

SBIR SUCCESSES



NBDC and SBIR/STTR

NBDC helps university faculty and other entrepreneurs understand the SBIR program, as well as the Small Business Technology Transfer (STTR), a program requiring university/entrepreneur collaboration.

NBDC business services—including market research, manufacturing, capital formation, and management structure assistance—can help grant seekers submit a successful SBIR proposal.



NATURE TECHNOLOGY CORPORATION

Developing and producing new vaccines is a complex, time-consuming, and costly process. Nature Technology Corporation (Nature Tech) in Lincoln developed fermentation technology to mass-produce DNA vaccines, which would allow cost-effective production of vaccines, such as a bird flu vaccine, for about a dollar per dose.

Clague Hodgson founded Nature Tech in 1997 and now has 8 full-time-equivalent employees. To begin the company, Hodgson negotiated royalty agreements for patents he developed while on faculty at Creighton University. Nature Tech currently gets revenue from multiple sources, including licensing of technology they've developed and manufacturing of DNA and vaccines.

Nature Tech's DNA fermentation process is being used by the National Institute of Health's Vaccine Research Center to make vaccines for avian flu (H5N1), currently in clinical trials, as well as for making vaccines against HIV-AIDS and Ebola virus.

Nature Tech uses Small Business Innovative Research (SBIR) grants to develop new technology. They have received five Phase I grants and one Phase II grant. Their company doesn't depend entirely on SBIR money but use it to supplement their research budget.

When it comes to writing the SBIR grants, Nature Tech offers some guiding principals.

- Develop new products using CORE technology (competence) – don't try to develop a new expertise or overcome a learning curve with SBIR funding.
- Be sure the product is worth developing – does it fit with your overall business strategy? Can you sell it?
- Use clear criteria for success, simply specified for reviewers.
- Describe the final product you hope to produce, but a Phase I project should test a small, critical piece associated with the product development. Test a specific hypothesis and provide convincing proof of concept – the key to getting much larger Phase II SBIR funding.
- Target the grant to the appropriate section of the agency by copying exact phrases from that division (topic) in the cover letter.
- Write grants to agencies (sections within agencies) that fund at least 20% of their applications. A well-qualified proposal can be funded at the 20% rate, but only superior proposals will be funded if the award rate is less than that.
- Have a business plan in place and show that you can commercialize the resulting products.



Dr. Jim Williams, Nature Tech's vice president for R&D, (picture above) is currently principal investigator on two SBIR grants (Phase I and Phase II), totaling more than \$1 million.



Aaron Carnes is a UNL graduate and chemical engineer who took the lead in developing NTC's DNA fermentation and purification processes.

Nature Tech points out that all the grants are competitive enough that companies must show they know what they're doing and have the capability to be successful. For National Institutes of Health grants, the reviewers are often academics. It is useful to think of them as your "customer" when writing the grant. You may find out who is on the committee, even though the specific reviewers are not known. Knowledge of the reviewer's expertise helps define the level of specificity required in the proposal.

Nature Tech has been very successful manufacturing plasmid DNA, using their HyperGRO™ process. They will produce custom batches for companies that need it occasionally or will engage in site licensing for regular users.

Nature Tech offers a full spectrum of biologics development services intended for biopharmaceutical companies, including vector design and development, production host strain development, process development and product development. The company's customers and partners include many of the largest pharmaceutical companies as well as smaller biotech firms. "You can come to us with a need and you will leave with a rationally designed product that is uniquely suited for its intended purpose," says Hodgson. As such, biologics fill a need that is left behind in the wake of small molecule drugs going off patent.

At the core of its activities are Nature Tech's inventions, which include products and processes for making nucleic acid-based vaccines and gene therapeutics. DNA vaccines provide for immunization with materials that are entirely gene-based and produced by the recipient's own cells, via the body's immunological response.

DNA vaccines can be easily, specifically, and rationally designed. Nature Tech's GENSA™ (Gene-Self-Assembly) technology is a key part of their vaccine development process, while Genome Mass Transfer (GMT) technology is their new, patented method for engineering host strains of bacteria—the living cell factories that are expressly designed to make biological products

Nature Tech doesn't try to get the maximum amount of money possible from royalty agreements. Rather, they negotiate a fair fee and make money from selling products (quantity). Hodgson plans to sell Nature Tech eventually. After a large pharmaceutical company has licensed a few Nature Tech products, it will make sense for them to just buy the firm. Meanwhile, Nature Tech continues to grow and develop new technologies to provide industry solutions for design, research, process development and manufacturing of biologics.

Nature Technology is found on the World Wide Web at <http://www.natx.com/>