

I N S I D E T H E M I N D S

Health Care Venture Capital Best Practices

*Top VCs and CEOs on Company Growth Plans,
Valuations, Exit Strategies, and
Raising Rounds of Capital*



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Value Creation for Health Care Startups

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Thought Leadership

In today's marketplace, large cap health care companies that are looking to expand their product line without diluting their earnings increasingly depend on the acquisition of small, early-stage health care companies. Venture capital (VC) investors continue to be attracted to funding early-stage health care companies that share certain characteristics that enable them to exit through initial public offerings (IPOs) or mergers and acquisitions (M&As) most successfully, including the ability to develop a unique and superior technology that is likely to have a significant clinical impact, and/or products that offer a competitive edge in the marketplace.

However, VC investors need to keep in mind that the key to successful investing in this area lies in knowing how much time and money a company is likely to need to validate its business plan to the point where it can prove valuable to another, larger company. Companies that can achieve that goal are generally led by a management team that knows how to manage their capital carefully, and are able to establish realistic development timelines that enable them to hit benchmark characteristics needed to achieve sufficient value creation—and a profitable exit.

Spotting Investment Opportunities

A look at recent exits in the medical device area of the health care industry shows that several companies have recently been able to generate post-IPO exit values of \$225 million to \$350 million on less than \$50 million in sales. The 1999 acquisition of Perclose Inc. by Abbott Laboratories for \$680 million is a notable example of the way in which a medical device company can maximize its value to achieve a profitable exit.

Perclose, which had approximately \$50 million in sales, had developed a unique suture technology that stood out in the marketplace. This technology, which provided a novel method for closing a femoral access wound, fundamentally challenged existing clinical thinking and standards of care, leading to improvements in patient care, greater catheter lab efficiency, and the creation of an entirely new market. In addition, the company ran a

highly efficient operation: during the seven years prior to its acquisition, it raised \$23 million in VC funding, as well as another \$54.5 million from an IPO and a follow-on offering. This means that after they did an initial public offering, they went back to the public market for an additional offering sometimes referred to as a secondary offering. Upon acquisition, the company was able to generate an impressive twelvefold multiple of sales.

More recently Kyphon acquired St. Francis Technologies, which offered a novel device for treating back pain, for \$700 million on \$32 million in sales. Medtronic then acquired Kyphon for \$4 billion, which clearly proved its clinical value, IP value, and franchise value.

Most health care companies that have been able to achieve similarly successful exits have likewise been able to demonstrate their technology's clinical impact, franchise value, strategic need, and sustainability, as a result of superior execution on their business plans. However, many companies have also been able to maximize return on investment (ROI) for their early VC investors (typically in scenarios where there was a relatively small initial capital investment) by staging a lower-value, early-stage exit—i.e., before demonstrating clinical impact, sales revenue, and sustainability. If it appears that a larger health care firm that wants to expand its franchise in a certain area is interested in an early-stage buyout deal, the management team and directors of the target company may decide not to invest the capital or take the time to clinically validate a technology, and pursue an early-stage, acquisition exit instead.

Analyzing a Company's Value Proposition: Franchise Value and Strategic Need

The first time we sit down with a CEO to discuss a VC investment, the number one question that I want to know the answer to is this: Where did the idea for this company come from? Did you start the company based on any prior work or study? I also need to know what clinical problem the entrepreneur is trying to solve and why the company's approach is unique and novel.

Additionally, I am very interested in the background of the CEO and his team—how experienced they are, and where they have had prior successes. De Novo focuses primarily on the clinical value of the technology. We speak to many leading experts in the clinical area to determine whether the technology or company we are evaluating truly is or has a technology that would enhance clinical practice. We also spend a great deal of time understanding the regulatory and clinical pathways that this technology or company may need to take.

We evaluate the reimbursement strategy and dig into their intellectual property—patents the company has filed. Finally, we develop an internal model based on the company's business plan to determine how many additional rounds the company may need before either an IPO or an M&A exit. We benchmark our internal model of future funding requirements, pre- and post-values and exit values against our own personal experience, our prior portfolio of like companies, and industry data relating to exits in like areas.

The answers to these questions are significant because there are generally two critical value drivers that we consider in any investment equation. The first is franchise value. Franchise value pertains to whether a company's technology and the resulting clinical application are indeed novel and superior. Companies with a high franchise value are usually the first to go to market in a new category and are therefore able to establish a dominant market presence through the creation of a new clinical franchise. Companies with high franchise value have been CTS, Perclose, St. Francis Technologies, and Kyphon.

The second big value driver is strategic need, which may not be viewed in the same way by an acquirer as it is by the entrepreneur. Establishing strategic need generally depends on a company's ability to create a competitive edge, typically through establishing a strong patent portfolio or some other means of preventing others in the marketplace from acquiring your intellectual property (IP). In some cases, a company's strategic need is enhanced by its ability to broaden an acquirer's product line or increase the efficiency of its sales force. In many cases, the value that is placed on a

technology, and the company behind that technology, is based on the fact that the acquirer plans to use it as a way to protect and preserve its own core businesses.

However, high premiums are rarely placed on strategic need alone. Most frequently, a company must demonstrate a strong combination of clinical impact and franchise value, along with strategic need, to generate significant value at exit.

Execution and Sustainability

Two other factors are crucial to maximizing the value needed for a company to achieve a successful exit in this industry area—execution and sustainability.

Execution, which relates to a company's organizational focus, is critical to the development of an early-stage company. A poorly run organization often wastes precious time and money—for example, a management team fails to correctly assess the time needed for the company to reach its key clinical and commercial milestones.

The key milestones a company must focus on and achieve to some extent depend on the round of investment; for example, in a Series A deal, which is generally a company very early in its development history, the key milestones may be the proof of principle determination/method of action proof of the company's specific technology, safety in an animal model, or initial prototypes based on proof of principle, and filing of their initial intellectual property. In a later-stage financing, the key milestones may be the achievement of the first-in-man studies or second-in-man studies targeted at showing clinical efficacy. Other critical milestones would be the filing of a 510(k) and approval; approval of a pivotal trial, completion of a clinical trial, filing a PMA (Premarket Approval) to the FDA (U.S. Food and Drug Administration), a design freeze of the product pending regulatory approval, and initial sales.

These startups cannot afford to waste money and miss those windows of opportunity. Markets change; reimbursement could be altered, transforming a novel technology into a commodity; a newer technology could enter the market. It is important that all startups understand that markets change and new competitors enter the market. They need to take advantage of these windows to achieve the next round of funding at a higher value. Companies that refuse to alter direction when needed typically miss their milestones and come close to running out of cash.

VCs and potential acquirers also place a good deal of value on a company's ability to achieve sustainable, predictable sales of its technology. Simply put, buyers want to know whether they will be able to generate long-lasting profits by acquiring a company and its technology. Profit sustainability is generally made possible by a large market, significant clinical impact, and the ability to establish or bolster a franchise. Successful time and money management is essential to sustainability; indeed, it is almost impossible to maximize returns without adequate funding that can give a company sufficient time to demonstrate clinical impact, franchise value, and sustainability.

Early-stage Valuation Strategies

The most interesting fact regarding valuation-setting strategies is that there is no real science to deriving Series A pre-money value. Rather, there are certain rules of thumb that many VCs use that revolve around percentage of ownership, based on their initial investment. For example, most venture capitalists want to own a minimum of 30 percent to 50 percent of the target company if they are the only Series A investor; if a syndicate is created, then each syndicate player—or at least the lead or co-lead—will target ownership in the neighborhood of 25 percent each.

Many of the top VCs, especially those firms where the partners themselves have extensive operating experience, have a very good understanding of how much money will initially be required to fund a target company to an important value creation milestone, such as completion of the initial prototype and proof of principle in a valid animal model. Furthermore, the

top VCs who have actually been CEOs themselves will generally have a very good command of the amount of additional capital that will be required in future funding rounds; and in most cases, they know what the pre and posts should be, based on history, experience, and current trends in the IPO and M&A markets.

Pre and posts relate to the pre-money value of the company prior to the venture capital round; it is the value the venture community has placed on the company. The post-money value is the value of the company immediately after the venture capital round is completed. For example, Company A in a Series A financing may have a pre-money value of \$5 million raising \$5 million; therefore, the post-money of Series A would be \$10 million.

Based on that knowledge, financial models can generally be developed that provide at least a basis for what the Series A pre-money should be; and that analysis, coupled with industry statistics on pre and post rounds, sets the boundaries around the initial valuation price. The keys to setting value for an early stage company generally include the answers to the following questions:

- How unique are the technology and the clinical problem that the company is solving?
- How much risk have they already removed—i.e., do they have a prototype, or have they determined the method of action with initial bench and animal tests? Method of action refers to understanding whether the technology the company is developing has scientific proof with respect to how it works and its response in a biological system, generally animals first.
- How experienced is the team?
- What is their intellectual property position? IP is one of the critical due diligence areas and one of the value drivers for a company. Medical device and bio-tech investing places a great deal of value on the protection of the technology. This protection comes from the filing and receiving of the patents covering the company's products and science.

- What is the regulatory path—510(k) or PMA? In medical devices there are two paths a company's technology can be categorized into—a 510(k) or a PMA. The 510(k) path for FDA approval is a much simpler path and is generally assigned to products that are not deemed overly complex with respect to the clinical claims the company is making. Generally, a 510(k) does not require randomized clinical trials for approval, since other products on the market can serve a predicates. A 510(k) approval can usually be received in three months. In contrast a PMA, Premarket Approval, is a more rigorous regulatory path, generally requiring a randomized clinical trial with specific criteria and efficacy claims with respect to the technology. A PMA is usually a two-year process to gain approval. An NDA, New Drug Approval, is a biotech path and is as complex as the PMA in the sense that a randomized clinical trial must be completed, with the results from that trial passing certain efficacy thresholds. (You may want to research the FDA approval process for more details.)

Valuation Trends

Historically, valuations for the health care industry have been, for the most part, relatively stable, especially for Series A funding rounds. However, there have been several instances over the last seven years where later private funding rounds have had higher than normal pre- and post-money values placed on them, especially when the IPO market was more forgiving with respect to the metrics required to go public. Such cases typically involved pre-revenue companies in large markets.

Indeed, in the last three years, hedge fund managers and other private equity players who have witnessed this more forgiving IPO market have bid up values, since they are focused on the short-term gain of a potential multiple of one or two times, or a 50 percent to 100 percent increase in IPO value, which is quite different from the venture capital returns targeting a minimum of three to five times their investment.

If you look at the data provided below, there are some real criteria with respect to private companies that recently went public by using the public

markets as a financing strategy. The data shows three distinct groups of companies, and the values placed on those companies post-IPO.

Valuation Tools and Models

Our VC firm believes that the best valuation tools and models are those that our investors have developed over time, based on experience. For example, we generally develop our own valuation criteria and financial model to triangulate on the proper pre-money valuation and the correct amount of cash that will be required to hit specific value-creation milestones.

We typically start out by attempting to understand the market size and opportunity for the target company's specific product. We then evaluate the uniqueness of that product within a specific clinical category. We also value companies and their potential for success based on how much prior bench and pre-clinical work has been accomplished to date in order to reduce the ongoing risk of development. Essentially, we are interested in the proof of principle beyond the technology. For example, a medical device is being developed for the treatment of obesity that uses the concept of neurostimulation. Proof of principle is the process of building a prototype stimulator that when attached to certain areas of the stomach in an animal trial produce weight loss in the animals, proving the method of stimulation has the desired effect.

We also evaluate the amount of capital that will be required to bring the technology to its full market launch, which incorporates to a large extent the regulatory path that is required—either a 510(k) or a PMA. The 510(k) regulatory path for most medical devices requires little if any major clinical trial work. In stark contrast, a PMA clinical path is generally quite expensive and comprehensive with respect to the nature of the clinical trial; generally, such trials not only must be randomized, but they also require enough positively impacted patients to show true clinical impact/efficacy.

Once we have determined the amount of time and capital needed to achieve FDA approval for a company's technology, we model the cost

required to launch a product, including the selling price; costs associated with manufacturing; and the product launch itself, including the revenue ramp and time required to reach the break-even point. Once we thoroughly understand the amount of capital and time required to reach a point where the company can become a profitable, growing business, we can then use market databases and experience to determine a reasonable exit value on the company—i.e., an M&A event or an IPO.

Once we have the full picture—essentially the best approximation of full capital requirements and time to exit—we can then determine a fair pre-money valuation at almost any point in time with respect to the company's progress and history.

Timing the Exit

Benchmarking a company's progress against the key success factors for a company in this industry—clinical impact, franchise value, strategic need, execution, and sustainability—is both a good measure of performance and a useful management tool to help determine when to exit and at what price.

For example, even a company with a groundbreaking technology may exit too early if its investors become overly concerned about its progress with respect to certain milestones without fully understanding its technology's future potential and impact. In such a scenario, the company may wind up exiting before hitting those inflection points where significantly higher values could be created. A top management team that is able to clearly articulate its requirements with respect to development time, as well as the money needed to hit its development targets, is typically able to have its exit runway extended to the proper inflection point and receive the funding it needs to get there.

Indeed, in most cases, a company's VC investors must be convinced that extending the company's time to exit will help it achieve a higher exit value. Therefore, a management team must be able to demonstrate that their product will ultimately have clinical value; that their market is large, growing, and underserved; and that significant value-creation milestones

can be achieved over the next few years. If they cannot make a convincing argument in those respects, they are unlikely to get their exit runway extended—and will likely be forced to accept a lower-value, early-stage exit.

Exit Market Trends

Entrepreneurs and VCs alike in today's health care marketplace are increasingly concerned that the amount of money typically required to achieve an exit in this industry has greatly increased over the past several years because of current market conditions and trends. As the IPO market has dried up, the requirements for going public largely depend on a company's ability to demonstrate a solid revenue stream based on widespread marketplace adoption of its technology, and sustainable growth. The timelines required to achieve this goal have also become much shorter. The importance of solid execution on the part of the management team, while always critical, has therefore become even greater. This trend began in 2000, after the Internet bubble. Today the IPO market has opened up again; however, companies that achieve the best value at IP and post-IPO are companies with revenue momentum.

Years ago, the surging IPO market provided many medical device companies with enough early-stage funding to prove their models successfully prior to exit. However, achieving the type of exit values that most VCs are looking for these days requires much more careful planning because the requirements for entering the public markets have become much more stringent. Although the amount of cash required varies, since much depends on the clinical area, the complexity of the product, and general market conditions, it generally runs about \$40 million to \$100 million of invested capital.

At the same time, there are far fewer likely acquirers for early-stage companies. The large-cap companies generally do not want to acquire an early-stage company, since most of the early-stage companies and technologies still require a lot of capital to finish the product and begin generating revenue. If a large- or mid-cap company acquires an early-stage company that still needs a lot of R&D investment, it affects their earnings

per share (EPS) and net income. Most public large caps and mid caps want companies that don't impact their bottom line but can quickly add to their revenue stream, making a management's team ability to successfully manage its capital and execute on its business plan increasingly important.

As for IPO versus M&A exits today, I think most venture investors would agree that an M&A transaction would be better, assuming the value was the same and the M&A transaction did not have any unusual back-end or earn-out payments.

Successful Exits

Most companies that are able to achieve successful M&A exits have both venture funding and public money. They also have solid cash positions that enable them to run efficient operations—and avoid accepting a lower-quality exit deal just to stay in business.

We have found that the average amount of revenue needed to achieve a premium exit in today's market is around \$30 million to \$40 million; and those exits are typically achieved within a four- to seven-year timeframe. Lower-value exits typically involve companies that have raised no more than \$11 million and wish to make their exit within just two to four years, before achieving true value in terms of clinical impact and sustainability.

Simply put, companies that achieve more successful, higher-value exits are those that have more cash and use it more effectively. They also use their time more wisely—in most cases, poor management leads to poor execution and direction. However, the right investors and the right management team can typically control and prevent that outcome. Indeed, even those companies with technologies that require complicated clinical trials and complex FDA regulatory strategies, if well-managed, can achieve successful exits in this industry.

Management Team Mistakes to Avoid

For a company to achieve the value levels that will allow it to exit most profitably, it must perform successfully during its early stages of development—which is the main reason VCs put so much emphasis on the quality of the management team when determining whether to invest in an early-stage health care company.

Fortunately, execution is highly controllable; an experienced management team knows how to organize its business plan around key issues. The key issues depend on the company's strategy and stage, but in medical devices, some of the key issues would be the completion of the first-in-man cases using the company's technology, final design freeze on the product, filing a 510(k), completion of any clinical cases necessary to receive CE Mark (European approval), initiation of a clinical trial, completion of a clinical trial and submission of the PMA, and the initial pilot launch of the product.

The experienced management team plans around these key issues to prevent such critical mistakes as program misdirection and lack of focus with respect to development strategies. At the same time, a good management team knows how to change direction based on new information. New information can be many things—for example, after initial bench models were built and bench tests completed on how the device works, the first animal tests were done where the product did not perform at all like the bench tests, and the new information from the animal tests helps the engineers come up with a better design, more adapted to a real biological system. In another example, a design for a medical device is built, but after running it through the required engineering fatigue tests, the material used in the product was simply not robust enough and requires a new material with much better fatigue characteristics. The speed at which engineering teams and management teams react to this new information is critical to get the program back on track.

Indeed, well-run, properly managed startups are generally able to get through the hard times that most new companies experience, simply because they are able to re-evaluate their business model and redirect their

engineering efforts, as required, to keep their technology development program on track for commercialization. Such companies also know how to stay focused to solve any problems that may arise in the product development process; as a result, they are generally able to achieve a launch date within a three- to four-year timeframe. The number one distraction occurs when the team is working on too many simultaneous projects without dedicating enough manpower and focus on the primary project.

Conversely, a management team that insists on sticking with an unsuccessful technology or market, refusing to alter its development approach even when all evidence indicates it should do so, will often wind up consuming too much of its capital before coming to the realization that its business model, technology—or even the team itself—is not what it should be. At that point, the team may attempt to make changes in its direction, redesign its technology, or revamp its leadership lineup; however, by then it is often too late to change course successfully. Only those companies that are capable of executing on their value-creation milestones with a two- to four-year timeframe are generally able to make efficient use of their funding, and achieve maximum value at exit.

Timeframe and achieving the key milestones are critical because venture capitalists generally fund a company with just enough cash to reach certain key milestones. If these milestones are missed, the timeframe expected to hit them becomes much longer, and since every month of delay consumes cash, the company can run out of money before it hits the key milestones that were agreed to. Most VCs would continue to add cash generally through an additional round, but because the milestones were not met, the value placed on the company for that next round would most likely be a “down round,” which means the value placed on the company from the prior round will be lowered to accommodate for the miss and added risk.

Future Trends

One trend in venture capital health care is certain: the population of the world is growing older and faster than at any other point in mankind’s history. This means the demand for new medical devices and drugs will

continue to be very robust. Also, since life expectancy is on the rise and people are living longer, new problems arise that twenty years ago were not issues because people had already. The breakthroughs in material sciences, stem cell research, MIMS, and new biologics are enabling medical devices and biopharma to advance, and at an incredible rate.

Also I believe that products in the future will be much more individualized to the patient, and the combination of new materials, MIMS devices for sensing biologic change, and having that information wireless-transmitted to not only the indwelling medical device, but also the doctor, will create great advances in medicine and patient care.

Achieving a Good Investment Track Record

To achieve the best investment track record, you invest in the best management teams with the best technology that is solving fundamental medical problems. This is a simple statement, but it is certainly not easily achieved.

As a venture capitalist, you must develop an approach to evaluating and investing in new areas. Much of the business and decisions to invest or not is more about art than science. What I mean is that after many years as an investor, you develop a feel for a good investment, which is based on many years of seeing which companies and investments were successful and why. You must develop a discipline and use your experience to develop a template for success that at least helps sort out which investments to make and which to pass on.

Venture capital is a long-range business model in the sense that it generally takes six to eight years or more for an investment in a company to mature to a point where a successful exit can be achieved at the multiple you recognize and your firm is targeting as acceptable. As a Venture capitalist, you cannot follow fads or trends that seem in vogue; you must stay grounded in what you know works—technology addressing real needs in the medical field.

The most challenging aspect is sorting out and discerning a good investment. Top venture capitalists may see as many as two hundred to three hundred new ideas and companies a year, and they will fund only eight to ten.

Advice for Entrepreneurs and VCs

For the entrepreneurs, the most important aspect of attracting VC money is to ensure that you have a well thought-out rationale behind the clinical problem you are trying to solve and that the technology you plan to develop is in fact novel and protectable. All too often smart engineers and MBS students have an idea that is not validated clinically—essentially, it is wonderful technology looking for a clinical problem, rather than starting with the clinical problem and working with doctors to determine through the development of technology how that clinical problem could be solved.

For the venture capitalists, my advice is to remember that health care investing is a long-range game and that investing in early-stage companies requires patience. Even with the best teams, unforeseen problems arise, and the VC must remain supportive and not over-react. I would also encourage VCs to thoroughly understand the development milestones a company needs to hit and match the investment to the milestones.

Richard M. Ferrari has been a successful CEO of several medical technology companies, both prior to and after co-founding De Novo in 2000. Following De Novo's investment in CryoVascular Systems, Mr. Ferrari became CEO, growing the initial five-person startup team to a company of twenty employees. He was instrumental in developing the clinical and product strategies and hiring the executive team.

In 2002, Mr. Ferrari led Paracor Medical, another De Novo portfolio company. He grew the company from four to twenty-two employees, refined the product strategy, raised its Series B financing, and hired his replacement CEO. Prior to co-founding De Novo Ventures, he was the co-founder and CEO of CardioThoracic Systems (CTSI), a company he led to an initial public offering in only seven months in 1996. CTSI, the market leader in disposable instruments and systems for performing minimally invasive beating-heart bypass surgery, was ultimately acquired by Guidant Corporation in November 1999. Before that, Rich was the CEO of Cardiovascular Imaging Systems (CVIS). As CEO, he orchestrated a successful IPO and ultimately sold the company to Boston Scientific Corporation in 1995.

In addition, Mr. Ferrari founded Saratoga Ventures in 1996, a venture capital partnership that has provided seed financing to startup medical technology companies, including Atrionix, Oratec, Enteric Medical, Trivascular, and Endotex. At Saratoga, he was chairman of Oratec, which was sold in 2001 to Smith & Nephew PLC.

Mr. Ferrari also co-founded the Medical Technology Group, which spun out Integrated Vascular Systems, an early-stage femoral artery closure company that was sold to Abbott and Angiosense, a needle-free, jet-injection, local drug delivery company.

Early in his career, Mr. Ferrari held the position of executive vice president and general manager of ADAC Laboratories.

Mr. Ferrari sits on the boards of BenVenue, CardioMind, MyoScience, Ovalis, Paracor Medical, Pulmonx, Simpírica, Spinal Kinetics and Spinal Modulation. His prior board involvement includes TriVascular.

Mr. Ferrari holds a BS degree from Ashland University and an MBA from the University of South Florida.



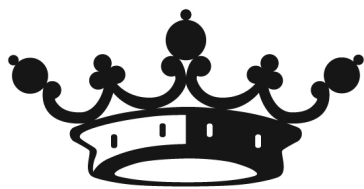
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