Mergers & Acquisitions in the Medical Device Industry: An Exploration of Factors Influencing Valuation

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MBA
MIT Sloan School of Management, 2007

Submitted to the Harvard-MIT Division of Health Sciences and Technology in Partial Fulfillment of the Requirement for the Degree of Master of Science in Health Sciences and Technology at the Massachusetts Institute of Technology

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MERGERS & ACQUISITIONS IN THE MEDICAL DEVICE INDUSTRY: 
AN EXPLORATION OF THE FACTORS INFLUENCING VALUATION 

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Abstract 

Valuing medical device companies and technologies is a complex process. Several different approaches and models are often used in combination to determine a transaction valuation. This research uses the Enterprise Value to Forward Sales model as a tool for valuing mergers and acquisitions in the device industry. This model was selected for its transportability across industry segments, ease of calculation, broad acceptance, and lack of detailed forecasting assumptions. This research seeks to: 1) explore the importance of 20 commonly cited factors in determining a medical device company EV/Sales multiple, 2) develop a model for forecasting the EV/Sales multiple of medical device transactions, and 3) assess the explanatory power of these factors in determining the enterprise value (measured in dollars) of pre-revenue transactions. For purposes of this analysis valuation was approached from a sector neutral or portfolio diversification perspective. Multivariate regression analysis was performed on a database of 352 M&A transactions announced between January 1, 1996 and December 31, 2007 to assess the importance of various factors and develop a model for forecasting EV/Sales multiples. Consistent with our expectations, supernormal growth, industry growth, market size, sector beta, position in market, venture funding, and IPO status were all significant factors in determining the multiple. Based on these factors, we developed a model that was 95% accurate in forecasting the EV/Sales multiple of medical device transactions that occurred between January and May of 2008. Based on the success of this model, we then explored the utility of these factors in determining the gross enterprise value of pre-revenue M&A transactions. As expected, this approach was not successful. Varying discount rates, timing assumptions, difficult to determine value synergies, and emotion are confounding factors which make it difficult to reliably forecast absolute dollar transaction valuations.

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To my family,

for their support & encouragement
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To the readers of this thesis, please feel free to direct any comments or questions that you may have to jason.robins@sloan.mit.edu

Thank you,

Jay
MERGERS & ACQUISITIONS IN THE MEDICAL DEVICE INDUSTRY: 
AN EXPLORATION OF THE FACTORS INFLUENCING VALUATION

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I. INTRODUCTION

Boston Scientific acquired Target Therapeutics for 12x forward revenue. Medtronic acquired Kyphon for 7x forward revenue. Guidant acquired Cardiothoracic Systems for 13x forward revenue. Zimmer acquired Centerpulse for 3x forward revenue. Nearly 800 medical device firms have been acquired between 1996 and 2007 at valuations ranging from 0.1x to 25x forward sales. This wide valuation gap and the diversity of the transactions cause one to reflect and ask the question: What are some of the factors that determine the valuation of a medical device company?

RESEARCH OBJECTIVES

This thesis attempts to answer that question and develop a model for forecasting the EV/Sales multiple to value a medical device company or technology.

As a former equity research analyst covering the medical device industry I have always been fascinated with the wide variety of approaches to valuing these companies and the numerous valuation techniques and standards associated with each approach. Despite this variety, all the techniques produce remarkably similar valuations. A common set of underlying factors seem to influence these valuations, which we explore in greater detail in this research.

The factor analysis and model in this research explore valuation from a neutral or portfolio diversification perspective. The paper is designed to address the needs of investors, business development/corporate executives (acquirers) and entrepreneurs (targets). All constituents will hopefully gain an understanding of the broad factors that influence valuation and which are most import to address/consider when considering a potential sale or investment. Those with sector specific needs can use this valuation framework as a baseline from which they can incorporate unique synergies specific to their situation.

This research explores valuation through the Enterprise Value to Forward Sales (EV/Sales) model. The author uses the EV/Sales model simply as a tool for this analysis. This thesis does not intend to prove or disprove the merits of using EV/Sales as a valuation technique according to modern corporate finance theory or its appropriateness for valuing medical device companies and technologies.

The EV/Sales model was chosen because: 1) it is widely used and accepted among both investors and industry constituents, 2) it is not dependent on a multitude of forecasting assumptions and 3) it is easy to calculate and understand. Conversations with research analysts and investments bankers reveal that it is well suited for valuing 95% of all medical device transactions, making it an appropriate tool for this analysis. The benefits and shortcomings of this approach are discussed in the Methods section of this research.

The model developed thorough this research is designed to be sector independent. While each sector may have its own unique technology and synergy benefits that could be captured in sector specific models, consistent with the intended audience, this paper approaches valuation from a general investor or acquirer perspective. A common set of valuation factors exists that explain a significant portion of the EV/Sales multiple. Using a multivariate regression model, these factors can be combined to provide a sector-independent valuation.

Twenty factors were explored to assess their contribution to the EV/Sales multiple. Traditional financial and market factors (profit margin, sales growth, position in market, market size) were
considered along with industry specific factors such as reimbursement and FDA benchmarks. The set is by no means exhaustive, but is sufficient to develop a model that offers sufficient explanatory power to forecast EV/Sales multiples.

Roughly 800 transactions have been completed in the Medical Device industry between 1996 and 2007 across 33 different sectors. Data were available for 386 of these transactions, which served as the sample set for factor analysis. Note that the sample was a close representation of the industry data in terms of sector mix, company size, vintage, etc. Regression analysis was performed to assess the explanatory power of each variable. The statistically relevant variables were then combined into a model to forecast EV/Sales. The model was validated against 2008 M&A activity.

In an attempt to value pre-revenue transactions, the same variables were used in a multifactor model to predict transaction value measured by the gross enterprise value (in $ millions) of the acquired targets. A forty company transaction database provided the underlying sample for this model. Regression analysis revealed this approach to be less successful in explaining transaction valuation. Varying discount rate assumptions, emotional valuation factors, bidding wars and pre-existing relationships were confounding factors that generated significant variation among deals.

Finally, this paper presents practical considerations for valuing medical device transactions, attempting to relate this work toward value creation and positioning companies for M&A transactions or fund raising. Valuation from the perspective of investors, business development executives and entrepreneurs is explored. Readers should walk away with an understanding of the motivations for M&A in the medical device industry, the key factors that drive valuation, the relative importance of those factors, a model for valuing a company, and a sense of how to approach valuation reasonably, given their particular perspective.
SIGNIFICANCE, UTILITY & IMPLICATIONS OF THIS RESEARCH

The goal of the research (broadly) is to explore the factors that influence the valuation of medical device companies and technologies. Readers will hopefully gain an understanding of how to use a multifactor EV/Sales model to value a venture, as well as how the factors influence the value of a venture, and what can be done with respect to those factors to enhance that valuation.

There are many models for valuing medical device companies and just as many methods for assigning an EV/Sales multiple. Multiple valuation is often criticized as one dimensional (considering only sales) and subjective. Traditionally, multiples have been assigned based on comparable companies’ current valuation, historical precedents, prior acquisitions, related transactions, or market conditions. It has always been more art than science. Consequently, issues always surfaced when attempting to value novel technologies or emerging sectors, as it was difficult to justify a given multiple.

This research attempts to develop a quantitative model based on relevant valuation factors for assigning EV/Sales multiples across the entire medical device industry. It will hopefully overcome some of the previously mentioned challenges associated with valuing novel technologies or new sectors with multiples. Additionally, such a model will remove the subjectivity associated with current multiple valuation approaches, providing an objective valuation based on quantitative inputs. This dynamic model can be updated to account for changing factors influencing the medical device industry and evolve with it.

For the entrepreneur, this research not only offers a framework for determining the value of a technology or a company, but also identifies the factors that the entrepreneur can control or address to enhance the value of their venture. By understanding what drives value, the entrepreneur can then allocate his/her limited resources toward activities that will generate the greatest value for the enterprise. This will help the entrepreneur sell his venture or raise capital at the highest possible valuation.

For the corporate or business development executive, this research provides a sector neutral model for valuing medical device technologies and companies. It is particularly useful when valuing new technologies or acquiring companies to diversify into a new sector. Based on this assessment, the acquirer can then adjust the valuation for any unique synergies they may be able to achieve. On the flip side, management of the target can attempt to address the factors that will enable them to maximize the value they would receive in an acquisition. Either way, the model provides an accurate baseline valuation.

For the venture capital investor and investment banker, this research provides the benchmarks and model for valuing transactions and pricing deals. Just like the entrepreneur, the venture capitalists can make investments to correct/improve the factors that will lead to higher valuations for exit strategies or in future financing rounds.

For the public equity investor, this model provides a framework for determining the EV/Sale multiple and hence the target price of a potential investment. This technique is particularly useful for those investing in M&A, LBO or arbitrage situations when the company will cease to exist as a public entity. It is also helpful for valuing IPOs (initial public offerings) as the value of the entity itself overshadows other investment considerations (beyond the control of the company) which can impact valuation.
II. HYPOTHESIS:

The thesis seeks to address three primary questions:

1) **What are some useful factors that determine an enterprise value to forward sales (EV/Sales) multiple for mergers and acquisitions or investments in the medical device industry?**

A broad range of factors are theorized to influence the valuation of medical device firms. Our background research has identified 20 financial, risk/return, regulatory, product, and firm specific factors (discussed in detail in the Methods section) thought to influence the valuation of a medical device technology or company from a portfolio diversification or sector neutral perspective. This thesis hypothesizes that supernormal growth, sales/distribution synergies, industry growth, and market size are the most useful of these 20 factors in determining the EV/Sales multiple of medical device companies or technologies. These factors exhibit significant variation between acquired companies to capture differentiation in EV/Sales multiples across sectors, company life cycle stage, competitive dynamics in each market, and the nature or potential of the target’s technologies. Consequently, these factors will likely offer the greatest explanatory value.

2) **Can these factors be combined into a model to forecast the EV/Sales multiple of future mergers and acquisitions in the medical device industry?**

Once the relative importance of these factors has been identified through retrospective regression analysis, they can be combined to generate a model for forecasting EV/Sales multiples. It is hypothesized that this model can accurately forecast the EV/Sales multiples of medical device mergers and acquisitions occurring in the first half of 2008. Thus the model may serve as a tool in forecasting the valuation of medical device companies or technologies.

3) **Are these factors also valuable in explaining the enterprise value (measured in actual dollars) of pre-revenue company acquisitions in the medical device industry?**

Valuing pre-revenue companies presents a greater challenge. Several models exist for valuing pre-revenue companies, yet there is greater variation in valuation than with established revenue-stage companies. This disparity begs the questions whether the factors identified in the above analysis would also prove useful explaining the enterprise value of pre-revenue companies. We hypothesize that these factors are not useful in explaining the enterprise value of pre-revenue companies. Difficult to value synergies, emotional factors, varying timing assumptions, and varying acquirer discount rates and risk tolerances play a significant role in valuing pre-revenue acquisitions, which could limit the explanatory power of these variables.
III. METHODS & MATERIALS

Summary. The EV/Sales multiple was chosen as the tool through which to explore valuation in the medical device industry. To conduct this analysis, the author identified through background research 20 factors thought to influence the EV/Sales multiple. A database of historical transactions was constructed to retrospectively evaluate (through multivariate regression analysis) the significance of these factors in explaining an EV/Sales multiple. Regression results were then used to construct models to forecast the EV/Sales multiple of future transactions. These models were then prospectively validated against medical device mergers and acquisitions occurring in the first half of 2008. Finally, the author evaluated the utility of these factors in explaining the enterprise value (measured in $ millions) of pre-revenue transactions occurring in the medical device industry.

EV / SALES MULTIPLE

This research explores valuation through the enterprise value to forward 12-month sales (EV/Sales) multiple. It is a common tool used by investment bankers, equity research analysts and corporate executives when valuing medical device companies and technologies. The author does not intend to argue the utility of this multiple as either a stand alone valuation technique or its utility or appropriateness for valuing medical device companies. It is simply the vehicle through which we are conducting this research.

The EV/Sales multiple is defined as:

Enterprise Value / Forward Year’s Sales

Enterprise value is defined as:

Equity Valuation + Debt – Less Cash & Equivalents

It is a measure of the value of the target’s total capitalization, including both equity and debt, which must be assumed or repaid in the event of a take over. Cash and equivalents are subtracted from the valuation because they are essentially a wash for the acquirer or investor and do not contribute to the firm’s or division’s ultimate valuation. Enterprise value is a measure of all claims on a business and provides a uniform platform for comparing companies, irrespective of capital structure decisions.

The multiple considers forward sales to account for the future growth prospects of the target rather than past performance (trailing revenue multiple). This forward number is particularly important when considering the small rapidly growing acquisition targets so common in this industry or the mature entities that may be facing declining growth prospects.

Several valuation techniques exist and many are used in combination to determine a final deal valuation. The EV/Sales multiple was chosen as the tool for this analysis because: 1) it is the most common technique used by all constituents in valuing medical device transactions. 2) It is transportable across all sectors of the industry. 3) It accounts for all claims on a company’s operations, irrespective of a company’s capital structure and financing decisions. 4) It does not require complex forecasting assumptions across multiple variables. 5) It encompasses an analysis of both the quantitative and qualitative factors that influence valuation. 6) Given the relative homogeneity of margins in the medical device industry and the fact that acquirers can
realize synergies and leverage their infrastructure to change the target’s margin profile, forward sales provide the most meaningful basis for evaluation and comparison across companies.

This model does have significant overlap with other valuation techniques. Many of the factors considered when practitioners assign an EV/Sales multiple (profit margins, sales forecasts, industry growth, etc.) are the underlying variables used to forecast the inputs for free cash flow and other discounted cash flow valuation models. Thus implicit forecasting assumptions for revenue (in this case), EBIT, EBITDA, EPS, Cash Flow, etc. are all in part connected. This may account for the correlation between alternative valuation models.

The sheer mechanics of the income statement also make the EV/Sales multiple easily transportable between different profitability or cash flow metrics. This is particularly true of the medical device industry, where potential income statement margins in a given sector evolve toward an expected mean. Hence one can easily make the mathematical adjustments to determine that a company with $100 million in sales trading for an 8x EV to sales multiple is worth 20x EV/EBIT at a 40% EBIT margin and that the same company with a 25% profit margin should trade at a 32x EV to earnings multiple. Empirical evidence indicates this relationship largely holds across all sectors of the medical device industry. Thus there is a sector neutral approach to valuing both revenue and profits.

**Advantages:** Modern financial theory cites several advantages to using an enterprise approach to valuation. First, it considers all claims on a firm's operations both equity and debt, offering greater comprehensiveness than equity techniques. Second, it is transportable across all companies in an industry, irrespective of capital structure. Third, it is simple to calculate and does not require a vast array of forecasting assumptions. Fourth, it offers the flexibility to be adjusted for special relationships, investments and other valuation considerations. Fifth, it can consider the valuation of different operating divisions independently and include/exclude non-core assets associated with a transaction. Sixth, it has been validated through financial and academic publications and is widely understood and employed across the financial community and industry.

**Disadvantages:** Modern financial theory cites several limitations to using a multiple approach to valuing companies/technologies. First, this approach is static, considering at valuation at a single point in time based on one period’s projected revenue and balance sheet structure. These factors can vary significantly over time. Second it does not consider cash flow requirements for funding projected growth. Third, it only looks at a single metric (sales, EBITDA, cash flow, etc.), not capturing a target’s other relative income statement or cash flow operating advantages. Fourth, equity and debt valuations may not reflect current market conditions (less of an issue for publicly traded companies).
FACTORS INFLUENCING VALUATION

In selecting factors for this analysis, we attempted to consider some of the important factors that both drive valuation and the success of a new medical therapy in the marketplace. Our conversations with investment bankers, medical device entrepreneurs, business development executives and management at medical device firms helped identify the factors relevant to this analysis. The factors serve as independent variables in our regression analysis. Factors considered in the analysis were:

**Sector and Sub-sector:** Exploration of these factors tests whether deal valuation is a function of the sector or sub-sector in which the target competes. Empirical evidence does not suggest a strong correlation as deals in many sectors seem to range between 2-7x forward sales. Certain subsectors like spine, however, tend to gravitate toward 6-10x forward sales. Hence it begs the question whether this is a function of the sector or another underlying factor across sectors. Sector and subsector data were based on classifications from Bloomberg and Windhover publications.

**Status of FDA clearance of major technologies:** Pre-revenue, pre-FDA clearance mergers and acquisitions in the medical device industry are rare, but their frequency is increasing. Historically acquirers have purchased companies following FDA clearance of a key technology, thus only assuming market or execution risk. FDA clearance status of key products at the time of acquisition was determined through corporate press releases.

**Multiple Regulatory Clearances:** Do multiple product companies command higher acquisition premiums than single product companies? While certain single products companies have commanded largest multiples due to their high growth prospects, others have been acquired at a discount to the industry average. Multiple product companies seem to be centered toward the middle to upper two-thirds of the multiple valuation range. For purposes of this analysis, data on the number of regulatory clearances were obtained from annual reports, corporate websites and company press releases.

**Type of Filings:** On average PMA products and companies seem to carry a larger acquisition premium than those with 510k clearance pathways. Class I devices, often undifferentiated commodity products, are generally acquired for the smallest multiples. This may speak to the nature of the technologies involved, their impact on treatment paradigms, the size of the markets they target and hence the profitability of their manufacturers. Data on the type of regulatory filings were obtained from annual reports, corporate websites and company press releases.

**Current Sales (Selling Product):** While most companies are acquired once they have established sales, there is a trend toward more pre-revenue deals. This observation raises two questions: 1) does the sales level of the target have an influence on the acquisition multiple (as they are likely fewer bidders for the largest companies) and 2) is revenue still a major consideration or will more deals be completed pre-revenue. Sales data at the time of the transaction were obtained from FactSet and corporate press releases.

**Sales Model:** Investment bankers covering the medical device industry have reported that companies with direct sales forces typically command higher acquisition multiples than those companies which use distributors. This may be a function of the greater financial strength and profitability of those companies capable of building a sales force. Data on a company's sales model were obtained from annual reports, corporate websites and company press releases.
Potential Profit Margin: As with all therapeutics, medical device firms earn healthy operating margins. While operating margins among the large, acquiring firms may vary. Overall they vary within a 7-8% range with commodity products earning 25-26% margins and novel technologies commanding 33-34%. Thus potential profit margin of the target may influence the acquisition multiple. Average profit margins for the sectors in which each of the targets compete was obtained from FactSet and Bloomberg.

Market Size: Acquisition multiples may also be correlated with market size, as novel therapies targeting large market opportunities can command some of the highest acquisition multiples. This offers a much better basis for comparison than corporate sales at the time of the acquisition, as sales are a measure of past performance or the target’s sales force’s effectiveness. Annual market sizes for each sector were obtained from Windhover publications and equity research reports from major investment banks.

Position in Market: The target’s position in the market based on market share also drives acquisition multiples. It reflects the underlying technologies competitive effectiveness relative to other therapies and the device’s ability to capture share in a given therapeutic segment. Market share data were obtained from equity research reports and company annual reports.

Projected 3-5 Year Growth Rate – Sector Growth Rate: The difference between the target’s projected growth rate and the sector growth rate (a.k.a. supernormal growth) reflects the target’s ability to earn extraordinary profits and gain market share. Financial theory holds that valuation multiples are positively correlated with the firm’s ability to grow in excess of industry growth rates. Target projected growth rates and industry growth rates were obtained from FactSet, Bloomberg, and equity research reports.

Sector Growth: A target’s total growth rate is a function of supernormal growth and sector growth. While supernormal growth reflects the target’s attractiveness relative to similar companies in its own sector, sector growth accounts for the sector’s attractiveness relative to the rest of the industry. Faster growing sectors are associated with higher acquisition multiples. Sector growth rates were obtained from equity research reports and corporate presentations.

Reimbursement (Binary): Given that reimbursement governs the adoption of new medical therapies, most technologies/companies are acquired once they have a coding or plan in place. The question arises whether this will be a significant variable given that it is the norm among almost all acquisitions. Status of reimbursement was obtained by examining CMS DRG codes and corporate filings to assess whether a given technology was covered by a CMS or private payer code.

Technology Acquisition (Binary): Many acquisitions are motivated by the need to acquire a new or disruptive technology that can impact market share in the segment in which the acquiring company competes. This is most evident in the cardiology, orthopedics and spinal sectors where innovation is rapid and new technologies can alter the competitive dynamics of the sector. To assess whether a technology acquisition was a strategic intent of the deal, corporate press releases and annual reports were examined to assess management’s motivation for the transaction.

Enabling Technology (Binary): IP is critical to the medical device industry and the need to secure access to patents and technologies have generated a great deal of licensing, litigation and M&A. Cardiology has been the most visible example, as there were a flood of acquisitions
related to stent and balloon catheter IP in the late 1990’s. To assess whether the need for an enabling technology was a strategic intent of the deal, corporate press releases and annual reports were examined to assess management’s motivation for the transaction.

Sales Synergies (Binary): Adding products to the rep’s sales bag provides a significant source of incremental operating leverage. Consequently large companies with established sales forces will seek to acquire companies/technologies with the same call/sales point in the hospital. To assess whether distribution advantages/synergies were a strategic intent of the deal, corporate press releases and annual reports were examined to assess management’s motivation for the transaction.

Portfolio Diversification (Binary): Large medical device firms facing declining growth prospects have utilized M&A as a way to diversify their portfolios, smooth earnings volatility, and accelerate/sustain top-line growth. This trend was particularly prevalent in between 1996 and 2003, but has slowed in recent years. To assess whether portfolio diversification was a strategic intent of the deal, corporate press releases and annual reports were examined to assess management’s motivation for the transaction.

Earnout Model (Binary): As earlier-stage deals become more common in the medical device industry, acquirers have borrowed the earn-out model from biotech and pharma to reduce the risk associated with these transactions. Consequently, the use of an option-based pricing model may have increased the valuation of targets, as acquiring companies now have a means of reducing cost in the event of non-performance. Data on the use of earn-out models were obtained from corporate press releases issued when a deal was announced and Deutsche Bank and Wachovia Securities M&A transaction databases.

Venture Backed (Binary): Investment bankers and venture capitalists both speculate that the presence of venture investors or other financial sponsor backing can both enhance a company’s chances of success and ability to achieve a successful exit (IPO or acquisition). This also begs the question what significance venture backing may contribute to valuation. Venture investment data were obtained from the SDC Platinum and VentureX databases.

IPO’ed prior M&A (Binary): The pooling method of accounting created a much friendlier environment for acquisitions and facilitated an easier pathway for M&A. The termination of pooling increased the number private companies acquired, but the impact on valuation remains uncertain. Data on IPO status of target companies were obtained from Windhover’s Transaction database and FactSet.

Acquirer Stock Performance prior to M&A: Financial theory holds that companies are more likely to make acquisitions when their stock prices have appreciated. These inflated equity valuations can serve as cheap currency to fund a deal. To test whether this theory holds in the medical device industry, the acquirer’s price appreciation in the 12 months prior to the deal announcement was examined. Price appreciation data for public acquirers were obtained from FactSet.

Sector Beta: In considering an acquisition as an investment, one must also consider risk in addition to any measure of potential return (profitability, market size, projected growth, ect.). To assess risk, equity beta by sector provides a rough sense of the relative risk inherent in each sector of the medical device index. Equity Betas from public companies were obtained from FactSet and Bloomberg.
DATA

The author constructed a database of mergers and acquisitions in the medical device industry to perform retrospective analysis on the extent to which various factors (detailed in the previous section) may contribute to explaining EV/Sales multiples in the medical device industry.

Transaction Data Sources

The M&A database used in this analysis was compiled from sundry sources including Windhover, In Vivo, MedTech Insight, The Grey Sheets, Medical Device Daily, corporate press releases, Wachovia Securities Equity Research, Deutsche Bank Equity Research, Bear Sterns Equity Research, VentureX, FactSet, First Call, and Bloomberg.

The database includes details on 786 proposed and completed transactions in the Medical Device industry over an 11 year period between January 1, 1996 and December 31, 2007. Summary statistics on transaction enterprise value, target sector, and acquirer were available for all 786 transactions. These data were obtained from In Vivo, Wachovia, Deutsche Bank, Bear Sterns and VentureX transaction databases.

Data on each of the 20 factors under evaluation were obtained from a variety of sources, as discussed in the previous section of this paper. Data on all 20 factors were only available for 352/786 transactions completed during this period. These 352 transactions serve as the sample set for multivariate regression analysis.

To validate the prospective forecasting accuracy of the model to be constructed in this research, data were compiled on the 28 medical device transactions occurring between January 1, 2008 and May 31, 2008. These data were obtained from the Windhover Medical Device transaction database and various corporate press releases.

Data on 40 pre-revenue transactions occurring between January 1, 1996 and December 31, 2007 were obtained from the same data sources mentioned above. This database served as the sample set to evaluate the explanatory value of the various factors in determining the enterprise value of pre-revenue transactions.

Data Limitations & Challenges

Comprehensiveness: The transaction database reflects, to the best of the author’s knowledge, all of the medical device transactions (both completed and proposed) between January 1, 1996 and December 31, 2007. This includes both corporate and product line sales. Data were compiled from Wachovia, Deutsche Bank, and Bear Sterns medical device transaction databases and from Windhover information services. Transactions not disclosed through the major news services as well as smaller European and Asian deals are likely underrepresented in the dataset. Hence there may be a large-firm, or venture funded bias in the dataset. Results of this analysis may be most pertinent to medical device firms and product lines that have validated proof of concept and proof of market.

Use of Estimates. Revenue multiples, the dependent variable across which transactions are compared, are based on 12-month forward sales estimates. This reflects the sales expected to be generated in the 12 months following the announcement of the acquisition. While this corrects for timing differences associated with using next year’s revenue estimate (current year + 1), wide variability does exist in the range of estimates. This analysis was based off forward
12-month consensus revenue estimates (median) as reported by FactSet for public companies or as reported in corporate press releases and acquirer SEC filings for private companies. The robustness of public company data is limited by the number of analysts covering the stock. The objectivity of the private company data may be questioned since it is largely coming from the acquirer, but is nonetheless valid given that the acquirer's due diligence and purchase decision were in part based on this estimate.

Sample bias: The model developed in this research is based on a subset of all transactions in the medical device industry (352/783). This assumes that certain factors influencing valuation (growth rates, nature of FDA filings, reimbursement, venture financing, etc.) make roughly the same contributions to valuation/multiples across all sectors. Data are more readily available for larger transactions and public companies which are more likely or required to disclose transaction details. Hence there may be an implicit large company bias in multiples predicted by this model.

Likewise data availability also generates a potential sector bias in the model, as our sample mix does not perfectly mirror the sector mix of transactions in the industry between 1996 and 2007. As expected sectors with larger, public company transactions material to the acquirers will be well documented (cardiovascular, spine, MI surgery) where as the sectors with smaller-scale transactions (diagnostics, analytical equipment) are under represented. There was a roughly 86% correlation between the overall industry mix and the regression sample mix. The following chart illustrates the industry versus sample mix of the data used in this analysis.

**MEDICAL DEVICE INDUSTRY TRANSACTION MIX: Industry vs. Sample Transactions**

<table>
<thead>
<tr>
<th>Sector</th>
<th>Industry</th>
<th>Sample</th>
<th>%</th>
</tr>
</thead>
</table>
| Diagnostics           | 83       | 16     | 19%
| Cardiovascular        | 82       | 51     | 62%
| Other                 | 63       | 19     | 30%
| Imaging               | 60       | 29     | 48%
| Orthopedics           | 58       | 34     | 59%
| Surgical Equipment    | 47       | 16     | 34%
| Monitoring            | 39       | 18     | 46%
| Dental                | 37       | 14     | 38%
| Ophthalmology         | 37       | 16     | 43%
| Urology               | 30       | 12     | 40%
| Respiratory           | 27       | 17     | 63%
| Spine                 | 25       | 17     | 68%
| Derm. & Wound Care    | 23       | 8      | 35%
| Vascular Devices      | 20       | 12     | 60%
| Drug Delivery         | 18       | 6      | 33%
| Surgical Supplies     | 17       | 14     | 82%
| Oncology              | 17       | 5      | 29%

<table>
<thead>
<tr>
<th>Sector</th>
<th>Industry</th>
<th>Sample</th>
<th>%</th>
</tr>
</thead>
</table>
| Diabetes              | 15       | 8      | 53%
| Neurology Devices     | 13       | 2      | 15%
| MI Surgery            | 13       | 10     | 77%
| Analytical Equip.     | 12       | 1      | 8%
| Neurostimulation      | 10       | 4      | 40%
| Critical Care         | 6        | 3      | 50%
| Women's Health        | 5        | 1      | 20%
| Neurovascular         | 5        | 2      | 40%
| Gastro / Bariatric    | 5        | 2      | 40%
| Orthobiologics        | 4        | 4      | 100%
| Cosmetic Surgery      | 4        | 1      | 25%
| Cardiac & Vascular Surg. | 4  | 4      | 100%
| Rehab Supplies        | 2        | 2      | 100%
| Perfusion             | 2        | 1      | 50%
| Neurosurgery          | 2        | 1      | 50%
| CRM                   | 2        | 2      | 100%

**Total:** 783    352    45%
METHODS

EV/SALES MULTIPLE FACTOR ANALYSIS

Regression analysis was performed to assess each factor's contribution to the EV/Sales model. The 20 previously mentioned factors served as the independent variables used in this analysis. Each factor was either a quantitative variable (if relevant data existed), or a binary variable based on characteristics exhibited by a given company.

The dependent variable was the EV/Sales multiple. Note that the EV/Sales multiples in our dataset were not normally distributed. Consistent with best statistical practices, the data were converted to a normal distribution by converting the multiples to a log scale, which permits unbiased multivariate regression analysis.

To assess relevance, each variable was evaluated for statistical significance at a 95% confidence interval. Data on all 20 factors were available for 352 of the 786 transactions in the database. Multivariate regression was then performed on those variables to identify 1) the statistical relevance of each variable and 2) the explanatory power of the regression equation based on a given combination of relevant variables.

The relevance of a variable to the model was based on both statistical relevance and contribution to the model. Statistical relevance was measured by the T-Stat for each variable, which to be considered statistically significant at a 95% CI had to be greater than or equal to 1.98. Statistical significance was also evaluated on a stand alone basis to see which variables offered explanatory power, but make be masked by autocorrelation in a multivariate model. This was balanced by a practical consideration of a given variables contribution to the EV/Sales multiple. For example, variables with a T-Stat close to statistical significance, but not significant, may offer a great deal of explanatory power in terms of contribution to the multiple projected by the regression equation. All else equal, this variable would likely be statistically significant with a larger sample size. The contribution will be based on the magnitude of the regression coefficient relative to other variables.

REGRESSION MODEL

We will attempt to develop two regression models: an overall industry model evaluating all transactions and a selective model based on a more refined dataset that excludes companies with less than $10 million in sales or special circumstance transactions. (Special circumstances include bankruptcy transactions and those transactions which may be valued off 2-3 year forward sales). Both models will include the statistically significant variables and those nearly statistically significant variables with sizable regression coefficients relative to the other variables. The models will be compared for accuracy in predicting multiples during the validation phase.

VALIDATION

To test the model, data from 2008 industry transactions will be evaluated. The independent variables will be plugged into both models to generate a projected EV/Sales multiple. This projected multiple will be compared to the EV/Sales multiple reported in the press. To assess the strength of the models, the correlation between the projected and actual multiples will be calculated.
FACTOR ANALYSIS OF PRE-REVENUE TRANSACTIONS

For purposes of this analysis, pre-revenue companies were defined as companies which did not have any revenue (product or royalty) projected in the 12 months after the acquisition announcement date. Hence these firms were all development-stage companies that faced FDA, market adoption, and reimbursement risk. This criterion was established to control for development risk profiles and assure that all firms were roughly at a comparable stage in their lifecycles. While variation still exists within this classification scheme (and may explain some of the valuation disparity among transactions), the author felt this was the available method to control for this risk given the data available for each transaction.

The methods used in the factor analysis of the EV/Sales multiples largely mirror the methods used in the factor analysis of the enterprise value of pre-revenue companies.

Regression analysis was performed to assess each factor's contribution to transaction Enterprise Value (measured in $ millions). The 20 previously mentioned factors served as the independent variables for this regression analysis. Each factor was either a quantitative variable (if relevant data existed), or a binary variable based on characteristics exhibited by a given company.

The dependent variable was the transaction Enterprise Value (measured in $US millions). Note that the transaction values in our dataset were not normally distributed. Consistent with best statistical practices, we attempted to adjust the data to a normal distribution by converting the multiples to a log scale, which permits unbiased multivariate regression analysis. Even after this adjustment, the small sample size and the bimodal distribution of the underlying dataset made reliable regression analysis challenging.

To assess relevance, each variable was evaluated for statistical significance at a 95% confidence interval. Data on the 20 factors were available for all 40 transactions in the database. Multivariate regression was then performed to identify 1) the statistical relevance of each variable and 2) the explanatory power of the regression equation based on a given combination of relevant variables.

The relevance of a variable to the model was based on both statistical relevance and contribution to the model. Statistical relevance was measured by the T-Stat for each variable, which to be considered statistically significant at a 95% CI had to be greater than or equal to 2.06. Statistical significance was also evaluated on a stand alone basis to see which variables offered explanatory power, but may be masked by autocorrelation in a multivariate model. This was balanced by a practical consideration of a given variables contribution to the EV/Sales multiple. For example, variables with a T-Stat close to statistical significance, but not significant, may offer a great deal of explanatory power in terms of the coefficient's contribution to the multiple projected by the regression equation. All else equal, this variable would likely be statistically significant with a larger sample size. The contribution will be based on the magnitude of the regression coefficient relative to other variables.
IV. RESULTS

SUMMARY STATISTICS OF EV/SALES DATA

Forward sales data were available for 352 out of 783 transactions in the medical device industry between 1996 and 2007. Summary statistics are presented below.

<table>
<thead>
<tr>
<th>MEDICAL DEVICE M&amp;A EV TO SALES STATISTICS BY SECTOR</th>
<th>(Sorted by Number of Transactions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Deals</td>
<td>Average EV/SALES Multiple</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>51</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>34</td>
</tr>
<tr>
<td>Imaging</td>
<td>29</td>
</tr>
<tr>
<td>Other</td>
<td>19</td>
</tr>
<tr>
<td>Monitoring</td>
<td>18</td>
</tr>
<tr>
<td>Respiratory</td>
<td>17</td>
</tr>
<tr>
<td>Spine</td>
<td>17</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>16</td>
</tr>
<tr>
<td>Surgical Equipment</td>
<td>16</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>16</td>
</tr>
<tr>
<td>Dental</td>
<td>14</td>
</tr>
<tr>
<td>Surgical Supplies</td>
<td>14</td>
</tr>
<tr>
<td>Urology</td>
<td>12</td>
</tr>
<tr>
<td>Vascular Devices</td>
<td>12</td>
</tr>
<tr>
<td>MI Surgery</td>
<td>10</td>
</tr>
<tr>
<td>Derm. &amp; Wound Care</td>
<td>8</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8</td>
</tr>
<tr>
<td>Drug Delivery</td>
<td>6</td>
</tr>
<tr>
<td>Oncology</td>
<td>5</td>
</tr>
<tr>
<td>Neurostimulation</td>
<td>4</td>
</tr>
<tr>
<td>Orthobiologics</td>
<td>4</td>
</tr>
<tr>
<td>Cardiac &amp; Vascular Surg.</td>
<td>4</td>
</tr>
<tr>
<td>Critical Care</td>
<td>3</td>
</tr>
<tr>
<td>Neurology Devices</td>
<td>2</td>
</tr>
<tr>
<td>Neurovascular</td>
<td>2</td>
</tr>
<tr>
<td>Gastro / Bariatric</td>
<td>2</td>
</tr>
<tr>
<td>Rehab Supplies</td>
<td>2</td>
</tr>
<tr>
<td>CRM</td>
<td>2</td>
</tr>
<tr>
<td>Analytical Equip.</td>
<td>1</td>
</tr>
<tr>
<td>Women's Health</td>
<td>1</td>
</tr>
<tr>
<td>Cosmetic Surgery</td>
<td>1</td>
</tr>
<tr>
<td>Perfusion</td>
<td>1</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>1</td>
</tr>
</tbody>
</table>

The median acquisition valuation of these transactions was 2.8x forward revenue. Note that this is a long-tail distribution with range of 0.12x to 25x forward sales and that significant variability exists between sectors. Acquisitions in the larger, mature sectors with lower growth rates (monitoring), typically command lower multiples than rapidly growing sectors driven by novel
technology (neurostimulation, spine). This suggests that sector and/or growth rate may play a role in determining valuation multiples.

Given the varying growth rates between sectors, the above chart also highlights the contribution value of 1% revenue growth to the EV/Sales multiple by sector (similar to a PEG ratio for public equities). Again it suggests that growth is valued differently across sectors. This data support background research which states that higher-than-sector average growth in large markets with multiple potential acquirers in search of sales synergies tend to be valued more than smaller, less competitive sectors. Hence the wide range in the contribution value (0.19 – 0.62x) in the different sectors of the industry. This suggests the importance of sector specific variables and growth rates in determining acquisition multiples.
EV/SALES MULTIPLE FACTOR ANALYSIS

Multivariate regression was performed to assess the statistical significance and contribution of the twenty previously discussed factors (independent variables) in explaining EV/Sales acquisition multiples (dependent variable). The raw industry EV/Sales multiple data were not normally distributed, as aggressive premiums paid for early stage companies and transactions valued based on 2 or 3 year forward revenue resulted in a long right tail distribution as seen below. EV to sales data were converted to log scale to normalize the data for regression analysis, consistent with best statistical analysis practices discussed in the methods section of this paper.

![EV/Forward Sales Multiples - Unadjusted](image1)

![EV/Forward Sales Multiples - Log Scale](image2)

**General Industry Model.** In the industry model the top 16 factors explained 58% of the variation (as measured by the multiple $r^2$ coefficient) in the EV/Sales multiples of M&A transactions. Nine of these factors were highly statistically significant, offering a great deal of explanatory power in determining the EV/Sales multiple.

Consistent with our hypothesis, supernormal growth, market size and sector growth offered the greatest explanatory value, as measured by T-Stats. Each factor also had a regression coefficient that was meaningful in terms of contribution to the EV/Sales model. Sales synergies were not a significant variable both in terms of explanatory power or contribution to the model. This may have been a flaw with the method for evaluating this variable which we explore in the Discussion section of this research.

Summary statistics of the regression analysis are presented in the table on the following page. Factors are listed in the order of statistical significance.
## Industry Regression Model

**Summary Statistics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>T-Stat</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>-0.62</td>
<td>-3.17</td>
<td>0.20</td>
</tr>
<tr>
<td>Supernormal Growth</td>
<td>2.66</td>
<td>10.21</td>
<td>0.26</td>
</tr>
<tr>
<td>Market Size</td>
<td>4.08E-05</td>
<td>4.75</td>
<td>8.60E-06</td>
</tr>
<tr>
<td>Sector Growth</td>
<td>1.27</td>
<td>3.99</td>
<td>0.32</td>
</tr>
<tr>
<td>Position in Market</td>
<td>-0.02</td>
<td>-3.92</td>
<td>0.00</td>
</tr>
<tr>
<td>Venture backed?</td>
<td>0.12</td>
<td>3.61</td>
<td>0.03</td>
</tr>
<tr>
<td>Sector Beta</td>
<td>0.26</td>
<td>2.62</td>
<td>0.10</td>
</tr>
<tr>
<td>Technology Acquisition</td>
<td>0.15</td>
<td>2.57</td>
<td>0.06</td>
</tr>
<tr>
<td>IPOed prior to M&amp;A</td>
<td>0.09</td>
<td>2.48</td>
<td>0.04</td>
</tr>
<tr>
<td>FDA Clearance</td>
<td>-0.11</td>
<td>-2.34</td>
<td>0.05</td>
</tr>
<tr>
<td>Potential Profit Margin</td>
<td>1.44</td>
<td>1.97</td>
<td>0.73</td>
</tr>
<tr>
<td>Type of Filing</td>
<td>0.02</td>
<td>1.72</td>
<td>0.01</td>
</tr>
<tr>
<td>Portfolio Diversification</td>
<td>0.05</td>
<td>1.32</td>
<td>0.04</td>
</tr>
<tr>
<td>Enabling Technology</td>
<td>0.07</td>
<td>1.25</td>
<td>0.05</td>
</tr>
<tr>
<td>Single Product Company</td>
<td>-0.04</td>
<td>-1.04</td>
<td>0.04</td>
</tr>
<tr>
<td>Sales Synergies</td>
<td>0.03</td>
<td>0.88</td>
<td>0.04</td>
</tr>
<tr>
<td>Sales Model</td>
<td>-0.03</td>
<td>-0.73</td>
<td>0.04</td>
</tr>
</tbody>
</table>

**Multiple R^2** 57.70%

**Sample Size** 352

*Statistically Significant Variables*
Selective Company Model. The top 16 independent variables in the Selective Model explained 62% of the variation (as measured by multiple $r^2$) in EV/Sales multiples. Ten of the variables were highly statistically significant with regression coefficients that have a meaningful impact on the generation of the EV/Sales multiple.

Note that 15/16 variables are also used in the Industry Model, though the magnitude of statistical contribution varies between the models. The main difference between the models is that Sales Synergies are replaced by Acquirer Prior 12 Month Stock Performance in the Selective Model. Sales Synergies appear to offer little explanatory value in the Selective Model. This finding runs contrary to our hypothesis and may be attributable to a flaw in our methodology. We explore this in greater detail in the Discussion section of this paper.

Consistent with our hypothesis, Supernormal Growth and Market Size were the top two factors in terms of explanatory value. Sector Growth ranked fifth overall in terms of statistical significance, with Position in Market and Venture Financing ranking three and four, respectively. It is also important to note that Sales Model, Enabling Technology, and Single Product Company factors were all statistically significant in this model.

Summary regression data are presented on the following page. Factors are ordered by statistical significance.

The relative explanatory power of the 20 factors explored in this research is presented in the chart on page 25. To calculate the explanatory power, regression analysis was performed on each variable individually for both the Industry and Selective Company databases and the $R^2$ coefficients were calculated. This largely confirmed our expectations as to which were the most important variables in explaining the EV/Sales multiple.
## Selective Company Regression Model
### Summary Statistics

<table>
<thead>
<tr>
<th></th>
<th>Coefficient</th>
<th>T-Stat</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intercept</strong></td>
<td>-0.40</td>
<td>-2.23</td>
<td>0.18</td>
</tr>
<tr>
<td>Supernormal Growth</td>
<td>3.35</td>
<td>12.46</td>
<td>0.27</td>
</tr>
<tr>
<td>Market Size</td>
<td>4.26E-05</td>
<td>5.25</td>
<td>8.12E-06</td>
</tr>
<tr>
<td>Position in Market</td>
<td>-0.02</td>
<td>-4.92</td>
<td>0.00</td>
</tr>
<tr>
<td>Venture backed?</td>
<td>0.11</td>
<td>3.32</td>
<td>0.03</td>
</tr>
<tr>
<td>Sector Growth</td>
<td>0.97</td>
<td>3.19</td>
<td>0.30</td>
</tr>
<tr>
<td>Technology Acquisition</td>
<td>0.14</td>
<td>2.72</td>
<td>0.05</td>
</tr>
<tr>
<td>IPOed prior to M&amp;A</td>
<td>0.08</td>
<td>2.29</td>
<td>0.03</td>
</tr>
<tr>
<td>Sales Model</td>
<td>-0.07</td>
<td>-2.25</td>
<td>0.03</td>
</tr>
<tr>
<td>Single Product Company</td>
<td>-0.07</td>
<td>-2.06</td>
<td>0.04</td>
</tr>
<tr>
<td>Enabling Technology</td>
<td>0.12</td>
<td>2.19</td>
<td>0.05</td>
</tr>
<tr>
<td>Potential Profit Margin</td>
<td>1.27</td>
<td>1.88</td>
<td>0.67</td>
</tr>
<tr>
<td>Sector Beta</td>
<td>0.18</td>
<td>1.81</td>
<td>0.10</td>
</tr>
<tr>
<td>FDA Clearance</td>
<td>-0.08</td>
<td>-1.77</td>
<td>0.04</td>
</tr>
<tr>
<td>Type of Filing</td>
<td>0.02</td>
<td>1.75</td>
<td>0.01</td>
</tr>
<tr>
<td>Portfolio Diversification</td>
<td>0.03</td>
<td>0.95</td>
<td>0.04</td>
</tr>
<tr>
<td>Acquirer Prior 12 Month Stock Performance</td>
<td>0.03</td>
<td>0.89</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>Multiple R^2</strong></td>
<td>61.90%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sample Size</strong></td>
<td>315</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

=Statistically Significant Variables
Explanatory Power of Each Individual Factor In EV/Sales Multiple (Measured by R^2)

Most Significant Variables

- FDA Clearance
- Mult. Clearances
- Supernormal Growth
- Sector Growth
- Venture Backed
- IPO'ed
- Market Size
- Market Position
- Sector Beta
- Single Product
- Filing Type
- Profit Margin

Selective Model - Industry Model
THE MODELS

Based on the above analysis, we have developed two models for calculating the EV/Forward Sales multiples for valuing M&A transactions in the medical device industry. The general industry model is designed to be used with any company with revenue projected in the next 12 months, whereas the selective company model is designed for established revenue stage companies. Both models are described in detail below.

1. Industry Model (for all Medical Device Companies with Revenue):

The general Industry Model incorporates the 16 variables that offered the greatest explanatory power in determining the EV/Sales multiple across all 352 companies in our transaction dataset. This model is intended to be a general valuation tool for any company with revenue expected within the next 12 months. It is not designed to be used with pre-revenue companies that have not received FDA clearance and are not expected to sell product within a year as forward pre-revenue multiples (EV/Sales multiples based on a forward one-year revenue estimate in a future period) were not included in the database and not validated through our regression analysis. Pre-revenue valuation is discussed in the next section of this report.

The complete Industry Model is illustrated on page 28. It is a simple logistic model based on our regression analysis. The projected logistic EV/Sales multiple is the dependent variable or output of the model. It must be converted from natural log scale to a normal number to obtain the projected EV/Sales multiple for a given company or technology under evaluation. The other side of the equation consists of an intercept plus the summation of the 16 independent variables' regression coefficients multiplied by their respective factor values. Thus the equation takes the form:

\[ \log (EV/Sales) = \text{Intercept} + \sum_{(n=16)} \text{Factor Coefficient Value} \times \text{Factor Value} \]

Factor coefficient values were derived through our regression analysis and were outlined above on page 22.

2. Selective Company Model (for Established Medical Device Companies with Revenue):

The Selective Model is a refinement of the Industry Model designed to value the "established" medical device companies with sales. This model introduces several constraints designed to remove some of the "special circumstances" that can influence the value of a transaction. First, this model requires companies to be currently selling product and for valuation to be based off of forward 1 year sales, eliminating some of the speculative bias surrounding FDA approval timelines, launch timetables, or valuation based off two or three years' forward revenue. Second, this model also excludes companies with pre-existing relationships that can impact valuation, special sale circumstances (pre-arranged buyout options or distressed sales), and embryonic companies with less than $10 million in revenue. These idiosyncratic factors can somewhat skew valuation parameters and their removal from the analysis may yield a better model for valuing "established" companies where boards can make unencumbered decisions.

The Selective Company Model incorporates the 16 variables that offered the greatest explanatory power in determining the EV/Sales multiple across all 315 companies in our refined transaction dataset. This dataset eliminates the 37 "special circumstance" transactions discussed above. Note that two variables were different than the Industry Model.
The complete Selective Company Model is illustrated on page 29. It is a simple logistic model based on our regression analysis. The creation and structure of this model largely mirror the Industry Model. The logistic projected EV/Sales multiple is the dependent variable or output of the model. It must be converted from natural log scale to a whole number to obtain the projected EV/Sales multiple for a given company or technology under evaluation. The other side of the equation consists of an intercept plus the summation of the 16 independent variables’ regression coefficients multiplied by their respective factor values. Thus the equation takes the form:

\[
\log (\text{EV/Sales}) = \text{Intercept} + \sum_{(n=16)} \text{Factor Coefficient Value} \times \text{Factor Value}
\]

Factor coefficient values were derived through our regression analysis and were outlined above on page 24.

In theory the two models should yield similar valuations for mature established companies, with the industry model potentially better suited for valuing the special situation transactions. Results of the validation testing are presented in the Validation section on page 31.
INDUSTRY MODEL
For use with all transactions

\[
\text{Log (EV/Sales Multiple)} = \text{Intercept} + \text{Supernormal Growth Coefficient} + \text{Market Size Coefficient} + \text{Sector Growth Rate Coefficient} - \text{Position in Market Coefficient} + \text{Venture Backed Coefficient} + \text{Sector Beta Coefficient} + \text{Technology Acquisition Coefficient} + \text{IPO Coefficient} - \text{FDA Clearance Coefficient} + \text{Potential Profit Margin Coefficient} + \text{Type of Filing Coefficient} + \text{Portfolio Diversification Coefficient} + \text{Enabling Technology Coefficient} - \text{Single Product Company Coefficient} + \text{Distribution Deal Coefficient} - \text{Sales Model Coefficient}
\]

\[
\text{X (Projected Growth Rate (%) - Sector Growth Rate (%))}
\]

Market Size ($ Millions)

Market Position (#)

Binary Result

Binary Result

Binary Result

Margin (%)

Approval Pathway (#)

Binary Result

Binary Result

Binary Result

Binary Result

Binary Result

Type of Model (#)

* Note Coefficients are ordered by statistical significance (high to low)

* Binary Result Factors (1 = Yes, 0 = No)
SELECTIVE COMPANY MODEL
For use with "normal" companies & transactions

Log (EV/Sales Multiple) = Intercept
+ Supernormal Growth Coefficient
+ Market Size Coefficient
- Position in Market Coefficient
+ Venture Backed Coefficient
+ Sector Growth Rate Coefficient
+ Technology Acquisition Coefficient
+ IPO Coefficient
- Sales Model Coefficient
+ Enabling Technology Coefficient
- Single Product Company Coefficient
+ Potential Profit Margin Coefficient
+ Sector Beta Coefficient
- FDA Clearance Coefficient
+ Type of Filing Coefficient
+ Portfolio Diversification Coefficient
+ Acquirer Prior 12 Month Stock Performance Coefficient

* Note Coefficients are ordered by statistical significance (high to low)
* Binary Result Factors (1 = Yes, 0 = No)
VALIDATION

Mergers and Acquisitions in the Medical Device Industry during the first half of 2008 were used to validate the models. Validity was assessed by calculating the correlation between the actual EV/Forward Sales multiples and the multiples predicted by each model. Data were available for 28 transactions, admittedly a limited dataset, as recessionary concerns and challenging financial conditions may have impacted the overall M&A market. Ideally, a greater dataset is necessary to achieve statistical validity and this analysis would be best performed again at the end of the year to revalidate results.

The Industry Model posted a surprisingly strong 96% correlation between actual and predicted EV/Sales multiples across all 28 transactions. Excluding special circumstance transactions (LBOs, bankruptcy/distressed sales and companies with less than $10 million in sales), the correlation between actual and predicted multiples increases to 98%. These results are remarkably better than the multiple R^2 of the industry model would have predicted, given that the sector mix of the 2008 transactions is a close approximation of the overall dataset sector mix.

As seen in the chart above, there were few significant deviations from the perfect correlation line. Nine transactions were undervalued by the model or overvalued by the acquirer (plotted below the line), including the two LBO deals denoted by the special circumstance boxes. Twelve transactions were slightly overvalued by the model or represented value purchases for the acquirer (plotted above the line) and 7 plotted close to the line. Even though this was a small sample size, there does not appear to be any sector, size, or growth profile effects systematically overvaluing or undervaluing transactions.
Note that there is a strong correlation between supernormal sales growth (projected growth – sector growth) and both the predicted and actual EV/Sales multiples. Once again, this suggests the importance of this independent variable.

The **Selective Model**, which controls for company size and distressed sales, demonstrated a 97% correlation between actual and predicted values. Again this was better than the regression model’s multiple $R^2$ coefficient would have suggested. Versus the Industry Model, the Selective Models seems to overvalue transactions with 11/23 deals plotting above the line (overvalued) and 4 plotting below (undervalued). As with the Industry Model, sector, size, growth profile and other independent variables did not bias any factor toward one side of the perfect correlation line. It is also important to note that, all else equal, there was a strong correlation between multiples and supernormal growth. Predicted versus actual multiples by sector are presented in the chart below.

It is interesting to note that the Industry Model provided slightly greater accuracy than the Selective Model. A broader set of data may generate different results, but overall we are surprisingly pleased with the accuracy of both forecasting models and believe both offer roughly equal utility.
FACTOR ANALYSIS OF PRE-REVENUE TRANSACTIONS

Regression Analysis. Multivariate regression analysis was performed to assess the relevance and explanatory power of the factors identified in the Industry and Selective Models in forecasting the enterprise value (in $millions) of pre-revenue transactions. A 40 company dataset provided the inputs for the model. Note that regression results are inherently challenged by the small sample size and the bimodal distribution of the underlying dataset.

As hypothesized, this model is clearly not viable for determining the enterprise value (in dollars) for a given pre-revenue transaction. The explanatory power of the model, as measured by multiple $R^2$, was a poor 44.7%. Only two of the sixteen variables (profit margin and venture financing) were statistically significant, and hence of value in potentially explaining the contribution to transaction values.

Results were further compounded by a significant degree of correlation (>35%) amongst 9 of the 16 independent variables. Individually, 14 of the 16 variables each explained less than 5% of less of the total variation in enterprise deal valuation. Additionally, the low sample size (n=40) was not well suited to explore 16 independent variables. Despite the small sample size, it appears the factors that influence pre-revenue transaction valuation are different than the factors that proved valuable in our other two models for companies with revenue projected in the next year. Regression results are presented on the next page.
<table>
<thead>
<tr>
<th>Factor</th>
<th>Coefficient (Log Scale)</th>
<th>T-Stat</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>-2.70</td>
<td>-0.95</td>
<td>2.85</td>
</tr>
<tr>
<td>Potential Profit Margin</td>
<td>17.70</td>
<td>2.47</td>
<td>7.16</td>
</tr>
<tr>
<td>Venture backed?</td>
<td>0.41</td>
<td>2.23</td>
<td>0.18</td>
</tr>
<tr>
<td>Acquirer Prior 12 Month Stock Performance</td>
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<td>0.13</td>
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<tr>
<td>Market Size</td>
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<td>-1.29</td>
<td>6.28E-05</td>
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<tr>
<td>Sector</td>
<td>-0.01</td>
<td>-1.24</td>
<td>0.01</td>
</tr>
<tr>
<td>Sales Synergies</td>
<td>0.26</td>
<td>1.14</td>
<td>0.23</td>
</tr>
<tr>
<td>Type of Filing</td>
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<td>-0.96</td>
<td>0.10</td>
</tr>
<tr>
<td>Single Product Company</td>
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<td>0.88</td>
<td>0.24</td>
</tr>
<tr>
<td>Earnout</td>
<td>0.14</td>
<td>0.72</td>
<td>0.20</td>
</tr>
<tr>
<td>Sector Beta</td>
<td>-1.07</td>
<td>-0.66</td>
<td>1.63</td>
</tr>
<tr>
<td>Portfolio Diversification</td>
<td>0.23</td>
<td>0.55</td>
<td>0.42</td>
</tr>
<tr>
<td>Enabling Technology</td>
<td>0.07</td>
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<tr>
<td>Sector Growth</td>
<td>0.60</td>
<td>0.28</td>
<td>2.12</td>
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<tr>
<td>Projected Growth - Sector Growth</td>
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<td>-0.04</td>
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<tr>
<td>Multiple R^2</td>
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</tr>
<tr>
<td>Sample Size</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Only two of the factors examined, potential profit margin and venture financing, were statistically significant (non-zero CI, T-Stat > 2.0) at a 95% confidence interval. Even when analyzed individually, profit margin and venture backing did not offer significant explanatory value. The individual regression R^2 values were 0.25 and 0.11, respectively. Most other variables offered little in explanatory value or relevance to the model.
V. DISCUSSION

MERGERS & ACQUISITIONS IN THE MEDICAL DEVICE INDUSTRY

The medical device industry has a long active history of consolidation through mergers and acquisitions. Be it orthopedics, cardiology, urology or minimally invasive surgery, the industry trends toward a natural oligopoly in which two to four firms horizontally integrate each therapeutic sector. A regular flood of development stage companies with new technologies mature into the next round of acquisition targets to feed the large players.

MOTIVATIONS FOR M&A

Why is M&A so prevalent in the medical device industry? The motivations for mergers and acquisitions in the industry are diverse. Rarely is there a single category or benefit that can explain every single transaction. Below we discuss some of the most commonly cited motivations, but the list is by no means exhaustive.

Background research from finance professionals, corporate and business development executives, and industry and academic literature point to eight major motivations for mergers and acquisitions in the medical device industry

1. Scale/Consolidation: InVivo, Boston Consulting Group and others who have written on mergers in acquisitions in the medical device industry generically cite “consolidation” and “economies of scale” when discussing the motivation for mergers and acquisitions in the medical device industry. Encompassed in this scale argument are operational advantages, production advantages, R&D advantages, regulatory advantages, consolidated managerial functions, increased financial strength and sales and marketing advantages.

On some level, this scale argument is absolutely correct, especially when discussing commodity-like products. Surgical supplies, sutures, catheters, imaging devices, patient monitoring systems, diagnostics, and syringes all enjoy significant scale benefits. Operational advantages from large scale production clearly underlie all of these sectors. Additionally the FDA regulatory pathway for these products (mainly Class II and Class I devices) provides for regulatory synergies. The firms acquiring such technologies typically have very similar products in house and are capable of achieving R&D synergies. The companies are also large enough to benefit from the consolidation of managerial and administrative functions. The concentrated sales points in the hospital also allow such firms to achieve significant sales and marketing advantages. Thus, these sectors are capable of achieving a roughly equal mix of synergies across operational and sales functions.

Deals in these sectors, represent fewer than 30% of medical device mergers and acquisitions between 1996 and 2007, with most of these transactions occurring prior to 2003. Few sectors are capable of achieving such broad based synergies through mergers and acquisitions. What is different about the rest of the industry?

PMA and therapeutic 510k regulatory pathway products and emerging technologies are sufficiently differentiated in regulatory, R&D, manufacturing and reimbursement requirements that they do not benefit from the same scale benefits from simply merging with another large player. Hence the medical device industry has few large integrated players across multiple therapeutic categories like biotech and pharma. It is these 70% of medical device technologies and M&A transactions that are not a good fit for the broad scale / consolidation argument.
Consider large scale deals involving major PMA and therapeutic 510k pathway devices - operational synergies pale in relation to sales and marketing synergies. In Zimmer’s acquisition of Centerpulse in 2003, sales and marketing synergies represented over 80% of the “scale” benefits. The same is true for other established technology acquisitions such as Medtronic-Kyphon, Advanced Medical Optics – Visx, Allergan – Inamed, Boston Scientific – Schneider, and Stryker – Howmedica.

High growth companies and novel technologies, similarly offer few operational synergies. The value created for the acquirers typically comes from sales and marketing synergies, such as launching a product in a new market or broadening the sales force’s bag (as in pharma). This typifies many smaller acquisitions (such as Boston Scientific’s acquisition of Embolic Protection), and roll-up strategies (such as EV3 and Integra Neurosciences) of new technologies. The startups with promising technologies need more help with market development and distribution than with any other operational factors. Similarly portfolio diversification strategies (Medtronic-Minimed acquisition) often cite cross-selling sales opportunities as motivation for a transaction. Post-integration most remain as independent operating entities under the acquirer’s umbrella.

Pre-revenue transactions, discussed later in this thesis, offer the greatest potential for regulatory, reimbursement and R&D synergies. This is where an acquirer’s previous experience in a market can offer some meaningful value, both in clinical trial strategy and securing reimbursement. This has more to do with generating time to market and launch advantages than absolute dollar cost savings in the development process.

Hence, the generic MBA vernacular of “scale” and “consolidation” may under-represent the true motivations for merger and acquisitions in the industry. A deeper analysis reveals that the true underlying motivations for the “other” 70% of acquisitions to be much more focused, as we have illustrated through our factor analysis.

2. Sales Synergies. The primary motivation for mergers and acquisitions in this industry are mostly related to sales and marketing. Given the relationship nature of medical device sales, group purchasing agreements, committed volume contacts, the few players with international sales horsepower, cross-selling opportunities, and tremendous opportunities for sales synergies through consolidation, the sales function takes on increased importance in the medical device industry relative to other medical therapies. Over 90% of the transactions analyzed in this research revealed that sales synergies were an important factor in the motivation for given deal.

Device sales require more than face time with physicians than biologics or pharmaceuticals, beyond just detailing. Device sales reps often scrub in with surgeons, managing instrument trays and assisting with other technical needs in the operating room, both before and after the procedure. Reps also play an important role in educating physicians on new devices and implantation techniques. With committed volume contracts, these reps are ever-present in the operating room at many hospitals. Consequently, it is not surprising that physicians form strong relationships with these reps, as the reps become familiar with the physicians implant techniques and preferences.

This is most apparent in cardiac surgery (particularly valve procedures) and orthopedics. These reps play an extremely important role in managing devices during procedures and preplanning device needs prior to surgery. In the case of orthopedics, reps often come to the OR during the
night and weekends to deliver trauma products. They also work with surgeons to help plan
device needs for upcoming procedures, including working to develop custom implants.

Hence, the sales force is a significant source of value for the orthopedics companies. Adding
new products to the sales reps' bag or acquiring additional sales reps can provide significant
income statement leverage. This had motivated major mergers like the Stryker-Howmedica
acquisition, DJ Orthopedics' acquisition strategy, and Biomet's acquisition of Interpore Cross.
Access to international sales reps and rounding out the product portfolio were behind Zimmer's
decision to outbid Smith & Nephew for Centerpulse.

Access to a skilled sales force also motivated Inverness as it sought to leverage the various
acquisitions in its diagnostics portfolio. Abbott's most successful device acquisitions were
companies with an existing sales force (Therasense for example), through which it could
leverage other products in the bag.

Likewise the conglomerates selling capital equipment can achieve significant leverage by
consolidating sales forces and rolling out acquired products through their existing installed base.
This motivation has driven consolidation and small company acquisitions in the imaging,
monitoring, oncology, ophthalmology, and diagnostics sectors.

From an investor perspective, acquisitions citing sales synergies have yielded some of the
greatest returns, as evidence by the acquirer's stock performance and ability to exceed earnings
expectations in many of the previously referenced transactions. The inability to capture project
sales synergies is the reason many acquiring companies end up disappointing Wall Street.

3. Therapeutic Economies of Scope: Companies achieve certain scope benefits from
exposure to a wide spectrum of products within a given therapeutic class. This is particularly
true of the cardiology and orthopedics sectors, where a broad portfolio of devices is helpful in
negotiating with private payers (insurance companies), large group purchasing organizations,
and securing committed volume contacts with various hospitals. This strategy has been
effective because companies are negotiating within one therapeutic class/department within a
hospital and all costs generally fall under the same operating budget. Empirical evidence
suggests that outside of capital equipment and commodity products where buying decisions are
made through central purchasing, scope benefits are less effective across therapeutic classes
due to competing departmental interests. Hospitals and payers almost always make
reimbursement decisions behind closed doors, making it difficult to negotiate across therapeutic
classes.

4. Portfolio Diversification. Given the inherent volatility in certain product lines, many of the
larger medical device firms have sought to diversify their product portfolio beyond a single
therapeutic bucket. Medtronic is the prime example. To accelerate growth in the mid-1990's as
the pacemaker and heart valve markets matured, the company began an aggressive acquisition
spree, moving into new high growth therapeutic arenas, such as spine, neurology/neurosurgery,
ENT, urology and diabetes. Similarly, J&J pursued the broadest diversification strategy in
devices when growth in its diagnostics business slowed, expanding its footprint to include
cardiology, orthopedics, spine, diabetes, ophthalmology, minimally invasive surgery and other
high growth sectors.

Boston Scientific, which had historically been an aggressive acquirer of interventional cardiology
technologies, realized the need to further diversify its portfolio in the face of rapid stent market
share shifts in the late 1990's. The company successfully acquired franchises in minimally
invasive surgery, urology, interventional neuroradiology and neurostimulation. Following the launch of its coated stent in 2004, the company sought to acquire Guidant to gain exposure to the cardiac rhythm management market and further diversify its revenue/earnings base.

The success of this strategy in meaningfully diversifying a company or adding a lasting growth engine to reduce volatility is debatable. There are several cases where diversification strategies have delivered tangible results (Medtronic and Sofamor Danek) and others where acquired targets have failed to deliver on expectations (Boston Scientific and Advanced Bionics). Based on available data, we suspect that only 60-70% of deals deliver expected results. The efficacy of diversification strategies in the industry represents an area for additional research.

One would think that there would be the opportunity for significant cost savings through centralized management and R&D prioritization, but the opposite is true. Many divisions operate as independent units within the larger company and most of the cost savings come from shared administrative functions. J&J and Medtronic, which arguably are the most diversified companies, bring in management expertise to help run acquired businesses, but operations are largely untouched. R&D decisions, sales and marketing decisions, business development, and clinical functions all remain the domain of the business units. This is stark contrast to the hospital supply, capital goods, and commodity products companies mentioned above, which centralize operations and exert greater control over acquired companies.

5. Earnings Targets. Closely related to the portfolio diversification strategy, or a byproduct of it, is the need to acquire new technologies to sustain growth rates and meet earnings targets. When Reg FD was instituted in 2000 to govern the disclosure of forward looking information to the public, many companies issued growth targets for revenue and earnings which had important implications for the valuation of their stock. As businesses naturally matured, companies turned to mergers and acquisitions as a means of meeting these targets and sustaining growth. J&J, Boston Scientific, Cooper, Baxter, Medtronic and several large serial acquirers needed a steady stream of startups and novel technologies targeting large markets to help sustain growth rates as their core business matured. These companies often diversified into new therapeutic arenas, where as the orthopedic companies sought to consolidate for sales synergies and acquire novel technologies in fragment parts of their own industry (dental, spine, etc.) to sustain growth. Ultimately the orthopedics companies were more successful at meeting earnings targets with this strategy than those companies pursuing a pure diversification strategy.

6. Roll-Up Strategies. Consolidating a fragmented market sector as part of a roll up strategy has been an increasingly popular motivation for mergers and acquisitions in the medical device industry. The benefits are primarily sales related, as a company with an existing sales force (often backed by a PE firm or other financial sponsor), buys a host of small firms with related technologies targeting the same call points/physicians/therapeutic sector. These devices can then be sold through the acquiring firm’s sales force to realize significant sales synergies. The most popular sectors have been urology, interventional cardiology/radiology/neuroradiology, neurosurgery, diabetes, bracing/sports medicine and subsectors of the orthopedic market.

American Medical Systems is one of the most successful firms pursuing a roll-up strategy. Since 1999, the company has purchased 9 smaller companies in an effort to consolidate the urology market. With an established sales force with strong physician relationships, American Medical Systems has been a powerful platform for launching new therapies. Inverness Medical in the diagnostics market, ReAble Therapeutics/DJ Orthopedics in the bracing/rehab market and EV3 in the interventional cardiology/neuroradiology markets represent similar success stories.
The common thread was that all had strong sales platforms through which they could launch new devices. Companies that have been less successful with this strategy have largely failed due to deficiencies in sales and marketing or weak management.

7. Defend Share / Competitive Motivations. The cardiology market is the prime example of where acquisitions to defend share or to obtain strategic benefits are most common. In the electrophysiology market, St. Jude, Boston Scientific and J&J have all made several small technology acquisitions to acquire novel ablation technologies. Each of these three players has significant share in this high margin market, where share losses have a significant impact on the bottom line (reverse leverage). Hence the cost of not acting and missing a technology evolution or losing a promising property to a competitor is quite high.

Market share motivations also underlie the acquisitions of complementary technologies. The interventional cardiology companies have been the most aggressive about acquiring products they can sell in combination with coronary stents. Acquiring these technologies/startup companies provides the stent companies with a broader sales bag. This makes the sales reps more productive/profitable and provides them with greater leverage with hospitals and group purchasers as they are able to negotiate around a broader portfolio of products. At the same time it strengthens their competitive position relative to the other players. This competitive acquisition mentality has been played out in embolic protection, vascular closure devices, radiation, balloon catheters and enabling technologies for drug-eluting stents.

8. Privatizations / Financial Sales. An increasing number of medical device firms have been purchased by financial sponsors. Several PE firms have been successful privatizing small device companies, restructuring them to increase their value and subsequently turning them over through IPOs or industry sales at a significant profit. Since 1998, there have been 22 financial sponsor transactions (3% of all transactions). Half of these occurred in the last three years alone, though with the recent credit crunch and resulting slow down in the private equity markets, that rate is unsustainable.

Many of the privatized companies were faced with operational challenges, management challenges, or capital constraints. The private equity firms were then able to restructure operations or provide the funding necessary to undertake clinical trials or acquire smaller product lines that would enhance the growth profile of the initial privatized target. Enhancing this growth rate is the key to creating value and commanding a higher acquisition multiple/valuation. Financial sponsors have been active in the orthopedics, urology, cardiology, and ophthalmology sectors. Troubled companies are the best targets, as the failure of hostile acquisitions in the industry limits the willingness of both acquirers and financial sponsors to pursue such transactions.

While the initial transactions were in the $140-200 million range (Smith & Nephew’s Bracing Business/DJ Orthopedics and American Medical Systems), two mega-transactions were completed in the past year. Bausch & Lomb was purchased for $4.5 billion and Biomet was purchased for $11.3 billion. This is less representative of a time effect and is more reflective of the financial sponsor’s increasing comfort with their ability to successfully manage and subsequently exit medical device firms.

Overview

Roughly 783 deals were completed between January 1, 1996 and December 31, 2007 across 33 different sectors of the medical device industry. Note that there is a vintage/age effect in the data as the most mature sectors have experienced the greatest level of M&A activity, while younger sectors and new technologies have just begun the consolidation process. This is representative of the natural evolution of the medical device industry, where both markets and technologies/companies must be validated prior to significant M&A activity.

The five sectors that have witnessed the greatest level for M&A activity between 1996-2007 accounted for 44% of all transactions. The one common theme among all these sectors: the potential for significant sales synergies through consolidation.

The diagnostics sector experienced significant global consolidation (83 transactions) during this period. The large in vitro diagnostics players (Abbott, J&J, Beckman Coulter, Olympus) added to their test menus and consolidated the number of capital equipment manufacturers (further streamlining the hospital sales process). The leading diabetes players acquired startups developing the next generation of more accurate, less invasive automated self-testing devices. Specialty diagnostics and molecular diagnostics also added to the acquisition frenzy.

Cardiology experienced the second greatest level of merger & technology acquisitions (82 deals) over the period, mostly in the interventional cardiology field. This highly profitable and rapidly growing market offered significant sales synergies. The large conglomerate-esque companies (Medtronic and J&J) made diversifying acquisitions to enter the space in the late-1990s and acquired coronary stent manufacturers. The stent market boom then spawned a flood of complementary technology acquisitions. The highly-profitable electrophysiology space also witnessed a similar acquisition boom as catheter technologies were developed for arrhythmia ablation. Continued innovation by startups in the Cardiology sector supplies a constant stream of acquisition candidates and assures continued M&A activity.

Other transactions (63 deals) represent a host of small niche technologies and products that do not fall neatly into any therapeutic or product category. This category includes pediatric products, safety products, generic hospital supplies, etc. The volume of these transactions speaks to the general level of M&A and the industry, as many are small commodity products.

Imaging (60 transactions) experienced a similar sales-synergy-driven consolidation much like the diagnostics sector. The leading players in the imaging sector are large conglomerates selling a diverse array of products into the hospital. Imaging systems are complementary products that these conglomerates could bundle with their IT and other systems sold to hospitals. Seamless integration is a big selling point that provides significant cost savings for hospitals and makes them more likely to purchase all capital equipment/IT from one integrated vendor and remain loyal to that vendor. Consequently, GE, Phillips, Toshiba and Siemens have been very effective at acquiring and integrating CT, X-Ray, Ultrasound, MRI, PET and other imaging systems with their IT and related hospital capital equipment systems.

Driven by the prospect of significant sales synergies and a significant flow of new high-margin technologies, the orthopedics sector has witnessed 58 mergers and acquisitions between 1996 and 2007. The sector has seen consolidation among the large players as sales synergies and the need for international distribution have motivated larger mergers such as Stryker-
Howmedica and Zimmer-Centerpulse. Smaller players have also been very acquisitive in search of sales synergies in niche segments such as bracing and sports medicine. The large reconstructive joint companies also sought to diversify their product lines by expanding in the arthroscopy and sports medicine markets to sustain/accelerate growth. If we include spine (25 deals) and orthobiologics (4 deals), orthopedics would be the most active sector in terms of the medical device M&A market. This is discussed in greater detail in the orthopedics section of this report.

The tables on the next page represent the mix of deals by sector.

There is a clear sector bias to the dollar volume of M&A transactions in the device industry. Not surprisingly, some of the largest sectors in terms of transaction volume (Cardiovascular, Orthopedics, Imaging) represent some of the largest sectors in terms of aggregate transaction enterprise value dollar volume. The following chart illustrates aggregated the enterprise value of companies acquired in a given sector.

<table>
<thead>
<tr>
<th>MEDICAL DEVICE M&amp;A TRANSACTION STATISTICS BY SECTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Sorted by Total Acquired Enterprise Value - $Millions)</td>
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<table>
<thead>
<tr>
<th>Sector</th>
<th>Total Deals</th>
<th>Total Acquired EV</th>
<th>Average Deal Size</th>
<th>Median Deal Size</th>
<th>Low ($Millions)</th>
<th>High ($Millions)</th>
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<tr>
<td>Cardiovascular</td>
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<td>$73,485</td>
<td>$896</td>
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<td>$55</td>
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<td>Other</td>
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<td>Dermatology &amp; Wound Care</td>
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<td>Cardiac &amp; Vascular</td>
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<tr>
<td>Surgery</td>
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<td>$1,303</td>
<td>$326</td>
<td>$224</td>
<td>$104.8</td>
<td>$750</td>
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Total

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<th>Average Deal Size</th>
<th>Median Deal Size</th>
<th>Low ($Millions)</th>
<th>High ($Millions)</th>
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Differences in the valuation of individual companies and technologies across sectors account for this disparity. Even when excluding the larger mega-transactions greater than $1 billion in enterprise value, certain sectors such as cardiology and orthopedics garner larger deal valuations, all else equal. The higher growth prospects, higher profit margins, and greater potential sales leverage make these companies/startups more valuable than the average firm in the industry. These companies also produce single use, consumable devices with multiple future product iterations. Multiple potential acquirers, the potential for bidding wars, and emotional factors can also increase the relative valuation of these companies, all else equal.

Likewise, diabetes companies were more highly valued during this period than the average company, all else equal. The high margin testing devices with recurring revenue streams and increasing reimbursement were an attractive target for large players and those rolling up the diabetes space. New testing algorithms and less invasive testing methods posed a significant threat to the existing test strip manufacturers, motivating several technology acquisitions. Similarly, there was consolidation among the larger players, which further increased the average deal size relative to other sectors.

Relatively small sectors in terms of transaction volume, such as spine, cosmetic surgery and neurostimulation, were disproportionately large in terms of transaction value. Neurostimulation was thought to be the next cardiac rhythm management sector, which saw rapid growth and consolidation in the early to mid-1990's. The cosmetic surgery sector grew 7x in five years, had mammoth margins and was nearly all private pay consumer business where reimbursement was not an issue. Spine was a high-growth, high-margin market, where new technologies were aggressively targeted by both the orthopedic and large device companies. These represented the faster growing sectors in the past 5-8 years and consequently commanded the highest valuations in the medical device industry.

Sectors undergoing consolidation by the conglomerates naturally ranked among the top sectors in terms of total acquired enterprise value. Imaging and diagnostics were near the top of the list, as the large players rolled up many of the smaller companies. The surgical equipment, monitoring, and dental sectors witnessed similar trends.

Conversely, other active sectors, such as neurology devices, oncology equipment, and analytical devices, which ranked in the middle third of sectors in terms of transaction volume, were in the bottom third in terms of aggregate acquired enterprise value. Aggressive roll ups were occurring in these sectors, yet slow growth prospects relative to other sectors and lower margins resulted in these companies commanding lower valuations.

In the next ten years, the small emerging device sectors, such as orthobiologics, gastric, and bariatric devices (which are beginning to command attractive valuations) will likely be among the leading sectors in terms of acquisitions. These emerging sectors are at roughly the same development stage as the neurostimulation and spine sectors were 8-10 years ago. There is a continual cycle of new sectors that come to dominate the M&A landscape in less than a decade. If this analysis were conducted in 1998, we would have seen cardiac rhythm management as the leading acquisition sector with cardiovascular acquisitions (and valuation) ramping. The one constant is that there is a group of large companies always ready to acquire the next group of startups with novel technologies.
Deal Size

The number and aggregate enterprise value of transactions in the medical device industry can vary significantly by year. Beyond company specific factors influencing valuation, the overall strength of the public equity markets, the medical device IPO market, the level of M&A activity, venture investors' need/desire for an exit, the availability of credit, and the general economic climate also influence deal valuation and volume.

The following chart illustrates M&A activity in the medical device market by year. The chart plots the number of deals completed in a given year versus the cumulative enterprise value (in millions of $US) of the transactions completed in each year.

All else equal, there has been an overall increase in M&A activity in the medical device markets over the past 11 years. Increased venture investment in development stage technologies, greater hospital/university technology licensing and startup activity, a growing network of medical device entrepreneurs, and large companies' appetite for new growth/profit drivers have all contributed to the increased level of transactions during this time period.

The increase in cumulative transaction value over time is a function of several factors (beyond the increase in number of deals). As seen in the table below, average transaction size and median transaction value can vary greatly year to year.
The overall strength of both the financial markets in general and the investing climate for medical devices and healthcare have a strong influence on M&A activity. When the IPO markets are hot and medical device public equity valuations have risen, more mid to large scale transactions (> $100 million enterprise valuation) are generally completed. Strong equity markets allow mid-sized publicly traded firms to use their inflated equity as a currency for acquisitions and provide financial sponsors with greater access to capital. It also makes it easier to justify a transaction in the minds of the board and investors.

Thus there is typically a decline in transaction values and the number of deals when the markets weaken (1999, 2002, 2005, 2007). One or two blockbuster transactions in a given year, however, can skew the numbers. Larger companies are typically indifferent to the general level of valuation. While disciplined in their targeting and valuation approach, their ample cash flows allow them to fund deals with cash in virtually any environment.

The one constant that has driven transaction volumes over the period are small start up and product line deals (less than $100 million enterprise valuation). Companies are always willing to invest in small product lines that provide sales synergies and deals less than $20 million (enterprise value) can be completed in virtually any market. While the emergence of private equity interest and large blockbuster transactions drove an increase in the cumulative and average transaction value over the period, the increase in the number of small transactions actually drove the median transaction value down over the period.

An analysis of transactions by size, as seen in the chart below, reveals that small transactions have seen the greatest increase in volume levels. The increase relates to two primary sources. First, the increased level of entrepreneurship and new ventures has created a larger pipeline of small technologies and niche properties ripe for acquisition. Second, larger companies have largely consolidated the “middle market” of the medical device industry and are increasingly forced to look toward smaller companies to help drive/sustain growth. This requires more early-stage investments, either technology acquisitions which the larger companies must develop in-house or corporate venture investments and co-development agreements.
Middle market ($100-$500 million enterprise valuation) and large company ($500 million - $1 billion) transaction volumes did not change materially over the period. Aggressive consolidation of the large and middle market players in the mid- to late-1990's by the ultra-large conglomerates and device companies significantly reduced the pool of companies in these categories. By 2000, there were few attractive large and mid-sized firms left. Those that were left in these segments often did not synergistically "fit" with the most acquisitive companies in the industry. As the ultra-large players then moved to acquire attractive, smaller development stage companies/technologies, fewer companies were left to develop into this middle market segment (or eventually the large company segment). Similarly, roll up strategies further reduced the supply of small companies capable of developing into this middle market category.

Ultra-large transactions (> $1 Billion) have also increased in the past five years. The conglomerates and large device players have increased in size to such a point that the scale of an acquisition capable of moving the revenue/EPS growth needle is formidable. A company with $80 million in sales and a $400-500 million enterprise valuation is no longer material to these companies' financial statements. Thus to sustain EPS and revenue growth, the ultra-large players are increasingly seeking to merge among themselves or acquire multiple promising early stage technologies (essentially outsourcing novel R&D) in the hopes that these startups will yield material 5 year results. PE firms have also begun to dapple in this sector in the mid-2000's and will likely continue to do so, as the law of large numbers, further reduces the growth profile of these companies. Driven by these factors, M&A in this segment should remain near current level.
The Acquirers

The top 15 acquiring firms in the medical device industry completed 217 acquisitions between 1996 and 2007 with a cumulative transaction enterprise deal value of $106.2 billion. This represents 28% of all deals completed in the industry during this period. Yet, these transactions represent 40% of the total acquired enterprise value in the industry, as some of the acquirers are consolidating mature sectors where the targets are large and others are paying significant multiples/valuations for smaller targets (all else equal) in high growth sectors.

Top 15 Medical Device Acquirers: Transaction Summary Statistics
Sorted By Total Acquired Enterprise Value (in $US Million)

<table>
<thead>
<tr>
<th>Acquirer</th>
<th>Total Deals</th>
<th>Total Acquired EV</th>
<th>Average Deal Size</th>
<th>Median Deal Size</th>
<th>Low</th>
<th>High</th>
<th>Notable Acquisitions</th>
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<tbody>
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Total 218 $106,196

Percentage of Industry Totals 28% 40%

These 15 companies made acquisitions across 24 out of the 33 sectors in the medical device industry. Consistent with the overall industry trends, cardiology, diagnostics, and imaging were the leading sectors in terms of deal volume. Reflecting the relative valuation disparities between sectors, cardiology, imaging, and spine were the largest in terms of dollar volume. An analysis of the top 15 companies' acquisition activity by sector is presented on the next two pages.
### Top 15 Medical Device Acquirers: Transaction Summary By Sector

#### Number of Transactions

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<tr>
<th>Company</th>
<th>Cardiovascular</th>
<th>Neurology</th>
<th>Spine</th>
<th>Orthopedics</th>
<th>Diabetes</th>
<th>Monitoring</th>
<th>Urology</th>
<th>Gastro</th>
<th>Dental</th>
<th>Imaging</th>
<th>Diagnostics</th>
<th>Oncology</th>
<th>Respiratory</th>
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1) Includes Neurovascular
2) Includes Neuro, Cardiac & MI Surgery

= Market Leader in Sector
= Top 3 Player in Sector
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<th>Medical Device Acquirers</th>
<th>Cardiology</th>
<th>Neurology</th>
<th>Spine</th>
<th>Orthopedics</th>
<th>Diabetes</th>
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<th>Gastro</th>
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<td>% of Sector Deal Value</td>
<td>59%</td>
<td>93%</td>
<td>75%</td>
<td>13%</td>
<td>42%</td>
<td>25%</td>
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<td>31%</td>
<td>16%</td>
<td>12%</td>
<td>58%</td>
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<td>16%</td>
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1) Includes Neurovascular
2) Includes Neuro, Cardiac & MI Surgery

- = Market Leader in Sector
- = Top 3 Player in Sector
GE, American Medical Systems, DENTSPLY, Inverness Medical, and OSI/Spacelabs all made acquisitions with a single sector of the industry. Each of these companies was largely pursuing a roll-up strategy to achieve sales synergies and scale within their respective sectors. OSI/Spacelabs consolidated several small, mature monitoring companies, hence the low cumulative valuation. Where as American Medical Systems rolled up the fragmented urology market, which largely consisted of small niche rapidly-growing technologies/firms. Hence the disparity in cumulative acquired enterprise value between the two firms as they were acquiring firms at opposite ends of the growth and product lifecycle spectrums. GE, on the other hand, consolidated the industry leaders in the imaging market which consisted of very large, mature companies selling high-priced capital equipment.

St. Jude, Guidant, Tyco, and Philips largely made acquisitions within their primary lines of business. Each also pursued a few diversifying acquisitions in search of new growth engines and to explore new markets. Both St. Jude and Guidant were focused on the highly profitable cardiology market and expended most of their acquisition capital to defend share and acquire technologies that offered sales synergies in the respective segments of the market. St. Jude’s diversification acquisition of Advanced Neuromodulation Systems leveraged the company’s expertise in electrical stimulation and programming. Guidant sought economies of scope by diversifying into the cardiac surgery market. After consolidating much of the mature monitoring market and achieving significant sales synergies, Philips needed new growth opportunities. Consequently, it sought to leverage its monitoring expertise in the high-growth respiratory market by acquiring Respironics. Likewise, Tyco healthcares sought to diversify into other sectors that could leverage its relationships with hospital central purchasing centers when the laparoscopic surgery market matured.

Integra and Cooper are indicative of smaller companies pursuing portfolio diversification/roll-up strategies. These acquirers largely targeted niche technologies in fragmented markets. While originally focused on synthetic skin and anti-adhesion technologies, Integra began a diversification program by acquiring small neurosurgery, neuromonitoring, diagnostics and spinal devices. Similarly, Cooper diversified beyond ophthalmology by making several small acquisitions to establish a women’s health franchise, surgical, imaging, and hospital supply businesses.

Medtronic, Boston Scientific, and J&J exemplify the large franchise diversification strategy. All three companies have sought to diversify their revenue base to reduce earnings volatility by acquiring large market leading franchises and promising novel technologies. Medtronic acquired market leaders in the rapidly growing interventional cardiology, spine, diabetes, neurology, and urology sectors. Over time it was able to support these large acquisitions by acquiring novel technologies in these sectors to sustain growth. J&J employed the same strategy when diversifying into the orthopedic, sports medicine, spine, interventional cardiology, neurology, and diabetes markets. No other companies have been as successful at achieving the benefits of diversification through acquisition as Medtronic and J&J.

Boston Scientific continually invested in the interventional cardiology sector to sustain its stent market leadership position. When faced with stent share losses, it realized the need to further diversify its revenue base. It acquired Target to expand into the interventional neuroradiology sector, where it could leverage its interventional cardiology development expertise. Boston successfully won the Guidant acquisition battle over J&J to acquire a leading CRM franchise. Its smaller acquisitions to diversify into critical care, urology and neurostimulation have been less successful. Consequently, Boston has failed to diversify much beyond cardiology and hence continues to experience above average revenue/EPS volatility.
EV/SALES MULTIPLE FACTOR ANALYSIS

Our analysis supports much of the background research on the role various factors play in determining an EV/Sales multiple. Results were largely consistent with our hypothesis, though we were surprised to find that Sales Synergies were not a significant factor in our models, when in practice they actually play a significant role in valuing transactions. Factors, in order of contribution to the multiple in our model, are discussed below.

**Projected Growth – Sector Growth.** The difference between the target’s projected 3-5 year growth rate and the sector growth rate was the greatest factor influencing the EV/Sales multiple of medical device M&A transactions. For both the industry and selective company regression models, it was clearly the most statistically significant variable with a T-Stat of 10.21 and 12.46, respectively. The regression coefficients also dwarfed other variables, illustrating the supernormal growth rate’s contribution to the model. Even when analyzed on a stand alone basis, this variable explained 38% of the variation (as measured by R^2) in the EV/Sales multiple in the industry model and 45% of the variation in the more selective model.

This finding is consistent with commonly accepted financial theory, which postulates that, all else equal, companies with supernormal growth rates will command higher valuations than companies growing in line with the industry average. Hence in an acquisitive industry where the larger players seek to sustain top-line and EPS growth by acquiring rapidly growing companies with novel technologies, it is not surprising that this factor would largely determine acquisition multiples. This finding also supports the wide intra-segment multiple disparity seen between acquisitions of small to mid size rapidly growing companies and more mature companies. Likewise, irrespective of sector, companies with similar growth profiles tend to be purchased for similar acquisition multiples. This confirms that the supernormal growth rate makes a much greater contribution to explaining multiples than the sector in which the target competes. The sector itself did not offer much explanatory power in the model.

**Market Size.** Given the importance of scale and leveraging infrastructure in the medical device industry, it is not surprising that market size (measured in $millions) is a statistically significant variable. However, in terms of contribution to actual acquisition multiples, it is less significant given the minute value of the regression coefficient. A company targeting a $5 billion market commands a multiple one half point higher than a company targeting a $1 billion market. Thus it was not surprising that market size explained a small portion of the variation in EV/Sales multiples when examined on a stand alone basis. The explanatory value as measured by R^2 was roughly 1% in both regression models.

This finding is not surprising as the valuation of an individual entity is more of a reflection of that entity’s ability to generate sales in a given market rather than the absolute size of the market. The EV/Sales valuation approach only considers the target’s forward sales, not total potential sales over time or total market potential. Also valuation is largely dependent on the economics which a single entity is able to capture, not the prospects of an entire market sector. Hence while a statistically significant factor, it makes intuitive sense that the absolute size of the market would not make a significant overall contribution toward the multiple itself.

**Sector Growth.** Total growth governs a firm’s ability to capture economics, synergies and scale. In this model total growth is comprised of sector growth and supernormal growth (projected growth – sector growth). Given the importance of supernormal growth in this model, it is not surprising that sector growth would make a meaningful, statistically significant contribution to the model as well. Hence all else equal, it is not surprising to see that companies
in more rapidly growing markets command larger EV/Sales multiples than companies in slower
growth markets. Rather than a binary sector classification, sector growth is the best means of
accounting for overall sector-specific differences in this model.

When analyzed on a stand alone basis, sector growth explained 14% of the multiple in the
industry model and 10% in the selective company model. Combined with supernormal growth,
these two variables explain over 45% of the EV/Sales multiple in these models. While less
statistically significant than market size, this sector growth offers a greater explanatory
contribution to the model.

**Position in Market.** Consistent with initial expectations, leading market positions are positively
correlated with valuation as the medical device industry evolves into a natural oligopoly in each
sector over time. This is supported by empirical evidence which shows that the acquisitions of
the number three and four established players in a maturing market such as monitoring or
dental typically command lower acquisition multiples than the number one and two players.
Emerging sectors or paradigm shifting technologies with high growth rates are the exception to
this trend. This variable was statistically significant in both models and when analyzed
independent of other variables, explained roughly 10% of the EV/Sales multiple as measured by
R^2.

**Venture-Backed.** Venture funded companies typically commanded an EV/Sales multiple 1.32x
higher than non-venture funded companies. This data support the author’s argument that
venture funding helps pre-screen technologies to add an extra stamp of credibility and that
venture investors are effective in advocating for exit valuations. This binary variable was
statistically significant in both models and when evaluated alone, yielded a R^2 coefficient of
18%. Results are not surprising given that venture capitalists have funded the most promising
devices that command highest valuations, while technologies sold between companies typically
command lower multiples. Hence the contribution to the model (as measured by the regression
coefficient) is a meaningful differentiator.

There are few examples of novel technologies where the presence of venture funding was able
to command a significantly different valuation than non-venture funded companies, all else
equal. Hence the delta may simply reflect a difference in the nature of the acquisition
candidates funded and may just be a casual rather than causal relationship since VCs typically
fund the most promising technologies/companies with the highest supernormal growth rates. A
sector specific study may yield better insights than an industry-wide study of this factor.

**Technology Acquisition:** Whether the deal was a technology acquisition or not was another
statistically significant binary variable. Technology acquisitions commanded 1.4x higher
EV/Sales multiples in both models. This is consistent with the author’s hypothesis. All else
equal, many of the most rapidly growing companies have developed novel technologies that
challenge existing markets and devices. Consequently these technologies are acquired by
larger, established firms that need growth engines, access to that technology or need to defend
their market share. It is not a surprise that there should be a premium associated with these
companies. There is a roughly 17% correlation between this variable and the supernormal
growth variable, which probably explains the 3% multiple R^2 coefficient in the regression
models and makes this a second tier variable in explaining the EV/Sales multiple.

**IPO’ed Prior to M&A.** This binary variable adds roughly 1.2x to the EV/Sales multiple if a
company went public prior to M&A. Like VC funding, taking a company public adds another
layer of vetting and validation to the underlying technology. Note that there is also a 35%
correlation between VC funded and IPO companies which may influence results. Additionally, one public company acquiring another can mean significant cost savings from consolidated administrative functions. This is especially true when one small- to mid-sized company acquires another. While statistically significant in both models, this variable is secondary in both explanatory power and value to growth rate variables.

**Sector Beta.** This variable was statistically significant in the industry model and nearly significant in the selective model. With a regression coefficient of .26 in the industry model and .18 in the selective model, this variable offers significant explanatory power in the determination of the EV/Sales multiple. When evaluated independently, this variable has a roughly .17 R^2 coefficient in both models. These findings are not surprising given that the higher beta sectors of the medical device industry have higher (and more volatile) growth profiles than more mature, slower growth sectors. Thus it was not surprising to find that sector beta was highly correlated with industry growth (.50 correlation coefficient) and potential profit margin (.60), both sector dependent variable. Consequently, we attribute much of the value of this variable as a predictor to sector specific characteristics rather than the explanatory power offer beta itself, which ranges between 0.7 and 1.3 across all of the companies in our sample.

**FDA Clearance.** Surprisingly this binary variable had negative coefficient in the regression equation in both models, implying that FDA approved technologies were less valuable than non-approved technologies. This variable was statistically significant in the industry and nearly significant in the selective company regression model. With a regression coefficient of roughly -.1 and a R^2 coefficient of less than .001 in each model however, it is not meaningful to the overall EV/Sales multiple. These findings may be skewed by the fact that several high multiple early-stage companies with technologies close to FDA clearance dominated the top end of the EV/Sales multiple spectrum, while most other companies acquired post-clearance. Eliminating these companies for the analysis explains why this variable was not significant in the selective company model.

**Enabling Technology.** This binary variable was included to determine the value of any important strategic benefits (blocking patents, freedom to operate, securing supply, ect.) provided by an acquisition. With a relatively small regression coefficient of 0.1 in both models, the explanatory power for the variable is moderate, which is confirmed by independent R^2 analysis. It was identified as a significant variable in the selective company model, which excluded 4 of 30 deals involving enabling technology in the industry model. These four excluded transactions were all very small on a dollar basis and multiple basis and their exclusion improved the statistical significance of the variable but offered little in terms of additional explanatory power.

**Single Product Company.** All else equal, single product companies commanded a lower EV/Sales multiple than multi-product companies. This binary variable had a small regression coefficient (< 0.1) in both models, but was statistically significant in the selective company model, which had a slightly greater mix of multi-product companies. This finding makes intuitive sense as all else equal multi-product companies offer some diversification benefits that may reduce the volatility of revenue growth and provide valuable sales/operational synergies.

**Sales Model.** This is the most unexpected result of the regression analysis. Direct distribution (binary variable) firms were found to have a negative, albeit very small (<-0.1) regression coefficient. This factor was only statistically significant in the selective company model. It was not statistically significant in the industry model (actually ranking among the bottom factors in terms of significance). This selective company model result runs counter to industry standard.
practice which highly values direct distribution because of the higher margins and greater economic benefits from sales leverage. The author believes the selective company model is a statistical anomaly generated by eliminating 21/232 direct sales companies in the upper half of the valuation spectrum between the models.

Potential Profit Margin (EBIT). This variable was nearly statistically significant in both models and provides a meaningful contribution to the EV/Sales models that should not be discounted. Lack of statistical significance was more of a function to the general homogeneity of device company margins, which generally run between 28% and 33%, and the fact that profit margins are highly correlated with industry growth and other sector specific characteristics. A larger sample size could have achieved statistical significance. Bankers and investors note the important link between margins and EV/Sales margins because, all else equal, companies with higher EBIT margins should command higher valuations. In their minds, it is a discriminating factor.

Sales Synergies (Sales Synergies). It was surprising to discover that sales synergies were not a significant variable. Sales synergies are one of the primary drivers of M&A and valuation in the device industry. We attribute the lack of significance to a data and a statistical methods problem rather than a lack of explanatory power. This analysis simply used a binary variable (yes/no) to evaluate sales synergies. This was an incorrect approach as synergies exist across the entire spectrum of acquisitions, irrespective EV/Sales multiples. It is the magnitude of those expected synergies that vary across the spectrum.

A more appropriate approach would have been to use the actual dollar value of sales synergies expected to be achieved in each deal as an independent variable. Such data are hard to find and required reading SEC documents and press releases for each of the 783 transactions to try to ascertain the data. In many cases it was not disclosed. If such data were available we believe this variable would have been both statistically significant and the regression coefficient would have been meaningful in calculating the multiple. Ascertain this data would likely improve the explanatory power of the models and validate the importance of this factor. This is an area for further research as empirical evidence supports the link between sales synergies and the EV/Sales multiple.

Other Variables of Note

Acquirer stock performance is not statistically significant in the broad dataset, but a small dataset of companies with less than a $2 billion market cap revealed that the acquirer’s prior 365 day stock price performance was a significant factor. This was consistent with expectations, given that small companies use their stock as currency to fund acquisitions. All else equal, these companies can and are more willing to pay more for acquisition targets when they can use their inflated currency (stock) to fund the deal. The inflated stock price results in less dilution (issuing fewer shares) from raising additional equity capital. This is not a significant motivating factor for the larger companies that make more frequent acquisitions and represent a greater portion of all acquisitions in our dataset. These companies typically fund acquisitions with cash. Hence it is not surprising to see that this trend was masked in the industry and selective company models.

Type of regulatory filing did not influence the model. One would have expected PMA technologies to command higher multiples, since these tend to be novel technologies targeting large market opportunities. This proved not to be a significant variable as many 510K technologies posted similar supernormal growth rates as PMA devices. This speaks to the fact
that execution and market adoption forces play a greater role post-clearance than the path a technology took to gain clearance. Again this speaks to the importance of supernormal and sector growth factors in valuing medical devices.

*Portfolio diversification* motives (binary variable) similarly did not provide any explanatory value. This suggests that bidding wars do not play the same role in diversification deals as they do with technology acquisition deals where they may be multiple bidders at play. These deals could be more random in nature with companies making acquisitions based on when the acquirer's own organic growth slows rather than a single property being attractive at a given time and attracting attention from multiple firms.

**Other Variables Not Considered**

Note that several other variables can potentially exert a significant influence on the EV/Sales multiple. Implicit assumptions about some of these variables were encompassed in the growth, profitability and strategic factors in our analysis.

**Reimbursement.** This is one of the most crucial factors governing the adoption of a new medical device. New coding or incremental reimbursement were critical to the market adoption and rapid conversion to some of the most successful medical device technologies in the past decade, including drug coated stents, bone morphogenic protein (BMP) for spinal surgery, and biventricular pacing devices for congestive heart failure. With appropriate coding in place, all three quickly became billion dollar markets or quickly increased the size of their respective markets by billions of dollars. The highly profitable, large sectors of the medical device market, such as orthopedics, cardiology and ophthalmology, recognize the importance of reimbursement. They all have powerful lobbying efforts and medical associations to help protect coding and reimbursement for their targeted procedures and devices.

Conversely, lack of reimbursement or inadequate reimbursement can significantly delay the market adoption of a new technology or significantly limit the size of the market for a new technology. CMS has a finite pool of reimbursement dollars and for a new device or technology to receive a code, reimbursement dollars must be taken from every other procedure to fund this new treatment. While the FDA considers equivalency when approving a new medical device, CMS and payers often seek some demonstrable measure of improved efficacy when granting a new code or providing incremental reimbursement. This implies that CMS and private payers impose a higher bar on new therapies, requiring more outcomes data than what is required for FDA approval.

Many startups and small companies focus on FDA approval, but fail to consider the needs of payers when designing their clinical trials. Consequently they receive FDA approval but lack the data necessary to obtain reimbursement coverage at launch. Hence their technologies fail to be rapidly adopted in the market. The companies must then fund post-approval studies to collect the necessary outcomes and economic data. There is significant opportunity cost in waiting on this data, as the companies are often foregoing a valuable period of unencumbered exclusivity on the market. Cambridge Heart and Kyphon are both prime examples of valuable technologies in the diagnostic and device spaces, respectively, which experienced slow adoption curves post-approval until reimbursement codes were established for their respective technologies.

Likewise, the artificial disc market failed to develop because the technology did not receive a dedicated reimbursement code and the existing codes could not cover the high cost of the device without exposing the hospital to sizable losses on each procedure. In this case, the
startups failed to power their clinical studies to demonstrate superiority over fusion and hence lacked the data necessary to justify an add-on payment or new code. Likewise their fall back strategy of piggybacking fusion codes was ineffective as hospitals were unwilling to accept large losses on the procedures without any evidence of clinical benefit. Growth estimates surrounding these technologies at the time of the acquisitions assumed some form of reimbursement would be in place. Valuations were not balanced against the risk of not obtaining reimbursement. Acquirers and investors failed to consider this possibility when they were completing their due diligence on these technologies.

Closely related to the factor of obtaining the code itself, companies must also consider whether the coding will make their technology profitable for the hospital. Certain smaller hospitals can not absorb large losses on procedures and hence place greater restrictions on device usage, such as tight usage guidelines tied to clinical data. This is most evident with new alternative bearing surfaces for reconstructive joints. Both hospitals and payers have established tight guidelines concerning which patients receive these high-price (high-margin for the device companies) devices. Likewise robotic surgery devices have not replaced laparoscopy for certain procedures, such as cholecystectomy, because the reimbursement codes do not provide sufficient coverage to make the procedures profitable for the hospital.

IP. Intellectual Property (IP) is the price of admission when developing a new medical device therapy. Everyone in the sector has IP around their technology. Given the life saving nature of medical device therapies, the FTC is reluctant to bar a company from operating in the space if there is a patent infringement concerning an approved product. Instead the matters get resolved in the courts through civil litigation, which usually requires companies to license technology for a fee and royalty payment.

Devices have short product lifecycles, making IP somewhat less significant than biopharma patents. Most patents are device patents, which are often obviated by incremental design changes and structural variations between competitors. These patents are very hard to defend as device design, materials, and operation can vary between competing devices. Process, method, and programming algorithm patents have much longer life spans (in terms of viability and defensibility) and, all else equal, may be more valuable.

The value of the IP is not transparent and has been tough for outsiders to evaluate. Likewise it has been difficult to discern valuation differences between blocking, defensive, and freedom to operate patents. Patent value is partially considered through our analysis of strategic variables (such as enabling technologies), but actually plays a significant role when creating companies and making acquisition decisions.

The interventional cardiology sector is the most litigious in the medical device industry. There have been no fewer than 20 suits among J&J, Medtronic, Boston Scientific, Guidant and Abbott (and all their previous acquisitions) related to stents and rapid exchange angioplasty systems. For example the Yak patent (held by Boston Scientific and Guidant) severely limited freedom to operate in the rapid exchange segment of the angioplasty balloon market. This forced Medtronic to develop its own version of rapid change catheters and forced J&J to cross-license the technology as part of a coronary stent design patent settlement. Yak is one of the most valuable and longest lasting patents (in terms of technical applicability) in the device market because it was well written and very hard to innovate around. This is the exception rather than the rule given then the short lifecycles of device technologies.
Likewise Cyberonics owns a powerful method patent around stimulation of the vagus nerve to influence the autonomic nervous system. The company was successfully able to use this defensive patent to protect its monopoly on stimulation of the vagus nerve for treating obesity, epilepsy and behavioral disorders.

It has also been common for the large acquirers to purchase or license technologies from academic or research centers, or acquire small companies to control the IP. The acquirers then may innovate around that IP or adapt their products, as Medtronic did with Cardiovention’s cardiopulmonary bypass technology patents. In some cases, acquirers simply choose to shelve the IP to prevent a new device from entering the market that would compete with their technology, as J&J has done in the endosurgical market.

Not surprising IP can have the greatest influence on novel technologies and startup companies. Inamed was forced to pay a royalty to J&J so that it could have freedom to operate and commercialize its LapBand device for obesity. J&J simply had IP around the device sitting on its shelf with no intent on commercializing the IP for that application near-term.

Kinetic Concepts was able to leverage its IP to stave off competition in the wound care market, enjoying a longer period of exclusivity on the market. The company was able to leverage uncertainty around competitors’ freedom to operate to build a sizable installed base of devices in a highly profitable “razor-razorblade model” market. In the end, the court did not uphold the company’s patents, but in the interim the uncertainty afforded by the litigation allowed Kinetic Concepts to achieve a significant first-mover strategic advantage over the competition.

Royalties are the most common resolution of IP disputes in the medical device industry. IP has a 70-80% chance of being upheld in court, making it a worthwhile investment. Those companies with infringing technology are required to typically pay a 3-7% revenue royalty for access to the IP in question. Most royalties are skewed toward the lower end of this range. This begs the question whether, in situations where the IP is in question, should investors immediately take a 5% discount to the enterprise value of the target or are there more subtleties to consider with respect to the competitive and strategic advantages of IP.

In our model, IP is somewhat encompassed by strategic variables and, in cases where IP is in question, the potential profit margin factor may be affected. In actuality it is a significant factor that merits independent analysis.

**Emotion.** It is important not to discount the role of emotional factors in valuation. This is the primary reason why certain companies plot well beyond what would have been predicted by the regression model (almost always biased to the upside). Hence “winners curse” is often associated with many medical device transactions, particularly in “hot” sectors with high growth prospects. Emotional factors are difficult to quantify and to some extent, are present in nearly every deal.

Acquirers often move as a herd, all seeking to consolidate or gain exposure to rapidly growing markets. This creates “hot” sectors of the industry where there may be several potential acquirers competing for the same targets. This is true of the cardiovascular and electrophysiology sectors, where many companies sold for premiums well beyond what would have been predicted by our model. The fear of losing out on a deal and not gaining exposure to the sector may have caused many acquirers to overpay for these targets.
Likewise companies can sometimes feel the need to do a deal to satisfy investors. Boston Scientific and Medtronic completed several acquisitions in the early 2000s when they were faced with declining growth prospects, it is unclear whether they were strictly financially motivated or that management felt they needed to complete an acquisition to enhance future growth prospects and tell a better story to investors. In the case of the latter, deal lust can often make management more willing to accept uncertain assumptions and hence overpay for a given target, especially if they fear losing that target to a competitor.

The same is true for small companies faced with declining growth in their lead (or only) product. They may overpay for a small development stage technology in the hopes of acquiring a new growth engine. Take Kyphon for example, which purchased St. Francis Medical for a substantial multiple in a “hot” sector. The acquisition multiple was greater than many industry pundits predicted, indicating that Kyphon may have made some liberal assumptions about growth prospects and may have ignored some of the risks associated with this acquisition. The same can be argued about Hansen Medical’s acquisition of Aortx. Other companies in similar situations, such as Intuitive Surgical and Varian Medical, have been much more disciplined in their acquisition approach, likely passing on some potential deals with lofty valuations.

Pre-existing Relationships. The existence of distribution, co-marketing, co-development, and acquirer venture investment relationships can also influence valuation. Our model made no provisions to account for such relationships. In actuality they can be quite valuable to the acquirer, granting them the option to purchase a target at a discounted price.

The Siemens-CTI relationship most clearly illustrates this point. CTI was a manufacturer of PET scanning systems, a novel imaging modality for detecting metastasis following cancer diagnoses. Siemens assisted CTI in a joint-venture like relationship and had a call option to purchase CTI for a pre-arranged revenue multiple. As the PET market rapidly developed and CTI enjoyed commercial success, Siemens exercised their option to purchase the company. The valuation was less than our model, bankers and industry experts would have otherwise predicted given the commercial success and strong growth forecasts for CTI’s PET scanners.

Corporate Venture investments often limit the attractiveness of a given technology or company, as, depending on the size of the investment, it can appear closely tied to the parent corporation. This has been particularly true of the cardiovascular sector, where J&J Development Corporation and Medtronic have been active. The corporate venture investors have a strong understanding of the market or technology and their inactivity or decision not to purchase a portfolio company may be perceived by external observers as negative validation of the technology or opportunity. This uncertainty can limit or discount the company’s potential acquisition multiple.

Distribution and co-development agreements can also work to the disadvantage of the target, as much of the value of the enterprise may be tied to their partner. This was the case of St. Jude and Getz Brothers. St. Jude was able to acquire the company for a very low multiple because St. Jude represented most of Getz revenue and created most of the value for the enterprise. Hence Getz had relatively few options other than to accept a low acquisition offer from St. Jude. The same is true of Edwards LifeSciences’ acquisition of its Japanese partner.
THE MODEL VERSUS PRACTICE

Values predicted by the models correspond very well with industry convention for valuing both acquisitions and the target prices for public equities. In comparing the characteristics of the companies in our data sample and the 2008 transactions with the practitioner's approach to assigning multiples, there are significant overlaps in terms of factors and how those factors are valued. The chart below summarizes how some investment bankers, equity research analysts, and venture capitalists approach medical device valuation based on comparables analysis.

Industry Convention for Valuing Medical Device Companies: EV/Forward Sales

With the exception of the target’s sales model (direct vs. distributions), industry standards are consistent with the model developed in this research. Factors such as sales synergies, technology acquisitions, large markets/market opportunities and reimbursement are positively correlated with valuation. The disposable/single use device categorization is highly correlated with the large potential profit margins, larger relative sector betas, and venture financing. Based on this empirical evidence, our model is a good quantitative approximation of the qualitative techniques both the business development and financial communities use to value medical device transactions. This would explain the high correlation between our model and actual transaction valuations in 2008.

The strongest link between the model developed in this thesis and industry standard valuation techniques is obviously forward growth estimates. The correlation between supernormal growth rates and the acquisition EV/Sales models is 60%, as evidence by the strong trend exhibited in the chart below.
The supernormal growth correlation exists irrespective of sector classification. Note that companies with similar supernormal growth rates command similar EV/Sales multiples across the entire spectrum of growth rates. While the majority of the fastest growing companies are cardiovascular and orthopedic companies, gastro, surgical, neurology and diabetes companies posting similar growth rates were able to command similar EV/Sales multiples. The slight differences in valuation were largely a function of differences in the potential market size and the underlying sector growth rates. If this chart were reproduced over the prior ten year period, the upper end of the spectrum would be populated with diagnostic, CT, MRI and laparoscopic surgical companies. The genre of the fastest growing companies may change in different periods, but the underlying nature of the relationship between supernormal growth and EV/Sales multiples is constant.

This strong correlation reflects the importance of supernormal growth to capturing value in the medical device industry. Underlying these growth assumptions are conclusions about the clinical efficacy of the device, its ability to penetrate the market, its ability to garner reimbursement and successfully capture market share for the acquirer. Growth does not always live up to expectations and market dynamics are fluid. The ability to justify this growth to acquirers or investors is essential to completing any transaction. Hence we see the importance of factors such as VC investment and taking a company public, which add credibility to the growth story and enhance valuation.
Limitations of the Approach:

Given that this model uses prior transaction multiples as comparables to forecast EV/Sales multiples, it must be updated to incorporate changes in valuation trends. Some of the noise in the model may have been a time series effect given that the number of players in the market, the nature of the transactions, the average size of transactions, and the underlying size of the sector markets have changed over time. Consequently the model needs to be updated periodically to reflect these changing trends and maintain its reliability.

An additional area for research would be to assess whether a five year transaction sample is more accurate for forecasting multiples than a ten year dataset, given that valuation paradigms may change over time. Such a dataset would remove the influence of outmoded approaches to valuation and incorporate changes in target profile preferences.

Changes in the industry mix may also influence the accuracy of the model. Five sectors dominated the M&A landscape over the past ten year period. As consolidation and technological innovation in these sectors slow, other emerging sectors will come to dominate the M&A landscape. This mix shift could affect variables such as sector growth, potential profit margin, sector beta, market growth, and type of regulatory filing, which will in turn affect the predictive accuracy of the model. This again underscores the dynamic nature of the model and the need for updates to assure forecasting accuracy.

While overall financial market conditions were weak, transactions in the Medical Device sector during the first four months of 2008 continued at roughly the same rate seen in 2006 and 2007. Consequently the model has only been validated in what can be considered a “normal” market for medical device transactions. In periods where the overall medical device markets are weak, model results may not be as robust. This could explain the discrepancy between robust validation testing results and the lower expected correlations suggested by the roughly 62% multiple R^2 coefficient of the models.

Financial sponsor transactions (PE, LBOs, etc.) were consistently undervalued by the model. These investors are highly cash flow oriented and they may be valuing synergies, cost cutting measures, tax savings, and other factors not captured by these models. Were data on the magnitude of such factors available, the dollar value of these synergies could have been incorporated into the model to improve forecasting accuracy.

Likewise data were not available to test other special circumstance transactions, which could impact valuation multiples. These would include competitive bidding situations, hostile takeovers, pre-transaction investments, co-distribution agreements, etc. The existence of such situations introduces a bias that will affect the transaction EV/Sales multiple. Consequently results will differ from model predictions.
The forecasting accuracy of the model reflects the fact that tangible factors and rational behavior govern well over 90% of the transactions in the medical device industry. There are however a small fraction of transactions where emotional factors, fear of losing a target or special circumstances (bankruptcy, pre-existing agreements) play a significant role in valuation. We have chosen to explore this disparity in the context of the spine market.

As seen in the table below, there is a wide range in the valuation of both established and pre-revenue companies.

### Selected Spinal Device Mergers and Acquisitions

*Sorted by Enterprise Value*

<table>
<thead>
<tr>
<th>Transaction Date</th>
<th>Target</th>
<th>Acquirer</th>
<th>Enterprise Value ($M)</th>
<th>EV/Sales Multiple</th>
<th>Revenue ($M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>July-07</td>
<td>Kyphon</td>
<td>Medtronic</td>
<td>$3,900</td>
<td>6.8</td>
<td>$524</td>
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<td>November-98</td>
<td>Sofamor Danek</td>
<td>Medtronic</td>
<td>$3,600</td>
<td>8.2</td>
<td>$440</td>
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<tr>
<td>December-06</td>
<td>St. Francis Medical Technologies</td>
<td>Kyphon</td>
<td>$725</td>
<td>10.7</td>
<td>$68</td>
</tr>
<tr>
<td>December-97</td>
<td>Spine-Tech</td>
<td>Sulzer Medica</td>
<td>$602</td>
<td>16.7</td>
<td>$36</td>
</tr>
<tr>
<td>July-04</td>
<td>SpineCore</td>
<td>Stryker</td>
<td>$360</td>
<td>NA</td>
<td>$0</td>
</tr>
<tr>
<td>February-03</td>
<td>Spinal Solutions</td>
<td>Synthes-Stratec</td>
<td>$350</td>
<td>NA</td>
<td>$0</td>
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<tr>
<td>July-06</td>
<td>Blackstone Medical</td>
<td>Orthofix</td>
<td>$333</td>
<td>3.2</td>
<td>$105</td>
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<tr>
<td>March-98</td>
<td>AcroMed</td>
<td>J&amp;J DePuy</td>
<td>$325</td>
<td>3.6</td>
<td>$90</td>
</tr>
<tr>
<td>May-03</td>
<td>Link Spine Group</td>
<td>DePuy AcroMed</td>
<td>$325</td>
<td>NA</td>
<td>$0</td>
</tr>
<tr>
<td>March-04</td>
<td>Interpore Cross</td>
<td>Biomet</td>
<td>$270</td>
<td>3.9</td>
<td>$71</td>
</tr>
<tr>
<td>June-02</td>
<td>Spinal Dynamics</td>
<td>Medtronic-Sofamor Danek</td>
<td>$270</td>
<td>NA</td>
<td>$0</td>
</tr>
<tr>
<td>February-02</td>
<td>Oratec Interventions</td>
<td>Smith &amp; Nephew</td>
<td>$259</td>
<td>5.3</td>
<td>$48</td>
</tr>
<tr>
<td>December-06</td>
<td>Disc-O-Tech Medical Technologies</td>
<td>Kyphon</td>
<td>$240</td>
<td>NA</td>
<td>$0</td>
</tr>
<tr>
<td>June-03</td>
<td>Spinal Concepts Inc.</td>
<td>Abbott</td>
<td>$167</td>
<td>6.2</td>
<td>$27</td>
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<tr>
<td>June-02</td>
<td>Surgical Dynamics</td>
<td>Stryker</td>
<td>$135</td>
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<td>$56</td>
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<td>September-06</td>
<td>Scient’X</td>
<td>Alphatec Spine</td>
<td>$127</td>
<td>5.6</td>
<td>$23</td>
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<td>February-07</td>
<td>Endius</td>
<td>Zimmer</td>
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<td>October-04</td>
<td>Spine Next</td>
<td>Abbott</td>
<td>$60</td>
<td>NA</td>
<td>$0</td>
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<td>October-03</td>
<td>Parallax</td>
<td>ArthroCare</td>
<td>$28</td>
<td>3.7</td>
<td>$8</td>
</tr>
<tr>
<td>May-01</td>
<td>American OsteoMedix</td>
<td>Interpore Cross</td>
<td>$26</td>
<td>2.3</td>
<td>$12</td>
</tr>
<tr>
<td>November-03</td>
<td>Vertelink Group</td>
<td>Medtronic</td>
<td>$22</td>
<td>NA</td>
<td>$0</td>
</tr>
<tr>
<td>June-05</td>
<td>RSB Spine's Cervical Plate Technology Assets</td>
<td>NuVasive</td>
<td>$15</td>
<td>5.3</td>
<td>$3</td>
</tr>
<tr>
<td>February-05</td>
<td>Osteoimplant</td>
<td>Encore Medical</td>
<td>$15</td>
<td>4.3</td>
<td>$3</td>
</tr>
<tr>
<td>October-03</td>
<td>Spinal Specialties</td>
<td>Integra LifeSciences</td>
<td>$6</td>
<td>1.2</td>
<td>$5</td>
</tr>
</tbody>
</table>

Revenue & Enterprise Value in $Millions
Kyphon – St. Francis. Kyphon’s acquisition of St. Francis is often cited as an example of lofty valuation where other factors may have played a role in the determining the acquisition multiple. St. Francis developed the XStop, a novel minimally invasive interspinous process decompression system for treating spinal stenosis. While a large market opportunity (over 400,000 new cases annually), some thought the device may also have application in the $1 billion spinal fusion hardware market. This was clearly a promising technology in the very “hot” spine market where multiple players would have likely been interested in the technology.

Kyphon was beginning to experience a slow down in the growth of its very successful minimally invasive system for treating vertebral body compression fractures. As investors began to question what was next for Kyphon, management sought to diversify and acquire some new growth drivers to leverage the company’s sales force.

The backdrop was set for Kyphon to overpay for St. Francis and our model reveals that they did, but not by as much as others have speculated. The 10.7x acquisition multiple based on forward sales estimate was somewhat misleading, as the financial press downplayed the growth prospects for St. Francis which generated closer to $60 million in CY 2007 sales, implying an actual multiple of 9.1x. Our Selective Company model would have predicted an 8.4x multiple and our Industry Model would have predicted a 7.1x multiple. Most bankers expected St. Francis to sell for 6.5-7.5x, slightly more than the multiple Abbott paid for Spinal Concepts given St. Francis’ differentiated approach and the relatively untapped opportunity in spinal stenosis.

The delta between the acquisition multiple and the projected multiple is attributable to: 1) sales synergies which Kyphon may have built into their model but are not captured in the portfolio diversification approach taken in our models. 2) Different modeling assumptions as Kyphon may have relied on greater growth rates or a faster technology adoption curve in their valuation than was disclosed in the financial press. This may have been justified given the greater than expected 2007 sales. 3) Emotion-driven overpayment for the technology, which would have been expected given the demand for high-growth spinal companies in a strong M&A market and Kyphon’s desire to diversify to sustain its growth.

Medtronic – Sofamor Danek. This is widely regarded as one of the most successful acquisitions in the past decade. Medtronic was seeking to diversify its revenue base in the late 1990’s and, through its footprint in neurosurgery, realized the potential for spinal hardware. Sofamor Danek was the leader in the spinal hardware market with a broad portfolio of fusion devices and surgical navigation systems. In the prior twelve months there had been two other major acquisitions in the spinal space and the orthopedic companies were beginning to express interest in the spine.

Amidst this backdrop, one would have expected Medtronic to overpay for Sofamor Danek. The opposite was true, as it was acquired for 8.2x, less than what would have been predicted by our model. Our Industry Model predicted an acquisition multiple of 10.6x and our Selective Company Model predicted a multiple of 11.8x.

Did Medtronic purchase Sofamor Danek for a discount? Absolutely. The spinal hardware market was in a period of uncertainty following the recall and complications arising from improper training and the aggressive use of pedicle screws. This somewhat tainted the market and raised concerns about the size of the market opportunity, the appropriate patient population, the sustainability of market growth and device adoption. As a result of this uncertainty, Medtronic acquired Sofamor Danek for less than it would have otherwise paid under normal market conditions.
Additionally, given the size of the company and the capital necessary for a deal, there were few legitimate players who could have completed the acquisition. The other leading candidates were busy digesting their own acquisitions at this time. J&J had already acquired a spinal hardware company, AcroMed, earlier in the year and Stryker was busy digesting the Howmedica acquisition. Hence the absence of bidders may have also worked in Medtronic’s favor.

**Biomet – Interpore Cross.** As Medtronic’s bone morphogenic protein was reshaping the spinal hardware market in 2003 and 2004, Biomet sought to further diversify its spine portfolio. It was also seeking access to an artificial disc technology to supplement or possibly accelerate its internal development programs.

Interpore Cross was a diversified spinal hardware company with a strong presence in allograft bone for use in fusion surgery. It also had a solid orthobiologics portfolio, giving Biomet greater exposure to the fastest growing segment of the spinal market. In addition to Interpore’s core spinal fusion hardware portfolio, the company had a strong artificial disc program that was running ahead of Biomet’s internal program’s timeline.

Interpore was growing slightly faster than the market overall, but did not stand out on the basis of its growth profile. The company was acquired for 3.9x sales, in line with the 3.9-4.0x range predicted by our models. Likewise, the financial community and the press believed this transaction was fairly valued. With sales synergies and sales force leverage, the transaction provided Biomet with operational efficiencies and development leverage to justify the deal. This is a case where the acquirer’s due diligence largely reflected market conditions and growth expectations, hence their offer was close to fair value.
IMPLICATIONS

This model provides a general framework for valuing medical device technologies and companies. The factors that influence valuation are universal. How to address those factors to maximize valuation varies by constituent. In this section of this research we explore how entrepreneurs, corporate executives, venture capitalists and public equity investors should consider each of these factors in seeking to 1) maximize the valuation of a given technology or company, 2) sources of leverage/value when making an acquisition, 3) understand risk, and 4) evaluate when making an investment.

The Entrepreneur/Small Company: The obvious question for these the CEO of a startup or growing company seeking to raise capital or sell to a larger player is: “When do I maximize valuation and what can I do to maximize valuation?”

Given the importance of supernormal growth to the EV/Sales model for valuing medical device companies and technologies, it comes down to timing. At what point can you tell a credible story that will convince acquirers/investors that your projected supernormal growth over the industry is achievable and justified.

For the established high-growth firm seeking to be acquired this may coincide with the launch of a new product with greater than expected uptake and share gains. It may also coincide with a CMS reimbursement decision that paves the way for greater than expected adoption or development challenges at a competitor. These are the factors that must be in place to mitigate the risks associated with your company’s projected growth rates.

For example, cardiovascular companies have a low benchmark as both investors and larger companies understand the market and the factors needed to succeed. Strong key opinion leading physician support, FDA clearance, and positive clinical data are sufficient to justify the supernormal growth projections and maximize the acquisition multiple. This has been demonstrated by the vascular closure companies, embolic protection companies, and EP ablation companies. In these cases building a large sales force and administrative infrastructure is actually a detriment to valuation because it creates redundancies for the potential acquirers, which already have large sales forces and do not need that infrastructure to justify proof of market.

The diabetes companies on the other hand need to make such investments. Given the issues associated with procuring retail shelf space and switching patients, it behooves such companies to make the investment. Launching new technologies and gathering product adoption data are critical to justifying proof of market. This is particularly true for first movers with novel technologies, such as drug pumps. Once Minimed and Disetronic validated the market, other companies such as Animas did not have to develop the same infrastructure to be acquired (for an even larger multiple). A similar trend has borne out in minimally invasive blood glucose monitoring, angioplasty balloon catheters, neurostimulation and spine.
All else equal, there reaches a point where once a technology and market have been validated, additional investments beyond proof of concept are no longer needed. In fact empirical evidence of recent transactions reveals that the second or third player in an emerging market sector can often be acquired for a larger multiple than the first-movers, which have validated the technology. This would imply that entrepreneurs and small companies who may not be first to market may be better off investing their limited funds in addressing technology issues and perfecting clinical trials to improve outcomes and demonstrate cost savings rather than rushing to be second to market with a sales force in the hopes of being quickly acquired. Of course this must be balanced by the risk of waiting too long and having another player outflank you on the technology front.

For the entrepreneur raising capital for a pre-revenue venture, it is a more challenging process. If the venture/technology targets an existing market and represents an improvement beyond existing technologies, the bar is lower in comparison to a green field therapy or novel approach. In the case of the incremental technology, the entrepreneur should focus on developing the technology and perfecting the clinical trials to demonstrate improved efficacy and cost-savings, much like the established firm running second or third in the clearance race. These investments generate the highest value in terms of enhancing growth and justifying market penetration and adoption. All else equal this makes a stronger argument for a larger supernormal growth rate to drive valuation than simply rushing to market (timing benefit) with a similar undifferentiated technology. The biggest failures in the industry have been companies like Cyberonics, which have attempted to rush a therapy to market and hype a growth story that lacks solid fundamentals.

For the company pioneering the new market or developing a novel technology, the message is similar: be thorough and invest in validation rather than cutting corners and rushing market. To maximize valuation, these companies need to both justify their supernormal growth argument and thoroughly explain the market opportunity. The model illustrates the importance of market size in determining the multiple. The successful company raising funds will be able to both justify the size of the potential market opportunity and how they will penetrate it in detail. Consequently these companies are best served by investing in the development milestones that will provide proof of 1) concept, 2) product, and 3) market. Again this centers around structuring product development and a trial that will satisfy the data needs of physicians, regulators and payers.

The artificial disc companies were successful at telling this story. Consequently, they were able to command substantial pre-revenue acquisition multiples, though post-sale, post-FDA clearance reimbursement challenges later hampered market development.
When considering fundraising, venture dollars provide the greatest benefit for increasing value over time. Venture investments provide a certain validation of the technology that is associated with higher exit valuations in M&A. Venture funds also provide the capital needed to conduct the large trials necessary to generate value through demonstrating clinical benefit/cost savings versus the standard of care. Of course, this must be balanced against the equity the founders and entrepreneurs must sacrifice. VC financing also facilitates an easier pathway to an IPO.

Public companies have, on average, been able to command higher acquisition multiples than private companies in the M&A process. It is seen as another round of validation of the technology/company, given the regulatory requirements and operational potential necessary to take a company public. Over 95% of device IPOs have FDA approved products, a sales force and are selling product. However, the bar for taking a company public continues to increase. Sarbanes-Oxley legislation had increased the legal burden of being a public company as well as the cost. This must be carefully balanced against the incremental multiple benefits.

**Corporate & Business Development Executives:** Acquirers of novel medical technologies and startups need to balance the risk of overpaying for a technology/company against the risk of losing that property to a competitor. The EV/Sales multiples projected by the models developed in this research represent the maximum an entrepreneur/target can expect to receive for his/her technology/company (assuming normal bargaining and negotiation theory holds). In theory, acquirers should not try to pay more than this projected multiple, unless they realize significant synergies not captured by the model.

Sales synergies are the one element not well captured by this model due to data limitations. As previously discussed, these sales synergies are a key source of value for the acquiring firm. Thus our model can serve as a baseline valuation, which acquiring firms can then adjust for the incremental value provided by their unique sales synergies. These can only be valued by corporate insiders and can vary greatly between acquirers.

The orthopedic companies have been highly effective at valuing such synergies and factoring them into M&A valuations. Clear examples are Zimmer’s valuation of international sales synergies to win the bidding war for Centerpulse and Stryker’s ability to forecast sales leverage and cross-selling opportunities in the Howmedica acquisition. Both companies were able to structure deals (factoring in synergies) for coveted targets and still manage to reap significant financial rewards.

As the counterparty to the targets, large companies are in an effective position to pressure acquisition targets on growth rate assumptions. This is particularly true in relation to the key assumptions underlying our model: industry growth, market size, and supernormal growth. Boston Scientific and Medtronic have been especially effective in employing this strategy in the cardiovascular sector when valuing novel and enabling technologies (AVE, Target, Schneider). On the surface, they have been less effective when purchasing small niche technologies targeting an established market (Percusurge, Interventional Technologies, Cardiac Pathways), where post-acquisition sales of the target’s products and incremental sales leverage seem to have lagged expectations. Empirical evidence suggests that acquirers tend to do best pressuring the industry pioneers or first movers on valuation. They are less effective (and may overpay) for later-stage deals in a new market or acquisitions of additional niche therapies in an established market which may not provide significant sales leverage.
Overpaying is the most significant risk that acquirers face. This has occurred most often when acquirers try to purchase pre-revenue companies or niche technologies. In the case of pre-revenue technologies, most of the large deals (involving novel technologies targeting large market opportunities such as artificial discs and percutaneous heart valves) have encountered clinical, reimbursement, or regulatory issues that prevented the acquirers from achieving the expected value. In this case, emotion drives a fear of being locked out of the market or losing technologies, which makes companies ignore certain risks, overvalue and hence overpay for the targets.

Contrast this with spinal hardware and stenting technologies, which were acquired post-clearance with multiple products selling into established markets. These acquisitions offered much greater returns for the acquirer with much lower risk profiles because the technologies were validated (FDA approved with reimbursement) and market tested (backed by adoption data). Given that these technology land grabs have rarely panned-out as expected, it may be in the best interest of the acquirers (in terms of risk/return profiles) to wait until such novel technologies are approved and validated.

Niche technologies have been a similar disappointment. Acquirers have paid sizable multiples for niche technologies with the expectation that they could realize significant synergies with their existing product lines. Many of these have failed to live up to expectations, such as St. Jude’s acquisition of EpiCor, J&J’s acquisition of Atrionix, and Boston Scientific’s acquisition of BEI Medical. Likewise, single product diversification deals, such as Medtronic’s acquisition of Vidamed, have not worked out as well as multi-product and platform acquisitions such as Medtronic’s acquisition of Xomed. The most successful diversification deals and technology acquisitions have been either multi-application or multi-product companies. Thus should one product or indication fail, additional opportunities exist.

On the other hand, roll-up strategies of discrete technologies have been successful. Having a portfolio of products to flow through a sales force to a single call point or group of physicians provides not only sales synergies, but also hedges against unexpected reimbursement or product clearance issues for a given device. Several players have employed this strategy in the fragmented urology, interventional neuroradiology, oncology, and sports medicine/bracing markets. Additional opportunities exist in small joint reconstruction, cosmetic surgery, and gastro/bariatric surgery. Roll-ups are the one circumstance where one small company acquiring another has worked out well, in an industry where discrete mergers between two small entities have traditionally been less successful.

The key to successful acquisitions and not overpaying is due diligence. Hence it is not surprising to see many of the diversification or niche product acquisitions disappoint both investors and management. When management does not understand the space they are diversifying into or the market dynamics or technology they are acquiring, regulatory, clinical and reimbursement missteps are to be expected. Consequently, these deals do not meet financial expectations and leave management scrambling.

Certain companies like J&J, Medtronic, Stryker, and Zimmer excel at both due diligence and negotiations. These companies also have the clinical, product development, and reimbursement expertise in place to help address problems and properly integrate new ventures. Abbott stands in stark contrast, where many of its device diversifications acquisitions under-perform because the company lacks the internal expertise to integrate and assist a diverse myriad of device technologies. This management expertise is critical. Even a small company like American Medical Systems was able to successfully execute several small
acquisitions in the urology space because management was savvy enough to understand the
drivers of the industry and supernormal growth to identify valuable targets and then address
operational challenges to keep the acquired technologies on track and unlock their value.

**Venture Capital Investors:** The VC community is in a unique position in that it plays both ends
of the spectrum, trying to minimize valuation when making an investment and trying to maximize
valuations on the way out. The model developed in this research offers venture capitalists a
quantitative model for objectively assigning EV/Sales multiples in their valuation models: be it
the discounted sales models they may use when making investments or the exit multiples they
consider when selling to a corporate buyer or planning an IPO.

The take away for the VCs is the same as the corporate buyers: a solid understanding of the
factors that underlie valuation is critical for successful investments. The most skilled VCs will be
able to identify the clinical, regulatory, reimbursement and market adoption challenges
(influencing factor inputs in the model) that an early stage device will face and then negotiate to
secure the investment at the appropriate valuation. As an investor, the successful VCs will then
take the necessary steps to help management develop the technology (address the appropriate
valuation factors) to the point where the potential market opportunity for the product and
projected growth (post-clearance) are maximized.

Financial sponsors are largely in the same boat as VCs. Some (such as Warburg) have been
successful at restructuring companies and executing roll up strategies to spin out strong IPO
candidates. This success has been predicated on an ability to initially assess a company in
terms of the challenges and drivers (market, clinical, reimbursement) that affect growth, then
correct those factors to create value by improving product clearance, reimbursement, and
market adoption prospects. As financial sponsors move up market to larger and more complex
companies (such as Biomet and Bausch & Lomb), achieving turn-arounds on the same scale
could prove challenging.

**Public Equity Investors:** At the end of the line are public equity investors. The models
developed in this research provide public investors with a sense of the maximum valuation at
which one of their investments will likely trade. This is the theoretical target price for an
investment. As with all investors (VCs or financial sponsors), an awareness of the factors that
drive valuation will help public investors focus on the relevant investment considerations. The
most successful medical device analysts/investors are capable of understanding how factors
relate to the industry/markets, and what will drive/sustain a supernormal growth rate.

The public markets introduce a complicating factor in that investors must deal with market
forces that can influence the stock price or make medical device stocks more or less attractive
relative to other industries, impacting valuation. The same forces do not influence the other
constituencies and can result in deviations between valuations predicted by our model and
actual trading levels. The model offers the greatest utility for setting price targets, evaluating
M&A arbitrage opportunities, IPO valuation and valuing merger opportunities, as other
emotional, market, and trading factors can influence the day to day prices of public equities.
PRE-REVENUE TRANSACTIONS

Overview. Pre-revenue company acquisitions have been rare in the medical device industry. Reimbursement challenges are often cited as the major reason for the lack of activity. Novel technologies and new therapeutic approaches are costly and often require dedicated reimbursement codes or special add-on payments. Many of the existing CMS DRG and CPT codes are often inadequate to compensate for the incremental value offered by a new device or novel treatment approach. Thus firms must also undertake cost-benefit studies and include cost/efficiency endpoints in clinical trials to assure they will have the data necessary to obtain reimbursement codes. This adds another dimension of risk to the development cycle.

Without reimbursement, many acquirers often fail to realize their expected returns on the investment, as the long and complex reimbursement process (which often requires additional studies for cost-effectiveness validation to satisfy payers) delays the sales ramp and lengthens the payback period. Consequently proof of market concerns often equal if not trump regulatory clearance concerns for new treatment approaches or novel devices.

Regulatory clearance is cited as the second greatest concern. While the clearance rate for medical device technologies is relatively high (>90%), the scope of the indication approved by the FDA can limit the market potential. This risk is greatest with devices and companies that are pioneering a new method of treatment. The hurdle is less for mature markets such as spinal fusion devices and EP ablation technologies, some of the more active pre-revenue sale sectors.

Valuation expectations and execution risk are the other most commonly cited factors. The venture community often has unrealistic valuation expectations for devices/companies targeting some of the largest medical device markets. Consequently, from the acquirer prospective, it is best to let the VCs bear the burden of commercializing the technology and then acquire the company if/when it experiences a regulatory or reimbursement stumble that delays the sales ramp. This stumble forces the VCs to lower valuation expectations rather than commit more capital and wait out a long recovery period for the situation to hopefully improve. This scenario underscores the execution risk inherent in launching a product, as devices have a more gradual revenue trajectory than drugs/biologics. Assessing the initial launch from the sidelines allows an acquirer to learn more about the market/technology development, and then make a more informed decision about the viability of a company/technology (and appropriate valuation) as problems arise.

Motivations. There are three primary motivations for acting early and purchasing these pre-revenue companies: 1) It may be easier and cheaper for the acquirer to purchase related or synergistic technology and develop it in house rather than purchase at a later date. This may also facilitate regulatory and product development synergies that are not available at a later purchase date. This typifies many of the lower valuation deals. 2) Fear of not acting and losing the target to a competitor. This is true of technology acquisitions where one party seeks to keep a given technology out of the hands of its competitors. 3) Land grabs - situations where a new transformational technology threatens an established market and the market leading firms then compete in a rush to acquire the startups developing that technology.

Portfolio diversification is rarely a reason to act early. Overpaying for a novel technology outside of the acquirer’s domain of expertise that proves challenging to commercialize can be costly. Medtronic’s acquisition of Transneuronix underscores this point. Poor initial clinical trial design required a second trial post-acquisition, delayed the product launch, and resulted in a lower than expected return on the investment.
Acting early to acquire a technology for competitive reasons has been most prevalent in the cardiology sector. Given the substantial value of the large firms’ franchises in cardiac rhythm management, interventional cardiology and cardiac surgery, these companies act quickly to acquire any new technology (incremental or novel) that may shift share in these profitable markets. This dynamic is most clearly evident in the EP ablation and interventional cardiology market over the past several years as Boston Scientific, St. Jude, and J&J have all made several pre-revenue acquisitions in the space to lock up technologies (even without adequate proof of efficacy or concept) to defend their franchises and market shares rather than lose these properties to the competition. Many of these deals ultimately failed to deliver on expectations and in the end were not critical to defending market share.

The definition of a “transformational technology” is subject to interpretation. The device industry has historically grown through incremental innovation, where new more efficacious versions of existing technologies accelerate growth in an existing market. Transformational technologies represent more of a step function or a new layer on the cumulative industry growth curve. These transformational technologies lead to the development of a new market or disrupt or change treatment paradigms in an existing market. Consequently acquirers often create land grab situations and rush to acquire these companies without proper proof of market or efficacy.

For purposes of this analysis, transformational technologies are broadly defined as novel medical technologies that have the potential to pioneer new device markets or medical specialties, significantly change treatment paradigms, and threaten to radically alter market share in established markets. These are not simple next generation product iterations or line extensions. Rather they represent new medical approaches to care that offer the potential to improve patient outcomes, quality of life, or reduce post-procedure complications.

Clearly novel technologies such as an endolumenal sleeve for the treatment of obesity are considered transformational technologies. This device opens a new market with a novel procedure that threatens established device and surgical treatment approaches. Likewise spinal fusion hardware, neurostimulation devices and coronary stents were all transformational technologies at one point. Conversely, alternative bearing surfaces for reconstructive hips, minimally invasive treatment approaches targeting existing procedures, or new delivery instrumentation for existing devices are not transformational.

Likewise, we consider drug coated stents to be transformational technologies rather than a line extension. This technology can be considered transformational because it involves establishing new reimbursement coding, going through a new regulatory pathway at the FDA, integrating various medical disciplines and changing treatment paradigms in a significant portion of the stent market. In a similar vein (or artery in this case), interventional heart valve technologies represent a transformational technology in that they are shifting heart valve replacement from the cardiac surgeon to the domain of the interventional cardiologist and will likely require new or amended reimbursement coding.

In the context of valuation, transformational technologies are anything that causes us to rethink existing valuation frameworks. This is obvious when trying to gauge the risk profile of a new device targeting a new market opportunity. Yet it is more challenging to appreciate this subtlety when trying to differentiate between 1) a new product targeting a similar or slightly different indication versus 2) a technology that can significantly alter the marketplace. Both have substantially different risk and return profiles. The former piggy-backs existing reimbursement codes and requires less market validation. The latter is the equivalent of a green field
opportunity or launching a new technology, which may require proof of concept, market and commercialization. Hence the approach to valuing these technologies in terms of discount rates, multiples, and comparables may vary substantially. Consequently, acquirers often overpay for the second group of companies as they may not fully understand the value drivers, factors governing market adoption, or the appropriate valuation frameworks.

**History.** Between 1996 and 2007 40 pre-revenue startup companies were purchased at a median enterprise value of $60 million. For purposes of this analysis, enterprise value included total transaction payments assuming all milestones were met and all milestone payments were received. Thus the acquirers purchased the targets in the belief that development would proceed as planned, not structuring the deal to miss a milestone in the hopes of obtaining the targets at a cheaper price. The following tables provide summary statistics of the major pre-revenue transactions completed over the 11 years of this study.

**Pre-Revenue Medical Device Transactions**

**Deal Statistics**

<table>
<thead>
<tr>
<th>Number of Transactions</th>
<th>40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Deal Value</td>
<td>$60 million</td>
</tr>
<tr>
<td>Largest Transaction</td>
<td>$375 million</td>
</tr>
<tr>
<td>Smallest Transaction</td>
<td>$2.6 million</td>
</tr>
<tr>
<td>Average</td>
<td>$94 million</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>$111 million</td>
</tr>
</tbody>
</table>

**Deal Size.** Partially owing to both risk profile and product lifecycle issues, most pre-revenue acquisitions in the medical device industry have not commanded significant enterprise valuations. Forty percent of the transactions (18/40) in our study were completed at an enterprise value of less than $50 million. Twelve of these transactions were small start-ups developing synergistic devices which were best combined with large portfolios to achieve clinical development synergies. Many of these technologies were targeting the interventional cardiology market. The remaining six transactions were development stage technologies transferred from one mature company to another.

Of the remaining transactions, 15 were completed in the $50-200 million valuation range and 7 were in the $200-375 million range. These were all classic technology acquisitions, in which larger industry players acquired a startup developing a disruptive technology that targeted an established market in which the larger players competed.

Note that deal size reporting and hence this analysis may be biased toward the larger transactions reported in the press and covered by the major database services. This analysis was forced to exclude four transactions with incomplete datasets from our regression, all were sub-$100 million enterprise value transactions.

The following table illustrates the number of pre-revenue acquisitions by enterprise value. Note that the data are not normally distributed.
Sector. There has clearly been a sector bias to the pre-revenue acquisitions in the medical device industry. Unlike pharma and biotech, where compounds and companies have been purchased across all sectors and therapeutic classes, pre-revenue transactions have occurred in only 10 of the roughly 33 sub-sectors of the medical device markets. The common thread amongst them - all but one are high growth, high margin sectors with rapid device evolution.

The majority of pre-revenue transactions (16) have occurred in the interventional cardiology and stent markets. The rapid rate of product adoption, rapid market share shifts, IP landscape, rapid product development cycles, and clinical trial synergies are the primary motivating factors for the large industry players. Given the initial success of these acquisitions and the larger companies' skill at developing/commercializing these technologies, there has been an increasing willingness among these companies to consider pre-revenue acquisitions within their domain of expertise.

Pre-revenue acquisitions of spinal device companies are more representative of a technology land-grab than a pre-planned development effort. Four of the seven pre-revenue transactions were part of a rush to lock up spinal disc technology, which occurred in a span of 16 months. This is further discussed in the pre-revenue case studies below. The success of these transactions will determine the extent to which the orthopedic companies conduct additional pre-revenue acquisitions.

Among the other sectors represented, heart valves and endovascular AAA devices are representative of land-grab acquisitions in promising new markets. The electrophysiology and
cardiac rhythm management acquisitions are more representative of technology acquisitions within the acquirers' domains of expertise.

The neurostimulation deal, Medtronic's acquisition of Transneuronix, was a technology play to lock up a leading development stage therapy outside of Medtronic's domain of therapeutic expertise.

The Dental, Minimally Invasive Surgery and Urology deals were all technology acquisitions in sectors in which the acquirers already competed.

The following table summarizes transactions by sector.

**Pre-Revenue Device Acquisitions By Sector**

<table>
<thead>
<tr>
<th>Sector</th>
<th>Number of Transactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI Surgery</td>
<td>1</td>
</tr>
<tr>
<td>Urology</td>
<td>1</td>
</tr>
<tr>
<td>Dental</td>
<td>1</td>
</tr>
<tr>
<td>Endovascular AAA</td>
<td>3</td>
</tr>
<tr>
<td>Cardiac Rhythm Management</td>
<td>3</td>
</tr>
<tr>
<td>Neurostimulation</td>
<td>1</td>
</tr>
<tr>
<td>Stents</td>
<td>5</td>
</tr>
<tr>
<td>Spine</td>
<td>7</td>
</tr>
<tr>
<td>Interventional Cardiology</td>
<td>11</td>
</tr>
<tr>
<td>Valves</td>
<td>4</td>
</tr>
</tbody>
</table>

Annual Trends. Note the frequency of these transactions is increasing over time as seen below. This is reflective of 1) a more challenging and variable IPO market, 2) the increased cost of taking a company public in the Sarbanes Oxley era, 3) the number of potential acquirers is increasing, 4) the maturation of several major products and markets, which has increased the need for new sources of incremental revenue to sustain revenue and EPS growth rates at the ultra-large medical device companies. Note that the level of acquisitions could have been higher in 2006-2007 if the IPO market had not improved, providing an alternative exit strategy for six firms that likely could have otherwise been sold to strategic buyers.
Pre-Revenue Factor Analysis

The results of our regression analysis confirm our hypothesis that other factors (both industry and company-specific) may play a greater role in explaining the value of pre-revenue transactions (on a dollar basis) than those factors that proved valuable in our other models for revenue-stage companies. Given the different challenges pre-revenue companies face in terms of proof of concept, proof of product, proof of market, FDA risk, financing risk, and execution risk, this is not surprising.

The statistical significance of potential profit margins in our analysis makes intuitive sense, given that discounted cash flow valuations are one of the more common techniques employed in valuing these pre-revenue transactions. Additionally, profitability speaks to the value of the underlying technology in terms of its clinical efficacy, reimbursement, market adoption potential, and future scale of the business. Margins are also a function of the company’s projected sales and cost structure, speaking to executional issues expected following the launch of a product. This significance may be just a casual relationship, as there does not seem to be a consistent valuation contribution from a 1% incremental profit margin across the industry.

It is not surprising that venture financing was also a statistically significant factor in our regression analysis. Venture firms have already done significant due diligence (debatable by firm) and identified what are arguably the most promising opportunities. In this case 29 of the 40 pre-revenue acquisitions were venture financed. Thus it is not surprising that most promising medical devices would be purchased during the development stage by large firms seeking new growth engines or seeking to defend market share. Consequently, these transactions
dominated the upper end of the valuation spectrum. Additionally, venture firms are willing to market any success of their portfolio companies in search of an exit, with their track record/pre-vetting arguably helping valuation. The combination of these factors is not surprisingly correlated with valuation levels.

As with the other models, venture financing is more of a casual than a causal relationship. The statistical significance of this variable speaks to the common underlying characteristics of the venture back companies rather than the stamp of VC funding itself. A more detailed analysis of these factors may provide a better model for valuing pre-revenue transactions.

It was surprising to see that neither supernormal growth nor sector growth were significant factors in the model. This is in part owed to the general homogeneity of the supernormal and sector growth rates of pre-revenue transactions, which were in a much tighter range than the other models. Due to this homogeneity across the valuation spectrum, these were some of the weakest factors in terms of both explanatory power and statistical significance.

Likewise, market size did not offer much in terms of explanatory power. Interestingly market size had a negative regression coefficient, implying that larger markets were worth less than small markets. This is more reflective of the fact that emerging technologies and new treatments (where markets may be small today) hold significant long term potential and command higher valuations than me-too or follow-on devices in a large existing market. This also supports the theory that valuation should be forward-looking.

It is clear that other underlying factors are driving much of the value of pre-revenue acquisitions and that this is not a reliable model for forecasting valuation. Clinical data, management team, market potential, projected market share, three to five year sales, and synergies are all other factors that may be influencing valuation. A more detailed study of the quantitative representations of these variables could offer greater explanatory value. Varying acquirer discount rates and timing assumptions can create substantial variation in enterprise value that can not be captured in our analysis. Analysis of the history and motivations of pre-revenue acquisitions also reveal that emotional factors play a significant role in the decision to purchase these companies. Given that this emotional component is not consistent across deals or acquirers, it is not surprising to discover that our objective multifactor model does not offer much value in explaining the enterprise value of these pre-revenue acquisitions.

PRE-REVENUE CASE STUDIES

**Artificial Discs.** The artificial disc market typifies a land-grab style series of pre-revenue acquisitions. Artificial discs were perceived to be a novel, disruptive technology in the spinal hardware market which threatened the market share and profits of the largest players. At greater than 34% incremental operating margins, these franchises are highly lucrative to the large companies. Hence established players were willing to take chances on early-stage acquisitions to defend market share and profits.

Artificial discs are implanted between the vertebrae to replace a patient’s damaged native intervertebral disc. This disruptive technology had the potential to significantly expand the size of the spinal hardware market by 1) introducing instrumentation into the 400,000 annual procedure U.S. discectomy market and 2) serving as a replacement for spinal fusion technology in certain cases. The spinal fusion hardware market was $1.2 billion in 2003, roughly a quarter to third of which was thought to be at risk of substitution from artificial disc technology.
The spinal hardware companies had made significant investments in locking up hospitals and surgical centers with discounted committed volume contracts, practice support programs, and practice startup programs. Given the increasing commodity like nature of the fusion technology, spinal hardware was becoming a relationship and service sale. The only threats to market share in this model are sales rep turnover and new disruptive technologies.

Artificial Discs were first developed and commercialized in the early 1980's, however the initial generation devices failed to demonstrate long-term efficacy. With improvements in design, materials, implant techniques, and instrumentation, the third generation of artificial discs began to show clinical promise in the early-2000s. That generation of devices demonstrated clinical efficacy similar to instrumented fusions, which illustrated the commercial promise. This occurred at a time when the long-term efficacy of fusion was called into question and surgeons were exploring non-fusion technologies.

Amidst this backdrop, the large players in the spine market were motivated to acquire pre-revenue artificial disc companies in an effort to secure this promising new technology. While the devices were backed by early clinical data, the long-term efficacy and the reimbursement situation remained uncertain. Additionally the market (and potential acquirers) were working under the assumption that these devices would command premium prices upon launch.

The following table illustrates the chronology, prices paid and expected FDA clearance timelines for the four major pre-revenue artificial disc transactions.

<table>
<thead>
<tr>
<th>Date</th>
<th>Target</th>
<th>Acquirer</th>
<th>Enterprise Value of Target ($ Million)</th>
<th>Expected FDA Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 28, 2002</td>
<td>Spinal Dynamics</td>
<td>Medtronic</td>
<td>$269.5</td>
<td>Q3 2005</td>
</tr>
<tr>
<td>February 6, 2003</td>
<td>Spinal Solutions</td>
<td>Synthes-Stratec</td>
<td>$350.0</td>
<td>Q4 2004</td>
</tr>
<tr>
<td>May 6, 2003</td>
<td>Link Spine Group</td>
<td>Johnson &amp; Johnson</td>
<td>$325.0</td>
<td>Q3 2004</td>
</tr>
<tr>
<td>July 21, 2004</td>
<td>SpineCore</td>
<td>Stryker</td>
<td>$360.0</td>
<td>2008</td>
</tr>
</tbody>
</table>

Prior to FDA clearance of these devices, companies were essentially in an arms race, with the value of each transaction generally increasing despite the greater time to market and increased development risk associated with each subsequent transaction. The other players in the spine market either chose to develop discs internally at this time (Zimmer) or acquired a technology through broader acquisition (Biomet's acquisition of Interpore Cross), avoiding this costly arms race.

While the values of these transactions may seem extreme on the surface (at least for the medical device market), the logic was seemingly justifiable at the time. With cannibalization of instrumented fusion procedures and the use of the discs in previously uninstrumented discectomy procedures, discs were thought to be a $1 billion plus market capable of growing.
10% annually by 2010. Under the assumption that each player could capture roughly 20% market share, that would conservatively translate into roughly $200 million in incremental annual sales. Even assuming a conservative 6x multiple on forward sales in 2008-2009 and discounting that back five years at a conservative 30% venture-like discount rate, the present value of these companies in 2003-2004 was roughly $325 million.

The acquisition spree stopped when, following FDA clearance of the first devices, CMS did not provide incremental reimbursement for the artificial discs. The clinical studies were not powered to demonstrate clinical improvement versus fusion, hence justifying incremental reimbursement proved challenging. Consequently the market developed much more slowly than expected and the underlying assumptions used to justify these pre-revenue acquisitions were invalidated.

Interestingly, pre-revenue transactions in the spine market largely evaporated after the disc market failed to develop as expected. While other promising new technologies, such as improved nucleus replacement systems and dynamic stabilization systems have emerged, the large spinal players have yet to make any additional pre-revenue acquisitions. This poses an interesting question for additional research – what are the factors (board concerns, public investor pressure, development concerns, valuation, etc.) that have prevented the large companies from pursuing additional acquisitions. This stands in stark contrast to their large pharmaceutical and biotech counterparts, which are more willing to pursue early-stage deals despite setbacks and failures.

**Percutaneous Heart Valves**

Replacement heart valves are an $800 million annual market which is growing roughly 4-5%. While largely a mature market, operating margins on these products approach 50% versus the low-30% range for most other implantable medical devices. The market is transitioning from mechanical valves requiring lifelong anticoagulant therapy to tissue valves (which do not require anticoagulants) as the growing long-term survival data support use of tissue valves in younger patients. This segment of the market is growing at roughly 10% annually. Edwards Lifesciences, which has the best long-term tissue valve survival data, is the leader in this segment with roughly 45% share.

Long-term data and product performance are the key drivers of market share, given the life-saving nature/critical function of the valves. Ease of implantation and instrumentation are important, given the invasiveness of the procedure and generally poor health of the patients. While sales rep relationships are somewhat important (especially in mechanical valves which are more commodity oriented), long-term data and product features are the key to growing/sustaining market share.

Percutaneous heart valves, implanted through catheter-based technologies like coronary artery stents, were a disruptive technology that threatened the landscape of the heart valve market. Several startup companies were developing catheter-based systems that would simplify the delivery of aortic valves. These devices offered the potential to cannibalize existing valve procedures (aortic valves represent roughly 55% of the roughly 300,000 annual valve procedures) and expand the market by treating the roughly 20,000-30,000 patients annually contraindicated for conventional valve replacement. While these systems initially required specially designed valves, it was theorized that existing valve designs, particularly tissue valves, could be adapted to these platforms.
When Percutaneous Valve Technologies demonstrated proof of concept in animals and initial human cases, the large valve players (Edwards, Medtronic, and St. Jude) took notice. Both industry pundits and cardiac surgeons began to speculate that this technology could transform the valve market just as stents changed bypass surgery. It appeared as if another technology land grab was inevitable, as five venture backed firms had promising technology at the time.

Edwards was the first to move, acquiring Percutaneous Valve Technologies, the most advanced catheter-based program, for $125 million. Then as news of device-related complications surfaced, it appeared that lengthy clinical trials would be needed to validate the technology for both FDA clearance and market adoption by cardiac surgeons (who were still skittish after a major heart valve failure/recall in the mid 1980's). At this time it appeared as if percutaneous valves would be more of a therapy of last resort for patients contraindicated for surgery than a first line therapy.

This effectively put an end to any potential technology land grab of pre-revenue valve companies for substantial valuations similar to the artificial disc market. Even traditionally optimistic venture capital investors acknowledged that the burden of commercialization would likely fall on their companies following the release of the device complications. Hence with the exception of Edwards's purchase of EV3’s percutaneous mitral valve repair program for a nominal price, activity in this therapeutic arena was stalled until Hansen Medical’s Acquisition of AorTx in 2007. Those familiar with the industry feel that the $40 million price paid is much reflective of Hansen’s need for revenue diversification and growth drivers than any material improvements in the value/promise of the underlying percutaneous valve technology.

The following table summarizes the major pre-revenue transaction in the percutaneous valve market.

### Pre-Revenue Acquisitions of Percutaneous Valve Companies

<table>
<thead>
<tr>
<th>Date</th>
<th>Target</th>
<th>Acquirer</th>
<th>Enterprise Value of Target ($ Million)</th>
<th>Expected FDA Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 15, 2003</td>
<td>Precutaneous Valve Technologies</td>
<td>Edwards Lifesciences</td>
<td>$125.0</td>
<td>2006</td>
</tr>
<tr>
<td>September 29, 2004</td>
<td>EV3’s Percutaneous Mitral Valve Repair</td>
<td>Edwards Lifesciences</td>
<td>$15.0</td>
<td>2008 +</td>
</tr>
<tr>
<td>November 1, 2007</td>
<td>AorTx</td>
<td>Hansen Medical</td>
<td>$40.0</td>
<td>2010</td>
</tr>
</tbody>
</table>
Practical Recommendations for Valuing Pre-Revenue Companies

A multi-factor model for forecasting the enterprise value (in dollars) of pre-revenue companies is not feasible based on our available dataset. While the limited dataset and abnormal distribution of the enterprise values of pre-revenue transactions pose statistical challenges to developing a regression model, non financial factors affecting the value of these companies pose another challenge to developing a reliable model. Consistent with our hypothesis, difficult to value synergies, emotional factors, and varying acquirer discount rates and risk tolerances play a significant role in determining the enterprise value for these pre-revenue companies.

Many of the factors not captured by our model (including development synergies, combination therapy development, regulatory expertise, and competitive/strategic benefits) play an important role in determining the value of pre-revenue companies. A model incorporating these variables may offer improved power in explaining the variation in the enterprise value of pre-revenue companies. Such data were not available for this analysis and represents an area for future research.

Other techniques such as discounted revenue multiple approaches, Monte Carlo analysis, and modeling simulations are better suited for valuing pre-revenue companies. These approaches allow the acquirers to factor in unique circumstances and synergies that can not be captured in our multifactor model to forecast transaction dollar values. Additionally these alternative techniques allow the acquirers (or investors) to make their own assumptions about discount rates and financing options.

It is clear that valuation of pre-revenue companies can also be significantly influenced by market conditions and emotion. As our case studies reveal, the fear of losing a target or the need to acquire a technology for competitive reasons can play a role in determining the valuation. In many cases this can mean an acquirer will overpay for a target. This emotional component is another reason a simple multifactor model may not be reliable and accurate for determining a transaction enterprise value for pre-revenue companies.
FUTURE RESEARCH

Several additional hypotheses emerged from this thesis as possible areas for future research. They are listed below:

1. How effective are diversification strategies in accelerating top-line and earnings growth rates in the medical device industry?

2. What are some useful factors that govern large companies' decisions to invest in novel technologies or pre-revenue companies targeting new therapeutic markets?

3. How do emotional factors influence the valuation of technologies and companies in the medical device industry?

4. What is the value of intellectual property in the medical device industry?

5. Which types of patents create the greatest value for medical device companies?

6. What factors are important in securing reimbursement for new medical device procedure codes at CMS?

7. How do reimbursement rates impact the valuation of medical device companies?

8. What role does procedural profitability play in the adoption of new technologies at the hospital?

9. What are successful strategies for increasing IPPS and OPPS reimbursement codes over time?

10. Can add-on payments be converted to new codes or added to existing codes and what factors would CMS consider in such a decision?

11. What factors govern the pricing of Medical Device IPOs and to what extent do they differ from the findings of this research?

12. What are successful clinical trial designs for both obtaining FDA approval and securing reimbursement? Under what circumstances are post-market reimbursement studies more effective than concurrent studies?
VI. CONCLUSIONS & RECOMMENDATIONS

Valuation is subjective. Ten investors or strategic buyers can analyze a target and come up with 10 different valuations using 50 different valuation methodologies. This research has hopefully provided the reader with a sector-neutral understanding of the factors that influence valuation and how they can address those factors to enhance the value of their company/technology. The models developed in this thesis provide an accurate framework upon which all constituencies can develop an independent/ portfolio diversification valuation of a company/technology, which they can then adjust to their unique circumstances.

The EV/Forward sales multiple is widely used for valuing medical device transactions due to its ease of use/lack of detailed assumptions and its transportability/comparability across different sectors of the industry. Consistent with the author's hypothesis supernormal growth is one of the most important factors (statistically significant and relevant) in determining EV/Sales multiples for medical device companies, as confirmed by regression analysis. This factor not only underscores the company/technology's ability to capture value, but also speaks to the quality of the technology, regulatory strategy, clinical data, reimbursement expectations, and market adoption, as all of these underlying factors play a critical role in forecasting forward sales.

Market size and sector growth, as hypothesized, are also significant factors in determining EV/Sales multiples. Sector growth speaks to the attractiveness and strength of the underlying market and the overall growth prospects of a technology/company. Market size addresses the scope of the opportunity being evaluated. All else equal, larger markets are more valuable than niche markets because they provide the opportunity to achieve more synergies (sales, development, technical or otherwise).

Consistent with our expectations, other important factors include sector beta (proxy for risk/return), venture funding or IPO (external validation), and position in market (scale and competitive position). Sales model (direct versus distribution) was significant in the Selective but not the Industry model, though most acquirers acknowledge that a direct sales force is more highly valued than a distributor network.

Contrary to our hypothesis and industry convention, the existence of sales synergies was not a significant factor. This finding represents a data shortcoming in our methodology in that we could not obtain actual forecasted sales synergies by transaction and were instead forced to use a binary variable. In practice, this is a critical variable considered in all transactions, as acquirers typically value synergies in their deals but the process lacks external transparency for competitive reasons.

Combining these factors we are able to develop an effective multifactor model for predicting the appropriate EV/Sales multiple for valuing a medical device company/technology. Both models (industry and selective) developed through this research were 96%+ accurate at predicting the acquisition values of medical device transactions completed in 2008. This strong correlation demonstrates the utility of the model for entrepreneurs, venture capitalists and corporate/business develop executives in providing an objective baseline valuation when evaluating medical device companies and technologies.

Each constituent can then adapt the model for any unique synergies or value they may bring to a target entity. This is an independent, quantitative approach to assigning an EV/Sales multiple...
that removes the subjectivity traditionally associated with attempting an EV/Sales valuation. It can be a powerful (and accurate) tool to use in tandem with other valuation approaches.

Armed with an understanding of the factors that drive valuation, as identified by this research, the relevant constituents can then invest resources to maximize the valuation of a given company/technology.

While our model is effective for valuing companies with revenue projected during the next year, valuing pre-revenue companies remains a challenge. This research attempted to adapt the relevant factors into a multifactor model for predicting the enterprise value of pre-revenue acquisitions. Consistent with our hypothesis, transaction values in absolute dollars are not a constant benchmark like multiples and the individual circumstances surrounding each transaction make such an approach impractical.

Multiples do play a role in the valuation of pre-revenue companies. They are used to value future sales, cash flow, or other metrics, which are then discounted back to the present value to obtain a final enterprise valuation for the firm. In many cases the multiples used for this purpose are the same multiples used to value firms with revenue. Hence our model offers utility for predicting enterprise value at a given point in the future. Without access to future valuations, timing assumptions, and discount rates, it is difficult for us to prove the efficacy of this approach.

This research provides a sector independent approach to identifying the factors that influence valuation in the medical device industry and combines those factors into a model that can provide all parties with an accurate and objective neutral-stance valuation. Each constituent can then make independent adjustments to his model to account for unique synergies or identify the factors through which they may enhance the value of a product/company. This practical approach to valuation provides a baseline for negotiations for all those involved in medical device investments/transactions.

This research has concluded that 1) supernormal growth, market size, sector growth, position in market and venture financing are useful variables in explaining the EV/Sales multiples of mergers and acquisitions in the medical device industry. 2) The regression models developed through this research offer a high degree of accuracy in prospectively forecasting the EV/Sales multiple of mergers and acquisitions in the medical device industry. 3) The factors that are useful in determining EV/Sales multiples of revenue-stage companies offer little value in explaining the enterprise value of pre-revenue transactions.
References


Databases


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