PHASE III
COMMERCIALIZATION™

SPRING 2010

POWERING THE NAVY
The Energy Roadmap
for the Future of the Fleet

COMPETITIVE INTELLIGENCE
Does your
business have it?

VC TRENDS
A Ray of Light for Cleantech

CONTENTS

EDITOR'S NOTE

In the Small Business Innovation Research (SBIR) community, commercialization is also referred to as Phase III. The *Phase III Commercialization*™ magazine is dedicated to exploring the many aspects of the commercialization processes utilized by small businesses working with civilian and mission agencies. Our approach cuts across disciplines and industries to focus on four broadly defined content areas – medical, energy, defense and space exploration. In every issue, we highlight commercialization strategies and challenges faced by small, advanced technology firms.

Three of the articles in this issue center on energy. The lead article describes the U.S. Navy's commitment to a set of ambitious energy goals announced at the Naval Energy Forum in October 2009. The implementation of these goals promises to transform the Navy's use of energy, perhaps as dramatically as the introduction of nuclear ships sixty years ago. A subsequent article provides insight into Secretary Chu's Energy Innovation Hubs. Modeled after Bell Labs, these innovation hubs will allow multidisciplinary researchers to collaborate under one roof on selected energy problems. The third article in this energy trilogy focuses on investment, both by the government and the private sector. North American companies raised $3.5 billion in venture capital investment in 2009, with solar, transportation and energy efficiency leading the way. The Department of Energy has both financial and programmatic incentives designed to assist companies and their investors accelerate the adoption of energy technologies.

From energy to the space race…and my, what a quarter this has been! The "game-changing" shift to commercial transportation of NASA's astronauts, with $50 million in stimulus-package funding to support two commercial crew launch vehicles and some key technologies, will result in drastic changes to NASA. Rounding out the articles in this issue, you will find an article on FDA and associated product development processes for medical devices, biologics, and/or new drugs. If you are looking to find competitive intelligence and avoid becoming a poor statistic whether in the defense, energy, medical or aerospace markets, then check out the guidance provided on how to best determine what the market needs.

We hope you enjoy this publication. Our goal is to provide insight and information to those who are intent on being successful in commercializing, transitioning or infusing their technologies into the marketplace. Please feel free to send us suggestions for future articles you would find of interest.

Sincerely,

Jenny C. Servo

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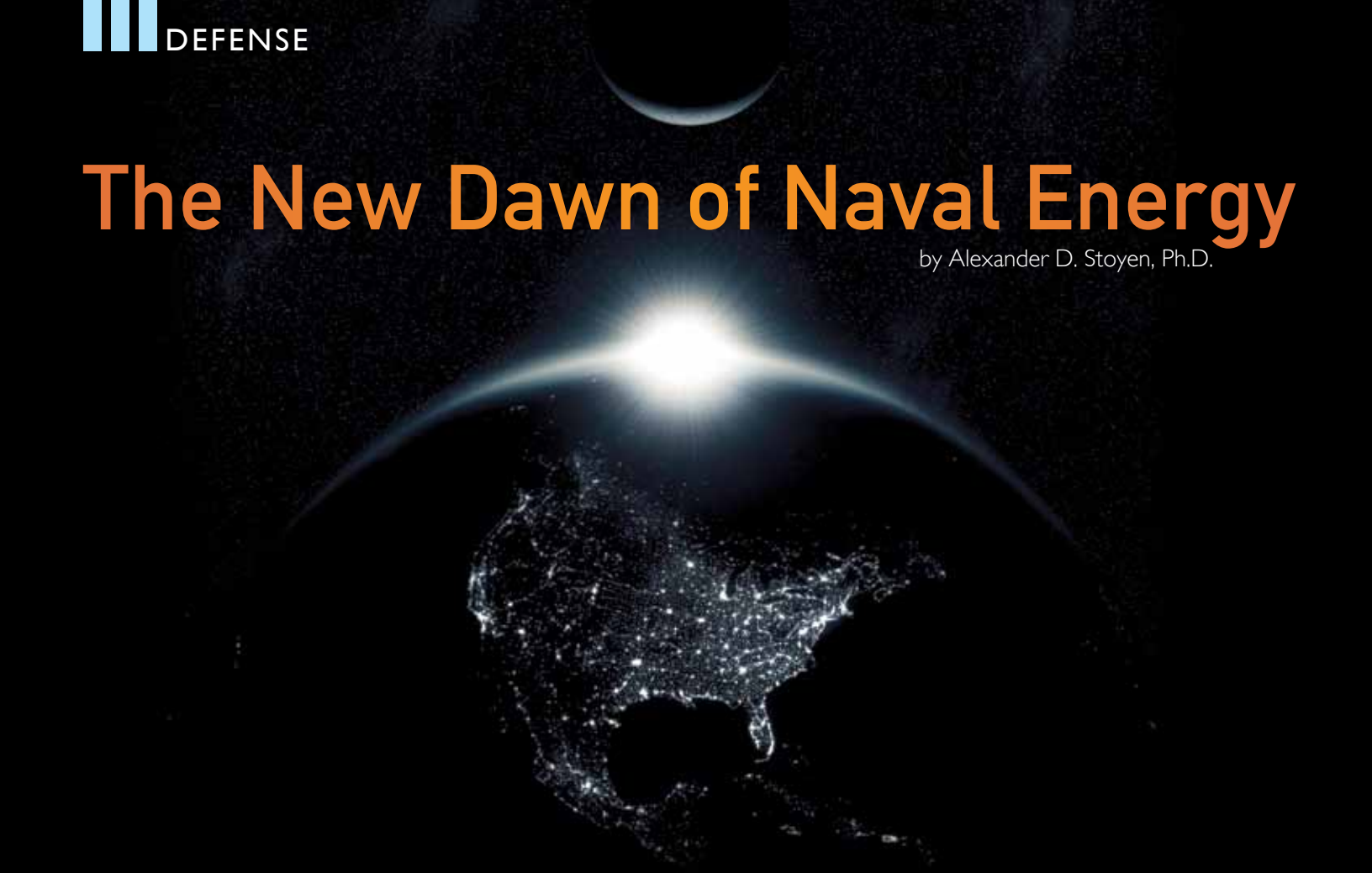
The New Dawn of Naval Energy

by Alexander D. Stoyen, Ph.D.



The U.S. Navy's Updated Energy Roadmap

Good ideas are not adopted automatically. They must be driven into practice with courageous patience.
— Admiral Hyman G. Rickover

Throughout its history, the United States Navy has led the way in innovation and technology. The all important energy field is no exception. A spectacular, contemporary example of such innovation is the creation and fielding of nuclear Navy ships. At the inception of the Naval Reactors program in 1949, a nuclear reactor required a plant the size of a city block. Yet the USS Nautilus (SSN-571) – the world's first nuclear submarine – sailed only five short years later, in 1954.

Sixty years after the commencement of the Naval Reactors program comes another great initiative. On Oct.14, 2009, the Hon. Ray Mabus, Secretary of the Navy announced a set of ambitious energy goals while speaking at the Naval Energy Forum. These goals will transform the Navy's use of energy, perhaps as dramatically as the introduction of nuclear ships did. Secretary Mabus specifically presented five bold goals:

1. Change the way the Navy and Marine Corps award contracts during the acquisition process to consider the lifetime energy cost of the system.
2. By 2012, create a "Green Strike Group" composed of nuclear vessels and ships powered by biofuels and deploy that fleet by 2016.
3. By 2015, reduce petroleum use in its 50,000 commercial vehicle fleet by 50 percent by phasing in hybrid fuel and electric vehicles.
4. Produce at least half the shore-based energy requirements from renewable sources, such as solar, wind and ocean.
5. By 2020, ensure at least 40 percent of the Navy's total energy consumption comes from alternative sources.

In these days of so much political debate with regard to alternatives fuels, conservationism and environmentalism, the Navy's goals are apolitical and focus mainly on reducing dependency on fossil fuels in a logical, proven manner. They increase the use of American-produced, innovative alternative fuels and further strengthen the Navy's traditional belief in being good shepherds of the seas. While some concern may be noted that reaching these goals could reduce the Navy's strength, on the contrary, the Navy will continue to modernize and protect our Nation, as it always has. It will just do it while using less fossil fuels.

THERE HAVE BEEN SOME OBJECTIONS to the Navy's use of nuclear power. While it is not the purpose of this article to take sides in the sixty year old debate on the use of nuclear power, it is nevertheless important to note two facts. First, all energy generation is, in principle, polluting. Some methods pollute substantially, including oil refinement, but alternative energy sources also cause some environmental issues, i.e. windmills erode soil and are a danger to wildlife and hydroelectric dams can wreak havoc on a river's ecosystem. Second, the Navy has an exceptional safety record with regard to nuclear power. Admiral Rickover's famous post Three Mile Island incident testimony to Congress comes to mind, highlighting the Navy's zero-reactor incident record – the record, which has continued for the thirty years that followed.

Many exciting initiatives are now starting as a direct effect of the Navy's new approach to energy. These initiatives will undoubtedly result in solid business opportunities for those small business enterprises that are innovators in the energy-pertinent areas of technology. As presented at the Naval Energy Forum, there are a number of emphases in the Navy's approach to the five energy targets.

> We are a better Navy and a better Marine Corps for innovation; we have led the world in the adoption of new energy strategies in the past. This is our legacy.
>
> – The Hon. Ray Maybus, Secretary of the Navy

The first emphasis is *energy efficiency*. Energy efficiency is reducing Navy energy consumption while maintaining or enhancing mission effectiveness. It is focused on immediate conservation efforts, mid-term technology modifications and long-term acquisition decisions. Among efforts under way are reduction of aircraft engine's use of fuel, reducing carbon footprints in Naval operations and employing Smart Grid energy management. Given the immediate and mid-term application emphasis, energy efficiency may be of most interest to those small businesses with reasonably mature technologies, requiring relatively little additional testing and evaluation to be fielded.

The second emphasis is *energy security*. Energy security is ensuring secure, sufficient, reliable and sustainable energy for Navy tactical forces and shore installations. Energy security is focused on transforming vulnerabilities into strategic and operational advantages by evaluating both the supply of and demand for energy. In this area, some of the efforts are fairly applied and would be most suited, again, for small businesses with nearly or ready to use technologies. For instance, the Navy is looking to qualify the use of domestic, non-petroleum fuel for tactical systems and platforms (such as ships and aircraft). On the other hand, other efforts may make substantial use of ongoing R&D. For instance, the Navy is working on the Versatile Affordable Advanced Turbine Engine (VAATE) technology, which is already familiar to some small businesses, including a number that will be exhibiting at the 2010 Navy TAP Forum this coming June.

The third emphasis is *environmental stewardship*. Environmental stewardship is focused on improving energy sustainability by reducing the Navy's carbon footprint and dependence on carbon-based fuels. Much of this effort is pursued through mature technology and product procurement, which once again may most benefit those small businesses with mature offerings. However, there is some exploratory work as well, which may interest many more small business providers. For instance, there is strong interest in large scale applications of ocean thermal energy conversion (OTEC).

The fourth emphasis, and likely that of most interest to small business technology innovators, is Energy Science and Technology. Energy S&T will increase Naval capabilities through advancements in fuels, renewable energy, power generation, storage, distribution and power loads. Energy S&T is an enabling factor for the goals and objectives of the emerging Department of the Navy Energy Strategy. Of course, the Navy has always invested in Energy S&T. Still, the new Navy energy goals add to the already present impetus of the ongoing investment in this area. A number of technology investment areas have been identified that will be of very high interest to small businesses. Fuels S&T examines fuels chemistry, material and engine effects and of course alternative fuel sources. Power Generation S&T invests in gas turbine engines, fuel cells, advanced generators, direct conversion and photovoltaics. Energy Storage S&T focuses on batteries and capacitors. Distribution and Control S&T brings innovation in architecture, switching and conditioning and thermal management. Power Loads S&T researches hull forms and propulsors.

Without a doubt, the five new Navy energy goals will bring about major new innovation, modernization and ultimately the emergence of an even stronger, smarter and energy-savvy Navy. The Navy investment towards the satisfaction of these targets, and in particular the new innovative product acquisition and S&T investment, present exceptional business opportunities for many small business innovators. Many of these innovators are already involved in important Navy programs and many more will be joining.

Hopefully, this brief article, which does not necessarily represent official views of the Navy, has served to inform interested small businesses of the exciting new dawn of naval energy and of its concomitant opportunities.

For more information, the reader is encouraged to contact the official points of contact as may be listed at the Office of Naval Research website www.onr.navy.mil and at other official Navy sites.

The fully burdened cost of a gallon of gasoline delivered to a piece of equipment in theater in Afghanistan, when transportation and protection costs are included, can in extreme cases reach nearly $400 a gallon.

Competitive Intelligence Blunders

How to Avoid Becoming a Statistic

by Pete Hunt

Hiring a marketing firm to perform primary research is not the only way to gain valuable insight into a targeted market. Small businesses can perform some small sample surveys on their own.

Does your firm perform competitive intelligence (CI) activities? If not, why not? Many respond that it costs too much, or that they already know their competitors, their customers and market, so they do not need to bother. But consider this: perhaps these businesses do not fully understand the benefits that can be acquired from competitive intelligence activities, as Dr. Fred R. David, noted author of strategic business management text books and articles, claims in an article titled *Competitive Intelligence Activity Among Small Firms*, which appeared in the *SAM Advanced Management Journal*.

Competitive intelligence is information you gather through various means about different aspects of the business, markets, products, trends, competitor activities and capabilities, to name a few. Gathering the information is only the first step. It means nothing until it has been thoroughly analyzed. Used appropriately, CI will allow firms to make strategic decisions as they guide the business forward.

SUCCINCTLY PUT, competitive intelligence does not involve spying or crystal balls, and it requires much more than a simple Internet search, rumor chasing or perusal of business publications. Competitive Intelligence has been defined by CI pioneer and Fuld & Company president Leonard Fuld as, "Information that has been analyzed to the point where you can make a decision."

The importance of performing a complete competitive analysis when launching a product or moving into a new market is demonstrated by the following story of Duncan Hines, as told by Eric Garland, president of Competitive Futures.

"My favorite story is the Duncan Hines product launch into Japan. A major producer of cake mix in the United States, they discovered that Asia was an untapped market. They did great market research on the Japanese per capita income, grocery spending, even consumer tastes to determine the right level of sweetness in their baked goods. A check of potential competition showed that there were virtually NO competitors in this space – an incredible Blue Ocean of profit just waiting! The product launch was a failure. It turns out the Japanese generally do not have OVENS in their apartments."

Without the knowledge to act on, a firm will inevitably continue on its current course of action. What would it have been worth to Duncan Hines if they had performed a little extra work up front, conducted primary research interviews with end-users, asking questions related to how they bake? Primary research would have saved Duncan Hines not only a little embarrassment, but more importantly, it would have saved them a good deal of money.

Obtaining information to perform competitive intelligence analysis activities takes on many forms. Two key components in the development of CI are *primary research* and *secondary research*. Secondary research involves gathering information from already published sources. This information can be gathered from several sources, which are available to the public at large, including the library, the internet and government agency reports, i.e. those provided by Congressional Research Service and the Government Accountability Office. There are also subscription/fee-based databases of information and targeted reports. Some of the best known databases are provided by groups such as Frost and Sullivan, BCC Research and Hoovers. Secondary research requires little, if any, face to face interactions. A skilled market researcher can glean appropriate information from secondary sources related to markets of interest and prepare a report that will provide the following key information:

- Major players
- Market share of participants
- Total market size and projected growth rates
- Major drivers and barriers to market entry
- Emerging trends
- Required regulations/certifications
- Intellectual property protection

A caveat to using secondary research is ensuring that the data is current and not outdated. This will depend on how rapidly the market of interest changes. Also, some reports may provide information that is somewhat related to, but not a perfect fit to what your firm is seeking to learn.

Primary research, on the other hand, involves talking directly with market participants, by conducting interviews with customers, end-users, and other market participants, by taking surveys or running focus groups, etc. Primary research may also involve making field observations or networking at appropriate conferences. And while many people, in general, have an aversion to this type of "cold calling" interaction with the market, these activities allow for garnering the most current, customized information from the specific marketplace in question. The combination of primary and secondary research provides for the strongest competitive intelligence analysis of a market. One without the other can leave potential holes in an analysis – like it did for Duncan Hines.

That being said, extensive primary research can be cost-prohibitive, which is why many small firms do not attempt it. However, it is not necessary to hire a large expensive marketing firm to gain some valuable insight into a targeted market. It can be accomplished by performing a small sample of phone interviews with targeted groups, conducted either within the firm or, if there are time/comfort restraints, by utilizing smaller firms that are understanding of and specialize in serving small businesses with limited budgets.

If a small firm decides to take on primary research in house, it must be understood that this call should not be treated as a sales pitch. If the interviewee expresses interest in the product/service during the call, that is an added bonus, but should not be the focus of the call. If the caller perceives the interviewer to be making a sales pitch, they will become less forthcoming and more defensive, limiting the research information that can be obtained. Since the intent of the call is to extract information from the interviewee for analysis, an attempt to make a sale can be a detriment.

Industry research shows that 75 percent of new product launches fail in the marketplace. Competitive intelligence will not guarantee success, but it will increase the likelihood that the market will respond positively to a product.

It may take 15 to 20 calls to gain two or three informative primary research interviews, but even that small of a sample can provide valuable market information to a small business.

Another objection to conducting interviews with industry participants is the concern of divulging proprietary information, but that level of detail should never be included when questioning market participants. There is a wealth of knowledge to be gained about the marketplace without ever mentioning the specific technology/product.

However, if a description of the technology is necessary to extract the specific information sought, it can be done in a non-proprietary manner. The preparation of a non-proprietary abstract to use as a discussion guide for the interviewer, is a helpful tool in reigning in the discussion and avoiding revealing too much information to the subject.

So how is it done? First the type of information to be acquired and the type of people to be targeted must be defined. Below are some sample, introductory questions that may be asked by a firm researching the prospects of commercialization of a new technology. The focus of the research is acquiring information concerning the perceived benefits of the new technology and the level of market pull it may create.

- What is currently done to solve the problem?
- How urgent is the need for this technology?
- How would you use the technology?
- Who are the key decision makers?
- How big is the market?
- Are there any major regulations?
- Are you aware of alternative solutions being developed?
- What product features are the most desired and price points?

Although a more complete guideline will be presented in a subsequent article, for now it is worth noting that in order to be efficient and effective at primary research, an analytical approach is required. To do that, a list of discrete assumptions should be developed to address product / technology sales and associated financial projections. These assumptions are the hypotheses that are being tested, which is not much different than what researchers do in the lab – they create a hypothesis and then conduct experiments to test the hypothesis.

In creating the list of assumptions that require validation, write down as many assumptions as needed, being careful not to lump together more than one assumption. Then, turn the assumptions into objectives. Objectives formalize the assumptions into specific items to be tested. From each objective, generate questions to be asked during an interview. A core list of 10 questions or less is recommended, so as not to exceed time constraints.

Keep in mind, it may take 15 to 20 calls to get 2 or 3 informative interviews, but even a small subset of responders (5 to 10) can provide a wealth of information. A variety of potential data to be gained includes:

- Fair Market Pricing
- Valuable Product Attributes
- Potential Competitive Products
- Market Limiting Regulations/Obstacles
- Additional Technology Uses
- Potential Customers

In some cases, a caller may even be interested enough to become an eventual customer or partner. While a small number of calls does not provide for an overarching, detailed analysis, it can provide some valuable nuggets of information for the small firm taking a new product to market.

Combining this primary research with a well-rounded secondary research report can prevent any small business from knowingly launching a product for a market that has "no ovens in which to bake their cake."

Dawnbreaker's professional market research staff have compiled several portals that are full of valuable secondary research on various topics. The portals are free of charge and can be accessed by visiting, www.dawnbreaker.com/portals.

Proprietary Information is information that is not public knowledge (such as test results or trade secrets), conveyed by a manufacturer to an external party due to its position in the procurement process. The recipient is generally duty bound to desist from making unauthorized use of the proprietary information.

FDA APPROVAL:

WHO NEEDS IT AND HOW TO GET IT

What do antibiotics, antacids, sunscreens, mascara, vitamins, stethoscopes, EKG machines, in-hospital and home diagnostic tests, wheelchairs, vaccines, blood bank refrigerators, flea and tick treatments, seafood, produce, television sets, cell phones and cigarettes have in common? In the United States, they are all regulated to some degree by the Food and Drug Administration; better known as the FDA.

by Richard V. Smerbeck

"Effective enforcement strategy creates public confidence in FDA oversight…which in turn keeps trust in the safety of FDA-regulated products from eroding. Such confidence is critical to the long-term interest of both consumers and industry."
— Margaret Hamburg, M.D., FDA Commissioner

THE FDA, a division of the Department of Health and Human Services, is the federal agency responsible for:

- Protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations
- Helping the public get the accurate, science-based information they need to use medicines and foods to improve their health

Reporting to the FDA Commissioner, the FDA consists of 7 centers and 1 office of responsibility, which are listed in the table below.

Considering the breadth of the FDA's responsibility, its rules and guidance will likely impact many small businesses developing new drugs, medical devices and biologics. With some research, the small business can ensure that the FDA's impact will be positive.

The Product Development Approval Process

Whether developing a new drug, medical device or biologic, the FDA has laid out a specific set of regulations and guidance which must be satisfied before marketing approval is granted. While meeting these regulations may seem a daunting task for a small business, the FDA has essentially laid out a road map to product commercialization. In other words, the FDA approval process is the product development plan. The small businesses should learn the approval requirements of each stage of development for their technologies. This will not only ensure that all resources expended will lead to product approval, but will also ensure the maximum value of a technology at any given stage of development.

FDA Center	Areas of Responsibility
Center for Drug Evaluation and Research	Safety and effectiveness of Rx and over the counter drugs
Center for Biologics Evaluation and Research	Safety and effectiveness of vaccines, nations blood supply, other biologics
Center for Devices and Radiological Health	Safety and effectiveness of medical devices, diagnostic tests, radiation emitting devices
Center for Food Safety and Applied Nutrition	Safety of domestic and imported food supply, cosmetics, dietary supplements
Center for Veterinary Medicine	Safety and effectiveness of veterinary drugs
Center for Tobacco Products	Implementation of the Family Smoking Prevention and Tobacco Control Act
National Center for Toxicological Research	Research to support regulatory decisions and reduce risks associated with FDA-regulated products
Office of Regulatory Affairs	Enforcement of laws and regulations

Due to the expense involved, the majority of small businesses developing new drugs, medical devices and biologics will not be the ultimate manufacturers, distributors and marketers of these products. It is more likely that they will license out to, or form a strategic partnership with, a larger company that already has a presence in the relevant market. Typically, the hand-off involves the licensee assuming the responsibility of clinical trials (if necessary) and completing product development including regulatory filings. All other things being equal, licensees, partners and potential investors will select a company that has properly completed any of the tasks required for regulatory approval versus a company that has not. It is a matter of the small company mitigating some of the financial and temporal risks that will be incurred by a potential partner or investor. Below, we consider some of these tasks that can be initiated or completed by a small company prior to reaching SBIR Phase III (external funding).

Drugs

Most startup activities revolve around the discovery phase of drug development including proof of efficacy in in vitro and in vivo models, characterization of the drug substance and possible dosage forms. The discovery activities are preparation for the Preclinical Phase activities. In the preclinical phase, the studies required to prove that the drug is safe for human use are prescribed by the FDA. These studies include:

- Improvement of manufacturing process and definition of product specifications
- Developing validated analytical methods and batch release specifications
- Toxicology testing as per Good Laboratory Practices (GLP's)
  - Safety pharmacology and pharmacodynamic studies
  - Toxicokinetic and Pharmacokinetic Studies
  - Acute Toxicity
  - Repeated dose toxicity trials
- Characterization of drug (ADME) Absorption, Distribution, Metabolism and Excretion
- Dosage form development with stability data
- Safety studies to support human dosing as per regulations

The FDA regulations covering these and other requirements for allowing human use can be found on the FDA Center for Drug Evaluation and Research website. While the cost of all of these tests will be beyond the budgets of that which can be funded via SBIR Phase I and II grants, some can be funded. The results from any of these studies can bring the drug closer to first human testing; an appealing aspect to a potential licensee, partner or investor.

Biologics

The preclinical activities for a biologic are the same as those for a drug with a couple of important additions. These are – in the case of some biologics – the need to test for adventitious agents and the need to develop an assay for biological potency. Adventitious agents are potentially harmful organisms that could be growing in the cell sources or culture medium of the biologic being produced. This testing ensures that any product tested will be safe. Unlike the case of a traditional drug, chemical structure does not always correlate with a biologics

function. A potency assay is required to show that the biologic will perform its desired function, when administered. An example of this could be a vaccine that when administered to immune system cells in the laboratory, induce the cells to multiply. Often times, the animal test developed and utilized by a small business to show a biologic's activity during discovery research can be the basis for the FDA required potency assay.

Medical Devices

Early product development activities that are critical to receiving expedient FDA market approval of a new medical device are properly classifying your device and, implementing relevant quality systems. Both of these activities can be easily accomplished by a small business.

Properly classifying a potential medical device will determine the regulatory pathway to be followed to gain FDA approval. Devices are classified as 1, 2 or 3. Device class descriptions and examples can be found in the table at right.

The time to commercialization can range from zero days (Class I) to a 90 day FDA review (Class II). I In some cases, a multiyear FDA review (Class III) is to be expected. Step-by-step guidelines for classifying a medical device can be found on the FDA CDRH website.

All Class II and III medical devices marketed in the U.S. must be manufactured under the quality systems described in 21 CFR (Code of Federal Regulations) 820. However, it is important to note that the designer of a medical device is considered to be a manufacturer, so the design process must fall within the quality systems. Design controls are critical, especially as the final design is being developed. This is to ensure that medical devices are designed to perform their desired function in a repeatable manner, which is consistent from unit to unit and lot to lot, and that changes to the medical device during the design phase are planned, verified and validated. Design controls are composed of:

- Design and Development Planning
- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Design Transfer
- Design Changes
- Design History File

Class	Description	Approval Path	Example
I	Safest devices	Preapproved	Walking Cane, Mechanical Toothbrush
II	Some risk if misused	Premarket Notification (510(k))	Blood Glucose Test
III	Misuse could result in severe injury or death	Premarket Application Approval (PMA)	Heart Valve

By implementing design controls, when the medical device is transferred to a licensee/partner, further development or scaled-up production can be readily accomplished. If design controls are not followed, the licensee/partner will have to reproduce much of the earlier work, which leads to a longer development time and greater expense. Small businesses that follow design controls are appealing to potential licensees, strategic partners and/or investors. For more information on medical device quality systems, read the FDA publication, *A Small Entity Compliance Guide First Edition*.

FDA and Small Businesses

The FDA does provide support services geared toward small businesses. These include the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) in the Center for Devices and Radiological Health, Small Business Assistance Programs in the five FDA regional offices, and the creation of small business assistance offices in each of the Centers.

Conclusion

Although most small businesses will not be the commercializing entity of their drug, medical device or biologic, they can be sure to fulfill, within their resource constraints, as many of the regulatory requirements as possible. This can be accomplished by following the well-documented regulations and product development processes mapped out by the FDA. Doing so will mitigate some of the uncertainty (time and money) inherent to drug, biologic and device development. Companies that take this approach will be more appealing to potential licensees, partners and investors. III

For more information on FDA regulations, guidelines, publications and small business assistance, visit the various FDA links found below.

- **FDA REGULATIONS FOR DRUGS FOR HUMAN USE**
  www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm
- **FDA REGULATIONS AND GUIDANCES FOR BIOLOGICS**
  www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/default.htm
- **FDA REGULATIONS AND GUIDANCES FOR MEDICAL DEVICES**
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
- **FDA INFORMATION FOR SMALL BUSINESSES**
  www.fda.gov/ForIndustry/SmallBusinessAssistance/SmallBusinessRepresentatives/default.htm
  www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm053133.htm
  www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ManufacturingQuestions/default.htm

FDA PUBLICATION:
Medical Device Quality Systems Manual: A Small Entity Compliance Guide
This publication is available on the fda.gov website by chapter. Visit the site and enter the title of the publication in the search engine in the top right hand corner. This will take you to the chapter listings.

Venture Capital Investment Trends

Solar and Other Cleantechs Heat Up Again

by Steve C. Orth

ENTREPRENEURS OFTEN RELY on early-stage and seed venture capital to support growth and maturation of their companies. Business angels, be they individuals or small groups of experienced businessmen, are organized to provide early-stage capital in the range of several-hundred thousand to several million dollars. However, venture capital (VC) firms are looking for larger deals.

Venture capital investment in new companies was soft in 2009. VC's invested $6.3 billion in start-up/seed and early stage companies nationwide in 2009. This, compared to the $6.9 billion invested at those stages in 2008. While this represents only a 9 percent decline, venture capital investments in businesses seeking to raise money in the later development stages of the business, known as "expansion" and "later stage" investments in VC-speak, were off 45 percent relative to 2008 ($21 billion down to $11.4 billion), according to a recent MoneyTree Report from PriceWaterhouseCoopers and the National Venture Capital Association.

"CASH FLOW INTO FUNDS IS DOWN – this tends to be a leading indicator. We are in a market where the number of deals has been shrinking. Capital going into new investments, relative to money going to investments already in place, is going down; and many investors, even for new investments, are going to later stage companies where the risk is lower and more capital can be deployed," Said Neal Dikeman, a partner at Jane Capital Partners in San Francisco.

One area that is still attracting strong attention from both the government and private sector is clean technology, or cleantech. Cleantech is widely referred to in broad categories – solar, transportation, energy efficiency, biofuels, smart grid, etc. While down 42 percent from 2008, North American companies still raised $3.5 billion in VC investment in cleantech for 2009. The leading sector was solar, which accounted for 22 percent of the total ($774 million). Transportation ($767 million), which includes batteries and fuel cells, and energy efficiency ($691 million), followed closely. The sectors toward which money flows are largely a function of successful investment exits. "Solar is the only sector that has seen consistent exits," explained Dikeman. "The smart grid has seen lots of growth, but the growth is new, so the money's not there yet. Transport has been a darling for a while."

With private sector investment in cleantech down, government programs can have a big impact on market success of cleantech technologies. There are several relatively new programs opportunistic entrepreneurs should be aware of:

- The Entreprenuer in Residence (EIR) Program: The EIR Program aims to support commercialization of viable DOE national laboratory technologies by placing venture capital firms in a position to work directly with the national labs.
- The DOE Technology Commercialization Showcase: This program strives to provide effective communication about promising technologies to potential investors.
- The DOE Technology Commercialization Fund (TCF): The (TCF) is designed to complement angel investment or early stage corporate product development. The fund totaled nearly $14.3 million in fiscal year 2007 and fiscal year 2008 and is administered by DOE-selected national laboratories.
- The DOE Loan Guarantee Program: This program paves the way for federal support of clean energy projects that use innovative technologies, and spurs further investment in these advanced technologies.

These programs and others can help take technologies mainstream. Solar received nearly 40 percent of its funding from the government before it went public, and the DOE Loan Guarantee Program has helped several later-stage companies, i.e. Tesla (transportation) and Solyndra (solar), with large infusions of capital, according to Dikeman.

Looking forward

So what are the anticipated trends going forward and how should entrepreneurs position themselves for success? Early stage investment may see some recovery in 2010, and it will be strongly influenced by the level of success enjoyed by VC firms as they exit their investments. Current activity levels are high, explained Dikeman, "There is certainly some light at the end of the tunnel. It will be interesting to see what happens with the exits. We had one IPO last year, A123 Systems (transportation). There are several lined up for this year in solar and transportation. If they go well, it would be a big shot in the arm for the early stage investor. Success with those exits would unlock more money to funds, which would unlock more money flow into the startups."

Still, it is a difficult environment to pursue capital and to make money. However, said Dikeman, it is a good time to be an investor. "Energy storage is hot again. Water continues to be hot, but it's hard to make money there. Solar is rough for early stage companies; later stages are big business as the sector moves downstream from the high-risk development stage. Transportation has a lot of activity and is stronger. Efficiency; interesting, but very broad. Biofuels; are probably getting weaker," Dikeman elucidated.

To stay on top of the trends and pursue capital for their companies, entrepreneurs are encouraged to:

- Stay diligent; all good deals get funded
- Be aware it's gotten very competitive in the early stages as money shifts later
- Leverage government programs
- Stay apprised of Cleantech IPO's and acquisitions.

There is no guarantee of funding. However, if nothing is ventured, nothing is gained. III

For more information on the EERE Commercialization Initiatives, visit www1.eere.energy.gov/commercialization/initiatives.html .

Websites for Government Energy Programs and Other Helpful Sources

Below are the websites for the government programs listed in the column to the left and a few other sites of interest.

- **Entrepreneur in Residence:** www1.eere.energy.gov/commercialization/entrepreneur_in_residence.html
- **Technology Commercialization Showcase:** www1.eere.energy.gov/commercialization/technology_commercialization_showcase.html
- **Technology Commercialization Fund:** www1.eere.energy.gov/commercialization/technology_commercialization_fund.html
- **DOE Loan Guarantee Program:** www.lgprogram.energy.gov
- **Equity Share License Agreement:** www1.eere.energy.gov/commercialization/entrepreneur_in_residence.html#license
- **Dawnbreaker *Phase III Commercialization* magazine archived issues:** www.dawnbreaker.com/P3magazine
- **Dawnbreaker Alternative Energy Portal:** www.dawnbreaker.com/portals/altenergy

While down 42 percent from 2008, North American companies still raised $3.5 billion in VC investment in cleantech 2009.

RUNNING IN THE COMMERCIAL SPACE RACE

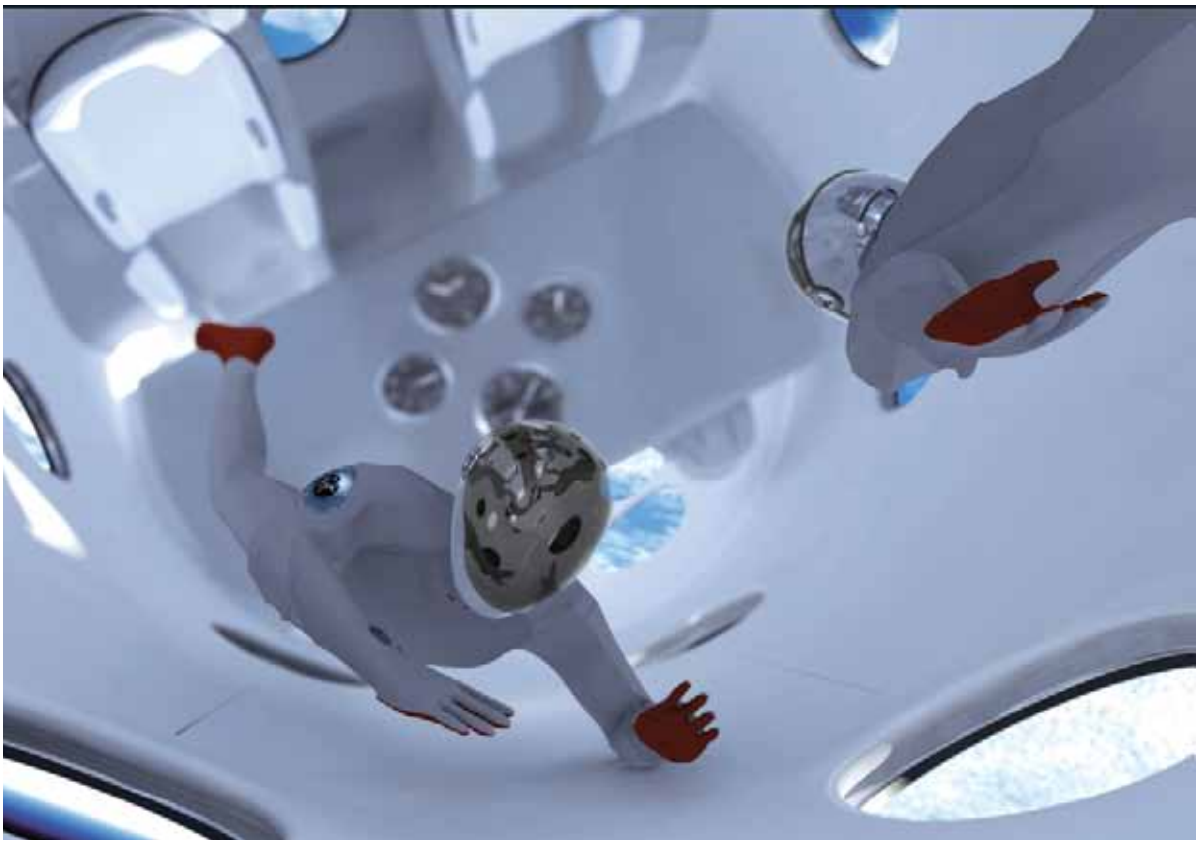


Image courtesy of Virgin Galactic LLC

Who will lead the pack in the commercial space industry?

NASA is kicking off its "game-changing" shift to commercial transportation for its astronauts with $50 million in stimulus-package spending that will support two commercial crew launch vehicles and some key technologies to keep them alive on the way to orbit and once they get there.

— *Aviation Week*, Feb. 3, 2010

by Todd J. Farrar and Ian Roth

A RACE IS ALREADY UNDERWAY in the commercial space sector, a race not against other nations but a race toward market dominance to provide a holistic space offering that includes everything from Expendable Launch Vehicles, Reusable Launch Vehicles, Reentry Vehicles and In-Space Technology, Commercial Human Spaceflight Training, as well as Spaceports. The market has already attracted substantial government funding, vested interest from large companies and substantial equity investments. The recent direction change and subsequent planned investments from NASA have now cemented the future of the commercial space industry. It is here, and it is about to get much larger – presenting a distinct opportunity for small businesses.

A Change in Direction

With the release of the President's 2011 budget request, it is clear that our next giant leap will not include footprints on familiar lunar soil, but will instead be headed toward the red planet, Mars. NASA's Constellation program, which was over budget and behind schedule, has been cancelled. A new direction, which relies partially on the private sector, is being established to address future space exploration challenges.

In a statement issued with the federal budget for FY2010, the White House Office of Science and Technology Policy said that "the entry of private industry into space, is an abrupt shift to harness our nation's entrepreneurial energies." The President's remarks at NASA on April 15, 2010, echoed that same sentiment, calling for a budget increase of $6 billion over the next five years to foster development of commercially operated systems capable of ferrying astronauts to and from the international space station.

Commercial Sector Spreads Its Wings

Companies like Space X, United Launch Alliance or Orbital Sciences Corporation (OSC) have already demonstrated an ability to provide a lower cost alternative for launching payloads into orbit than NASA's planned Ares Launcher. These companies already have launchers, capsules and demonstration cargo contracts with NASA. SpaceX founder, Elon Musk, is hopeful that his firm can even deliver Astronauts to the ISS for less then the current price of $50 million per person charged by the Russians to NASA.

SpaceX, and other commercial space companies such as Virgin Galactic, Blue Origin, Bigelow Aerospace and Orbital Sciences have plans for exploration vehicles for manned spaceflight. Spaceports in California, Alaska, Oklahoma and Florida are both publicly and privately financed, and appear to be attracting/hosting clusters of technologies and companies actively working toward the commercial exploitation of space. Spaceport America, which had a recent ground breaking and makes claims of being America's first commercial spaceport, will serve as a hub for flight tourism. In April 2008, the *Washington Post* reported that most commercial space companies plan to finish testing their rockets and rocket planes within a few years. Moreover, the Federal Aviation Administration estimated that the market for space tourism would exceed $1 billion a year by 2021. Interest in the sector has increased as seen via the recent NASA-funded $75 million Commercial Reusable Suborbital Research (CRuSR) program. Two years ago, the program – intended to fund new research opportunities presented by Reusable Suborbital Vehicles – had fewer than 50 investigators come to present proposals. At the most recent meeting over 250 people attended.

The new NASA plans announced by the Obama administration in April, anticipate that the cultivation of private-sector space launchers will create 10,000 new jobs across the country over the next five years, while building an Orion-based rescue ship will preserve critical jobs for federal contractors in Colorado, Texas and Florida. The administration also expects to bring up to 10,000 jobs to Florida's Space Coast, by 2012, through investments in the Kennedy Space Center.

Government Funding Expansion

Up until this point, the commercial space industry has been largely funded on the back of a few Fortune 500 entrepreneurs looking to put their money where their passion is. However, with what amounts to a shoestring budget, the commercial space industry has already raised eyebrows in its ability to offer low cost alternatives for manned and unmanned space exploration. Many firms have enabled technologies that range from re-useable launch vehicles to next generation spaceports with little to no government support, which has made this growing sector hard to ignore. Now that it appears the space industry will begin to receive an infusion of funding needed to expand its commercial viability, it is clear that in the future, America will explore space by leveraging the technologies, ideas and innovations developed in the private sector.

Until now, NASA's annual commitment to the commercial space sector has only been in the tens of millions of dollars, but is now set to grow to several billions annually.

With private sector investments, as well as support from NASA in the form of Space Act Agreements from the Commercial Crew and Cargo Program Office (C3P0), both Orbital Sciences and SpaceX have already developed rockets and launch vehicles that have undergone Critical Design Reviews (CDR) and testing. Future milestones will result in system flight demonstrations in the 2011 time period. This has all been accomplished on time and at a fraction of the cost of a typical organic government program.

In a public radio interview, Jeff Greason, president and CEO of XCOR Aerospace and a member of the Augustine Commission, who believes that using private companies for shorter flights will free NASA to focus on deep space research, explained that, "when NASA tries to be an operator of transportation services, they're not playing to their strengths. We are opening up, or should be opening up, new frontiers for humanity. And you don't do that going around and around in lower orbit. That's not the same as exploration." The Augustine Commission found that it might be cheaper and faster for the government to buy rides to low Earth orbit for its astronauts, than to fund the Constellation Program to completion.

NASA's FY 2011 budget estimates, which with the top line increase of $6 billion over five years reaches $100 billion for FY 2011–2015, include significant and sustained investments in some of the following areas:

- Research and development on heavy-lift and propulsion technologies

"The entry of private industry into space is an abrupt shift to harness our nation's entrepreneurial energies." — The White House Office of Science and Technology Policy

Image courtesy of SpaceX

- Transformative technology development and flagship technology demonstrations to pursue new approaches to space exploration
- U.S. commercial spaceflight capabilities
- Cross-cutting technology development aimed at improving NASA, other government, and commercial space capabilities
- Accelerating the next wave of Climate change research and observations spacecraft
- NextGen and green aviation

Small Business Roles in the Commercial Space Sector Expansion

Success for a small firm will likely hinge on the willingness among key players in this market to work with other companies.

Clearly the commercial space industry is on the cusp of dramatic growth and rapid change. New business models for success will be developed and a value chain will be established. A technology that would have received flight demonstration through the space shuttle program may now have to rely on SpaceX or Orbital.

Orbital's Taurus II, a medium-lift rocket, already has a $1.88 billion Commercial Resupply Services (CRS) contract for eight flights to the International Space Station. SpaceX has a $1.6 billion CRS contract for 12 flights using its Falcon 9 rocket. SpaceX has even begun preliminary training with future station astronauts that will ride aboard its Dragon cargo vehicle.

For a small company, entering this market successfully may not be easy, but there are paths to take, which are broadening significantly, as NASA's scope is changing. Partnering with larger, more established firms and SBIR awards are two paths for small firms to follow. NASA specifically mentions the SBIR/STTR programs as sources of innovation for Space Technology moving forward.

Some successful commercial space participants, such as Paragon, Sierra Nevada Corporation and Orion Propulsion, Inc. (OPI), are examples of companies that have experienced significant accomplishments with funding from Phase I and Phase II SBIR awards. According to Mark Fisher, the director for Dynetics Space Systems, formerly known as OPI, "SBIR funding was the basis for staying alive." The SBIR program allowed OPI to not only demonstrate that they could build hardware that was flight worthy, but also allowed them to compete for and win contracts to deliver flight hardware, and allowed them to work with companies such as SpaceX and Bigelow Aerospace. SBIR participation also led OPI's recent acquisition by Dynetics Space Systems.

Fisher said that OPI focused on building up internal capabilities prior to receiving their Phase I award to avoid long lead times and a reliance on sub-contractors or government support. During Phase I efforts, OPI could leverage these established capabilities to deliver hardware or to do things such as testing that would have otherwise been very difficult for most Phase I companies to do.

As an example, he mentioned a propulsion system they were working on for a NASA Phase I. OPI felt that it was important to perform tests in a vacuum so, using their own capital, they built a vacuum test chamber, which allowed OPI to test fairly cheaply, as they ran the system themselves. In addition, this internal testing capability allowed OPI to be highly cost competitive in the commercial space arena. OPI also demonstrated that they could successfully test thrusters for a few hundred thousand, while larger companies were quoting well over $1 million for the same testing. Having established in house capabilities, OPI is also able to perform testing for NASA. By controlling everything, cradle to grave, from propulsion development to testing, OPI was able to leverage SBIR funding to become a successful player in the commercial space arena.

The formula for leveraging SBIR funding to become a successful market participant, to enter a new market and not only be able to gain but also to sustain a competitive advantage, will most likely be different for every firm. That said, key success factors for one firm might dovetail or overlap with another firm's approach. For OPI several factors have been critical to their success in the commercial space arena.

1. Project/Technology needs to be based on engineering and has to be an innovative idea.
2. Relationship Building – Receiving an SBIR award does not mean you will be successful; you have to go out and talk to people, build relationships.
3. Deliver a better solution, faster and cheaper than what is currently available.

With the shifting focus toward the commercial sector a successful business model will likely emphasize technology commercialization, either independently or through a relationship with an established key player, rather than via NASA infusion. So success for a small firm will likely hinge on the willingness among key players in this market to work with other companies.

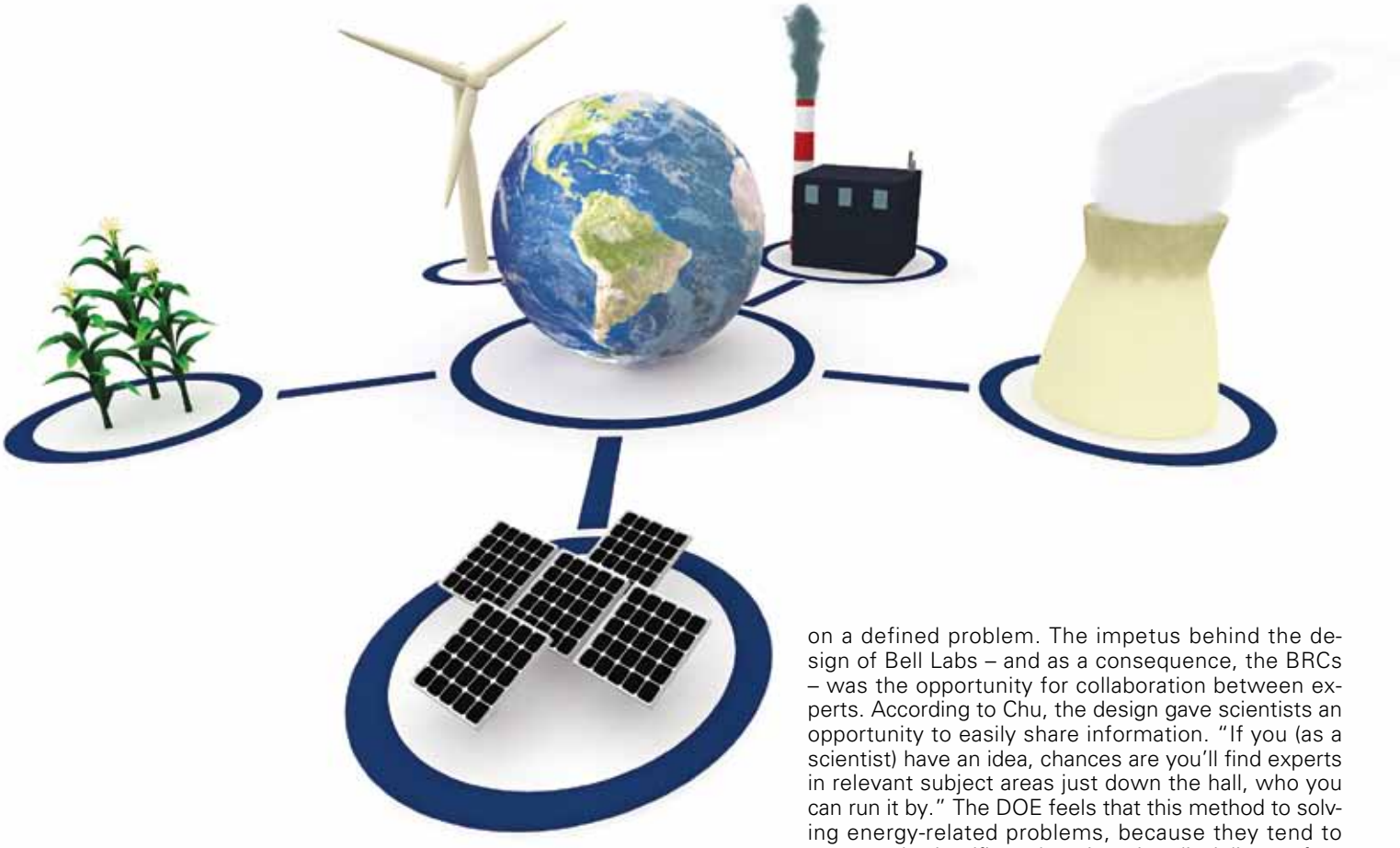
Time will tell how the shifting focus of NASA will effect the dynamics of the commercial space market. Gaining market entry will take more than a novel solution to a problem. It will take a firm that can leverage internal capabilities, provide hard to find expertise and create unique solutions that have a clear value propsition to a key player. Despite these challenges it seems that there is no shortage of smaller enterprises trying to enter this market, a willingness to face these challenges may come from a love and passion for space. ■

For more detailed information on the budget allocations and commercial opportunities see www.nasa.gov/pdf/420990main_FY_201_%20Budget_Overview_1_Feb_2010.pdf

What's all the "HUB"-bub About?

DOE Launches Three New Energy Innovation Hubs

by Mitch Lairmore and Phillip Miller



"Everybody in America should have a stake in legislation that can transform our energy system into one that's far more efficient, far cleaner, and provide energy independence for America – making the best use of resources we have in abundance." — President Obama, Oct. 23, 2009

THE OBAMA ADMINISTRATION has made a commitment to doubling America's investment in science and pursuing transformative breakthroughs in technology to meet energy and climate challenges. As part of this strategy, the Department of Energy has launched three *Energy Innovation Hubs*. According to the DOE's description of the new hubs, they are modeled, in part, after the Department's successful Bioenergy Research Centers (BRCs). The Hubs will help advance highly promising areas of energy science and engineering from the early stage of research to the point where the technology can be handed off to the private sector.

As will be explained in this article, small high-tech energy firms should view these hubs as a potential funding opportunity, looking forward.

The "Bell Labs" for Energy Research

For some background on the development of the Energy Innovation Hubs, it is helpful to examine Dept. of Energy Secretary, Steven Chu's, career influences. Secretary Chu spent his early career at Bell Labs, where the work that he did earned him a Nobel Prize in Physics in 1997. Chu established the BRCs mentioned above, based on the Bell Lab model of placing multidisciplinary researchers under one roof to focus on a defined problem. The impetus behind the design of Bell Labs – and as a consequence, the BRCs – was the opportunity for collaboration between experts. According to Chu, the design gave scientists an opportunity to easily share information. "If you (as a scientist) have an idea, chances are you'll find experts in relevant subject areas just down the hall, who you can run it by." The DOE feels that this method to solving energy-related problems, because they tend to transcend scientific and engineering disciplines, often requires the collaboration of physicists, materials scientists, mechanical engineers and microbiologists. This also solves the organization problem of isolated researchers. The success of the DOE BRC's led to the Energy Innovation Hubs concept.

Areas of Research Receiving Congressional Funding

For the 2010 FY budget, Chu requested funding of $280 million for the establishment of eight Energy Innovation Hubs in the same fiscal year. These eight hubs focused on the following areas of research:

1. Extreme Materials
2. Modeling and Simulation of Reactors
3. Solar Electricity
4. Carbon Capture and Storage
5. Focus of Grid Materials, Devices and Systems
6. Fuels from Sunlight
7. Batteries and Energy Storage
8. Energy Efficient Building Systems Design

Only three of the requested areas of research received funding from Congress for FY2010.

1. Fuels from Sunlight
2. Energy Efficient Building Systems Design
3. Modeling and Simulation of Reactors.

"Given the urgency of our challenges in both energy and climate, we need to do everything we can to mobilize our Nation's scientific and technological talent to accelerate the pace of innovation."
— Secretary Chu

1 Fuels from Sunlight

The key question for establishing the Fuels from Sunlight Hub is – "*How can we derive fuels directly from sunlight in an efficient and economical way?*" According to the DOE's Energy Hub website, the following is a list of critical issues concerning the production of fuels from sunlight:

- Replicating or reverse engineering the natural photosynthetic system with inorganic materials or hybrid bio-inorganic systems. Advances here require a more profound understanding of the subtle and complex chemistry of plant life, particularly in understanding the marvelous ability by which plants regulate the photosynthetic apparatus and repair themselves when damaged, both critical factors in the construction of a robust, man-made solar fuel generator.

- Using solar photovoltaics to drive the splitting of water or the reduction of carbon dioxide in an electrochemical cell, which requires the design and discovery of novel nano-engineered materials that catalyze the water splitting reaction and that are efficient, cost effective, environmentally benign, and have long-term stability and reliability.

- Artificially connecting biochemical systems that can combine water, sunlight, and even carbon dioxide to produce hydrogen or another chemical fuel in a man-made chemical reactor. The key to this approach is identifying the "software" for the synthetic cell, which can guide the process to the desired product.

The hub for Fuels from Sunlight began to solicit its first round of proposals in December 2009 with a funding ceiling of $120 million. This solicitation (DE-FOA-0000214) closed in March 2010.

2 Energy Efficient Building Systems Design

The second established hub focused on energy efficient building systems design with an emphasis on "*How can we design, construct and retrofit commercial and residential buildings that are vastly more energy efficient than today's buildings?*"

This hub will integrate smart materials, designs, and systems to tune building usage that will conserve energy, as well as maximize the functioning of lighting, heating, air conditioning and electricity to reduce energy demand. Areas of greatest interest include improved exterior shell materials, membranes of energy efficient windows, insulation, improved approaches to building design, systems control, and energy distribution networks.

Anchored around the DOE-funded Energy Innovation Hub is a multi-agency funded pilot program called the Energy Regional Innovation Cluster (E-RIC). The E-RIC pilot initiative is designed to spur regional economic growth while developing innovative energy efficient building technologies, designs and systems. The seven federal agencies funding E-RIC are the DOE, SBA, NSF and Dept. of Commerce, NIST, Dept. of Education and Dept. of Labor.

E-RIC released a combined Funding Opportunity Announcement (FOA) *www.energy.gov/hubs/documents/ERIC_FOA.pdf*.The FOA makes available awards of up to $129.7 million over five years. The agencies involved in this effort are making available up to $129.7 million over 5 years for this pilot project. Per the DOE's E-RIC webpage, the following is the breakdown of awards by agency:

- Department of Energy will provide up to $22 million in the first year of the award (with additional amounts of up to $25 million per year for four additional years, subject to availability of appropriations), for an Energy Innovation Hub based at a university, DOE national laboratory, nonprofit organization or private firm, partnering closely with local or state government officials.

- Department of Commerce will provide up to $3 million in Public Works and Economic Development funds and up to $2 million in Economic Adjustment Assistance funds for a single award over a period of performance not to exceed 5 years.

- National Institute of Standards and Technology will provide up to $500,000 for a one-year award, with the possibility of additional amounts being awarded for two additional years. Funding will be made available to an existing DOC-funded NIST/MEP Center that will use the additional funds to provide services dedicated to the Consortium's effort to support the E-RIC and transition technology to industry.

- Small Business Administration will provide up to $300,000 in the first year, with three one-year options for renewal grants up to $300,000 per year. These funds will be made available to an existing SBA-funded Small Business Development Center that will use the additional funds to provide services dedicated to the Consortium's effort to grow the E-RIC.

The Dept. of Labor, Dept. of Education, and National Science Foundation will support collaboration between the Consortium and recipients of funding under complementary, existing programs at their respective agencies.

- The Department of Labor will engage local and regional networks of Workforce Investment Boards and

Energy POCs

- **For more information on the Hubs,** visit hubs.energy.gov
- **For more information regarding the BRCs, contact:**

- **Russ Miller**
  Mgr. of BESC Tech. Transfer & Partnerships
  (865) 574-8746.
- **Pam Seidenman**
  JBEI Business Development Manager
  (510) 486-6461 • PSSeidenman@lbl.gov
- **Steve Slater**
  GLRC Programs Manager,
  (608) 890-2502 • scslater@glbrc.wisc.edu

Other Energy webpages of Interest

- **Energy Innovation Hubs FAQ's**
  www.energy.gov/hubs/qanda.htm
- **Energy Frontier Research Centers**
  www.er.doe.gov/bes/EFRC/index.html
- **Adv. Projects Research Agency - Energy (ARPA-E)**
  arpa-e.energy.gov
- **DOE Website - Secretary Chu's Budget Presentation**
  www.energy.gov/about/budget.htm

One-Stop Career centers to ensure that workers reap the maximum benefit from this initiative. Which is expected to not only help reduce the energy costs of buildings, but also spur the creation of new jobs in green and energy efficient industries.

- ED encourages state eligible agencies, and local and regional secondary and postsecondary educational agencies and institutions receiving funding under the Carl D. Perkins Career and Technical Education Act of 2006 to act as E-RIC Partners. It also encourages support of career and technical education projects and activities that eliminate gaps between the supply and demand for workers in specialized fields within the E-RIC.

- Existing NSF award recipients that are also Co-applicants or E-RIC Partners of the winning Consortium, may be eligible for supplemental funding from NSF.

The E-RIC is meant to not only focus on issues surrounding energy efficient building systems, but also to integrate this Hub into a broader regional economic development initiative.

3 Modeling and Simulation of Reactors

The final Hub receiving congressional funding for FY2010 is the Modeling and Simulation of Reactors. The key question establishing the focus of this Hub is, "*How can we use modeling and simulation technologies to make significant leaps forward in nuclear reactor design and engineering?*" This Hub will provide validated advanced modeling and simulation tools necessary to enable fundamental change in how the U.S. designs and licenses nuclear power and waste management technologies. This has the potential to improve the performance and reduce the costs of new nuclear facilities.

The FOA (reference number DE-FOA-0000170) was posted in January 2010 with a closing date of March 2010. A synopsis of solicitation can be found by visiting grants.gov and searching by reference number DE-FOA-0000170. Interested parties can also register to receive notification of future funding opportunities.

How might the Hubs interact with small businesses?

According to DOE spokeswoman, Jennifer Lee, small businesses are encouraged to participate in the Energy Innovation Hubs. One specific highlight is the Energy Efficient Building Systems Regional Innovation Cluster Initiative, which includes the involvement of the Small Business Administration. Though the initial Funding Opportunity Announcements (FOA's) issued have closed for all three Energy Innovation Hubs, there should be additional opportunities for awardees to contract with small businesses. To give a picture of how the Energy Hubs will most likely interact with small businesses (because establishment of the Hubs is still in process), it is helpful to examine the ways that DOE BRCs, the model for the Energy Hubs, are currently working with smaller firms.

The BRC consists of three organizations: (1) the Bioenergy Science Center (BESC) which is led by the DOE's Oak Ridge National Laboratory, (2) Great Lakes Bioenergy Research Center (GLRC) which is led by the University of Wisconsin, and (3) the Joint BioEnergy Institute (JBEI), which is led by the Lawrence Berkeley National Laboratory.

According to Russ Miller, manager of the BESC Technology Transfer and Partnerships, the BESC interacts with industry via several avenues. All BESC partners perform research at the Oak Ridge National Laboratory, and with DOE approval, small businesses can become partners. Four small businesses, Verenium, Mascoma, Arborgen and Ceres, are currently partners. BESC also has an Industry Affiliates program, which currently counts a small business in its ranks. These affiliates can participate in all bio-energy-related training, receive notices of publications and invitations to technical conferences.

The GLRC even had a small business, Lucigen, that was part of the center's original proposal, according to Steve Slater, the center's associate director and manager of Scientific Programs. Slater also said that the GLRC is currently establishing a small business affiliation program, though there are no small business contracting opportunities available at this time, unless the small business has a unique analytical capability based on the basic research focus of the GLRC.

Again, the Energy Hubs are based on the BRCs model, so it is anticipated that they will operate in much the same manner as far as offering partnering opportunities for small firms. Those interested in these potential funding opportunities should monitor the Energy Hubs website (at left) and stay informed as the program takes a more permanent form.

For more information on applying for E-RIC funds, visit www.energy.gov/hubs/apply.htm. The application is due May 6, 2010.

The intellectual property of BESC is available for licensing and can be viewed on the center's website, bioenergycenter.org/licensing

DOE R&D Programs Working Together

Will the DOE's other energy R&D programs, in particular the recently launched Energy Frontier Research Centers and ARPA-E, benefit from the proposed Energy Innovation Hubs?

Management of R&D can impact the pace of innovation. The rapid pace of development of radar, the transistor, and the atomic bomb occurred in part because of the management model employed. These achievements were organized around a particular challenge, with a highly integrated management model in which outstanding scientist-leaders actively managed a team of scientists, engineers, and technicians.

The Hubs are inspired by the lessons of these past successes. They will differ from the Department's other core energy R&D programs in their larger scale, their higher degree of integration of scientific research with engineering development, and their singular focus on driving energy technology solutions to their fundamental limits.

Taken together, DOE's ongoing programs in energy R&D and technology demonstration and deployment, the recently launched Energy Frontier Research Centers, ARPA-E, and the proposed Energy Innovation Hubs comprise a robust portfolio of unique energy R&D modalities that complement each other and that maximize the Nation's ability to achieve energy breakthroughs as quickly as possible.

DoE Energy R&D Programs
Unique energy R&D modalities that complement each other

	ENERGY INNOVATION HUBS	ENERGY FRONTIER RESEARCH CENTERS	ADVANCED PROJECTS RESEARCH AGENCY – ENERGY (ARPA-E)
DESCRIPTION & 2011 FUNDING REQUEST	$107 MILLION Large set of investigators spanning science, engineering, and policy disciplines focused on a single critical national need identified by the Department.	$140 MILLION Mostly multi-institutional centers composed of a self-assembled group of investigators, often spanning several science and engineering disciplines focused on the long term basic research needed to overcome roadblocks to revolutionary energy technologies in a particular area.	$300 MILLION Modeled after the successful Defense Advanced Research Projects Agency (DARPA), ARPA-E's mission is to fund projects that will develop transformational technologies that reduce America's dependence on foreign energy imports; reduce U.S. energy related emissions (including greenhouse gasses); improve energy efficiency across all sectors of the U.S. economy and ensure that the U.S. maintains its leadership in developing and deploying advanced energy technologies.
INVESTIGATORS AND THEIR INSTITUTIONS	Large set of investigators spanning multiple science and engineering disciplines and possibly including other non-science areas such as energy policy, economics, and market analysis. May be led by Labs or universities, nonprofit organizations or private firms. The model is the three existing Office of Science Bio-energy Research Centers.	Self-assembled group of ~6–12 senior investigators. May be led by DOE laboratories or universities. About two thirds of 46 EFRCs are led by universities.	Single investigator, small group, or small teams.
CENTRAL LOCATION?	Lead institution must provide a central location and strong scientific leadership. There must be a culture of empowered central research management.	Mostly multi-institutional centers, but with a clearly defined lead institution responsible for management.	Variable depending on project
DIVERSITY OF DISCIPLINES PER AWARD	Many	Several	Few
PERIOD OF AWARD AND MANAGEMENT	5 years. Managed by Offices across DOE. A Board of Advisors consisting of senior leadership will coordinate across DOE.	5 years. Managed by the Basic Energy Sciences program in the DOE Office of Science.	1–3 years. Managed by ARPA-E, which reports to the Secretary of Energy
AWARD AMOUNT	~$22 million in the first year with up to $10 million for infrastructure start-up; ~$25 million per year in subsequent years.	$ 2–5 million per year	$ 0.5–10 million per year
CORE MOTIVATION	Integrate from fundamental research through potential commercialization. The breadth and emphasis of activities will be influenced by the nature of the Hub. Some Hubs may place a greater emphasis on basic and applied research, while others may focus more on technology development. DOE determines the topical areas of the Hubs and FOAs are topic-specific.	Fundamental research with a link to new energy technologies or technology roadblocks. The investigators proposed the subject matter from among a large set of scientific grand challenges and energy-relevant topics identified in and the FOA.	High risk translational research driven by the potential for significant commercial impact in the near-term. In general, DOE determines the topics of interest, except for the initial FOA, which was broad-based.

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 well-prepared 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, 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 $2 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 medical, energy, defense and space exploration.

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Comments

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