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Perspective

MedTech Insights From US-Based VC's, Strategic's and Industry Experts

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As innovation continues to underwhelm, Licensing & Acquisition activity will remain healthy — with a focus on emerging markets. Strategic's are more comfortable with small- to mid-size tuck-in's while VC's will require significantly larger exits to sustain themselves. Through it all, data continues to rule — no outcomes, no income — and cost savings technologies are gaining in preference.

Overview and Summary

Over the past six months, I've had the opportunity to attend (or speak to participants attending) various MedTech industry conferences in the US. I've taken the liberty of summarizing the latest thinking from US-based Venture Capital firms (VC's), strategic's and industry experts regarding pre-revenue and revenue-generating companies, the FDA and the device industry. Their "Top 10 Insights" include:

- Licensing and Acquisition is expected to remain strong over the next few years
- The environment for early-stage investment remains "treacherous" and is largely being ignored
- Although the transaction process for strategic's has gotten more disciplined and deliberate, about 50% of deals successfully concluded by strategic's remain opportunistic in nature. Opportunities in emerging markets remain hot.
- Strategic's are more comfortable with tuck-in's of up to $300 million while VC's require exits in the $700 million to $1 billion range to sustain themselves
- Strategic's are de-risking licensing and/or acquisition opportunities by offering less money up-front but including milestones or earn-outs as part of the deal economics
- An equity investment by a strategic in a start-up is seen as validation of the start-up's technology -- not necessarily as a negative by a potential acquirer
- VC's continue to encourage start-up's to build a European presence, secure compelling data and then look to be acquired
- VC's are showing a preference for smaller vs. "mega-funds"
- Stategic's and VC's agree that "data will continue to rule" **— no outcomes, no income.** In addition, VC's see a shift from a "technology arms race to a cost savings arms race"
- The FDA is starting to take a more collegial and less combative approach with the MedTech industry

The Detail

Venture Capital (VC) Firms By Their Own Admission……

- May not have hit bottom yet, but are getting closer!
- Have returned, on average, an anemic IRR of ~1% to investors over the last 10 years
- Clearly funded "too many technologies and incremental stuff" over the past decade — Over 170 start-up spine companies were funded in 2003 thru 2006; only about a dozen are left today
- Probably can't live on $100 million exits; need $700 million to $1 billion exits. Looking for — and needing — "home-runs" to survive
- If investing in smaller deals, "need to get 7 of 10 right to make a good living"
- Mega-funds ($1 billion) may not be working; smaller funds may be better. However, even with smaller funds, still looking at bigger opportunities
- Are shifting investment monies to health care IT, including digital health
- Proposed route for a start-up is building a European presence, securing compelling data and looking for L&A
- If a start-up can get to $50 million sales on its own, the company should do it and not bother with VC's
- Chaos will bring opportunity

What VC's Are Saying They Like from Start-Up's……

- Technologies that reduce the cost of health care (shift from a "technology arms race to a cost savings arms race") — Make a device that solves a real need and is priced fairly — Have a model that fits today's health care environment, including ability to sell to a hospital value analysis committee
- Compelling clinical and/or economic data — outside US data is fine (and may actually be preferred). **"If you don't have outcomes, you won't have income"**
- A well thought out reimbursement plan (select VC's are now sharing reimbursement plans from start-up's with outside reimbursement experts for validation)
- Meaningful IP protection with broad claims
- A leadership team with an ability to execute
- The ability (either in US or O-US) to get to positive cash flow — or a transaction — for <$20 million investment
- Technologies that can exceed $100 million of annual revenues
- A deep and narrow sales/marketing approach (1-2 countries in Europe; select areas in US)
- "De-risked" technologies — from a technical, regulatory, clinical, and reimbursement standpoint
- Keeping core technology, innovation, quality and customer support internally and outsourcing regulatory, manufacturing and even marketing
- CEO's who promote their companies and technologies — without overdoing it

What VC's Are Saying They Don't Like About Start-Up's……

- Those not having their own due diligence buttoned-down (with focus on IP, licensing, ownership structure)

- Companies/technologies who lack a value proposition — or can't demonstrate economic value — for today's key constituents, including payer, hospital, surgeon and patient
- CEO's/companies that are capital in-efficient ("the days of spending $30 to $40 million to get a device to market are gone")
- Companies who rush to full national launch with limited capital and without clinical or economic results
- Incremental technology improvements that increase cost with limited or no clinical benefits
- CEO's who aren't aware of their "blind spots"
- CEO's who ask for more VC investment money, but are not willing to invest themselves

What VC's Are Saying They Like About Strategic's……

- Those (1 or more) who are prepared to invest (along with VC's) up to $10 million total in start-up's across all rounds

Strategic's By Their Own Admission……

- Are becoming more strategic and selective about Licensing and Acquisition (L&A) opportunities, but about 50% of their deals are sought-out and 50% opportunistic
- Confirm that their L&A processes are becoming more disciplined, deliberate and formal
- Confirm that integration is being considered in the very earliest stages of their transaction processes
- Confirm that Business Development teams are having to do more, with fewer resources
- Confirm that it is easier to integrate a product than a company
- Won't hesitate to acquire a technology if it's better than what they're working on internally
- Feel that equity investments from strategic partners are viewed more as validation of a technology — as opposed to a negative
- Confirm that more deals are starting out as investments

What Strategic's Are Saying They Like……

…..When Making Equity Investments (Applicable To Select Strategic's Only) Investing in Series B (or later) rounds

- Having VC to take lead role and set valuation so strategic can then defend internally
- Limiting investment to a maximum 19.9%

…..When Transacting With Later-Stage Pre-Revenue or Revenue Generating Companies

- Opportunities that are their core or at least adjacent to the core (1-step removed but with an understanding of customer base and technology)
- Tuck-in acquisitions (of up to $300 million) that are perceived as less risky and can be more easily integrated

- Products/technologies that will provide a sustainable competitive advantage – and a “top 3” position in a defined category
- Opportunities in emerging markets (for Medtronic — “Asia is the focus, with a higher priority in emerging markets”)
- Putting less money up-front with earn-outs having “meaningful but achievable milestones”; the earlier the stage, the more significant the earn-out. Admission, however, that “earn-outs can be complicated”
- IP that is strong, in order, well documented and properly secured
- Clear regulatory pathway
- Reimbursement
- Clinical evidence
- Developed quality systems and processes for manufactured or vended products (“it can take 9 months or more to get quality systems up to standard”)
- Strong management team that demonstrated capital efficiency as an early-stage company and show how/where cash flow occurs

What Strategic’s Are Saying They Don’t Like……

……..When Making equity Investments (Applicable To Select Strategic’s Only)

- Leading equity investment rounds
- Investing in Series A rounds or working with start-up’s involved in early clinicals
- Impairment

……….When Transacting With Later Stage Pre-Revenue or Revenue Generating Companies

- Straying too far from “the core”
- Deals that are dilutive (at least dilutive over an identified period of time)
- Companies having surgeon consultants or product designers who account for a high percentage of company revenues
- Companies with growth margins below industry average — and slipping
- Companies with commodity products sold on price that lack clinical and/or economic data for products
- Companies with off-label sales

What VC’s Are Saying About Strategic’s

- Typically driven by greed or fear
- Lack a comprehensive L&A strategy and are more opportunistic
- Can’t innovate on their own
- “In two years, they’ll be screaming for products for their pipelines”
- Have had difficulties integrating prior deals and are more risk adverse
- Companies that seem to be most active and held in highest regard : Medtronic, JNJ, Abbott, Covidien and Bard.

What Strategic’s Are Saying About VC’s

- VC’s no longer throwing around “stupid money”
- Lack of early-stage investment is concerning, but good ideas are still being funded (Note: VC’s are suggesting that all good ideas are NOT being funded)
- VC’s have been forced to do a better job with their due diligence

What MedTech Industry Experts Are Saying……

- Licensing and Acquisition is expected to remain strong over the next few years – Select device companies remain flush with cash and leaders from even small and mid-size companies (SNN, RTI, Integra, OrthoFix, Globus) admit that "they're seeking acquisitions". In addition, continued revenue headwinds and underwhelming internal innovation will force companies to spend to acquire and "move the sales needle". Finally, larger companies have seen JNJ "push the envelope" with the Synthes acquisition. This will potentially enhance JNJ's bundling capabilities — and its leverage — with hospitals and may accelerate consolidation.
- Pendulum may be swinging back — ever so slightly — at FDA — There may be "a change in tone" at the FDA. Most recently, the agency has been less combative, more collegial and more willing to listen. Although most still have a wait-and-see attitude, there is cautious optimism regarding the FDA's promise of greater transparency and centralization.
- MedTech may be the solution — not the problem — to healthcare costs — A study recently released by AdvaMed confirmed that prices for Medical technology have remained consistently low over a 21-year period, growing at less than 50% the rate of overall prices in the economy and only 20% the rate for other medical goods and services. Device and diagnostic prices have increased at an average rate of 1%, compared to the Consumer Price Index of 4.7% and the Medical Services CPI of 5%. Overall, devices account for less than 6% of total healthcare costs — versus ~70% of all costs to treat chronic diseases.

Don Urbanowicz is Principal of Urbanowicz Consulting (UC), a medical device advisory firm with a musculoskeletal focus seeking to enable clients to achieve strategic and transaction-related goals by capitalizing on market opportunities. UC offers a unique perspective on how large global companies approach strategy, valuation, negotiations, due diligence and integration, and a thorough understanding of achieving success throughout all phases of the transaction process. Please learn more online at www.urbanowiczconsulting.com, and contact Don Urbanowicz at durbanowicz@du-llc.com.