FINANCING OF PRODUCT INNOVATION BY SMALL FIRMS
CASE STUDIES IN THE MEDICAL DEVICES INDUSTRY

John Rapoport

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Small Business Administration
Office of Advocacy

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EXECUTIVE SUMMARY

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This report summarizes case studies of 13 small firms which introduced new medical device products, mostly in the 1975-1988 time period. The firms each had less than 30 employees at the time the product was introduced and most were start-ups established to introduce the new product. The case studies concentrate on the costs of innovative activity and the sources of financing used by the firms in the time period prior to the introduction of the innovation. Each case includes narrative description of the firm's origin and early development as well as quantitative estimates of the costs and funds raised. Cases are based on material provided by firm executives in personal interviews.

Four stages of innovative activity were examined: R&D, clinical trials, manufacturing preparation, and marketing start-up. Most firms did not perform all 4 of these activities. Frequently some R&D was performed by an academic or medical institution and often the small firm transferred marketing rights to a larger firm which carried out marketing start-up activity.

All but one of the cases used multiple sources of funds, usually 2-4 different sources. The most frequently used source (9 cases) was personal funds of the company founder. Next most frequent sources (6 cases each) were cash flow from other products or services and funds obtained from another organization involved in the innovation process. Five cases involved public sales of securities. Infrequently used sources of funds were bank loans, venture capital firms and government sources.
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I. INTRODUCTION

Small business firms play a major role in technological innovation. Despite the great importance of large corporate R&D labs the small firm surprisingly often turns out to be the source of major new technologies and frequently an important innovation is the reason a small firm grows big. This study examines the costs and financing of innovation by small firms in the medical devices industry.

Financing any activity for small firms is difficult because they often cannot obtain long term debt or equity finance in regular capital markets. It may be particularly hard for small firms to obtain funds for innovation because of the inherent riskiness of such activity. At the start of a R&D project there is uncertainty about the time, cost and success of the project. Even if the R&D achieves its technical goals, the product may not meet the market test for commercial success. While a large firm may diversify away some risk by having a large portfolio of research projects, the small firm typically has one or a few ongoing projects. Investment in small firms' innovative activity in such situations is unlikely to appeal to risk averse investors. In addition, frequently the small firm engaged in innovation is a new firm, without a track record. This lack of information about the experience of management and capabilities of the firm makes it difficult for suppliers of funds to assess the merits of a potential investment.

Since small firms are an important source of innovations and because innovation itself is an activity for which market incentives
may not be sufficient to induce the socially optimal investment, small firms' difficulties in obtaining funds for innovation are of policy importance. In the U.S. as well as other countries government has attempted to aid small business in innovative activity through policies such as loans or loan guarantees, management training and counseling, and structuring public procurement to assure access for small business. In addition, of course, more general policies such as tax treatment of capital gains, policies affecting interest rate and credit conditions and patent or licensing regulations can have important impacts on small firms. (For a review of government policies toward small firms in U.S. as well as other industrial countries, see Rothwell and Zegveld, 1982)

In this study I examine in some detail the economic and financial aspects of innovation by small firms in the medical devices industry. For each case study I document the sources of funds used in the innovation process, the costs of the specific activities involved and the relationships between the small firm and other firms or organizations which played some role. In most cases the innovation development took place along with the firm's origin, i.e. the firm was a start-up created to introduce a specific new product. In a few cases, however, the firm was established prior to the innovation idea and either had been in another industry previously or had not innovated before.

The plan of this report is as follows. In the next section I review the relevant literature and some of the unique characteristics of innovation in the medical devices industry.
Section III presents the methodology used to identify and develop the case studies. In section IV the cases themselves are presented. Section V contains descriptive statistical analysis of the cases. Section VI is a discussion and conclusion.
II. THE FIRM AND INDUSTRY CONTEXT

A. The Small Firm as Innovator

As the importance of the small firm as a source of innovation has been recognized, the innovative small company has attracted increasing attention in the literature. I do not attempt a comprehensive review of that literature here but simply will mention a few of the major issues which bear particularly on financing and may help to guide the evaluation of our case studies. (For a comprehensive review, drawing on both U.S. and foreign experience see Rothwell and Zegveld, (1982))

Some writers have focussed on the origin and development of small high technology firms. For example, Bullock (1983) characterizes the process as one of "hardening". In his terminology, a "soft" company is one which is engaged primarily in consultancy services or providing technical solutions to specific problems for a few clients. Such a company may be started by an academic and represents a method of technology transfer from the university to the commercial environment. Over time the firm evolves to a "hard" company, i.e. one which introduces and sells a standardized product to many buyers. The financing of such a company is frequently accomplished easily with the use of internal funds. The soft phase does not require much initial investment and as the company matures the transition to innovation of a standard product can be financed in large part by the cash flow from the
"softer" activities. Thus the innovation is not dependent on external sources of finance.

Two other patterns are referred to by Bullock as the "warm garage" start up, the classical success story of the individual inventor, and the "industrial spin-out" company where a small firm is started by an entrepreneur who leaves a larger company in the same general area of technology to pursue a particular innovation. Both of these companies are "hard" from the outset and are more dependent on external financing.

Whatever the form of the start-up company, certain personality characteristics seem to be typical of the founder of a new technologically based company. The most important is perhaps a desire for independence. As Rothwell and Zegfeld note, "technological entrepreneurship is an intensely personal and idiosyncratic act" (Rothwell and Zegfeld, page 92). The founders of these companies have a high degree of motivation and a desire to run their own show. This can condition to some extent the type of finance source used. The entrepreneur must balance the need for external capital against the likelihood that a supplier of funds may require some say in how the business is run.

An innovative small company need not be a new firm. As Herbert Fusfeld notes, "Policy discussions on this subject include three quite separate words—small, new and technical—in referring to activity for bringing technical advances into commercial use through entrepreneurial activity. There is a tendency to use the three words interchangeably in connection with such activity." (Fusfeld, page 247). Such use is of course misleading. An innovation can come
from a small firm which has been long established and produces other products either in the same industry or a different one. The sources of finance open to such a firm are very different from those available to a start-up firm which is being established to develop and introduce a new product. In particular, the existing firm can use retained profits from its other products to finance the investment in R&D and other activities necessary to innovate.

Various steps in the financing of new innovative companies have been identified. One set of definitions commonly used in the venture capital industry is shown in Figure I. These are useful to get an idea of the typical process a firm goes through but they may imply a more regular and routine process than actually exists. The suggestion is that there is a regular progression from new product concept to publically financed company. This need not be the case however. Some steps may be omitted or the order may be different than the definitions imply. Some firms may never become public, or even aspire to do so. Also, financing a company is not identical to the financing of an innovation. An innovation may involve work by several companies or other organizations and from a social viewpoint resources expended by all of them represent costs of innovation. Thus where possible I will attempt to identify funds used in the innovation process even if they aren't funds used by the firm which is the primary innovator.
Figure I
Definitions of Stages of Venture Capital Financing

Seed: A relatively small amount of capital provided to an inventor or entrepreneur to prove a concept. It may involve product development but rarely involves initial marketing.

Startup: Financing provided to companies for use in product development and initial marketing. Companies may be in the process of being organized or have been in business a short time (1 year or less), but have not sold their product commercially. Generally such firms would have assembled the key management, prepared a business plan and made market studies.

First stage: Financing provided to companies that have expended their initial capital (often in developing a prototype) and require funds to initiate commercial manufacturing and sales.

Second stage: Working capital for the initial expansion of a company which is producing and shipping and has growing accounts receivable and inventories. Although the company has clearly made progress it may not yet be showing a profit.

Third stage: Funds provided for the major growth expansion of a company whose sales volume is increasing and which is breaking even or profitable. These funds are utilized for further plant expansion, marketing, and working capital or development of an improved product.

Fourth stage: The last round of private financing prior to, but not in anticipation of, a public offering or prior to the point at which a company can qualify for credit-oriented institutional term financing.

Bridge Financing: Financing for a company expecting to go public within 6 months to a year.

There is also a difference between the social and private view of the relevant goal of the process. The venture capital framework suggests that a firm's reaching a state of profitability and continued growth defines success. However, an innovation can be a success from a social viewpoint even if it is not profitable for the firm. (Romeo and Rapoport (1984), Mansfield et al. (1977)) In the extreme case, perhaps, a small firm might innovate a new product but be unable to profitably market it after the initial introduction and go bankrupt. From the standpoint of the owners of the small firm or from a management viewpoint this is clearly not "success". However, if the innovative product is transferred to another firm which continues to market it, or if the technology contributes to other innovations, there may well be a net social benefit from the firm's innovative activity and it should be counted as successful from the viewpoint of society.

B. The Innovation Process

The innovation process is non-routine and different for each new product. However, certain activities are undertaken in most product innovations and a breakdown of the process into specific stages is useful. While R&D is often an important precursor of innovation, activities beyond R&D are needed before a new product is introduced to the market. Thus one must be careful not to equate the cost of R&D with the cost of innovation. Studies have shown that R&D may
account only for about half the costs of innovation, with manufacturing preparation and marketing activity accounting for the rest. (Mansfield et al. (1977), U. S. Department of Commerce (1967))

The different specific activities can have different sources of finance. The later activities, i.e. manufacturing start-up and marketing start-up may be perceived as less risky by external investors since the technical problems have already been solved. Thus it is possible that R&D can be internally financed and on the basis of successful R&D results a firm may attract external finance for the later stages of the innovation process.

Another implication of the breakdown of the innovative process into stages of activity which is particularly relevant in the case of small firms is that different activities may be carried out by different organizations. A large firm typically can undertake all the necessary activities from basic research through the marketing and distribution of the new product. At the very start of the innovation process, the decision about what to work on, it has been noted critically that often large firms are subject to the "not invented here" syndrome, a reluctance to work on technologies which have not been internally developed. Small firms, at least new small firms, do not have this luxury. With no backlog of internally developed technology they obviously cannot restrict their scope in this way. Thus, they may be more likely to seek out and pursue innovation ideas obtained from university or other basic research organizations.

Also at the later stages of the innovation process, the small firm may be more likely than a large firm to cooperate with, or
transfer technology to another organization. A study of joint ventures found that innovation was an important focus of collaboration between large and small firms. The authors noted: "Some technology-transfer JVs seem to involve a large firm financing a small firm's research into a new product (and perhaps contributing some to development and marketing). The large firm buys a 'piece of the action' by supplying capital for the small firm at what is essentially a lower rate than the small firm could obtain in capital markets" (Berg, Duncan and Friedman, page 71).

Such things create certain problems for researchers attempting to study the process of industrial innovation. "The innovation" is not always easily definable and not always easy to associate with a single firm as "the innovator". Numerous firms, as well as academic or other research organizations, may be associated with a particular area of technology and the nature of scientific and technological advance is that it is cumulative and current developments depend on what has gone before. The underlying scientific base is essential for most innovations and the nature of the flow of technological and scientific information means that any attempt to attribute certain results to specific actors will probably oversimplify a complex process.

The end point of the innovation process is not always clear. A patent or invention is not an innovation since an invention per se has not produced any economic impact. The usual practice is to define innovation as the introduction of a new product to the market, i.e. to focus on the initial sale of a new manufactured item. This, however, doesn't necessarily mark the end of a firm's
development effort since frequently the product is constantly being improved, refined or modified. Also the time period and the marketing expense between the first sale and large scale distribution may be significant.

B. The Medical Devices Industry

The medical devices industry is an area of active technological change. It is also an industry in which government policy plays a particularly important role. In evaluating the case studies it is important to understand some of the characteristics of the industry structure and regulatory environment.

Medical devices are regulated by the federal government through the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act. Modeled after the existing drug regulation framework, the Amendments charge the Food and Drug Administration with regulating the safety of new medical device products. The regulation is organized on a three-level basis. Class I (General Controls) requires manufacturers to maintain Good Manufacturing Practices, to register their establishments with the FDA, and to meet requirements regarding things like labeling and record keeping. All products are subject to Class I regulation and for some products these are the only regulations which apply. Class II (Performance Standards) requires a product to meet criteria established for a product of its type. A product is usually classified in Class II if the FDA determines that it is substantially equivalent to a
device already on the market. Class III (Pre-market Approval) the highest level of regulation, requires that a firm provide evidence that the new product is safe before being allowed to sell it. Typically this requires clinical trials similar to those required for new drugs. Most new products are regulated in Class II. An FDA analysis based on 1984 data reported that Class I was the highest regulatory class for about 14% of all establishments while about 7% of establishments had Class III products. (Gieser, page 33)

Government policy affects the demand for medical innovations as well as the supply. The economic success of many medical device products is tied to decisions about reimbursement for services requiring their use. Medicare and Medicaid, the major government health insurance programs, are major buyers of many medical services. In addition decisions of federal agencies about what therapies or devices are eligible for coverage are often looked to by private insurers for guidance as to when a device or service has moved from the "experimental" category which is typically not a covered benefit to a service eligible for reimbursement. (Demlo et al., 1984)

Economic implications of government regulation for innovation in the biomedical industry were explored by Roberts and Hauptman (1987). They note that technologically novel products in this area have high perceived risk associated with their use and thus attract the most stringent FDA attention. They argue that the costs of regulatory compliance, including both direct costs of activities required by regulation as well as the possible delay in product introduction which can result, raised the threshold financial capital needed to
start a new firm in this industry above what it would be for a similar firm in other technologically based industries. Their estimate is that the threshold amount is $850,000-1,000,000 (in 1970-75 dollars.)

Most firms in the industry are small. According to the FDA, in 1984 about half of the firms had fewer than 20 employees and about 3/4 of firms in the industry had fewer than 100 employees. Small firms tended to be self owned, single site operations, while those with over 100 employees were somewhat more likely to owned by another firm. The number of self owned single site establishments was also increasing faster than the number of other establishments. (Gieser, p. 17-23). Of course not all new firms are established to introduce innovations but this picture certainly suggests an industry where small firm innovation is active and important. The Division of Small Manufacturers Assistance has been established within the Food and Drug Administration to assist small business in complying with the medical device regulations.
III. METHODS

The question of how to define "small firm" had to be addressed at the outset in order to determine the population of firms for study. Employment of 500 employees is commonly used to mark the upper limit of firm size in studies of small firms. Many studies of small firm's innovative performance have been based on data sets using this definition. (Acs and Audretsch, (1987) for example) This seemed inappropriate for this study however. A firm of several hundred employees is typically an established company with several products and frequently a complex financial structure. Such firms certainly innovate but it is hard to tie any particular innovation to a given set of financial arrangements. R&D is financed out of the firm's overall cash flow or from debt and equity finance obtained in public securities markets. A much more specific link between finance and innovation could be made with firms at the very bottom of the size range, typically start-up firms. It is also there that problems in obtaining funds are likely to be most acute, where information about how firms are financed is less available from public sources and where the need for policy intervention most likely. This study's focus is therefore on very small firms, newly established companies which are typically started for the specific purpose of innovating or small companies which introduce innovations early in their life. Indeed some of our cases even go back beyond the date of formation of the company to when an individual inventor was working on his own without any specific business organization.
To select firms as case study subjects the following procedure was used. The Medical Device Register is an annual trade directory which lists all firms registered with the FDA as manufacturers or sellers of medical devices. From the latest edition of this volume firms in the Northeastern U.S. which manufactured medical devices were identified. The directory also shows for most firms the number of employees and the ownership of the firm. I selected those firms with under 100 employees which were not owned by a larger company. This produced a list of several hundred firms. Many of these firms, of course, were not involved in innovative activity. Firms which were likely to be involved in innovation were identified from two additional sources: The Directory of American Research and Technology, which lists firms active in R&D, and the Medical Devices, Diagnostics and Instrumentation Report, a weekly newsletter, which among other things mentions new product developments and regulatory approvals. Small firms on the list of medical device manufacturers which were also in one of these two sources were further considered as possible case studies. Finally, I eliminated those firms whose main business was consulting or contract manufacturing rather than making and selling standardized products. Also firms for which medical devices were only a sideline rather than a significant part of the business were not included. This process produced a group of about 30 firms as possible subjects.

Firms from this list were contacted by phone to see if they were suitable cases and if they would be willing to participate. Some were eliminated on the basis of this brief phone interview because they had not in fact introduced any new products, were not
in the medical devices industry or because some of the information from the directories had changed or was incorrect. A few firms refused to participate in the study because executives did not have time to be interviewed or were concerned about confidentiality. Where firms were willing to participate a visit for a personal interview was scheduled. (One case is an exception to this—information for it was compiled only by mail and phone interview.) In most firms the person interviewed was the founder and current chief executive of the firm. In a few cases the interview was with an executive other than the firm's founder.

The above procedure would appear to have produced a reasonably representative sample of small firms active in innovative activity in the past 5-10 years, although it is not a strictly random sample. Several specific possible omissions might be noted however. Firms which introduced new products and then failed would not have been picked up by this procedure. In the constantly changing population of small firms undoubtedly there are firms who attempt innovation and whose work never reaches the market or does reach the market but does not last very long. Several potential case studies identified from directories ended when attempts to contact the firm ran into a disconnected telephone or a "no forwarding address" report from the post office. Another group of firms which were probably missed were those which started small and very rapidly grew large or were acquired by large companies. They did not linger in the small firm stage long enough to be reported in the directories and picked up by the search procedures.
The interview format was initially unstructured. The respondent was asked to explain the circumstances surrounding the establishment of the firm, particularly the sources of funds for the initial capitalization. In this discussion it usually became evident that the firm had been started specifically to develop and commercialize a particular innovation. Where this was not clear, or where the firm had initially been started in an industry other than medical devices, I asked the respondent to identify the first important medical device innovation the firm had introduced and that was the innovation discussed.

The interview then covered the specific activities leading up to the introduction of the new product. Four stages of innovative activity were used: 1) R&D. This included scientific research and development work leading to the development of a working prototype, 2) Clinical trials. This stage, involving testing the new device on human subjects frequently was required by the FDA regulatory process, 3) Manufacturing preparation and start up includes things like detailed manufacturing drawings, design and construction of manufacturing facilities, and training production workers, 4) Marketing start-up includes activities necessary to sell and distribute the product, such as advertising, training sales representatives, attendance at trade shows etc. Such activity before the first sale and delivery of the new product were included. For each of these four stages, the respondent was asked to estimate the expenditure required and to indicate the source of funds used to cover this expenditure. He was also asked for each stage to indicate any use of technology external to the firm, and any
technical or financial arrangements between the firm and other organizations.

Following the interview, the respondent was mailed a draft of the case study and asked to check it for accuracy, completeness and confidentiality. Responses to this request sometimes produced changes or additions which were incorporated in the case.
IV. CASE STUDIES

Each case study is presented in three sections. The first is a narrative report of the growth of the firm and the development of its innovation. The attempt here is to present factual historical information as derived from interviews with executives and material provided by them. The organization is chronological and a summary chronology is often included. To preserve confidentiality the cases are presented without using firm names or details of the products which permit them to be identified. No facts have been altered however. The second part of the case study is a data summary sheet. (Figure II) Here I try to organize the information about the case in a form which will be useful for comparisons and statistical analysis. The first section gives the dates of firm creation and innovation introduction, firm size and diversification information, and the regulatory status of the product innovation. Then a table showing costs and timing of each of the four stages of innovative activity is presented. The dollar figures here are estimates by interview respondents. They are in current dollars of the year to which they refer. Since almost all of the figures refer to the late 1970's and early 1980's and because they are only rough estimates they are not deflated to a constant dollar amount.
FIGURE II

Case number:

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established:

Date of product introduction:

Employees as of that date:

Ownership:

Other products:

As of summer, 1988

Employees:

Ownership:

Other products:

FDA Regulatory Status:

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
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<tr>
<td>R&amp;D</td>
<td></td>
</tr>
<tr>
<td>Clinical trials</td>
<td></td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td></td>
</tr>
<tr>
<td>Marketing start-up</td>
<td></td>
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</table>
STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

R&D

Clinical Trials

Manufacturing prep

Marketing start-up

A) 1. Subject firm
   2. Educational/Medical Institution
   3. Other firm as contractor
   4. Other firm with substantial independence

B) 1. Founders' personal funds
   2. Cash flow from other products/services
   3. Private placement of securities
   4. Public sale of securities
   5. Government source
   6. Bank loan
   7. Other organization involved in innovation process
   8. Venture capital firm
   9. Other source
The last table on the data summary sheet gives information about the performance and financing of each stage of innovative activity. Performance refers to the organization primarily responsible for actually carrying out the work. There are four categories here: 1) The firm may have done the work itself in its own facilities with its own employees. 2) The work may have been performed in a university or medical institution. 3) The work may have been done by another firm under contract to the subject firm. This category is used where the subject firm retains substantial control over the details of the work. For example, a firm may hire a contractor to prepare blueprints or to perform certain specific lab tests. 4) The responsibility for the activity may be totally or mostly shifted to another firm which has substantial independence in performing the work. For example, the marketing rights for the product may be transferred to another company which sells it under its own name. Such a company has complete independence about what specific marketing start-up activities to undertake. The classification into categories is in part subjective, of course, but the respondents provided enough detail about the inter-firm arrangements so a distinction was possible. I attempted to identify the primary responsibility for the activity. For example, clinical trials require patients, so a firm cannot do them without the help of doctors or hospitals. However, if a firm designed and supervised the trials itself, it was counted as performer of this activity. On the other hand if a consulting firm was hired to conduct trials fully, the consultant would be counted as performer.
The second column of the table refers to sources of funds for financing of the activity. Nine possible sources are identified. The source of funds of course need not be the same as the performer. For example, if the company founder paid a medical school researcher to do some experiments the performer of R&D would be "medical institution" but the source of funds would be categorized as "founder's personal funds". If a large firm received marketing rights to the product in exchange for providing funds for the subject firm's R&D, the funds source for R&D and marketing start-up would both be "other organization involved in the innovation process" while the performer of R&D would be "subject firm" and performer of marketing start-up would be "other firm with substantial independence." Thus I use the performance-financing distinction to try to sort out the technical and financial relationships of the small firm with other organizations.

Finally, there is a brief section of comments about the case study. In this I attempt to point out aspects of the particular case which seem unique, which seem representative of wider issues or which are of interest for other reasons. Following are the reports of the 13 cases:
Case No. 1

This innovation is a device used typically in an intensive care setting to treat patients with serious, often life threatening, conditions. The type of device is in common use but the new device exceeds existing products in one important performance dimension. Therefore the FDA has determined that the innovation is not substantially equivalent to existing products and thus is classified as a Class III device requiring clinical trials prior to pre-market approval. Clinical trials are currently underway and FDA approval is anticipated in 1989.

The innovating firm currently has 5 employees. It is a joint venture between members of a medical group practice and Firm A, a company whose primary business is in the aerospace industry. Firm A was established in 1976 and currently has about 50 employees. It produces no medical products. The joint venture was formed in late 1985 although collaborative work between the physicians and Firm A had been going on informally for about 2 years prior to that.

The physician who is the primary inventor of the device was familiar with a device useful for treating small children. It was not possible to use this method on adult patients however. The physician and an engineer from firm A met socially and discovered complementary interests and expertise. The engineer and his associates at Firm A had background in an area of technology which was relevant to the design of the new product.
The major activities carried out thus far in the innovation process include: 1) Experiments to investigate mechanical and electronic principles related to design of the device, 2) Animal studies, 3) Trials on humans at one hospital, 4) Multi-center clinical trials (continuing as of mid-1988). Additional activities needed prior to innovation are 5) Establishment of manufacturing facilities and manufacturing start-up, and 6) Marketing start-up.

The innovation used multiple sources of financing. These are:
A) Funds from the physician group and Firm A, at first informally and later in the joint venture. B) A research grant from the teaching hospital with which the physician inventor is associated. C) An award from a military agency of the U.S. government under the SBIR program. Firm A had prior experience with this program in connection with its work in aerospace. A first proposal for the medical device project was unsuccessful. In response to a second proposal a Phase I award was received. A Phase II award is likely. D) A loan from a state government agency concerned with helping development of new products. The loan payback includes a royalty based on sales of the product. Firm A had no prior experience with this state agency but at the time of application for this funding the firm had fairly high political visibility as a result of a state award it received as an outstanding small business. E) A credit line with a local commercial bank.

One funding source was explored but did not result in any funds being obtained. The state has a program to encourage business-education collaboration. The joint venture applied for these funds
with a medical school located in the state, but this application was not successful.

A chronology, including events, work underway and funding is as follows:

Late 1983-late 1985. Experimental work on the underlying technology, machine design and animal tests. Total expenditure during this time period was $100,000. A research grant of $30,000 from the teaching hospital supported this work. Remaining funds came from the physician group and Firm A, participating equally.


January - December, 1986. Several machines were built and tested to be used for initial human trials. FDA approval for such testing was received in July and clinical trials were begun at the teaching hospital. Expenditure on these activities was $25,000. Source of funds was the initial investments in the joint venture.

January - December, 1987. Clinical trials at the teaching hospital continued. The joint venture obtained its own lab, manufacturing and office space. About 20 machines were built in preparation for multi-center clinical trials. Expenditures were about $350,000. The Phase I SBIR award was received during this time period. Most of the rest of the funding came
from the state agency. There was some small added investment by the owners of the joint venture.


As of June 1988 clinical trials are continuing. The firm anticipates receiving FDA approval for marketing in late 1988 and the first product sales taking place in 1989. The following are the firm's estimates based on those assumptions. They refer to activities taking place before the first sales of the product.

Manufacturing preparation and start up will include the lease of additional space, acquisition of manufacturing equipment, hiring and training of production workers. Estimated costs are about $300,000. Marketing start-up will include hiring and training salespeople, advertising and attendance at trade shows. Estimated cost is about $200,000.

The funds expected to be available for this work include: Funds unused from the initial state agency loan ($200,000), an additional loan from the state agency ($300,000), the SBIR phase II award ($250,000) and a credit line from a commercial bank ($250,000).
Comments on the case

Although both partners in this joint venture are "small" it looks in many respects like a big firm-small firm collaboration. The physician group was the source of the initial idea and provides medical expertise and access to hospitals and patients for clinical testing. The industrial firm provides complementary technical expertise but also is the major source of financing. The financing does not come from the "deep pocket" of a large firm but is very much conditioned by the expertise, contacts and resources of the aerospace company. Accustomed to dealing with government as a customer in its main line of business the firm was knowledgeable about the SBIR program and turned to it as a possible source for the joint venture's financing. Similarly the state government financing had its roots in the firm's contacts and visibility within the state government. What resulted was a sophisticated and successful use of available public programs to provide a large part of the financing for the innovation project. This came however, after the early stages of innovative activity had been carried out with internal and academic funding.
Case number: 1

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: December, 1985

Date of product introduction: expected 1989

Employees as of that date: expected about 25

Ownership: private (joint venture)

Other products: none

As of summer, 1988

Employees: 5

Ownership: private (joint venture)

Other products: none

FDA Regulatory Status: Class III

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1983-1986</td>
</tr>
<tr>
<td>Clinical trial</td>
<td>1987</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1988-1989</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1988-1989</td>
</tr>
</tbody>
</table>
### STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th></th>
<th>Performer</th>
<th>Funds sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1, 2</td>
<td>2, 5, 7</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>1</td>
<td>2, 5</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1</td>
<td>2, 5, 6</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1</td>
<td>2, 5, 6</td>
</tr>
</tbody>
</table>

**A)**
1. Subject firm
2. Educational/Medical Institution
3. Other firm as contractor
4. Other firm with substantial independence

**B)**
1. Founders' personal funds
2. Cash flow from other products/services
3. Private placement of securities
4. Public sale of securities
5. Government source
6. Bank loan
7. Other organization involved in innovation process
8. Venture capital firm
9. Other source
Case No. 2

The innovation which is the subject of this case study is a monitoring system introduced in 1986. The firm which introduced it was established in 1984 but is successor to a firm which had been started in the early 1970's growing out of work done by an academic research group.

Some of the founders of the present company were members of a research group at an engineering school in the early 1970's. Through social contact with an academic physician they became aware of the need for better measurement of one clinical dimension of a certain type of patient. Supported by a grant from the doctor's medical school, they developed a device to solve the problem. When they became aware of market demand for it, a small private company was formed in 1974 to market the device. This was in fact not the preference of the group. They would have preferred at that point to sell the technology to a large firm and there was interest expressed by such a firm but mutually acceptable terms could not be reached.

In the late 1970's the company was profitable but in the early 1980's was badly hurt by competition from a very large company which began selling a more complete system for the same purpose. The small company's activity diminished and growth ceased. In 1983 the owners resolved to try to re-invigorate the business, brought in several additional associates with different expertise and formed a new company which was to buy out the old one.
During 1984 an extensive search for financing of the new business was conducted. Sources explored included venture capital, joint ventures, and loans. Most venture capital firms wanted the individuals to supply more personal equity investment than they were willing or able to do. After about a year-long search, agreement was reached with a small, relatively young venture capital firm. A private placement raised $250,000 and shortly thereafter an initial public offering raised $1.35 million.

In 1985 the firm recognized the need to sell a product complementary to their original device in order to compete with the complete system sold by the large competitor. It identified a suitable product in the early stages of development by a small R&D company. In exchange for $100,000 plus stock in the innovating firm the R&D company agreed to work with the innovator in further developing the product. The innovator would receive patent rights to the innovation with the small R&D firm helping as consultants (in addition, of course, to now being stockholders). The estimated costs of development of the innovation, through the prototype stage were: a) $50,000 spent by the small R&D firm prior to the affiliation, b) the $100,000 representing the payment by the innovator to the R&D firm to support their work, and c) $120,000 spent by the innovator on R&D which it performed. Additional costs involved in going from prototype stage to introduction included $40,000 for manufacturing preparation and start-up and $40,000 for clinical trials and marketing start up activity. The device was first sold in late 1986.
The firm did not at that time have a sales force adequate to market the new product effectively, nor did it have funds to expand its sales force. An attempt was made to raise funds through a secondary public offering but this was unsuccessful. A contract was signed with a marketing company which received exclusive rights to market the product in exchange for a guarantee of $2 million revenue each year. This agreement lasted only 6 months, at which time it was ended and the company undertook to market the product itself. Additional funds were provided at about that time by the original venture capitalists who raised about $1 million through placement of convertible debt.

The company currently has about 30 employees and has expanded its product line to a family of related products. It is not yet profitable but projects breakeven in several months.

A summary chronology of events and finance sources is as follows:

1971 Work by academic group on initial device. Support by research grant from a medical school.

1974 Formation of predecessor company

1975-1980 Period of profitable operation of predecessor firm

1981-1983 Increased competition and stagnation of predecessor firm

1983-84 Formation of current firm and search for funds.
1984 Venture capital firm raised $250,000 with private placement

1985 Initial public offering raised $1.35 mil.

1986 Purchase of patent rights from R&D firm. R&D on innovation. Introduction of innovation

1987 Contract with marketing company, guarantee of $2 million annual revenue. End of arrangement with marketing company. Private placement raised $750,000

1988 Additional funds from stock offering
Comments on the case

Financing here was a major problem requiring a fairly long systematic search. Ultimately the firm was successful in obtaining funds from venture capitalists. The search for funds came at a fairly advanced stage in the history of the technology and firm (if one considers the predecessor firm and technology as continuous with more recent firm and innovation). Thus there was something of a track record for investors to consider, although the recent performance had not been good.

Competition between large and small firms was apparently important here. The technological competition from the large firm initially hurt the (predecessor) small firm but was in fact the spur to renewed effort, reorganization, and innovative activity. The small firm, in combination with an even smaller R&D company was able to innovate a product to meet the large firm competition. While it's too soon to tell for sure, it appears that the small firm's product is a viable alternative in the market to that sold by the very large company.
Case number: 2

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1984

Date of product introduction: 1986

Employees as of that date: 12

Ownership: public

Other products: No

As of summer, 1988

Employees: 30

Ownership: public

Other products: Yes, other medical products

FDA Regulatory Status: Class II

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td></td>
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<tr>
<td>1970-74</td>
<td>small</td>
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<tr>
<td>1985-86</td>
<td>270</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>1986</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1986</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1986</td>
</tr>
</tbody>
</table>
STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th>Performer A</th>
<th>Funds sources B</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1,3</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>1</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1,4</td>
</tr>
</tbody>
</table>

A) 1. Subject firm
   2. Educational/Medical Institution
   3. Other firm as contractor
   4. Other firm with substantial independence

B) 1. Founders' personal funds
   2. Cash flow from other products/services
   3. Private placement of securities
   4. Public sale of securities
   5. Government source
   6. Bank loan
   7. Other organization involved in innovation process
   8. Venture capital firm
   9. Other source
Case No. 3

These innovations are a group of about 15 metal surgical instruments innovated and produced by the same firm. The innovating firm was established in 1965 and its initial products were items used as accessories for machine tools. In the late 1960's the firm introduced its first medical device and the surgical instruments now account for about one third of its business. The firm currently has 12 employees.

Entry into the medical device market occurred in 1968 as a result of a doctor's noticing one of the firm's machine tool products and suggesting a modification of it which would be useful in surgery. After a few months of design work (estimated cost $5000) the medical device was in the prototype stage and shortly after that was on the market. Additional cost involved in going from prototype to manufactured product was about $3000, mostly for blueprints done by a consultant. This pattern and cost figures are typical of the other new medical products introduced over the past 20 years.

The firm initially marketed its products itself through advertising in medical journals at minimal cost. In the early 1970's it was approached by a large (Fortune 500) company which offered to buy products and market them. This is the marketing arrangement currently used by the firm. It sells products to the large company which advertises and markets them under its own name. The innovating firm retains patent rights. While the one large company
accounts for most of the sales of the products the innovator has on occasion marketed innovations through other large firms.

Several other aspects of the relationship between the innovating small firm and the large firm are of interest. Frequently new product ideas come from doctors to whom the small firm is introduced by the larger firm. The large firm also shares the responsibility for regulatory compliance and provides advice on FDA Good Manufacturing Practices. The large firm does not, however, contribute to R&D costs or gain any patent right to the technology itself.

Almost all the financing of the firm's innovative activity has come from the initial private investment of the owners and the internally generated funds from sales of products. There have been occasional short term commercial bank loans to aid with cash flow problems. The only other source of external funds is in the case of a few innovations where a health care institution or doctor has made a contribution to R&D costs of a specific product which they have suggested. In return for this investment, as well as their idea suggestion, they receive the prototype plus a royalty on future sales of the product.
Comments on the case

This closely held family firm has been very conservative in its financing. Although the large firm which markets its products has offered to pay for some R&D the small firm has refused such offers, being very concerned about keeping the rights to its technology. It has also not entered into an exclusive marketing agreement and in fact has on occasion chosen another marketing approach for a specific product.

The firm's diversification may permit such an approach. Although not diversified according to some definitions (its products are all in the metalworking industry) it sells a variety of medical products as well as the majority of its products which are machine tool accessories. Sales of other products thus provides an adequate cash flow to finance innovative activity on new medical devices.
**Case number: 3**

**Data Summary Sheet**

**FIRM AND INNOVATION DATA**

- **Date firm established:** 1965
- **Date of product introduction:** 1968
- **Employees as of that date:** under 10
- **Ownership:** private
- **Other products:** yes

**As of summer, 1988**

- **Employees:** 12
- **Ownership:** private
- **Other products:** yes, medical products about 1/3

**FDA Regulatory Status:** N. A.

**STAGES OF INNOVATIVE ACTIVITY: Costs and timing**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
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<td>5</td>
</tr>
<tr>
<td>Clinical trials</td>
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<td></td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>few weeks</td>
<td>3</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>minimal</td>
<td>N.A.</td>
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</table>
## STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th>Performer</th>
<th>Funds sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1, 2, 9</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>not done</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>3, 1, 2</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>4, 7</td>
</tr>
</tbody>
</table>

**A)**  
1. Subject firm  
2. Educational/Medical Institution  
3. Other firm as contractor  
4. Other firm with substantial independence  

**B)**  
1. Founders' personal funds  
2. Cash flow from other products/services  
3. Private placement of securities  
4. Public sale of securities  
5. Government source  
6. Bank loan  
7. Other organization involved in innovation process  
8. Venture capital firm  
9. Other source  

* Refers to a typical product innovation
Case No. 4

This device is used in connection with a common invasive procedure. It is made of a new material, different from that used in the previously available products. Its effect is to reduce the time required for the procedure and also reduce the risk of complications.

The innovating firm currently has 10 employees and gross sales of about $700,000 per year, all derived from sales of the innovation. The product was first marketed in May of 1986. The firm had been established in April of 1983 for the specific purpose of developing and introducing the innovation.

Initial research on formulation of the material was done by a polymer chemist working independently in a home workshop. In late 1982 he approached the innovating firm's president who was then, and still is, associated with a small consulting firm in the health care area. At that time the chemist had only a very general idea of possible applications of the new material. The president, with personal funds, supported the chemist's continued work for about one year at total costs of about $24,000. In April of 1983 the innovating firm was established by the president, one of his associates from the consulting firm, the chemist and two academic physicians. The initial capitalization of the firm ($1,500,000) was supplied almost entirely by the president.

Work during the rest of 1983 and 1984 involved pilot plant activity and initial clinical tests. Expenditures increased sharply at the end of 1983 when manufacturing space was rented and two
people were employed. Estimated expenditure for the time period mid-1983 through end of 1984 was $200,000, most of which was rent for the facility.

Until 1984 the company had hoped and expected that the new product would be regulated by the FDA as a class II device, which does not require extensive clinical testing. The FDA decision however was that the Class III procedures must be followed. This required additional animal tests and clinical trials on humans. This work was carried out in the time period mid-1984 to early 1986. Animal studies were carried out by another firm. Also during this time period employment was expanded to 10 people and manufacturing was scaled up from the pilot plant level in order to build inventory in anticipation of receiving FDA approval to market. This approval was received in early 1986 and the product was introduced in May of that year. Estimated cost of activity during the 1985-early 1986 time period in addition to expenditures for contracted animal tests is about $500,000 including $50,000 for marketing start-up expense.

Funds prior to the introduction of the product came almost entirely from the personal resources of the company president. Fairly significant attempts were made during 1985 to attract venture capital. A financial consultant was hired to explore such possibilities. There was some interest on the part of venture capital suppliers but agreement could not be reached on terms.

The following is a chronology of events, work underway and expenditures:
Late 1982 - April 1983  Work by chemist supported financially by the company's president  ($24,000)

April 1983  Innovating firm established

April 1983 - October 1983  Continued work by chemist

October 1983 - 1984  Rental of space.  Pilot plant operation.  Two additional employees.  ($200,000 expenditure)

Late 1984-early 1986  Animal studies and additional clinical studies.  Scale up of manufacturing operation.  Expansion of employment to 10 people.  Search for external financing.  Marketing start-up.  ($500,000 expenditure)

Comments on the case

This case is unusual in a couple of respects.  First, the driving force in this innovation was the technology rather than the market.  The new material was not invented to satisfy a particular need.  The material was invented first and then the need was identified.

Second, there was no outside financing used in this innovation.  The firm has been financed entirely from personal resources of the company founder.
Case number: 4

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1983

Date of product introduction: 1986

Employees as of that date: 10

Ownership: private

Other products: None

As of summer, 1988

Employees: 10

Ownership: private

Other products: None

FDA Regulatory Status: Class III

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
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</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1982-1985</td>
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<tr>
<td>Clinical trials</td>
<td>1985</td>
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<tr>
<td>Manufacturing prep</td>
<td>1984-86</td>
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<tr>
<td>Marketing start-up</td>
<td>1986</td>
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</tbody>
</table>
## STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th>Performer A</th>
<th>Funds sources B</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1, 3</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>1</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1</td>
</tr>
</tbody>
</table>

A) 1. Subject firm  
   2. Educational/Medical Institution  
   3. Other firm as contractor  
   4. Other firm with substantial independence

B) 1. Founders' personal funds  
   2. Cash flow from other products/services  
   3. Private placement of securities  
   4. Public sale of securities  
   5. Government source  
   6. Bank loan  
   7. Other organization involved in innovation process  
   8. Venture capital firm  
   9. Other source
Case No. 5

This innovation is an invasive monitoring device used in hospital intensive care units or similar settings. It was introduced in 1973 by a privately owned firm with about 20 employees which had been established in the mid-1950's to manufacture and sell parts and supplies for a type of (non-medical) scientific equipment. The monitoring device was the firm's first medical product.

In the late 1960's the firm's owner became aware that a physician holding a research fellowship at a local medical school had an idea for a new type of monitor. The physician's work had been funded by university research funds. The firm contacted the physician and an agreement was reached whereby the firm would participate in the development of the device and would commercialize it. The firm would contribute to a fund to support the physician's future work. The size of the contribution was to be based on sales of the device.

During the time period 1968-1973 the firm worked to develop the product. Estimated expenses were $500,000 with about 70% of that going to R&D, 20% to manufacturing preparation and 10% to marketing start-up. This was funded entirely from the owner's resources and earnings from the continuing sales of scientific equipment parts. Even though this created substantial financial strain on the company the owner was unwilling to seek outside funding since it would involve some loss of control and autonomy.

Although the product was introduced in 1973 it sold poorly initially. Realizing that it lacked sophistication in marketing
medical products the company recruited an executive with some background in this area. A contract was signed with a large drug company providing that the drug company would underwrite some additional clinical trials, "cosmetic" product redesign to make it more marketable, and other marketing expenses. The product would be sold under the drug firm's label. The drug firm guaranteed purchase of about $50,000 worth of monitors per year for a three year period.

In 1974 the drug company spent an estimated $100,000 on redesign and marketing for the product. However the drug company cancelled the contract after 1 year. Factors contributing to this decision included the sale by the drug company of the relevant division to another owner, which was less interested in the innovation, and a recognition that wide marketability of the product was dependent on results of some clinical work that had not yet been accomplished. Thus in 1975 the innovating firm was still lacking funds and attempted to market the product itself. Over the next 5 years the product sales built up to a profitable level and in the early 1980's the monitor surpassed the firm's scientific equipment parts business in contribution to sales. This growth was helped importantly by the work of an academic physician (not the original inventor) who became interested in the product and, with university research funding, did the necessary clinical work and helped publicize the product to the medical community.

In the early 1980's another technology was developed for a key component of the monitor. The firm had an opportunity to acquire rights to this when it was first developed but did not do so. This was potentially important competition but after several other firms
failed to use the new technology successfully the company was able to acquire rights to it and incorporate it in their product. A summary chronology is as follows:


1968  Contact with academic physician and agreement with him to have firm develop product. (Contributions to physician's research fund to be based on product sales.)


1973  Product introduction  3 year contract signed with large drug firm.


1975 - 1980  Slow growth of product sales through marketing by the firm itself aided by academic physician. Product and firm's other products generated enough funds to sustain activity. Physician's research work funded by his university.

1982  Acquisition of rights to new technology.
Comments on the case

The views of the company founder on the importance of maintaining tight personal control and independence were important here. The financial drain from work on the innovation endangered the very existence of the company in the early 1970's. In the view of our interview respondent (who was an executive not the founder of the firm) outside funding probably would have been available if it had been sought and the failure to do so delayed progress by several years. By the mid-1970's the company founder had realized that lack of expertise in medical product marketing was hurting the prospects for the innovation's success and recruited an executive experienced in this area who negotiated the drug company agreement which did bring some external finance, as well as technological resources, to bear on the innovation's development.
Case number: 5

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1955

Date of product introduction: 1973

Employees as of that date: 20

Ownership: private

Other products: yes, non-medical

As of summer, 1988

Employees: 20

Ownership: private

Other products: yes

FDA Regulatory Status: N. A.

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Stage</th>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1968-1973</td>
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</tr>
<tr>
<td>Clinical trials</td>
<td>1971-1975</td>
<td>small</td>
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<tr>
<td>Manufacturing prep</td>
<td>1973</td>
<td>100</td>
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<tr>
<td>Marketing start-up</td>
<td>1973-1975</td>
<td>150</td>
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</table>
STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th></th>
<th>Performer</th>
<th>Funds sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1,2</td>
<td>1,2</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>1,4</td>
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<td>Manufacturing prep</td>
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<td>1,2</td>
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<tr>
<td>Marketing start-up</td>
<td>1,4</td>
<td>1,2,7</td>
</tr>
</tbody>
</table>

A) 1. Subject firm  
    2. Educational/Medical Institution  
    3. Other firm as contractor  
    4. Other firm with substantial independence  

B) 1. Founders' personal funds  
    2. Cash flow from other products/services  
    3. Private placement of securities  
    4. Public sale of securities  
    5. Government source  
    6. Bank loan  
    7. Other organization involved in innovation process  
    8. Venture capital firm  
    9. Other source
The innovating firm in this case study (Firm A) was established in 1978 and has gone through a series of changes of ownership and organization since then. The company which it is now a part of (Firm B) is currently under reorganization. The assets of the company will be bought by a large pharmaceutical company. The innovation, introduced in 1981, is a device used in most surgical operations. It is not patented but manufacturing knowledge is important and the product has been protected to some extent through trade secrets.

The founder of Firm A had worked for a very large health care company for about 20 years prior to the late 1960's. His responsibilities in that company were in the general area of technology applicable to the innovation. In 1968 he left the large health care company and for 9 years was in business as the founder of two small firms related to medical technology but not primarily in the technological area of the innovation which is the subject of this case study.

Firm A was established in 1978. The very large health care firm which was the founder's former employer had a small ownership interest in the new company. R&D on the innovation took place over the next 4 years at an estimated cost of $500,000. This came partly from the founder's personal funds, partly from profits from contract research, partly from venture capital and partly from the very large firm. Clinical trials and other activities needed to gain regulatory approval were carried out by another, somewhat bigger,
medical products supplier which received the right to market the new product. Estimated costs to this company were $200,000 for trials and regulatory activity and $50,000 for marketing start-up expense. Firm A manufactured the product and spent about $300,000 on manufacturing preparation. Marketing was unsuccessful and rights to market the product were sold to another company shortly after 1981.

By 1984, Firm A had grown to about 20 employees and $700,000 annual gross sales of the product but still had no expertise in marketing the new product. In 1985 Firm A agreed to be acquired by Firm B. The latter firm was a newly established small company which was primarily oriented to marketing and sales rather than to R&D. Over the next 3 years Firm B raised $15 million in financing, partly from a public offering and partly from private sources, including many doctors. In 1986 Firm B contracted with a large medical products distributor to market the innovation and received substantial payments ($3 million) in advance for supplies of the product. In 1987 it was revealed that the president of Firm B had diverted much of the company's resources to his personal use. The president was forced to resign and is currently under federal securities law investigation. The company entered bankruptcy proceedings. A large pharmaceutical company is planning to acquire the assets of Firm B and a likely outcome of current litigation and reorganization is that this firm will completely take over the rights to the technology and business of the firm.

A chronology of the events in this case is as follows:
1950-1968 Founder of firm A is employed by very large health care firm.

1968-1977 Founder of firm A establishes and runs 2 small companies.

1978 Firm A established

1978-1981 R&D on innovation. About $500,000 raised

1981 Larger firm does clinical trials, takes care of regulatory approvals and receives marketing rights

1981 Product introduced

1982 Marketing unsuccessful. Rights transferred to another firm

1984 Firm B established as sales and marketing company

1985 Firm B acquires Firm A, including rights to market innovation

1985-1987 Firm B raises $15 million

1986 Marketing rights to innovation sold

1987 President of Firm B accused of wrongdoing, resigns. Firm B enters bankruptcy.
1988 Large pharmaceutical firm plans to acquire assets of Firm B.

Comments on the case

This case would seem to fit into the category of "industrial spin out", with the founder's previous employer being the basic source of the technological expertise and having some financial interest in the small company. The importance and difficulty of marketing is also evident here. The firm which invented and developed the product had neither the funds nor the expertise to market it. Several firms, both large and small have tried to market this product with varying degrees of success and the product's future is still unclear. Financing was not a major problem although the economic significance of this is clouded by the apparently fraudulent activities of the president of Firm B during the period when large sums were being raised.
Case number: 6

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1978
Date of product introduction: 1981
Employees as of that date: under 10
Ownership: private
Other products: none

As of summer, 1988
Employees: 23
Ownership: public
Other products: yes, other medical products

FDA Regulatory Status: Class III

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
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<tbody>
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<td>1981</td>
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<tr>
<td>Marketing start-up</td>
<td>1981</td>
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</table>
STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th></th>
<th>Performer A</th>
<th>Funds sources B</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1</td>
<td>1, 2, 8, 9</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1</td>
<td>1, 2, 8</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>4</td>
<td>7</td>
</tr>
</tbody>
</table>

A) 1. Subject firm  
2. Educational/Medical Institution  
3. Other firm as contractor  
4. Other firm with substantial independence  

B) 1. Founders' personal funds  
2. Cash flow from other products/services  
3. Private placement of securities  
4. Public sale of securities  
5. Government source  
6. Bank loan  
7. Other organization involved in innovation process  
8. Venture capital firm  
9. Other source
Case No. 7

This innovation is a device used to diagnose certain serious conditions. The diagnostic information, in addition to being useful for physicians can also be presented in a form which can be used by patients to initiate self care as instructed by the physician.

The device was introduced in early 1985 by a firm which was established in early 1983 for the specific purpose of developing this device. Clinical research supporting the general concept for the device had been carried out for several years prior to 1983 and was available to the firm in the medical literature. However, the particular technological approach taken by this innovation was not the same as that used by similar products and the device is patented. The founders of the company were two people with previous experience in the medical equipment business and an academic physician.

Costs of engineering and developing a prototype were about $100,000. Clinical trials were carried out as part of the R&D process although such trials are not required by regulation for this type of product. The costs of these trials included expenses for providing the equipment used and grants of support to the institutions where the trials were conducted. These expenses were about $100,000. Additional costs during the R&D work were payments to medical advisors of about $50,000. A key component used in the device was developed by NASA which sold the firm an exclusive license for its use.
The innovating firm did not (and does not currently) manufacture the device. The manufacturing is done under contract by other firms. The innovator did however incur costs for manufacturing preparation, including manufacturing engineering, detailed specifications and tooling. Expenses here were about $150,000. Costs of manufacturing start up were borne by the contract manufacturers. Marketing start up included hiring and training a sales force and preparing marketing materials. The marketing start-up costs totalled about $500,000.

Three sources of funds were used during the 1983-1985 time period before the innovation was introduced. Initial funding came from a R&D limited partnership in which the firm was a 1% owner and the sole general partner. An initial public offering of stock raised $1.8 million. Private placement of convertible securities generated an additional $2 million. The firm did consider seriously venture capital but that alternative was viewed as too costly and thus less attractive.

Since 1985 the firm has maintained an active research program and has grown rapidly. Several new models of the device have been introduced. Currently the firm employs over 100 people and has sales in excess of $10 million.

A chronology of events is as follows:

1983 (Feb.) Firm established

1983 R&D limited partnership raised $250,000
1983 (Dec.) Initial public offering of securities raised $1.8 million.

1984 Private placements raised $2 million

1983-1985 R&D and other innovative activity

1985 (Feb.) Introduction of innovation

Comments on the case

This firm skipped the typical early stages of financing with founder's personal funds. Within a year of its establishment it had obtained substantial funds in public securities markets. This was at least part due to the fact that the founders of the company had substantial previous business experience and financial contacts. The total funds raised prior to the introduction of the innovation exceeded significantly the costs of innovative activity. This probably accounts in part for the firm's ability to very quickly introduce new modifications of the product and to grow quite rapidly in the years after the innovation was introduced.
Case number: 7

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1983

Date of product introduction: 1985

Employees as of that date: 30

Ownership: public

Other products: No

As of summer, 1988

Employees: 106

Ownership: public

Other products: Yes, related medical products

FDA Regulatory Status: Class II

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1983-85</td>
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<tr>
<td>Clinical trials</td>
<td>1984-85</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1985</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1985-86</td>
</tr>
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</table>
**STAGES OF INNOVATIVE ACTIVITY: Performance and Financing**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Performer A</th>
<th>Funds sources B</th>
</tr>
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<tbody>
<tr>
<td>R&amp;D</td>
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<td>3,4,9</td>
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<tr>
<td>Clinical Trials</td>
<td>1</td>
<td>3,4,9</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1,3</td>
<td>3,4</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1</td>
<td>3,4</td>
</tr>
</tbody>
</table>

A) 1. Subject firm  
2. Educational/Medical Institution  
3. Other firm as contractor  
4. Other firm with substantial independence

B) 1. Founders' personal funds  
2. Cash flow from other products/services  
3. Private placement of securities  
4. Public sale of securities  
5. Government source  
6. Bank loan  
7. Other organization involved in innovation process  
8. Venture capital firm  
9. Other source
Case No. 8

This device is used to aid a patient's recovery from a surgical procedure. It was introduced in 1986 by a firm which had been established in 1977 to develop and commercialize this product. The firm currently has about 25 employees and gross sales of $5 million, all derived from sales of the innovation.

The technology was initially used for a different medical purpose by a firm which went bankrupt in 1977. The founder of the innovating firm, a scientist with personal financial resources derived from success in an industry unrelated to health care, saw potential in the technology and bought a patent from the failed firm for $50,000. He took the idea to an academic physician and supported studies by the physician over the next 6 years. These included animal studies and pilot human studies applying the technology to its present use.

By 1983 the potential commercial success of the product was more evident and the founder sought additional funding for further work. He considered taking the firm public but decided instead to look for a "partner". About 6 organizations expressed an interest and the founder chose to affiliate with a major (Fortune 500) drug company. The form of the deal was a sale of marketing rights. For $8 million (half immediately and half when the product was approved by the FDA for marketing) the drug company bought the right to distribute the new product. Most of the $8 million was prepayment for products to be sold.
The years 1983-1986 were spent on final prototype design, tooling and preparation for manufacture in quantity and multicenter clinical trials needed to gain FDA approval. This was received, and the product was introduced in early 1986.

In 1987 the marketing agreement with the drug company was dissolved. A large part of the prepaid advance was still outstanding and the drug company received for it an equity interest in the innovating firm. The firm began marketing its product through another firm. In 1988 the firm ended that arrangement and moved to undertake marketing itself.

A chronology of events showing estimated costs and activities is as follows:

1977 Purchase of patent ($50,000)

1977-1979 Animal studies by academic physician. ($100,000/yr)

1980-1982 Continued research including pilot human studies by academic physician. ($200,000/yr)

1983 Affiliation with large drug company

1983-1986 Final design of product ($300,000). Tooling and engineering ($500,000). Multicenter clinical studies

1986 Regulatory approval and product introduction
Prior to 1983 all funds were from personal resources of the company founder. After 1983 the major source of funds was the advance from the large drug company.

Comments on the case

The small company played a major role here in transferring technology from the industrial sector to the academic and back to the business firm. What is somewhat atypical however, is that the company was in fact the initiator of the academic work and the source of financial support for it. Thus the small firm during the early stages of the process played the role of financier, technology-transfer agent and manager of academic work. At a later stage of the innovation process however the company turned to outside financial support in the form of the marketing agreement with the big company. The large company financed the later parts of development and clinical trials for the innovation.
Case number: 8

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1977

Date of product introduction: 1986

Employees as of that date: 15

Ownership: Private

Other products: None

As of summer, 1988

Employees: 23

Ownership: Private

Other products: None

FDA Regulatory Status: Class III

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1977-1984</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>1983-86</td>
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<tr>
<td>Manufacturing prep</td>
<td>1983-86</td>
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<tr>
<td>Marketing start-up</td>
<td>1983-86</td>
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</tbody>
</table>
STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th>PerformerA</th>
<th>Funds sourcesB</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>2</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>2</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>4</td>
</tr>
</tbody>
</table>

A) 1. Subject firm  
2. Educational/Medical Institution  
3. Other firm as contractor  
4. Other firm with substantial independence

B) 1. Founders' personal funds  
2. Cash flow from other products/services  
3. Private placement of securities  
4. Public sale of securities  
5. Government source  
6. Bank loan  
7. Other organization involved in innovation process  
8. Venture capital firm  
9. Other source
This case study involves two related firms and two product innovations. Firm A currently has about 30 employees and annual gross sales of about $850,000. It was established initially to develop a medical product (a monitor) which never did progress to the point of commercial success. Its major product currently in the medical area is a device used in diagnosis. This technology was obtained through a merger. The device is currently sold only for research use. An application for regulatory approval of sales for clinical use is pending. Firm B is a subsidiary of Firm A. The technology underlying the diagnostic device was developed by Firm B, which was acquired by Firm A in 1986.

**Firm A - Invasive monitor**

Firm A was established in 1983 to develop and commercialize the technology for an invasive monitoring device which had been patented by a university scientist. The patent was the outgrowth of about 7 years of university work, funded by NIH grants and other academic research funds. Estimated cost of that work is $750,000. Firm A reached a licensing agreement with the university which gave the firm the right to develop, manufacture and sell the monitor, paying a royalty to the university. The university had the right to terminate the agreement if the firm did not introduce the product to the market by a specific date in 1987.
Investments in Firm A through 1985 came to about $700,000 including the initial investments of the company founders and funds raised from private placements. An initial public offering of securities in early 1986 raised an additional $3.5 million.

From 1984 through 1987 Firm A spent about $1.5 million for R&D and other activities related to the invasive monitor. Regulatory approval was not obtained as quickly as initially anticipated, with the FDA requiring additional testing. As of the contractual date in 1987 the company had not been successful in introducing the product to the market and the university exercised its right to terminate the licensing agreement. The company is investigating the possibility of legal action against the university in this matter. Thus this technology has not yet reached the market.

In 1986 Firm A acquired an electronics firm with about 15 employees and gross sales of $800,000 per year. Most of the sales of the electronics firm were in non-medical areas. A subsidiary, Firm B in our case study, was engaged in the development of a medical diagnostic device.

**Firm B - Diagnostic device**

The privately held electronics firm was established in the 1960's and since that time has manufactured a variety of products. Its medical device interest began in 1984. At that time a partner in the electronics firm was acquainted with a university biomedical engineer. (The university here was different than the one involved in the invasive monitor above.) Through him the company partner
became aware of the technology for the diagnostic product and established Firm B to develop and commercialize it. A license was obtained from the university. Initial funding was from the electronics company's revenues but by mid-1985 more funds were needed and a decision was made to take the company public. An offering was planned but was not successful as the underwriting firm abandoned the project in early 1986. At about that time the merger with Firm A was proposed and the owners of Firm B saw that as an attractive alternative for obtaining the funds needed to continue work on the innovation.

The expenditure on the diagnostic product, funded initially by the electronics firm and after the merger by Firm A, included about $500,000, about $50,000 of which is for marketing start-up. Manufacturing start-up cost was minimal since the manufacture of this product requires the same skills as needed for other products made by the electronics firm. The product was introduced to the market for research use in 1987. Regulatory approval and sales for clinical use is anticipated within a year.

The following is a chronology including both cases:

1964 Firm B established in electronics industry

1976-1983 University research on monitoring device

1983 Firm A established to commercialize monitoring device
1984 Firm B initiates work on diagnostic device

1984-1986 Work on monitor by Firm A, on diagnostic device by Firm B

1986 Initial Public Offering by Firm A raises $3.5 million

1986 Firm A acquires Firm B

1987 University terminates licensing agreement for monitor

Diagnostic device introduced for research use.

Comments on the case

Both of these firms were attempting to transfer technology from the academic sector to the commercial sector. One (Firm A with the monitor) apparently failed. The other (Firm B with the diagnostic device) seems on track for success. It is interesting, and perhaps ironic, that it was the unsuccessful innovation project which was able to appeal successfully to the public securities markets for funds. Of course, the market for corporate control, i.e. the merger, later corrected (salvaged?) this mistake. Much of the funds which investors directed toward the monitor development in early 1986 were being used by late 1987 for the diagnostic product.
Case number: 9

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1983

Date of product introduction: not introduced

Employees as of that date:

Ownership:

Other products:

As of summer, 1988

Employees: 30

Ownership: public

Other products: yes, other medical

FDA Regulatory Status: N.A.

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
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<td></td>
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<tr>
<td>1984-87</td>
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<tr>
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<tr>
<td>Marketing start-up</td>
<td>not done</td>
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</table>
STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th></th>
<th>Performer^A</th>
<th>Funds sources^B</th>
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<tr>
<td>R&amp;D</td>
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<td>1.3.4</td>
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<tr>
<td>Clinical Trials</td>
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<td>1.3.4</td>
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<tr>
<td>Manufacturing prep</td>
<td>not done</td>
<td></td>
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<tr>
<td>Marketing start-up</td>
<td>not done</td>
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</tr>
</tbody>
</table>

A) 1. Subject firm  
2. Educational/Medical Institution  
3. Other firm as contractor  
4. Other firm with substantial independence

B) 1. Founders' personal funds  
2. Cash flow from other products/services  
3. Private placement of securities  
4. Public sale of securities  
5. Government source  
6. Bank loan  
7. Other organization involved in innovation process  
8. Venture capital firm  
9. Other source
Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1965
Date of product introduction: 1987 (for research use)
Employees as of that date: 15
Ownership: public
Other products: yes, non-medical electronics

As of summer, 1988
Employees: 20
Ownership: public
Other products: yes

FDA Regulatory Status: Class II

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th></th>
<th>Time</th>
<th>Cost ($000)</th>
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<tr>
<td>Clinical trials</td>
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<td>Manufacturing prep</td>
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<td>Marketing start-up</td>
<td>1987</td>
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STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
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<tr>
<th>PerformerA</th>
<th>Funds sourcesB</th>
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</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1,2</td>
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<tr>
<td>Clinical Trials</td>
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<tr>
<td>Manufacturing prep</td>
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<tr>
<td>Marketing start-up</td>
<td>1</td>
</tr>
</tbody>
</table>

A) 1. Subject firm
    2. Educational/Medical Institution
    3. Other firm as contractor
    4. Other firm with substantial independence

B) 1. Founders' personal funds
    2. Cash flow from other products/services
    3. Private placement of securities
    4. Public sale of securities
    5. Government source
    6. Bank loan
    7. Other organization involved in innovation process
    8. Venture capital firm
    9. Other source
Case No. 11

The innovation in this case study is a device used in the ambulatory treatment of a condition causing infertility. The firm was established by a physician and an engineer who had been the physician’s patient and suggested a technological approach to dealing with the medical condition. The product was introduced in mid-1985 at which time the company had 5 employees.

The physician had been doing some independent research on the condition in the course of his medical practice during the mid-1970’s. Collaboration between the physician and engineer began in 1978 and a very crude prototype device was obtained by the end of 1979. Prior to 1980 the collaboration was informal and self-financed at a relatively low level of expenditure. The firm was incorporated in early 1980 with initial capitalization of $20,000 contributed by the two founders.

During 1980-1982 activity included further development of the prototype and investigation of manufacturing techniques. This work was handicapped by lack of adequate funding for equipment. Some additional funds, about $40,000, were raised during this time period from family and friends of the founders. During 1982 the company entered into an agreement with a design consultant who contributed to the development of the innovation as well as a second product. Major external funding was obtained through an initial public offering in late 1982. That stock offering yielded about $1 million which funded activity over the next three years.
Activity during the 1983-1985 time period was mainly clinical testing of the device in preparation for pre-marketing approval as a Class III product. Initially the firm contracted out the clinical trials but was not satisfied with the contractor's performance and ultimately took over direct responsibility for this. A rough estimate of the costs of clinical testing is $300,000-$500,000.

Approval to market was obtained in late 1984. At that time the firm moved to establish a production facility, increased employment from 2 to 5 people and began marketing start-up. The device was first distributed in mid-1985. Costs of manufacturing start-up were minimal. Marketing expense during the first year ran about $200,000.

Currently the firm's marketing program for the innovation is considerably scaled down. It has several other products in various stages of development and has purchased a majority share of another firm which sells medical products. Since 1985 additional funds have been raised through both private and public stock sales, specifically about $900,000 raised by the company through private placements in 1986 and an initial public offering by its majority owned subsidiary in late 1986. Its sales for 1987 were about $500,000.

A summary chronology is as follows:

1973-1978 Interest in the problem by physician in the course of medical practice

1978 Start of collaboration between physician and engineer
1979 Very crude prototype


1982 (Nov.) Initial public offering raised about $1 million

1983-1985 Clinical testing

1985 (May) Product introduced

Comments on the case

In the view of the interview respondent, financing difficulties delayed progress significantly in the years after 1979. The appropriate manufacturing method required a greater investment in equipment than the founders could finance on their own. Thus work was slowed until late 1982 when the public offering was successful.

The innovation currently is not selling as well as anticipated. The company feels that the marketing program was not cost effective and has suspended it. The firm now has diversified into other medical product areas with products currently on the market as well as new products under development.
Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1980
Date of product introduction: 1985
Employees as of that date: 5
Ownership: public
Other products: none

As of summer, 1988
Employees: 15
Ownership: public
Other products: yes, other medical products

FDA regulatory status: Class III

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1978-83</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>1983-85</td>
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<tr>
<td>Manufacturing prep</td>
<td>1985</td>
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<tr>
<td>Marketing start-up</td>
<td>1985</td>
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</table>
### STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th>Performer</th>
<th>Funds sources</th>
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<td>3,1</td>
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<tr>
<td>Clinical Trials</td>
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<tr>
<td>Manufacturing prep</td>
<td>4</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>4</td>
</tr>
</tbody>
</table>

**A)** 1. Subject firm  
2. Educational/Medical Institution  
3. Other firm as contractor  
4. Other firm with substantial independence

**B)** 1. Founders' personal funds  
2. Cash flow from other products/services  
3. Private placement of securities  
4. Public sale of securities  
5. Government source  
6. Bank loan  
7. Other organization involved in innovation process  
8. Venture capital firm  
9. Other source
This case involves two firms and two product innovations. Firm A introduced a video system for hospital use in 1975 at which time the firm had about 4 employees. Firm A is currently owned by Firm B, which was established in 1983. Firm B is the innovator of a monitoring device which has been sold to a few users since late 1986 but has not yet been marketed on a full scale basis. Firm B, including its subsidiary, currently employs 12 people.

**Firm A -- Video system**

The founder of Firm A, an engineer, was employed in the early 1970's as a product development executive for a firm mostly involved in military contract work. The military contracting firm failed and the engineer in 1974 started his own business as a manufacturer's representative for firms in the video and medical product areas. The initial capitalization for this business came from consulting fees. As the business developed, it turned from simply selling products to systems integration, i.e. designing a complete system using the products of various manufacturers to meet the needs of customers. The firm identified a particular need of hospitals and began marketing a video system designed to meet this need in 1975.

Throughout the late 1970's the firm's activities were financed totally through personally guaranteed loans to the company founder. When this source of funds was unable to supply needed capital other possibilities were explored. Market conditions at the time made
equity financing difficult to obtain and venture capital was available only on unattractive terms. The firm agreed to be acquired in 1982 by a small firm which was a sales representative for manufacturers of telecommunications equipment. Over the next 4 years this firm’s main telecommunications business expanded rapidly and video was deemphasized. Thus in 1986 when Firm B offered to acquire the video subsidiary the merger seemed advantageous and was completed.

Out of pocket expenditure on R&D for the hospital video system was minimal. Engineering was done by the company founder and a partner on a "sweat equity" basis in the course of operating the business and selling other video and medical products. The firm does not manufacture any system components but does engineer and install the system at hospitals. Marketing start-up expense was minimal since the firm already had hospital relationships as a result of selling other products.

**Firm B - Monitor**

This product idea goes back to a patent obtained by a physician in 1976. At that time electronics technology did not exist to turn the patent into a commercial product. In 1981 the doctor approached an executive with experience in other business with the product idea and they raised $150,000 in seed money to undertake preliminary development and explore commercial possibilities. These funds were obtained as loans from private sources.
By late 1982 a crude prototype was completed and a decision made to seek further funding. Firm B was established in mid 1983 and during the 1983-85 time period effort was directed to approaching venture capital firms. With the help of such a firm, the company went public in 1985 and raised about $3 million. R&D work as well as engineering and manufacturing was contracted out, with the firm serving as organizer and monitor of the various contractors. Regulatory approval was obtained in late 1985 but technical problems with the device itself as well as the necessity for a learning process by the manufacturer to take place delayed product introduction.

The 1986-1987 time period was a time of financial stress for the firm. The product was not ready for introduction as soon as had been anticipated. The firm accumulated inventories of product not ready for sale and significant vendor debt. The acquisition of Firm A took place in 1986. This was seen as a way to obtain cash flow from Firm A's going business as well as to strengthen the management team. Several possible new sources of working capital financing did not work out and the stock market crash in October 1987 made new public equity financing unlikely. Personal loans from officers and directors provided some funds.

In 1987 the firm became aware of a foreign company that had developed a similar, although not identical product. The products were alike enough, however, so that it would not be possible to market them both in the U.S. without patent infringement difficulties. Talks with the foreign firm were initiated and the following arrangement was discussed: The foreign firm, which was
financially strong, would provide some funds to Firm B, with options to eventually acquire more than half of its stock. The foreign firm's product would be sold in the U.S. through Firm B initially since of the two products it was deemed more attractive to the U.S. market. The technology which Firm B had developed would likely be the basis for a later generation of the monitor. As of mid-1988, this agreement is almost finalized.

A chronology including both cases is as follows:

Pre-1974 Engineer employed by large defense contractor

1974 Defense contractor fails. Engineer starts Firm A.

1975 Video system introduced

1976 Physician obtains patent related to monitor

1981 Physician approaches business executive with monitor product

1981-1982 Physician and executive raise $150,000 and develop crude prototype monitor.

1982 Firm A acquired by telecommunications company

1983 Firm B established and begins search for additional financing.

1985 Initial public offering by Firm B raises $3 million
1986 Firm B acquires Firm A from telecommunications company

1987 Negotiations with foreign firm initiated.

Comments on the cases

This case highlights the importance of a "going business" as a source for funds as well as a source of ideas for innovation. The video system developed by Firm A was clearly market driven in that the innovator had identified the market need through having been in touch with customers for his other products. While financial requirements for its development were minimal, the funds needed were available from ongoing sales activities. The merger between the two firms was a response to firm B's need for funds and the attractiveness of Firm's A's going business as a continuing source of funds over time.

Although Firm B had been successful in an appeal to the public for funds in 1985, it was by 1987 again in a period of financial stress because of delays in product introduction. In retrospect, Firm B believes that the difficulties were due to the fact that it contracted out too much of the engineering and manufacturing work and did not have enough of an in-house technical capability to monitor or make effective use of the work performed by the contractors.
**Case number: 12**

**Data Summary Sheet**

**FIRM AND INNOVATION DATA**

- **Date firm established:** 1974
- **Date of product introduction:** 1975
- **Employees as of that date:** under 5
- **Ownership:** private
- **Other products:** yes, both medical and nonmedical

**As of summer, 1988**

- **Employees:** 12
- **Ownership:** owned by a public firm
- **Other products:** yes
- **FDA Regulatory Status:** N.A.

**STAGES OF INNOVATIVE ACTIVITY: Costs and timing**

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1974-74</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>none</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>none</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1975, small</td>
</tr>
</tbody>
</table>
### STAGES OF INNOVATIVE ACTIVITY: Performance and Financing

<table>
<thead>
<tr>
<th>Performer&lt;sup&gt;A&lt;/sup&gt;</th>
<th>Funds sources&lt;sup&gt;B&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>none</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>none</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>1</td>
</tr>
</tbody>
</table>

A) 1. Subject firm  
2. Educational/Medical Institution  
3. Other firm as contractor  
4. Other firm with substantial independence  

B) 1. Founders' personal funds  
2. Cash flow from other products/services  
3. Private placement of securities  
4. Public sale of securities  
5. Government source  
6. Bank loan  
7. Other organization involved in innovation process  
8. Venture capital firm  
9. Other source
Case number: 13

Data Summary Sheet

FIRM AND INNOVATION DATA

Date firm established: 1983

Date of product introduction: 1986

Employees as of that date: 6

Ownership: public

Other products: no

As of summer, 1988

Employees: 12

Ownership: public

Other products: yes

FDA Regulatory Status: Class II

STAGES OF INNOVATIVE ACTIVITY: Costs and timing

<table>
<thead>
<tr>
<th>Time</th>
<th>Cost ($000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1981-1986</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>N.A.</td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1984-84</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td></td>
</tr>
</tbody>
</table>
**STAGES OF INNOVATIVE ACTIVITY: Performance and Financing**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Performer</th>
<th>Funds sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>1,3</td>
<td>1,3</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>N.A.</td>
<td></td>
</tr>
<tr>
<td>Manufacturing prep</td>
<td>1,3</td>
<td>1,4</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>not yet done</td>
<td></td>
</tr>
</tbody>
</table>

A) 1. Subject firm  
2. Educational/Medical Institution  
3. Other firm as contractor  
4. Other firm with substantial independence

B) 1. Founders' personal funds  
2. Cash flow from other products/services  
3. Private placement of securities  
4. Public sale of securities  
5. Government source  
6. Bank loan  
7. Other organization involved in innovation process  
8. Venture capital firm  
9. Other source
V. DESCRIPTIVE STATISTICAL ANALYSIS

In this section I summarize statistically information about the case studies. Table I presents basic data about the 13 firms. Most were established in the 1975-1985 time period. Their innovations, of course, came somewhat later, with 8 of the 13 products being introduced after 1980 and 2 not yet having reached the market as of mid-1988. In more than half of the cases the innovation was introduced within 3 years of the establishment of the firm. In two cases the innovation came 18 years after the firm's establishment. In both of these cases, however, the firm had been active for most of its life in another industry and the innovation came within a few years after its interest in medical devices began.

The firms are very small. Most had under 20 employees when they introduced their new products. Many are still quite small as of July, 1988, although most have grown somewhat since their new product introduction. With one exception, however, none have really "taken off" to greatly increased size. It is by no means clear that all will ultimately even survive. Many are not currently profitable and while most interview respondents were optimistic about the future of their companies they recognized the risks involved. At the time of product introduction 7 firms were privately owned corporations and 4 were public. (Two have not yet introduced their product.) As of July, 1988, 8 were publically held firms.
### Table I

**CHARACTERISTICS OF CASE STUDY FIRMS AND INNOVATIONS**

<table>
<thead>
<tr>
<th>Date Firm Established</th>
<th>No. of Firms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before 1970</td>
<td>3</td>
</tr>
<tr>
<td>1971-1975</td>
<td>1</td>
</tr>
<tr>
<td>1976-1980</td>
<td>3</td>
</tr>
<tr>
<td>1981-1985</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Innovation Introduced</th>
<th>No. of Firms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before 1970</td>
<td>1</td>
</tr>
<tr>
<td>1971-1980</td>
<td>2</td>
</tr>
<tr>
<td>1981-1985</td>
<td>3</td>
</tr>
<tr>
<td>1986-1988</td>
<td>5</td>
</tr>
<tr>
<td>Not yet introduced</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Employees - when Innovation Introduced</th>
</tr>
</thead>
<tbody>
<tr>
<td>under 10</td>
</tr>
<tr>
<td>10-20</td>
</tr>
<tr>
<td>21-30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Employees - July 1988</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 10</td>
</tr>
<tr>
<td>10-20</td>
</tr>
<tr>
<td>21-30</td>
</tr>
<tr>
<td>over 30</td>
</tr>
</tbody>
</table>
The product innovations include products sold to hospitals, to physicians and directly to consumers. Three of the firms are, as of July 1988, one product firms with the innovation accounting for all of their business. Five now sell other medical products and five are diversified into non-medical areas. Nine of the product innovations are regulated by the FDA, five in Class III and four in Class II. (The four which escape regulation do so either because of the specific characteristics of the product or because it was on the market before 1976 when the Medical Devices Amendments to the Food and Drug Law came into effect.) Most firms reported costs of less than $1,000,000 for all activities prior to introduction of the product innovation. This of course does not represent the total funds raised. It is a lower bound for that number since firms had to cover the cost. However most firms raised more than that. The additional funds were used for activities not specifically related to this innovation or represent working capital held as of the date of innovation. Several of the firms were experiencing financial stress as of July, 1988 and were actively seeking additional funds at that time. Table II shows for each stage of innovative activity the mean and median cost for those firms reporting costs. Where costs are not reported it may represent a stage not performed, e.g. clinical trials not required, data simply not available, or activity performed by another entity whose costs are unknown. Clinical trials and R&D appear to be the most expensive activities. Comparison of the mean and median figures indicates that a few very expensive projects influence the mean.
The data from this sample are consistent with the hypothesis noted earlier than FDA regulation may raise the costs of start up of new firms (Roberts and Hauptman, 1987). For the five innovations in the most stringent regulatory category, Class III, the range for costs of all innovative activities together ranged from $640,000 to $4,750,000 (median: $975,000). The four innovations in Class II had cost ranging from $150,000 to $900,000 (median: $425,000) Thus the more heavily regulated innovations were more expensive to achieve. However, since a major criterion for deciding regulatory classification is whether or not the new product is "substantially equivalent" to an existing product, this may simply show that it is more expensive to achieve a significant state of the art advance rather than a "me-too" type innovation.
<table>
<thead>
<tr>
<th>Stage</th>
<th>No with costs reported</th>
<th>Median cost</th>
<th>Mean cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>R &amp; D</td>
<td>12</td>
<td>255</td>
<td>460</td>
</tr>
<tr>
<td>Clinical test</td>
<td>7</td>
<td>200</td>
<td>585</td>
</tr>
<tr>
<td>Manufacturing prep.</td>
<td>10</td>
<td>125</td>
<td>179</td>
</tr>
<tr>
<td>Marketing start-up</td>
<td>10</td>
<td>100</td>
<td>147</td>
</tr>
</tbody>
</table>
Table III shows the sources of funds used by each firm. The last column of this table makes clear that multiple sources of funds is the rule here. Most common was reliance on 2-4 different sources of funds, with 10 of the 13 cases in that range. As might be expected, the most frequently used source (9 cases) was the company founder's personal funds. Cash flow from other products or services and other organizations involved in the innovation process were next most frequent (each used 6 times). The former source is important either in Bullock's "soft" start-up pattern where revenues from consulting services finance the innovation process or where the innovating firm was previously active in another industry. Contributions from other organizations involved in the innovation process occurred mostly where a larger firm entered into a marketing agreement with the small firm. Five firms sold stock to the public and four of those also reported private placement of securities. Used relatively infrequently were bank loans, government sources of funds and venture capital firms.

Two of the biggest sources of funds in terms of amount raised were public sales of securities and funds from another organization involved in the innovation process, typically a larger firm. There is some suggestion in the table that these sources may be substitutes, i.e. that they are not likely to both be drawn on by the same project. Five cases had public stock offerings and 6 indicate funds from another organization involved in the process. There is little overlap among these groups—only 1 case reports use of both of these sources.
Table III

**SOURCES OF FUNDS USED**

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Source of Funds</th>
<th>Number of Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>X</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>X X</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>X X</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>X</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>X X</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>X X</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>X X</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>X X</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td>11</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td>12</td>
<td>X X</td>
<td>2</td>
</tr>
<tr>
<td>13</td>
<td>X X</td>
<td>3</td>
</tr>
</tbody>
</table>

No of times used
9 6 4 5 1 1 6 2 5

* 1. Founders' personal funds
  2. Cash flow from other products/services
  3. Private placement of securities
  4. Public sale of securities
  5. Government source
  6. Bank loan
  7. Other organization involved in innovation process
  8. Venture capital firm
  9. Other source
The performance of innovative activities is examined in Table IV. As might be expected, the subject firms played important roles at all stages of the innovative process. However participation by other organizations was also noteworthy. In 5 cases a university or medical institution performed R&D work. Also in 5 cases the marketing start-up activity was performed by another, typically larger, firm. The great extent of participation by other organizations is evident in Table V, which focuses on the number of stages performed in each case by the subject firm. In no case did the firm perform all four stages by itself and 9 cases saw the firms as the sole performer of no more than 2 stages. In 7 cases the firm was involved at all in three or fewer stages.

Table VI examines the relation between stages of activity and the source of funds. There are no strong relationships apparent here. If a source of funds is used for one stage, it is likely to be used for the others. This is perhaps not surprising given the short time elapsed between the establishment of the firm and the innovation date for most of these cases. If funding was obtained near the start of the time period it was likely to be drawn on for all ongoing activities.
Table IV

PERFORMANCE OF STAGES OF INNOVATIVE ACTIVITY
(No. of case studies)*

<table>
<thead>
<tr>
<th>Stage of Activity</th>
<th>Stage not performed</th>
<th>Subject firm</th>
<th>Academic medical</th>
<th>Other firm (contract)</th>
<th>Other firm (indep)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R &amp; D</td>
<td>0</td>
<td>12</td>
<td>5</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>4</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Mfg Prep</td>
<td>2</td>
<td>10</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Mktg start</td>
<td>2</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
</tbody>
</table>

* Rows add to more than 13 since 2 or more organizations could participate in a stage of activity.
Table V
NUMBER OF STAGES OF INNOVATIVE ACTIVITY
PERFORMED BY SUBJECT FIRM

<table>
<thead>
<tr>
<th>No. of firms which were sole performer of</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>One stage</td>
<td>4</td>
</tr>
<tr>
<td>Two stages</td>
<td>4</td>
</tr>
<tr>
<td>Three stages</td>
<td>4</td>
</tr>
<tr>
<td>Four stages</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of firms which were performers (sole or with another) of</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>One stage</td>
<td>2</td>
</tr>
<tr>
<td>Two stages</td>
<td>4</td>
</tr>
<tr>
<td>Three stages</td>
<td>1</td>
</tr>
<tr>
<td>Four stages</td>
<td>6</td>
</tr>
</tbody>
</table>
Table VI
STAGES OF INNOVATIVE ACTIVITY AND SOURCE OF FUNDS
(No. of firms)

<table>
<thead>
<tr>
<th>Source of Funds*</th>
<th>R &amp; D</th>
<th>Clinical trials</th>
<th>Manufacturing preparation</th>
<th>Marketing start-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9</td>
<td>4</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>2</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>4</td>
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<td>3</td>
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<td>6</td>
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<tr>
<td>7</td>
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<td>4</td>
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<tr>
<td>8</td>
<td>2</td>
<td>1</td>
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</tr>
<tr>
<td>9</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

* 1. Founders' personal funds
2. Cash flow from other products/services
3. Private placement of securities
4. Public sale of securities
5. Government source
6. Bank loan
7. Other organization involved in innovation process
8. Venture capital firm
9. Other source
VI. DISCUSSION

The cases exhibit great diversity and thus generalizations are hard to make. In any case such a small and non-random sample of firms would not support any strong statistical tests. However some patterns did occur in many cases and seem worthy of comment. The following should be taken as tentative hypotheses rather than definite conclusions.

Almost all the firms used multiple funding sources. Even where large sums were raised from a public securities sale, this was preceded and occasionally followed by funds from private sources, raised typically outside the established capital markets. The most common pattern was for a firm to rely on 2-4 different sources of funds for the work prior to the introduction of the product innovation.

In light of the considerable publicity which has focussed on venture capital markets and organizations, it is perhaps surprising that there was relatively limited use of venture capital firms as sources of funds. A number of interview respondents mentioned many conversations with venture capitalists in their search for funds but noted that such firms "drove a hard bargain" and thus they did not ultimately choose such financing. As one executive noted, "These guys [i.e. venture capitalists] will fund ten projects knowing that 9 will fail and the 1 big success will more than cover those losses. Their terms are based on this assumption. Why should I have to pay for the failure of 9 other firms?" He did not mention, or perhaps
even consider, the possibility that his firm would be one of the failures. Such optimism is undoubtedly unrealistic in a statistical sense but is characteristic of entrepreneurs—they don’t embark on a venture assuming it will fail. In any case, the executive above, and several others in our sample considered but eventually rejected the venture capital route.

It is noteworthy that most firms in our sample did not perform all the stages of innovative activity. This may well be a difference between small and large firm innovation. Large firms can carry an innovation project through from start to finish. Small firms may perform only part of the innovation process. In our sample, small firms seemed particularly involved in the transfer of technology from the university or medical research stage through the development of a product. The marketing of the innovation was frequently carried out by a large firm.

One implication of this is that statistical studies which rely on mention of the first commercial introduction of a product to identify the innovator may understate the role of the small firm. Much recent work has been based on data compiled through search of trade literature for new product introductions. (Gellman (1982), Acs and Audretsch(1987)) When a new product developed and manufactured by a small firm first reaches the market in the catalog of a large firm under its own trade name, as happened in several cases in this study, who should get “credit” for the innovation? It is well established use of the term “innovation” in the literature that innovation does not occur until a product is introduced to the market, and such usage is not inappropriate. However, it would seem
that if cases like this are common, innovation counts could be misleading as to the technological contributions of the small firm.

Useful as innovation count data are, they do oversimplify what is a complex process. Rather than asking "Are large or small firms more innovative?" it might be more useful to concentrate on the qualitative differences between large and small firm activities. Herman Fusfeld has made the point well. He writes:

"The fact is, of course, that start-up technically oriented companies, usually small, and major corporations with large technical staffs both contribute to the process of technical change, both provide opportunities for creativity, and both produce economic growth. Innovation in this context covers the range of activities involved in the generation and application of science and technology, including the introduction of commercially acceptable products, processes, and services. Large corporations engage in all of these, but have a unique role in concentrating technical resources to generate significant technical advances. Start-up companies emphasize the applications of new technology and the introduction into commercial use." (Fusfeld, page 248)

There are some other implications of the transfer of the innovation process from a small to a larger company at the point of initial marketing. In several of our cases this was the result of an arrangement which was in part financial. That is, the sale of marketing rights was seen by the small firm as a way to raise funds to carry out development activity or other stages of the innovation process. The factors underlying such transactions are both financial and real economic factors. Financially, the small firm tends to run out of funds at about this stage in the process, having
used earlier funding to support R&D. The offer from the larger company to buy marketing rights, or a large order of the product, and to pay in advance for it provides an injection of funds when they are needed and at apparently low out of pocket cost for the small firm. What the small firm gives up, of course, is the control over the marketing of the innovation. There are also real economic factors which suggest that such arrangements are socially efficient however. The larger firm has expertise in marketing which the small firm may not have, and more important, has in place already a distribution network. The existence of significant economies of scale and economies of scope in marketing mean that it is cheaper for the larger firm to introduce the new product to the market than it would be for the small company.

In a number of cases where such marketing arrangements were made the agreement broke down after a fairly short time period. This was in fact more common than long term success of such contracts. This suggests that such agreements are hard to monitor and enforce. Typically the small firm believes that the large firm is not putting enough effort into marketing the product. The large firm, on the other hand, may complain that the small firm is not meeting contractual requirements as to quality and quantity of the product itself. One interview respondent, whose firm had not entered into such an agreement, suggested that this kind of outcome was neither unforeseen or undesired by the large company. In his view many large companies attempted to sign such agreements deliberately to delay the introduction of a technology which could be competitive with items already in their product line.
Several cases suggested the importance of **mergers among small firms**. This seems to be a topic which has received little attention, with the literature concentrating mostly on large firm mergers or the merger between a small and a large firm. In two of our cases a business combination provided funds for a small firm with a new product under development. The partner supplying funds in one case was a firm with cash available but whose own innovation project had been blocked by a contractual dispute. In the other case, one partner provided funds since it was a going business and could provide funding out of profits.

It was clear in many of the cases that the date of introduction of the new product did not mark the end of the need for external financing. Many firms anticipated a considerable time period until the new product generated enough internal funds to be self sufficient. The scale up of manufacturing and marketing required significant investment and increased need for funds. It was also at this time that firms moved to obtain some measure of diversification either by merger or introducing modifications of their product or other, entirely different, products.

The limitations of research based on only 13 cases are obvious. Are the patterns observed here unique to the medical device industry or are they found in other industry settings? To what extent are the financing decisions of small innovative firms conditioned by the regulatory environment, the entrepreneurial personality, or opportunities for relationships with larger firms? The next step is to go beyond description to develop theoretical models subject to
empirical test. It is hoped that these cases have helped to identify topics and approaches suitable for use in further research.
REFERENCES


Berg, Stanford, Jerome Duncan, and Philip Friedman, Joint Venture Strategies and Corporate Innovation (Oelgeschlager, Gunn & Hain, 1982)


