FIRE 1: A New Model for Early-Stage Device Incubation

by
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Bringing strategic partners in at anything but the latest stage used to be anathema to start-ups, who feared corporate alliances meant ceding valuable rights and compromising an exit. But now mega-incubator The Foundry is teaming with Covidien on FIRE 1, which aims to bring in strategics at the earliest possible point – before the project is even selected.

Over a decade ago, executives at Menlo Park, CA-based The Foundry launched what would become arguably the medtech industry's most successful medical device incubator, with more than a dozen companies to its credit, including Evalve, Concentric, and Ardian. If The Foundry didn't invent device incubation, it has come as close as any organization to establishing and proving the model. But now, as The Foundry prepares to launch its 15th company, Foundry executives have begun a new program that may reinvent device incubation itself.

A New Approach

For more than a decade, The Foundry's model was pretty straightforward. "We'd start a new company, create some stock, and then do a Series A financing with our closest venture partners to kick it off," says Hanson Gifford, a Managing Partner at The Foundry. "Then, over time, we'd figure out what the company was going to be and grow it."

By 2013, however, the world had changed. Most notably, The Foundry's investor partners all found themselves in new situations – situations specific to each fund but largely illustrative of the current state of medtech venture financing. "Morgenthaler Ventures no longer existed," Gifford goes on. "Split Rock had cut back dramatically on its medical device investing, and Versant was at the tail end of its fund and wasn't eager to make seed-stage investments so late in that fund's life. So we had to try a new approach."

Moreover, says Gifford, the bar for success had gone up. "To think that we were just going to find three new VCs and raise some money to start a company wasn't going to work," he notes. "There are fewer Series A financings getting done [now], even though the quality of deals going unfunded has gone way up." (*See Figure 1*.) In addition, the geography of device company formation has shifted, with Europe and specifically Ireland assuming a greater role while US start-ups face a raft of challenges: difficult early-stage financing, a challenging reimbursement and regulatory climate, and longer times to exit.

So last year, The Foundry launched FIRE 1 (which legally stands for Foundry Innovation and REsearch 1, Limited; unofficially it's just Foundry IREland 1), a new project in a new geography with a new set of partners, including Lightstone Ventures, formed when the life science arms of venture firms Morgenthaler and ATV merged, and, perhaps more importantly, **Covidien PLC**, a leading device manufacturer.

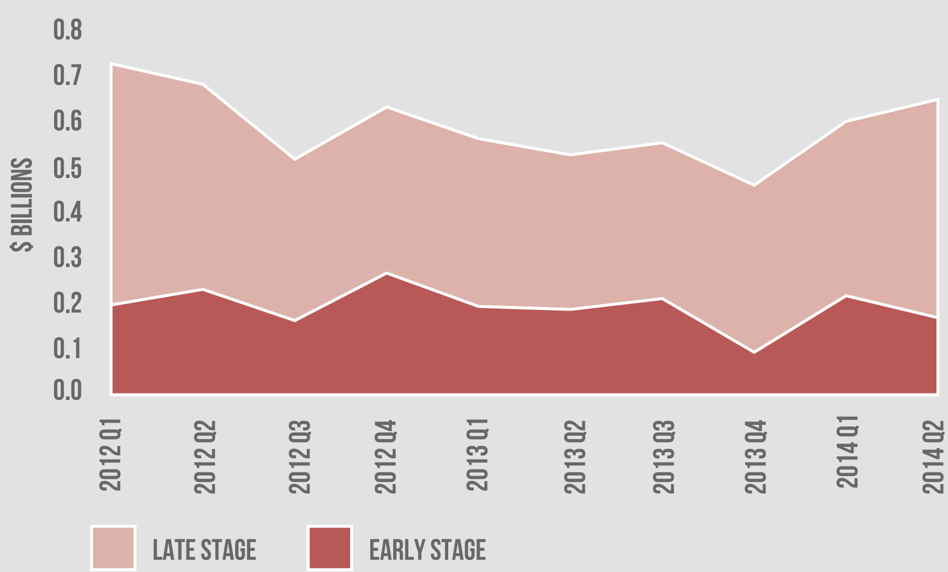
For Foundry executives, the partnership with a VC and a strategic reflects a new reality about device incubation. Lightstone was selected not just because of The Foundry's historical relationship with Morgenthaler, but also because, as a venture fund based in Ireland, it had relationships with and access to capital outside the US. Covidien was chosen as a partner because large device companies are not only the presumed exit for device start-ups but because they are now getting involved in start-ups at earlier and earlier stages.

"It now takes, on average, six to ten years and $50 million" to build a successful device company, says Gifford. "Where are we going to get that, as there are fewer and fewer US-based medical device-focused VCs? Well, there's a lot of venture capital available internationally, and the other source is the strategics. Other venture investors can decide to invest in other areas, but large medical device companies still need new device start-ups."

Over the years, Foundry executives had spoken to nearly all of the large strategics about some kind of novel collaboration, says Gifford, about "how we can get closer to each other in the incubation process." In a lot of cases, those discussions were direct and more specific: was there a project that had stalled or been de-funded within the large corporation that the Foundry might spin out and take over?

Covidien's commitment came, Gifford says, "all the way from [CEO] Joe Almeida down." In fact, he says, Covidien came to them asking if they could somehow work together. Almeida "actually pushed his group to investigate how to build an incubator internally," he continues, only to come to the conclusion that Covidien was better off working with an independent organization. Indeed, given executive turnover and the pressure of quarterly earnings, big companies often struggle with the long time horizons of incubation, say Foundry officials.

1 Medical Device Funding by Stage, 2012–Q2 2014



Source: PricewaterhouseCoopers (PwC)-NVCA *MoneyTree* Report, August 2014, based on data from Thomson Reuters.

Will Build to Suit

For The Foundry, a very early collaboration with a major strategic also made sense. Over the past several years, both large and small companies have sought to engage earlier and earlier, not just in acquisition discussions but in financing rounds as well. "For the past six years or more," says Foundry Managing Partner Mark Deem, "we've been saying to ourselves, 'I don't know why we spend a lot of time trying to guess what the big companies want to buy.' The sign on our front door should read, 'Will Build to Suit.'"

Indeed, Deem notes that Foundry executives are, for the most part, "agnostic about what we incubate." The firm's track record includes companies in, obviously, cardiovascular devices, but also orthopedics, bariatrics/metabolic, and a major effort in ophthalmology with the incubator ForSight Labs. The Foundry has even worked with a start-up targeting hyperhidrosis. Given The Foundry's wide-ranging interests, he says, "Why shouldn't we work with the business development and venture groups within big companies to understand their roadmap better so that we can all get things done faster and improve our hit rate?"

FOR COVIDIEN:
A BOX TO THINK OUTSIDE OF

As venture capital has become more difficult to come by, corporate involvement in start-ups has become more common. And, it has moved earlier in the food chain, in the form of both Series A and B investments and structured deals, which give strategics an early peek into technology and rights to acquisition down the road. But for Covidien, the strategic partner in FIRE 1, the new project also represents something else: a new way to think about innovation.

Stacy Enxing Seng, Entrepreneur-in-Residence (EIR) at Covidien notes that "broadening the innovation focus" of Covidien was a core tenet of the company's 20/20 strategic vision. What that means, she goes on, is "bringing to the forefront diversity of innovation." Like many, if not most, device companies, Covidien pursues innovation through multiple channels: internal R&D, for which spending has increased at Covidien in recent years; acquisitions of companies with innovative technologies; and the formation several years ago of a venture arm, Covidien Ventures – all three relatively standard initiatives at large medtech companies.

The last two, in particular, represent a recognition on Covidien's part that large corporations "can't develop everything internally," Enxing Seng notes. As Covidien officials considered their various approaches, she says, they kept asking themselves whether there are other approaches or paths to innovation, paths "that we could influence a bit more with a group that is comfortable innovating big ideas that might still be aligned with the Covidien businesses, and that also has a demonstrated track record" in developing those ideas. Those discussions, held with Enxing Seng's colleague at Covidien Ventures, Dan Sheehan, led naturally to The Foundry, which Enxing Seng notes "has a rich history of targeting and tackling major disease states and other areas ripe for innovation."

The ultimate idea, she says was "to create an incubator concept that has the structure of a venture investment, but is aligned a bit more closely to our long term business model." Within FIRE 1, she notes, Covidien's financial contribution will come through Covidien Ventures, as it invests side by side with Lightstone and NEA. Enxing Seng's role is as "an operating executive in a director's role to represent Covidien's interest," an executive, she points out, "with a history of developing technology and looking at acquisitions."

As noted, both corporate investments and structured deals are becoming more common these days – think of the role **St. Jude Medical Inc.** played with Nanostim's leadless pacemaker or Medtronic's role in Ardian's development of renal denervation devices. But in both of those cases, the strategics' involvement came after the project or technology had been identified and significant development had already taken place

But the Foundry does like to tackle large, disruptive technologies – such as renal denervation and mitral valve repair. Thus, one of the things that appealed to Foundry executives was Covidien's willingness to look at white spaces. Discussions about similar projects with other companies too often "looked more like line extensions of [their] existing product lines than anything we'd be interested in doing."

The Appeal of Ireland

Interestingly, the decision to locate the project in Ireland pre-dated Covidien's participation in the project, notwithstanding the fact that the corporation's global headquarters are located there. Deem notes that not only is there ready capital available in Ireland, "there's the potential for less-dilutive and non-dilutive funds. And Ireland has one of the largest communities of highly skilled medical device employees in Europe." Moreover, the current discussion around non-repatriated cash led Foundry officials to believe that strategics would increasingly be looking for ex-US companies to acquire in order to put that cash to work (an advantage that that US tax authorities are now trying to quash). The fact

– thus de-risking the project to a large degree for the strategic.

By contrast, Covidien's participation in FIRE 1 began before the project's technology was decided upon, indeed before the decision where to begin had even been settled. Moreover, in most structured deals – if not all minority investments – the assumption is that the strategic partner will ultimately be an acquirer, giving it a kind of heightened role in the subsequent development. Enxing Seng insists that Covidien's role in the project, at least at this early stage, is that of equal partner. "It's very collaborative in spirit," she says. "Covidien doesn't have a greater or lesser say – we all have an equal vote."

That said, the FIRE 1 team clearly has an incentive to bias toward the kinds of opportunities that sync well with Covidien's broader goals and will lead in time to a Covidien acquisition – hence The Foundry team's visits to all of the Covidien business units to better understand their needs. "We have, as you can imagine, a checklist of things that would meet our requirements and the FIRE 1 team knows that and will take that into consideration," says Enxing Seng. And while, "technically, Covidien will not make the decision" as to which technology the project selects, she says, " we have shared with the incubator some of the ideas around what we'd like to see in the future in some of our businesses, to allow the team to assess and research those areas."

Given that Covidien's most direct involvement will be through its venture arm, Covidien would, like any investor, hope to see at minimum a good return on its investment, notes Enxing Seng. "But ideally, it will also be something we'd like to bring into the company." Whether that's a tuck-in acquisition closely related to one of the company's existing product lines or something in a wholly new space isn't specified, though, "ideally it would be sooner rather than later and leveragable into one of our businesses," she says.

If there's a challenge to the model for Covidien, it may lie in creating the discipline among a strong, diverse group of interests to work together toward a common goal. "We have to be disciplined enough to select one idea," says Enxing Seng, "and we're either going to win or lose with that idea."

However, that diversity of perspectives may be a strength as well. "What makes this unique is, first and foremost, the people we have around the table," she goes on. "I think that having Covidien Ventures, NEA, and Lightstone, along with The Foundry, is pretty special." For Covidien, she notes, the opportunity and the challenge are the same: how to "incubate or develop something that we either do not have the domain capability or cannot get to on our own given the already committed internal development pipeline."

Whether FIRE 1 is successful, of course, remains to be seen, though Enxing Seng says that the early stages of the collaboration "have been very, very positive." Still, in some respects, the elephant in the room may be Medtronic's recent proposed merger with Covidien. Could that deal upend this one? "The reality is that it's up to Medtronic," she says.

–David Cassak

that venture partner Lightstone had an office in Ireland made that country a logical place to start the project, hence FIRE 1.

For now, The Foundry has not tapped any Irish VCs; launched right around Christmas of last year, FIRE 1 is a partnership among The Foundry, Covidien, Lightstone, and one other VC, US-based mega-fund New Enterprise Associates (NEA). The team has yet to settle on a specific technology, but it clearly will be one

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that appeals to Covidien strategically, either as a white space opportunity or as a major adjunct to one of its current areas of interest. Early this year, Foundry executives spent time with Covidien units in the US and throughout Europe, meeting with R&D and clinical teams as well as senior management, trying to understand their businesses better and glean clinical and technology areas they'd like to get into.

Each of the partners in FIRE 1 has a say over which project will be pursued. But clearly, Covidien's needs and wishes loom large. "Ideally this is something Covidien will get excited about and want to acquire," says Deem. He points to Covidien's most recent big deal – the $800 million acquisition of Given Imaging – as indication of the company's willingness to "place big bets and undertake a major market development effort." Says Deem, "I think all strategics gravitate toward areas they know. But [Covidien] appears to be much more open to big bets than some of the other strategics we had talked to." Touring the various Covidien operations, Foundry officials were trying "to get a baseline knowledge for us to factor into our calculation as we evaluate opportunities," Deem explains. FIRE 1 isn't precluded from doing something outside of Covidien's current businesses, he continues. "But the more it fits, the better."

Mitigating Risk

Given its track record, The Foundry had little problem finding venture firms willing to be part of FIRE 1. (Covidien Ventures, the company's VC arm, will make the investment on behalf of Covidien.) But the question is, with early-stage capital scarce and many small companies and their investors looking to collaborate earlier and earlier with large device companies, could The Foundry have done something similar directly with Covidien, thereby obviating the need to deal with venture capital at all?

Deem notes that Covidien actually wanted to have Lightstone and NEA as part of the program. Covidien Ventures, like any venture fund, likes to be part of a strong syndicate: "they like to have other knowledgeable people around the table to help with the decision-making process and help with the funding," he says. Plus, even for a large corporation, the $30-50 million that might eventually be needed is a significant amount of money. (For the VCs, Covidien provides the potential for "major risk mitigation" both because of the company's presumed role at exit and because of their ability to invest.)

And having VCs involved offers its own form of risk mitigation for The Foundry. Big companies undergo changes from time to time – executive turnover, strategic re-directions, shifts in priorities, etc. – that long-term projects need to be protected against. The assumption is that FIRE 1 will develop a technology that ultimately will find a home at Covidien. But just in case that doesn't happen, having Lightstone and NEA on board means the project can go ahead independent of the corporate role should Covidien re-think its participation at some point.

Indeed, timing is somewhat of an issue. Certainly, many device VCs today are shifting from early stage to late stage precisely because time-to-exit has lengthened from five years to nearly ten, straining their investment model. Hanson Gifford notes that "the eight to 10-year time frame doesn't work well for the venture capital community, but it frankly doesn't work well for corporations either. It's just a very challenging timeline, and everyone's looking for a way to

FOR LIGHTSTONE: A FASTER, LESS EXPENSIVE EXIT

Jason Lettmann, a partner at Lightstone Ventures located in Dublin, Ireland, points out that Lightstone, which was formed through the merger of the life science practices of two other venture capital firms, Morgenthaler and ATV, has been "a long-time supporter and believer in the Foundry," having invested in nearly a dozen of its companies, including Ardian and Cabochon Aesthetics (which was acquired by Merz North America Inc.). For Lightstone, FIRE 1 represents "the next iteration of The Foundry," and bears many similarities to previous Foundry projects, with two main differences: first, the involvement of strategic partners at the earliest stages and second, the decision to locate the company in Ireland.

"We've worked with strategics in previous Foundry deals," Lettmann goes on, "but never at Series A." From an investor's perspective, he says, FIRE 1 is similar to previous Foundry projects "in that both the investors and the Foundry have to be in agreement as to what to pursue; the added wrinkle now is that Covidien is part of this and they have an equal say at the table. All three have to be in agreement."

Still, for FIRE 1's investors, Covidien, with its implicit promise of an early exit, may punch above its weight in the arrangement. Noting that Foundry officials have spent time with the senior management and R&D groups at Covidien, Lettmann says "they have a pretty good sense of what might be of interest to Covidien. We're going to try to find something that is up their alley and, if this model works, it should lead to Covidien being more comfortable [with the project selected]. Because it's aligned with their strategic interests, they might ultimately acquire it earlier than they might have if they weren't involved."

Even if successful, Lettmann doesn't believe FIRE 1 will necessarily create a new way to structure all deals. "This is one model," he says. "It's not the only model." Though different in some respects, he points to other, recent structured deals between start-ups and corporates, all of which share a common goal. "We need to figure out ways to get to an exit more quickly, using less capital," he adds. "That's paramount to any successful early-stage company strategy."

Consistent with that goal is the decision to launch the company in Ireland. "I think there are also benefits in our ability to execute in a more capital efficient way here [in Ireland]," says Lettmann. He argues that start-up companies in Ireland can, if managed properly, go further on less money than they can in the US. He points to the example of stroke company Neuravi Ltd. "They've gone from concept to 50 patients on €6 million," he goes on. "With the right development team and The Foundry, I think we can get this done for less than we would in California."

One other potential advantage to locating in Ireland: the ability of corporates to use un-repatriated cash reserves. "That allows an acquirer to buy the company at what is essentially a lower cost of capital," says Lettmann [although recent changes to US tax regulations could mute those benefits]. That advantage, combined with more efficient use of capital and an earlier participation in the deal, "offer a couple of carrots that allow them to acquire the company at a price that they wouldn't if they were just bidding on it externally."

If there are any drawbacks, it is that FIRE 1 engages with just one strategic. "There's always the worry that you've tied yourself to one horse and that could limit the options down the road," says Lettmann. Still, that exclusivity doesn't necessarily mean that FIRE 1's investors won't see a robust valuation at exit. Lettmann points to Lightstone's experience with Ardian, where Medtronic was the sole corporate investor, and adds, "We've also seen the model work in spades on the biotech side of our portfolio."

And against that possible drawback, bringing strategics in early has offsetting advantages. "We think having them involved early helps," says Lettmann, "particularly as [the strategics] get bigger through consolidation, as it naturally takes more time for them to get their heads around a deal. I think the net benefit is greater than the drawback."

Lettmann points to the recent surge in structured deals as an indication that big device companies are looking for new paths to innovation. FIRE1 is "a twist on this earlier-stage approach," he says. "There have been a number of structured deals as strategics try to go in earlier and bridge the gap between finding important new technology and doing dilutive early-stage acquisitions. These kinds of deals provide a way to do that."

–David Cassak

shorten the timeline." A more focused approach to incubation just might do that.

Certainly The Foundry isn't the first incubator to test such a model; in biotech, in particular, venture firms and corporations have experimented with closer early collaborations for the past couple of years. There have also been similar build-to-suit experiments in medtech, including some that go back a decade or more when companies like **Boston Scientific Corp.** took very early stakes in companies with the longer-term intention of acquiring them. But, as Mark Deem notes, "a lot of those projects were one-off arrangements based on specific products that were not only already defined, but in some cases, were already in development. I don't know that anyone else has done as much of a black-box project as we've done with Covidien."

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Bringing Players Together

In the end, what really differentiates FIRE 1 is its ability to bring together players like The Foundry, Covidien, and venture firms like NEA and Lightstone – as well as the decision to locate the project in the robust start-up geography that is Ireland.

The roles played by The Foundry and Lightstone and NEA are, of course, critical. But the real success of FIRE 1 – and its larger significance for the device industry – may lie in providing a new model for company creation at a time when early-stage capital is scarce and the role of Big Device companies begins earlier and earlier in the process. In that regard, the real import of the project may lie in whether over the long-term it delivers something that Covidien is ultimately willing to buy. Still, nothing underscores the vagaries of corporate life like the recently announced merger between Covidien and **Medtronic Inc.**; whether that deal will affect FIRE1 in any way remains to be seen. (Interestingly, while Medtronic was an early investor in Ardian and the company's eventual acquirer, Covidien has never acquired a Foundry company.)

Absent any official announcement from Medtronic, FIRE 1 executives are optimistic that they'll continue the project. Medtronic has historically been an active and creative deal-maker, committed to bringing innovative technology to the fore. And in some regards, FIRE 1 simply represents a new way of developing technology, one that could better align the corporation's interests than more traditional minority interests because it gives the company an earlier say in the technology to be developed. Hanson Gifford concedes that right now and for the next several months, FIRE 1 isn't likely to get a lot of attention at Medtronic, but he notes that in its early pronouncements about the deal, Medtronic officials said that they were going to take any savings from the merged companies and invest in innovative technologies. "If they're really forward-looking and looking for great opportunities, and if this model and approach work, I think there's a good chance [the merged company] will embrace it." Perhaps the real question is whether others in the device community will embrace the model as well.