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The brave new business of medical entrepreneurship at UNC Kenan-Flagler, featuring TransEnterix president, Todd Pope

From Innovation to Income

By Nancy E. Oates

You always suspected your belly button could serve a useful purpose. [TransEnterix](#) found it: a portal to make invasive abdominal surgery less traumatic. With its Spider medical device, TransEnterix revolutionized the \$5 billion-a-year laparoscopy market by creating a device no bigger around than a dime to insert surgical instruments into the abdomen via the belly button. Once inside, the instruments open up like an umbrella to work from various angles, eliminating the need for multiple incisions. And the scar is hidden in the navel.

Less risk, faster recovery, lower cost and less time off work for the patient, said Todd Pope (AB '87), CEO of TransEnterix. Everybody wins. No wonder TransEnterix was able to raise \$60 million in venture capital funding in two years and move on to its second generation product within a year of Spider's April 2010 launch.

Breakthrough developments in life sciences bring more products and treatments to market faster, and new laws and regulations create systemic opportunities. At the same time, the tight economy has pinched the flow of grants and venture financing, making research funding ultracompetitive. Health-care economics are changing fundamentally, said Ted Zoller, director of [UNC Kenan-Flagler's Center for Entrepreneurial Studies](#) and associate professor of strategy and entrepreneurship.

"The economy is driven by two important trends: an extraordinary amount of innovation occurring in the medical marketplace and a counter pressure to make caring for patients much more affordable," Zoller said. "Individuals engaged in medical innovation are in the best position to influence and grow our economy, which will be driven largely by this important growth sector undergoing substantial transition due to the economy."

Consequently, the business school has made some changes to better position its graduates for success in the health-care field. UNC Kenan-Flagler has formed a partnership with UNC's medical school to teach doctors and researchers the strategic application of business principles and open business students to commercialization opportunities of medical innovations. Called the UNC Health Care Entrepreneurship Initiative, the collaboration has built an ecosystem of people attuned to taking medical innovation to the next level.

Zoller's benchmarking analysis of all the partnerships between medical and business schools revealed none in entrepreneurship. The UNC Health Care Entrepreneurship Initiative is the first looking at the innovation marketplace.

Dr. Cam Patterson (EMBA '08) has been appointed to a new post at the medical school as associate dean for health-care entrepreneurship. This new position allows him to establish a foot in both the business and medical campuses at UNC.

"Both schools have been very successful, and we haven't felt compelled to work together before," Patterson said. "But the health-care field is changing so quickly, we're partnering to innovate our way through the challenges and provide national leadership in a very complicated environment."

Patterson, chief of cardiology at UNC Hospitals and founder of the lab management company Dyzen, applied business operations strategy within UNC Hospitals to the issue of door-to-balloon time, the lapse between when a heart attack victim enters the emergency room until a stent or catheter is inserted to open the blocked artery. Using business principles, he broke the process into discrete steps—recognize the chest pain, order an electrocardiogram, call a cardiologist, mobilize the cath lab, transport the patient and so forth—and figured out where the bottlenecks occurred and how to resolve them. He cut the door-to-balloon time to half of what it was when he took over the department five years ago.

"That shows what a partnership between business and medical expertise can do to improve the quality of care for patients," he said.

Challenges unique to the healthcare field often block the path from idea to commercialization, said Fred McCoy (BSBA '79), vice chair of [Synecor](#), which specializes in creating medical device companies. Synecor, cofounded by cardiologist and inventor Dr. Richard Stack and serial entrepreneur Bill Starling (BSBA '75), launched TransEnterix and commercialized Biostent, vascular scaffolding that is reabsorbed once blood flow resumes.

“Our most significant challenge is clarity on timely access to the U.S. market; Food & Drug Administration approvals have become a good deal less predictable,” McCoy said. A pharmaceutical or medical device idea must come from a clear understanding of physician and patient unmet needs. The company must be able to conduct early prototyping, then endure what can be a long process of clinical trials to prove that it works. It must be patented, and the lengthy patent approval process reduces the time it can generate revenue exclusively for the inventing company.

Every step requires money, said Neal Fowler (MBA '88), CEO of [Liquidia Technologies](#), which specializes in novel platforms for vaccines and precise chemotherapy delivery.

Liquidia followed a typical financing course, beginning with angel funding by individuals and corporations who invest in exchange for an equity stake, before it moved to a Series A round of venture capital funding, in which managed funds invest as an equity stake in hopes of realizing a return through an IPO or licensure to a major corporation.

But then the [Gates Foundation](#) made an unusual offer, the first of its kind. Foundation money typically comes in the form of a grant, considered *nondilutive* funding because rather than requiring an equity stake, the grantor expects the research will further one of its goals.

With Liquidia, the Gates Foundation made an equity investment of \$10 million, because of Liquidia's innovative technology and the fact that the missions of Liquidia and

Gates align—Liquidia's focus on vaccines and the Gates Foundation's aid to developing countries.

“We'll benefit from the immense expertise and resources the Gates Foundation has going forward,” Fowler said.

Even Todd Pope, despite relative fundraising success at TransEnterix, admitted, “Raising capital is never easy.”

An investor asks five questions in evaluating risk, Pope said. Is it a big market? Is it a growing field? Can you build a good management team in your current geography? Do you have reimbursement challenges? Are you going to be able to get approval from the regulatory body?

Funding is increasingly competitive in a tight economy, and the pressure continues after financing. “Our competitors do \$3 billion to \$4 billion in sales per year,” Pope said. “We're a startup.”

Spencer Williamson (MBA '91), CEO of [Intelliject](#), laid the foundation for his career in medical innovation at major corporations before building a company around a drug/device combination product that aims to replace the EpiPen, the epinephrine injection relied upon by those prone to severe allergic reactions.

“I came into this eyes wide open to the risk,” Williamson said. “About 80 to 90 percent of life sciences startups fail.”

The two most important decisions small businesses make, he said, are “who you hire and who you take money from.” Make sure you and your investors stay aligned in your goals, he said, and create a team of people who have passion, curiosity and the drive to get continually smarter.

“The only competitive edge you have as a company is if you can learn and react faster than your competition,” he said.

Beyond the innovative idea, the proven efficacy, the funding and the regulatory hurdles, a product won't be successful until someone buys it. That's where UNC Kenan-Flagler graduates have an edge, said marketing professor Dave Roberts, cofounder, with Jan-Benedict E.M. Steenkamp, Knox Massey Distinguished Professor of Marketing and area chair of marketing, of UNC Kenan-Flagler's new Center for Integrated Marketing and Sales.

“Very few schools teach sales,” Roberts said. “Even fewer teach sales strategy.”

Sales can be either transactional or consultative; the market is bifurcating and the split has been accelerating. Technology is replacing transactional sales interactions (through direct sales over the Internet, for example), but consultative sales positions are increasing as the need for business-to-business solution sales increases. Roberts uses hospital situations as background for sales calls and presentations, because hospitals often have both types of selling going on.

“The B2B world has ‘buying centers,’ different people involved in a buying decision,” he said. “A hospital has multiple buying centers, which makes selling to a hospital much more complicated. You have hospital management, nursing staff, physicians and procurement, and they all have sway and needs, and sometimes those needs conflict.”

Roberts' classes complement Ted Zoller's Launching the Venture program, stressing the frequent need for a channel for distribution and selling through third parties rather than focusing on traditional direct sales.

Launching the Venture, begun in 2003, encourages entrepreneurship in frontline workers in their fields, including clinicians, physicians and researchers.

"My sense is that the U.S. has one truly competitive marketplace remaining," Zoller said, "and that's in health-care innovation and clinical care."