

A Biomedical Device Business Plan for Medcraften Devices Inc. to Develop a Fluid Medication Dispenser

By

Charles Davidson Louison

SUBMITTED TO THE DEPARTMENT OF MECHANICAL ENGINEERING IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

BACHELOR OF SCIENCE
AT THE
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Author: _____

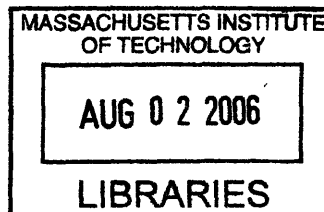
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ARCHIVES

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Charles Davidson Louison

**Submitted to the Department of Mechanical Engineering
On May 9th, 2006 in Partial Fulfillment of the
Requirements for the Degree of Bachelor's of Science in
Mechanical Engineering.**

Abstract

This thesis surrounds an analysis to understand what it would take for a company to successfully launch a prescription fluid dispensing device. This device would in theory be able to dispense medication at any time daily in correspondence to a patient's prescription. This thesis does not surround the actual development of a prototype, but gives a clear background into its technology. Other areas of research in this report include potential alliances and acquisitions of this company. This report gives a background into the target market, how the market will benefit from this device, and who the potential competitors of this device could be. Also explored are a potential advisory board for this company and how staff will be organized. Although the people on the advisory board and company's staff do exist, they are not actually involved in the conception of the thesis' device. This thesis uses techniques learned in management, engineering, and biomedical enterprise courses at MIT to give a real world case of how an effective biomedical device company can be formed and effectively managed.

Thesis Supervisor: Noubar Afeyan

Title: Senior Lecturer, Sloan School of Management

Biographical Note:

Charles Louison is a student in the Mechanical Engineering Department at MIT. Under the 2A coursework plan he has been able to take a concentration of classes outside of the traditional mechanical engineering course plan. Charles has taken 4 courses in the Biomedical Enterprise Program, a program that is jointly administered by the Harvard-MIT Division of Health Sciences and Technology and the Sloan school of Management, which works to show students a collaborative curriculum focused on the intense process of product advance and commercialization in the health care industry. Charles has had a passion for learning the essentials in this field since high school where he developed a business plan for a device to regenerate hearing. Charles will graduate with a Bachelor's degree in Mechanical Engineering in June 2006 and will enroll in Duke University for graduate school. He plans to study engineering management in the healthcare industry to receive a Master's of Engineering Management in June 2007.

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Executive Summary

Description of Business

Medicraften Devices Inc. offers a primary product, the Medipenz, which dispenses prescription fluid medication to patients at pharmacies. Ordinarily, if one would want medication they would get a prescription from a doctor and travel to a neighborhood pharmacy. The pharmacist would then figure out which medication patients need and find medicine from an inventory to give to the patient. Waiting in line and getting medications is often a long process especially in areas of high traffic or on days where many customers are in the pharmacy. This product gives pharmacists a reliable, quick, and accurate way of improving their pharmacies. The product platform was based on 6 months of research at Duke University Labs.

Opportunity and market overview

The global pharmaceutical market has reached 602 billion dollars as of last year.¹ In the United States, there are more than 33,000 pharmacies run by established chain pharmacy companies, superstores and mass merchandisers. In addition, there are another 20,000 independently run pharmacies. Jointly, these 53,000 pharmacies enable practice environments for 128,000 pharmacists so that a majority of Americans have the ability to access a nearby pharmacy. In the past years the drug industry has undergone a rapid growth. The number of retail prescriptions given out yearly grew from 2 billion in 1992 to over 3.2 billion three years ago. Chain pharmacy gave out roughly 60% of the 3.2 billion prescriptions, which gives us 2 billion prescriptions yearly, or 5.5 million daily.

Pharmacies also receive an additional 160 million dollars from the remaining items in their stores. ²

With pharmacy growth high customer satisfaction is of great interest. Pharmacists claim that pharmacies of today need to improve efficiency without adding staff. With the introduction of new medications daily and a wider knowledge base of available medication due to direct to consumer advertising pharmacists need to spend more time counseling their patients in the pharmacies rather than finding the exact medications. This is where robotic technology can help pharmacists stay ahead by allowing more time for personal contact with their customers.

Product Offering

Medicraften's product platform is the Medipenz system, a primary product which dispenses prescription fluid medication to patients at pharmacies. This system helps health system pharmacies who are challenged to do more with less today: completing more prescriptions with a smaller pharmacist workforce, keeping error incidence down, and to allow more time for patient counseling and maintenance. With our robotic fluid dispensing system and small size we can help pharmacies work more efficiently.

The Medipenz system can fill a normal size of suspension medication in 15 seconds, a slightly larger bottle in 27 seconds, and a version for familial use in 48 seconds. By doing this the Medipenz can cut a pharmacy's employees' workload in half by allowing pharmacists the ability to fill over 200 prescriptions in a short period of time. When a command is processed in the computer console a grip holds a bottle and is then

pushed towards a nozzle which fills up the bottle with the appropriate fluid medication. The bottle is then labeled, capped and sorted by the patient's last name. When the machine is out of a certain medication a message is sent to alert the pharmacy to facilitate a refill. There will be also a safety feature: when a refill bottle is put into the machine the system checks the bottle to ensure that this bottle is correct. If it is not, the machine sends off an alarm to alert the employee that a mistake was made. The machine also stops processes when this happens ensuring that the process is safe. This machine is not seen as a replacement for the pharmacy employee, but as an assistant to allow pharmacists to have an active role with their patients.

Business Strategy

Medicraften Devices will start off as a spin off technology from Duke University Mechanical Engineering Labs where a prototype was built and the underlying principles including the design of the product were developed. With a collaboration agreement, Duke Licensing office allows all rights to the product, but Duke University will receive 33% of the profit of for the Medipenz system.

The product will be shown at global and national trade shows to get the industry informed of what our product can do and to sign up our first clients. The marketing strategy involves a plan to market to pharmacies who want to the newest technologies for their pharmacy. There has also been a case study of how Parata Systems marketed their product to the industry and also we plan to market our product to many of the pharmacies that Parata uses aiming to make the whole pharmaceutical medication delivery mechanized.

This product will be marketed nationally to pharmacies who will hear the good results from the innovation interested customers. In year 4 we hope to be able to market our product to the whole pharmacy industry including making deals with pharmacy chains such as Rite Aid and Walgreens. We plan to use some of the funds generated in funding for the development of the product to make it faster and smaller. There will also be an investment of funds into research and development gives our product the ability to connect with Parata Systems products. We plan to do this to make our company attractive for acquisition by Parata later on.

Competition

There is currently no machine capable of dispensing fluid prescription medication on the market. However, if one looks at companies in our sphere of technology, you could find some potential future competition. These companies could be potential competitors if they can acquire our technology and use it for personal use. However, with our company profile and patent protection we can hold onto our product's rights for a future acquisition.

Some companies in our sphere are E-pill and Parata systems. They have currently designed mechanized prescription medication machines for today's market.

E-pill is a company that specializes in pill reminder devices. E-pill, which is a limited liability corporation for 6 years, is the leading provider of such product as a pill organizer, a medical watch that sounds when pills need to be taken, and automatic pill dispenser, a pill box organizer, medical jewelry, a pill identification organizer and a multi-alarm timer. Although E-pill sells a wide array of products, the company's

recognition comes from its primary product the Automatic Pill Dispenser. This machine is an easy management system for anyone who has a problem remembering or organizing their daily medication. This system allows individuals to take the right quantity of medications on schedule and also record that patients take their medication. This machine can also tell a patient's primary physician that they are consuming their medication

Another asset of our product is attention to health concerns. Some health concerns are alleviated knowing that your prescription will never contact the machine thereby avoiding possible contamination. ⁴

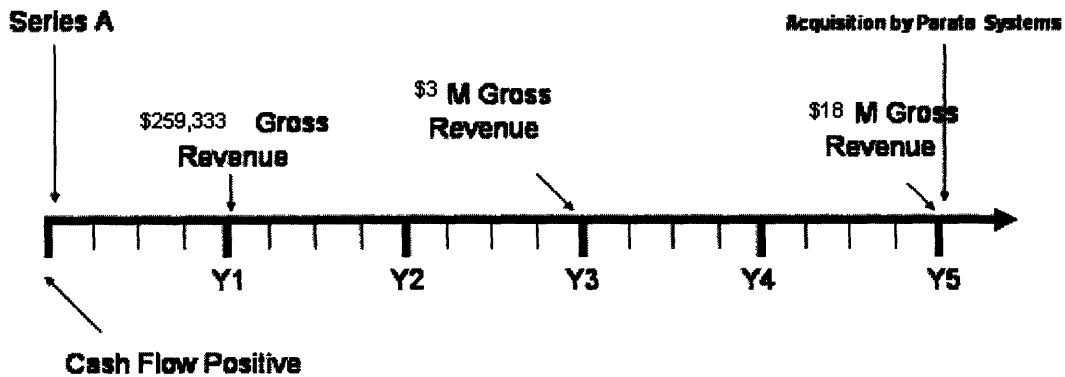
The Parata systems machine is most like our product but works in the pill sphere of the pharmacy while our product stays in the fluid medication part of the sphere. Parata was founded in 2001. The Parata systems product model is a machine that is put into pharmacies to automatically dispense pills. Parata systems launched their production-ready model in the middle of 2003 with availability to sell to their market at the same time, with manufacturing capabilities to scale to market demand. ⁶

Space is not an issue with the system as the Parata RDS was designed to fit the presented pharmacy layout, substituting one shelving unit. By Parata's attention to space the system saves each pharmacy space and is cost effective as it gets rid of a need to make a big design change in each owner's pharmacy. ⁶

Parata's vision is to drive pharmacy performance to a higher level. Parata RDS increases stores' productivity and relieves pharmacists of manually intensive pill-counting for more time with patients. Patients benefit from shorter wait times and more time with their pharmacist. ⁶

Financial Prospects

Exhibit D is an excerpt of the Medicaften the pro forma income statement simplified for analysis. As might be expected the major operating expense in the first couple of years is from salaries. Included in the salary figure are the engineers, the support and office staff, as well the sales force. Medicaften will be cash-flow positive from the beginning which is consequence of having a product that is ready to supplied to pharmacies at day one. Although we are cash flow positive we will need money to support our R&D budget to keep our technology above industry standard. We hope to have a deluge of customers to bring our number of deals in at a healthy rate to keep a competitive profit. ⁴



Sales Force		1	5	10	15
# of Deals	10	100	140	290	450
Engineers	3	5	28	48	88

Team

Charles Louison, Acting CEO - Charles is a graduating mechanical engineering senior at M.I.T. and has taken four courses in M.I.T.'s exclusive Biomedical entrepreneurship program, which is aimed at exposing students to an integrated curriculum pertaining to the difficult process of product development and commercialization in today's health care industry. Charles also will be gaining experience as a graduate student at Duke University's innovative Master's of Engineering

Ross Whitaker, VP of Product Services - Ross is a current graduate student at the University of Michigan and he did his undergraduate degree at Johns Hopkins. Co-Developed, designed, and constructed a computer-guided pill dispensing machine that enabled a quadriplegic man to lead a more independent life

Paul Stemniski VP of Engineering, - Paul has 3 years experience working for St. Jude Medical and completed his undergraduate study in biomedical engineering at Johns Hopkins. Co-Developed, designed, and constructed a computer-guided pill dispensing machine that enabled a quadriplegic man to lead a more independent life

Milestones

2006

- Procure money for first round financing.
- Actively search for a CEO with healthcare experience.
- Sell product to 10 companies.

2007

- Hire VP of Sales, Expand engineering workforce
- Expand marketing scheme to pharmacies already using the Parata Systems. Sell product to 100 companies.

2008

- Expand engineering workforce and sales workforce.
- Sell Medipenz and service contracts to 140 Companies.

2009

- Sell Medipenz and service contracts to 290 pharmacies.

2010

- Sell Medipenz to 450 pharmacies.
- Develop Technologies to allow product platform to complement Parata Systems platform.

2011

- Begin preparations for acquisition by Parata Systems.

Financing

In order to get Medicraften Devices to go on we hope to get the following funding for the next four years

- \$2 million: Fixed Costs including as rent, leases, salaries, etc.
- \$3 million: research and development expenses
- \$500,000 : patent and legal costs to preserve strong IP position
- \$500,000: unpredicted expenses that we may incur

In conclusion, we hope to receive \$7 million in venture capitalist financial support in the 2006-2007 time frames. Looking ahead, we expect we will need an additional \$5 million for research and development. We expect to be acquired by Parata Systems, a large robotic dispensing company, in the 2011-2014 timeframe.

Medicraften Devices Business Plan

Medicraften Devices, Inc. is a North Carolina based corporation founded in 2006. This company makes products that allow pharmacies and potentially in the future other healthcare services the ability to rapidly and effectively deliver fluid medications to the patients who need them. Medicraften Devices foresees that the mechanization of the prescription delivery in pharmacies will become the suggested option for today's pharmacies today and a requirement for tomorrow's pharmacies. Our technology allows pharmacists to deliver fluid medication to patients faster and with less error. By doing this we allow pharmacists to spend more time developing relationships to advise their customers. Our primary technology was developed at Duke University Laboratories within a year.

Prescription market Opportunities/New Opportunities

The global pharmaceutical market has reached 602 billion dollars as of last year.¹ In the United States, there are more than 33,000 pharmacies run by established chain pharmacy companies, superstores and mass merchandisers. In addition, there are another 20,000 independently run pharmacies. Jointly, these 53,000 pharmacies enable practice environments for 128,000 pharmacists so that a majority of Americans have the ability to access a nearby pharmacy. In the past years the drug industry has undergone a rapid growth. The number of retail prescriptions given out yearly grew from 2 billion in 1992 to over 3.2 billion three years ago. Chain pharmacy gave out roughly 60% of the 3.2 billion prescriptions, which gives us 2 billion prescriptions yearly, or 5.5 million daily.

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Technology in the pharmacies also makes it easier for everyone. Now pharmacists can tell what patients came in when, what medication they were prescribed, what size bottle the medication in on a computer rather than sorting through papers. With this new system pharmacists can put in a patients' order, talk and advise them about pharmaceutical information and then have the prescription filled at the conclusion.³

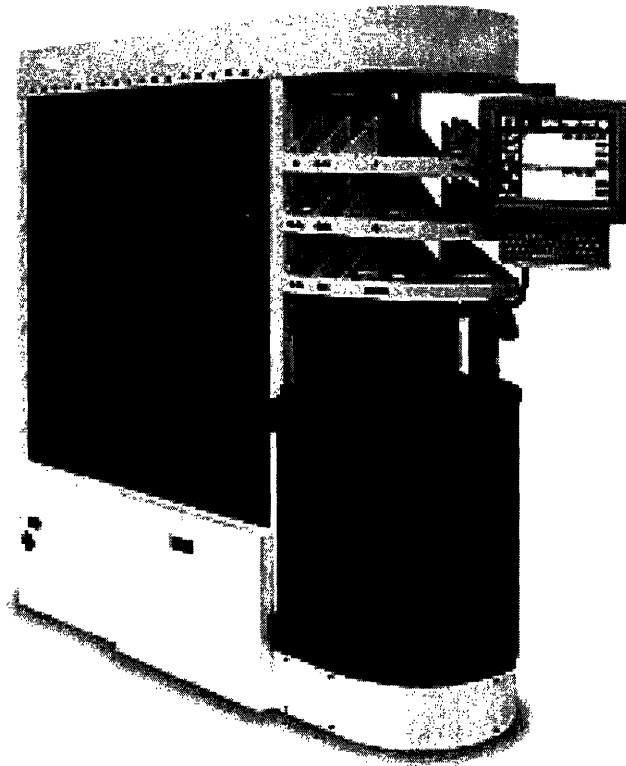
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Our system uses technology that uses little moving parts making the possibility for system crash minimal. This is because most of our system will use circuits rather than a series of mechanical functions. However, if our platform fails we will have technical engineers able to monitor calls from our home location. As our company gets bigger we hope to hire more engineers to provide on site management for all our customers. We will also provide a comprehensive owner's manual for the system so that in the beginning customers can read along with engineers on our site to gauge what problems occur. We also hope to help this transition processes by making a series of warning lights than can alert the customer what exactly is wrong with their machine. Our design for our product

was designed to meet the specifications of the current Parata Systems prototype so that at acquisition both our and Parata's machine's could work side by side in pharmacies. These units can be used to fully mechanize a pharmacy.



Value Proposition

We plan to sell each product platform for \$100,000. The customer will agree to pay this as pharmacies can receive a tax incentive after buying our machine due to the “Jobs and Growth Tax Relief Reconciliation Act of 2003”.⁵ This act is an economic stimulus effort that gives tax incentives for principal purchases. Using these benefits companies who purchase our system can save nearly \$25,000 in the year they purchase this machine. We also plan to add value to our company by charging for replacement parts and service. We also help by improving companies’ accuracy.

Customers/Partners

The product will be shown at global and national trade shows to get the industry informed of what our product can do and to sign up our first clients. The marketing strategy involves a plan to market to pharmacies who want to the newest technologies for their pharmacy. There has also been a case study of how Parata Systems marketed their product to the industry and also we plan to market our product to many of the pharmacies that Parata uses aiming to make the whole pharmaceutical medication delivery mechanized.

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Parata's vision is to drive pharmacy performance to a higher level. Parata RDS increases stores' productivity and relieves pharmacists of manually intensive pill-counting for more time with patients. Patients benefit from shorter wait times and more time with their pharmacist. ⁶

Our company's part of the market, the mechanization of fluid dispensing in pharmacies has not been explored before. However the proliferation of companies that have successfully marketed their products in the pharmacy and hospital sphere of the industry allows for a great entry into the field. Our concept will make sense to potential clients with its relative known technology. This also makes a good deal for acquisition by

bigger companies. We look especially at Parata systems that can take our product and successfully add it to their product line or infuse it with their already highly successful products.

Team

An important part of any company is the emphasis on having an initial great team to take the company off the ground. At Medcraften Devices we believe it is more important to have a first class management team with average technology than have a first-rate technology with a second-rate management team because the strong management team is more likely to succeed. One false impression about entrepreneurship is that it is an individual behavior. What we have found is that entrepreneurial behavior succeeds more often when performed by teams. We have already attracted the following 3 people in this sphere.

Charles Louison, Acting CEO - Charles is a graduating mechanical engineering senior at M.I.T. and has taken four courses in M.I.T.'s exclusive Biomedical entrepreneurship program, which is aimed at exposing students to an integrated curriculum pertaining to the difficult process of product development and commercialization in today's health care industry. Charles also will be gaining experience as a graduate student at Duke University's innovative Master's of Engineering

Ross Whitaker, VP of Product Services - Ross is a current graduate student at the

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Medical and completed his undergraduate study in biomedical engineering at

Johns Hopkins. Co-Developed, designed, and constructed a computer-guided pill dispensing machine that enabled a quadriplegic man to lead a more independent life

The three make a dynamic product engineering and design team, but to create a great business as we said before involves a team with first rate technologists, marketing savvy individuals, and some people with valuable leadership experience. This is true especially in an era where venture capitalists are known to invest primarily in companies with “grey haired” presidents meaning companies led by management with decades of work experience.

We hope to expand from 3 employees to 8 in the next year. In this expanding phase we hope to hire a President & Chief Executive Officer (CEO), a Vice President of Sales , a Vice President of Marketing, a Chief Operating Officer (COO)/Chief Financial Officer(CFO), and a Vice President of Human Resources. During this expanding phase the three current employees of Medicraften will serve different roles. Charles will serve as Vice President of Product Development responsible for any new iterations of our prototype. Paul will serve as Vice President of Product services and be responsible that Medicraften is a vanguard in our industry in the areas of service and support. Paul will

serve as the VP of engineering and be directly responsible that our manufacturing and engineering is cutting edge.

We will recruit a President & CEO with an extensive business background. We will employ someone to this position with 15 years of more of experience in healthcare management. In the position of Vice President of Customer & Industry Relations we will to employ a pharmacist or leader in the pharmaceutical field with valuable experience in working with patients, pharmacists, and consumers in the drug development market. This is so that one could have a valuable insight on what benefits this industry and consumers could use. In the position of Vice President of sales we will to recruit an individual with over 10 years experience in pharmaceutical sales. A master's of business administration degree is preferred for this position. In the position of Vice President of Marketing we will have someone with over a decade of experience in healthcare marketing to ensure that our strategy can effectively reflect our market's concerns. We prefer someone with an MBA for this position. In the position of COO/CFO we will have someone with 15 years of more of financial experience although we would prefer financial experience in the healthcare industry to know where we should invest our budget. An MBA is required for this position. Our VP of Human resources will have over 10 years of human resource experience to recruit high impact employees for the next 10 years.

Board of Directors:

At Medicraften we currently have employees with a detailed background in our technology and passion for our product. However, we realize that to be fully respected in our field we need the expertise and backing of recognized individuals in the field of

engineering and pharmaceuticals. At Medcraften, we are proud to have 6 such dedicated individuals comprising our Board of Directors.

Charles L. Cooney, Ph.D.

Professor of Chemical & Biochemical Engineering,
Faculty Director, Deshpande Center for Technological Innovation,
& Co-Director, Program on the Pharmaceutical Industry (POPI),
Massachusetts Institute of Technology

James Bradburn

Americas Pharmaceutical Manufacturing Solution Executive,
IBM Business Consulting Services

G.K. Raju, Ph.D.

Executive Director, Pharmaceutical Manufacturing Initiative (PHARMI),
Program on the Pharmaceutical Industry (POPI),
Massachusetts Institute of Technology;
& Chairman & CEO Light Pharma Incorporated.

Bonnie Haferkamp

Life Sciences Marketing Leader
Rockwell Automation

Robert Nicol, M.B.A., M.S.

Director of Sequencing Operations,
The Broad Institute of MIT & Harvard University,
& Ph.D. Candidate, Engineering Systems Division (ESD), Massachusetts Institute of
Technology

David Simchi-Levi, Ph.D

Professor of Civil & Environmental Engineering
& Engineering Systems Division (ESD),
Co-Director, Leaders For Manufacturing (LFM)
& System Design & Management (SDM) Programs,
Massachusetts Institute of Technology

Business Strategy

Medicraften Devices will start off as a spin off technology from Duke University Mechanical Engineering Labs where a prototype was built and the underlying principles including the design of the product were developed. With a collaboration agreement, Duke Licensing office allows all rights to the product, but Duke University will receive 33% of the profit of for the Medipenz system.

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Milestones

2006

- Move Medicaften Devices Inc. into Research Triangle in Durham, NC
- Procure money for first round financing.
- Actively search for a CEO with healthcare experience.
- Hire CEO/President by December.
- Market full scale product at national trade shows .
- Sell product to 10 companies.
- Actively search for a VP of sales

2007

- Hire VP of Sales.
- Expand engineering workforce
- Expand marketing scheme to pharmacies already using the Parata Systems.
- Sell Product to 100 companies.

- Actively Search to hire a VP of Marketing, a Chief Operating Officer (COO)/Chief Financial Officer(CFO), and a Vice President of Human Resources.

2008

- Hire VP of Vice President of Marketing, a Chief Operating Officer (COO)/Chief Financial Officer(CFO), and a Vice President of Human Resources.
- Expand engineering workforce and sales workforce.
- Sell Medipenz and service contracts to 140 Companies.

2009

- Sell Medipenz and service contracts to 290 pharmacies.
- Hire more employees for engineering and sales department.

2010

- Sell Medipenz to 450 pharmacies.
- Develop technologies to allow product platform to complement Parata Systems platform.

2011

- Begin preparations for Acquisition by Parata Systems

Financials

Pro Forma Income Statement 2006-2010

(all numbers in thousands)

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Headcount					
	3	6	33	58	103
Units Sold	10	100	140	290	450
Medipenz System	1000000	1000000	1400000	2900000	4500000
Service Contracts	100000	1000000	1400000	2900000	4500000
Replacement Parts	0	0	150000	1100000	3200000
Revenues	1100000	11000000	15550000	33000000	52700000
Cost of Manufacturing	100000	1000000	1400000	2900000	4500000
Cost of Installation	10000	100000	140000	290000	450000
Cost of Delivery	1000	10000	14000	29000	45000
Cost of Goods Sold	111000	1110000	1554000	3219000	4995000
Salaries and Benefits	100000	150000	1000000	2000000	4000000
Research and Development	300000	7250000	7250000	10000000	15000000
Legal & other Professional	100000	500000	500000	650000	850000
G&A (Rent and utilities)	100000	100000	100000	350000	350000
Operating costs	600000	8000000	8850000	13000000	20200000
Income Before Taxes	389000	1890000	5146000	16781000	27505000
Taxes	129666.66	630000	1715333.3	5593666.6	9168333.3
Income After Taxes	259333.33	1260000	3430666.6	11187333.3	18336666.6

Revenues are expected to be generated from three main areas: Service Contracts, our main product, the Medipenz system and replacement parts.

Service contracts will make revenue as customers who want to use our system will pay an additional cost to have their system repaired in the future. This will also include telephone support, and software updates for the computing system.

The Medipenz system is our main product platform of the fluid dispensing prescription machine. It will retail for \$100,000.

Replacement Parts will include anything on the machine that may breakdown. It will also include parts of the machine that can be upgraded to make the machine work quicker than the starting product launching this year.

Cost of Goods Sold includes 3 areas: Cost of Manufacturing, Cost of Installation, and Cost of Delivery.

Cost of Manufacturing involves the cost to make every machine which currently costs \$10,000

Cost of Installation which includes to install in each customer's pharmacy is billed at \$1,000.

Cost of delivery to every pharmacy has been billed at \$100.

Operating Costs are covered into 4 major parts: Salaries and Benefits, Research and Development, Legal & Other Professional, and rent and additional costs.

Salaries and Benefits – This cost represents the direct cost of human capital. Costs for this are directly related to employees of Medicraften and slow increases due to inflation.

Research & Development –Research and Development make up most of our costs and we aim to make our product the best in the industry. .

Legal & Other Professional – This part is made up of applying for patents, lawyers to represent the firm, and maintaining ownership of our product’s technology.

General & Administrative – G&A covers rent, non-research, utilities, administrative costs and any other costs the company may have.

We then used our revenues, cost of goods sold, and operating costs along with a current tax rate to come up with our income after taxes.

Profitability

Medicraften Devices hopes to maintain its service through a combination of selling our product, service contracts, replacement parts, and external financing. Although we are net positive in year one we need external financing to keep our research and development costs covered so we can be at the top of this highly competitive field.

The Offering

In order to get Medicraften Devices to go on we hope to get the following funding for the next four years

- \$2 million: Fixed Costs including as rent, leases, salaries, etc.
- \$3 million: research and development expenses
- \$500,000 : patent and legal costs to preserve strong IP position
- \$500,000: unpredicted expenses that we may incur

In conclusion, we hope to receive **\$7 million in** Venture Capitalist financial support in the 2006-2007 time frames. Looking ahead, we expect we will need an additional \$5 million for research and development. We expect to be acquired by Parata Systems, a large robotic dispensing company, in the 2011-2014 timeframe.

Risk Factors

Uncertainties arising from competition. The field we are going into is relatively new. We don't know if our same technology is being developed in another lab somewhere in or outside the US. We are also not sure if other existing companies who have bigger R&D budgets can effectively target our company's market by making a faster and quicker machine.

Uncertainties arising from patents and proprietary rights We are not sure if anyone owns patents that can rival our patents and potentially stop our product's progress. This is why we are investing so much in the legal department of our company to find these patents or find ways to develop our technology without conflicting with existing patents.

Uncertainties arising from government regulation.

We know pill dispensing machines have faced little government regulation but we are trying to understand how this will differ with fluid medications. Will we have to be held liable with direct contact of our machine with different fluid medications? Can parts of our machine become contaminated requiring us to constantly replace parts? These issues may be brought up by the government.

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