Case Study

Aquionics[1]

Overview

Aquionics is a biotech start-up that has developed proprietary technology for treatment of glaucoma and with the potential for other applications to be developed later. The Company has tested its product on animals, but has yet to conduct the human-subject clinical testing that is required before the product can be marketed. The entrepreneur faces a difficult and complex strategic decision. The fundamental issue is a trade-off between protecting the value of the intellectual property and limiting the costs and risk of developing the product for commercial use. By carrying out all testing and manufacturing in-house, Aquionics can substantially reduce the risk that others will learn to imitate its success. However, keeping the testing and manufacturing activities in-house requires substantial up-front investments in facilities and deprives the company of near-term cash flows that could be derived from licensing the technology.

The entrepreneur is not particularly concerned with the threat of competition in its application to treatment of glaucoma, where he believes patents held by Aquionics will protect it from imitators. His concern is that by allowing others to gain experience with the technology, Aquionics would be impairing the value of its options to develop other related applications of the technology.

The Alternatives

Commercial development of the product would occur in two stages. The first stage is human clinical testing and the second is commercial manufacturing. Aquionics is considering three approaches for completing the clinical testing. First, it can construct a laboratory facility that is sufficient for carrying out the small-scale manufacturing and testing procedures that are needed for the human clinical testing stage. The Company estimates that, in present valued dollars, the cost of such a facility would be $5 million. One advantage of this approach is that, once the lab is constructed, it would be available for clinical testing of related applications of the technology, raising the value of those applications. Second, Aquionics can sub-contract the clinical testing to an existing laboratory. While it can easily find such a laboratory, the Company is concerned that the risk of losing control of the technology is increased. The present valued cost of sub-contracting this stage of product development is estimated to be $2 million. The third alternative is the simplest. Aquionics can license the technology for treatment of glaucoma to an existing firm that is capable of conducting both the human clinical testing and commercial-scale manufacturing and marketing of the product. It expects that by this approach it could collect an initial license fee of $2 million and a 5 percent royalty on future sales. The initial fee would be collected even if the product did not obtain FDA approval or was not marketed commercially for other reasons. In the event that the

[1] Data and the company name have been disguised to preserve confidentiality.

product receives FDA approval after the testing phase, the Company believes the present value of licensing royalties will be $10 million.

If Aquionics selects either of the first two alternatives for developing the product, it must provide separately for commercial production and marketing. Two alternatives are under consideration. First, the Company, itself, can undertake commercial-scale manufacturing of the product. If it does, a present valued investment in manufacturing facilities of $6 million is needed. In this case, the Company would partner with an existing pharmaceutical firm to market the product. Aquionics believes the present value of cash flows from manufacturing the product itself will be $20 million, if the product is approved. Alternatively, it can license both manufacturing and marketing to the pharmaceutical firm in exchange for a licensing fee. The present value of royalties from licensing manufacturing and marketing is expected to be $12 million, if approved. Aquionics is concerned that, by licensing manufacturing, it will jeopardize the value of related products it could develop.

Assessing the Risks

In its efforts to assess the various alternatives, the Company has focused on three scenarios. Overall, there is a 70 percent chance that clinical testing will gain FDA approval and be successful, leaving a 30 percent chance of failure and abandonment, in which case commercial development will not occur and the company would lose any investment it may have made.

If the product is approved, there are two possible outcomes. One is that, the product is a success and that success affords opportunities to develop a number of related products. Aquionics has analyzed this possibility, and believes that the probability of this scenario (conditional on FDA approval) is 40 percent. In this scenario, the net present value of those products depends on how widely shared the information about the technology has become. If Aquionics conducts the clinical studies itself, and also undertakes commercial manufacturing, the value of related products is estimated to be $5 million. If it subcontracts clinical testing or licenses commercial manufacturing, the value of related products is reduced by half. If it licenses both clinical testing and manufacturing, the value of related products is reduced to $1 million.

The other scenario, if FDA approval is obtained, is one where clinical testing is a success, but related applications are not found. In this case the product returns are unchanged but the value of related products is zero, irrespective of which approach is used to develop the product. The probability of this scenario (conditional on FDA approval) is estimated to be 60 percent.

How would you advise the entrepreneur?