Intent on starting a business, Loleta Robinson (who has a medical degree and an M.B.A.), enrolled in ACTIVATE, a year-long University of Maryland, Baltimore program for aspiring entrepreneurial women. She and another student, chemical engineer Colleen Nye, M.B.A.—whose pharmaceutical project management background complemented Robinson’s biotech and diagnostic experience—co-founded Syan Biosciences in 2006 to develop a lab-on-a-chip for in vitro diagnostic testing.

“We teamed with a University of Maryland Biotechnology Institute inventor, who's developing a lab-on-a-chip with a unique polymer,” explains Robinson. “We're still improving the prototype, utilizing grants and personal savings for financing.” One grant covers a university-paid postdoc, working on campus with their inventor. Syan’s goal is “to commercialize a hand-held device that will be more accurate for analysis, compared to the competitors.” The founders hope to start selling it by mid 2011, initially as a research-use-only product.

“The hardest part was the personal decision to take the risk, make that leap of faith, leave a stable biotech job to work full time at starting a company. I debated for six months,” confides Robinson. Now, as chief medical officer, she savors being in charge, especially “being able to think creatively, to have individual concepts you can actually apply to something.”

“If you lift your head from the lab bench and look at the world, what you’ll see is the business of science,” predicts Judith Kjelstrom, director of the Biotechnology Program at University of California, Davis. You might even envision a new science-based business: yours. It's tough turning a discovery or concept into a company, yet thousands of scientists try it every year. Here's what to expect, where to find assistance, and what other bioentrepreneurs have experienced.
Cultivating an Alternative

Ever since he heard about biofuel photobioreactors, Bryan Willson, has seen raw power in tiny algae, nature’s fastest-growing organisms. His 2006 startup, Solix Biofuels in Fort Collins, Colorado, will convert cheaply mass-produced, algae-derived oil into biodiesel.

However, the Colorado State University mechanical engineering professor realized, “The biology and energy had to be tightly coupled to produce acceptable yield at economical cost.” Solix continues its work to increase algae growth rate and oil content, then reduce the capital and energy expenditures of production to keep costs below $80 per barrel. Expecting 80 percent more oil use in China and India by 2035—more than current supplies can meet—Willson sees enormous opportunity.

Its first outside funding round, in late 2008, raised $10.5 million to build the first facility producing commercial, cost-effective feedstocks and biofuel from algae. “[Entrepreneurs] always think success will be quick. I consider Solix very successful, but we’ve come to realize it’s a marathon, not a sprint,” says Willson, its chief technology officer.

Solving a Need

Vikki Hazelwood encourages her biomedical engineering senior project students at Stevens Institute of Technology in Hoboken, New Jersey, to solve an actual unmet medical need. In 2004, she met Norman Marcus, a New York University Medical College physician, who had patented a unique methodology to identify a pain’s myofascial trigger point. “It required a cumbersome, heavy device, making it difficult to provide access and training to other physicians,” she recalls.

A three-student team improved the technology by miniaturizing the device to a pocket-size prototype in early 2005. The improved device and method “locates the exact muscle[s] generating the pain,” explains Hazelwood. “It is the first to use neuromuscular electrical stimulation as a diagnostic tool, and offers an effective treatment strategy that can drive down health care costs for chronic pain.”

By that summer, SPOC (for Stevens Proof of Concept) was a limited liability corporation, or LLC, and caught the attention of Connecticut Innovations, a quasi-public authority investing in regional technology development. CI offered $500,000 in seed money—if SPOC would establish headquarters in Connecticut. Hazelwood, part-time CEO and President, and Marcus, chief medical officer, agreed. One student-inventor is now a full-time employee.

When SPOC met its milestones on time and under budget, CI provided another $300,000. In 2008, SPOC received US Food and Drug Administration 510 clearance, after Phase 1 clinical trials at NYU Medical Center and a pilot study at Kaiser Permanente Hospital. Now seeking $5 million in series A venture capital, SPOC has a subcontractor; with additional funds, manufacturing could optimistically start by late 2009, predicts Hazelwood.

Where to Start

What will your business offer: a new medical device, an innovative procedure, an alternate fuel, a unique vaccine? Step one is assessing your idea and its viability, to make sure it’s worth the lengthy bioentrepreneurial passage.

Delve into professional literature. Scour journal articles covering your, or closely related, areas. Solix’s Willson pored over papers from the National Renewable Energies Laboratory, which had tested 3,000 of 500,000 algae species before abandoning what he considered promising research.

Explore the competition. At scientific conferences, evaluate presentations and exhibits about anything germane to your own focus. What’s missing? Do you see a previously unrecognized
difficulty, or a potentially faster, safer, more effective, or less costly solution? Study ads in relevant professional publications and exhibitor lists from related conferences. Talk to potential customers—consumers, corporations, institutions, or scientists—about your idea. Surveys can gauge interest among potential purchasers. Instead of pricey private research firms, consider hiring marketing students in an M.B.A. program.

Pinpoint a clear need and the likeliest market for what you’ll offer. Could you produce it at a price affordable to this segment?

Who Owns What?

Nothing’s free: investors want something tangible in return. Often, it’s a claim to your idea.

Protecting your work is vital. If your research utilized university facilities, expertise, or funds, the institution generally owns the patents. When a company licenses the patent from a university, the co-inventor named on that patent will earn royalties (shared among university, department, and inventors). Graduate students listed on a patent could eventually see royalty income. Technology transfer offices (university clearinghouses for discoveries) can advise on who owns a particular patent. If none exists for your discovery, a provisional patent can protect your work for one year in the US, allowing the technology transfer office time to file it, if necessary.

An outside investor means a partnership, not a loan, stresses Tony Stenco, executive director of the National Council of Entrepreneurial Technology Transfer (NCET2). “Investors have the upper hand, because of the risks. Rights, royalties, and patents all go into the company. The question becomes, who owns the company? Founders can start at 100 percent, but after several rounds of funding, end up at 10 percent to 20 percent.”

Who Can Help?

First, tap accessible, unpaid expertise. Sometimes law or business schools welcome real-life projects for students. Local business organizations might provide mentors to startups committing to stay in the area.

Find relevant, local nonprofit groups. The Council for Entrepreneurial Development (www.CEDnc.org), America’s oldest, largest support group for emerging companies, serves the Southeast. Based at North Carolina’s Research Triangle Park, CED affords its 5,500 active members networking, mentoring, and capital formation resources.

Fill in gaps. Hazelwood’s 25 years in biotech sales and marketing proved invaluable to SPOC. Yet, “Even with such experience, it’s important to hire the right kind of help,” she stresses. SPOC chose able experts in regulatory issues, reimbursement, and prototype development, plus outstanding board members.

Accumulate industry know-how. Judith Kjelstrom’s University of California, Davis Biotechnology Program requires a three-to-six-month paid internship, preferably at a biotech firm. “Get involved in many startups as an early employee,” suggests Stenco. “Hook up with enough founders before becoming one, and you’ll learn enough to succeed, by experiencing failures on someone else’s dime.” (If you have a unique, time-sensitive discovery, though, patent it first, he adds.)

Robinson believes that jobs planning and implementing clinical trials and new product introductions prepared her well for Syan’s diverse responsibilities. Willson calls his experience launching a previous startup “a huge factor. Learning new technology in an unproven field plus learning to start a company equals too many unknowns.”
Follow the Money

Bringing an idea to market costs millions. If you don’t have a billionaire relative, here are some other options:

**Venture capitalists.** “Angel” investors typically invest $50,000 to $500,000; venture capitalists $500,000 to $5,000,000—“only in things they know. Any category has far fewer investors than people think,” Stenco finds.

Investors seek 10-fold return in five to seven years. Winners compensate for the 70 percent to 80 percent likely to lose money (often all of it), says Stenco. In economic downturns, “great companies get funded, but at lower values. Devices are desirable now—they don’t take as much time or money.”

All startups gamble on uncertainties, like market downturns, unexpected technical issues in moving a new product from prototype to production, or attracting enough customers. “You don’t know how it will work out without years of trying. Most entrepreneurs fail up to seven times before making it,” reports Stenco. (Recently, a Harvard Business School team reported a 22 percent success rate—defined as going public—among first-time entrepreneurs receiving venture capital.)

**Corporate partners with related interests.** Disillusioned by a Silicon Valley capital hunt, Willson switched paths, sharing Solix’s approach and progress with the scientific community. After hearing their conference presentations, Valero Energy and the Southern Ute Alternative Energy approached Solix. Now, they are long-term strategic partners.

**Incubators.** Often quasi-public or university-based, incubators offer startups strong financial and operational support. To spur Connecticut’s economy, CI invests in early-stage technology companies, university-industry research collaborations, technology transfer, and clean energy initiatives (www.ctinnovations.com). Willson founded CSU’s Engines and Energy Conversion Lab, which has launched numerous companies, directly or indirectly, sometimes in partnership with the university.

Some large pharmaceutical firms have investment arms, or incubators. Seeking new broad-platform candidates for its R&D pipeline, Pfizer’s La Jolla, California, incubator offers early-stage startups financial and operational support, exercising acquisition rights after two to three years. Biogen Idec, in Cambridge, Massachusetts, prefers startups with specific therapeutic projects. Corporate incubators provide experts, equipment, and resources. Unfortunately, if the parent company doesn’t buy a startup, its venture capital appeal diminishes. And even if the startup is lucky enough to make a major discovery that can bring millions of dollars, it may not be able to operate as an independent company if the incubator retains ownership of the discoveries.

**Government sources.** Federal, regional, and state agencies provide bioentrepreneurship grants. Investigate each agency’s preferences meticulously. Ali Andilibi, who formerly managed the National Science Foundation’s biotechnology portfolio, explains: “NSF wants proposals on novel techniques, not just improvements on existing ones.” NIH supports both innovation and “optimization that can benefit patients—such as making a cancer drug less toxic or more potent,” says Andilibi, now program director of the US National Cancer Institute’s Small Business Innovation Research (SBIR) Development Center in Bethesda, Maryland.

NIH and NSF are investigator-driven; other agencies, like the Department of Defense, more mission-driven. NIH invests about $650 million annually in SBIR and small business technology
transfer (STTR) programs. STTR requires an academic partner for the business. A good track record is a plus; preliminary results help.

NCI’s new Bridge award will assist SBIR recipients moving toward commercialization. “The business must secure meaningful outside investment from a third party—venture capitalist, angel, or state agency. The application should include letters from investors and must convince reviewers that the project will succeed, both scientifically and commercially. “Be in a business mindset, as well as a science mindset,” Andalibi suggests.

After Phase 1 or Phase 2 trials, some savvy firms reach out, because Phase 3 is expensive. If big pharma is interested in buying or financing the operation, “NCI gladly provides a portion. With the costs of taking a drug to market, we want to make sure our SBIR projects make it, in order to benefit patients.” The Bridge program began in September 2008; NCI expects to award $5 million to $10 million during its first year.

With a one-year grant from Maryland Industrial Partnership (MIPS), Syan Biosciences has applied for multiple NIH STTR grants. “While developing our prototype, the challenge is gathering enough data which positively supports our product, to convince grantors we’re worthy of money,” says Robinson. “My biggest surprise was how slow and hard it is to get a grant—all the writing, nuances, and time.”

Improve your odds. Does your idea fit several government agencies? Call a program director for feedback. Carefully customize the same application for different grantors. (However, you can accept only one federal grant.)

**Selling Your Idea**

Successful startups present their strategy convincingly in a thorough, thoughtful business plan. To enter UC Davis’s business plan competition, Kjelstrom encourages her science and engineering graduate students to seek help from an MBA student for refining concepts and targeting a specific market.

In seeking venture capital, “think like an investor in terms of a portfolio,” advises Stenco. Robinson concurs. “We have pitched to investors, but are considered too early to fund.” Placing third in the 2008 Rockville Economic Development Institute’s business plan competition, Syan Biosciences’ founders garnered “experience and good advice from judges, as well as contacts that will be necessary moving forward.” For award applications, too, “make sure another pair of eyes looks at it,” Andalibi urges. Utilize resources at nearby graduate schools or tech transfer offices.

What must you convey? That your team is capable of taking its research and idea from lab to marketplace. Highlight each member’s track record. “For commercialization, have the right kind of advisers or consultants wherever the company is lacking,” Andalibi recommends. “We like to see strong science, but also a very strong commercial underpinning.”

While entrepreneurs are always optimists, “don’t be unrealistic about what you can achieve,” Andalibi cautions. Aim high—but stay grounded.
Resources Online

For a university perspective on technology transfer, intellectual property, patents, and other protections, visit www.innovationaccess.ucdavis.edu

InnoCentive, launched by Eli Lilly and Company, posts challenges to scientists worldwide. Top solutions win $5,000 to $1,000,000. www.InnoCentive.com

NCET’s free webinar course on commercialization is at http://ncet2.org/UpcomingEvents/researcher-commercialization/webinar-course-on-researcher-commercialization-the-essentials/

NIH grants are described at http://grants1.nih.gov/grants/oer.htm

At www.freshpatents.com, check recent US Patent and Trade Office applications. On www.uspto.gov, learn everything about patents, including which were approved.

Information on companies and trends in every market sector is available at www.Researchandmarkets.com.

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Featured Participants

Biogen Idec - www.biogenidec.com

Colorado State University - www.colostate.edu

Connecticut Innovations - www.ctinnovations.com

Maryland Industrial Partnership - www.mips.umd.edu

National Council of Entrepreneurial Technology Transfer - www.ncet2.org

National Renewable Energies Laboratory - www.nrel.gov

National Science Foundation - www.nsf.gov

New York University Medical College - www.med.nyu.edu

Pfizer - www.pfizer.com
Solix Biofuels - www.solixbiofuels.com
Southern Ute Alternative Energy - www.suaellc.com
Stevens Institute of Technology - www.stevens.edu
Sygan Biosciences - www.syanbio.com
The Council for Entrepreneurial Development - www.cednc.org
University of California, Davis - www.ucdavis.edu
University of Maryland Biotechnology Institute - www.umbi.umd.edu
University of Maryland, Baltimore - www.umaryland.edu
US National Cancer Institute’s Small Business Innovation Research Development Center - sbir.cancer.gov
Valero Energy - www.valero.com

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