

# Valuation Of Biotechnology—Stage Of Clinical Development Is Most Important

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## Complexity of Valuation of Biotechnology

Valuation of biotechnology is very complex. There are a number of factors impacting the value of biotechnology companies and their assets that are difficult to evaluate. One major question is: will this development company ever have a product that will reach the market and generate sales? Other factors impacting the valuation of biotechnology include: expected time to market, expected market size, product pricing, expected market penetration, the strength of the technology and intellectual property, presence of major pharmaceutical partners, attitudes towards certain

scientific developments (e.g. stem cell research, cloning and genetically modified organisms), competitive products in development, competitive products in the market, and management strength.

The volatility of the sector adds further difficulty to the valuator's task.

However, we have observed that when determining value, the market places significant emphasis on the stage of clinical development. In this paper we examine this hypothesis.

## Stage of Clinical Development

Development of a therapeutic for the treatment of disease requires a process of obtaining regulatory ap-

proval for the sale of the drug. Each country has its own regulatory body such as the Food and Drug Administration (FDA) in the U.S. and the Health Protection Branch (HPB) in Canada.

In order for a drug to be approved for sale or use by consumers, there are several stages of clinical development. The objectives of the phases of clinical development can be summarized as shown in Table 1.

The typical costs and success rates can be summarized as shown in Table 2.<sup>1</sup>

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Table 1. From the initial idea to the marketplace: The typical drug development & approval process

2-3 Years	1 Year	6 Years			1-2 Years		
An Average of 10 Years							
Research	Preclinical Development	Clinical Development			Review & Approval	Commercialisation	
Idea ▼ Target ▼ Hit ▼ Lead ▼ Candidate Drug	To assess: • Safety • Biological activity	Phase I To evaluate: • Pharmacokinetics & pharmacodynamics (absorption, distribution, metabolism & excretion) • Safety	Phase II To evaluate: • Efficacy • Safety • Optimal dosage & regimen	Phase III To evaluate: • Efficacy • Safety of long term use	Regulatory Submission for Approval	Review & approval by regulatory authorities	• The drug is made available to the public • Post marketing studies pharmacovigilance on a long term basis
Laboratory	Laboratory & animal studies	20-50 healthy subjects (patients in specific cases)	100-300 patients suffering from the disease the drug is intended to treat	500-5,000 patients suffering from the disease the drug is intended to treat			

Source: Biochem Pharma, 1998 Annual Report

**Table 2. The typical regulatory path for drugs is long, costly and uncertain.**

	Preclinical	Phase I	Phase II	Phase III	Submission for new drug approval	Phase IV
	Investigational New Drug				New Drug Approval	
<b>Typical number of patients</b>	N/A	20-80	100-300	1,000-3,000	N/A	Varies
<b>Timing</b>						
Years	1.6	1.5	1.5	2.5	1.5	5.0
<b>Cost per compound</b>						
\$ million	5.9	7.3	18.9	43.3	1.0	12.5
<b>Attrition rate</b>						
Number of compounds tested for each drug approved	10.0	5.0	3.5	1.5	1.0	1.0
<b>Total cost per approved drug</b>						
\$ million	59.0	36.5	66.2	65.0	1.0	12.5

**\$240 million**

Source: PERI study of 117 development projects of 20 pharmaceutical companies; Nature Biotechnology, December 15, 1997, McKinsey data.

**Determination of Sample of Companies**

In deriving a sample of companies to evaluate our hypothesis, we used the following criteria:

1. The company is engaged in the development of a human therapeutic.
2. The company is not in financial difficulty.
3. The company’s lead therapeutic is in (or expected to launch—for pre-clinical companies) human clinical trials.
4. The company does not have significant revenues.

After applying the above criteria our sample contained 30 companies, (see Appendix 1).

We then segregated the companies into three groups according to the stage of development of their lead therapeutic.

1. Pre-clinical and phase I
2. Phase II
3. Phase III

**Calculation of Technology Value**

We determined the technology value as follows:

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1. A Genetic Revolution in Healthcare, *McKinsey Quarterly*, 1999 number 4.

1. We calculated the market capitalization of each of the companies as of December 31, 2001.

2. We calculated the technology value by subtracting the cash and marketable securities from the market capitalization. We used the balances from companies’ financial statements closest to December 31, 2001.

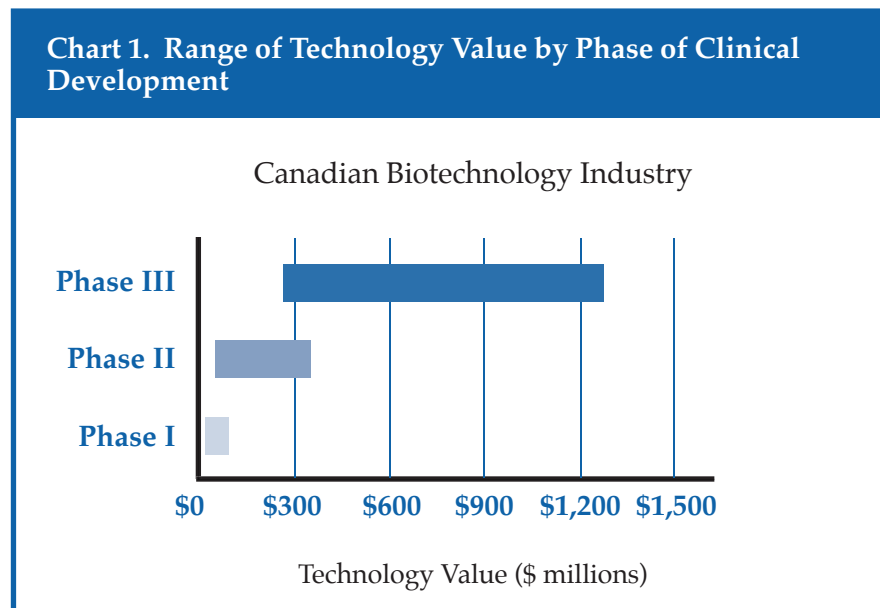
**Conclusions**

1. Stage of clinical development is the most important factor when determining the fair market value of

biotechnology companies and their assets.

2. The stage of clinical development incorporates other major valuation drivers such as expected time to market, strength of the science and technology, management, and intellectual property. Clearly, strength in these other areas will help lead to success in the clinic.

3. The range of technology values for Canadian public therapeutic development companies at December 31, 2001 was as shown in Chart 1.



**Appendix 1. Canadian Biotechnology Industry  
Market Value of Companies—Biotech Industry—Phase III Clinical Trials  
At December 31, 2001**

Name	Area of Study	Number of Projects in Phase					Market Capitalization (CND\$ millions)	Cash & Cash Equivalents (CND\$ millions)	Market Securities & Short term investments (CND\$ millions)	Technology Value (CND\$ millions)	Most Recent Quarterly Financial Statement Available
		Pre	I	II	III	Post III					
1. AEterna Laboratories Inc.	Cancer & Cosmetic Ingredients		1	2	2		\$261.4	\$26.7	\$31.5	\$203.2	9/30/2001
2. Angiotech Pharmaceuticals Inc.	Inflammatory Diseases and Surgical Instruments	6	2	1	2		\$1,386.4	\$3.2	\$152.9	\$1,230.3	9/30/2001
3. Biomira Inc.	Cancer			2	1		\$348.1	\$26.4	\$55.5	\$266.2	9/30/2001
4. Hemosol Inc.	Blood Substitutes, Cardiac, Cancers	5	2	1	1	1	\$300.7	\$27.4	\$68.4	\$204.9	9/30/2001
5. Inex Pharmaceutical Corp.	Cancer, Infectious Diseases	4		3	1		\$275.3	\$7.5	\$26.5	\$241.3	9/30/2001
6. Stressgen Biotechnologies Corp.	Stress Protein-Based Immunotherapeutics	3			1		\$264.8	\$1.4	\$46.0	\$217.4	9/30/2001
7. Theratechnologies Inc.	COPD, Hip Fractures, Cell Therapy, Immune	4	1	5		1	\$369.5	\$31.8	\$29.0	\$308.7	8/31/2001
<b>Average</b>		4	2	2			\$458.0	\$17.8	\$58.5	\$381.7	

Notes: 1 Cash and Marketable Securities figures as per most recent quarterly financial statements