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NeuroMotion Case Study

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This case was prepared by Beth Graham under the direction of Dr. Jim Graham, director of Venture Development at the University of Calgary, with the support of a grant from the Alberta Heritage Foundation for Medical Research to encourage discussion and learning about technology commercialization. The case is based on interviews with some but not all of the mentioned participants and while it is believed to be reasonably accurate, may not represent all the facts or views of the participants.

The Problem

Tom Rice, acting CEO of NeuroMotion Inc., was anticipating a problem. He had heard that NeuroMotion, a new medical device company, might receive only half of the \$6 million financing it had planned for. He called Business Manager Tricia Cisakowski and Chief Financial Officer Christine Stacey into his office to help develop a new strategy to deal with this potential setback.

Assuming full financing of \$6 million, their strategy for penetrating the market was an aggressive plan involving the commercialization of all of NeuroMotion's products in rapid succession. The products were the **Glove**, the **WalkAid**, and the **Tremor Control Cuff**. Decreasing risk was a key strategy in the formation of NeuroMotion. Increasing the number of product offerings increased the probability that the company would generate significant sales, which made it a more attractive investment opportunity. In addition, if one product did not do as well as anticipated, perhaps another product would be more successful.

Their aggressive \$6 million plan involved completing the reengineering and redesign of these products, getting regulatory approvals, promoting the products with high-quality collaterals (manuals and videos), gaining exposure to the market through multi-centre clinical trials and close relationships with thought leaders, obtaining recognition through publications, and selling the products using an internal sales force and a concentric selling model. NeuroMotion planned to further add value through the patenting process, market research and the development of a strong and knowledgeable team to manage the commercialization process.

If only \$3 million was received from investors, NeuroMotion had to choose between following the aggressive commercialization plan developed for \$6 million in financing or devising a slower, more cautious plan.

Rice, Cisakowski and Stacey decided that a slower plan should involve the promotion of only two products -- the **Glove** and the **WalkAid**. This slower plan meant that the products developed would be supported by less extensive clinical trials and there would be an overall reduction in spending on their development and lower quality collaterals. Consequently, sales would ramp up slower, and the company would be less attractive to follow-on investors. In addition, the longer it took to get a foothold in the marketplace, the greater the risk from potential competitors. NeuroMotion was depending on the **WalkAid** and the **Glove** to generate significant revenue to fund the development of follow-up products, such as the **Tremor Control Cuff** and other products being developed by the Neuroscience Department of the University of Alberta. Another drawback to the slower approach was that it would probably be more expensive in the long run than the aggressive plan.

A key plus of the go-slow plan was that the \$3 million would last eighteen months, giving management a full year before they had to seek additional financing. If they chose to follow the aggressive plan with \$3 million investment rather than \$6 million, they would likely have to begin fund raising after only six months. None of them liked the idea of having to raise new funds at the same time as they were developing their products. They also considered whether NeuroMotion would be at an opportune stage to receive additional funding after only six months of operation, with no finished products, no sales and only partial management team in place, and so close to when the previous round of financing was raised.

Rice, Cisakowski and Stacey agreed to weigh the pros and cons of each approach and then make a decision as to the strategy to pursue. A decision had to be made quickly. Both courses of action involved risk...

The Products

The two main start-up products for NeuroMotion are the Glove and the WalkAid. These products complement one another as they are both based on FES (Functional Electrical Stimulation) and are aimed at a similar target market. (Detailed descriptions of NeuroMotion products are presented in Appendix A.)

The Glove and the WalkAid were developed to assist people who are motion-impaired in their daily living. The customer's motivation for purchasing the products would be to regain lost motor function.

The **Glove** is an electric device that improves the tenodesis grip (pinch grip between the thumb and forefinger) as well as hand opening and closing.

The **WalkAid** treats foot-drop, a condition in which individuals are unable to engage the muscles needed to lift their foot off the ground.

The **Tremor Control Cuff** reduces tremor over 80 per cent in patients with essential, Parkinsonian and cerebellar tremor. In this product, electrical stimulation is delivered out-of-phase with each tremor cycle, selectively counteracting and suppressing the tremor.

The Company

Beginnings

NeuroMotion has its roots in two University of Alberta spin-off companies -- Neurokinetics Inc. and Bio Motion Ltd. Both companies had been researching similar technologies and decided to pool their resources to enter the market with their products.

- **Bio Motion** was owned and operated by Dr. Richard Stein, a professor in the Neuroscience department at the University of Alberta, and Kelvin James, a member of Stein's research team. Stein and his research team had developed a medical device called the WalkAid. The WalkAid addressed the problem of foot drop where a person is unable to clear the ground with their foot when walking -- a common condition occurring after a stroke or spinal cord injury. The technology was based on FES (functional electrical stimulation). FES uses electrical currents to produce controlled activation of the neuromuscular system, resulting in movement, sensory response or therapeutic effects.
- **Neurokinetics** was started by Dr. Arthur Prochazka, also a neuroscience professor at the University of Alberta and a recognized expert in the field. Like Bio Motion, Neurokinetics' research was also based on FES technology. The company had developed an innovative medical device called the Glove. It improves the tenodesis grip (pinch grip between the thumb and forefinger) as well as hand opening and closing in some people with quadriplegia.

In January, 1995, Neurokinetics and Bio Motion met separately with NeuroResearch Inc. (NRI), the business entity associated with the Neuroscience Network of Centres of Excellence (NNCE). (One of the objectives of the NNCE is to promote spin-off companies.) Each company had developed a business plan, and wanted to discuss funding for the commercialization of research projects.

The NNCE suggested that Neurokinetics and Bio Motion merge to form a single company. The reasoning was that if the two companies pooled their resources, they would have a viable company to attract investment. NNCE commissioned Ernst & Young to draw up a business plan to illustrate the effects of combining Neurokinetics and Bio Motion. This plan recommended that the two companies combine their efforts.

The Alberta Heritage Foundation for Medical Research (AHFMR) also suggested that Prochazka and Stein join forces. AHFMR had already provided each company with Phase I and Phase II technology commercialization funding (approximately \$100,000 each). If the two companies merged, AHFMR suggested that the resulting company might be eligible for Phase III funding to start up the new company and improve its ability to attract investors.

NeuroMotion is formed

In December 1995, **NeuroMotion Inc.** was founded through a merger of Neurokinetics and Bio Motion. Shortly thereafter, the company had secured \$500,000 in technology commercialization funding from AHFMR. NeuroMotion aimed initially to commercialize inventions and developments created within the Rehabilitation Neuroscience group at the University of Alberta.

The mission of the Alberta-based medical device company was to enhance the mobility of persons suffering from neurological diseases or injuries through the development of therapeutic devices, diagnostic devices, and devices for the restoration of function. Its objective was to become an efficient, profitable vehicle for rapid development of high-value added, cost-effective products based on early research discoveries. Through strategic and commercial partnerships, NeuroMotion's proprietary products would be developed and distributed worldwide.

While NeuroMotion had recognized expertise in research, engineering and the clinical aspects of its products, the company had very little experience in management, marketing and sales. The first step to solving this problem was recruiting Tom Rice, an experienced business professional, as CEO. Rice had previously been hired by NRI to assess the original companies in the spring of 1995.

Rice's job was to launch NeuroMotion's two lead products: the Glove (developed by Neurokinetics) and the WalkAid (developed by Bio Motion). Once they were established in the market, products selected to follow included the Tremor Control Cuff. NeuroMotion was also looking for two additional products from within the University of Alberta as well from outside sources.

The use of electrical stimulation in general was gaining momentum and there were several companies poised to supply medical products to the market. (See Appendix B for a discussion of competing technologies.) Aside from FES (functional electrical stimulation), other companies had developed devices using Transcutaneous Electrical Nerve Stimulation (TENS), and Neuromuscular Electrical Stimulation (NES).

The risks involved in entering the FES market were high. If the FES market really heated up, new entrants became direct competitors. It was estimated that these competitors would be two years behind NeuroMotion if they decided to enter the market.

Company structure

NeuroMotion established its own management team. Prochazka, Stein and James continued as researchers at the University of Alberta. Their involvement with the company might include research on potential products which could then be developed by NeuroMotion, or contract research for NeuroMotion.

The NeuroMotion management team is made up of Rice as Chief Executive Officer, Cisakowski as General Operations Manager, and Christine Stacey as Chief Financial Officer. The Board of Directors consisted of Rice, Prochazka, Stein, and two nominees of the Neuroscience Partners Limited Partnership.

NeuroMotion has two bases of operation: one in Edmonton and the other in the Twin Cities of Minneapolis-St. Paul. Research and development, initial clinical research and manufacturing is based in Edmonton. Sales and marketing will eventually be conducted from the Twin Cities.

The company operates as a semi-virtual corporation, with the majority of staff hired on an as-needed rather than permanent basis. The core team is augmented by a cadre of outside resources including advisors in the areas of regulatory affairs, engineering design, industrial design, market research, project management, and clinical research. Personnel communicate through e-mail, fax and phone.

This operational structure has a number of advantages and disadvantages.

Advantages

- lower overhead costs because of smaller facilities
- ability to operate at a more controlled “burn rate of money” until the products are approved for market
- ability to retain qualified people that may not otherwise be available on a full-time basis, either because of cost, availability or geography.

Disadvantages

- potential barriers to effective and timely communication (although e-mail, fax and phone seems to alleviate much of this problem)
- possible lack of commitment by those retained only as consultants.

NeuroMotion ownership

NeuroMotion was incorporated such that it was owned 50 per cent each by Neurokinetics Inc. (Prochazka) and Bio Motion Ltd. (Stein and James).

Neuroscience Partners Limited Partnership -- a joint venture between NeuroResearch Inc. and MDS Health Ventures, which is managed by MDS -- invested \$250,000 into NeuroMotion in exchange for 17 per cent equity. Five per cent equity was given to the Neuroscience Network of Centres of Excellence as an incentive to supply commercializable technologies in the future.

The structure of the company was unencumbered by complicated share structures and multiple minority shareholders.

Funding structure

The way in which the two lead products would be launched depended on the type and source of financing that NeuroMotion could obtain.

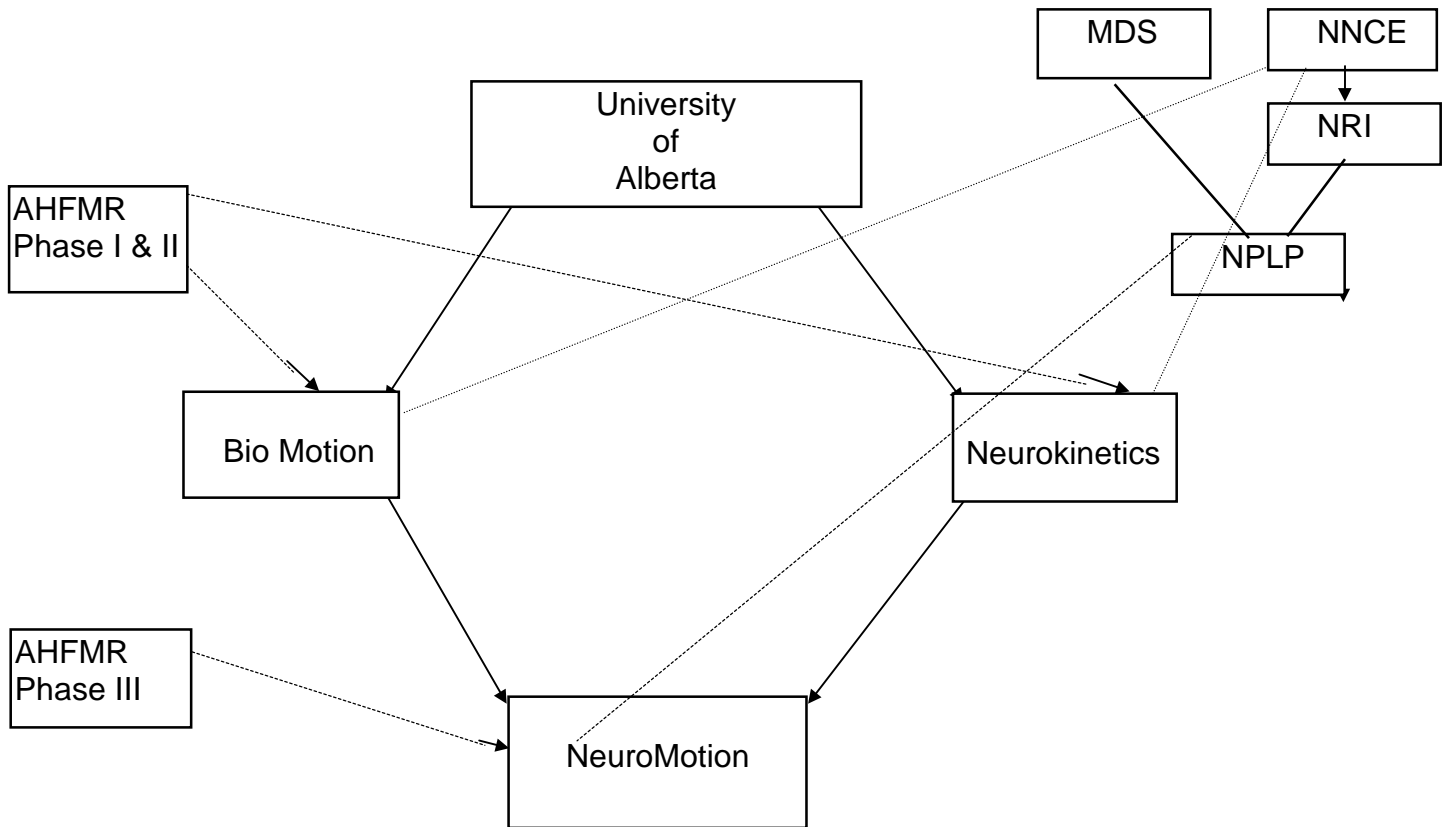
The company sought financing from AHFMR (Phase III funding), and the MDS Neuroscience Partners Limited Partnership. The company also planned to approach the National Research Council's Industrial Research Assistance Program for investment.

Rice estimated that NeuroMotion needed \$8 million to bring the company to positive cash flow and profitability. The business plan requested equity investment totaling \$6 million which would allow the company to pursue an aggressive product development plan.

However, there was the possibility that the company may receive only \$3 million. In this case, if the company decided to follow the initial plan, it would mean that six months down the road more funding would have to be found.

The other option that NeuroMotion was considering was a less aggressive plan involving fewer people and less product development. This plan would allow the company to operate for 18 months, giving it one year before having to raise more funds. In the long run, it would probably cost more to follow this plan, but it was possible that such an approach would be essential for survival.

The following chart illustrates the funding structure of NeuroMotion.



NNCE (Neuroscience Network of Centres of Excellence) consists of 18 universities and institutes that are recognized for their expertise in the field of neuroscience. The network is responsible for targeting potential business ventures.

NRI (NeuroResearch Inc.) is the business entity of the NNCE. NRI was established to handle the outflow of intellectual property from the NNCE. It has a mandate to offer the Neuroscience Partners Limited Partnership fund first right-of-refusal for all research emanating from the NNCE. NRI negotiates with the Neuroscience Partners Limited Partnership on behalf of the NNCE's spin-off companies. NeuroMotion went through the NRI in order to be considered for funding.

NPLP (Neuroscience Partners Limited Partnership) is a \$52.5 million venture capital fund, managed by MDS, that supports the development and commercialization of drug products and devices for a wide range of neurological disorders. It was one of North America's first funds to focus on the early stage

development and commercialization of treatments for disorders affecting the brain and central nervous system.

MDS Health Ventures is Canada's largest, most successful, technology-based health and life sciences company. MDS manages the Neuroscience Partners Limited Partnership, as a joint venture with NRI. If NeuroMotion received funding from Canada's most successful medical venture fund, it would be easier to attract syndicate venture funding which would ensure a long-term source of funds.

AHFMR (Alberta Heritage Foundation for Medical Research) runs a program for the commercialization of technology. The program assists Alberta innovators with the transfer of new ideas and scientific findings into successful commercial health related products and processes. It is structured to promote research/industry/business collaboration. Three different phases, or levels of funding, are involved in the Technology Commercialization program. Prochazka and Stein had received Phase I & II funding for their separate businesses. NeuroMotion received \$500,000 in Phase III funding.

NeuroMotion personnel

Tom Rice, Ph.D. A business professional with over 24 years experience as an executive, consultant, investor and researcher in the medical products industry. He also has considerable experience as a consultant for start-up companies. Rice brought substantial venture capital contacts to NeuroMotion through his involvement in Vencap, a venture capital fund. He was employed as a part-time CEO for approximately three, then became full time. He was a *de facto* MDS appointee, who had verbally agreed to a three month contract with NeuroMotion. He operates out of Edmonton and Minneapolis-St. Paul.

Tricia Cisakowski had worked with Neurokinetics for a year and a half before NeuroMotion was formed. She is a professional with extensive experience in research and business management. Cisakowski was the General Operations Manager for NeuroMotion, retained on a monthly basis.

Christine Stacey is a chartered accountant with substantial experience in financial and business management, and venture funding for start-up companies. Stacey is NeuroMotion's Chief Financial Officer.

Arthur Prochazka, Ph.D., was the founder of Neurokinetics Inc. He does research and develops products for NeuroMotion, and continues his position at the University of Alberta. He was one of the founding members of the Board of Directors.

Richard Stein, Ph.D., and **Kelvin James**, research assistant, were founders of Bio Motion Ltd. They do research and develop new products for NeuroMotion,

and continue to maintain their positions at the University of Alberta. Stein was one of the founding members of the Board of Directors.

The Issues

Clinical trials

Both the WalkAid and the Glove had been in clinical trials in major rehabilitation centres worldwide, and the researchers had received valuable feedback from the users. However, further trials were necessary in order to:

- help the devices meet regulatory requirements
- gain feedback for product development from those involved in the trials
- help establish distribution channels through the therapists involved
- reveal how the market would accept the products and alert the researchers as to what changes still needed to be made
- enable NeuroMotion to gather data on test outcomes and cost effectiveness to support claims and third party payers
- create a demand from customers
- give the devices exposure to the potential market and create a demand for the product.

The initial plan was to conduct additional clinical trials of the final design of each of the devices. This would involve a short-term two-centre trial followed by multi-centre trial.

With a reduction in available financing, NeuroMotion was considering limiting the number and scope of these clinical trials. The alternative plan brought only the Glove and the WalkAid into clinical trials. It also meant that the two products would only be involved in one multi-centre trial each. This process would be much slower and the follow-up products (such as the Tremor Control Cuff) would wait to undergo clinical trials until further financing was available.

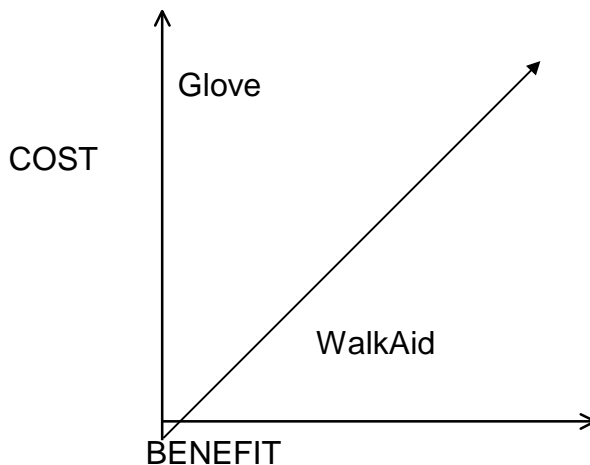
Evaluating the products

A marketing consultant was hired to address the customer need for the two main products. Relative value was assessed by discerning how much time and effort was required on the part of the user to attain the benefits of the product. The consultant concluded that the WalkAid provided more relative value to the customer than the Glove for the following reasons:

- The Glove was used for one or two tasks, whereas the WalkAid was being used all day.

- The WalkAid was more compact and more cosmetically appealing because it could be hidden from view.
- The WalkAid was easier to put on and take off.
- There was still some difficulty in programming the Glove for new users.
- Adjusting the Glove was time consuming for a motion-impaired individual.

The chart below illustrates the relative value of the Glove and the WalkAid. The Y axis measures the time and energy needed from customers before they obtain a benefit. The X axis measures the benefit received from the device in everyday living. Anything above the intersecting line indicates that costs outweigh benefits. Anything below the intersecting line indicates that benefits outweigh costs. Each member of the NeuroMotion management team drew this chart, and the results were virtually identical. This is an approximation of what was drawn.



The WalkAid was considered to provide a great amount of benefit with minimal time and effort (cost) invested. At this stage in its development, the Glove offered less benefit for the amount of time and effort a patient had to put into it.

To improve the relative value of the Glove, the research team worked on making it much easier to use in order to motivate customers to use the Glove for a variety of tasks rather than just one or two.

Consultants

As a start-up operation, NeuroMotion knew there was a great need to carefully plan operational, manufacturing, reimbursement, clinical and marketing activities. NeuroMotion required expert advice in a number of areas.

Regulatory & GMP - A regulatory consultant was hired to provide expert advice in order to obtain regulatory approval for the United States and Europe. The devices would also be required to meet Canadian standards. Regulations needed to be met before the products could be placed on the market. The process of regulatory approval is long and involved. Hiring a consultant can reduce the overall cost by ensuring that regulations are met as quickly as possible so that products will be ready for market. The costs involved for receiving regulatory approval include testing, labeling, safety inspections, and ongoing filing and reporting.

Reimbursement - Reimbursement is a crucial issue for NeuroMotion. Medical institutions exercise a great deal of influence on users of medical devices. If the physicians and therapists accept the device as an innovative tool for increasing an individual's independence, then the buying decision is half complete. The patient must then be able to get the product paid for. A consultant was hired to determine how best to convince reimbursement agencies of the device's necessity to patients. Reimbursement agencies in North America include: insurance agencies, Medicare, Managed Care/ Health Maintenance Organizations (HMOs), the Veterans' Association, Workers Compensation Boards, other associations for the motion impaired (e.g. Aids to Daily Living) and community associations (e.g. the Shriners). Many programs restrict the allocation of funds to certain equipment or services. The consultant, therefore, had to establish a method of gaining recognition with these agencies to achieve inclusion in allowable purchases.

Clinical Trials - A clinical consultant works closely with the clinical research organization contracted to design ongoing clinical trials. Clinical trials must be designed so that the results can be used to prove cost effectiveness and gain regulatory approval.

Industrial Design - A human factors/industrial design consultant assists in further developing NeuroMotion's products, especially in the area of user interface.

Intellectual property

In the early stages of product development, the researchers had the choice to obtain full ownership of their technology or grant it to the University of Alberta. Prior to setting up NeuroMotion, Stein and James retained full ownership of the WalkAid for their company, Bio Motion. On the other hand, Prochazka had assigned rights for the Glove to the University of Alberta. The University in turn licensed the glove back to his company, Neurokinetics. It was imperative that NeuroMotion own the products that it would market. Therefore one of the start-up goals of the company was to obtain the rights to the WalkAid and the Glove.

Obtaining the intellectual property rights to the WalkAid was straightforward.

An agreement was reached with the University on the Glove such that if NeuroMotion raised \$500,000 in operating capital and met specified milestones within two years, then the Glove would be assigned to them. If they failed to meet these conditions within that time then the assignment of the Glove patent could be "clawed back" by the University of Alberta. NeuroMotion has managed to raise the funds and meet the projected milestones. Consequently, The University of Alberta has granted an assignment of the patent for the Glove to the company.

It was determined that both the WalkAid and Glove would be best protected by worldwide patents. The first step towards protecting the Glove was filing a PCT Application in October of 1994. Patent applications for the WalkAid were filed in the United States and Canada in September, 1995. Plans were made to file a PCT patent application for the WalkAid in September, 1996, which would give worldwide protection to the WalkAid.

Marketing and sales

The entire field of electrotherapy has been growing since 1992 and is poised to enter a period of increasing growth. Forecasts call for it to reach \$193.8 million US (excluding FES) by 2002 and then grow at an annual rate of 7.3 per cent, driven by favourable demographic trends and increases in incidences of trauma. Growth will also be influenced by improvements in technology, emergence of clinical studies showing improved effectiveness, and increased awareness about the field and its ability to reduce overall health care costs. An important development in the neuromuscular stimulation market is the development of products for home use.

In defining the specific markets that NeuroMotion's products addressed, the company looked at the number of people suffering from particular injuries or diseases that led to motion impairments and the level of dysfunction that resulted.

- **Spinal cord injury.** There are about 200,000 individuals in the United States with spinal cord injury. The annual incidence of spinal cord injury is 10,000 new cases per year. In order to be able to use the Glove, people with quadriplegia must have some residual voluntary wrist extension with weak or absent thumb and finger movement. Typically, people with an injury at cervical joints 6 or 7 fall into this category. When factors such as physical suitability and acceptance are taken into account, the estimate of potential users in the United States is approximately 17,000 persons. Of the 10,000 new cases per year, there are approximately 900 potential new users.

WalkAid was originally developed for stroke patients. Because NeuroMotion had conducted limited studies on its applications to spinal cord injured patients, it was difficult to estimate the number of people who would benefit from the WalkAid. The market was conservatively estimated at 11,000 users.

- **Stroke.** In the United States there are approximately 2.1 million stroke survivors, many with residual hemiplegia (paralysis of one side of the body). There are approximately 350,000 new stroke survivors added yearly. The motor deficits range from mild weakness in the affected arm to complete paralysis and spastic rigidity. In order to be a candidate for the Glove, stroke patients must have good shoulder and elbow control. Clinical opinion differs on the exact percentage who can use the glove, but it is probably in the range of 5 to 10 per cent of stroke survivors, which conservatively translates to approximately 22,000 individuals. The stroke market for the WalkAid was estimated at 36,000 persons.
- **Tremor.** NeuroMotion plans to implement the Tremor Control Cuff in order to reach the tremor prone market. The system is still in development. Prochazka and his team of researchers believe that individuals with essential and cerebral tremor will benefit from this invention. Tremor is the single largest neurological problem in the United States. There are approximately 3 to 4 million patients with essential tremor. The potential market for NeuroMotion's Tremor Control product is estimated at \$10 million worldwide at maturity.

NeuroMotion believes it can capture 5-20 per cent of the available US market for its products at maturity. The company projected that worldwide sales would eventually grow to twice that of the US market.

The following table summarizes NeuroMotion's analysis of the US and world-wide market potential for its first three products. This table also shows NeuroMotion's estimates of its worldwide sales of these products at maturity on a yearly basis.

(U.S. dollars)					
Product	Total US Units-possible	Price / Unit	Total US Market \$'s	Total World-wide Market \$'s	NeuroMotion Sales at Maturity \$'s
WalkAid	72,000	\$750	\$54 million	\$108 million	\$13 million
Glove	29,170	\$2,500	\$72 million	\$144 million	\$20 million
Tremor Control Cuff	40,000	\$2,500	\$100 million	\$200 million	\$10 million
Totals			\$226 million	\$452 million	\$43 million

Distribution

Because NeuroMotion's products are leading edge, the company is best served by creating its own distribution channel. Therefore, NeuroMotion is approaching the market directly, placing its products in the hands of leaders in key rehabilitation centres throughout the world. As the products are innovative, the strategy is one of concentric selling, initially focusing on early adapters and thought leaders. A number of key centres have already been introduced to the WalkAid and the Glove through clinical trials. Both Stein and Prochazka have extensive connections to major rehabilitation centres.

For broad distribution, NeuroMotion will evaluate various channels such as manufacturers, representatives, distributors, or partnering with other companies that have their own distribution channels in place. NeuroMotion anticipates that the route to market would vary from country to country, depending on local circumstances.

Through these efforts -- in conjunction with a series of publications, presentations, trade show displays and a modest amount of advertising -- NeuroMotion will create an awareness of its products and a market pull. The extent to which NeuroMotion pursues this marketing plan depends upon funding.

Finances

A decrease in market risk was a key factor in the formation of NeuroMotion. By increasing the number of technologies offered to the public, the company gained security. If one product did not do as well as anticipated, perhaps another product would be more successful.

NeuroMotion's aim was to add value to the Glove and the WalkAid through the patenting process, clinical trials, regulatory approvals, market research and the development of a strong and knowledgeable team to manage product development and commercialization.

If the company received less than the \$6 million it sought, a new strategy would be employed. Any saving however, increased the risk of failure for the company.

- For example, if NeuroMotion cut the number of clinical trials, the amount of information available for product refinement would be reduced, the product would be introduced to fewer clinicians, and information needed in developing sales packages would be diminished.
- Another alternative would be to introduce all the products sequentially, using the revenues from the first product to finance subsequent products. Again, if the first product was not successful, the company would be in danger of failing before the next products were introduced.
- As well, expenses such as patent development, sales, marketing or outside consultant costs could be reduced, but each reduction would leave the company exposed to new risks.

The operating forecast and unit sales projections are presented in Appendix C.

The Next Step

Rice, Cisakowski, and Stacey met again to discuss the future of NeuroMotion. At the end of the meeting they concluded that if they received only \$3 million dollars in funding, the company would take the slower approach. They began to develop a business plan that would accommodate this reduction in funds yet continue to follow NeuroMotion's initial objectives. What would the slow approach cost them? What were its rewards?

APPENDIX A: NeuroMotion Products

The two main start-up products for NeuroMotion are the Glove and the WalkAid. These products complement one another as they are both based on FES (Functional Electrical Stimulation) and are aimed at a similar target market.

The Glove and the WalkAid were developed to assist people who are motion-impaired in their daily living. The customer's motivation for purchasing the products would be to regain lost motor function.

The **Glove** was developed by Dr. Arthur Prochazka, a neuroscientist at the University of Alberta and the founder of Neurokinetics Inc. It is an electric device that improves the tenodesis grip (pinch grip between the thumb and forefinger) as well as hand opening and closing. Because the stimuli that provide this improved hand capability are triggered by wrist movement, potential users must have some residual motion in their wrist to activate the device.

The glove is fingerless and made from a stretchy neoprene material, similar to a skin diver's wetsuit. During clinical trials, patients were able to regain skills such as lifting heavy objects, using a hammer, opening doors with round smooth knobs, and eating finger foods. Users also showed increased efficiency in performing tasks that they could already do with the aid of other devices (splints and orthoses). These tasks included writing, using cutlery, toothbrushes, keys, and drinking from a cup or glass.

The clinical trials to date on the Glove were sponsored by the University of Alberta.

The **WalkAid** was developed by Dr. Richard Stein, a neuroscientist at the University of Alberta, and Kelvin James, a member of Stein's research team. Both were the founders of Bio Motion Ltd. The WalkAid treats foot-drop, a condition in which individuals are unable to engage the muscles needed to lift their foot off the ground. As a result, the foot is dragged when walking. The WalkAid is a fully self-contained unit equipped with a number of novel features:

- a tilt sensor which allows adjustment of the threshold angles for turning the stimulation on and off
- electronics and stimulating electrodes
- a stretchable, breathable garment.

The WalkAid has also been in clinical trials, sponsored by the University of Alberta.

Both the WalkAid and the Glove are controlled by computer programs that provide an easy-to-use interface between the clinician and the device. The

clinician can communicate directly with the device to set the logic and stimulus parameters.

Another potential product is the **Tremor Control Cuff** which reduces tremor over 80 per cent in patients with essential, Parkinsonian and cerebellar tremor. In this product, electrical stimulation is delivered out-of-phase with each tremor cycle, selectively counteracting and suppressing the tremor.

APPENDIX B: Competing Products

Glove competitors

At the time of NeuroMotion's formation, the only closely competitive technologies came from companies such as NESS and NeuroControl. Neither of these companies were particularly strong financially and each of them had products that were more complicated and more expensive than NeuroMotion's.

The **Handmaster**, developed by NESS, was based on research conducted by Dr. Roger Nathan at Ben Gurion University in Israel. The device rigidly splinted the wrist and activated muscles according to a pre-stored pattern when a button was pushed on the control box. The control box was separate from the device. While the device was commercially available in Canada, none had been sold and in the United States as FDA approval had not been received. Some Handmasters had been sold in Europe. The cost of the entire system was \$3000 US.

The main drawbacks of the Handmaster were: the electrode placement not being customized, the separate control box and wires, and the fact that it was not suitable for patients with active wrist movement.

Prehension orthoses (wrist driven and ratchet orthosis) were devices that had successfully been used by some quadriplegic people. However, many were discarded because of problems in getting them on and off, pain caused by ill-fitting devices and poor cosmetic acceptability. It was also difficult to find an orthotist who would custom fit these devices. The cost of these orthoses was approximately \$1500 US.

The **Free Hand System** was developed by NeuroControl. It used implanted FES technology and was not yet commercially available. It was a relatively complex, invasive device requiring surgical implantation of electrodes and a stimulating unit similar to a cardiac pacemaker. Following implantation, there was a fairly extensive and complicated procedure to program an effective hand grasp. Training was required to become proficient with the system. The cost was approximately \$30,000 US.

Potential users had to wait at least two years after their injury before being considered for the implant. NeuroMotion developed a strong rapport with Neurocontrol and it was suggested that the Glove be used in the interim, while the patient awaited surgery.

Tendon transfers had been performed by orthopedic or plastic surgeons in some centres to improve upper extremity function following spinal cord injury. Potential candidates had to wait at least one year after their injury to be considered, and had to meet certain physical and psychological criteria. This approach required a significant time and financial commitment and the functional outcomes were unpredictable. As with the Free Hand system, the Glove might have a role to play in the period preceding tendon transfers.

The advantages of the Glove over the existing solutions were:

- Easy to put on and take off
- One self-contained unit, no wires or outside control boxes
- Implantation and surgery not required
- Easy to use
- Comfortable, lightweight and breathable -- made of stretchy neoprene and lycra mesh
- Cosmetically acceptable
- Reasonable cost: \$3500 CDN
- Users control the stimulation and the duration through wrist action, and are not limited to preprogrammed stimulation
- Users have the ability to perform tasks they could not otherwise perform: manipulating heavy objects, picking up objects, and using tools
- Washable

WalkAid competitors

A number of **foot-drop stimulators** have been designed and built over the years (Mikrofes, VeriDFS and I-GO). In addition, large manufacturers such as Medtronic and Empi had developed protocols for adapting their neuromuscular stimulators to be used for foot-drop.

These devices had not received widespread acceptance for a number of reasons. The systems had several pieces, all of which had to be connected together accurately which could be difficult and time consuming, particularly for a person who had cognitive impairments or loss of manual dexterity. Wires connecting the various components could become disconnected or break during use. These systems were often activated by a foot switch which did not always work reliably on different surfaces. The placement of the foot switch was also a problem. In some positions enough pressure was not generated to activate the switch.

Ankle foot orthoses (AFOs) also addressed the problem of foot drop, but they had a number of limitations compared to the WalkAid. The limitations included:

- With an AFO, the muscles were unused and would atrophy further. The WalkAid provided effective joint positioning by eliciting activity from the weakened or inactive muscle groups and facilitated neuromuscular re-education through active muscle contraction and by providing sensory input to the central nervous system.
- A conventional orthosis provided the desired positioning during one phase of the gait cycle, but interfered with motions essential to the normal completion of other phases of gait.
- When an AFO was used to correct foot-drop, it caused an increase in the flexion movement at the knee, as the foot moved from heel strike to flat foot. In a patient with insufficient quadriceps strength to stabilize the knee, this could result in knee buckling. The WalkAid allowed the ankle to move freely into plantar flexion from heel strike to flat foot with no increase in the flexion moment created at the knee.
- An AFO was a plastic shell that could be uncomfortable, constraining, unattractive and did not breathe in hot weather. It was unable to accommodate changes in girth resulting from swelling. In contrast, the WalkAid was fully self contained, in a breathable garment, which allowed barefoot walking and would be essentially invisible when worn under pants or a skirt.

The advantages of the WalkAid over existing systems were:

- A fully self contained unit without the hassles of wires and outside control boxes.
- Control circuitry built into the unit.
- Filtering and timing circuits built into the electronics so that a maximum reliability in triggering could be obtained.
- Easy to put on and take off.
- Self positioning. Could be placed on the leg quickly and reproducibly.
- Comfortable: made of stretchy, breathable neoprene.
- The electrodes were attached to the device and were reproducibly positioned each time the WalkAid was put on.
- Washable.

APPENDIX C: Summary Financials

Operating Forecast

(Thousands of Canadian dollars)

Year	1996	1997	1998	1999	2000
Net Sales	7	502	3,333	12,330	36,673
Cost of goods sold	<u>1</u>	<u>93</u>	<u>655</u>	<u>2,045</u>	<u>5,898</u>
Gross Margin	6	409	2,678	10,285	30,775
Expenses					
General and admin	765	999	1,158	1,354	3,786
Product development	957	1,602	1,451	1,213	1,213
Sales and marketing	<u>273</u>	<u>1,174</u>	<u>2,091</u>	<u>2,466</u>	<u>7,334</u>
	1,995	3,775	4,700	5,033	12,333
Net income (loss) before income taxes	(1,989)	(3,366)	(2,022)	5,252	18,442

Unit Sales Projections

Year	1996	1997	1998	1999	2000
WalkAid	8	188	1,185	3,541	8,341
Glove		38	224	672	1,193
Tremor	-	8	285	1,364	3,890
New Product 1	-	52	295	360	360
New Product 2	-	-	-	945	4,385
New Product 3	-	-	-	-	985
Accessories	-	938	11,985	16,748	56,751

Questions for Discussion

1. What are the advantages and disadvantages of combining the two companies into NeuroMotion?
2. What are the advantages and disadvantages of operating a virtual corporation?
3. What is the role of the research team with the new firm? Who influences the purchase of the NeuroMotion products?
4. What are the advantages and disadvantages of each of the following as a method of reducing expenditures:
 - a) fewer clinical trials
 - b) lower marketing expenditures
 - c) more selective patent protection
 - d) sequential introduction of products
 - e) shortened product development
5. What would you recommend Tom Rice do if he receives \$ 3,000,000 funding?
6. How do the tasks in managing a research group differ from the task of running a commercial company?