- A premarketing approval (PMA) application rather than a 510(k) probably will have to be filed with the FDA for approval of any cytokine diagnostic. As a PMA is more expensive and time-consuming to prepare than a 510(k), diagnostic companies are expected to shy away from pursuing PMAs unless they can be assured of a payback — something that has not been established for cytokines.

The research market is a different story. Many of the diagnostics industry's larger and smaller participants produce a variety of assays for detecting the presence of cytokines or measuring their amount. For example, **Boehringer Mannheim Corp (Indianapolis, IN)** produces antibodies to all of the cytokines discussed in this article, as well as a broad number of other growth factors. The much smaller R&D Systems produces its line of Quantkine immunoassays for 29 cytokines and claims that it is the broadest product line for cytokines for the research market.

However, research into diagnostics for cytokines has not reached the end of history. A number of companies are investigating cytokine assays that would be more sensitive than existing ones. For example, two companies reported on new assays for cytokines at the Oak Ridge Conference, which was held April 14 and 15 in Tampa, FL. They are:

- **Fujirebio Inc (Tokyo, Japan)** is developing a chemiluminescent assay for IL-6 that uses crystal ferrite particles coated with gelatin as a solid phase and CSPD as a substrate. The two-step sandwich assay can provide results in 2 minutes. Fujirebio researchers have used the assay on the Lumipulse 1200 system to detect a minimum level of IL-6 in serum 0.5 pg/ml. The average level of IL-6 in normal serum is 2.6 pg/ml.

- **T Cell Diagnostics, Inc (Cambridge, MA)** reported on a refinement of the standard microtiter plate enzyme immunoassay containing a strepavidin-coated microtiter plate, a horseradish peroxidase-labeled anti-fluorescein conjugate, and fluoresceinated or dual-labeled bovine serum antibody controls. The assay has been used to determine levels of IL-8 and gamma interferon, as well as other analytes.

MACRO ISSUES

Talking the Language Of Venture Capitalists

Summary

Do venture capitalists and entrepreneurs speak the same language? Sometimes, but not always. And, when scientific entrepreneurs find themselves needing the assistance of a venture capitalist, Cool Hand Luke's proverbial failure to communicate can prevent a much-needed financing.

There are, however, a few simple steps that can be taken to bridge the communication gap between the scientific entrepreneur and the venture capitalist. First of all, the process of due diligence in which financiers thoroughly research a company before providing an investment can be equally effective when used in reverse. Entrepreneurs who investigate the financier and know the potential backer's expectations will find it much easier to explain the competitive advantage of their products. Secondly, a financier who can be convinced of the market potential of a product can usually be persuaded to risk a financial commitment to the enterprise. So, product attributes should not only be defined accurately, but should also be described in comparison with competitors. Finally, venture capitalists require communication that enhances, not muddles, the entrepreneur's case for support. Too often, competitive advantage is poorly stated or omitted in business plans that are crammed with convoluted technical descriptions which do not link a product to market demand or need.

This article is intended to provide executives of small companies and entrepreneurs a short guide to communicating effectively with venture capital firms. Although some of this material may seem obvious to those who have had experience with financings, THE GENESIS REPORT/Dx *is publishing this information in response to requests from companies and individuals that have yet to obtain their first funding.*

(Most of the information in this article was provided by Nora Carrol, president of ***First Forward Inc (Alexandria, VA)****, a firm that provides business planning, capital formation, and strategic marketing services to emerging and expanding companies. Additional insights from the venture capitalist's perspective were provided by Franklin J Iris, president of* ***Iris & Associates (Wayne, NJ)****, a medical-industry consulting firm.)*

Communicating Competitive Advantage With a Different Type of Creature

Imagine this hypothetical conversation:

> "We've discovered a real breakthrough in diagnostic monitoring of gene therapy. All we need is $6 million to complete the clinical trials, publish the research in professional journals, and start production."
>
> "That's nice. I didn't know my jeans needed therapy."

The conversation between a senior scientist at a start-up diagnostic firm and a venture capitalist is fictitious, but the point is real: too many scientists, researchers, and technologists do not communicate clearly when they approach financiers to acquire an equity or debt investment or loan, or to negotiate a joint venture essential to commercializing their product or service. Even individuals and organizations who have been clever enough to win research grants may not realize that, in venture capitalists, entrepreneurs face a different creature than the peers they dealt with when applying for a grant. The venture capitalist must be sufficiently convinced of the market potential of a product to embark on the process of reading, understanding, and relating to the business plan to the point that he or she can be persuaded to risk a financial commitment to the enterprise.

The importance of communicating clearly with venture capital firms cannot be overemphasized. Venture capitalists are a major source of funding to the biotechnology and diagnostics industries. According to the annual survey of the biotechnology industry by the accounting and consulting firm **Ernst & Young (New York, NY)**, venture capitalists raised more than $459 million for the biotechnology industry in 1993. This is more than double the $217 million obtained in 1992. (Separate figures for the diagnostics industry are not available.)

Financiers who risk capital want substantial proof that their investments will be in products with significant potential in the marketplace. The venture capitalist's focus is on return on investment (ROI), which is based on the ability of a product to reach and maintain leadership by offering market-perceived benefits superior to competitors' products. In short, investors want to put their money into a company that has products with a competitive advantage. For entrepreneurs about to face financiers, it is critical to understand the product qualities that translate into competitive advantage and to effectively communicate those qualities to financiers.

Expressing competitive advantage requires the entrepreneur to understand both the capital market — the financiers — and the end-user buying market. Financiers have preconceptions based on factors as varied as education, sociocultural attitudes, personal preferences, and prejudices, as well as professional investment experiences. Given this subjective assortment, before the business plans are presented or financing requests made, an entrepreneur must know as much as possible about the personalities and behaviors of the financiers being approached. The process of due diligence — the thorough research of a prospect conducted by financiers when considering an investment — can be equally effective when used in reverse. Investigate the financier, know his or her expectations — and communicating competitive advantage will be that much easier.

Targeting the Correct Venture Capitalists

Equally important for the start-up company is to know the correct venture capital firm to approach. For example, some firms specialize in early-stage financing, while others concentrate on late-stage financing.

Companies seeking financing should also identify the venture capitalist's work in different industries in order to make sure that the firm is comfortable with what their industry demands. It is also important to locate the partner in the firm who specializes in the start-up company's industry and present the business plan directly to that person, rather than making an unsolicited mailing. Venture capital firms are very entrepreneurial. If a partner is approached with a deal and is too busy, he or she may not necessarily pass it to another partner. When partners think they have an ownership in a plan, they regard the plan as their plan.

New companies will want to deal with a financier who is managing two to three deals in health care or diagnostics.

While some venture capital firms specialize in biotechnology or health care financings, many firms are eclectic in their investment approach. One way to find the right firm and the right individual in that firm is to attend meetings of state biotechnology or venture capital organizations. Another way is to contact other small firms that have raised money. While not everyone wants to seek help from a competitor, obtaining a competitor's advice may be necessary in a very small industry.

It is unlikely that any one firm will finance the whole risk, unless there is a very small financing need. A start-up should establish business relationships with a number of financiers, not just with one venture capital firm. This can be achieved by getting a lead investor that will bring in other investors at a very early stage. However, it is more prudent to get at least a couple of financing partners.

Product Attributes Define Competitive Advantage

Competitive advantage is grounded in the relationship between products and their competitors. Technical description alone is insufficient. The advantage must be defined through comparative product and innovation attributes.

Experience is the most effective way to illustrate competitive advantage. Because diagnostic product development encompasses clinical trials, financing requests need to use successful experience (trial results) when available as the primary product attribute, and to position the competitive advantage according to the trial results. For example, how accurate is the test in discriminating "healthy" from "sick" individuals? While such data will be available with late-stage programs, early financings often are needed to get to the point that permits the accumulation of critical data. Isolated "breadboard" components may be useful only in establishing overall proof-of-principle, especially for an instrument/reagent system. Start-ups are then caught between a rock and a hard place: they don't have the funds to develop the system to prove that it works as promised in a business plan.

The results of trials should be identified in comparison to competitors rather than in isolation. Claims of competitive advantage would then have to be based on the prior reputation of a company, which requires credence or faith in the producer.

Innovation Attributes

How can you compare the innovation of products in development to products on the market or to other products in development? Most entrepreneurs believe that *their* new products are innovative. Defining innovative attributes can help the entrepreneur establish and communicate competitive advantage both within the start-up company and, just as importantly, to the financial community.

Product innovations are divided into four groups — more or less compatible, complex, observable, trialable — or a combination of all four. In real marketplace terms, compatibility means that a product offers either an incremental improvement over existing technology (more compatible), or a genuine breakthrough that will turn technologies or foundations of knowledge on their heads (less compatible). Head-turning may be highly exciting at first glance, but — remembering the investor's focus on ROI — may also generate a bad case of jitters if the investor thinks an entire industry needs reinvention to absorb the innovation.

Similarly, complexity can imply either a comparatively simple adjustment within the marketplace (less complex) or the upheaval required for the new product to sell (more complex).

In the diagnostics market, observability and trialability coincide at the clinical testing stage, but what about in the financial and user marketplaces? Can prospective investors and users rely solely on the producer's trials to satisfy their questions and concerns about innovation? Beta-site testing (the controlled evaluation of a product at selected users' locations) can provide information that can direct the last stages of product fine-tuning and provide powerful testimony of product performance in real laboratories. This hard, convincing data can bring about the financing needed to progress to production. Defining the product's innovative attributes in market-competitive language is the communication step needed to convince financiers to take a chance.

Why Can't the Industry Teach Its Techies How to Speak?

Wailing like Professor Higgins complaint in "My Fair Lady" of "Why can't the English teach their children how to speak?," financiers gripe that too many business plans are Byzantine in structure and addling in content. Detailed technology descriptions often read more like a patent application. Too often, competitive advantage is poorly stated or omitted in favor of convoluted technical descriptions that do not link technological advances to market demand or need. Establishing competitive advantage requires clear, business-oriented communication focusing on benefits to the user. In fact, the more extreme the innovation, the more the comparative benefits of a product need to be emphasized.

Competitive advantage comes from differentiating your product from the pack. Differentiation means change, and change makes people anxious. A financier's relative ability to accept and invest in change can be estimated by assessing his or her personal and professional perceptions and then communicating the product's competitive advantage to reflect those perceptions. Key questions to ask include:

- Does this financier invest in diagnostic technology because of a commitment to diagnostic research? Or is the investor interested only in proprietary technology with patents and trade secrets that help to prevent market entry by competitors? Diagnostics happens to be an industry predisposed to such marketplace protection.

- Does the investor want an affiliation with the new company's name because it is prestigious? Or does the investor foresee an opportunity for hands-on management of a new product line, a position on the board, and a decision-making role in further corporate development?

The value of such thinking is shown by an experience at First Forward that involved identifying prospective financiers for a company in the communication technology industry. The company's product was past prototype but not yet marketed. A $5 million equity or debt investment was needed to support a multifacility digital, fiber-optic communication network within a specific consumer environment. Previous attempts to generate commitments from technology-oriented venture capitalists who wanted highly protected opportunities failed because the network is not proprietary and has little or no technological barrier to market entry.

The network's benefits are in its application of existing technology to an untapped marketplace in which early market share, not patents, represent the profit potential. The business plan was revised to emphasize this benefit, and new investment and acquisition prospects with a track record in communication projects emphasizing new or improved applications were identified. Early-stage negotiations are underway.

People Are A Key Ingredient

While positioning the company's technology may be half the battle of getting a venture capitalist's attention, the importance of having the right people in the company is the other half. One way to get the attention of venture capitalists is to have people who can add credibility to a start-up company. The most credible people have:

- Successful experiences in developing small businesses

- Experience in raising capital.

The importance of personnel with a proven track record cannot be underestimated. The experience doesn't absolutely need to be successful. If it is entirely favorable, that's very positive, but even executives who have learned from unsuccessful ventures can lend credence to the organization's awareness of what it takes to run a start-up company. Of course, companies can start without having personnel with proven track records, but this is just one more hurdle that must be overcome to attract attention from venture capitalists. In addition to employing people with a track record, it's important to have individuals who bring energy, personality, drive, and intelligence to the start-up company. There is no room for laid-back corporate types.

Reality Check

Start-up companies must learn to read signals. Companies that have presented a plan to 8 to 10 venture capital firms and haven't received any results may have a very tough row to hoe. Rather than hitting on 1 out of 10 financing opportunities, they might have a long-shot concept facing 1 in 100 odds and may need to reevaluate their corporate strategy and business plan.