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KEYS TO
CREATING VALUE
FOR EARLY-STAGE
MEDICAL DEVICE
COMPANIES

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Medical Device Valuations

Keys to Creating Value for Early-Stage Medical Device Companies

Small caps that exit successfully via M&A tend to share characteristics that enable significant value creation. Start-ups can use them as a template to gauge their own potential for success.

By Richard Ferrari

The 1999 sale of **Perclose Inc.** to **Abbott Laboratories Inc.** for \$680 million on sales of approximately \$50 million established an upper threshold for maximizing value of a medical device company. Perclose, which developed a novel suture technology, ran an especially efficient operation: over its seven-year pre-acquisition history it raised approximately \$23 million in venture capital, another \$54.5 million from an IPO and a follow-on offering and generated a hefty 12x multiple of sales on the acquisition by Abbott. Similarly, **VidaMed Inc.** (acquired by **Medtronic Inc.**), **CardioThoracic Systems Inc.** (CTS; bought by **Guidant Corp.**), **Oratec Interventions Inc.** (an absorbed division of **Smith & Nephew PLC**), and **PercuSurge Inc.** (acquired by Medtronic) all generated exit values, in most cases post-IPO, ranging from \$225 million to \$350 million on less than \$50 million in sales.

The exit values for those five firms make them stand-outs among the universe of small cap medical device companies. Importantly, they possess a common set of characteristics that enabled significant value creation and their successful exit through M&A. Indeed, those characteristics, which include the development of a novel, best-in-breed technology with significant clinical impact, having a set of products that deliver a competitive edge, and careful execution of their respective business plans (including managing capital and timelines), can serve as a template for early-stage medical device companies, and help define the parameters necessary for

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them to engineer their way towards an outcome that maximizes value. Companies that are able to hit the mark in all or most of those categories can expect the greatest rewards.

That is not to say that every start-up has to hit the ball out of the park, however. Start-up's can still achieve a successful exit for early investors even though their achievements only reflect a few of the key characteristics; the key is to know how far to continue development and how much to expect for their efforts. Indeed, one crucial element of success is to know what window of time is required for a company to validate its work and blossom.

The Seven Common Characteristics

The five benchmark companies noted above all had significant market caps—above \$200 million—and their acquisition prices occurred at high multiples of sales. (See *Exhibit 1*.) Other companies have maximized ROI for their early investors with exits at lower values in absolute dollars owing to a smaller amount of capital invested. In general, these exits occurred earlier, prior to demonstrating clinical impact, sales revenue, and sustainability. (See *Exhibit 2*.)

Although no single characteristic is enough to maximize value, experience suggests a combination of certain key characteristics is required to generate an exit value above \$200 million. The five successful companies, for example, grade highly in most if not all of the success-enabling activities. Even VidaMed, which for years fell short on execution, stumbled until it brought in a hard-nosed president and CEO, Randy Lindholm, who had spent more than 15 years at General Electric Co.'s GE Medical Systems. Eventually (after 11 years), it obtained a good exit because of the clinical impact, novelty, and need for its first-in-class product line of minimally invasive

Benchmark Companies*

EXHIBIT 1

Company	Clinical Impact	Franchise Value	Strategic Need	Execution	Capital	Sustainability	Years To Acquisition	Exit (Value, acquirer)
Perclose	Substantial	High	High	Excellent	VC-\$23 million; IPO-\$34.74 million (also \$19.7 million follow-on offering)	High	7	IPO, acquired (\$680 million, Abbott)
VidaMed	Substantial	High	High	Average	VC-\$21 million; IPO-\$20.8 million (also \$4.3 post-IPO private placement)	High	11	IPO, acquired (\$326 million, Medtronic)
Cardio-Thoracic Systems	Medium	High	High	Excellent	VC-\$5.6 million; IPO-\$74 million	High	4	IPO, acquired (\$313 million, Guidant)
Oratec	Medium	High	High	Excellent	VC-\$36 million; IPO-\$52 million	High	7	IPO, acquired (\$310 million, not including a prior \$9.2 million investment by acquirer, Smith & Nephew)
Percu-Surge	Substantial	Medium	High	Excellent	VC-\$53.75 million	Medium	5	Acquired (\$225 million, Medtronic)

*These rankings are informal and based solely on De Novo observations.
SOURCE: De Novo Ventures; Windhover's *Strategic Intelligence Systems*

radiofrequency devices for benign prostatic hypertrophy (BPH).

Nor are the seven parameters comprehensive of those things a company must achieve. It's difficult to understand how a franchise can be created and a sustainable business maintained without a strong intellectual property position, for one thing. Other characteristics are similarly implied. While physician adoption, for example, is not considered a separate characteristic, it is without question a critical underlying element and an intimate part of having successful clinical impact.

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Clinical Impact

Clinical impact is a fundamental characteristic and the most important benchmark for success of a medical device company. Almost all firms that generate premium M&A exits have products that fundamentally alter the pre-existing practice of therapy or diagnosis. Take Perclose, whose suture catheter provides a novel method for closing a femoral access wound. Perclose fundamentally changed the clinical thinking and challenged the standard of care in the cardiac cath lab (pressure with sandbags). The improvements in patient care, comfort and cath lab efficiency were immediate. A new way of thinking emerged, creating an entirely new market.

CTS similarly challenged the standard method of performing bypass surgery and pioneered a new market. It created a technology and procedure that enabled coronary artery bypass surgery to be accomplished while the heart remained beating, with attendant advantages to the patient and overall cost savings to the hospital. (Because the procedure was difficult and time consuming for surgeons, however, with roughly equivalent results to the standard of care, off-pump bypass surgery only captured about a third of the market.) Oratec, with its heat-generating catheter for treating back pain, was more successful in driving change in clinical practice and expanded the market for its acquirer, Smith & Nephew, as did PercuSurge's embolic protection device for Medtronic.

An acquirer willing to pay a premium multiple of sales more often than not will require best-of-breed, clinically validated products. Each of our benchmark companies had the resources to run clinical trials and establish its clinical impact. But management and directors may also rightly decide not to invest the capital nor take the time needed to clinically validate a technology, instead choosing an earlier exit. **Atrionix Inc.**, for example, had only generated equivocal data on its catheter-based system for treating atrial fibrillation at the time of its acquisition by **Johnson & Johnson's Cordis Corp.** But because Cordis badly wanted to expand its franchise, Atrionix decided only four years after its founding to accept a buyout at a multiple of just under six. On the other hand, having a best-of-breed technology is not prerequisite if an early-stage company is successful in other aspects. **Boston Scientific Corp.'s Enteric Medical Technologies Inc.** was able to generate more than a 10x return primarily based on the novelty of its approach to treating gastroesophageal reflux disease (GERD) and the size of the GERD market.

Franchise Value and Strategic Need

The industry first began talking about franchise value in the mid-1990s, a time of robust M&A activity in medical devices, as elsewhere. The premiums paid to companies could not be

Companies with Shorter Exit Routes*

EXHIBIT 2

Company	Clinical Impact	Franchise Value	Strategic Need	Execution	Capital	Sustainability	Years to Acquisition	Exit (Value, acquirer)
Enteric Medical	Medium	Medium	Medium	Good	VC-\$12 million	Medium	3	Acquired (\$124 million, Boston Scientific)
Vascular Science	Medium	Medium	High	Excellent	VC-\$10.5 million	Medium	3	Acquired (\$95 million [including milestone payments], St. Jude)
Embolic Protection	Medium	Medium	High	Excellent	VC-\$12 million	Medium	2	Acquired (\$75 million, Boston Scientific)
AneuRx	Medium	Medium	High	Excellent	VC-\$14 million	Medium	2.5	Acquired (\$75 million, Medtronic)
Atrionix	Medium	Medium	Medium	Good	VC-\$11 million	Medium	4	Acquired (\$62.8 million, J&J/Cordis)

*These rankings are informal and based solely on De Novo observations.

SOURCE: De Novo Ventures; Windhover's *Strategic Intelligence Systems*

modeled by traditional methodologies because CEOs, bankers, and acquirers needed a means to describe or justify the higher value and multiples being applied.

Franchise value implies that a company's technology and the resulting clinical application are in fact novel and clearly the best of breed. In almost all cases, companies with high franchise value are the first to market in an entirely new category. They establish a dominant presence and

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create a new clinical franchise. The recent acquisition of **Advanced Bionics Corp.** by Boston Scientific generated a 9x multiple of sales (not including earn out) based largely on franchise value.

A second critical value driver is strategic need. Technologies that may seem strategic from one point of view may not be seen in the same light by an acquirer, and vice versa. More often than not, strategic need is about creating an edge against competition, either by strengthening a patent portfolio or by preventing others from acquiring the IP. Other reasons may fall into the category of broadening a product line or increasing the efficiency of the sales force to maximize the revenue per procedure from each sales call.

Strategic need can create value by way of a competitive threat or offensive move against a competitor. Sometimes the value placed on a technology and company by an acquirer is simply due to the fact that the acquirer is looking forward as a way to protect and preserve its core business. (Recent cases in point: Boston Scientific's acquisition of **Advanced Stent Technologies Inc.** (AST), for IP and to protect its competitive edge, as well as **St. Jude Medical Inc.**'s acquisition of **Epicor Medical Inc.** and **Stryker Corp.**'s acquisition of **SpineCore Inc.**)

On the surface, franchise value and strategic need (the extent to which an acquisition furthers the long-term goals of the acquirer) are quite similar. But it's difficult to find high premiums being paid on strategic need alone. Among recent M&A technology plays, J&J's January 2001 acquisition of Heartport Inc. for \$81 million was, like Boston Scientific's takeout of AST, driven by a compelling need to lock up competitive IP; the acquisition of **Percutaneous Valve Technologies Inc.** (PVT) by **Edwards Lifesciences Corp.** for \$125 million netted a good multiple given PVT's equivocal clinical data; while the purchases by Medtronic Inc. of **TransVascular Inc.** and **Coalescent Surgical Inc.**, each for approximately \$60 million, barely got investors out with a gain.

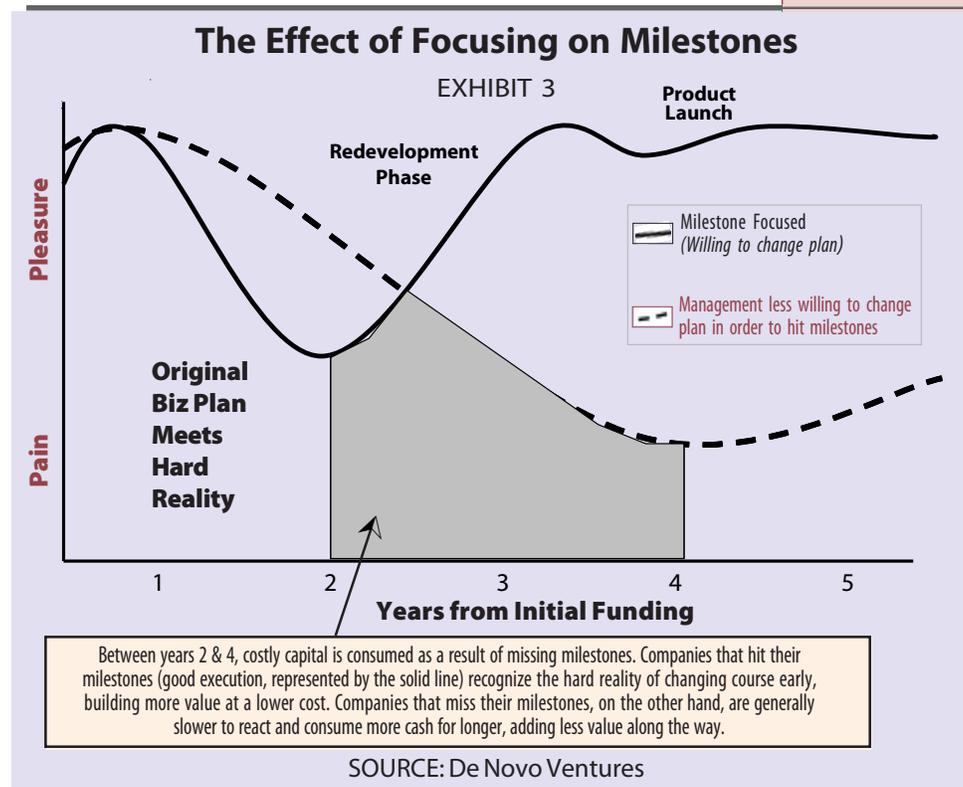
For the most part, companies that are still emerging and only beginning to establish the other key characteristics command lower exit values. The combination of clinical impact, franchise value, strategic need, and the other characteristics generates significantly more value. Moreover, each of the four technology-based acquisitions noted above provided that acquirer with new or better access to a customer base that was a strategic component of its long-term growth plans.

The Value of Execution

A company's performance during the early stages of its development is critical to maximizing value. This explains why VCs place so much emphasis on the management team. Not only is execution important, it is controllable; an experienced team knows how to organize itself around key issues, thereby preventing situations such as program misdirection and lack of appropriate development focus from taking hold, while at the same time preserving the ability to change direction based on new information.

Execution, which may also be thought of as organizational focus, is intimately linked to time and money. A poorly run organization wastes precious time and inhibits the company's ability to hit the market at the optimum time. An inaccurate assessment of the time needed to reach a company's key clinical and commercial milestones consumes cash. Windows of opportunity are only open for so long. A mismanaged organization consumes its initial funding without ever hitting the milestones necessary to achieve the next round of financing quickly and at a higher value than the previous round.

Charting the value of execution points to this problem. Well-run organizations move through the inevitable hard-reality low period, re-evaluate their business model, and redirect their engineering efforts as needed to keep a program on track for commercialization. These organi-



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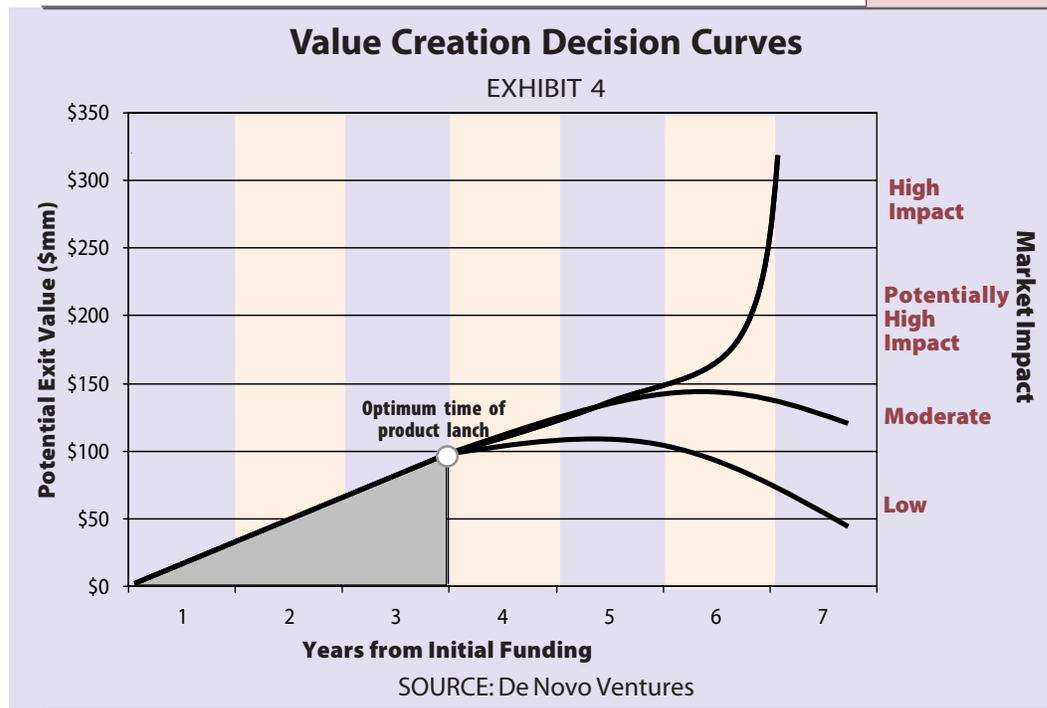
zations remain focused and answer the product development questions necessary to make a product work and hit their launch date around the 3-4 year time frame. An organization that is wedded to the technology and refuses to alter its approach often consumes more cash before it hits hard reality and realizes too late that it must change direction and redesign. (See Exhibit 3.) Indeed, execution is inexorably linked to management of capital and time, two additional critical factors for a successful exit.

The dynamic has played out countless times in venture-backed companies. Almost all startups hit hard-reality points early on; the good ones are capable of changing direction and re-engineering quickly to maintain their cash and still achieve their value creation milestones. The companies that refuse to alter direction and re-engineer their programs, on the other hand, miss the milestone, run dangerously close to being out of cash and consequently fall into a state of limbo where they have lost their edge and missed the window of opportunity. Without question this scenario produces very poor return for the investors and employees. Too many companies follow a path of being wedded to a technology or market for too long. Consequently they consume much more money than they should before realizing that the company's model, technology, or management are wrong. Companies capable of executing on the value creation milestones within a time frame of 2-4 years on efficient use of their funds are better positioned to achieve maximum value.

Sustainability

In thinking about M&A and the amount of quantitative analysis and models built to justify an acquisition or an IPO, analysts place extensive weight on the sustainable, predictable sales of the acquired technology. Indeed, buyers want to know whether acquiring a company and its technology is going to generate long-lasting profits. A large market, significant clinical impact, and the ability to establish or bolster a franchise for the acquirer is critical to profit sustainability.

Sustainability therefore implies successful management of both capital and time. Maximizing returns is almost impossible without funding adequate to give a company the time to demonstrate clinical impact, franchise value, and sustainability. Most companies with successful exits had not only venture dollars, but also public money: the five companies in Exhibit 1, for example, averaged \$66 million in private and public capital. They also had solid cash positions at the time of acquisition; enabling them to run efficient operations and avoid accepting a less-than-optimal deal in order to ensure survival. The average amount of cash to establish those premium exits appears to be in the \$30-40 million range and in all cases (except VidaMed) was achieved in a 4-7 year timeframe. The lower exit-value companies in Exhibit 2, on the other hand, raised \$11 million and their exits were 2-4 years prior to any real value being placed on clinical impact and sustainability. In the majority of cases, therefore, companies that achieved higher values had more cash and used it very effectively.



Because it relates to execution and funding, effective time management is also to a large extent controllable. More often than not, poor management creates poor execution and direction—witness the early issues at VidaMed. With the right investors and management team, however, this phenomenon is controllable. Even technologies that require more involved clinical trials and a more complex FDA strategy may appear to be uncontrollable, but if managed well, are.

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When to Exit?

Benchmarking against the characteristics for success is a way to gauge performance and can be used as a management tool to help determine when, and at what price, to exit. The characteristics for obtaining a successful exit can be plotted against the exit values.

A company with a ground-breaking technology may exit too early. Investors become concerned over the progress against milestones and the timetables without understanding future potential and impact. These situations generally result in exits before hitting the inflection point where much higher values could be generated. (See *Exhibit 4.*) Conversely, a top team that can articulate the requirements in terms of time and money is able to have the company's runway extended to this inflection point. The investors will have to be convinced that extending the company's runway will in fact achieve a much higher exit value. This type of scenario occurs every day. If the management is unable to reinforce and demonstrate that a product will in fact have clinical value, that the market is still underserved, large and growing, and that over the next few years significant value creation milestones will be achieved, it should take the lower exit value scenario.

In the past four years, market conditions have driven up the amount of money required to bring a company to a maximizing event—a major concern of not just the venture capital community but also to entrepreneurs. As the IPO market dried up and the requirements for going public shifted back to a solid revenue stream, showing adoption and growth, the timelines required to demonstrate this characteristic have also shifted. The importance of solid execution has always been critical, but over the last few years has been even more so.

The IPO market provided Perclose, VidaMed, CTS, Oratec, and PercuSurge access to adequate cash early on, enabling them to prove their models. But today, achieving the exit values that most VCs seek takes much more careful planning since the requirement to tap into the public markets has become much more difficult.

Indeed, market conditions dictate an increasing emphasis on both execution and management of capital. Moreover, there's only a short list of likely acquirers, further reduced by J&J's purchase of Guidant Corp. (See "*Elephant Cha-Cha: The J&J/Guidant Deal,*" in this month's issue of IN VIVO.) The good news is that large cap companies still depend on small medical device companies as a source to expand their offerings without earnings dilution, and funding will therefore continue to be available for novel, clinically relevant products that serve large and growing markets. The challenge for executives is to manage capital and establish realistic timelines that enable their firms to hit those benchmark characteristics that define a successful value creation and exit.

Ferrari, a managing director of De Novo Ventures, was formerly CEO of Cardiovascular Imaging Systems Inc., co-founder and CEO of CardioThoracic Systems Inc., and founding CEO of Cryovascular Systems Inc. and Paracor Surgical Inc. He is a recipient of the Mallinckrodt Award for Excellence in Medicine and twice a finalist for the Entrepreneur of the Year Award.

💡 Comments? Send an e-mail message to the editor at slevin@windhover.com

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