WINTER 2007–08

PHASE II COMMERCIALIZATION

FINANCING ALTERNATIVE ENERGY PROJECTS Small Business, Government and Wall Street Working Together

NIH ROADMAP: INITIATIVES AND OPPORTUNITIES The Future of Medical Research and the Funding to Move it Forward

MANUFACTURING 101: FROM R&D TO PRODUCT PRODUCTION

The Options Available and Key Factors for Success

THE ANGEL PERSPECTIVE

Building a Lasting Relationship



CONTENTS

6	Commercialization Strategies A discussion of "commercialization strategy" as it applies to small busi- nesses—offering some advice and considerations to be made when mov- ing the company towards the ultimate goal of commercialization. Jenny C. Servo
9	Financing Alternative Energy Projects A look at the momentum being gained with new alternative energy fund- ing opportunities and the hurdles that still remain. John G. Servo
12	NIH Roadmap: Initiatives and Opportunities A concise discussion on the NIH Roadmap—the path to the future of medical research—and various NIH funding sources available to small businesses in the health care arena. Carol B. Van Buren
15	Manufacturing 101: From R&D to Product Production Advice for small R&D firms considering the move to the manufacturing sector as a means to commercialize technology. Robert F. Larsen
18	The Angel Perspective Tips from an angel investor on how to "catch the eye" of a savvy investor, and how to prepare for the formal presentation once the angel has an interest. Steve C. Orth
21	Getting the Right Licensing Deal A concise guide for small businesses wishing to use licensing as a means to commercialize a technology. Jenny C. Servo
23	Early Stage Investor Expectations and a Quick Valuation Approach A guide for meeting investor expectations and assessing technology value, with an outline of various funding methods.

EDITOR'S NOTE

Commercialization has become THE issue of importance, particularly for advanced technology firms relying heavily on government R&D funding. Commercialization is a sweeping term applied to a single outcome and the multitude of tasks involved with reaching it. That outcome is defined by sales, putting the product, process or service into the market place, and making money with it—either from increased savings and/or profitability.

In the Small Business Innovation Research (SBIR) community, commercialization is also referred to as Phase III. *Phase III Commercialization*[™] magazine, a publication in its first year, is dedicated to the many aspects of this process. Our approach cuts across agencies, disciplines and industries and focuses on three broadly defined content areas—medical, energy and defense. In every issue, we also highlight commercialization strategies that advanced technology firms use and potential financing options. Our goal is to provide insight and information to those who are intent on being successful in transitioning, commercializing or infusing their technology into the marketplace.



Enjoy this publication and feel free to send me suggestions for future articles of interest to you.

Sincerely, (Sour Jenny C. Servo, Ph.D.

Jenny C. Servo, Ph.D. President, Dawnbreaker, Inc. *The Commercialization Company*

REVIEW BOARD

David Metzger

A partner at Arnold and Porter, LLP and a member of the Virginia, District of Columbia and Wisconsin Bar Associations, Metzger practices in the area of government contracts, concentrating on all aspects of federal government contracting law. Admitted to practice before the U.S. Supreme Court, Court of Federal Claims and Court of Appeals for the Federal Circuit, he has prosecuted and/or defended bid protests, terminations for default, and suits involving prime contractors and subcontractors. He received his B.A. and his J.D. from University of Wisconsin.



Brent Brown

Managing partner of Madison Parker Capital, Brown is an active advisor and partner to leading advanced enabling material and technology companies. Through his career, including time as an investment banker for Canaccord Capital where he helped to develop the firm's Advanced Enabling Materials franchise, he has been involved with the financing, acquisition and/or sale of nearly 24 companies with an aggregate value of \$2.5 billion. Brown has a B.S. in engineering from the U.S. Military Academy at West Point, a master's in engineering from Southern Methodist University and an MBA from Harvard.

Richard Sun

Founder and owner of Sun & Co., Sun brings more than 30 years of banking and investment experience to his clients—offering capabilities in startups, venture capital, private equity investment and fund management. A veteran in a wide range of industries, he has originated, structured, placed and closed over 70 deals valued at over \$4B and has originated and led over 30 advisory assignments valued at over \$7B. Sun holds a bachelor's degree from Princeton and an MBA from New York University.



Jo Anne Goodnight

The NIH and DHHS Public Health Service SBIR/STTR program coordinator, Goodnight also serves as acting director for the Division of Special Programs in the Office of Extramural Research. In her 25 years of government service, she has held a variety of positions encompassing research, program administration and management for the U.S. Department of Agriculture, the Food and Drug Administration and the National Institutes of Health. She has also published numerous scientific studies during her tenure. Goodnight holds a Bachelor of Science in microbiology from Virginia Tech.



John May

Co-author of the book, *Every Business Needs an Angel*, May is the managing partner of New Vantage Group, a Vienna, Va. based firm that mobilizes private equity capital into early-stage companies. He administers four regional angel funds—the Dinner Club, eMedia Club, the Washington Dinner Club and Active Angel Investors, and has joint ventures with other angel networks. May also works in the venture fund arena, serving as an investment director and general partner in Seraphim Capital based in London and as the managing general partner of two U.S.-based venture capital firms.



Tallam Nguti, Esq.

Presently senior patent counsel for Xerox Corporation, Nguti received a B.S. in engineering from Purdue University, an MBA from Purdue's Krannert School of Business, and a J.D. from Valparaiso University. Prior to law school, he worked for 12 years—first as a managerial trainee for Johnson & Johnson, and then as a manufacturing engineer for Zenith Radio, BRK Electronics and Lever Brothers. In the 20 years since law school, Nguti has worked as a patent attorney, counseling many small inventors and start-ups—obtaining more than 500 patents for clients.



Dennis Thompson

Dennis Thompson serves as the executive director of the Doyle Center for Manufacturing Technology. Throughout more than 30 years, he has held positions at Chrysler, Stanadyne, Advanced Drainage Systems, Remington Arms and Catalyst Connection. Thompson holds an M.S. in business management from Renssalaer Polytechnic Institute at the Hartford Graduate Center.



CONTRIBUTORS

Jenny C. Servo, Ph.D.

The founder of Dawnbreaker, Jenny Servo specializes in designing government agency programs and assisting small, advanced technolgy firms with organizational development, market research and business and strategic planning. A frequent SBIR conference speaker, she has also written extensively on innovation and is the senior author of the books Business Planning for Scientists and Engineers, Knock Their Socks Off: Making Winning Presentations to Investors and Indicators of Commercial Potential. Servo holds an M.S. from the University of Kansas and a Ph.D. from the University of Rochester.



John G. Servo

John Servo, a Dawnbreaker vice president, utilizes his 20+ year sales career in assisting primarily advanced energy technology clients with strategic planning, market research and contract negotiations. Working with firms that participate in company conducted programs for the DOE, DoD and DOC, he also has the primary responsibility for interfacing with the investment community and managing participation for the investment events that culminate most of Dawnbreaker's programs. These events, referred to as Commercialization Opportunity Forums, are largely attended by corporate executives and venture capital firms.

Carol B. Van Buren

Carol Van Buren, a portfolio manager for Dawnbreaker, specializes in the medical R&D and biotech arenas. Working for companies including Kodak and PACS/ Digital Medical Imaging Solutions, Van Buren has held a variety of roles in the biotech and health care industry, including new business development, strategic marketing and sales, product management and medical R&D. She holds a B.A. in biology/chemistry, an M.S. in preventive medicine, and has completed her doctoral training in Clinical & Chronic Disease Epidemiology combined with Health Policy, Finance and Management at Johns Hopkins.

Terry M. McMahon, MBA Terry McMahon, a Dawnbreaker portfolio manager, has an extensive background in marketing, product development and both business and strategic planning. During his nearly 40 year career, he has, among

many other things, served as a marketing director for an Eastman Kodak venture company and led business development efforts for a \$190 million global parts and service business. McMahon holds an associate degree in electrical technology, a B.S. in business management and an MBA in finance.



Robert F. Larsen

Steve C. Orth

Bob Larsen, a manufacturing consultant and portfolio manager at Dawnbreaker, is focused mainly on manufacturing assessments. Larsen's 25 year professional career has been spent directing the growth of domestic and international original equipment manufacturing and service businesses. He was general manager and senior vice president for multiple divisions of Lockheed Martin, and at TransTechnology and Puritan Bennett. His B.S. in business is from New York Institute of Technology. During the Vietnam War, Larsen served as crew chief for a U.S. Army helicopter gun team.

Steve Orth joined Dawnbreaker in 2003 as a portfo-

lio manager, concentrating on investor related issues.

Prior to that time, he spent 17 years working in the

photonics, technology and aerospace industries. His

career began at Grumman Corp., moving then to sales

and business development roles at EG&G in military

and commercial fluid power applications, followed by

management of domestic and international sales ac-

tivities at Burleigh Instruments. He holds a B.S. in me-

chanical engineering from Clarkson University and a

B.S. in physics from SUNY at Potsdam.









COMMERCIALIZATION STRATEGIES

The phrase "commercialization strategy" is used frequently in the literature associated with the Small Business Innovation Research (SBIR) program. In most solicitations it is referenced in the following fashion "your company's strategy for converting the proposed research into a product or a non-R&D service with widespread commercial use—including private sector and/or military markets"—but what does that mean? How can this concept be operationalized in a way that is useful?

fter reflecting upon the stage-gate model of new product development expert Dr. Robert G. Cooper, it seemed both useful and instructive to define commercialization strategy for small advanced technology firms in the following way: A commercialization strategy is the series of financing options that a company entertains to move its technology from concept to the marketplace.

Table 1: Stages in the Commercialization Process - Robert Cooper

Initial Screening Step 1: Step 2: Preliminary market assessment Step 3: Preliminary technical assessment Detailed Market study Step 4: Predevelopment business/financial analysis Step 5: Step 6: Product development Step 7: In-house product test Step 8: Customer test of products Step 9: Trial sell Step 10: Trial production Step 11: Precommercialization business analysis Step 12: Production start-up Step 13: Market launch

Milestones

First, let's examine the concept of milestones. Dr. Cooper defined thirteen steps, also known as milestones or gates, associated with the successful introduction of new products in large businesses. At each step an evaluation of the opportunity is conducted and an additional round of funding is requested to support the subsequent stage of development. A go/no-go decision is made at each evaluation point [gate]. It is important to note that the milestones in Table 1 are NOT all technical in nature, and that market, technical and financial assessments are made in an iterative fashion throughout the commercialization process.

The milestones for an SBIR-funded technology do not have to be identical to the steps identified by Cooper. However, the milestones should be meaningful to the technology at hand and critical for continued technology maturation. Sample milestones might include securing FDA approval, flight certification, or becoming ISO 9001 certified. However, it is important to keep in mind that the milestones selected should NOT all be technical in nature, but must include others such as Intellectual Property Protection, Market Test and Scale-up, as appropriate.

Milestones are half of the equation, with potential funding sources being the other vital ingredient, which defines a commercialization strategy. Small businesses are not financially well-endowed and therefore, unlike large firms, must turn outwards when seeking additional funding for growth. Sources of external funding, to which small businesses often turn, include Federal Agencies, business angels, Fortune 500 companies, venture capital and state-level departments of economic development. When turning to these external sources for funding, it is vital that the small business understand the expectations that each funding source has and what criteria it uses to evaluate whether or not it will invest and/or provide funding to the small business. Figure 1 shows the most common financing options. The financing options available to a firm vary over time and depend upon a number of items, including the management's vision for the future, business philosophy, stage of technology development, market risk, competitive activities and window of opportunity. The manner in which these items affect the choice of financing options is discussed in the figure below.



Management's **vision** serves as an anchor point. Any strategy must begin with a reflection upon what management wishes to achieve in the future. This begins with a personal search to decide if the firm is to remain a contract R&D house and license the technology to others, or if the firm is to perform most business functions itself (manufacturing, sales, customer support). These are important considerations and they affect the preliminary shape of the commercialization strategy.

A commercialization strategy will also be affected by **personal philosophies** about business. Some founders start with the desire to grow the company without giving up any equity. Others may decide that they don't care who else makes money from their business, as long as they retain the right to do what they enjoy most and make good money in the process. Such philosophies usually go unexpressed, but certainly affect the choices made by an entrepreneur in developing a commercialization strategy.

Companies that are developing a technology platform with the ability to affect multiple industries must also include an assessment of which applications they think they will develop first. This should be discussed in their commercialization strategy and potential markets rank ordered in terms of their readiness. A company should position itself to hit market **windows of opportunity**.

Vision, business philosophies, and a logical assessment of market opportunities are all important considerations to make in developing your commercialization strategy.

Table 2 (above right) is a simple expression of a commercialization strategy. It is referred to as a licensing strategy, as this was the last step in the process. A clarification of the vision and the business philosophy are identified and then major milestones and financing methods are outlined.

Table 2: Vision: Life-style firmBusiness Philosophy: I am in business to do what I enjoy!			
MILESTONE	FINANCING METHOD		
Start-up	Sweat equity		
Concept development	SBIR Phase 1		
Intellectual property protection	Retained earnings		
Application Development	Licensee		
Production	Licensee		

It is important to note that a company with this vision will not be of interest to an equity investor, as the objectives of the founder are not aligned with said investor. Therefore, the vision shapes the funding options that are available. In this strategy, manufacturing, customer support, marketing and sales are all done by the licensee. This is a shared approach to bringing a product to market, where the government provides some funding, as do the company founders and the licensee.

Advanced technology firms have a voracious appetite for capital. Therefore, when one has developed a preliminary commercialization strategy, it can be further expanded and turned into action items.

When examined in this fashion [milestones and potential funding sources], the concept of "commercialization strategy" becomes a powerful heuristic that can assist small businesses in understanding the multi-faceted activities associated with transforming a concept into a product with widespread commercial use.

In this issue, a number of strategies and funding options are discussed, including government programs to fund small business initiatives in energy and medical research; as well as licensing and equity investments from business angels and venture capitalists. Food for thought as you consider your commercialization strategies.

Stage-Gate Process - A value based roadmap for driving product innovation projects from idea concept to launch and beyond.



For more info on Dr. Cooper's Stage-Gate System, visit: www.prod-dev.com/ stage-gate.shtml

Table 3: Licensing Strategy				
Milestone	Financing Method	When \$ Is Needed	When To Begin Search	Who Is Responsible
Concept Development	SBIR Phase 1	March 30, 2008	Begin to contact topic authors as soon; develop and submit proposal	John Smith, Bob Jones
Intellectual Property Protection	Retained earnings	January, 2009	Protect initially as trade scret; begin discussions with legal counsel (Nov. 2008); file provisional as appropriate	John Smith
Application Development	Licensee	December, 2009	Begin discussions with potential li- censees once IP protection is in place	Bob Jones
Production	Licensee	June, 2011	On-going development of relationship with potential licensees 2009–2011. Negotiate agreement and have include clauses to motivate performance	John Smith

Financing Alternative Energy Projects Small Business, Government and Wall Street Working Together



As confidence in renewable technol-

ogies continues to grow and the U.S.

government's commitment to the

sector increases, the investors will

inevitably follow.

Renewable energy is all the buzz now. With global warming, fluctuating markets and energy security concerns, the interest is warranted. The question remains: is this buzz making it easier for small, advanced technology firms to finance the commercialization of their technology? Is it making it more economical for renewable energy projects to get off the ground?

Though moving a renewable energy project forward can be a difficult prospect, finding funding is not impossible and may be getting a little easier for those who have a proven technology on the cusp of commercialization. In an interview with Walter S. Howes,

managing partner of Verdigris Capital, LLC and former director of the DOE Loan Guarantee program, we discuss the challenges facing small alternative energy firms and how programs, such as the DOE Loan Guarantee, may assist businesses in securing the funding necessary to move forward.

Risk Aversion

Risk aversion is the name of the game for many financiers, project owners and EPCs in the renewable energy arena, and their concerns are legitimate. Energy projects have extraordinarily long timelines from the pilot stage to full-scale production. They are labor intensive and have monster-sized budgets. These problems abound in projects of both accepted and alternative energy technologies.

measured in years not in months," says Howes. "The development cycle for an advanced wind-farm may be a one to two year cycle, but as we know, the development cycle for an advanced nuclear facility or a very advanced coal plant may be many years. ... The cost is large and these are projects that could have a 50 to 100 year life-cycle—investors are appropriately cautious."

A good example of the exorbitant cost—a significant element of discouragement for investors—is found in a July 2007 *New York Times* article, "Costs Surge for Building Power Plants." In this piece, General Electric estimates that building a new nuclear power plant will cost them an astronomical \$2,000 to \$3,000 per kilo-

watt of capacity (the standard industry metric), even though the plant will have a much shorter build time than plants built in the past.

In 2005, when Duke Energy began the process of building two coal-fired power plants (twin 800-megawatt units) to replace several aging facilities, they anticipated spending \$2

billion. Less than two years later, the cost to build just one plant skyrocketed to \$1.83 billion—an 80 percent increase in an 18 month period. The rapid increase in raw material costs, including copper and nickel, is partly to blame. But whatever the cause, an energy project is a drawn-out process with exorbitantly rising costs, which do not appear to be abating.

Even the DOE's FutureGen Initiative to build the cleanest fossil fuel fired plant in the world is estimated to cost \$1.5

"The cost is so large and these are projects that could have a 50 to 100 year life cycle—investors are appropriately cautious." — Walter S. Howes

"The development cycles for these projects are typically

The Role of Renewable Energy Consumption in the Nation's Energy Supply, 2006



Renewable Energy Profile, 2006

Renewable Energy Consumption	Quadrillion Btu	Change 2005-2006 (Percent)
Biomass	3.27	7 5.2
Biofuels	0.75	8 27.6
Waste	0.40	4 0.3
Wood Derived Fuels	2.11	4 -0.1
Geothermal Energy	0.34	9 1.8
Hydroelectric Conventional	2.89	0 6.9
Solar/ PV Energy	0.07	0 6.5
Wind Energy	0.258	
Total	6.84	4 6.9

Source: www.eia.doe.gov

billion over 10 years and involve an alliance of 12 companies. The magnitude of the expenditure required to build a new energy project is difficult to grasp and takes a good deal of fortitude on behalf of all concerned parties.

Other Barriers

Cost and time involved are the big barriers to success, but they aren't the only hurdles to cross. There are other issues for both the small alternative energy business and potential investors to think through.

- What will it cost to prove a technology is commercially viable?
- Can the bugs of said technology be easily worked out?
- How stable will the off-take prices be?
- What of feedstock prices?

These issues are just the tip of the iceberg, and this iceberg isn't shrinking due to global warming.

The approval process, an expensive, lengthy procedure with no guarantee of passage, must also be considered. Then there are siting issues, which can be contentious, very public and can impede a conventional energy project. The siting issues with alternative energy can be more complicated, depending on the energy type and the public's perception of possible dangers, threats or difficulties that could be brought to bear around the proposed site.

And then there is the broad scope of alternative energy as a whole. "At this point, there is so much activity in the multiple areas of alternative energy, not only in the U.S., but around the world, it is difficult to know with absolute certainty what the 'next big thing' will be and therefore, it is difficult to gauge what to invest in," says Howes.

Alternative Energy's Stock is Rising

But it isn't all doom and gloom. "There are areas in alternative energy that are now being considered 'comfortable' technologies. Many wind and some solar technologies, as well as a few of the hybrid technologies and bio-fuels for transportation are being considered more mainstream and reliable, therefore commercially viable technologies. It's probable that most investment activity will take place in those areas over the next couple of years," Howes remarks. (See charts to the left for information on U.S. renewable energy consumption.)

While not an easy prospect, there are numerous tax and financial incentives in place for alternative energy projects, with new ones being added weekly. There has also been an influx of investment firms aggressively wading into the alternative energy waters. Money is flowing into alternative energy companies so fast that the warning signs of a bubble are appearing now. Investments in alternative energy by U.S. venture capital firms reached \$2.6 billion from 168 deals in the first three quarters of 2007, according to data from Thomson Financial and the National Venture Capital Association. This level of investment represents the highest dollar volume ever, exceeding full-year 2006 investment dollar volume, which reached \$1.8 billion from 180 deals.

This is partly driven by the rapidly rising oil prices, explains Howes. "The impact of oil prices has been dramatic. It means that many of the alternative energy projects/technologies that were not cost effective at \$30 to \$40 a barrel are now much more economically feasible. This is spurring a huge amount of investment in R&D. While most on Wall Street believe that oil prices will come down, the real question is, what is the net future cost of oil that Wall Street is willing to assume and invest in?" One commonly held thought among investors is that a \$50 barrel of oil represents a watershed pricing. While the bad news of higher oil prices remains, there is good news in that many of these technologies will exceed their break-even costs, and lower capital investments will be available.

As confidence in renewable technologies continues to grow, and the U.S. government's commitment to the sector increases, the investor dollars will continue to follow.

DOE Loan Guarantee Program

Part of the government's commitment to stimulating investment and commercialization of clean energy technologies is the DOE Loan Guarantee Program. Currently in its pilot phase, the DOE Loan Guarantee program was created through Section XVII of the Energy Policy Act of 2005. This legislation authorizes the Secretary of Energy to make loan guarantees for projects that avoid, reduce or sequester air pollutants or anthropogenic emissions of greenhouse gases; and employ new or significantly improved technologies as compared to commercial technologies in service of the United States at the time the guarantee is issued. (See page 11 for a list of eligible project categories.)

"Loan guarantees are supposed to encourage the use and commercialization of a new technology that reduces green-house gases and other pollutants. It can cover nearly any technology in the ten chosen areas, as long as it makes the processes more efficient and reduces greenhouse gas," explains Howes. The pilot program for the Loan Guarantee program is currently underway and they [the DOE] are working to find the best way to move forward."

Keep in mind that the DOE Loan Guarantee program does not provide funding per se, it just guarantees that if the project fails for some reason, the bank will not suffer a loss. "The loan guarantee is there to help reduce the cost and the risk of the commercial loan and make it easier for the project to gain financing," says Howes. "This will do two things: 1) it will increase the supply of financing to the renewable energy sector and 2) it should reduce the cost of capital for those projects. One way or another, the projects that do receive financing need to generate revenues, as those loans need to be paid back."

In October 2007, the DOE invited 16 project sponsors, all of whom had submitted pre-applications in Fall 2006, to submit full applications for loan guarantees. The advanced technology areas involved in the projects include fossil energy, biomass, solar, hydrogen, industrial energy efficiency, electricity delivery, alternative fuel vehicles and energy efficiency. As of this magazine's printing, Congress was considering the DOE's budget request for \$9 million in loan guarantee authority and \$8.4 million to run the Loan Guarantee office—both actions being crucial to the successful implementation and execution of the program.

As for an SBIR company moving into Phase III, Howes believes that this program could be instrumental in

commercializing a product/technology. "Let's take for example a solar technology: If a company has come up with a new solar collection/solar concentrating technology and they have verified on some level that it works, but they haven't yet been able to scale it up to deploy it into a large energy project, then this could be a tool they could use to pursue follow-on, structured financing," explains Howes.

"It should be kept in mind that the DOE Loan Guarantee program could take some time at the offset," Howes cautions. "It is a new program with a relatively small staff and it doesn't work in a vacuum—it must work with OMB."

When deciding whether or not the DOE Loan Guarantee is the right program, a small business should keep in mind that a loan guarantee should not be a "go/no go" decider. "If you are unable to get any capital without a loan guarantee, then it isn't the appropriate tool. But, if it would expand your access to capital and decrease the rate, then it could be a useful tool. My advice to small businesses is to find and add skilled financial engineers and people who understand loan guarantees to their team. These people will help to navigate the complicated rules and to keep the exorbitant expenses of energy project work at a minimum," says Howes.

The next issue of Phase III Commercialization[™] will focus on additional funding sources available to small alternative energy firms on the state and local level, such as accelerated depreciation and power production credits, and will include an interview with a successful small business in the alternative energy arena. **III**

DOE Loan Guarantee Program

Areas of technology eligible for DOE Loan Guarantee

Title XVII of the Energy Policy Act of 2005 authorizes the Secretary of Energy, after consultation with the Secretary of Treasury, to make loan guarantees for projects that avoid, reduce, or sequester air pollutants or anthropogenic emissions of greenhouse gases; and employ new or significantly improved technologies as compared to commercial technologies in service of the United States at the time the guarantee is issued.



Title XVII identifies ten discrete categories of projects that are eligible for a loan guarantee, including those that employ:

- 1. Renewable energy systems;
- Advanced fossil energy technology (including coal gasification);
- Hydrogen fuel cell technology for residential industrial or transportation application;
- 4. Advanced nuclear energy facilities;
- Carbon capture and sequestration practices and technologies, including agricultural and forestry practices that store and sequester carbon;
- 6. Efficient electrical generation, transmission and distribution technologies;
- 7. Efficient end-use energy technologies;
- Production facilities for fuel efficient vehicles, including hybrid and advanced diesel vehicles;
- 9. Pollution control equipment; and
- 10. Refineries, meaning facilities at which crude oil is refined into gasoline.

For federal alternative energy opportunities, visit: www.eere.energy.gov

NIH Roadmap: Initiatives and Opportunities



The Future of Medical Research and the Funding to Move it Forward

by Carol B. Van Buren

When Dr. Elias Zerhouni undertook his post as Director of the National Institutes of Health (NIH) in 2002, he introduced the concept of a "roadmap" for medical research that would identify significant opportunities and challenges that should be addressed by NIH as a whole—not just by individual Institutes or Centers. Convening a series of meetings involving more than 300 nationally recognized leaders in industry, government, academia and the public the work on creating the Roadmap commenced. These meetings provided the framework for the NIH Roadmap and thereby, the future of medical research.

Initial Directions

The Roadmap's initial vision and priorities were divided into three broad themes, New Pathways to Discovery, Research Teams of the Future and Re-engineering the Clinical Research Enterprise, each with its own set of initiatives. (See page 13 for a breakdown of the themes and the initiatives.)

A good deal of progress has been made in the intervening years, including the creation of the National Technology Centers for Networks and Pathways, the Molecular Libraries Screening Center Network (MLSCN), the NIH Director's Pioneer Awards and Clinical Research Networks/NECTAR, among others.

The Roadmap initiatives have generated funding opportunities for a variety of organizations, including small businesses, individuals, not-for-profits and academic institutions. Below are listed some relevant Roadmap solicitations and notices, with more information and funding sources to be found at: http://nihroadmap.nih. gov/grants/index.asp.

Molecular Libraries Screening Center Network

Notice of Opportunity for Fast Track Entry of Assay Development Projects into the Roadmap Molecular Libraries Screening Center Network NOT-RM-07-012

Solicitation of Compounds for High Throughput Screening (HTS) in the Molecular Libraries Screening Centers Network (MLSCN) NOT-RM-07-005

NIH Director's Pioneer Awards

2008 NIH Director's Pioneer Award Program (DP1) RFA-RM-08-013

Clinical and Translational Science Awards

Notice of Intent to Publish a Limited Solicitation for Pilot Projects in Informatics for Clinical and Translational Science Awards NOT-RR-07-012

One initiative of the Roadmap, found under the theme of Research Teams of the Future, may be of special interest to small businesses—the Public-Private Partnership Program. While this program does not provide funding, it will, among other tasks, serve as the point of contact for entities wishing to partner with the NIH. The program is to provide contact information, as well as advice concerning the initiation, establishment and implementation of new partnerships, complementing the ongoing effort of the Institutes and Centers in their work with the private sector. For more information on the Public-Private Partnership program, visit: http://nihroadmap.nih.gov/publicprivate/.

Roadmap 1.5

With the first wave of projects successfully underway, the NIH spent the second half of 2006 soliciting the scientific community, patient advocates and the public at large, for ideas to form new initiatives that would address challenges in biomedical research. Following considerable scientific discussion, the decision was to focus on four broad areas: Major Roadmap Initiatives, Pilot Studies, Coordination Areas and Strategic Planning Areas, with requests for applications (RFAs) relating to these initiatives and studies to be released on a variable timeline in late 2007 through mid-2008.

Initiatives and Studies

In May 2007, four specific topics were chosen by the Institutes and Centers' Directors to move forward as Major Roadmap Initiatives. The first two, Microbiome and Epigenetics Programs, are to be implemented as five year programs. The remaining two programs, Protein Capture Tools and Phenotyping Services/Tools, are being implemented in stages, with second phase funding contingent on outcomes of the first phase research. Only one Pilot Program was chosen for support at the May meeting—the Genetic Connectivity Map (CMAP). (See topics with descriptions and potential funding opportunities below).

Coordination and Strategic Planning

As for the working groups attached to Coordination Areas and Strategic Planning Areas, their activities are still ongoing. The Coordination Area groups are assessing current efforts in the areas of Regenerative Medicine, Pharmacogenomics and Bioinformatics.

The Strategic Planning Area groups are focusing their activities on topics in Training/Careers, Health Disparities and Science of Science Administration. For more information concerning the Coordination Areas and Strategic Planning, visit: http://nihroadmap.nih.gov/ grants/sbir-sttr.asp.

What does this mean for Small Business?

It is essential to note that the Roadmap is not set in stone and that it will change as knowledge and technology move forward. Creating sweeping change in an agency as large as the NIH and in an area as critical as human health cannot be done overnight, but can certainly create unique opportunities for innovative small businesses. The Roadmap is an effective tool for small firms in the health care market, allowing them to follow what areas/challenges the NIH considers crucial to the future of health care. This can ultimately lead to funding, either through NIH initiatives directly or through contracting/partnering with other businesses.

Areas that are deemed important to NIH and hold promise for the future will likely receive funding in one way or another. A statement that, given the 8.2 percent inThe Roadmap is an effective tool for small firms in the health care market, allowing them to follow what areas/ challenges the NIH considers crucial to the future of health care. This can ultimately lead to funding, either through NIH initiatives directly or through contracting/partnering with other businesses.

Major Roadmap Initiatives Five Year Programs

Microbiome- The proposed Human Microbiome Project is focused on characterizing the microbial content of sites in the human body and then examining whether or not changes in the microbiome can be related to disease.

- Funding for the initial research for this project was \$8.2 million for FY2007. The funding was awarded to sequencing centers at The Baylor College of Medicine, The Broad Institute, The J. Craig Venter Institute and Washington University.
- While there is no solicitation currently listed for this initiative, NIH intends to offer one in FY2008, which will be found here: nihroadmap.nih.gov/hmp/grants.asp.

Epigenetics- Epigenetics is the study of stable genetic modifications that result in changes in gene expression and function without a corresponding alteration in DNA sequence. These epigenetic changes have been associated with diseases. A catalog, the epigenome, was created, noting the epigenetic modifications that are known to occur in the genome, but further progress requires the development of better methods to detect the modifications and a clearer understanding of factors causing the changes.

• There has only been one solicitation listed for Epigenetics, with a dedline of Oct. 31, 2007. Other solicitations are expected in FY2008 and will be found here: http://nihroadmap. nih.gov/epigenomics/grants.asp.

Stage One Programs

As of this publication's printing, there are no solicitations currently listed for these initiatives.

Protein Capture Tools / Proteome Tools- This initiative would support developing high-quality probes, specific to every protein in the human body, as well as those in requested animal models, and making them available to the scientific community. The information would allow the characterization of protein function in both health and in disease and would provide a way to monitor the markers of a disease.

Phenotyping Services and Tools- The goal of programs in this area would be the development of resources to catalog human phenotypes, ultimately characterizing complex diseases and disorders.

Pilot Study

Genetic Connectivity Map (CMAP)- CMAP is an effort to discover and demonstrate the linkages between diseases, drug candidates and genetic manipulation.

- This effort is being led by the Broad Institute with more information, including data from the study and a web-based tool for scientists to perform their own analyses, available at their site www.broad.mit.edu/cmap/.
- An article concerning the CMAP and its uses was recently published in the Sept. 28, 2007 issue of *Science* magazine.



crease in spending provided to the NIH by the 109th Congress from FY2007 to FY2008, seems to hold true.

Stay in Touch and Informed

With so many areas to cover, it is important to network and stay connected to potential funding sources at the NIH. Each Institute and Center has a liaison for the Roadmap. The relevant contact for each can be found on the NIH Roadmap site, visit http://nihroadmap.nih.gov/ricl.asp.

The NIH also provides a tool to assist those seeking funding. It is the electronic publication called the NIH Guide. The Guide, published weekly, provides highlights of all NIH funding opportunities and notices. To learn more and to register to receive the publication, visit: http://grants.nih.gov/grants/ guide/WeeklyIndex.cfm.

And though it would not meet the criteria of Phase III commercialization funding, the SBIR/STTR program also has Roadmap-relevant opportunities. These can be found by visiting: http://nihroadmap.nih.gov/grants/sbir-sttr.asp.

Ultimately, the NIH Roadmap is creating opportunities for small businesses and the future of medical research certainly looks bright, when looking in the right directions.

"The talented scientists and institutions we have nurtured are stepping up to the challenge. For example, NIH now receives twice as many applications for grants than before the doubling of its budget. Due to the marked competition for funds across so many novel areas of research and health challenges, competition for grants and the quality of projects submitted to NIH is better than ever. We anticipate that the FY2008 budget will again support about one-fifth of applications submitted, as opposed to one-third in FY2003. We focused our budget request on maximizing the number of competing grants for new and established scientists.

To encourage innovation and sustain the next generation of scientists to the greatest extent possible, we have also developed programs for new investigators and for pioneering highrisk/high-impact investigator-initiated research, the mainstay of fundamental discoveries."

—Dr. Elias Zerhouni, March 19, 2007 remarks from FY2008 Budget Request to the Senate.

Main Areas of Focus for the NIH Roadmap

New Pathways to Discovery

This area of the Roadmap addresses the need to advance understanding of complex biological systems and the accessibility of technologies, databases and resources. With the completion of the human genome sequence and recent discoveries in molecular/cell biology a better medical research "toolbox" is in the works.

Research Teams of the Future

This area of the Roadmap encourages scientists of varying disciplines to collaborate and expand their approach to the scientific enterprise. This should stimulate new ways of combining skills and disciplines, in both the physical and biological sciences. The intent is to accelerate scientific findings from bench to bedside.

Re-Engineering the Clinical Research Enterprise

The NIH is focused on the transition of basic research discoveries into drugs, treatments and methods for prevention and the simplification of the regulatory process. NIH intends to promote better integration of existing clinical research networks, improve the training of clinical researchers and encourage the development of technologies to advance the assessment of clinical outcomes.

Initiatives

- Building Blocks, Biological Pathways and Networks
- Molecular Libraries and Molecular Imaging
- Structural Biology
- Bioinformatics and Computational Biology
- Nanomedicine

Initiatives

- High-risk Research
- Interdisciplinary Research
- Public-Private Partnerships

Initiatives

- Clinical Research Networks/NECTAR
- Clinical Research Policy Analysis and Coordination
- Clinical Research Workforce Training
- Dynamic Assessment of Patient-reported Chronic Disease Outcomes
- Translational Research

Manufacturing 101: From R&D to Product Production

by Robert F. Larsen

A s a technology matures, R&D firms often consider whether they should become a manufacturer, contract-out production to a third party or license the technology to another entity. What should an R&D firm consider in making this decision? How does the starting point for an R&D firm differ from that of a manufacturer when deciding whether or not to take on another product line?

A mature manufacturer is wellversed in contracts, contract requirements, associated risks and often has an ISO 9000 certification. (See page 17 for more info on ISO.) Before production begins, the company will have a mutual, written agreement in place with the contracting office (customer). A mature manufacturer also understands fully the steps to be taken during production and the necessary business infrastructure required to support

the new opportunity. During the planning stage, the design and development process is prepared and the tooling required for the program identified. The specifications needed for procurement are ready and the selection of qualified suppliers and sub-contractors is accomplished. All of these items are addressed before production begins. If, by contrast, a company is new to production, the organization must learn to address these issues and put in place risk mitigating processes. The company must decide how to best address Low Rate Initial Production (LRIP) and Full Rate Production (FRP) (see term definitions on page 16)—both of which will need to be approached analytically and with full documentation. While

The road to success begins with a very careful reading of the contract and mapping deliverables and performance expectations to the contract. Failure to deliver on the terms of a contract can result in contract default.

the aspiration and desire to manufacture a product may be present in an R&D firm, the necessary resources and the aptitude for this business function may not be present. What to do? What are the next steps? What options are available?

It is necessary that a small business identify and review core competencies and skills—

making certain this assessment is grounded in reality, not in aspirations for the future. Long and short-term goals should be laid out with the necessary manufacturing capabilities and the funding requirements assessed. Once this is accomplished, a plan of action can and must be developed. It should be kept in mind that a bad decision at this point can throw a business off its game, and could possibly cause irreparable damage.

The Options

So, what options are open to small R&D firms looking to break into manufacturing? Three options should be considered, each of which has its own distinct risk factors (see Table 1).

The company could decide to manufacture and market the product itself, utilizing in-house resources. This option carries with it a potentially high risk, especially if the

company is new to manufacturing. The cost of entry will be significant and will require an investment in personnel, facilities, capital equipment and material. Ensuring, at the outset, that the company has both the human and financial resources that will be required is critical for successful delivery of quality products, on time and on budget.

PLANNING IS IMPERATIVE FOR MANUFACTURING SUCCESS

Low Rate Initial

Production (LRIP) is the phase of initial, smallquantity production of the product, for a defined period of time, typically after the prototype has been fully qualified (tested and accepted). This process tests the manufacturing and produce-ability process and will surface any issues that need to be addressed before full rate production.

Engineering Design Plan

This is the design plan for the product to be manufactured. It should be well thought out, detailed and documented. The plan should be mapped to product performance and/or product contract deliverables.

Manufacturing Engineering Plan

The manufacturing engineering plan will include the blueprints, tooling/floor space schematics and work instructions to ensure the product makes a seamless transition from design engineering to manufacturing.

Manufacturing Plan

The manufacturing plan must consider manufacturing floor space for un-interrupted flow, the control, evaluation and calibration of all tools, jigs and test figures, as well as material handling processes, training and environmental issues.

Quality Plan

The quality plan should be mapped to the product performance and/or contract deliverables and should consider all aspects of the process, from design through final testing/qualification.

Procurement Plan

This plan should consider alternative suppliers, sole source suppliers and/or international suppliers. There needs to be a supplier qualification and rating process in place.

Configuration Control (Traceability)

This contractual requirement necessitates a documented plan to maintain configuration control by finished product serial number and a documented audit process to ensure control is maintained.

Life Cycle Support Plan

This may be a contractual requirement, which means that the company needs to have and maintain sufficient amounts of spare parts and support mechanisms. This is to ensure the customer will have a functioning product over a predetermined period of time.

Full Rate Production (*FRP*) is the phase when a standard amount

a standard amount of product quantity is required per month by government or contracting agent, as outlined by the contract or purchase order. A second option is to partner with an established manufacturing company, which could serve as a contract manufacturer. For a small firm, this option has a midto-high level risk. The small business still has contractual obligations. However, the small business can avoid the costs associated with scale-up and may also be perceived as a more credible supplier, if a reputable third party is used.

The third option is to license the rights to a manufacturing and distribution company. This option is low risk, and depending on the agreement, the synergy with the licensee, the strength of the intellectual property and the industry—licensing may yield a low to modest return on investment. A small business can negotiate the transfer of contract liability to the licensee, as long as the customer and contracting officer are in agreement. This would relieve the small business of most, if not all, contractual liability.

Small business with limited manufacturing knowledge and/or experience may find it beneficial to engage a third party to assist in deciding which option works best. Critical to the decision-making process is: a design for manufacturing review, the development of a model manufacturing process, and the costing and simulation of the manufacturing process at different production levels (LRIP and FRP), including both inventory and logistics considerations. This effort can ensure both the

Table 1

Manufacturing Options for Small R&D Firms	Risk Level	Financial Return
In-house Manufacturing and Marketing	High	High
Contract-out production to an established Manufacturing Firm	Mid to High	Mid
License Rights to a Manufacturing Firm	Low	Low

customer and investor feel secure with the launch of a new product. Once the manufacturing option has been decided upon, there are guidelines to be followed to ensure success in the manufacturing sector.

Key Success Factors

For those firms that are looking to become a Phase III supplier, either commercially and/or to the Dept. of Defense, the road to success begins with a careful reading of the contract and/or purchase order, followed by the mapping of deliverables and performance requirements to the contract. Ambiguity in a contract and making assumptions can prove to be expensive and detrimental to a business. Failure to deliver on the terms of a contract can result in contract default.

No matter the manufacturing option decided upon, it is vital that performance requirements be written into an agreement that is acceptable to and understood by both parties. The most basic and fundamental step a company should make, at the outset, is to tie deliverables and performance requirements back to the contract. If this is not done, assumptions will be made and the relationship will go awry.

If any of the production is to be outsourced to a manufacturing firm, be sure to select a company with a quality reputation for the sustainable production of a product of this type. Selecting a manufacturing partner should be done via a systematic and well-documented process. The potential partner should be financially viable, have a compatible culture and have appropriate engineering staff, facilities and manufacturing capabilities.

Irrespective of the strategy selected, it is vital to maintain consistent customer/supplier contact via e-mail, phone and face-to-face meetings. While the meetings may only be twice a year, quarterly or monthly, there is no substitute for meeting in person. Doing so reduces miscommunication which can ultimately result in considerable cost savings.

Manufacturing Quality: ISO and ISO 9000 Defined

ISO is a network of the national standards institutes of 157 countries, with one member per country, and a Central Secretariat in Geneva, Switzerland. Its purpose is to facilitate international trade by providing a single set of standards that are recognized and respected. ISO is a non-governmental organization that occupies a special position between the public and private sectors.

The ISO 9000 is among ISO's best known standards and addresses quality management. ISO 9000 currently includes three quality standards: ISO 9000:2005, ISO 9001:2000 and ISO 9004:2000. ISO 9001:2000 presents requirements, while ISO 9000:2005 and ISO 9004:2000 present guidelines. All of these are process standards, not product standards.

ISO's purpose is to facilitate international trade by providing a single set of standards that people everywhere would recognize and respect. Manufacturing plants that receive certification can attest that their stated quality processes are adhered to in practice. The ISO 9000:2000 standards apply to all kinds of organizations in all kinds of areas. Some of these areas include:

- manufacturing
- processing
- servicing
- printing
- forestry
- electronics
- steel
- computing
- legal services
- financial services
- accounting
- trucking
- banking
- retailing
- drilling
- recycling
- aerospace
- construction
- exploration
- textiles

- pharmaceuticals
- oil and gas
- pulp and paper
- petrochemicals
- publishing
- shipping
- energy
- telecommunications
- plastics
- metals
- research
- health care
- hospitality
- utilities
- pest control
- aviation
- machine tools
 - food processing
 - agriculture
- government

- education
- recreation
- fabrication
- sanitation
- software dev.
- consumer products
- transportation
- design
- instrumentation
- tourism
- communications
- biotechnology
- chemicals
- engineering
- farming
- entertainment
- horticulture
- consulting
- insurance



Proper quality management is widely acknowledged to improve business, often having a positive effect on investment, market share, sales growth, sales margins, competitive advantage and avoidance of litigation.

The Angel Perspective by Steve C. Orth

BEDI

PLAN

Building a Lasting Relationship

In the last issue of *Phase III Commercialization*[™], in an interview with business angel Richard Sun, we discussed what small business owners should look for when it is time to build a relationship with an angel. In this issue, we continue our discussion with Sun, focusing on the flip side of the equation of the small business/angel investor relationship. We will explore what an angel investor is looking for when considering an investment in a small firm and offer some valuable tips to small businesses to help them stand out when courting the investment of a successful angel.

FROND

OUNGE

KITCHEN

AREA

The Angel's Perspective

Obviously, angels are very risk tolerant. They are fully aware that early stage investing can be dicey, but given the example of their obvious business success, do not take foolish chances, rather they skillfully assess their risks and move forward from there. "Great management tends to gravitate toward great products," says Richard Sun, president of Sun & Co. "An angel may see an entrepreneur with a superb product, but no money, no management, no marketing plan, no business plan—just raw potential—and say, 'Why don't we put a new company around this?'"

Like any investor, business angels have many investment options and are more likely to support lower risk, higher return opportunities. Therefore, startup companies with great products, little or no competition (including competition from other startups), large markets, key differentiators and realistic and sensible business plans that can be quickly achieved with a plausible path to success are going to be on the top of the angel's lists of companies in which to invest. They are looking for companies that can scale.

When meeting with potential angels, entrepreneurs need to know what to present, what will catch attention. Think from the perspective of the investor. "Where would you invest? In a business with a complex product and a complex, incomprehensible plan or in one with a product, market and plan that is easy to understand?" asks Sun.

Talking to an Angel

Communications with the investor have to be unambiguous. The entrepreneur should use short sentences and layman's terms. To pique an investor's interest, start with a one page summary that describes the essence of the business. According to Sun, "Most investors are either positively or negatively inclined to give serious consideration to your business after about 90 seconds. They make snap decisions based upon their personal experience. If you can't present the essence of your business in that time frame, you probably don't understand your business very well. And you probably aren't very likely to be a success—unless you get somebody that can make the pitch for you."

Once an angel's interest has been gained, entrepreneurs will want to be prepared to give a 15 minute, 10 to 15 slide presentation to the interested investor, keeping in mind that there will be questions asked afterwards (See page 20 for possible questions). An investor description, between 10 to 20 pages, should also be prepared. That document should describe the business model, where the business stands, the background of management, expectations for the future and an overview the plan to get there.

1% Inspiration, 99% Perspiration and Planning

But, before diving right into the paperwork, the business person needs to keep in mind that while preparing these documents is important, they are just the tip of the iceberg. "These documents should be prepared after you've done all the planning and thinking about how you're going to do your business. Once you've done all the underlying work, the presentation materials are essentially written and will flow naturally and be very credible," explains Sun.

A business angel that sees multiple proposals a week will immediately spot a boilerplate plan that lacks the substance that would have been provided if the necessary, underlying work had been completed. Many business plans look the same, utilize the same buzzwords and have the same conservative projections. "This will make an angel's eyes glaze over. The investor is looking for the unique. If you start out looking over someone else's business model and you work from that, you'll be a clone and you will be rejected rather quickly," says Sun.

Start by building your message from the bottom up giving deep thought to what the business is and how it will unfold. Create the business plan highlighting what is special about the business, not with a bunch of jargon. Have your friends and associates read it for clarity and punch first. Hard as it may be for an entrepreneur to hear, Sun says that, "if you aren't capable of thinking about a business this way and describing your business, you need to reevaluate where you are and where you are going."

As his final piece of advice for technology entrepreneurs, Sun offers a new way to look at the story of building a better mousetrap. "The fellow that said, 'Build a better mousetrap and the world will beat a path to your door!' while probably well-respected in the academic community, is most likely not well noted for his entrepreneurial skills or business success in commercializing mousetraps. In fact, if you've got a better mousetrap the world will not, in all likelihood, beat a path to your door. The way to get that mousetrap commercialized is to identify a group of people with a track record of, and a passion for, catching mice in large numbers." Most Angels work in their geographic area, though there are a few that work nation-wide. Here are a few of web addresses for National Angel Networks:

- investorscircle.net
- gatheringofangels.com

Inc.com provides an easy to navigate Angel Investor Directory, which can be found at:

 inc.com/guides/ start_biz/24011.html

Most investors are either positively or negatively inclined to give serious consideration to your business after about 90 seconds.

DAWNBREAKER® OFFERS SMALL BUSINESS SERVICES



MANUFACTURING ASSESSMENT

Successfully transitioning your company into the manufacturing arena offers unforseen challenges. Make the transition a seamless one by looking to Dawnbreaker.

A manufacturing assessment conducted by Dawnbreaker consists of an on-site evaluation of all aspects of production including engineering design; inventory, process, and quality control; suppliers, facilities, and packaging. We assist with understanding your contractual obligations to potential customers, highlight areas of potential risk and suggest mitigation techniques.



SOME QUESTIONS

AN ANGEL MAY ASK

CONCERNING:

Your Product

- What, specifically, does your company produce and how is it better than the competition?
- Do you hold any patents? If so, what, specifically, do they protect?

The Marketplace

- How large is the specific market for your product and what is its expected growth?
- Where does your company fit into the market?
- What will it take to get customers to use your product, rather than someone else's?

Product Development

- What work remains?
- What are your major development risks or challenges?

Sales and Marketing

- How would you describe your selling cycle?
- How do you plan to raise customer awareness of your product and stimulate buying?
- What channels of distribution do you plan to use to deliver products?

Business Leadership and Management

- What led you to start this business?
- What is your professional background?
- How is the management of this company structured?
- What credentials do the members of the management team have regarding:
 - Financial management?
 - Product development and production?
 - Sales and Marketing?

Financials

- What is the estimated revenue for the next five years?
- What is the estimation of profits for the next five years?
- Is there possibly an IPO or an acquisition in the future?

The Requested Funding

- What is the current "burn-rate" for the company?
- How much capital would be necessary to take the company to next stage?
- How much capital have the company founders invested to date?

Getting the Right Licensing Deal

Patience, Perseverence and Playing by the Rules

Licensing is often used by small businesses as a Phase III commercialization strategy. Yet, with few exceptions, it is rare that an SBIRfunded company makes significant money from licensing. A myriad of reasons account for this, most stemming from an initial poor analysis of the potential licensees, coupled with a lack of understanding of the terms and conditions in the signed agreement.

by Jenny C. Servo

icensing can be very profitable for a small business, but only when approached correctly. For example, Albany Molecular Research, a small business started in 1991 has made over \$340M in royalties for the formulation that became Allegra®. By contrast, Peter Cooper, the inventor of Jell-O®, sold his patent and brand for a flat fee of \$450. Sales of Jell-O related products worldwide have totaled billions of dollars, but Cooper did not reap the benefits of those sales because of the arrangement he entered. Outlined in this article, there are three areas of focus for small businesses considering licensing a product.

Selecting a Licensee

Think about it, the motivation to license-out a technology is the increased likelihood that it will reach the marketplace and generate a return [royalties]. To do this the licensor must place the technology with a licensee that has the means and incentive to bring the product to market. However, if the licensee has little or no experience in the particular technology area; lacks sales and distribution channels in the target market; or has frequent turn-over in management—it is unlikely that the deal will be successful in generating revenue for either party.

A significant problem is that many small businesses fail to conduct a good assessment of potential licensees and therefore, place their technology poorly. Others become weary during the negotiation process and end up granting all rights to a licensee that does not have the means to exploit the technology fully across all application areas and geographic regions. This severly limits the licensor's potential return, which could have been expanded by entering into multiple licensing agreements with additional candidates having strengths in areas the initial licensee lacked.

Before entering negotiations, small businesses should conduct due diligence on potential licensees. Good licensing candidates have the following attributes:

- 1. Expertise in a closely related technology area
- 2. Production capabilities
- 3. Marketing and distribution channels into targeted markets
- 4. Financial and management stability
- 5. A strategic vision into which your technology fits, and
- 6. A good reputation

There are multiple ways to find potential licensees. Check into what companies are citing the company's patents and/or research. There is a reason for this interest and the company's intellectual property may be of great advantage to them. By contrast, it could also be a threat to their strategic direction, so it is important to ascertain the reasons underlying their interest in this intellectual property. Another approach is to determine whose business could be positively impacted by the addition of the technology to be offered.

Preparing for Licensing

Once the domain of potential licensees is determined and due diligence conducted, time should be spent developing a negotiations check list. Each of the following items should be carefully thought out and put in writing, to assist in guiding the negotiations.

- **1** What is being made available to license? Enumerate the patents (issued and pending), trademarks, trade secrets, know how, and copyrights that will be brought to the table.
- 2 Who is on the licensing team? There should be an attorney, an accountant and a business manager on the decision making team.
- **3** Determine how the license will be partitioned. Is the opportunity being divided by application area? By geographic region?
- 4 What rights are to be retained? Is an exclusive or non-exclusive relationship being offered? Retaining the right to conduct research in the area is a must.
- 5 What else is being brought to the deal—drawings, customers, facility, certifications?

- What is necessary to bring this product to market? What level of marketing and sales effort is needed? What distribution channels? Will additional development work be required? Will the licensee have to invest in new or modified production equipment?
- What are the sales projections and market penetration goals? Various scenarios should be developed so that there is a basis for determining potential revenues resulting from royalties. Also, if the technology results in a cost savings, determine the amount of savings.
- B What about royalty rates, base and audit? How will the royalty rate be determined? Will the 25% rule be applied or will the company use industry standards? What will the base be and how are terms such as net sales defined? How will the performance be audited?
- What sort of consulting agreement is required? Is the company seeking an on-going consulting agreement with the licensee and a role in further development?

Agreeing to Terms and Conditions -

A question small businesses considering licensing often ask is, "Is there a standard licensing agreement?" As frustrating as it may be, the answer is, "No." Licensing agreements address standard sets of issues, but they do so in very different ways. Typical issues include the clarification of license scope, the definition of licensee and licensor, indemnification, grant-backs, improvements, best efforts, ability to sublicense, the basis for royalties and many other items. For each of these issues, many alternative positions exist and are the basis for negotiation. The following is a brief discussion of some of these issues and their implications.

INDEMNIFICATION – In the case of a lawsuit, who will hold the other harmless and be responsible for paying the attorneys fees and penalties? Clearly, this is something that each party wants the other to be responsible for. When the phrase "The licensor will indemnify and hold harmless the licensee" appears, it means that the small business will accept this responsibility. By contrast, if the order of key terms are inverted "The licensee will indemnify and hold harmless the licensor", it means that the licensee will accept that financial liability.

BEST EFFORTS – The best efforts clause indicates the obligation that the licensee will undertake to bring this product to market. The phrase "best efforts" is very amorphous and allows significant wiggle room for a potential licensee. By contrast, it is to the advantage of the small business to negotiate a clarification, or specific efforts that will be undertaken, including the number of trade shows in which the product will be showcased at specific times; the number of engineers that

will be put on the project, and of the investment that will be made in scale-up. Again, the licensee would prefer the use of the phrase "best efforts," but it is to the advantage of the small business to try and obtain specificity regarding the specific efforts in the licensing agreement.

SUB-LICENSE – Most licensing agreements contain a section regarding the right to sub-license. However, the clauses that may be inserted in an agreement may specify that the licensor needs to be consulted and must approve a sub-license or, conversely, the right to sub-license may just be given to the licensee, requiring no further involvement from the licensor.

ROYALTY BASE – Many licensors focus almost exclusively on the discussion regarding royalty rate, but attend insufficiently to the base—the number to which that royalty rate will be applied. Will the royalty be applied to gross sales, or to net sales, or even to savings? How are each of these defined specifically by the licensor? How will performance be monitored?

It is critical to understand the implications of each of the terms and conditions in a licensing agreement and evaluate all clauses with an attorney. The objective is to determine if the terms presented incentivize the licensee to perform and also contain clauses to protect the licensor's interests. Be sure that that agreement contains clear options for termination of a license for non-performance and/or reversion from an exclusive to a non-exclusive license for failure to perform. In the next issue, there will be a discussion of licensing and royalty audits.



Early Stage Investor Expectations and a Quick Valuation Approach

by Terry M. McMahon

Many advanced R&D firms will need equity investment to bring their technology to market.

equity investment to bring their technology to market. The first round of funding, also known as seed money, was most likely provided by the company founders and friends, supplemented by SBIR awards, and was used to conduct high-risk research and development.

Once these development efforts have met with success, attention more urgently shifts to seeking other sources of funding to complete the commercialization process and bring the new technology to market. It is not uncommon for young R&D companies to have little experience with the investor community and investor expectations. The purpose of this article is to clarify their expectations and provide guidance on how to prepare for success in obtaining financing.

Of fundamental import is conducting an opportunity assessment for the technology or product. This starts with identifying customer needs that can be uniquely addressed by the company's technology. The opportunity assessment should touch upon:

- The baseline technology being used to address the needs of targeted customers. Then the shortfalls presented by the current technology, the magnitude of the necessary improvements needed and the customer's sense of urgency for finding a better solution should be determined.
- The value proposition, which indicates the magnitude of improvement and the economic benefits and

also allows a customer to justify the purchase of the technology.

• The size of the market opportunity. Indicating the number of potential customers and confirming that the group is large enough to justify a commercialization effort that offers an attractive return on investment.

This assessment is at the heart of the company's business plan, developed to show the commercialization road map and used in approaching investors. (See outline for creating a business plan on page 24). A good business plan is based on a rigorous assessment of your assumptions. An investor expects that a company will do the hard work involved with segmenting and sizing the opportunity. Company representatives must be intimately familiar with the source of information substantiating every detail of the entire business plan. Investors see the business plan as a reflection of the company and the commitment and drive of management.

It is important to note that investors do not wish to meet with companies that do not have a complete business plan ready for their review. While a venture capitalist (VC) does not expect company leaders to be experts in all fields, they do expect the management team to have answers to their questions. Bear in mind that statements made in the business plan should be substantiated as much as possible and that overly optimistic projections can raise many questions. "While a venture capitalist does not expect company leaders to be experts in all fields, they do expect the management to have answers to their questions."

This isn't just about selling a financial plan to investors, but

"Now is the time to be honest and open. Investors do not want big surprises down the road, especially if they could have been avoided." the company's vision and future goals need to be well presented, as well as the way the management team will assist the business in achieving its potential. The venture capitalist will want to know exactly how much money is being requested and how it will be used. They also want to clearly understand how the investment will be repaid and what the exit strategy will be.

Make Sure the Plan is Complete

What does it take to have a complete, impressive and effective business plan? As to the actual length of the report, it depends on the complexity of the business and may be as many as 20 to 30 pages. When beginning the writing process, start by including all of the relevant details of the company's past and a list of its key players. There should be a concise description of the five year plan, making certain to mention key problems and the plans to overcome them. Now is the time to be honest and open. Investors do not want big surprises down the road, especially if they could have been avoided.

Be Realistic

It is also important to be realistic and reasonable about the amount of money needed to attain the company's goals, with the thought in mind that it often takes more money than initial estimates predict. When considering the valuation of the company and the contributions made by each team member, do not cut corners. As for forecasting, again, be realistic. The VC is going to be conservative, so back up estimates and explain any assumptions being made.

The Making of a Good Business Plan

Remember that a business plan has a five year horizon. The detailed outline below is organized in a way that will assist in building a logical business case for both internal and external use.

- 1. Executive Summary
- 2. Company & Technology
- 3. Industry Overview
- 4. Customers
- 5. Market
- 6. Competitors
- 7. Marketing / Sales Plan
- 8. R&D Plan
- 9. Manufacturing/Engineering Plan
- 10. Human Resource Plan
- 11. Contingencies
- 12. Financials
- 12.1. Financial Objectives
- 12.2. Plans for obtaining investors or strategic alliance
- 12.3. Pro Forma Profit & Loss statements
- 12.4. Pro Forma Cash Flow projections
- 12.5. Pro Forma Balance Sheet

Plan for the Exit Scenario

The company's Pro Forma Financials (i.e. projected cash flow and income statements) should extend a minimum of five years out, which is often the time period an investor looks to for an exit scenario.

Because venture capital is extremely expensive, startup companies will have lower valuations and often have to make significant concessions in getting their first round of funding—especially if initially funded by VC's. Due to this circumstance, entrepreneurs should negotiate with multiple providers of capital, which could either raise a company's valuation or speed up the process—bringing a final deal, amenable to all parties, to the table more quickly.

Investment Returns and Percent Ownership Required

So, what do venture capitalists expect for returns and what percent of the company will an entrepreneur have to give up in exchange for this investment?

Table 1		Years to Exit—X Times Investment				
Stage of Investment	Expected IRR	1	2	3	4	5
Seed	60% +/yr					10.49
Startup	50%				5.06	
Early Stage	40%			2.74		
2nd Stage	30%		1.69			
Near Exit	25%	1.25				

The answer depends on the stage of investment and the time to exit. The chart above shows the expected returns for each stage of investment. Another question is how much equity in the firm will need to be relinquished in order to receive this investment? This is where Pro Forma Financials become important.

Valuation—The VC Method

One valuation method, called the Venture Capital Method, bases the valuation on net income projected in the last year of the exit (typically the fifth year). This approach discounts optimistic future earnings to present value, at a subjective required rate of return specified by investors. A typical Venture Capital Method approach contains the following steps:

- 1. Estimate the company's net income at the time the investor plans on harvesting. This estimate will often be based on the sales and profit margin projections provided by the entrepreneur.
- 2. Determine the appropriate price to earnings (P/E) ratio, by studying current multiples for companies with similar economic characteristics.
- 3. Calculate the projected terminal value by multiplying net income by the P/E ratio.
- 4. The terminal value can then be discounted to find the present value of the investment. VC's use discount rates ranging from 35 to 80 percent to account for the optimism typically present in the cash flow forecasts of entrepreneurs.

The following example shows that the company's value in year five, when sold, will be \$30 million based on a Price Earnings Ratio of 15X. For an investment of \$1M, the percentage of the company required to earn 10X, or \$10 M, would be 33%.

Table 2

Example VC Method			
any tion	Revenue in yr 5 Net profit 5th yr (after taxes)	\$20M 10% = \$2M	
Comp	P/E ratio for industry Company value	15x \$30M	
Investor Data	Investment Exit yr Required ROI Required valuation % company required	\$1M 5th year 60% = 10x \$10M 33% = \$10M/\$30M	
	Pre money value* \$2M = (\$30M-\$10M)/10 * Pre money value is the value of a company just prior to receiving new capital into the company		

Many investors use EBITDA rather than net earning to value a company. EBITDA, which stands for Earnings Before Interest, Taxes, Depreciation and Amortization, strips out the affects of leverage and accounting assumptions regarding write-offs of

investments. When used, the Price Earnings Ratio is replaced with the EBITDA multiple—the Enterprise Value of the Company (equity plus debt) divided by EBITDA. The multiples tend to be lower than P/E ratios.

The disadvantages of the Venture Capital Method are:

- Company value is linked to a single year of company earnings.
- Other sources of capital may have a lower cost of capital.
- Comparable companies for deriving the P/E ratio are frequently not truly comparable.
- Typically applied before new ventures have reached stable cash flow growth.
- The investor will use the same technique to come to a drastically lower valuation than the founder (see sidebar below).

Despite all these negatives, the Venture Capital Method is a valid valuation approach for new ventures. This valuation method is a "quick and dirty" or "back of the envelope" approach and thus can be used by virtually anyone.

Because of its simplicity and the fact that the technique strongly benefits the providers of capital funding new ventures, the method is widely used. Thus, entrepreneurs need to be prepared to counter its use with more accurate valuation methodologies and understand these alternative approaches. In the next edition of this magazine, some of these alternative methods will be discussed.

THE VENTURE CAPITAL METHOD: AN INVESTORS PERSPECTIVE

Literal use of this valuation technique by a founder will almost certainly increase the valuation gap between the investor and the founder, and that increase may preclude obtaining otherwise available financing. Founders expect to be the next Microsoft; investors expect that they will write-off or break even on 90 percent of their startup and early stage investments—including the promising ones—and the odds are worse when the founder has the "I am the next Bill Gates" disease.

Investors see founders who are improperly fixated on "How much of my company am I giving up?" The more relevant questions are: "How do I successfully commercialize it and what does it take?" and "How much can I make off it?" Ninety percent of a failure is worth less than 10 percent of a success.

First, the investor will dramatically discount the projections by assuming slower revenue growth, higher costs and lower margins—all of which result in a lower exit value occurring later. Remember, few successful companies implement their original business model and even those that do are usually behind schedule and over budget.

Investors expect insightful, rigorous planning reflected in detailed projections, but they use them to evaluate the business acumen and realism of the founders, more than to estimate the value of the company.

Second, for startup and early stage companies, investors focus on time investment earned much more than IRR (internal rate of return), usually expecting ten times the investment. The investor does not expect a liquidity event for these companies for four to seven years, so the pay off will be over ten times. IRRs have serious limitations above a 20–30 percent annual return, especially for valuing individual companies. They are useful for comparing portfolios, and even then, they have serious limitations, especially the re-investment and timing assumptions.

Thus, using this method, with the optimism embedded even in "conservative" projections, the founders are likely to value the company at several times what the investor will value it.

Companies, like any investment, are valued by the lowest of three methods:

- The income they are expected to produce (the method used here),
- comparables (the valuation for other promising companies in which the investor can invest), and
- replacement cost (what does it cost a competitor to duplicate the product, management team, etc. and work around IP protection).

Since investors are seeing many investment opportunities (dozens a week) and they usually have the opportunity to invest in other equally promising companies well below the valuation derived by this valuation technique, the comparables method will often limit the value. Even where the investor sees a higher return possibility, it will be reflected more in a desire to invest, perhaps at a slightly higher valuation or in other deal terms. Rarely, will it actually set the valuation.

High-quality projections are necessary to get the investment, but won't usually drive the valuation.



Although it is a certainty that every business in today's world needs a presence on the web, what is uncertain is how to jump onto the information superhighway without crashing and burning. Let Dawnbreaker[®] show you how. **>**

You've made a few tentative steps towards marketing your business on the web. You've registered a "dot com" address along the line of www. mybusinessname.com.

Then you created a webpage highlighting your business, but it isn't creating the expected traffic and there hasn't been time to update, or even maintain the page due to other responsibilities.

All you want is a well-designed, easy-to-use site that will serve your business well and will make you money. Dawnbreaker, the *Commercialization Company*, can help.

A leading service provider to high-tech firms, Dawnbreaker is now offering professional web design services to private, small business clients.

To learn more about Dawnbreaker Small Business Services or to arrange to have your website designed, contact Lyn Barnett at (585) 617-9429 or at Ibarnett@dawnbreaker.com. To view Dawnbreaker's marketing portfolio, visit: dawnbreaker.com/marketing Until you contact Dawnbreaker's professional web designers here are some tips to help you with your website:

Remember that **less is more**. Simplicity and ease of navigation is key to keeping the interest of a potential client.

Create a **logical and intuitive structure** for your site, with sections and subsections that make sense to the target audience and stay consistent throughout.

Make it quick. Test your front page. If it takes longer than 15 seconds for it to load, you are going to lose business.

Use **readable** and professional-looking **fonts** and colors. Light colored text and bright colors can be distracting or utterly unreadable.

Minimize your use of imagery and don't forget to **keep some white space**. Clutter can equal confusion, which can lead, ultimately, to the loss of business.

Design your visuals to **appeal to the target audience**, while staying within your brand and conveying the qualities you'd like associated with your business.

Keep disabled visitors in mind and code your site with accepted standards that will **increase accessibility**.

About Us ...

Dawnbreaker[®], Inc.

Dawnbreaker specializes in providing commercialization assistance to small advanced technology firms and their investors. Since 1990, we have worked with over 2,500 firms that have received funding from the Small Business Innovation Research (SBIR) program, the Small Business Technology Transfer (STTR) program, the Advanced Technology Program (ATP), and others.

Dawnbreaker's depth is in understanding the intent, method and objectives of the SBIR and STTR programs. Having worked within large corporations and small businesses, our staff understands the perspective and financial imperatives of both and is uniquely wellprepared to assist companies in planning for and succeeding in transitioning to Phase III (Commercial phase).

The success of our services is reflected not only in our track record, which includes a 60 to 1 return on investment, but also in the percentage of companies that receive investment and/ or increased sales within 12–18 month of a programs' culminating Opportunity Forum[®]. To date, over \$1 billion has been secured by participating firms. For more information, visit our website at www.dawnbreaker.com.

Phase III Commercialization™ Magazine

Phase III Commercialization[™] magazine is a publication of Dawnbreaker, Inc. and is meant to provide information, gleaned from our highly knowledgeable staff, to advanced technology firms, prime contractors, program managers and investors in the areas of health care, energy and defense.

Editors and Designers for Phase III Commercialization

Executive Editor Dr. Jenny C. Servo Art Director Adrienne Stiles

Managing Editor Julie A. Smith *Graphic Designer* Brian Boucheron

Comments

We welcome comments and questions from our readers. Please feel free to email us at phase3editor@dawnbreaker.com.

All mail should be sent to: Editor, *Phase III Commercialization* Dawnbreaker, Inc. 2117 Buffalo Rd., Suite 193 Rochester, NY 14624



There's more to discover about Dawnbreaker[®]...



Services available for small businesses, government agencies and prime contractors. Contact Lyn Barnett: Phone: (585) 617-9430 | Email: lbarnett@dawnbreaker.com

> PRESORTED FIRST-CLASS MAIL U.S. POSTAGE PAID ROCHESTER, NY PERMIT NO. 676