ACQUISITION OF MEDICAL DEVICE START-UPS

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DEDICATION

To my brother, Hari, for his support, encouragement and guidance.

To my parents, for their selfless love.

To my wife, Archana, for her sacrifices, patience and encouragement, during this time back in school. Without her love and support, I would never have gotten this far.

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All errors are my responsibility alone.

CONTENTS

| EXECUTIVE SUMMARY | 5 |
|--|---|
| INTRODUCTION | 7 |
| MOTIVATION | 8 |
| MEDICAL DEVICES | 9 |
| MARKET SIZE AND GROWTH RATE10 | 0 |
| MARKET PLACE SEGMENTATION 12 | 2 |
| LEADING MEDICAL DEVICE COMPANIES14 | 4 |
| MEDICAL DEVICE START-UPS 15 | 5 |
| DEVELOPMENT AND REGULATORY APPROVAL PROCESS 16 | 6 |
| VENTURE CAPITAL 18 | 8 |
| EXIT OPTIONS FOR MEDICAL DEVICE START-UPS 21 | 1 |
| CORPORATE VENTURE CAPITAL 23 | 3 |
| HYPOTHESES | 5 |
| METHODS AND DATA SOURCES 28 | 8 |
| RESULTS | 1 |
| DISCUSSION | 3 |
| LIMITATIONS | 6 |
| CONCLUSION | 7 |
| REFERENCES | 9 |
| APPENDIX |) |

Executive Summary

This paper examines the characteristics of venture-funded medical device companies that were successfully acquired, and their valuation at acquisition. It analyzes the impact of different factors of the investors, the investment timing, the intellectual property obtained by the start-up and the capital market environment, on the valuation of the firm at the time of acquisition. Specifically, it was hypothesized that the following factors are associated with the deal value:

| Factor | Metric | Impact on Valuation |
|-----------------------------------|---|---------------------|
| Smart Money Backing (Largest) | Capital under Management of largest VC investor | Increase Valuation |
| Smart Money Backing (Experienced) | Total Rounds of Experience most experienced VC investor | Increase Valuation |
| Syndicate of Investors | Number of Investors | Increase Valuation |
| Corporate backing | Whether there is Corporate Venture Capital investment | Increase Valuation |
| Staging of Investment | Number of Rounds | Increase Valuation |
| Investment in the firm | Total Estimated Investment | Increase Valuation |
| Established systems, Transparency | Target is a public company | Increase Valuation |
| Stage of Development | Length of time since first Venture investment | Increase Valuation |
| Capital Market Levels | S&P 500, NADAQ Composite, Dow Jones Med. Equp Indices | Increase Valuation |
| Intellectual Property | Number of US Patents assigned | Increase Valuation |

Figure 1: Hypotheses

For the analysis, I built a database using deal transaction data from VenturXpert, and other data from SDC Thomson Financials, Compustat, press releases and the US Patent Office website. I filtered the deals to include the Venture Economics classifications of Medical/Health Products, Medical Diagnostics, and Medical Therapeutics, for deals that were announced from January1998 to April 2006. After eliminating duplicate entries and deals for which data was not disclosed or available, a total of 90 deals were identified for analysis.

The summary of data for this sample of start up companies that succeeded in getting acquired is shown in Figure 2.

| | N | lean | Me | edian | St | d Dev | Max | Min |
|--|----|------|----|-------|----|-------|----------|--------|
| Transaction Value (Constant 2006 \$) (\$MM) | \$ | 147 | \$ | 91 | \$ | 207 | \$ 1,291 | \$ 0.4 |
| Total Investment (Constant 2006 \$) (\$MM) | \$ | 36 | \$ | 29 | \$ | 34 | \$ 191 | \$ 0.3 |
| Years since first investment | | 5.6 | | 5.3 | | 3.3 | 16.9 | 0.7 |
| Number of Investors | | 6.2 | | 5 | | 4.2 | 18 | 1 |
| Number of investing rounds | | 4.5 | | 4 | | 3.0 | 11 | 1 |
| Valuation to Investment ratio (Unadjusted) | | 25.4 | | 3.8 | | 116.8 | 1053.0 | 0 |
| Valuation to Investment ratio (Constant 2006 \$) | | 22.7 | | 3.54 | | 103.9 | 936.7 | 0.03 |
| Number of Patents | | 15.1 | | 7.0 | | 20.5 | 86.0 | 0 |

Figure 2: Characteristics of Targets at Acquisition

There were Corporate Venture Capital investments in 26 of the 90 target companies that were acquired (29%), and 16 (17%) of these companies were already public.

A multi-variate linear regression analysis was done on the data, looking at the transaction value as the dependent variable. The factors that were analyzed were able to explain 27% of the variation in deal value for the total data set. The Results of the analysis are shown in Figure 3.

| | | | Statistically Significant? | | |
|--------------------------------------|----------|---------|----------------------------|-----------|--|
| Term | Estimate | P Value | At 95% CL | At 70% CL | |
| Target Current Public Status[Public] | (44.77) | 0.13 | No | Yes | |
| Corporate Venture Capital?[Yes] | 30.78 | 0.22 | No | Yes | |
| Years since first investment | 29.72 | <.0001 | Yes | Yes | |
| Number of Investors | (10.07) | 0.21 | No | Yes | |
| Num. of investing rounds | (5.64) | 0.56 | No | No | |
| Infl. Adj total investmt (\$MM) | 0.891 | 0.27 | No | Yes | |
| Dow Jones Med Eq | 0.354 | 0.20 | No | Yes | |
| Number of Patents | 0.305 | 0.78 | No | No | |
| NASDAQ Composite | 0.025 | 0.76 | No | No | |
| Max. size of investing firm | 0.012 | 0.00 | Yes | Yes | |
| Rounds Experience of Investor | (0.001) | 0.57 | No | No | |
| S&P 500 | (0.001) | 1.00 | No | No | |

Figure 3: Regression Analysis Results

The two factors that had a surprising impact on valuation were the Target's public status and the number of investors. Private companies were on average, associated with a higher deal value (\$45 MM) than public companies (p value= 0.13). This went against the hypothesis that companies that had already gone public would attract higher valuations because of better governance systems and transparency. The second surprising result was that the number of investors was negatively associated with the valuation (p value=0.21). Most of the other hypotheses were supported at different levels of statistical significance. Having a corporate investor funding the company is associated with higher valuation. Larger investors are associated with statistically significant increases in valuation. The most significant impact is that of the "years since first funded", which suggests that companies are rewarded for the added risks and costs of developing their technologies further. These effects are captured in the regression analysis done in this thesis. I conclude that start-up companies should carefully review their options regarding their investors and the stage to which they develop technologies before acquisition, based on their firm specific risks and costs, as those decisions have a discernible impact on exit valuation.

Introduction

In the medical device space, a large proportion of the breakthrough inventions are developed by small firms that use private equity to bring their technologies from concept to varying stages of development. Medical Device companies spend a large proportion (11.4 % in 2002) of their sales on R&D, second only to Pharmaceutical companies. Smaller companies, in the meanwhile, spent 343 % of their sales in the same year¹. [The Lewin Group (AdvaMed), 2004].

Private Equity financing is a critical factor that enables small start-ups to develop new technologies without a viable revenue stream to support the necessary R&D expenditure. In the medical device space, it has been noted that Venture Capital firms (VC's) use high risk capital to invest in early stage companies, and look for "exits" through either an Initial Public Offering (IPO) or through the sale of the start-up to an established firm. Corporations are also involved in varying degrees in early venture investments, through what is sometimes called Corporate Venture Capital (CVC), mainly for strategic reasons. Through CVC investments, some corporations hope, that as an insider, they would be able to judge better whether a particular company is a good target for acquisition.

In this paper I review the exits through acquisition, from the perspective of venture backed start-ups, and hypothesize that factors related to the nature of investors, the type of investment, the impact of capital markets and the Intellectual Property of the company are associated with a higher exit valuation.

This paper is organized as following. First, I review the medical device industry, the market segmentation, size and growth forecasts, and the leading Medical Device manufacturers. The next section discusses Medical Device start-ups and the typical development and commercialization pathway. The hypotheses are laid out next, along with the methodology of the analysis planned, and then each factor is discussed individually. Finally, we look at the results of the analysis, the limitations of the study, and draw conclusions.

Motivation

The topic of this paper was chosen due to my interest in the medical device space, and from my interaction with my thesis advisors, Dr. Rox Anderson, Director of the Wellman Center of Photomedicine at the Massachusetts General Hospital (MGH), and with Dr. Jonathan Rosen, Director of Technology Implementation, Center for Integration of Medicine and Innovative Technology (CIMIT).

A promising technology based on the next generation Optical Coherence Tomography (OCT), called Optical Frequency Domain Imaging is being developed by Dr. Gary Tearney and his group at the Wellman Center, for specific applications including GI tract imaging. The MGH licensing office, called the office of Corporate Sponsored Research & Licensing (CSRL), CIMIT, which had funded part of the project, and the Project team were evaluating the different options to take the development of this technology forward. These discussions, some of which I was involved in, revolved around how long the project should be financed internally within MGH (Partners Healthcare), when the start-up should be out looking for external funding, how long an exit would take, how much money is typically raised, what are the ranges of deal values at acquisitions and so on. While many practitioners in the field have rules of thumb regarding valuation, a preliminary review of the literature showed a lack of published data specific to venture backed medical device acquisitions. Hence, I undertook the research and analysis presented in this thesis.

Statement on Conflict of Interest: There are no conflicts of interest that I am aware of in this study.

Medical Devices

The Center for Devices and Radiological Health at the Food and Drug Administration, the major regulatory body in the United States, defines² a medical device as:

"A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

The medical device industry has played a key role in the advancement of medical care around the world. Products like pacemakers, defibrillators, insulin pumps, laparoscopic devices for minimally invasive surgery, orthopedic implants and more accurate diagnostic techniques that are able to detect diseases earlier have transformed the health care system, dramatically improving patient outcomes and speeding recovery time.

Market Size and Growth Rate

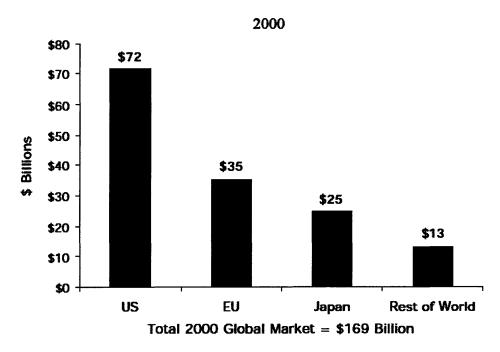


Figure 4: International Markets for the Medical Devices and Diagnostics Industry

Source: AdvaMed

The Medical Device industry includes a wide variety of products from some decidedly low-tech "durable medical equipment" (DME) like bed pans to high technology products like pacemakers. Generally, the industry is analyzed by each category separately, and it is difficult to obtain recent data on the entire space. A report in the Medical Device Technology Journal ³ in 2004, says that the US Medical equipment market is projected to grow by 8% between 2001 and 2006, to reach \$105 billion in 2006. The Advanced Medical Technology Association (AdvaMed), is the main trade association of medical device companies, and has laid out some illuminating data through it medical technology report, 2004¹. It reports that the US market size was \$72 Billion dollars in 2000, accounting for about 43 % of the world market. The growth rate in the US and the different parts of the world is shown in Figure 4. The Rest of the world, including markets in Asia, Latin America and Eastern Europe show the highest growth rates, due in part due to the relatively small base that they currently have (~8% of the world market). The global market, according to the same report, has been growing at a fair paced clip of 10.6% during the period 1991-1996.

Following is data taken from DataStream of the Dow Jones Medical Equipment Index (Developed markets) compared with the S&P 500 and the NASDAQ composite index. With a compounded annual growth rate (CAGR) of 14% percent, it is clear that the Medical Devices Market has vastly outperformed the broader stock market in recent years.

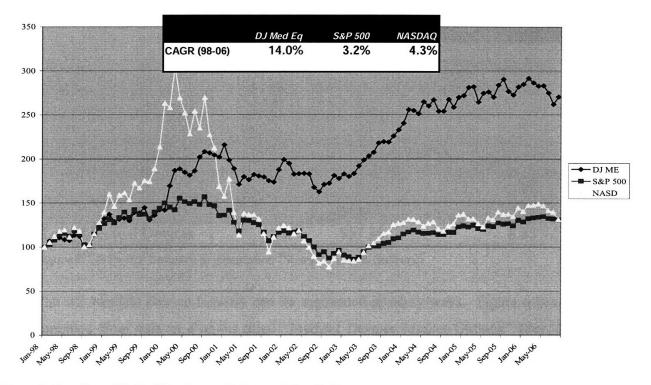


Figure 5: Dow Jones Medical Equipment Index vs. Other Indices (Source: DataStream)

Market Place Segmentation

| Market Segment | 2002 Forecast (\$ BN) | Growth Rates (02-05) |
|--------------------------|-----------------------|----------------------|
| Cardiology | \$9.22 | 14.10% |
| Orthopedic | \$9.19 | 11.10% |
| Drug Delivery | \$5.19 | 4.70% |
| Surgical Instrumentation | \$3.78 | 3.40% |
| Durables | \$3.42 | 4.40% |
| Audiology | \$3.29 | 11.10% |
| Ophthalmology | \$3.19 | 8.30% |
| Wound Care | \$2.87 | 8.30% |
| Infection Control | \$2.71 | 2.30% |
| Respiratory | \$1.52 | 8.60% |
| Neurology | \$0.73 | 13.90% |
| Endoscopes/Imaging | \$0.73 | 3.80% |
| Biomaterials | \$0.51 | 11.90% |
| Hemostats | \$0.37 | 12.50% |
| Miscellaneous | \$10.87 | 8.70% |
| Total Medical Devices | \$57.59 | 8.83 % |

Figure 6: US Device Industry Segmentation (Source: Frost & Sullivan)

The US Medical Device industry can be segmented in many ways. Figure 6 has been compiled from data in a report titled "Medical Devices Market Outlook" May, 2005, from the market research firm Frost & Sullivan. It should be noted, that since 2002 many new technologies, including drug eluting stents, that have seen a huge growth in the market have been introduced that are not adequately represented in this table.

Below, I briefly describe the major segments, in terms of the products it includes. [Source: Frost & Sullivan]

Cardiovascular devices are the largest segment in the medical devices market accounting for about 23% of the total medical devices market. This market includes drug eluting and bare metal stents, angioplasty devices, heart valves and pacemakers.

Orthopedic Equipment is the second largest segment, and includes joint implants such as hip and knee implants, and spine care products.

Wound Care and Management includes the traditional wound dressings, and a growing number of advanced therapies such as moist, interactive, and antimicrobial dressings.

Surgical Instruments: Laser and electrosurgery devices are the fast growing groups identified in this segment.

Neurology Equipment has the neurostimulation segment which is forecasted to grow at a high rate

Drug Delivery and infusion systems segment is dominated by needles, syringes, and medication solutions. The high growth areas are implantable drug and insulin infusion pumps.

Ophthalmic Equipment includes contact lenses and LASIK surgeries.

Hearing Aids include technologically programmable and non programmable technologically advanced hearing aids including cochlear implants.

Respiratory and Anesthesia Equipment market accounted for roughly 1.7 percent of the total U.S. medical device market revenues in 2004.

Endoscopy Systems: The total endoscopy market, includes visualization equipment such as cameras light sources, monitors VCR's and digital recorders, and scopes,

Infection Control: Includes products such as gloves, drapes and other disinfection and Sterilization Equipment.

Durable Medical Equipment is a very broad segment including bedpans, crutches, wheel chairs and other mobility aids, and fitness equipment.

Biomaterials and Hemostats: The major biomaterials market today include hyaluronic acid and collagen.

Miscellaneous: As defined by Frost & Sullivan, this included urological, dental and renal (Dialysis Equipment) market groups. The dialysis equipment market accounted for roughly 3.3 percent of the total U.S. medical device market revenues in 2004 (\$2.09 B). Another major segment that is apparently not covered in the report above is the **glucose monitoring segment**, which is estimated to be greater than \$4 BN dollars in the US, in 2005.

Leading Medical Device Companies

The leading Medical devices companies by revenue [Frost & Sullivan, 2004]⁴ are shown in Figure 7.

Johnson & Johnson Baxter International Inc. Medtronic, Inc. Becton Dickinson & Co. Guidant Corp. Boston Scientific Corp. Stryker Corp. Smith & Nephew plc. St. Jude Medical, Inc. C.R. Bard, Inc. Zimmer Holdings, Inc. **Dentsply International** Invacare Corp. Biomet, Inc. Steris Corporation Varian Medical Systems Edwards Lifesciences Corp. Sybron Dental Specialties **CONMED** Corporation Respironics, Inc.

Figure 7: List of Top Medical Device Companies by Revenue. (Source: Frost and Sullivan)

Of the top medical devices companies, most are "pure plays" in a few segments of the medical device industries. The notable exceptions are Johnson & Johnson and Baxter Healthcare, which have products beyond medical devices, while Becton Dickinson has broad product lines across many medical device segments. Also of note, nine of the top ten medical device companies in the world are U.S. based.

Medical Device Start-ups

Generally, larger medical device companies have been successful in developing and commercializing incremental improvements of current devices. But, the development of breakthrough medical innovations and technologies are generally brought forth by venture-backed start-up companies. "Typically, a physician and/or engineer inventor conceives of a device solution to an unmet clinical challenge, initiates the patent process, and builds preliminary device prototypes. Preliminary bench and animal testing may be performed using the inventor's or an acquaintance's personal funding (angel investors). Further development typically requires engaging a team of engineers who work closely with physician advisors to bring the concept through the "design-build-test-redesign" cycle of bench and animal testing. This preclinical stage typically takes 2 to 3 years and depending on the nature of the device may consume US\$10 to \$20 million before the device is ready for clinical testing. These capital requirements exceed the means of most angel syndicates and are typically obtained from venture capital firms in the form of equity financing." [Kaplan et al, 2004].

Figure 8 shows the number of companies that have less than 20 employees in the industry compared to the medium and larger established ones [The Lewin Group, AdvaMed 2004].

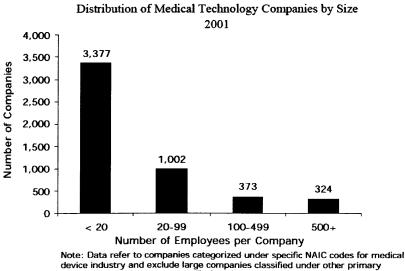


Figure 8: Size Distribution of Medical Device Companies (2001) (Source: AdvaMed/US Department of Commerce)

device industry and exclude large companies classified under other primary industries that also possess medical device divisions.

Source: U.S. Department of Commerce

Development and Regulatory Approval Process

The Center for Devices and Radiological Health (CDRH) division of the FDA is responsible for the regulation of medical devices in the US. For regulatory purposes, devices are classified according their perceived risk level into Class I, II or III (increasing risk levels).

Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval (PMA)⁵. A premarket notification or 510(K) must demonstrate "substantial equivalence" to another approved device that is called the "predicate" device. A premarket approval, an actual approval of the device by the FDA, is required for Class III devices that "pose a significant risk of illness or injury" or those "found not substantially equivalent to Class I and II predicate though the 510(k) process. These devices are generally life-sustaining/supporting, of substantial importance in preventing impairment of human health. Kaplan et al give an excellent review of the typical steps that a start-up has to go through in order to get through the regulatory hurdles and the investor required mile stones, for a class III device. Approval of the PMA requires clinical data demonstrating reasonable assurance that the device is safe and effective in the target population. Clinical testing of an unapproved significant-risk medical device requires FDA approval in the form of an Investigational Device Exemption (IDE). The IDE application provides information to the FDA on device design and qualification, as well as on the study protocol. First Clinical use is a key milestone for any technology, and companies, seeking the quickest path, generally shift (>75%) this testing outside the US. First Clinical Use testing, when done within the US, are rarely (<25%) done at large academic institutions, due to the bureaucracy associated for IRB (Institutional Review Board) approval.

Clinical development of a new class III device is typically divided into pilot and pivotal trial phases. The purpose of the pilot phase (starting with first clinical use) is to establish safety and to assist in design of the pivotal trial. Pilot-phase testing is typically limited to fewer than 100 patients treated at a few centers. The purpose of the pivotal trial is to generate data that define patient populations in which use of the device is safe and effective. [Kaplan, et al, 2004]

Maisel ["Medical Device Regulation"- Maisel 2004], also explains in simple terms the steps that go into the approval of a medical device, in Figure 9.

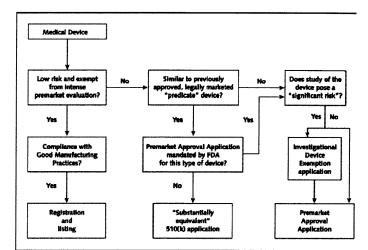
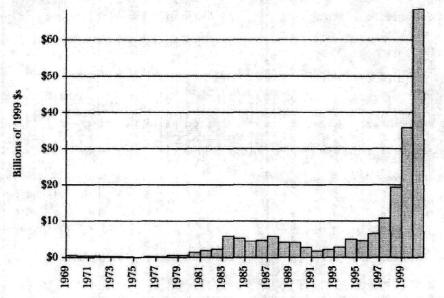


Figure 9: Medical Device Approval Process (Source: Maisel 2004)

Some medical devices are perceived to be low risk and are exempt from close scrutiny by the U.S. Food and Drug Administration (*FDA*). In some cases, the device's manufacturer need only demonstrate compliance with Good Manufacturing Practices and then register and list the device with the FDA. Medium-risk devices that have the same intended use and same technological characteristics as a previously approved, legally marketed product are considered "substantially equivalent" to this "predicate" device and may be evaluated with a 510(k) application. This application requires demonstration that the previous so new questions of safety or effectiveness. The FDA markets the more comprehensive Premarket Approval Application for certain higher-risk devices or devices that naise new questions of safety or effectiveness. Investigational devices undergoing clinical study require an Investigational Device Exemption if they potentially pose a "significant risk" to the patient.

Venture Capital

Venture Capital has been defined in the finance world as "the investment by professional investors of long-term, unquoted, risk equity finance in new firms, where the primary reward is an eventual capital gain..." [Wright and Robbie, 1998]. Venture Capitalists concentrate investments in early stage and high technology companies where information asymmetries are highest. [Gompers, 1995]. Gompers and Lerner (2001)⁶ give a good account of the evolution of the venture capital industry, from the American Research and Development firm, established in 1946 by MIT President Karl Compton and General Georges Doriot, Harvard Business School Professor, through the US Government's effort to spur the VC industry (Small Business Investment Companies) program, to the practices of modern day venture capitalists. The commitments to the Venture Capitals are shown in Figure 10. Figure 11 shows that the majority of the investors in Venture Capital funds, are institutional investors, like pension funds and corporations. [Gompers, 2001]



Commitments to the Venture Capital Industry (billions of 1999 dollars)

Note: Commitments are defined as the amount of money that is pledged to U.S. venture capital funds in that year.

Source: Venture Economics and Asset Alternatives.

Figure 10: Venture Capital Industry Commitments (Source: Gompers, 2001)

| | 1979 | 1983 | 1987 | 1991 | 1995 | 1999* |
|--|----------|------|------|------|------|-------|
| First closing of funds | | | - | | | |
| Number of funds | 27 | 147 | 112 | 34 | 84 | 204 |
| Size (billions of 1999 \$) | .53 | 6.01 | 5.93 | 1.69 | 4.60 | 37.46 |
| Sources of funds | | | | | | |
| Private pension funds | 31% | 26% | 27% | 25% | 38% | 9% |
| Public pension funds | b | 5% | 12% | 17% | ъ | 9% |
| Corporations | 17% | 12% | 10% | 4% | 2% | 16% |
| Individuals | 23% | 21% | 12% | 12% | 17% | 19% |
| Endowments | 10% | 8% | 10% | 24% | 22% | 15% |
| Insurance companies/banks | 4% | 12% | 15% | 6% | 18% | 11% |
| Foreign investors/other | 15% | 16% | 14% | 12% | 3% | 22% |
| Independent venture partnerships as a share of | | | | | | |
| the total venture pool" | | 68% | 78% | 80% | | |

Summary Statistics for Venture Capital Fund-raising by Independent Venture Partnerships

"In 2000, there were 228 funds raised with total committed capital of \$67.7 billion.

^bPublic pension funds are included with private pension funds in these years.

"This series is defined differently in different years. In some years, the Venture Capital Journal states that non-bank SBICs and publicly traded venture funds are included with independent venture partnerships. In other years, these funds are counted in other categories. It is not available for 1979 and after 1994. Source: Compiled from the unpublished Venture Economics funds database and various issues of the Venture Capital Journal. The numbers differ slightly from Lerner and Gompers (1996) due to continuing emendations to the funds database.

Figure 11: Source of Venture Capital Funds (Source: Gompers, 2001)

According to Fred Dotzler⁷ at De Novo Ventures, a leading medical device investor, the five major activities of a venture capitalist are:

- Solicit or create investment opportunities
- Evaluate companies
- Negotiate the terms of investments
- Help build successful companies
- Liquidate investments

From the start-up's perspective, according to a survey done by Dotzler, the most important area where venture capitalists add value was "in the arena of advice and introductions for financing". This includes advice on the amount of money to raise, the timing of investment, and which investors to target. The next most important area is to "help in establishing and reviewing the company's strategic focus". Other important areas where VC's provide value is in recruiting management, being a sounding board to CEOs and having "a strong sense of when a company is ready and market condition are favorable to complete an IPO" and "whether to sell a company as a path to liquidity".

The Medical device Industry is also very dependent on venture capital investments for bringing forth technologies, from concept to first clinical use and the regulatory process, to product commercialization. Thus, a testable hypothesis is that the value of start-up companies is dependent on "smart money" investors.

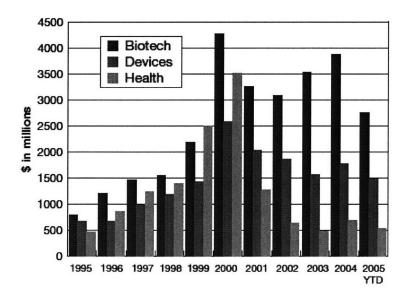
According the Q3 2005 "Venture Capital Investment in Health Industries Report"⁸, Medical Devices account for about 9% of all venture capital investments (Figure 12)

Figure 12: Percentage of Venture Capital Investments in Health Care (Source: MoneyTree Survey)

| Industry | % of Total Venture Capital Dollars (YTD Q3 2004) | % of Total Ventur Capital Dollars (YTD Q3 2005) | | |
|---------------------------------------|--|---|--|--|
| Biotechnology | 17.8% | 16.9% | | |
| Medical Devices and Equipment | 8.3% | 8.9% | | |
| Healthcare Services and Technology | 3.3% | 3.2% | | |
| Total Health Industries | 29.5% | 29.0% | | |

Venture Investments, in general, were severely curtailed after the dot com bubble burst in 2000. Figure 13 shows the historical pattern of VC investment in the broader health care industries [MoneyTree Survey, 2005]. According to the report, Medical Device investments have seen an increase of 11% in Q3 2005, compared to the same period in the previous year.

Figure 13: Historical Pattern of VC investments in Health Care (Source: MoneyTree Survey)



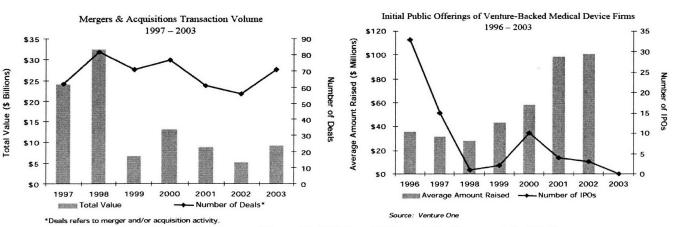
Sector Investments, 1995-YTD 2005

Exit Options for Medical Device Start-ups

David Strupp Jr. recently authored an article in *Nature*⁹, about the change being seen in the Biotechnology space "Success has been typically defined by the ability to maintain independence as a publicly traded company. In this sense, it is interesting to compare the biotech industry to the medical device industry. Unlike in the biotech industry, in the medical device industry, a successful exit is defined as a sale to one of the large-cap companies. Although there are many notable exceptions, the sale of a biotech company has most often been associated with failure, not success. This is changing.... An M&A exit will likely become more common and both the investors and the management teams should begin to define success by the sale of the company."

In Medical Devices, the preferred exit option generally has been through a sale to a larger medical device company. This has to do with the long and costly road to full development, and the high risks associated with regulatory oversight and commercialization. Figure 14[The Lewin Group, AdvaMed 2004] shows the IPO market and M&A activity for medical devices from 1997-2003.

The IPO exits for Medical Devices came drastically down from the high of the mid to late 1990s, to completely dry up n 2003. Since then there have been a few more IPO's each year but, not at the previous levels. The M&A exit has been a more reliable way for medical device start-ups and their investors to get to their liquidity event. There is "a feeling that M&A is less risky, less complicated, and takes less time to conclude than a comparable IPO- coupled with less interest on the part of venture capitalists generally to sever on the board of a public company in view of today's liability issues"¹⁰.



Source: Windhover's Strategic Transaction Database

The increased number of acquisitions evident in this space, perhaps, reflects the

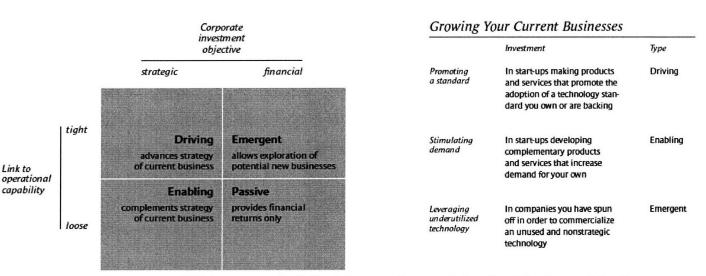
Figure 14: M&A and IPO activity (Source: AdvaMed)

acceptance by large companies that internal R&D development cannot take replace innovative and nimble start-ups. Start-up companies that are facing tougher challenges to go public, have to figure out their exit strategy- whether it is through an acquisition, an IPO, or even an acquisition after an IPO. A testable hypothesis is whether companies that get acquired post IPO get a higher valuation that those that directly move toward an acquisition.

Corporate Venture Capital

Corporations also invest in start-ups, through a form of venture capital termed Corporate Venture Capital (CVC). Corporate Venture Capital has seen dramatic shifts in investment patterns. CVC investing was at its peak in 2000, when quarterly investments rose from \$468 MM at the end of 1998 to \$6.2 BN in early 2000. After the economy turned, however, quarterly investing tumbled to \$848 MM, and one third of the companies stopped making these investments¹¹. Since "CVC's are dependent on surplus cash on the balance sheet of the parent corporation... CVC activity has cycled through economic conditions with more volatility than the cycles seen in traditional VC^{12} .

Generally, at least the stated primary objective of a company engaged in corporate venturing is strategic in nature; with financial returns an important, but secondary motivation. Chesbrough lays out a framework to think about CVC, which is summarized in Figure 15





Link to

A corporate VC investment is defined by two characteristics: its objective and the degree to which the operations of the investing company and the start-up are linked. Objective can be strategic (increase sales and profits of the corporation's own business), or financial, "a corporation seeks to do as well as or better than private VC investors, due to what it sees as its superior knowledge of markets and technologies, its strong balance sheet, and its ability to be a patient investor".

The second defining characteristic of CVC, according to Chesbrough, is the degree to

which start-up is linked to the investing company's current operational capabilities. (Use of company's manufacturing plants, distribution channels, technology, or brand etc). Companies that have investments that fit the "Passive" category are generally the ones that leave the field in the time of a downturn. This category is a version of the discredited conglomerate model that prevailed in the 60's. The investment types with more "staying power" are the Driving and Enabling types, while Emergent investments, Chesbrough postulates, should be used by companies in economic boom times.

From the start-up's perspective, an investment from a corporation could grant the technical know how, market knowledge and resources, and a potential interest in acquisition down the line. In addition the investment could give additional credibility in the eyes of would-be suitors, employees and other investors. This leads us to a hypothesis that having CVC investment would raise the valuation at acquisition for the start-up.

Hypotheses

The following factors are hypothesized to have an effect on the value of an acquisition of a medical device start up.

Size and Experience of Venture Capital Investors

VC's are a high cost source of capital. Entrepreneurs still approach VC's for funding their companies, because of the additional value added by the "Smart money" that has been detailed in an earlier section. It is noted that while returns for the VC industry on the whole is not different than returns on the S&P 500, there are specific firms and funds that have persistently high returns for their investors.

Hypothesis 1: Companies with investing firms with larger capital under management, and with more experience (prior rounds of investment) are associated with higher deal values.

Investment by Corporate Venture Capital

Corporations invest in start-ups primarily for strategic reasons. Investments by companies currently in the industry could signal potential interest in an acquisition or some validation of the concept.

Hypothesis 2: Companies in which Corporations have invested as CVC's are associated with higher deal values.

Staging of Investments and Development of Enterprise

Gompers¹³ explains the importance of project governance in VC investing in start up companies, due to the asymmetric information. To minimize potential agency costs, VC's use control mechanisms including the staging of capital infusions. As the firm develops from an early stage start-up completing set milestones, the investors fund successively more rounds of investment.

Hypothesis 3: The Valuation of the firm is positively associated with more rounds of VC investments, the total amount of investments and the number of years since the first venture investment

Syndication of Investment

Lerner¹⁴ has documented that syndication is commonplace in VC investments. One of the

rationales for the syndication is to have a more robust screening process. Earlier studies¹⁵ have shown investments made only if several independent observers agree, may be superior to ones in which projects are funded after one affirmative decision. Hypothesis 4: The number of investors is associated with a higher deal value.

Intellectual Property

The cornerstone of a life science company is its intellectual property. [Nicola¹⁶, 2006]. A strong IP position that gives the company the freedom to operate, and the ability to exclude others, would be much more valuable to Investors.

The metric of the number of patents is obviously a very weak measure of the strength of the IP of a company. A single patent, that has strong claims, can be much stronger than a dozen weakly worded patents. In addition, I am not accounting for licenses to patents that a company may have obtained. Having acknowledged these weaknesses, I chose to use the number of patents assigned to, as an objective measure that I was able obtain for all the targets.

Hypothesis 5: The number of patents assigned to the company is associated with a higher deal value.

Capital Markets

Valuation of start-ups, at acquisition, is fundamentally linked to the broader capital markets, as the acquiring corporations themselves are valued in the public markets. As discussed earlier in the section on medical devices, the sector has strongly outperformed the general market over the past few years (CAGR of 14% versus growth rates of less than 4% for the NADAQ and S&P 500). However, some of the major acquirers in this space are not included in the DJ Medical Equipment index, and hence I have also included the broader indices for the analysis.

Hypothesis 6: The deal value is associated with higher NASDAQ composite levels, S&P 500 and Dow Jones Medical Equipment (Developed world) index.

Corporate Governance and Transparency

When a company accesses the public markets for capital, there are many requirements imposed on it by the Securities Exchange Commission (SEC) that serves to increase the

transparency of the company's operations, and reduce the problem of information asymmetries for potential acquirers.

Hypothesis 7: Valuation of a public company would be higher than that of a privately held company.

The Hypotheses are summarized in Figure 16.

| Factor | Metric | Impact on Valuation |
|-----------------------------------|---|---------------------|
| Smart Money Backing (Largest) | Capital under Management of largest VC investor | Increase Valuation |
| Smart Money Backing (Experienced) | Total Rounds of Experience most experienced VC investor | Increase Valuation |
| Syndicate of Investors | Number of Investors | Increase Valuation |
| Corporate backing | Whether there is Corporate Venture Capital investment | Increase Valuation |
| Staging of Investment | Number of Rounds | Increase Valuation |
| Investment in the firm | Total Estimated Investment | Increase Valuation |
| Established systems, Transparency | Target is a public company | Increase Valuation |
| Stage of Development | Length of time since first Venture investment | Increase Valuation |
| Capital Market Levels | S&P 500, NADAQ Composite, Dow Jones Med. Equp Indices | Increase Valuation |
| Intellectual Property | Number of US Patents assigned | Increase Valuation |

Figure 16: Hypotheses Summary

Methods and Data Sources

To identify the acquisitions in the device space, I used the VenturXpert (Venture Economics) database. Other databases that also contained data, but not limited to venture backed companies were Recap (Recombinant Capital), which had especially relevant data for biotech deals, and MedTrack. Data on the characteristics of the start up companies and the funding investors were taken using Thomson Financial SDC Platinum interface to query the VenturXpert's Mergers and Acquisitions database.

The deals were chosen according to the following criteria:

Announcement of Deal: Between January 1998 and April 2006.

Industry classification: Venture Economics Industry sub groups under Medical Diagnostics (5100), Medical Therapeutics (5200) and Medical Health Products (5300).

Where the transaction value was disclosed

There were 100 deals that satisfied these criteria. I then removed deals that included duplicate entries, and deals on which additional information (for example investment amounts and dates) was unavailable. From the SDC interface I retrieved data on the Target Name, Acquirer Name, Date of Announcement, Name of Venture Funds and Firms, the capital under management, the number of rounds of investment that the company completed, the number of years since the company first received venture investment, the investment made in each round of the company and the total investment in the company. I used the US Patent Office database to query the number of patents that were assigned to the Target prior to the announcement of the deal. From the US Department of Labor's Bureau of Labor Statistics website I obtained the historical Consumer Price Index and adjusted the transaction values, and the amount invested at each round in the company to constant 2006 dollars. Using the Datastream service, I obtained stock index levels (NASDAQ composite, S&P 500 and Dow Jones Medical Equipment (Developed World) indices).

I used SAS Project R and JMP software for statistical analysis. The actual number of data-points used for analysis was 90 deals.

Characteristics of Acquired Companies

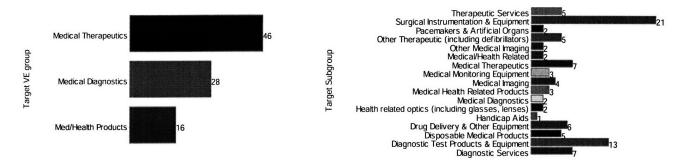


Figure 17: Subgroups of Acquired Companies

Among the 90 deals, there were 46 companies in the "Medical Therapeutics" group, 28 in the "Medical Diagnostic" group and 16 in the "Medical/Health Products" groups. (See Appendix for list of deals) The diversity of the industry is indicated by Figure 17 (b), which shows that the companies can be divided further into 17 categories. Surgical Instrumentation and Equipment accounted for the largest number of target companies. Even within these categories, companies may be in very different disease spaces and may not be comparable. For example, the Surgical Instrumentation and Equipment category included CardioThoracic systems, AFx (Guidant), Spinal Concepts and Image-guided Neurologics, companies in three very different disease areas. A preliminary regression analysis showed that the valuation was not significantly correlated to the VE groups, and subgroups.

The characteristics of companies that were successfully acquired is shown in Figure 18 (N=90). Investors in the field generally talk about a ball park of \$150 MM at exit for a

| | M | lean | Me | edian | St | d Dev | Max | Min |
|--|----|------|----|-------|----|-------|---------|--------|
| Transaction Value (Constant 2006 \$) (\$MM) | \$ | 147 | \$ | 91 | \$ | 207 | \$ 1,29 | \$ 0.4 |
| Total Investment (Constant 2006 \$) (\$MM) | \$ | 36 | \$ | 29 | \$ | 34 | \$ 19 | \$ 0.3 |
| Years since first investment | | 5.6 | | 5.3 | | 3.3 | 16 | 9 0.7 |
| Number of Investors | | 6.2 | | 5.0 | | 4.2 | 18 | 0 1 |
| Number of investing rounds | | 4.5 | | 4.0 | | 3.0 | 11 | 0 1 |
| Valuation to Investment ratio (Unadjusted) | | 25.4 | | 3.8 | | 116.8 | 1053 | 0 0 |
| Valuation to Investment ratio (Constant 2006 \$) | | 22.7 | | 3.54 | | 103.9 | 936 | 7 0.03 |
| Number of Patents | | 15.1 | | 7.0 | | 20.5 | 86 | 0 0 |

17%

29%

medical device company. The dataset that I analyzed bears that rule of thumb out, with an average acquisition valuation of \$147 MM. The Median deal value was, however, lower at \$91 MM, and the data had a large range reflected by the high standard deviation of \$207 MM. The maximum deal value was \$1.29 Billion and the minimum \$400,000. On average, it took a company slightly under six years from the date of first investment, with an additional round of investment every 1.2 years, to get acquired. The acquired company had, on average, six separate investors financing about \$36 MM of successive investments and obtaining more than 15 US patents. The vast majority (83%) of the acquired companies that were still venture backed, had not gone public, and slightly less than 29% of these companies were backed by Corporate Venture Capital. (All Dollar values have been converted to Constant 2006 dollars).

The average multiple of total investment was skewed by a few outliers, to 22.7 X while the median was 3.54 X, after adjusting for inflation. Unadjusted, the median multiple was 3.8X.

I ran a multiple regression of the inflation adjusted transaction value (\$MM) as the dependent variable, with the following independent variables:

| Hypothesis | Metric |
|------------|--------------------------------------|
| 1 | Max. size of investing firm |
| 1 | Rounds Experience of Investor |
| 2 | Corporate Venture Capital?[Yes] |
| 3 | Infl. Adj total investmt (\$MM) |
| 3 | Num. of investing rounds |
| 3 | Years since first investment |
| 4 | Number of Investors |
| 5 | Number of Patents |
| 6 | Dow Jones Med Eq |
| 6 | NASDAQ Composite |
| 6 | S&P 500 |
| 7 | Target Current Public Status[Public] |

Results

Figure 19 summarizes the impact of the different factors on the valuation of the Target

| | | | Statistically Significant? | | | |
|--------------------------------------|----------|---------|----------------------------|-----------|--|--|
| Term | Estimate | P Value | At 95% CL | At 70% CL | | |
| Target Current Public Status[Public] | (44.77) | 0.13 | No | Yes | | |
| Corporate Venture Capital?[Yes] | 30.78 | 0.22 | No | Yes | | |
| Years since first investment | 29.72 | <.0001 | Yes | Yes | | |
| Number of Investors | (10.07) | 0.21 | No | Yes | | |
| Num. of investing rounds | (5.64) | 0.56 | No | No | | |
| Infl. Adj total investmt (\$MM) | 0.891 | 0.27 | No | Yes | | |
| Dow Jones Med Eq | 0.354 | 0.20 | No | Yes | | |
| Number of Patents | 0.305 | 0.78 | No | No | | |
| NASDAQ Composite | 0.025 | 0.76 | No | No | | |
| Max. size of investing firm | 0.012 | 0.015 | Yes | Yes | | |
| Rounds Experience of Investor | (0.001) | 0.57 | No | No | | |
| S&P 500 | (0.001) | 1.00 | No | No | | |

Figure 19: Regression Analysis Parameter Estimates

company at acquisition. I have identified in *bold-italics* or **bold**, the factors whose estimates were statistically significant at 95% Confidence Interval and 70% Confidence Interval respectively. The model had an R squared of 37% and an adjusted R squared of 27%.

A complete report on the regression analysis is shown in Figure 20.

| Response Inflation Adj T | ransa | ction Valu | ie (\$MM) | | | | |
|---|--|--|--|--|---|--|--|
| Actual by Predicted Plo | ot | | | | | | |
| 1400 | | / | 2 | | | | |
| <u>5</u> _ ¹²⁰⁰⁻ | / | / / | | | | | |
| -000 gg | / / | | | | | | |
| -008 A ans | | | | | | | |
| | / | | | | | | |
| or to a 400- | | | -11 | | | | |
| | - | | | | | | |
| | | | | | | | |
| - 0- | | | | | | | |
| -200 | 1 | | | | | | |
| | | 00 1000120 | | | | | |
| Inflation Adj Tra | | | /M) | | | | |
| Predicted P=0.00 | 02 RS0 | q=0.37 | | | | | |
| RMSE=176.8 | | | | | | | |
| Summary of Fit | | | | | | | |
| |).36831 | | | | Fim | | |
| 1 3 |).26986 76.800 | | | | Figu | | |
| | 47.151 | | | | Rep | | |
| Observations (or Sum Wgts) | | 0 | | | | | |
| Analysis of Variance | | | | | | | |
| Source DF Sum of Squ | ares N | lean Square | F Ratio | | | | |
| Model 12 14033 | | 116948 | | | | | |
| Error 77 24068 | 95.9 | 31258 | Prob > F | | | | |
| C. Total 89 38102 | 71.9 | | 0.0002* | | | | |
| Parameter Estimates | | | | | | | |
| Term | | Estimate | Std Error | t Ratio Pro | b> t | | |
| Intercept | | -182.0012 | 248.3374 | -0.73 0.46 | 59 | | |
| Infl. Adj total investmt (\$MM) | | 0.8913742 | 0 806436 | 1.11 0.27 | 25 | | |
| | | | | | | | |
| Years since first investment | | 29.724994 | 6.91227 | 4.30 <.00 | 001* | | |
| Years since first investment Target Current Public Status[P | rivate] | 44.770677 | 6.91227 29.55487 | 1.51 0.13 | 001* 339 | | |
| Years since first investment Target Current Public Status[P Number of Investors | rivate] | 44.770677 -10.06867 | 6.91227 29.55487 7.970353 | 1.51 0.13 -1.26 0.21 | 001* 39 03 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds | rivate] | 44.770677 -10.06867 -5.639671 | 6.91227 29.55487 7.970353 9.715376 | 1.51 0.13 -1.26 0.21 -0.58 0.56 | 001* 339 03 333 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm | - | 44.770677 -10.06867 -5.639671 0.0119638 | 6.91227 29.55487 7.970353 9.715376 0.003625 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 | 001* 339 03 333 115* | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor | | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 | 001* 339 03 333 915* 881 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No | | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 | 001* 339 03 333 115* 881 68 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite | | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 | 001* 339 03 333 115* 881 68 68 001 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 | | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 | 001* 339 03 333 115* 881 68 68 001 884 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite | | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 | 001* 339 03 333 115* 881 68 68 901 984 661 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq | | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 | 001* 339 03 333 115* 881 68 68 901 984 661 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents | | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 | 001* 339 03 333 115* 881 68 68 901 984 661 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents Effect Tests |] Nparn 1 | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 n DF Sut 1 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 1.085376 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 | 001* 139 03 133 115* 181 68 101 184 161 197 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents Effect Tests Source |) Nparn 1 1 | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 n DF Sut 1 1 1 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 1.085376 m of Squares 38189.79 578054.48 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 F Ratio 1.2217 18.4928 | 001* 339 03 333 115* 881 68 68 601 884 661 97 Prob > F 0.2725 <.0001* | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents Effect Tests Source Infl. Adj total investmt (\$MM) Years since first investment Target Current Public Status |) Nparn 1 1 | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 n DF Sun 1 1 1 1 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 1.085376 m of Squares 38189.79 578054.48 71729.16 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 F Ratio 1.2217 18.4928 2.2947 | 001* 339 03 333 115* 881 68 68 601 884 661 97 Prob > F 0.2725 <.0001* 0.1339 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents Effect Tests Source Infl. Adj total investmt (\$MM) Years since first investment Target Current Public Status Number of Investors |) Nparn 1 1 1 1 | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 n DF Sun 1 1 1 1 1 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 1.085376 0.271251 1.085376 0.271251 1.085376 0.271251 1.085376 0.271251 1.085376 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 F Ratio 1.2217 18.4928 2.2947 1.5958 | 001* 39 03 33 115* 68 68 68 60 108 4 61 97 Prob > F 0.2725 <.0001* 0.1339 0.2103 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents Effect Tests Source Infl. Adj total investmt (\$MM) Years since first investment Target Current Public Status Number of Investors Num. of investing rounds |) Nparn 1 1 1 1 1 | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 n DF Sun 1 1 1 1 1 1 1 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 1.085376 0.271251 1.085376 0.271251 1.085376 0.271251 1.085376 0.271251 1.085376 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 F Ratio 1.2217 18.4928 2.2947 1.5958 0.3370 | 001* 339 03 333 115* 68 68 60 108 46 61 97 Prob > F 0.2725 <.0001* 0.1339 0.2103 0.5633 | | |
| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents Effect Tests Source Infl. Adj total investmt (\$MM) Years since first investment Target Current Public Status Number of Investors Num. of investing rounds Max. size of investing firm |) Nparn 1 1 1 1 1 1 | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 n DF Sun 1 1 1 1 1 1 1 1 1 1 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 1.085376 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 F Ratio 1.2217 18.4928 2.2947 1.5958 0.3370 10.8909 | 001* 339 03 333 115* 881 68 68 601 97 Prob > F 0.2725 <.0001* 0.1339 0.2103 0.5633 0.0015* | | |
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| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents Effect Tests Source Infl. Adj total investmt (\$MM) Years since first investment Target Current Public Status Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital? | Nparn 1 1 1 1 1 1 1 1 | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 M 1 1 1 1 1 1 1 1 1 1 1 1 1 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 1.085376 0.2712510000000000000000000000000000000000 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 EXAMPLE EXAMPLE Xerror 1.2217 18.4928 2.2947 1.5958 0.3370 10.8909 0.3287 1.5508 | 001* 339 03 333 115* 881 68 68 601 984 661 997 Prob > F 0.2725 <.0001* 0.1339 0.2103 0.5633 0.0015* 0.5681 0.2168 | | |
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| Years since first investment Target Current Public Status[P Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital?[No NASDAQ Composite S&P 500 Dow Jones Med Eq Number of Patents Effect Tests Source Infl. Adj total investmt (\$MM) Years since first investment Target Current Public Status Number of Investors Num. of investing rounds Max. size of investing firm Rounds Experience of Investor Corporate Venture Capital? NASDAQ Composite | Nparn 1 1 1 1 1 1 1 1 1 1 | 44.770677 -10.06867 -5.639671 0.0119638 -0.001101 -30.77662 0.025468 -0.000722 0.353719 0.3045963 0.3045963 0.3045963 1 1 1 1 1 1 1 1 1 1 1 1 | 6.91227 29.55487 7.970353 9.715376 0.003625 0.00192 24.71425 0.083111 0.352912 0.271251 1.085376 0.2712510000000000000000000000000000000000 | 1.51 0.13 -1.26 0.21 -0.58 0.56 3.30 0.00 -0.57 0.56 -1.25 0.21 0.31 0.76 0.00 0.99 1.30 0.19 0.28 0.77 F Ratio 1.2217 18.4928 2.2947 1.5958 0.3370 10.8909 0.3287 1.5508 0.0939 0.939 | 001* 339 03 333 115* 881 68 68 601 184 661 97 Prob > F 0.2725 <.0001* 0.1339 0.2103 0.5633 0.0015* 0.5681 0.2168 0.7601 | | |

Figure 20: Regression Analysis Output Report

Discussion

The overall model had an adjusted R squared of 27%. This is comparable to the explanatory power of a previous study¹⁷ that looked at licensing deals in the biotech space. Given the fact that I considered a diverse group of companies and sub-categories, and since I did not take into account market dynamics of specific companies, including market size, growth, nature of competition, technology and the like, (discussed in the next section), the explanatory power of the model was surprising high.

Arnold et al, in their study in Nature in 2002 titled "Value Drivers in Licensing deals" commented that "46-68%... (of the variability in deal value)... cannot be accounted for by defined quantitative criteria" They then hypothesize that "manager perceptions regarding ...quality of management, and scientists, business strategies... and negotiation skills" could additionally explain the variability.

In the same study, the statistical significance of the factors were divided into p<0.5, p<0.3, and p>0.3. I have adopted the same confidence levels (95% and 70%) in this study.

Below, I discuss each of the Hypotheses that we had formed and the results of the analysis.

<u>Smart Money- Hypothesis 1</u>: Companies with investing firms that have larger capital under management, and with more rounds of experience are associated with higher deal values:

Result: Companies that have investors with larger capital under management were significantly (p=0.015) correlated with higher valuation at acquisition. (Regression parameter estimate 0.012). Each additional \$100 MM dollars of capital that the largest investor in the company has under management, the acquisition value is expected to go up by \$1.2 MM. The experience of the investors, as measured by the rounds of experience, was not significantly correlated with higher valuation in this sample.

<u>Corporate Venture Capital- Hypothesis 2:</u> Companies in which Corporations have invested as CVC's are associated with higher deal values:

Result: The analysis showed that companies with investments by corporations had a higher (Estimated Δ : \$30.78MM) observed acquisition prices. The association was

significant at a confidence level of 78%

<u>Investment Staging- Hypothesis 3:</u> The Valuation of the firm is positively associated with more rounds of VC investments, the total amount of investments and the number of years since the first venture investment:

Result: The valuation of companies was positively correlated to the years since the first investment, with a parameter estimate of 29.7 (Δ = \$29.7 MM for each year since funding) and the effect was highly statistically significant (p<0.001). The valuation was also slightly positively correlated with the total investment in the company (Parameter Estimate: 0.89) at a confidence level of 73%. The effect of the number of investing rounds was not statistically significant.

<u>Investor Syndicate- Hypothesis 4:</u> The number of investors is associated with a higher deal value:

Result: One of the two surprising results in this study was that the number of investors was **negatively** correlated with the valuation of the firm at acquisition. The negative impact was moderately high (parameter estimate: 10.07; ie Δ = (\$10) MM for each additional investor)), at a confidence level of 79%.

Explanations for this surprising finding are not obvious. Most VC's in a syndicate would agree to be represented on the company board by one or two lead investors, and this practice would seem to rule out the lack of cohesive direction for the company as a tenable explanation. One explanation could be that companies in which the original investors had stopped funding at some point may obtain investments from other VC's in subsequent rounds.

<u>Intellectual Property- Hypothesis 5:</u> The number of patents assigned to the company is associated with a higher deal value.

Result: The effect of the number of patents on the acquisition value was not statistically significant. As I mentioned earlier, this could be because the number of patents assigned is a weak measure of the Intellectual Property of the company.

<u>Capital Markets Level- Hypothesis 6</u>: The deal value is associated with higher NASDAQ composite levels, S&P 500 and Dow Jones Medical Equipment (Developed world) index. Result: The acquisition valuation was positively impacted by the DJ Medical Equipment index (Parameter estimate: 0.354) at a confidence level of 80%. The impact of the broader indices (S&P 500 and NASDAQ) was not statistically significant.

<u>Corporate Governance- Hypothesis 7:</u> Valuation of a public company would be higher than that of a privately held company.

Result: The second surprising result of my analysis was that public companies had a statistically significant (87% confidence level) **negative** impact [Δ = \$(44.7) MM if public], on the deal value. Explanations for this may be that corporations do not pay a premium for corporate governance systems which they would have to replace in most cases, and the lack of transparency may tend to make corporations overpay for their private targets, compared to the public ones.

Limitations

This study has the following limitations:

- By the very nature of the inclusion criteria through which I selected the companies that were acquired by other companies, I am analyzing only companies that were, in some measures, successful. According to AdvaMed (referenced in the medical device start-up section), there were more than 4,300 companies that had less than 100 employees. The vast majority of these companies will not succeed in going public or getting acquired, and I have not included those companies in this study. In effect, this analysis is looking at the characteristics of "successful" start-ups and the impact of different factors on the *extent* of success as measured by the valuation.
- [Arnold et al, 2002] surveyed a panel of manager on the relative importance of specific value drivers in licensing deals, as perceived by licensing managers. They were: Market (including market size, potential, patient population), Stage in development of product, Strategy and competition as the four most important factors biotech deals. That analysis found that only the type of partner, stage of development, scope, and type of deal had a significant effect on the alliance, and further reported that these factors only accounted for 32% to 52% of the variability in deal value. In the present study, I have not considered any of these factors explicitly. The factors that I chose revolved around the financing of the venture, and the IP assets of the company. These factors were able to account for 27% of the variability in the data set.
- The Analysis, by design, is looking at only venture backed firms.
- For the IP assets of the start-up, I have considered only the number of patents assigned to them. To improve the analysis, we could consider the number of independent claims, as well as a more detailed analysis of the IP position vis-à-vis the competition in the field.

Conclusion

In this paper, I have done the following:

- Compiled database on venture backed device deals from different sources, for analysis.
- Researched background material on Venture Capital, Corporate Venture Capital, Medical Device Industry and regulations
- Laid out characteristics of successful start-ups in the medical device space from a financing and IP perspective
- Formed hypotheses and ran regression analysis to prove or disprove the thesis.

The analysis agreed with conventional wisdom for the most part. The mean value at acquisition (in Constant 2006 \$) was about \$147 MM, however, the median value was lower at \$91 MM, reflecting the outlier effect of a few large acquisitions. The median valuation at acquisition was 3.8 times the total investment in the firm, in nominal terms and 3.5 X, inflation adjusted. The regression analysis coefficients and confidence levels can aid companies in assessing their own potential exit values, if they succeed in getting acquired.

The two factors that had a surprising impact on valuation were the Target's public status and the number of investors. Private companies were on average, associated with a higher deal value than public companies (p value= 0.13). This went against the hypothesis that companies that had already gone public would attract higher valuations because of better governance systems and transparency. The second surprising result was that the number of investors was negatively associated with the valuation (p value=0.21). Further studies would be helpful to investigate whether these two results are an anomaly or not.

Based on this study, I conclude that start-up companies should carefully review options regarding their investors and the stage to which they develop technologies before acquisition. The impact of smart money, as shown by larger firms with more money under capitalization, was highly statistically significant. Having a corporate investor funding the company, gives it more credibility and potential access to the larger company's resources, and, in my analysis, is associated with a significantly higher valuation.

The broader capital market did not seem to impact the valuation, but the sector-specific Dow Jones Medical Equipment Index was positively correlated to the price companies were willing to pay for an acquisition. Thus timing of the acquisition is also important to the valuation.

In this study the effect of the number of patents was not shown to be statistically significant. This analysis can be improved by more granular measures of Intellectual Property of the target.

Companies try to balance the potential for a higher value at exit with the risks and costs of further development. In this analysis, the years since first investment had a statistically significant impact on valuation. This suggests that companies that may have breakthrough technologies should develop their products significantly from technology development through clinical trials toward commercialization, before pursuing opportunities for getting acquired. A future study that reviews the valuation of medical device companies by the stage of development or commercialization, at the time of acquisition would be useful for companies to make this decision.

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APPENDIX: DEAL LIST

List of medical device deals from VenturXpert, announced January 1998 to April 2006.

Transaction values shown in this list are actual values, **not** adjusted for inflation.

| Deal # | Date Announced | Target Name | Acquiror Name | | Transaction Value (\$ MM) | |
|----------|--------------------|------------------------------|---------------------------------|----------|------------------------------|--|
| | | | | | | |
| 1 | 10/10/2005 Accelle | | Kohlberg, Kravis, Roberts & Co. | \$ | 1,270.00 | |
| 2 | 6/22/2001 Accum | - | Radiometer A/S | \$ | 9.70 | |
| 3 | 1/22/2004 AFx, In | IC. | Guidant Corporation | \$ | 45.00 | |
| 4 | 9/15/1999 Allianc | | Kohlberg, Kravis, Roberts & Co. | \$ | 821.60 | |
| 5 | 12/16/2005 Animas | Corporation | Johnson & Johnson | \$ | 518.00 | |
| 6 | 8/9/2002 Appriva | a Medical, Inc. | MICROVENA Corporation | \$ | 80.00 | |
| 7 | 7/1/2004 Atto Bi | oscienc | BD BioSciences | \$ | 25.00 | |
| 8 | 11/9/2000 Avail N | fedical Products, Inc. | UBS Capital Americas II LLC | \$ | 94.00 | |
| 9 | 12/23/1998 Ballard | Medical Products | Kimberly-Clark Corporation | \$ | 761.30 | |
| 10 | 5/14/2002 BEI Me | edical Systems Company, Inc. | Boston Scientific Corporation | \$ | 95.63 | |
| 11 | 2/9/1999 Biomet | ric Imaging, Inc. | Becton Dickinson | \$ | 85.00 | |
| 12 | 9/2/1998 BioStar | , Inc. | Thermo Bioanalysis Corp | \$ | 28.90 | |
| 13 | 7/7/2000 Cadent | Medical Corporation | Cardiac Science, Inc. | \$ | 24.75 | |
| 14 | 6/29/2001 Cardiac | - | Boston Scientific Corporation | \$ | 115.00 | |
| 15 | | Thoracic Systems, Inc. | Guidant Corporation | \$ | 315.85 | |
| 16 | 11/29/2001 Chattan | • | Encore Medical Corporation | \$ | 37.00 | |
| 17 | 3/28/2002 Circe B | | ICN Pharmaceuticals, Inc. | \$ | 26.00 | |
| 18 | | Pathology Laboratories, Inc. | Sonic Healthcare Ltd | S | 300.00 | |
| 19 | 8/6/1999 CoCens | | Purdue Pharma L.P. | \$ | 9.48 | |
| 20 | | dated Vision Group, Inc. | National Vision Inc | Š | 88.00 | |
| 20 | | Delivery Systems, Inc. | pSiVida Ltd | Š | 104.00 | |
| 21 | 12/15/2005 CorSolu | | Matria Healthcare Inc | Š | 445.00 | |
| 22 | 12/16/2002 CryoGe | • | American Medical Systems, Inc. | ŝ | 40.00 | |
| 23 | 2/12/2002 Cryode | • | Microtek Medical, Inc. | Š | 11.90 | |
| 24 | | s Centers of America, Inc. | Renal Care Group, Inc. | ŝ | 98.31 | |
| 25 | 10/3/2003 EBM S | | HealthGate Data Corporation | \$ | 0.38 | |
| 20 27 | 9/15/1999 Ecton, 1 | • | Acuson Corporation | \$ | 40.00 | |
| 27 | 2/22/2001 Emboli | | Boston Scientific Corporation | \$ | 75.00 | |
| 28 | 2/11/2002 Endolog | | Radiance Medical Systems Inc | \$ | 28.12 | |
| 29 30 | | | Medtronic, Inc. | \$ | 67.00 | |
| | 12/19/2001 Endone | - | | \$ \$ | 35.00 | |
| 31 | | Medical Technologies, Inc. | Boston Scientific Corporation | \$ \$ | 185.00 | |
| 32 | 5/3/2003 EpiCor | | St. Jude Medical, Inc. | 3 S | 67.3 | |
| 33 | 7/26/1999 Exogen | | Smith & Nephew Inc | - | | |
| 34 | 7/24/2000 First M | | Sigma-Aldrich Corp | \$ | 55.0 | |
| 35 | | Bioscience Corporation | Tecan AG | \$ | 10.0 | |
| 36 | 3/31/2004 Gelifex | | Synthes, Inc. | \$ | 15.0 | |
| 37 | | Aedical Supply, Inc. | McKesson Corporation | \$ | 154.0 | |
| 38 | | Guided Neurologics | Medtronic, Inc. | \$ | 68.0 | |
| 39 | 8/30/2000 Implant | | Biomet, Inc. | \$ | 175.0 | |
| 40 | 11/24/2003 Implex | | Zimmer Holdings Inc | \$ | 108.0 | |
| 41 | 8/4/1998 InContr | | Guidant Corporation | \$ | 116.8 | |
| 42 | 3/17/2004 Infusion | - | Zoll Medical Corp | \$ | 6.6 | |
| 43 | 11/9/1999 Innovas | sive Devices, Inc. | Johnson & Johnson | \$ | 83.0 | |
| 44 | 7/2/2001 InSight | Health Services Corporation | Investor Group | \$ | 255.6 | |
| 45 | - | ed Vascular Systems | Abbott Laboratories | \$ | 65.0 | |

-Continued on next page-

-Continued from previous page-

| Deal # | Date Target Name Announced | Acquiror Name | Transaction Value (\$ MM) | |
|----------|--|--|------------------------------|--------|
| | | | | |
| 46 | 12/14/2004 InterScope Technologies, Inc. | Trestle Corporation | \$ | 1.17 |
| 47 | 1/5/2001 IntraTherapeutics, Inc. | SulzerMedica | \$ | 145.00 |
| 48 | 2/16/2005 Ischemia Technologies, Inc. | Inverness Medical Innovations, Inc. | \$ | 24.00 |
| 49 | 2/20/2001 LXN Corporation | Inverness Medical Innovations, Inc. | \$ | 29.30 |
| 50 | 9/15/2005 Medical Metrx Solutions | AIG Alteris Health | \$ | 21.90 |
| 51 | 1/21/2000 Medtrex | Johnson & Johnson (Ethicon Endo-Surgery) | \$ | 7.40 |
| 52 | 6/7/1999 Metra Biosystems, Inc. | Quidel Corp. | \$ | 22.73 |
| 53 | 12/14/2004 Microline, Inc. | Pentax Corp | \$ | 48.00 |
| 54 | 11/5/2002 MicroNet Medical | Advanced Neuromodulations Systems, Inc. | \$ | 5.72 |
| 55 | 1/13/1998 Mobile Technology, Inc. | Alliance Imaging, Inc. | \$ | 100.00 |
| 56 | 9/27/2004 Molecular Staging, Inc. | Qiagen N.V. | \$ | 28.50 |
| 57 | 8/15/2002 MQ Associates, Inc. | J.P. Morgan Partners | \$ | 350.00 |
| 58 | 12/12/2005 National Imaging Associates, Inc. | Magellan Health Services Inc | \$ | 122.00 |
| 59 | 6/7/1999 NeoPath, Inc. | AutoCyte, Inc. | \$ | 107.50 |
| 60 | 3/1/2004 Novacept, Inc. | Cytyc Corporation | \$ | 325.00 |
| 61 | 10/14/2003 Oculex Pharmaceuticals, Inc. | Allergan, Inc. | \$ | 230.00 |
| 62 | 4/4/2000 Optical Resources Group, Inc. | Hoya Corp | \$ | 76.21 |
| 63 | 9/6/2004 Opus Medical, Inc. | ArthroCare Corporation | \$ | 90.00 |
| 64 | 5/26/2005 Pathology Partners, Inc. | Caris Ltd | \$ | 120.00 |
| 65 | 10/19/2000 Percusurge, Inc. | Medtronic, Inc. | \$ | 225.00 |
| 66 | 12/15/2003 Percutaneous Valve Technologies, Inc. | Edwards Lifesciences Corp | \$ | 125.00 |
| 67 | 7/21/2004 Physicians Dialysis, Inc. | DaVita, Inc. | \$ | 150.00 |
| 68 | 4/25/2003 Prism Enterprises, Inc. | CooperSurgical, Inc. | \$ | 23.00 |
| 69 | 10/18/2001 Pro-Duct Health, Inc. | Cytyc Corporation | \$ | 167.45 |
| 70 | 2/9/2005 Proxima Therapeutics, Inc. | Cytyc Corporation | \$ | 160.00 |
| 71 | 6/7/2002 ReGen Biologics, Inc. | Aros Corp. | \$ | 14.40 |
| 72 | 9/28/2001 Rehab Associates | Benchmark Medical, Inc. | \$ | 5.48 |
| 73 | 5/10/1999 ReSound Corporation | GN Great Nordic Ltd | \$ | 185.37 |
| 74 | 4/14/2005 Rubicon Medical Corporation | Boston Scientific Corporation | \$ | 99.25 |
| 75 | 3/20/2006 SightLine Technologies, Ltd. | Stryker Corp | \$ | 50.00 |
| 76 | 4/15/1999 SMT Health Services, Inc. | Alliance Imaging, Inc. | \$ | 105.80 |
| 77 | 6/2/2003 Spinal Concepts, Inc. | Abbott Laboratories | \$ | 170.00 |
| 78 | 6/28/2002 Spinal Dynamics Corporation | Medtronic, Inc. | \$ | 269.50 |
| 78 79 | 7/21/2004 SpineCore, Inc. | Stryker Corp | \$ | 120.00 |
| 80 | 2/14/2001 Survivalink Corporation | Cardiac Science, Inc. | \$ | 79.86 |
| 81 | 10/25/1998 TheraTech, Inc. | Watson Pharmaceuticals, Inc. | \$ | 312.69 |
| 82 | 2/21/2002 Timm Medical Technologies, Inc. | Endocare, Inc. | \$ | 33.63 |
| 83 | 8/11/2003 TransVascular, Inc. | Medtronic, Inc. | ŝ | 60.00 |
| 83 | 12/13/2004 US Labs, Inc. | Laboratory Corporation of America Holdings | \$ | 155.00 |
| 85 | 2/15/2005 Velocimed, Inc. | St. Jude Medical, Inc. | \$ | 82.50 |
| 85 86 | 3/1/2006 Venetec International, Inc. | CR Bard Inc | \$ | 166.00 |
| 80 87 | | GE Medical Systems | \$ | 50.0 |
| | 2/13/2002 Visualization Technology, Inc. | • | \$ | 10.6 |
| 88 | 3/13/2001 VitalCom, Inc. | Data Critical Corporation Valleylab, Inc. | 5 \$ | |
| 89 | 7/5/2005 Vivant Medical, Inc. | • | | 66.00 |
| 90 | 9/28/2004 X-Ceptor Therapeutics, Inc. | Exelixis Inc | \$ | 23.8 |

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