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How to Build Great Companies

An Interview with Hank Plain

by
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KEY POINTS

- After an early success as the CEO of Perclose, Hank Plain has spent the last decade and a half mentoring and investing in companies, first as Vice Chairman of The Foundry and, more recently, as part of Lightstone Ventures, a VC firm formed a couple of years ago from the medtech teams of Morgenthaler and ATV and focused on medical devices.

- Though he recognizes that the VC model isn't perfect, Plain insists that the right VC group can be extremely valuable for start-up companies, though he advises start-ups to do the same kind of due diligence on potential investors that investors do on potential investments.

- New sources of capital from strategics as well as investors and government agencies in places like Ireland and Singapore can help offset a decline in capital available from traditional US-based VCs; in fact, Lightstone itself has recently set up an office in Singapore.

- For all of the challenges they face, Plain is optimistic about the future of venture-backed medtech companies, largely because the demand on the part of big companies for novel technologies is rising, while the supply of small companies has fallen dramatically over the past several years.

In his 30 years or so in medical devices, Hank Plain has seen the medical device industry's good times and bad. Having left Eli Lilly in the mid-1990s for femoral artery closure device start-up Perclose, a John Simpson company, Plain took what even company officials thought would be a minor opportunity and turned it into a $680 million success and the building block for what has become **Abbott Laboratories**' cardiovascular business.

Hank Plain

Perclose was successful beyond both Plain's and Simpson's wildest dreams. But the experience convinced Plain that he didn't want to run another public medical device company. Instead, after turning down offers from a number of venture capital firms, he joined incubator *extraordinaire* The Foundry where, as Vice Chairman, he helped bring companies like Evalve in mitral valves (now part of Abbott) and Concentric Medical in stroke (acquired by **Stryker Corp.**) to the fore. Not that there weren't stumbles along the way—Xtent (in interventional cardiology) and obesity

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company Satiety come to mind—but since about a decade ago, The Foundry's success has been unparalleled, and Plain was an integral member of a team that has turned out more successful companies than any other incubator in medtech.

During the same period, independent of The Foundry, Plain also played an important role in the fortunes of companies like Acclarent in the ENT space, now part of **Johnson & Johnson**, and cardiology company AccessClosure (bought by **Cardinal Health**). More recently, Plain was in on the founding of Lightstone Ventures, a medtech-focused venture firm formed by the merger of the device teams of Morgenthaler Ventures and Advanced Technology Ventures (ATV). And though he's well aware of the challenges and obstacles that start-ups face today, Plain remains optimistic about the future of the venture-backed medtech industry—optimistic that there are still large unmet clinical needs that will reward small companies with important technologies, and that new sources of capital are springing up, from strategics and ex-US investors, to fill the gap left by the departure in recent years of so many VC firms that have historically invested in medtech companies.

But what really drives Plain's optimism is a world view that holds that for all of the changes among the medtech multinationals, their need for new technologies to fuel pipelines is stronger than ever. "It's Economics 101," he says. "The demand on the part of large companies is higher than it's ever been and it's only going to go higher because they need new differentiated products." At the same time, venture capital for life-science start-ups has dried up, such that the number of start-ups has declined by 60-70% over the last several years. Large medtech companies are well aware of this gap, Plain says. In the following interview, adapted from a session at the recent Innovation in Medtech conference in Dublin, Plain talks about his career and about the future of the medical device industry.

The MedTech Strategist: ***Hank, let's begin by talking about your first CEO role, which was at Perclose. How did you get to Perclose and what did you see as the likely trajectory of the company when you got there?***

Hank Plain: I joined Perclose in 1993 after 12 years at Eli Lilly. In those days Lilly invested heavily in developing their own management through multiple cross-functional assignments. I had ten different jobs in multiple divisions during my 12 years, which was great training for the Perclose CEO role. At Perclose, we were developing a suture-based vascular closure device. We were fourth to the market, but we were the market leader at the time we sold the company. We took the company public in 1995 and sold it to Abbott Labs in 1999.

MTS: ***I know you were recruited to Perclose by John Simpson. What did he tell you about the company when he approached you?***

Plain: Perclose and LocalMed were two companies that my mentor, Dr. John Simpson, and his colleagues started in April of 1992. LocalMed focused on drug delivery for treating coronary disease. John's entire professional life has been dedicated to curing coronary and peripheral artery disease, and he was never a big fan of stents. He and others thought local drug delivery would be the cure for coronary disease. Perclose, on the other hand, was developing this little vascular closure device. While John was recruiting me, I asked him what he thought a reasonable acquisition value for Perclose might be. John said he thought the exit would be probably $30-40 million. So, I took the job thinking that 5% of Perclose at a $30 million exit value was pretty attractive. In the end, we wound up selling it to Abbott for $680 million.

MTS: ***That was a great exit. But I know it wasn't that easy, that, in fact, you waited for someone to come in and buy the company when it might have gone for $30 or $40 million but that didn't happen. What did you have to do to get Perclose to the point where it was worth $680 million?***

Plain: I think it's true of anyone who's been successful in the medical device industry that you have to be good at adapting and persevering. It made all the sense in the world to me when I took the CEO job that Guidant, J&J or Boston Scientific or one of the other major players in interventional cardiology ought to own Perclose. I assumed that after we completed the clinical trial and received US approval, we'd get acquired. But I wound up being like the Maytag repair man—the phone just never

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rang. So we focused on building the company to $100 million in sales. Ultimately, we were contacted by Abbott because they wanted to get into the interventional cardiology space and Perclose was a way of putting their toe in the water with a strong sales and marketing team. It was the first of several acquisitions they did. And when Guidant sold to Boston Scientific, Abbott wound up with the spinoff of one of the best interventional cardiology businesses in the industry. Perclose was one of the first small steps toward what became Abbott Vascular.

Reflecting back, the medtech challenges over the last decade have wiped out 70% or more of the early-stage venture funds in the US.

MTS: ***There are lots of ways of calculating valuations. But there's a huge difference between the $30-40 million John Simpson envisioned and the $680 million Abbott paid. Did the purchase price surprise you? Did you ever go back to John Simpson and tell him he was wrong?***

Plain: No. In fairness, John was just focused on helping patients and not much of an investment banker when it came to predicting exit value. He was key to building the company to a great success. The reality is, at the time of the sale, we were a publicly traded company, on our way to $100 million in sales. So it was a nice multiple, but it wasn't outrageous. Abbott paid a premium, but the public stock market value set the price. I remember a friend of mine who told me when he heard the purchase price, he thought the press release had the decimal point in the wrong place. So there were some who were surprised.

MTS: ***How long did you stay at Abbott after the deal?***

Plain: I was there for nine months after the acquisition. Actually, I'd planned to stay at Abbott, but it's very difficult to make the transition from running a company to being just a part of the management team. It had been a long race with Perclose. After seven years, it was time for me to move on.

MTS: ***Was that your decision? Or did Abbott kind of hint that it was time for you to leave?***

Plain: No, they were surprised when I departed. I was working for Rick Gonzales at the time [now CEO of Abbott's spun-off pharmaceutical company, Abbvie]—he was one of the best bosses I ever had—and he wanted me to stay because they didn't have a lot of experience in the cardiology space. Fortunately, I got out before they found out how little I knew. It was good timing on my part.

MTS: ***Having taken Perclose to a $680 million exit, I would imagine that in 1999, when you left, you'd have had your pick of CEO jobs. But you joined the incubator, The Foundry, which was just starting at that time. What appealed to you about The Foundry and why didn't you take some other CEO post or join a VC firm?***

Plain: I decided after Perclose that the one thing I never wanted to do again was be a public company CEO. It was tough then; today, it's off-the-charts difficult. I admire the guys who do it. The opportunities that presented at the time were to join either a venture capital firm or The Foundry.

If you hang around this industry long enough, you realize that medtech goes through cycles. 1999 was the era of the IT/dot-com boom. I interviewed with one of the venture firms that had done medical device investing but had shifted to doing more IT investing. A former medtech VC who switched to IT asked me in the interview process, 'Why would we invest in medical devices? We're printing money with our IT companies.'

I heard that a lot and decided I didn't want to fight that fight, day in and day out. So I joined The Foundry instead, and frankly, it was the smartest thing I've ever done. I've been fortunate to have had great mentors along the way, people like John Simpson, Tom Fogarty, Paul Yock, Allan Will, and many others. But joining The Foundry was transformational—to be a part of that incredibly bright engineering team was a great opportunity. Since I've never invented anything in my life, my one fear was that they had already come up with all of their good ideas. I wasn't so sure about the whole serial entrepreneur thing. When I joined, we were working on the third Foundry start-up company. While I was there, we started eight companies and now they're on their 15th company. But The Foundry isn't about the quantity of companies started; it's about quality companies with technologies that benefit patients and about putting great teams together. Since I'm not an

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inventor, I hope I contributed by helping build great management teams and getting the companies financed.

MTS: ***I think it's beyond question that The Foundry has been a phenomenal engine for turning out great companies. But some people may not remember that there were a few missteps early on, companies that weren't successful. To your mind, what was the difference between successful companies like Concentric, Evalve, Ardian [in renal denervation, acquired by* Medtronic plc*], and Twelve [mitral valve company acquired by Medtronic] and those that weren't, like Satiety and Xtent?***

Plain: Well, some companies just take longer to succeed. Concentric had something like a ten-year path to success. But sometimes it's just a matter of bad timing. This industry has faced some really difficult times in my career. If you go back to 1995 or 1996, there were medtech companies going public based on a device drawing on a napkin. Those were great times, but will probably never be repeated. By the mid-2000s, when some of The Foundry's early companies were in clinical trials, it was a very difficult time for small medtech companies, particularly in dealing with the FDA. That period wiped out a lot of good companies.

MTS: ***Like Xtent…***

Plain: Like Xtent and Satiety.

MTS: ***What was it about the regulatory climate that stymied Satiety and Xtent?***

Plain: Xtent developed a customizable coronary drug-eluting stent (DES) that allowed cardiologists to match the length of the stent specifically to the length of the lesion in the coronary arteries. It had the potential to eliminate the cost and complexity of overlapping multiple DES. Their early clinical data was incredibly promising. We tried to get the FDA to approve our IDE to do a large US randomized clinical trial to prove the benefit of our stent in diffuse disease and difficult lesions. But at the time, the FDA was totally wound around the axle regarding concerns raised about LST (late stent thrombosis) and drug-eluting stents. FDA delayed the IDE for nearly two years, and the company basically ran out of money. Would Xtent have gone on to great success and benefitted millions of patients? Who knows? But I think the company should have been allowed to prove the safety and efficacy in a randomized trial. That was a very dark period for medtech due to the unpredictability of dealing with the FDA.

With Satiety, the FDA raised the efficacy bar so high on obesity devices that although we successfully completed the US clinical trial, we didn't submit it for approval. Since then, the FDA has approved obesity devices with lower efficacy. To their credit, and I'll give Jeff Shuren [Director of the FDA's CDRH] props for this, I think the FDA has changed dramatically and is now much more predictable. We're seeing companies today go through a very thoughtful FDA process. For example, we knew that our mitral valve replacement company, Twelve, was certainly going to require a PMA process, and it should. But other companies with devices that have a reasonable risk profile are being considered for a 510(k) or a *de novo* 510(k) regulatory path. I don't think the FDA is our industry's biggest problem anymore.

There are other challenges for new technology, like reimbursement and early-stage financing. Reflecting back, the medtech challenges over the last decade have wiped out 70% or more of the early-stage venture funds in the US. That's why we're so excited about the opportunities in Ireland and appreciate the support of EI [Enterprise Ireland] and the ISIF [the Irish Strategic Investment Fund]. At Lightstone Ventures, we're finding new sources of capital all over the world, like Ireland and Singapore. In our legacy funds at Morgenthaler and ATV, whose healthcare teams came together to start Lightstone, 20% of our funds came from outside the US. At Lightstone, that number is about 60%. [*Editor's Note – Lightstone recently set up an office in Singapore, working with the government and other financing sources to invest in medtech companies.*]

MTS: ***Before we get to Lightstone and your move into venture capital, I want to ask about the companies you were involved in that weren't part of The Foundry, companies like Acclarent and AccessClosure. How did those opportunities come to you and what did you do for those companies? Was there any perceived conflict of interest within The Foundry when you were working, for example, on Acclarent?***

Plain: When I joined the Foundry, I had the opportunity to take a couple of outside board seats. And I chose wisely. I was on Josh Makower's Exploramed/NEA company board for TransVascular when we sold it to Medtronic. He then asked me to join the Acclarent board just before we achieved FDA clearance. I helped recruit CEO Bill Facteau,

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my former colleague at Perclose. There is nothing more rewarding than seeing one of my team do such a great job building a strong company in a completely new space. I was Chairman of Fred Khosravi's company Embolic Protection for nine months before we sold it to Boston Scientific. I told Fred it was the best summer job I ever had. Fred then asked me to join the AccessClosure board. The company grew to $85 million in sales but had the most difficult intellectual property and fundraising challenge I've ever experienced. Ultimately, Fred, CEO Greg Casciaro, and their team executed flawlessly on the commercial and legal fronts, which led to the acquisition by Cardinal Health.

At Lightstone Ventures, we're finding new sources of capital all over the world, like Ireland and Singapore. In our legacy funds at Morgenthaler and ATV, 20% of our funds came from outside the US. At Lightstone, that number is about 60%.

MTS: ***Let's get back to Lightstone and your move into venture capital. Earlier, you were kind in describing the state of venture capital in the early 2000s. You once told me that the reason you didn't join a venture capital firm was because they were so screwed up at the time. US-based venture capital went through a robust period in the mid-2000s, but it's been in a bit of a funk since then. Why did you join Lightstone? What had changed between 2000 and 2010? And, more to the point, do you think venture capital is still screwed up? Or is it fixing itself?***

Plain: Well, many venture capital partnerships are dysfunctional. The reason that I said no to venture capital seven times before I said yes is that at most firms, when you do due diligence, many of the partners don't get along. Fortunately, I've been lucky to enjoy my partners and benefit from their insights.

MTS: ***You mean that the partners don't get along with each other internally, not that they don't get along with other VCs.***

Plain: Yes, internally. VCs get along with VCs at other firms because they need to work together to syndicate deals. But internally, there too often isn't the same feeling. There's a lot of competition between the IT teams and the healthcare teams and even sometimes between the biotech teams and the medtech teams. And we've seen that play out with a lot of good investors being forced out of various firms, which is unfortunate.

But my decision to join Lightstone was easy. Look, nobody's feeling too sorry for VCs, I understand that. I still have enough of an entrepreneurial mindset that I have self-loathing as a VC. But I've co-invested for 15 years with my Lightstone partners Mike Carusi and Jean George, along with Jason Lettmann, who runs our Dublin, Ireland, operation. We came together to form Lightstone because having worked together on so many deals, it was clear that we were like-minded; we saw risks and opportunities the same way. And if you look at the pattern of our investments, we work with the same serial entrepreneurs and management teams we've worked with for years: Hanson Gifford and Mark Deem [of The Foundry] are venture partners, and we're backing companies started by Josh Makower and Fred Khosravi [of the incubator Incept].These serial entrepreneurs have been the source of my and our greatest company successes.

MTS: ***It sounds like one of the things you're saying, at least implicitly, is that start-up CEOs looking for capital should look at the intra-firm relationships and partnerships at the VCs they're thinking of approaching.***

Plain: You're absolutely right. As a former entrepreneur, one thing I'd say is that VCs do an enormous amount of due diligence on CEOs, their track record, the company, its team and products. And in many cases, entrepreneurs don't do the same diligence on their venture investors. The belief is that 'all money is green.' One thing that has killed many good companies is dysfunction on the board—having VCs who aren't supportive and see success only if they win and everyone else loses.

MTS: ***I've heard that so often from CEOs. They find themselves with investors who want to get out the minute things start going south. They want to get their money back before everyone else. That said, it's easier for a VC to say no to an entrepreneur than for an entrepreneur to say no to a VC. Would you ever advise a CEO not to take venture money when it's offered?***

Plain: Yes. I wouldn't advise them to take any money from an investor if they haven't done any due diligence

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on the investor. I also wouldn't advise them to take any venture money if they're working on a very capital-efficient project, where the idea is to take the company to a certain stage and sell it. In that case, venture capital may not make sense. But the right venture capital group can be extremely valuable.

MTS: ***I think one of the most interesting things about you is that, for all that you've seen and accomplished, in contrast to so many discouraging views, you're not only optimistic about the future of venture capital in medical devices, you believe the venture model still works.***

Plain: That's right.

MTS: ***What makes you optimistic when so many others are pessimistic?***

Plain: We've had a very consistent investment pattern. We've historically invested in companies working on big ideas that will change how medicine is practiced—Ardian, Acclarent, Transcend, Twelve. For example, we love companies developing devices that are alternatives to drugs. Everyone would like to think there's a magic pill for every disease, but the reality is, drugs often have side effects, limited efficacy, or compliance issues. (*Also see "The GERD Device Market: At the Crossroads," this issue.*) If you can deal with one or more of those problems with a truly therapeutic device, then you have high strategic relevance to large medtech acquirers. And if you have a device that competes in large drug markets, you can bring companies like GSK, J&J, and Merck into the bidding process. That changes the exit potential value from the typical $150 million to something closer to $1 billion.

With my venture board load, my bandwidth is limited. I'd rather take my time to find one of these big opportunities than to take ten shots on goal with smaller opportunities. But the real reason I'm optimistic, and the reason I think this industry has turned the corner, is we're seeing new sources of capital from around the world, and, at the same time, the large medtech companies are starved for growth and need to acquire. It's Economics 101: the demand on the part of large companies is higher than it's ever been and only going to go higher because they need new differentiated products. At the same time, because there was so little venture capital available, the supply of companies getting started has gone down over the last several years by 60-70%. If you talk to the large medtech companies, they all recognize this. The reason many large medtech companies are increasing venture investing is because innovation is the lifeblood of their future so they are filling the VC void. For example, when Medtronic acquired our portfolio company Twelve after treating only six patients, the early acquisition was driven by a scarcity of viable alternatives. I think we're going to see more of this as the supply of start-up companies is constrained by a lack of funding sources.

> ***One thing that has killed many good companies is dysfunction on the board—having VCs who aren't supportive and see success only if they win and everyone else loses.***

Over the past five years, nearly every major medical device company has had a CEO change. When new CEOs come in, they have new initiatives, all aimed at fixing the problem of declining internal growth. And very often that means they come back to a strategy of growth through acquisition.

I'm also encouraged to see the large medtech companies doing more venture investing. At Lightstone, we work hard to build those strategic relationships. With the decline of traditional venture capital sources, we're seeing more strategic investment, even in early rounds. We work on those relationships, and we also try to invest in areas where we think there is high strategic relevance for the big company acquirers.

MTS: ***Given your relationship with The Foundry, what do you think of The Foundry's FIRE1 program, which engaged a single strategic partner, Medtronic, before the project has even been selected, and committed to them? As an investor, does that model appeal to you? Or are there issues with it that make you nervous? (See "FIRE1: A New Model for Early-Stage Device Development,"*** **The MedTech Strategist*****, October 10, 2014.)***

Plain: Well, there's always the risk that once you've decided on a project with Medtronic's input, they'll get to the decision point on the option and decide they don't want to acquire the company. With FIRE1, we've done everything we can to structure the deal to make sure that we are

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going to do something in an area that Covidien initially, and then Medtronic, are keenly interested in, that there's buy-in throughout the organization, and there are incentives to make them want to buy the company. There's also both a carrot and stick if they decide not to move forward.

If you have a device that competes in large drug markets, you can bring companies like GSK, J&J, and Merck into the bidding process. That changes the exit potential value from the typical $150 million to something closer to $1 billion.

MTS: ***The Foundry had a great exit with Twelve, as did a number of other mitral valve companies, all reflecting how hot mitral valve space is right now** (see "Transcatheter Mitral Devices: The Dam Finally Bursts with a Flood of Deals," **The MedTech Strategist,** August 31, 2015)**. Over the past couple of decades, we've seen a number of clinical or technology areas that have, at one point or another, been really hot: mitral valve, renal denervation for a while, spine several years ago. Hot spaces are hot because they're big with lots of opportunity. But that also means they attract a lot of people. Given your experience with Twelve, what's your feeling about investing in a crowded space that is only getting more crowded? Does all that activity make you want to jump in because it speaks to the opportunity? Or do you worry about a market that is over-heated in which most companies will not find an exit?***

Plain: We don't really look at where other people are investing. We identify markets that we think have a lot of opportunity, whether other investors agree or not. There are some markets we particularly like, such as devices in drug markets where we think the exit can be over-sized—for example, we've invested in a company **Holaira Inc.**, which is in the COPD space. [*See "Beyond Aridan: Lightstone's Contrarian Bet that Big Investments in Early-Stage Devices Can Pay,"* The MedTech Strategist, *October 29, 2014.]* We've also started to do investments in consumer medtech, where there is an intersection between real clinical need and consumer self-pay, avoiding reimbursement by third parties. I personally believe that the big opportunities are investing in wearable devices that provide a real clinical benefit. I'm not excited about wearable devices that just counts steps. But consumer, self-pay devices addressing a real clinical need and a straightforward regulatory path—that's the trifecta for us.

MTS: ***And, as long as those criteria are met, it doesn't really bother you if a lot of other companies are staking out the same space?***

Plain: What we really focus on is the team. That's why I like serial entrepreneurs—they have a track record that suggests they can out-execute less experienced teams.

MTS: ***As a final word, you look at a lot of companies. Do you have any tips or advice for the CEO of a small company who's struggling to raise money? Is there anything they can do in this environment to make themselves stand out? Or is it more often a matter of looking at yourself in the mirror and making an honest assessment of your likelihood of success?***

Plain: I think perseverance is the critical element. What I like about the medtech ecosystem here in Ireland is local companies are capable of being very capital efficient. I also like the fact that, in contrast with the US, there are incentives and funding sources that encourage and support start-ups. In the US, our government raised regulatory hurdles, taxed the industry, and made reimbursement of new technology almost impossible. Over the next 20 years, I think Ireland is going to become a leader in medtech innovation, as it already is for manufacturing. If you look at how medtech evolved in Silicon Valley, it followed a very similar fact pattern. It just takes time.

The other piece of advice I have is to reach out to individuals who've had success who can mentor young CEOs. In Silicon Valley, almost everything is facilitated by the network. Who can make that introduction to help you creatively find capital? And, finally, success will be determined by your ability to persevere and overcome obstacles. It always comes down to your team—and I define that term broadly. It's the quality of your inventor engineers, clinical advisors, management team, investors, and the board.

MTS: ***Given your success and the people you've been associated with, I can't imagine anyone not answering your phone call or email.***

Plain: I'm not sure about that. But I've been blessed to work with some really great teams and technologies.

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