

## Term Sheet

For your reference, here is a list of vocabulary terms that are mentioned in this lesson.

**Development cycle [for a biopharma company]** - The process from discovery of a therapeutic target, through preclinical and clinical trials, regulatory approval, and commercialization.

**Product lifecycle** - The course of a product following its introduction, adoption, maturity, and decline. Different strategy will apply at different stages.

**Pre-commercial lifecycle** - The phase that involves R&D, preclinical and clinical development, FDA filing, and launch planning.

**Commercial lifecycle** - The phase that generates revenue from an entity or product going through the pre-commercial lifecycle; it involves launch planning, market development, sales, and discontinuation.

**Contract research organization (CRO)** - An external organization that enters into a contract for different aspects of the research and development of a product. CROs often provide a more affordable option or simplify situations where a company is unable to develop the in-house expertise.

**Virtual drug development** - When a biopharma enterprise contracts out multiple aspects of development to CROs. In some cases, outsourced drug developers will design the development strategy itself that will then be implemented across the more specialized CROs. The lack of overhead and investment to bring expertise in-house reduces the risks associated with a failed drug candidate.

**Clinical development** - Research trials done in humans. Clinical trials for safety and efficacy are a required component of FDA approval.

**Series A financing** - Early financing, coming only after seed funding. This allows the company to secure capital for growth or further development in exchange for equity in the company. This equity may come with stricter terms than later stage (Series B, Series C) funding.

**Publicly-traded company** - A publicly traded company is one where the general public may buy and sell shares of a company's stock. Like other forms of financing, the company is able to raise capital in exchange for equity in the company, but here that equity is dispersed amongst many shares and many shareholders. The initial public offering (IPO), when the company first makes shares available to the public, is a badge of success for a newly formed company. The regulations that govern public companies require various financial disclosures that are not faced by a private company.

**Fully integrated company** - A company that controls all aspects of bringing a product to market (e.g., R&D, manufacturing, marketing, and distribution).

**Clinical stage** - FDA trials of a new product proceed through a defined set of clinical stages to assess the product's safety and efficacy. They begin at Phase 1 with a small trial, usually the first time testing in humans, emphasizing safety. Phase 3 is a much larger, longer trial comparing efficacy against the current standard of care.

**Pre-clinical development** - The research prior to the clinical trials. This may include animal or in vitro studies. Preclinical development is essential in preparation for human trials and a possible indicator of clinical success.

**Portfolio (of a company)** - A collection of financial assets. While traditional financial assets include stocks, bonds, or commodities, in the context of a research organizations, many of these assets will be intellectual property.

### Advanced topics:

**Competitive landscape** - Enumeration of the competition that a company faces, both direct and indirect. This will include the strengths and weaknesses of the competitors and how those fit the customer's needs.

**Market segmentation** - The groups of customers that have similar needs or might respond similarly to a product. Such segments might include income level, age, geography, or, in the case of a therapeutic agent, disease severity and subtype. Understanding market segmentation can identify an area of competitive advantage.

**Market opportunity assessment** - A projection or forecast of sales of a product, typically reported in dollars.

**Forecasting** - Prediction of key drivers (e.g., market size, market share, revenues).

