

Interview with Amar Sawhney

(A#2009800107)

Written By Stephen Levin
Issue: *IN VIVO* Jun. 2009
Section: Feature Articles (Long Article)
Article Type: Corporate Strategy
Industry Segment: Supplies, Equipment and Devices
Subject/Market Dynamic: Incubators (venture)
Companies: Boston Scientific Corp.
Summary: In Vivo interviews device entrepreneur Amar Sawhney whose engineering background led him to Focal Inc. There Sawhney advanced important developments in sealant technology that eventually formed the basis of Confluent Surgical, the first company launched by Incept, Sawhney and fellow entrepreneur's Fred Khosravi's device incubator.

Further Analysis:	Title	Magazine	Issue	Article ID
	Interview with Fred Khosravi	<i>IN VIVO</i>	Jun. 2009	<u>2009800108</u>
	AccessClosure: FDA Clearance--Yes; Product Launch--Not Yet	<i>IN VIVO</i>	Jun. 2009	<u>2009800119</u>
	Fred Khosravi & Amar Sawhney: Dynamic Device Development Duo	<i>IN VIVO</i>	Jun. 2009	<u>2009800123</u>
	Interview with Fred Khosravi	<i>IN VIVO</i>	Jun. 2009	<u>2009800108</u>
	Fred Khosravi & Amar Sawhney: Dynamic Device Development Duo	<i>IN VIVO</i>	Jun. 2009	<u>2009800123</u>
	Confluent Surgical Inc.	<i>Start-Up</i>	Jan. 2000	<u>2000900010</u>
	Surgical Sealants: Is there a Cohesive Strategy?	<i>Start-Up</i>	Jun. 1999	<u>1999900100</u>

Access these articles using Windhover's Strategic Intelligence Systems or online store (www.windhover.com/buy) or call customer service at 203-838-4401 ext. 226.

Article begins on the next page . . .

© 2009, 2000 Windhover Information Inc.

No part of this publication may be reproduced or modified in any form, or incorporated into any information retrieval system without the written permission of Windhover Information Inc. (203-838-4401 ext. 232). This information is intended for the recipient only. Any further distribution is in

direct violation of copyright laws.

Interview with Amar Sawhney

By Stephen Levin

Q: IN VIVO: Let's start with your background and how you got into the medical device industry.

Amar Sawhney, PhD: I did my undergrad work in chemical engineering at the Indian Institute of Technology in Delhi, India, and then got a fellowship to continue my studies at the University of Texas at Austin. There I worked with a young professor, Dr. Jeff Hubbell, who was working on innovative approaches to biomaterials. He, I, and a post-doctoral fellow, Dr. C.P. Pathak, developed a light-activated *in situ* polymerization process for water soluble polymers. This basically enabled us to perform chemistry in contact with living tissue without killing that tissue, which is critical for processes such as tissue repair. Before that, people would use super glue-type substances and other sealant products, but in the process would kill layers of tissue. Our work was the first time anyone had done this without harming a single cell, and we triggered this process through light-activation; that was our claim to fame.

My dissertation was on cross-species transplantation, specifically to create a xenografted pancreas using pig cells that could be protected from the human immune system by individual hydrogel jackets, which were formed by *in situ* polymerization. That work led to the creation of Novocell in 1999, a cell therapy company that still exists in San Diego. After graduating with my PhD in chemical engineering, I had a choice of either joining Novocell or working with a company called Focal that was in the process of being created by the Mayfield venture firm. Focal approached us to license our polymer technology to use both with and without drugs, and I chose to work with them. Bob Langer of MIT was involved with the company, and when we started, it was basically Mark Levin and I in an empty office.

Q: How did Focal use your technology and what were your responsibilities with the company?

My technology was first used in Focal's initial product, which was a sealant for adhesion prevention. The company added a bunch of experienced business people and I was kind of pushed to the side since I was viewed primarily as an academic. Initially that was fine with me because I thought they knew what they were doing. But then we did the pilot clinical trial in Europe on the adhesion prevention product and it failed miserably, putting the company into a death spiral. At that point, Dave Clapper was hired from Ethicon Endosurgery as the CEO.

Dave was a believer in sealant technology, and asked me to put a team together to develop sealants. At the time, many people in the company had doubts about whether we could get our polymers to stick to anything, but our team proved that our sealants worked nicely. The success of this project led to a collaboration between Focal and J&J, with J&J funding this effort. Our success in this effort further convinced everyone at Focal that the company's future was in sealants, and those products eventually received FDA approval, the first being a lung sealant, and became the foundation of the company.

Q: Despite that success, you left Focal not long after. Why did you leave the company and what was your next project?

At Focal, I was not running the company and didn't have input into many aspects of the business, so I decided to start my own company. At first, I asked Focal if they would agree to a spin-out of some technology they were not working on, and after several months of deliberation, they finally said no, at which point I said I was leaving. I agreed to a one-year non-compete and started Confluent Surgical, which was based on technology that did not involve light activation.

Q: In addition to not using light activation, how did Confluent initially differ from Focal? And eventually the two became competitors, so how did that come about?

When I started Confluent, at first I differentiated the company not only by not using light activation, but also by avoiding surgical sealants, and focusing on adhesion prevention. I tried to provide all the features that I knew customers were looking for things like spray-on application and easier applicators. Then, about a year and a half later, after my non-compete had expired, Confluent went into surgical sealants, which is when we started competing with Focal.

Q: Confluent marked not only your first start-up company, but also the beginning of your longstanding and very productive entrepreneurial partnership with Fred Khosravi through the launch of your incubator although I know you don't like that word Incept. How did you get to know Fred and what led the two of you to start Incept?

I got to know Fred when both of us were at Focal and we got to be close friends. In 1998 when I was starting Confluent, he had already started EndoTex. Since that made him an experienced entrepreneur, I went to him for advice in launching Confluent. He thought the idea had some promise and we decided to work on it together. We started talking about how to go about starting companies and how to avoid some of the mistakes we made at Focal. For example, Focal retained the rights to around 50 of my patents that I could not make use of. Since they were not utilizing much of that IP, it basically goes to waste and does not benefit anyone, not companies, not investors, and not patients. Instead of repeating that kind of situation, Fred and I started thinking about using a different model to create companies and that's how the idea for Incept was born.

Q: In a nutshell, how would you summarize the basic concept behind Incept?

The basic idea is that Fred and I decided to create a holding company that would own all of our intellectual property and that we would be partners in that company. That becomes particularly important in the case of a platform technology, which is really too much to put in any one company. We would then license the IP on a field-specific basis to only companies that we launch, so that, for example, IP for a new embolic protection device would go to EPI (Emboloc Protection Inc., which was acquired by **Boston Scientific Corp.**) [W#200110033] and IP for a surgical sealant would go to Confluent. That was the foundation of Incept.

Another objective of ours in starting Incept was that we realized that entrepreneurs spend an inordinate amount of time and take a lot of risk in focusing on a single company. If it doesn't amount to anything, they have nothing to show for their effort. From the beginning, Fred and I believed our partnership had great potential and we thought it made sense to diversify our risks by sharing in each other's upside, a kind of hedging strategy for entrepreneurs. Obviously, you don't know early on whether any of these start-ups will work out, so we decided to use Incept almost as an entrepreneur's guild where we diversify our equity base.

Initially our thought was to spread the risk and reward among multiple, additional partners. But we soon realized that we were very fortunate in whatever success these ventures had, especially given the high risk of start-up companies, and that while we were prepared for this risk, you never know how others would react, and we confined the structure to our partnership.

Because companies come and go, we wanted to build something more evergreen that was based on the continuity of relationships not only between us, but also involving friends, clinicians, operational people, and others that we could continue to work with again and again in a kind of extended company lifecycle. We wanted to establish a platform to continue these relationships with people we like and enjoy working with. And we have expanded on that to include investors, law firms, and other service providers. It's become a pretty cozy community, but one that is kept honest because each deal has to stand on its own merit.

Q: You live in the Boston area and Fred lives in the San Francisco area. Where is Incept based?

In a sense, it is based in both of those areas because that is where we are. But Incept itself does not have a formal headquarters. We work out of our existing companies' locations, depending on which one of us is heading the new company. We try to keep Incept as virtual as possible to reduce the need for and cost of

infrastructure, as opposed to more traditional incubators that have a lot more space and employees. We wanted to avoid that kind of situation because those things increase your burn rate and force you to go out and raise more money, which puts you in a position of having someone else you have to answer to. That would dilute our partnership, which is another reason we decided not to take that approach. Incept is built on a model much like Dell, which is to make a sale and then make the product. For us, it is almost a case of needing to have a licensee company in mind before we create the IP for that company.

At that point, we do have a few full-time Incept employees, and they divide their time among several companies. As a result, the companies benefit by getting very high level expertise at a much lower cost than if they had to hire people themselves, so it's a win-win proposition. The employees also benefit because they get a diversified equity base, which goes back to our concept of entrepreneurial hedging. Also, Incept's overhead is kept to a minimum because these salaries are charged to our existing companies.

Q: You and Fred have built what appears to be a successful serial entrepreneurship model through Incept, having launched nine companies in nearly 11 years, starting with Confluent, with no failures, in terms of having to shut down a company, and three M&A exits. Given how closely the two of you are involved in this process, isn't scalability an issue?

You're right scalability is an issue. One thing we learned at Focal is that when you do too many things at the same time in one company, nothing really gets done. You have to have focus. One of the ways we provide focus and scalability is through each of us cultivating leaders among employees in our existing companies.

The other thing we realized is that scalability occurs in two dimensions. We could add a whole bunch of partners within Incept, but we realized that our partnership was working well because it was not just about money, but it was based on the tremendous personal respect that we have for one another. We weren't so naïve as to think that relationship could be successfully scaled to include numerous other partners.

But we also recognized the need to address the breadth vs. depth issue because if everybody is doing everything, then in reality nobody is doing anything. To address that need, we decided to cultivate and support the individuals in our companies who want to take on leadership roles. We do that by focusing them on a kind of vertical career path in which we will let them do as much as they can do and then we step in to supplement them in areas where we have more experience. Essentially we use the same kind of mentoring approach that Fred experienced at ACS and Guidant, and which he passed along to me.

Exhibit 1

Companies Created By Incept

COMPANY	PRODUCT AREA
Confluent Surgical Inc. (Acquired by Tyco, now Covidien)	Surgical sealants
Emboloc Protection Inc. (Acquired by Boston Scientific)	Emboloc protection
MarketRx Inc. (Acquired by Cognizant)	Sales & marketing software
AccessClosure Inc.	Vascular closure
Sadra Medical Inc.	Percutaneous heart valves
I-Therapeutix Inc.	Ophthalmic therapy products
SquareOne Inc.	Ostial coronary stents
HotSpur Inc.	Thrombectomy/dialysis graft devices
Augmenix Inc.	Radiation oncology products

SOURCE: Incept

Q: You mentioned that Incept looks for platform technologies, but obviously most opportunities are not true platforms. Incept has had examples of both, having a polymer platform that started with Confluent and led to AccessClosure, but you've also had companies focused on unrelated technologies, such as SquareOne, which is a stent company, and Sadra Medical, a percutaneous heart valve company. Talk about managing the development of both types of start-ups.

One of the reasons we have been able to do such a variety of companies is that, by keeping Incept nearly virtual, we have avoided being driven by the financing focus of the companies we launch. Obviously, financing is a critical part of the process, but by not being beholden to particular large venture groups or other investors, and by working with people we have previously done deals with, we have been able to maintain our focus on the products and the patients. This has allowed us to do a variety of types of deals of all sizes, not just for huge, billion dollar market opportunities. For example, Confluent was acquired by Tyco for \$250 million. [W#200610112]

You're right in that, on the one hand, we have a group of companies based on the polymer platform technology that I invented, starting with Confluent and then moving to AccessClosure, our femoral artery closure company (see "*AccessClosure: FDA Clearance Yes, Product Launch Not Yet*," this issue [A#2009800119]) and then to I-Therapeutix, which is working on ocular therapies, including bandages, sealants, and drug delivery products. Then on the other side, we have companies that are more application-focused, such as SquareOne and Sadra.

The differences in the two groups of companies also evolve from the fact that Fred and I have complementary skills and personalities that come together with our unified vision of our partnership. Fred has a tremendous engineering background and clinical connections, particularly in the cardiovascular field. That runs through a number of our companies, including AccessClosure, EPI, SquareOne, and Sadra. Fred is also very strong on the execution front. He will look for spaces where there is an emerging need and be able to spot the next-generation technology and out-compete the competition to bring a superior product to market more quickly. AccessClosure is an example of that because numerous other companies have tried and failed in the

femoral artery closure space, where we think Access will be a big success.

My background in hydrogel materials led to a fundamental discovery that you can do chemistry on living tissue inside the body. By starting with liquids, I found that you can go into remote parts of the body, solidify a material, and it will remain where you put it, enabling you to deliver drugs locally and help heal tissue in specific locations. All types of organs and tissue can benefit from this and no one company can do it justice, which is why it lends itself so nicely to a platform strategy. We could either keep spinning companies out that use this technology or, if we parked it in one company, there would only be a couple of products that come out of it and you would sacrifice a lot of value, which is what happened to Focal.

We learned from that mistake in forming Incept and decided to use this technology as a platform for launching hydrogel companies across different surgical disciplines. We started with Confluent, which was working in neuro, spine, and gynecology. Then came I-Therapeutix, which is working in ophthalmology, and now we're starting Augmenix, which is in radiation oncology and urology. And sometimes, fortuitously, these patterns intersect. AccessClosure lies at the intersection of the hydrogel technology and the cardiovascular space; it's in the sweet spot of both of our strengths. Otherwise, there are both horizontal and vertical elements to our company creation. The horizontal element shares a common technology, while the vertical element shares a common expertise and clinical focus.

Q: How do you and Fred determine who runs a particular start-up? Is it based on the underlying technology with you running the hydrogel companies and Fred heading the cardiovascular start-ups?

The technology is part of that decision, but geography is also important because the two of us are on opposite coasts. You don't want to be just a figurehead because our role in each company is very critical in making sure that we have successes and not failures. A venture group or a traditional incubator may have a basket of companies and some may fail along the way and that's okay the VC or incubator will survive. We are a little more selective and because Incept is self-funded, there is no external pressure on us to create more companies than we are comfortable doing. We wait until all the necessary elements come together on any specific deal: the market need, a technology solution, and a team that we can put together and when those elements are aligned then we launch a new company. We are not saying that we are smarter than everyone else; we take our time in putting a deal together so that rather than forcing something to happen, we let it occur naturally.

Q: You don't like the word incubator. What is a more accurate way to describe Incept?

It's an enabler of new technology development.

Q: If you look at the traditional incubator model in the device industry, one has to question how successful it has been in terms of building viable companies and achieving exits. Do you believe the incubator model has been successful in adding value to the company creation process and how is Incept different from that model?

It has not been a successful model. The traditional incubator is a hard model to succeed at because the entrepreneur is coming in at the earliest stages of the company and taking most of that risk, whether it be capital risk or technology risk, and then it is a long time before you reach liquidity. And in that process, if you have taken on external financing early on, the entrepreneur also has seen a loss of control. And in that loss of control, there is also a loss of acute responsibility for obsessing about making the company successful.

Ultimately, the critical question for start-up companies is: who is really responsible for obsessing about our success? When that gets lost, the chances of success decrease. That may take a while because you've taken money from the outside to demonstrate liquidity, and those liquidity cycles can be long. It is just like an early stage VC fund starting up for the first time there are growing pains. So it is possible that when these incubators mature in 10 or 15 years, they could turn out to be powerful things, but in the meantime it is hard for them to survive because if they are not generating returns, they will have trouble attracting investors.

Q: Other serial entrepreneurs have adopted similar approaches with platform technologies, where they have spun out companies in different clinical spaces that employ a common technology. Stuart Edwards comes to mind with radio-frequency ablation. One criticism of that approach is that it doesn't create as much value as if the different applications resided within a single company. Why do you choose to create separate companies for different clinical uses of your hydrogel technology?

With a true platform technology, which is what we believe we have, more and more applications continue to emerge. No one company can really develop all of these different products. Take Confluent as an example: we started with a product for biosurgery and tissue repair, and they now have a lung sealant, a dura sealant, a spinal sealant, a vascular sealant, and an adhesion prevention devices, and they're working on many other projects. Those are just the projects that were underway when Tyco bought the company and that will keep them busy for years. At I-Therapeutix, we started by using the hydrogel to make an ophthalmic bandage and a sealant, and we have since moved on to develop liquid punctum plugs and a drug delivery system that could take care of glaucoma and dry eye, possibly making eye drops obsolete. And there's much more we can do just in ophthalmics.

This technology is so rich that there is a tremendous amount of product applications still to be developed in a variety of fields, which would not occur in a single large company. That is because in a large company, the risk-reward situation does not encourage people to dig deeper and develop these new applications and products. Taking risk is not encouraged and as a result, many potential advances go undeveloped.

Another reason why these technologies are better developed through separate companies in different clinical areas is that successful device companies are customer-intimate in their respective space. It is very difficult to be customer-intimate with many people across different clinical applications. A technology platform is not a basis on which to unify a company. Customers are the basis around which to unify a company.

Q: In diversifying the technology among a number of start-ups, do you lose some of the efficiencies that would result from having a single large company?

Initially, we set up our hydrogel platform much like a large biotech company with our own animal facility, pilot production plant, tissue culture labs, and analytical instrumentation. While it looked very impressive, it was tremendously capital inefficient, which led us to conclude that this was not the right way to go. Instead, we decided that it was better to build strategic relationships in each of these areas with dependable suppliers. It may be a little bit easier to manage the supply chain for the hydrogel companies than for our more traditional device start-ups, but the principle remains the same. And that extends to service providers like law firms and design firms, and also to investors and venture firms. We tend to use the same people in many of our companies and deals.

Rather than being less efficient than a large company, we believe our approach is more efficient. For example, within two years of forming I-Therapeutix, the company completed its preclinical work, entered its pivotal clinical trial, and received CE mark approval and only spent around \$1 million. Very few other companies could move that quickly. We are able to be more efficient because we are able to leverage a lot of work that has been done before, almost as if we were part of the same company; we just don't need to have it all under one umbrella.

Another reason for maintaining these separate companies is that, if everything were under one entity, it becomes very difficult to realize partial liquidity. If a company has both neuro and gynecology products, and an acquirer is interested in one but not the other, you have to do the acquisition of that individual product as an asset sale, taxation is inefficient, and no one makes as much money. Instead, if you maintain these as separate entities, but they are still leveraging all the background and expertise that Incept can bring in terms of accelerating product development, the result is a much cleaner and more profitable acquisition.

Q: What is Incept's financing strategy for its start-ups? You mentioned that you often work with many of the same venture investors and I know that you also put your own money into your deals, so how do you finance your companies?

First, let me say that we really need to believe in an idea before we take anyone else's money because we see that as a tremendous responsibility. We'd rather lose our own money than lose someone else's. Typically, once we come up with an idea for a new company, Incept puts up around \$100,000 to \$150,000 of its own money, sometimes more, to put together a business plan and do enough early work to establish proof of concept and maybe get to the point of having a working prototype. Then we would invite other people to invest, and we would either convert our investment into equity or, if there is enough interest around the table in fully funding the company, we might take our money back and let other people fund it.

Q: Do you work exclusively with VCs or will you use angel investors to provide some early funding for your companies?

We work with both angels and VCs. The angels are often physicians we work with, principals of other Incept companies who have done well, and friends and family.

Q: Who are some of the venture firms that Incept has worked with most often over the years?

The four we have probably worked with most are Onset Ventures, SV Lifesciences, Three Arch, and Ascension Health Ventures.

Q: Where do the ideas come from for Incept's new companies and what are Incept's newest companies? Are they all internally generated or do you look outside of your current companies for new technologies?

Many of our ideas are internally generated. Between the two of us and the people at our existing companies, we seem to have no shortage of potential new ideas for companies. Also, as you would imagine, we are constantly in contact with physicians and industry people that either we know or that know of us and they also suggest new ideas. But clearly we have many more ideas for companies than we are able to implement.

Our two newest companies are probably SquareOne, which developed the *BullsEye* ostial coronary stent, and HotSpur, which is working on thrombectomy devices.

Q: Which of your companies are you and Fred currently focused on most directly?

I'm currently running I-Therapeutix and Augmenix, which is the radiation oncology company, and Fred is running AccessClosure and is the chairman of Sadra Medical and SquareOne.

Q: One-third of the nine companies that have come out of Incept in its 11 year history have had M&A exits, and, perhaps even more noteworthy, you have never shut down one of your companies. Which of your companies have been acquired, and given what you said about the abundance of new ideas, how do you know when it is time to start a new company?

EPI, our embolic protection company, was our first exit. It was acquired by Boston Scientific in 2001 for \$75 million. Next was Confluent, which was bought by what then was US Surgical, now Covidien, for \$245 million in 2006, and then we had marketRx, which developed sales and marketing software mostly for pharmaceutical companies, that was acquired in 2007 for a total of \$165 million.

You're right that we have never shut one of our companies down, which is something we feel very good about. We really don't start companies on the front end until we have a liquidity event on the back end, so that's how we manage to stay focused on our current companies.

In terms of knowing when and how to start a new company, rather than comparing it to a standard cookbook approach, we prefer to compare the process to making yogurt. In making yogurt, you take a small amount from the previous batch and put it into new milk and that is what gives you your consistency. The same is true with our companies. Each one gets started the same way and we believe that the higher order of success that we have achieved is because of the culture and the value system we have established. That culture gets transferred literally from one company to another because not only are Fred and I working on these new companies, but other people from our previous companies are there as well, propagating that DNA in the same fashion. That is one of the important factors that sets Incept apart.

As a result, as you said, there is a scalability problem. We can't do a whole bunch of these companies. That forces us to impose a certain discipline in determining when is the appropriate time and when do we have the available bandwidth to launch a new project. As our companies are acquired, that frees up the bandwidth for us to go ahead with new start-ups. Our current goal is to exit at least one company every year and start one or two new companies each year.

Our ability to start our next company is really driven by two things: liquidity from previous deals, which helps drive an evergreen process for the investors that continue to work with us, and the ability to put the right leadership in place and not have to bring in people from outside of our companies. If we have those two things in place, then the ideas are there that we can go ahead and launch the next opportunity.