders' equity	13,241.6	12,801.8
	35,634.9	31,853.4

Source: 1999 Merck & Co. Annual Report.

Exhibit 3 Compound Success Rates by Stage



Source: PhRMA, based on data from Center for the Study of Drug Development, Tuft University, 1995.