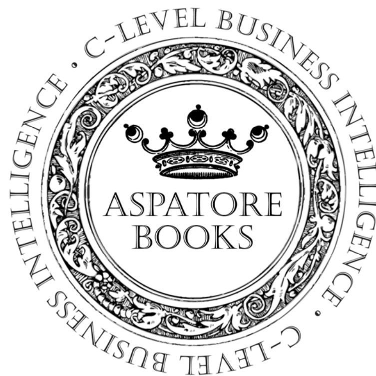
INSIDE THE MINDS

Medical Devices Venture Capital

Top Venture Capitalists and CEOs on Valuations, Funding, Growth, and Exit Strategies



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Life as an Entrepreneur, Medical Device CEO, and New Venture Capital Investor

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Starting with a Clear Compelling Vision

As the CEO of OraSure Technologies (NASDAQ: OSUR), I was always selling our vision to make oral fluids the most convenient and reliable biological marker for the collection and detection of infectious diseases and drugs of abuse in the world.

Our value proposition was really quite simple. We believed that people would much prefer to swab an oral fluid collector in their mouth than prick their finger to collect a blood sample or urinate in a cup for a drugs of abuse test. If we were right about oral fluids becoming a preferred collection method and we could claim equivalent performance results, then we would be chasing existing markets that represented more than 69 million tests annually and new revenue opportunities in excess of $500 million.

With a clear vision and simple value proposition, our goal was to convert existing blood and urine testing markets to an oral fluid testing platform. Conservative estimates were in the range of 50 percent. Many investors logically speculated that the conversion rate could be inevitably higher due to the obvious convenient collection advantages. At a 50 percent conversion rate, this would translate into many years of sustainable revenue growth for our company and a terrific value proposition for potential investors.

With a clear and compelling vision, a strong value proposition, and defensible market metrics to support your growth plans, I believe you will have a strong foundation for funding the growth of your business.

Develop a Set of Core Values to Live By

I believe that employees look to management to provide leadership and to set the tone as they grow. For us, as co-founders of our business, we developed a set of "core values" that provided us with a clear and unambiguous set of guidelines. We were very proud to share our values with our employees and our stakeholders, and we actively challenged our employees and our management team to hold us to these high standards, through good times and bad.

Our core values were trust, agility, innovation, and quality. As an emerging growth medical device company, these values reflected the way we wanted to run our business. If we could be perceived both internally with our employees and externally by our customers as living these values, then we believed that it would help to differentiate us from our competition in a powerful way.

Importantly, we spent a lot of time to devise definitions for these core values that were unique to our organization and we proudly plastered them all over the building and gave each employee their own laminated copy to display on their desk as part of the new employee orientation process:

> *Trust* – Develop trust by delivering total quality, solving problems quickly, and resolving issues equitably.
>
> *Agility* – Respond quickly and efficiently to capture opportunities, and adapt our operating plans to meet unpredictable and inevitable change.
>
> *Innovation* – Encourage risk-taking and create partnerships to achieve the most user-friendly and technologically advanced solutions possible.
>
> *Quality* – Maintain the highest level of quality in every aspect of our business, always striving to exceed regulatory and marketplace expectations.

Establish Clear Stakeholder Expectations

In addition to establishing core values, we thought it was essential to weave these values into clear commitments to excellence for each of our major stakeholders:

Customers – Provide solutions to improve customer profitability, maintain open, honest relationships, and deliver high levels of customer satisfaction.

Employees – Cultivate a culture based on our core values; provide an environment where employees can grow both personally and professionally; provide a competitive compensation package; and share in the long-term success of the company through equity participation.

Stockholders – Communicate frequently and candidly to stockholders, and maximize stockholder value by delivering substantial capital appreciation.

Family – Respect and honor the needs of our families, and maintain a balance between work and play.

Suppliers – Establish long-term business relationships based on trust, quality, and a fair value for all our supplies and service providers.

Community – Support the local community through a mix of community activities and charitable contributions. Take a leadership role in economic development through job creation and use of local suppliers and service providers whenever possible.

All this may seem like a distraction from running the business, but I am convinced, after many years of routinely "living" our core values to each stakeholder, that it had a major positive impact on the success of our

business and for building an entrepreneurial culture that was obvious to anyone that entered our facilities.

Funding Our Growth – Pre-Venture Capital

When we started, we fully expected to fund our business with venture capitalists (VCs). But after being rejected by many of the local and regional VC firms, we had to scramble to find other creative sources of capital merely to survive. We were absolutely clueless how hard it would be for a bunch of twenty-nine-year-old guys to secure VC funding. And as I look back twenty years later in my new role as a VC, I wouldn't have funded us either at that time due to our irrationally high revenue predictions and complete lack of management experience operating as a new start-up business!

So for the first ten years of our business, we financed our growth by securing funding from local and state economic development agencies, angel investors, strategic partnerships, distribution agreements, and conventional bank financing. In addition to these sources of funding, we almost starved ourselves to ensure that all of the monies that we received went into growing the business.

Local and state economic development agencies were terrific sources of seed capital for us in the early days. We were housed in a state funded incubator with many other entrepreneurs who were chasing their dreams and equally struggling to make ends meet on a daily basis. This seed capital of almost $250,000 came in the form of grants and it provided enormous credibility for us as we tried to get our business off the ground.

Local angel investors provided us with almost $6 million of capital in three rounds over the first seven years of our business. These accredited investors were generally entrepreneurs themselves; they understood the risks inherently experienced by early stage companies, and with few exceptions, they did not challenge us about our pre-money fully diluted valuations. All of our angel investors received common stock, with none of the bells and whistles or restrictions that were inevitably going to come with conventional VC financing.

In the early days of our business, we licensed our first product, Sunsense Towellettes, a single application sunscreen product for sports and recreation enthusiasts, to Schering-Plough. This deal brought us much needed distribution, minimum annual revenue payments, and enormous credibility as we were licensing our first product to the dominant market leader in the space less than eighteen months after forming the company.

As we expanded our product lines, we opted to partner for distribution rights rather than build it ourselves. Each distribution agreement required minimum performance standards to retain distribution rights. Sure there were plenty of distributors who failed miserably and we hung onto them way too long, but in general, we were able to generate somewhat reliable minimum payments for our products that we could count on. With good cash flow, this allowed us to try to supplement our growth capital needs with conventional commercial bank financing.

For reasons that I did not understand until many years later, we were able to secure lines of credit that eventually grew to more than $8 million from a local bank. This allowed us to fund our growing receivables, build our inventory, and fund much needed capital equipment for our growing research and development requirements. At our stage of growth, securing bank financing was very unusual, but it obviously allowed us to use financial leverage to help us retain more equity for our investors, our employees, and for the co-founders of the company.

Venture Capital Funding

After being totally rejected ten years earlier by the VC community, we were a bit skeptical, if not downright cynical, about the need for, or the benefit of, expanding our stockholder base from angel investors to include VC investors.

But during those past ten years, despite radically revising our vision several times, we finally thought that we had a clear compelling vision, an eight-year track record of increased quarter to quarter revenue growth, and a story that we thought may lead us to an initial public offering (IPO) over the next several years. If this were true, then it was time to seek VC

investors who could bring us the expertise to prepare for a liquidity event sometime over the next few years.

It didn't hurt that in 1998 there was a market frenzy for technology stocks. With almost $15 million in revenue, solid gross margins, and what we believed was a platform technology in the diagnostic space, we hit the road to raise $3 million in VC financing. Less than sixty days later, we had secured $9.2 million from two new VC fund investors and some additional capital from our angel investors.

Although this looks impressive on the surface, as you peeled back the layers, it turned out to be a down round from a valuation perspective. We had all of these new preferred stock terms that were very scary if things did not go well, we had to hold formal board meetings, and our entrepreneurial ways would slowly begin to be swallowed into a more conventional autocratic way of doing business. Needless to say, the game had changed forever!

Going Public – Merging With a Strategic Partner

We went public in September 2000, less than eighteen months after securing our first and only round of VC financing.

My instincts were correct that the main reason to secure VC financing was to set ourselves up for a liquidity event. Our VC investors were absolutely terrific at accessing the best middle market investment bankers. No long dating process or deferral to the new rookie banker right out of school with a tier one MBA who had no practical work experience. We skipped all that and moved right to the front of the line. Whether we were there on our own merits or due to the pipeline of future deal flow with the VC firm really did not matter. The fact was that we moved to the front of the line. The good old boy network was alive and working and I was glad to be escorted in!

The job for our VCs and the investment bankers was made simple because I cut a deal to merge with Epitope, Inc. (NASDAQ: EPTO). The CEO of Epitope and I both shared the same compelling vision to make oral fluids the most convenient and reliable biological marker for the collection and

detection of infectious diseases and drugs of abuse in the world. In a Perkins restaurant on the south side of Bethlehem, Pennsylvania, we outlined the terms of a deal on the back of a napkin. The new story of OraSure was about to begin.

Bragging Rights

We merged with Epitope in September 2000 to form OraSure Technologies Inc. (NASDAQ: OSUR) in an all stock transaction that netted our investors a value of $255 million on paper on the day of the merger.

Because of the merger, we had created a liquidity event for our shareholders that every entrepreneur dreams will occur some day. It was our own little version of the American Dream come true. For our investors, no one could ever take away from us the following bragging rights:

> Original Angel Investors: *70 times cash return in under ten years*
> Venture Capital Investors: *8 times cash return in under two years*
> Co-founders (3): *$72 total tax basis, thirteen years of sweat equity, $87 million*

We were also very proud that our employees participated in this liquidity event in a meaningful way. My partners and I always believed that our employees were an integral part of our success and that they should share in the value that they helped create.

Qualities to Look For in a Medical Device CEO

A CEO in this industry must have a passion for his business; a long-standing reputation of trustworthiness; and a record as a confirmed workaholic. He or she must also be financially astute; have a great understanding of the market demand for his products/services; and be transparent in his communications regarding performance against his stated objectives. I also believe sweat equity beats a hired gun any day.

> *Passion Sells* – I can't count the number of times that investors would say that they got excited about our business because of my enthusiasm, my large equity position, and the personal guarantees that I signed to fund the business.

Trustworthy – What more do I need to say? As I recall our core value of trust, you earn a reputation as an honest person by delivering total quality, solving problems quickly, and resolving issues equitably.

Confirmed Workaholic – Anybody who thinks that growing a medical device business is not a 24/7 passion of love, get out. Unfortunately, e-mail and my BlackBerry made it even easier to take my business wherever I went.

Financially Astute – I have a huge bias on this topic, but I strongly believe that the most successful medical device companies will have a financially astute CEO and an equally, if not stronger, CFO who are constantly looking for ways to improve the bottom line of the business.

Understand Your Markets – My four-year stint at Procter & Gamble as a financial analyst taught me invaluable lessons about branding a product and the importance to fully understand your customers, their habits and practices, and how to deliver a quality product that builds brand loyalty over a long period of time.

Transparency – I tried to communicate as openly and candidly with our employees, our customers, and our investors as reasonably possible. It is amazing to me how honest communications will build loyalty that will help you through the inevitable ups and downs of growing your medical device business. People love to cheer on the entrepreneur and they will inevitably give you the benefit of the doubt if you let them share in your journey.

The Power of the Press

Throughout my entrepreneurial business adventure, the media has had a critical role in the development of our company. The media had an amazing impact on raising our profile with investors and with our customers. A few of my all time favorites:

Local Newspaper – In our first year, a local business reporter wrote a story about our company and our new product in the Sunday edition of the local paper. This article opened many doors and it provided a lot of credibility for our new start-up company.

The Price is Right – Our first product, Sunsense towellettes, a single application sunscreen product for sports and recreation enthusiasts, was included in a segment of this popular game show. Twenty seconds of fame for $1,000 and a market of more than 10 million viewers!

The Wall Street Journal – Our sunscreen product was featured in a small article buried deep in the middle section of the paper on a random Friday the 13th. Thematically, they focused on the product novelty and our backgrounds as former P&G employees. We made thousands of copies of this article as we attempted to secure additional angel funding for our company at that time.

A year later, we got another bigger and better placement in the *Wall Street Journal*. We had just cut a deal to license our first product worldwide to Coppertone. The 1000-pound gorilla was partnering with the new player on the block.

CNN/Bull's Eye – After Secretary of Health and Human Services Tommy Thompson announced FDA clearance for OraQuick, the world's only rapid oral fluid HIV test, we were barraged by the media. On that day, we traded more than 21 million shares, obviously a bit higher than our historical three-month daily average of roughly 200,000 shares. The power of the media was simply unbelievable.

NASDAQ Market – We were honored to open the NASDAQ Market for World AIDS Day. With the only rapid oral fluid HIV test in the world, this was a very high profile and symbolic moment for our company, our employees, and for the fight against this terrible disease.

The Importance of Full Disclosure

I had a long-standing practice of preparing quarterly financial statements in a format similar to a conventional 10-Q with a colorful CEO letter that often described in painful detail the status of our emerging growth business. No lawyers to dilute the message and I would make many forward-looking statements. We would also make sure that the financials were mailed within thirty days of the end of each quarter.

At the end of the year, we would also prepare a full annual report in a format that mimicked a 10-K report and would attempt to incorporate the best practices of public companies at that time.

In retrospect, this process was invaluable in many ways. First, it forced me to evaluate our progress on a quarterly basis. I would take a hard look at our results, and if they were not satisfactory, make immediate changes. Agility in motion. Second, investors were never left in the dark regarding our performance. As a CEO, one of my many golden rules was that I hated to be surprised. Investors are no different. Third, funding sources were generally amazed at our level of financial reporting. It made it easy for the credit department at our local bank to review our performance and it also simplified the due diligence process with VCs and investment bankers when we merged with Epitope to form OraSure Technologies in September of 2000.

As I start my next adventure as a VC, I have been baffled at the lack of basic financial information that is available for our review. I had always assumed that every private company prepared quarterly detailed financial statements for their investors. I now realize that we were the exception to the rule, and I strongly believe that this is another best practice that separated us from our peers as we were emerging as a growth-oriented medical device company.

Executive Compensation Issues

Because we were twenty-nine-years old and single and willing to live in substandard off-campus college housing, it was not essential that we had “fair market” salaries when we started our business in 1987.

No doubt that this substandard compensation model got old very quickly and it required us to sometimes find part-time jobs and run up small fortunes in personal credit card debt, but bottom line, my partners and I were willing to do whatever it took to fund our start-up business.

As we began to grow, we would try to raise our salaries slowly, but if the trade-off was to buy some much needed equipment, fund our growing working capital needs, or hire our next key employee, we would take a wait-and-see approach to our own salaries. It was just the way it was. This got really complicated as we morphed from single guys to married with plans of families some day. Those pressures of family were new and exciting, but stressful nonetheless in our pay as you go approach to executive compensation. Truly, the life of an early stage undercapitalized entrepreneurial venture!

I was often asked to speak to entrepreneurs and college students about the success of our growing franchise. Why not, we were twice on *Inc. 500's* list of fastest growing privately held companies. We must be rich and successful beyond anyone's wildest dreams. The following slide was my way of bringing this all back into perspective:

The First 12 Years

December 1987:

I had $5,000 in cash, no debt, a dog, and a dream . . .

July 2000:

I had $50,000 in cash, $8 million in personal guarantees, a wife, a son, a new dog, and a dream . . .

Needless to say, I have come a long way since that time, but I still feel strongly that sweat equity is a trait that is very important but it is often lost for many of today's medical device CEOs.

I think that many VC and public company boards have come to some false sense of entitlement for its CEO's compensation packages. I am routinely dismayed when boards give CEOs big cash compensation packages and "pay for a pulse" restricted stock options that are not tied more closely to the performance of the company. I think it is a shame to operate this way and feel it is a major disservice to investors and to the companies' employees who made it all possible.

As a co-founder and large equity stockholder, I was quite proud of the fact that we earned our money the old-fashioned way. As I begin this new venture from the other side of the table as a VC investor, I will strive to find a good balance between fair market value and the long-term value of sweat equity.

Measuring Growth

As a growth-oriented company, sustainable revenue growth was always our number one priority. As a medical device company, investors valued us at eight to ten times revenues for high growth (+25 percent per year), five times revenues for average growth (5 to 10 percent), and one to three times revenues for low/no growth. Needless to say, I wanted there to be no dispute that we were fully committed to deliver high growth.

Following closely behind revenue growth, gross margins are a major indicator that you have a sustainable business model. If you can maintain gross margins of at least 60 percent in our industry, and develop a path to reach 70 percent gross margins, then you have a highly defensible case for creating substantial shareholder value in the future for your investors.

My third indicator that we were growing profitably was tracking total product revenues per full-time employee. Employee productivity was an important measure for our company to ensure that we did not get too far ahead of ourselves. Growth is difficult to manage, but I was always aware of where we were with this metric and I would emphasize it during our

annual budget review process. Albeit a lofty goal, my long-term goal at OraSure was to reach more than $500,000 in sales per employee with 70 percent gross margins. If we achieved those lofty objectives, we would be continuing to create substantial stockholder value long into the future.

Top Three Goals Year In and Year Out

Our top three goals for our company were always to beat our budget; secure at least one major new customer or strategic partner; and expand into new markets or territories.

If we beat our budget, we would exceed investor expectations, pay out nice bonuses, and make our bankers happy. What else do you need?

Securing a new major customer or high-profile strategic partner was essential to our business model. We were an emerging growth products company that had its share of false starts, underperformance, and enormous stock volatility. Customers and strategic partners helped provide new sources of revenue and helped to validate our emerging new technology story.

Our story began almost entirely as a domestic business model. Top line growth is never easy, but expanding into new markets and territories is always an obvious place for the CEO to devote a major portion of his or her attention.

Difficult Hurdles to Growing Your Company

Looking back over the last twenty years, I would say access to capital, increasingly difficult regulatory hurdles, resistance to change, and people issues were at the top of the list of difficult situations faced while growing the company.

I have already talked at length about the almost constant need to access the capital markets to grow your medical device business. We were forced to be creative when the VCs rejected us in the beginning. But that minor setback helped us to learn to be more entrepreneurial and creative in funding our business in the early stages. In the end, this turned out to be the least costly way to finance our business and it saved us large chunks of equity, but it seemed to be a never-ending priority that often consumed more than 50

percent of the CEO's time. And don't kid yourself—if you are out raising money, you cannot be fully focused on running the business, no matter how many hours you spend at your job.

Over the past several years, the regulatory hurdles have gotten extremely complicated and onerous for an emerging medical device company. It now takes more time, more people, and lots more money than in the "old days." For an early stage company, these costs can tank any aspiring new product and/or technology company. My personal experience with the FDA and other regulatory agencies has been nothing short of outstanding. These dedicated people were invaluable to help us sort through the myriad of regulatory issues that needed to be accomplished before we could secure the necessary FDA clearances to sell our products. That said, the regulatory hurdles are not for the faint of heart.

I continue to be baffled to see how long it takes new customers to change habits and practices, regardless of how good your new product or technology may be. People are generally risk adverse, and when they do consider change, they will do it in a slow and deliberate way. You must find risk takers who want to be the first to try your new product or technology. You must find these early adopters that help you establish creditability with the broader marketplace. Don't forget the old adage that "it always takes longer than you think it should."

We had great employees at OraSure, but as we quickly grew the employee ranks, I was surprised to see the enormous amount of time that was consumed with the everyday issues of running a business. Health care, compensation, recruiting, and maintaining morale were just a few of the endless myriad of issues that will consume large chunks of your time. These are all very important issues that demand your undivided attention, but you must remember that investors will almost never give you any credit for caring for your employees. Unfortunate but true.

Dealing with Venture Capital Investors

Once you bring institutional money into the equation, the entrepreneur and co-founders of any business must accept the fact that their world will never be the same again.

Entrepreneurs must be willing to acknowledge that the preferred stock offering will include terminology that makes their role as the CEO as optional and at the sole discretion of the VC investors. The CEO must realize that they are really now just employees at will like every other employee in their company.

These same entrepreneurs and CEOs must be willing to accept the fact that most VCs think that entrepreneurs do not make good managers of growth oriented medical device companies. Most VCs already have a deep list of ready and waiting former CEOs with some sort of record that are ready to quickly step in at the first signs of difficulties. It's just the way it is.

VC investors have a fiduciary responsibility to their investors the same way that the founders have a responsibility to their investors. The motivation is generally aligned from a shareholder maximization perspective, but the approach may be radically different once the VC investors are legally in charge.

Raising Capital in the Medical Device Industry

Depending on the stage of your business and the amount of capital required, there are several options to consider when raising capital in the medical device space.

There are many specialized VC firms that specialize in the medical device industry. There is plenty of money on the streets today for companies that have a compelling business model, strong management, and reasonable performance milestones. With the Internet and resources like the National Venture Capital Association (NVCA), these firms are readily accessible for virtually any qualified investment prospect.

In addition to your traditional VC sources, there are many local and regional economic development agencies committed to making early stage medical device and biotechnology investments. In my home state of Pennsylvania, there are many options for aspiring entrepreneurs with a great idea. The level of capital available is generally limited for these economic development agencies, but for an early stage company, these resources may be a great first step.

If you have a proven record of making money for investors in the past, you may very well be able to attract angel investors into your new business venture.

Finding a Good Investment Partner

I initially funded our business through angel investors. These accredited investors invest primarily in people, their record, and the potential for high alternative investment returns. I have typically found this class of investors to be patient and passive; however, routine, open book style communication through quarterly shareholder letters is essential. Without a record, this is a tough crowd to crack into and the funding levels may be somewhat limiting.

When I look for VC investors, I am looking for what value-added services that they can/will provide besides growth capital. Mentoring, industry networking, and leadership in identifying major exit strategy opportunities are important.

As we formed Originate Ventures, a new $30 million VC fund, we focused on helping early stage companies build strong brands to maximize their growth potential. We believe that there is substantial value in matching investors that understand the entrepreneurial journey and can help the entrepreneurs avoid the pitfalls typically encountered in the early stage development of a company.

Corporate partnering is also a great way to finance your business if you can figure out how the corporate partner may benefit from your product or technology in the future. This is often a tricky process, and you may have to give up too much of your company in exchange for the funding that you need, but this has been a viable option for many early stage medical device companies and should not be overlooked as you evaluate your funding options. Exchanging certain distribution rights to narrow markets is another viable alternative to consider.

Networking is a major key to success in finding funding for any medical device company. Any time that a credible source can make an introduction

with an unqualified recommendation, your chances for securing funding on favorable terms goes up substantially.

The Fundraising Process: The Two-Minute Pitch

The best advice that I could give to any CEO who is going through the VC fundraising process in this field is to learn to give a powerful two-minute elevator pitch. You have to assume that investors have endless opportunities to invest capital, and you must learn to give them a compelling reason to stop what they are doing and to get immediately interested in your value proposition.

When I raised $50 million in a secondary offering as the CEO of OraSure, I made 107 presentations in twenty-three cities in thirteen days. No meeting lasted more than thirty minutes. If I did not have their undivided attention in the first two minutes, I might as well have packed my bag and moved on to the next presentation. People are busy—bottom line first, and make it stick.

If you get past the first two minutes and you know that you have the attention of the potential investors, make sure that your presentation is simple and addresses the main selling points in your investment thesis.

Know Your Market Value

It is also essential for any CEO who is involved in the fundraising process to fully understand their market valuation before starting to raise money. As a private company, this is often as much an art as it is a science, so you must be prepared to defend your fully diluted pre-money valuation and have a reasonable methodology with market comparatives to support your position.

I have been surprised to see in my first few months as a VC that many entrepreneurs do not even know the definition of a fully diluted pre-money valuation nor do they understand precisely what the use of proceeds will be used for. I think the CEO greatly compromises his or her credibility if they have not carefully considered these fundamental questions and have defensible answers. In most cases, I think that the VCs will reject these

companies due to a lack of basic financial understanding of their business. If the VC does proceed with further due diligence, you can bet that the valuation will not be near as high as the entrepreneur anticipates. But how can the entrepreneur be upset since they did not strongly defend their own valuation from the very beginning?

Some entrepreneurs might say that they don't want to set the price too low and leave something on the table or set it too high and alienate the VC from the beginning. I would disagree with that logic. It is never too low for a savvy VC investor but they will be quick to tell you if it is too high. If you are too far apart on valuation, and the entrepreneur is unwilling to budge, at least you will save everyone a lot of time and wasted emotional energy.

What is meant by "fully diluted pre-money valuation"?

In calculating a fully diluted pre-money valuation, you must add all existing common stock, preferred stock, warrants, options, convertible debt, and any other equity arrangements as if they are fully converted into common stock. The total converted shares are then multiplied by the most recent price for common stock that was sold by the company.

Entrepreneurs should understand this is one of the most misunderstood and highly contentious items between VCs and the entrepreneur and it always will be.

Timing – When is it best to raise capital?

It is always best to raise capital after achieving a major milestone event. For example, securing an important strategic distribution partnership or landing a major new customer. If you can be perceived as a hot prospect, the basic laws of supply and demand will kick in and you should be able to secure your funding on more favorable terms in a shorter period than normally expected.

For early stage medical device companies, hitting a critical technical milestone, achieving favorable clinical trial results, or reaching certain regulatory hurdles are all important inflection points for raising capital. For early stage medical device investors, they may very well be more focused on

what the "step up" in value may be if you successfully achieve your developmental milestones than they are in thinking about market valuations or exit values. You need to understand the mind-set of your investors and know at what stage they invest, what their critical success factors are, and how you fit best in their investment criteria.

How much capital should you raise?

I think it is always important to raise sufficient capital to at least get you through your next major milestone event. After carefully calculating the cost to get to that next major milestone, double or triple that amount, since it always seems to take twice as long and cost twice as much money than originally anticipated.

What is too much capital?

When I went for my first round of VC financing I was seeking $3 million. I ended up raising $9.2 million in under sixty days in a "down round." The best advice that I could get at the time suggested that I should never turn capital down and that I should take it whenever it was available. Although I had not used that logic for the first ten years of my business, I took the money and went back to running the business.

Less than eighteen months later, we went public as part of a strategic merger with an existing public company. At that time, we had more than $9 million on our balance sheet. In our case, I diluted our investors more than really required. In the end, it all worked out amazingly well, but I will never forget that event.

What is a "down round"?

A down round is a term commonly used to indicate that the fully diluted pre-money valuation on a per share basis is lower than previous rounds of fundraising.

The typical reason for a down round is often due to lower than anticipated revenues, failure to reach certain technical milestones, or material changes in general market condition (i.e., post dot.com or post 9/11).

What if I need money and have not performed?

This is a very difficult situation to be in, but unfortunately, this is the case for many companies seeking funding in the medical device business. Expect a down round. Be quick to explain why you failed to deliver in the past and how that will never happen again. Hopefully, your business proposition is compelling enough that someone will give you another chance. But either way, it will be very expensive.

Develop a Broad Network of Contacts

The best resource I had during my fundraising efforts was my outside general counsel. His law practice was focused on VCs, he was highly respected and in high demand, and he knew everyone. When he made a phone call to a potential funding source, he would generally get a call back within a day or two. After that, I was on my own. But for me, if a door was opened, I could generally close the deal.

In addition to your general counsel, don't be bashful to reach out to your other professional advisers including, but not limited to, local accountants, bankers, and the economic development agencies. If you know other entrepreneurs that have received funding in the past, don't be bashful to talk to them as well.

Avoid Bad Investors

Probably the best piece of financing advice that I ever received was to always avoid bad investors. Do your homework. Investors develop a reputation for an investment "style," and you should make sure that your styles are compatible.

When I was raising money from angel investors, I would inevitably run into a few potential investors that expected "special terms." They would want exclusive rights to supply some type of commodity service (i.e., property and casualty insurance, printing services) in exchange for a nominal cash investment. Just say no. It is not fair to other investors.

In my first few months as a VC, I have found that some early stage companies had given suppliers stock in lieu of cash. I think this is a fatal flaw and will come back to haunt you sometime in the future. Delay

payments, renegotiate terms, but don't give up your equity to a supplier under any circumstances. That is just a really bad idea.

Should I offer terms to a VC investor?

When it comes to VC financing, it should be noted that most VCs have a standardized template for preferred stock term sheets. However, I always opted to prepare the first draft of any term sheet because taking the first cut at terms of the deal ultimately saves you time and money, and sets the overall tone for the deal. If you are too far apart, you will learn that sooner than later, and you can redirect your energies to a funding source that may be more willing to accept your terms. On the other hand, if you are routinely rejected because your terms are unreasonable, take note and regroup. It is far better to revise your terms than to run out of money and then be left without any cash and no negotiating leverage whatsoever.

Deal Killers – Due Diligence

If you have a non-binding term sheet in place, and the due diligence has started, it is essential that there are no skeletons in the closet. Assure yourself, if they exist, they will be found. When they are found, you will likely kill the deal and will make it difficult for future sources of capital to take you seriously. It is a small industry and people do talk, so never give them a legitimate reason to say that you tried to hide something or that you cannot be trusted.

I always treated my banker like my best friend. Friends will stick with you through the worst of times as long as they trust you. If they don't trust you, even your best friends will usually hit the road, too. Investors are no different. It should come as no surprise.

VC Investors – When will they invest more money?

There are many variables to consider when evaluating whether or not an existing VC investor will reinvest when additional capital is required. Some of the most obvious reasons are based on the company's actual performance, up or down valuation, the amount of capital needed, the

capital position of the fund itself, and the actual current ownership of the fund in the company.

If the VC investor got in at a good price and there is a large step-up in value, it may be psychologically difficult for the VC to pay more. If the valuation has gone sideways, why put more money in, except to encourage others to follow. If it is a down round, the VC investor is likely to have downside protection and they may see this as an opportunity to really crank up their ownership position or they may be almost begging others to invest because they don't want to put in any more money, but don't want to write off their investment either. If a VC has deployed all their capital in a fund and has not raised additional capital, they may not be able to invest even if they wanted to.

Given a choice, as a medical device CEO, I think that I would generally prefer to bring in new money from new sources in almost all circumstances. In this way, I am diversifying my investor base and hopefully I am bringing in additional talent to help guide me in growing the business in the future.

Timing the Exit Strategy

The main exit strategy options for medical device companies generally would include sale to a strategic partner; merger with an existing public company; and roll-up to a private equity group. Although an IPO is another option to consider, it has been out of favor for quite some time and is one of the most difficult options available in the market today.

Liquidity expectations should be routinely discussed in order to normalize expectations between management and its investors. Since it is part of the CEO's normal responsibilities to seek liquidity events at the discretion of the board of directors, it is important that the board and management see eye to eye.

Market forces may well affect your timing as well. The medical device industry goes through many wild cycles and if your timing is out of sync with the market, even the best companies may not have exits that meet their valuation or timing expectations.

Risk Factors That Impact the Exit Timeline

In the medical device market, the product life cycle for any new product or technology is always highly debatable due to the rapid pace of technological change in the marketplace today.

Additionally, risk factors in the prospectus may seem to be there just for liability protection purposes, but any one of the typical risk factors could severely affect the timeline to an exit. They should not be taken for granted. They include, but are not limited to the following:

- New technologies may make your product/technology obsolete
- Face bigger and better financed competitors
- May not get your patents issued and may infringe on the patent rights of others
- Your clinical trial results may not be satisfactory
- May not be able to meet the FDA requirements to secure approval for your medical device
- May not be able to raise money in the future on terms that are as favorable as they are today
- The list goes on and on…

A good medical device company CEO is always reassessing the situation to ensure that these risk factors will not materially negatively impact the value of his business going forward if at all possible. But force majeure is a real factor in this space, and investors are well aware that there are many factors outside the control of management that can negatively impact the results and the viability of any medical device business.

Sometimes Exit Strategies and Liquidity Are Not the Same

I was naive to think that I had created a liquidity event for the co-founders of our company when we merged with Epitope to form OraSure (NASDAQ: OSUR). As the CEO and an insider, it was virtually impossible to liquidate any material portion of my large equity position because we were thinly traded and the "message" to the street was perceived as a huge negative. It was a common way of thinking that if the CEO is selling any stock whatsoever, then there must be something seriously wrong. Sell now,

ask questions later. Wow, this made it virtually impossible to diversify my highly concentrated position despite almost sixteen years of sweat equity and lots of personal debt.

In the end, the only way to really liquidate my highly concentrated equity position in OraSure was to retire. Walk away and quietly diversify my position without being under the microscope of investors. So that is what I did.

Lessons Learned as an Entrepreneur

I have often been asked to speak to groups about what lessons that I have learned as an entrepreneur. They are really quite simple but quite meaningful to me:

- Write your own vision statement
- Think outside the box
- The greatest ideas are often the simplest
- Money does not buy happiness
- Love what you do or get out
- Fight for your causes
- Embrace change—do not be left behind
- Be honest with yourself and others
- A handshake beats an e-mail any day
- Periodically rethink, revise, and rewrite your vision

Journey to the "Dark Side"

Using a popular *Star Wars* phrase, if an entrepreneur moves from being a medical device CEO to being a VC, many of your peers will assume that you are taking the path to the "Dark Side."

I spent the last twenty years as a serial entrepreneur. I raised more than $100 million from an eclectic mix of local economic development agencies, angel investors, strategic corporate partners, VCs, and from institutional investors. Our journey was often a rocky one. I lost count of the number of times that I thought that all bets were off, that we would not reach our next milestone, and that funding may dry up forever. We never gave up and in

the end, the fruits of our labor paid off handsomely for our investors, our employees, and for the co-founders of the business.

After three years of retirement, I was excited to jump back in the game on the other side of the table as a VC. In 2007, I co-founded Originate Ventures (www.originateventures.com), a start-up VC firm that seeks to make VC investments in growth-oriented product and service companies in Eastern Pennsylvania and the surrounding area. We raised $30 million to start the fund, and it should come as no surprise that the bulk of the money came from angel investors and local and state economic development agencies. My partner and I contributed $4 million of the total and this was very important to me that we lead by example. You should know that it is always easier to sell investors on your vision when you have serious amount of "skin" in the game. My partner and I would not have it any other way.

Our vision is quite simple: "Entrepreneurs investing in entrepreneurs." We expect to achieve our vision by executing the following business model:

- Build strong brands by taking a clear, compelling, and unique idea and enabling scale
- Compress time to market by shortening the time from business concept to brand
- Achieve superior returns and create win-win situations for Originate and our portfolio companies

We also developed a set of core values that provides us with a clear and unambiguous set of guidelines. As a medical device CEO, my core values were trust, agility, innovation, and quality. In our new lives as VC investors, they are as follows:

- *Integrity* – Truth & Transparency
- *Innovation* – Creativity & Initiative
- *Agility* – Responsiveness & Decisiveness
- *Mutuality* – Fair & Equitable
- *Accountability* – Responsible & Accessible
- *Philanthropy* – Community, Support & Betterment

We expect to be entrepreneurial and will evaluate opportunities within a broad range of investment criteria:

- Invest $500,000 to $4 million per portfolio company
- Invest in early stage, growth, or special situations
- Seek high margin (>50 percent), high growth and high value
- Identify great product ideas with large target markets
- Preference given to strong, passionate entrepreneurial management teams
- Expect returns of at least five times in five years

We look forward to starting this new journey where we can apply our entrepreneurial experiences to our portfolio companies. We recognize there will always be a fine line between the needs of the entrepreneur and the fiduciary responsibility to our private equity investors, and we look forward to that challenge.

I look forward to writing the next chapter in my entrepreneurial journey.

Mike Gausling has spent twenty years as a serial entrepreneur and was co-founder and former CEO of OraSure Technologies (NASDAQ: OSUR). Mr. Gausling helped build OraSure from a start-up to more than $50 million in annual sales and a market capitalization of more than $500 million. OraSure is best known for developing, manufacturing, and selling the world's first and only rapid oral fluid HIV test. Mr. Gausling retired from OraSure in 2004 at age forty-six.

In 2007, after three years of reinventing his relationship with his family, running a marathon, building a lake house, and struggling to ride a bike in the mountains near the 2004 Tour de France, Mr. Gausling co-founded Originate Ventures, a $30 million venture capital fund focused on investing in early stage companies in Eastern Pennsylvania.

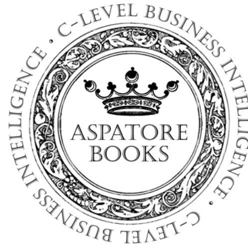
Altogether, Mr. Gausling has raised more than $100 million as an entrepreneur and as a venture capitalist to fund early stage growth-oriented businesses. He has raised money from angel investors, venture capitalists, commercial banks, and from institutional investors.

Mr. Gausling currently serves as a board member and audit chair at KNBT Bancorp (NASDAQ: KNBT). Since Mr. Gausling joined the board in 2000, the bank has grown from $800 million in assets to be one of the largest community banks in northeastern Pennsylvania, with more than $3 billion in assets. In September 2007, KNBT announced that it would merge with another regional bank resulting in combined assets totaling more than $8.7 billion.

Mr. Gausling is currently the treasurer of LVIP, a local nonprofit land development company. LVIP recently acquired a large former Bethlehem Steel brownfield site and expects to invest $100 million in the redevelopment of the site into prime industrial, retail, and commercial space.

Mr. Gausling also serves on the health care advisory board of Safeguard Scientifics (NYSE: SFE), a publicly traded venture capital firm located in Philadelphia.

Dedication: *This chapter is dedicated to my wife Sharon and my son Andrei.*



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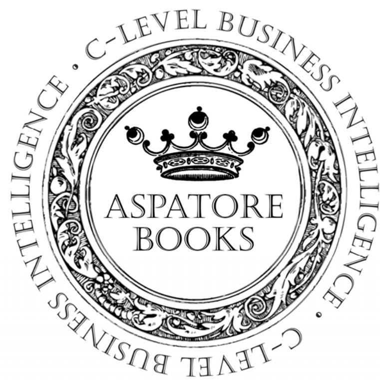
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