National Cancer Institute

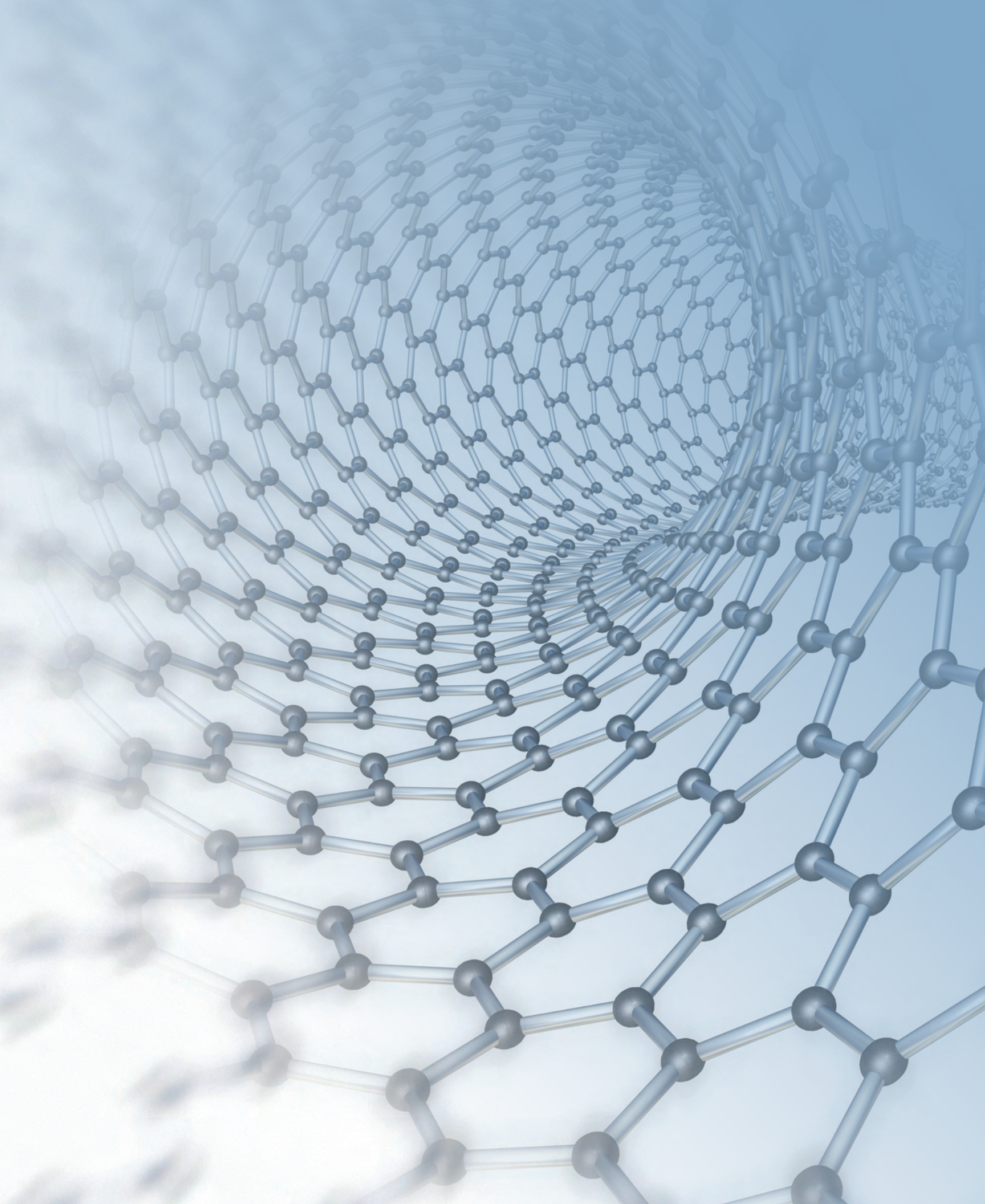
2012 NCI SBIR Investor Forum

April 18, 2012

Agilent Technologies
Aristotle Room
5301 Stevens Creek Blvd.
Santa Clara, CA 95051

Small Business Innovation Research (SBIR) &
Small Business Technology Transfer (STTR) Programs

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



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Welcome

April 18, 2012

Welcome to the annual National Cancer Institute (NCI) Small Business Innovation Research (SBIR) Investor Forum. Thank you for participating in such an important event. The forum is an excellent opportunity for you to learn more about the most promising small businesses developing innovative technologies for the treatment, diagnosis, and prevention of cancer. The 18 presenting companies were chosen from a highly competitive field of applicants based on their strength of research, product development, and market potential.

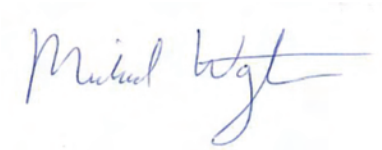
The NCI SBIR & STTR Programs represent a portfolio of over **400 projects** and an annual budget of over **$115 million**. The NCI SBIR Program is an integral source of capital that enables small businesses to move promising technologies through development and towards commercialization and remains one of the largest sources of early stage, non-dilutive technology financing available in the United States.

This is an exciting time to get involved with the SBIR Program. New legislation has increased the percentage of federal funding reserved for small businesses and expanded eligibility rules to include companies majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms. The NCI SBIR Development Center has also implemented a number of initiatives to maximize our impact, such as the Bridge Award, a $3 million funding opportunity that allows investors to work with the NCI to leverage their investments in the most promising companies. Today's investor forum is another valuable initiative designed to further help companies drive the commercialization of novel products to fight cancer.

We are pleased to play an active role in connecting the small businesses we are funding with investors. It is no secret that in today's economic climate, early-stage life sciences companies face challenges in accessing the capital needed to advance their discoveries. By doing our part to facilitate the success of these companies, we are also helping to ultimately fulfill the mission of NCI to reduce the burden of cancer.

Today's agenda was designed to allow ample time for you to interact with these companies and to learn about their products and investment opportunities. I encourage you to meet with them one-on-one. The NCI SBIR Development Center staff is also available today and going forward to discuss the many ways that the NCI can work with your organization to support the commercialization of emerging cancer technologies.

Throughout the day, I encourage you to participate by asking questions, sharing thoughts, networking with others, and learning more about these innovative companies which we believe are poised to play an important role in the fight against cancer.



Michael Weingarten, M.A.
Director, NCI SBIR Development Center

SBIR & STTR

Welcome

April 18, 2012

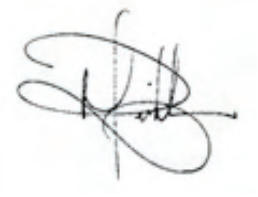
On behalf of Prescience International, I'd like to welcome you to the National Cancer Institute (NCI) Small Business Innovation Research (SBIR) Investor Forum. We are privileged to partner with the NCI in featuring best-in-class oncology companies.

With the recent economic challenges in securing startup funding, the Investor Forum is an important mechanism to support companies that are addressing the growing challenge of cancer. The companies selected to be here today are on the leading edge of innovation and will be considered for funding and partnerships to transform their discoveries into patient care.

As an operator of life-science innovation centers and institutes such as Janssen Research & Development's Janssen Labs, San Jose BioCenter, and UC Berkeley BioExec Institute, Prescience International focuses on accelerating the commercialization of science to advance medical care. As such, we have seen firsthand how funding sources have grown more cautious and scarce over the past few years and we are committed to finding ways to fill this gap. This is why we applaud the NCI's creative and proactive approaches to support the conversion of research into patient care. In fact, the NCI SBIR program has been one of the most visionary and entrepreneurial agencies in recognizing the need to expand its focus from funding science to helping it reach the bedside. For example, the NCI Phase II Bridge Award, aimed at doubling down on subsequent investment dollars, incentivizes both companies and investors to continue the long, expensive and risky development path to market. At Prescience, we take great pride in joining forces with an institution that not only takes the necessary early high-risk investments in our future innovation, but also acts on the bigger picture of patient care.

Today, we challenge you as investors and partners to play your part; to support innovation you believe can make a difference. My hope is that together we are more powerful in fighting a disease that continues to evolve and grow.

Sincerely,



Melinda Richter
Founder & CEO, Prescience International

PRESCIENCE INTERNATIONAL

Agenda

8:00 a.m. – 8:30 a.m.	**Registration and Breakfast**
8:35 a.m. – 8:45 a.m.	**Welcome** Speaker: Melinda Richter, M.B.A., Founder and CEO, Prescience International
8:45 a.m. – 8:50 a.m.	**Welcome from Janssen Pharmaceuticals**
8:50 a.m. – 9:00 a.m.	**The 2012 Investor Forum – Setting the Stage** Speaker: Michael Weingarten, M.A., Director, NCI SBIR Development Center
9:00 a.m. – 9:30 a.m.	**Keynote: Provocative Questions: Identifying Perplexing Problems to Drive Progress Against Cancer** Speaker: Ed Harlow, Ph.D., Special Advisor to the Director, NCI Ludwig Professor of Cancer Research and Teaching Professor of Biological Chemistry and Molecular Pharmacology, Harvard Medical School

Company Presentations

9:30 a.m. – 9:45 a.m.	Omniox, Inc.
9:45 a.m. – 10:00 a.m.	Altor BioScience Corporation
10:00 a.m. – 10:15 a.m.	A&G Pharmaceutical, Inc.
10:15 a.m. – 10:30 a.m.	NovoMedix, LLC
10:30 a.m. – 11:00 a.m.	**Networking Break/Partnering Meetings**
11:00 a.m. – 11:30 a.m.	**Catalyzing the Commercialization of Next Generation Cancer Technologies - An Update from the NCI SBIR Program** Speaker: Michael Weingarten, M.A., Director, NCI SBIR Development Center

Company Presentations

11:30 a.m. – 11:45 a.m.	Centrose, LLC
11:45 a.m. – 12:00 p.m.	Celek Pharmaceuticals, LLC
12:00 p.m. – 12:15 p.m.	AcuityBio Corpoation
12:15 p.m. – 12:30 p.m.	Thermedical, Inc.
12:30 p.m. – 12:45 p.m.	Oncoscope, Inc.

Agenda

12:45 p.m. – 12:50 p.m.	**Remarks from Mohr Davidow Ventures**
12:50 p.m. – 1:35 p.m.	**Lunch**
1:35 p.m. – 1:45 p.m.	**NHLBI Initiatives to Enhance the Commercial Potential of Innovations** Speaker: Jodi Black, Ph.D., Deputy Director, Division of Extramural Research Activities, National Heart Lung and Blood Institute, National Institutes of Health

Company Presentations

1:45 p.m. – 2:00 p.m.	Gamma Medica, Inc.
2:00 p.m. – 2:15 p.m.	Guided Therapeutics, Inc.
2:15 p.m. – 2:30 p.m.	Metabolomx
2:30 p.m. – 2:45 p.m.	Arbor Vita Corporation
2:45 p.m. – 3:00 p.m.	ApoCell, Inc.
3:00 p.m. – 3:30 p.m.	**Networking Break/Partnering Meetings**

Company Presentations

3:30 p.m. – 3:45 p.m.	Vala Sciences, Inc.
3:45 p.m. – 4:00 p.m.	Nortis, Inc.
4:00 p.m. – 4:15 p.m.	Firefly BioWorks, Inc.
4:15 p.m. – 4:30 p.m.	BioMarker Strategies, LLC

4:30 p.m. – 5:15 p.m. **Panel: Investor Perspectives on the Next Big Thing in Cancer Research**

Moderator: Michael J. O'Donnell, Partner, Morrison Foerster

Panelists:

- Alex DeWinter, Ph.D., Partner, Mohr Davidow Ventures
- Armen Shanafelt, Ph.D., Venture Partner, Lilly Ventures
- Brian Atwood, M.B.A., Managing Director, Versant Ventures
- Jeff Settleman, Ph.D., Senior Director, Oncology Discovery, Genentech

5:15 p.m. – 6:30 p.m. **Networking Reception**

Follow us on Twitter and join the conversation #NCIsbirIF

SBIR & STTR Programs at NCI

Leading Small Business Innovation and Commercialization in the Fight against Cancer

Small businesses are a vital resource for the development of innovative technologies and a mainstay of the American economy. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs were created by the U.S. Congress to strengthen the role of small, innovative companies in federally supported research and development. The National Cancer Institute (NCI) SBIR & STTR Programs seek small business participation in the development and commercialization of technologies that will help in the prevention, diagnosis, and treatment of cancer. The NCI SBIR & STTR Programs offer funding for small businesses developing cancer-related technologies, including: therapeutic agents and devices, diagnostics, research tools, innovations in the fields of imaging, cancer prevention, cancer control and epidemiology, and digital health. Entrepreneurs and small businesses in these areas are encouraged to explore grant and contract funding opportunities, as well as the numerous resources and assistance programs available to SBIR & STTR awardees.

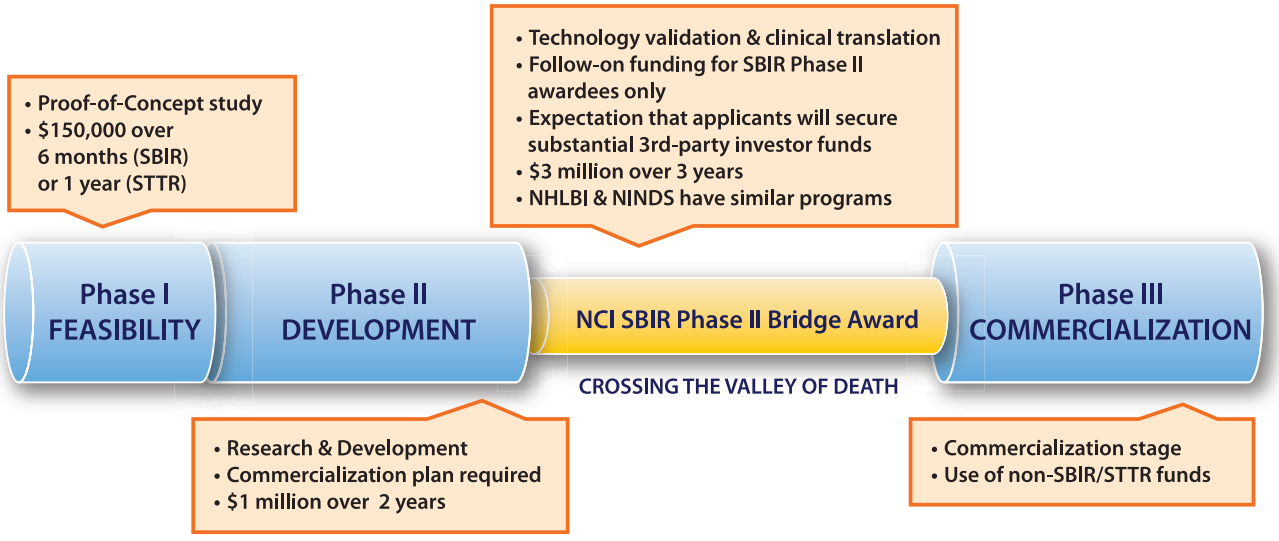
Program Goals

The SBIR & STTR Programs act as NCI's catalyst of innovation for developing and commercializing novel technologies and products to achieve NCI's mission to prevent, diagnose, and treat cancer. The NCI SBIR & STTR Programs serve as one of the largest sources of early-stage cancer technology financing in the United States.

The goals of the SBIR & STTR Programs are to:

- Stimulate technological innovation
- Meet Federal research and development needs
- Foster and encourage participation in innovation and entrepreneurship by socially and economically disadvantaged persons
- Increase private-sector commercialization of innovations derived from Federal research and development funding

Three Phases of the SBIR & STTR Programs



NCI may award budgets above the recommended guidelines, if appropriately justified.

SBIR & STTR Programs at NCI

Eligibility

The SBIR & STTR Reauthorization Act of 2011 introduced changes to eligibility, including the expansion of eligibility to small businesses majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms. At the time of printing this booklet, specific guidance had not yet been issued on the exact implementation of those changes. For the most current eligibility and application guidelines, please visit sbir.cancer.gov.

SBIR: Small Business Innovation Research

The NCI SBIR Program funds small business projects in early-stage research and development which have the potential for commercialization.

To participate in the NCI SBIR Program

- The small business concern (SBC) must be an organized for-profit business of 500 employees or fewer (including affiliates), located in the United States
- The SBC must be:
  - At least 51 percent U.S.-owned by individuals and independently operated

  OR
  - At least 51 percent owned and controlled by another for-profit business concern that is at least 51 percent U.S.-owned by individuals and independently operated
- The Principal Investigator's primary employment must be with the SBC at the time of award and for the duration of the project period
- At least 2/3 of the R&D work must be done by the proposing SBC for a Phase I, and at least 1/2 of the work for a Phase II

STTR: Small Business Technology Transfer

The NCI STTR Program is similar in structure to the SBIR Program but funds cooperative research and development projects involving a small business and a research institution (i.e., college or university, federally-funded research and development center, or non-profit research institution). The purpose of the STTR Program is to create an effective vehicle for moving ideas from our nation's research institutions to the commercial market.

To participate in the NCI STTR Program

- The SBC must meet the same size and ownership guidelines as for the SBIR Program. There is no size limit on the research institution
- The company must be engaged in a formal cooperative research and development effort with a U.S. research institution (i.e., college or university, federally-funded research and development center, or non-profit research institution)
- A minimum of 40 percent of the work must be done by the small business and a minimum of 30 percent of the work must be done by the research institution
- The Principal Investigator's primary employment may be with either the SBC or the research institution

For more detailed eligibility criteria, visit http://sbir.cancer.gov/about/eligibility.

SBIR & STTR Programs at NCI

Benefits of the SBIR & STTR Programs

The National Cancer Institute is committed to catalyzing the development of innovative technologies that advance cancer research, prevention, diagnosis, and treatment. NCI has been involved in more than 70 percent of the anticancer therapeutics on the market today and is working diligently to support the development of the next generation of cancer technologies. The NCI SBIR Development Center understands that attracting promising small businesses and investors committed to supporting technology development is critical in the fight against cancer. That is why the NCI SBIR Development Center helps small businesses progress from the early technology development phase towards commercialization, by funding research, facilitating strategic partnerships, and providing advice to companies. The NCI SBIR & STTR Programs provide a range of incentives for small businesses and investors to consider SBIR & STTR funding:

- Awards are not loans; no repayment is required.
- Funding is non-dilutive capital and does not impact the company's stock or shares.
- Intellectual property rights to technologies developed under these programs are retained by the small business concern.
- Awards provide recognition, verification, and visibility.
- Projects are vetted through NIH's rigorous scientific peer review.
- Funding can be used as a leveraging tool to attract additional funding.

Companies and investors alike have benefited from working with the NCI SBIR Program. Companies such as MedImmune, Illumina, Affymetrix, and Accuray all received early-stage technology funding from the NCI SBIR Program. The next wave of leading SBIR-funded small businesses developed relationships at the 2010 NCI Investor Forum that led to deals of over $230 million. If you are interested in learning more about SBIR's portfolio of projects and the small businesses leading them, please do contact us today at the NCI Investor Forum and throughout the year.

Providing Guidance, Support, and Connections to Further Science

The NCI SBIR Development Center was created in 2008 to advance the goals of the NCI SBIR & STTR Programs. It is staffed by a dedicated team of scientists with wide-ranging and extensive technical and industry experience. Each program director collaborates with other NCI divisions to integrate small business initiatives with NCI priorities. Program directors provide oversight throughout the award period and mentor awardees in their technology goals and commercialization strategy. They also connect awardees to a comprehensive network of industry, investor, and academic partners, as well as valuable NIH and NCI resources.

NCI SBIR Program staff actively engages in outreach efforts to the small business community, entrepreneurship organizations, and industry leaders in order to attract the most innovative small businesses to apply for SBIR/STTR funding and demystify the application process for potential awardees. Outreach efforts include participation in leading trade conferences, prestigious scientific meetings, and workshops held in key biotechnology industry clusters across the United States.

NCI SBIR Development Center Initiatives

Driving Innovation in Emerging High Impact Technology Areas: Contract Solicitations

In 2007, a new initiative was launched to promote NCI-directed research and development through contract solicitations. The goal is to drive innovation in emerging high impact technology areas within the mission of the NCI that are ripe for private sector investment. NCI SBIR Development Center staff develop contract topics that lend themselves to ground-breaking solutions based on strong scientific and market needs.

SBIR & STTR Programs at NCI

Crossing the "Valley of Death": The NCI SBIR Phase II Bridge Award

The SBIR Phase II Bridge Award is a novel public-private partnership that facilitates the transition of small businesses into commercially viable entities. Launched in 2008 to create more funding opportunities for small businesses in a risk-averse economic climate, the Bridge Award provides up to **$3 million** over three years beyond the SBIR Phase II Award to help awardees cross the "Valley of Death" – the funding gap between the usual end of SBIR funding for a project and the subsequent round of financing needed to commercialize the technology.

NCI funding mitigates risk for external investors and incentivizes investments earlier in the development process by giving competitive preference to applicants who can secure third-party investments that equal or exceed the requested NCI funds. This mutually beneficial partnership provides shared investment risk between NCI and external investors, as well as shared technology and company vetting through scientifically rigorous NIH peer review that complements due diligence performed by third-party investors.

From FY 2009 – 2011, 12 Bridge Awardees have leveraged their total **$31.4 million** of Federal funding with **$72.7 million** in third-party investment, slightly more than $2 of third-party investment per $1 of Federal funding. Projects range from first-in-class cancer therapeutics to innovative imaging devices that enable earlier cancer diagnosis.

Four of the companies presenting at this year's Investor Forum are Bridge Awardees: Guided Therapeutics, Gamma Medica, Altor BioScience, and Oncoscope.

Connecting Awardees with Investors: The NCI SBIR Investor Forum

The 2012 NCI SBIR Investor Forum is the third such event designed to connect the top NCI SBIR awardees with life science investors and strategic partners. Presenting companies were reviewed by a panel of investment and industry experts and selected to showcase their innovative technologies. **In 2010, relationships established at the NCI SBIR Investor Forum resulted in more than $230 million in deals to advance companies on the cutting-edge of cancer technology development.**

NIH Technical Assistance Programs

To help NIH SBIR awardees move their products into the marketplace, NIH has developed programs to provide technical and commercialization assistance specific to the individual needs of NIH SBIR awardees. Additional information about these programs is available at http://grants.nih.gov/grants/funding/tap.htm.

Niche Assessment Program (NAP)

NAP helps Phase I awardees assess market opportunities, evaluate the needs and concerns of their end-users, and discover new markets for possible entry of their SBIR-developed technology. For more information, visit http://grants.nih.gov/grants/funding/nap.htm.

Commercialization Assistance Program (CAP)

CAP assists Phase II awardees with developing and implementing an appropriate business strategy to commercialize the products or services that have resulted from NIH-supported SBIR awards. Advice is provided regarding business plan development, as well as regulatory and licensing issues. For more information, visit http://grants.nih.gov/grants/funding/cap.

SBIR & STTR Programs at NCI

Additional NIH Resources

NIH and NCI have a number of programs beyond grant funding to accelerate the development of therapeutics and diagnostics. A few resources are listed below.

NCI Clinical Assay Development Program (CADP)

The NCI's CADP provides access to tissue and laboratory resources for analytical and clinical validation of assays. Eligible applicants must have a working prototype assay with a clearly defined clinical use. The next submission deadline is June 15, 2012. For more information, visit http://cadp.cancer.gov.

NCI Experimental Therapeutics (NExT)

The NExT pipeline is designed to assist the clinical translation of novel therapeutic interventions by providing access to drug discovery and development resources. NCI partners with successful applicants to facilitate the milestone-driven progression of new anticancer drugs (small molecules, biologics) and imaging agents towards clinical evaluation and registration. The next submission deadline is June 15, 2012. For more information, visit http://next.cancer.gov.

Bridging Interventional Development Gaps (BrIDGs)

Formerly known as NIH-RAID, the BrIDGs program makes available, on a competitive basis, certain critical resources needed for the development of new therapeutic agents. Successful applicants receive access to NIH contractors who conduct preclinical studies at no cost to the investigator. In general, synthesis, formulation, pharmacokinetic, and toxicology services in support of investigator-held Investigational New Drug (IND) applications to the FDA are available. For more information, visit http://nctt.nih.gov/bridgs.

Therapeutics for Rare and Neglected Diseases (TRND)

The TRND program performs preclinical and early clinical development of new drugs for rare and neglected diseases, and develops new technologies and paradigms to improve the efficiency of therapeutic development for these diseases. Applicants collaborate with intramural NIH drug development scientists to develop the projects into clinical stage programs. For more information, visit http://nctt.nih.gov/trnd.

NCI SBIR & STTR Funding Opportunities

Contract Solicitations

Application typically due in November

The NCI SBIR Development Center offers contract funding opportunities once a year in a range of novel technology areas to help successfully finance and advance innovations towards commercialization. From FY 2011– 2012, NCI directed more than $20 million to fund targeted areas of innovation through SBIR contract topics. This funding for small businesses supports the research and development of anti-cancer agents, biomarkers, health information technology, nanotechnology, proteomics, pharmacodynamic assays, and many other areas of interest to the NCI.

Phase II Bridge Award

New announcement coming soon

The SBIR Phase II Bridge Award is specifically designed to augment previously funded NIH-wide SBIR Phase II projects that require additional funding to achieve key technical and regulatory milestones along the path toward commercialization.

Grant Funding Opportunities

Omnibus Solicitation

Applications due: April 5; August 5; December 5

The Omnibus solicitation encourages investigator-initiated grant applications in a broad range of areas. Funding opportunities are intended for U.S. small businesses that have the research capabilities and technological expertise to contribute to the research and development missions of the awarding components identified in the Omnibus solicitation.

Cancer Diagnostic and Therapeutic Agents Enabled by Nanotechnology (PAR-10-286)

Applications due: July 9, 2012; November 9, 2012; March 8, 2013; July 8, 2013

This Funding Opportunity Announcement (FOA) encourages proposals to develop new, or to improve existing application(s) of, nanotechnology-based therapeutics and/or *in vivo* diagnostics. This FOA will specifically support pre-clinical optimization and testing of these cancer-relevant nanotechnology applications against the intended cancer type. To facilitate these steps, the NCI will assist the awardees in various ways, including the support through the NCI-sponsored Nanotechnology Characterization Laboratory.

Image-Guided Cancer Interventions (PA-10-079/PA-10-080)

Applications due: August 5, 2012; December 5, 2012

This FOA encourages proposals for the development and clinical validation of systems for image-guided interventions (IGIs) for cancer. Specifically, the goals of this program are to provide support for: the development and optimization of fully integrated cancer imaging, monitoring, and therapy systems; the validation of integrated IGI systems through clinical evaluations; the development of multiple prototype integrated IGI systems as required for multisite clinical evaluations; and partnerships among small business, large business, and academic clinical centers, as well as small business joint ventures, in order to reach the research goals.

For the most current NCI SBIR & STTR funding opportunities, visit sbir.cancer.gov/funding, sign-up to receive e-mail notifications, and follow us on Twitter @NCIsbir.

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Speakers

Michael Weingarten, M.A.

Director, NCI SBIR Development Center

Michael Weingarten is the Director for the Small Business Innovation Research (SBIR) Development Center at the National Cancer Institute (NCI), one of 27 Institutes of the National Institutes of Health (NIH) in Bethesda, Md. In this role, Mr. Weingarten leads a team of nine Program Directors who manage all aspects of the NCI SBIR & STTR Programs including a portfolio of over $115 million in grants and contracts annually. The SBIR & STTR Programs are NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

In his current role, Mr. Weingarten has implemented a set of key initiatives to optimize the performance of the NCI SBIR Program at the NIH. Michael established a new model at the NCI to manage the program via the development of a dedicated SBIR Development Center. This Center is staffed with leading experts from both industry and the NIH who have specialized experience in developing and commercializing cancer technologies, managing small businesses, as well as fostering strategic partnerships to advance cancer research concepts to clinical practice.

Under Mr. Weingarten's leadership, the NCI SBIR Development Center has launched a range of innovative programs to facilitate the success of small businesses in the cancer space. One of these initiatives is a program for the NIH known as the SBIR Phase II Bridge Award, which more than triples the amount of funding available to applicants through the NCI SBIR Program. The Phase II Bridge Award helps small businesses "bridge" the funding gap known as the "Valley of Death," that currently exists between the end of the SBIR Phase II Award and the next round of financing needed to advance a promising cancer therapy or imaging technology. This award also incentivizes partnerships between NIH's SBIR Phase II awardees and third-party investors and/or strategic partners.

Now in its fourth year, the NCI has issued twelve Bridge Awards for a total of $31 million in NCI funding. These awards support multi-year projects in cancer imaging, molecular diagnostics, and drug development. Two Bridge Awardees have already advanced their research to Phase II clinical trials. Mr. Weingarten also developed the concept for the NCI SBIR Investor Forum to further help small businesses raise funds from investors or strategic partners.

Prior to joining the NIH, Mr. Weingarten was the manager of partnership development activities for NASA's Technology Transfer program which included the SBIR program. In his 12 years with NASA Headquarters in Washington, D.C., Mr. Weingarten played a major role in the creation and design of NASA's Technology Transfer program – a network of 10 NASA research centers and six regional technology transfer centers.

Mr. Weingarten has a bachelor's degree in political science from Northwestern University, Chicago, Ill., and a master's degree in political science from Columbia University in New York City.

Session Description

Catalyzing the Commercialization of Next Generation Cancer Technologies – An Update from the NCI SBIR Program

11:00 a.m. – 11:30 a.m.

The Small Business Innovation Research (SBIR) program is a critical source of non-dilutive financing for early stage companies, providing over $2 billion annually to develop next generation technologies. New legislation signed on December 31, 2011 introduced exciting changes that will increase the funding levels dedicated to the program and expand eligibility to small businesses that are majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms. These changes will make it possible for more companies and investors to capitalize on new initiatives at the National Cancer Institute's (NCI) SBIR Development Center that go beyond funding to help promising startups advance technology development toward commercialization. These initiatives help fill the gap in the availability of early stage funding created when investors and strategic partners moved towards clinical-stage investments. SBIR funds serve as a key bridge between initial angel funding and more significant angel capital, venture capital, or strategic partnerships. New initiatives, such as the NCI SBIR Bridge Award ($3 million awards where NCI co-invests with private investors) and an Investor Forum (connecting innovative SBIR awardees with top tier investors and partners) are examples of how SBIR programs facilitate the follow-on investments needed to move a product towards the market. There are early signs of the success of these programs. Third-party investors, including venture capitalists and other strategic partners (e.g., big pharma) **have provided over $72 million** in funding to Bridge Awardees. This provides NCI a leverage of more than 2 to 1 for every dollar it invests. Relationships established at the 2010 Investor Forum have resulted in more than $230 million in deals– an amount that reflects **twice** the value of the entire NCI SBIR budget. Changes introduced in the legislation make it easier than ever for small businesses and private investors to leverage Federal investment in research and development.

Speakers

Jodi B. Black, Ph.D.

Deputy Director, Division of Extramural Research Activities, National Heart Lung and Blood Institute, National Institutes of Health

Dr. Black has over 20 years of scientific research and research administration experience with a diverse background in basic and clinical science, programmatic administration, and leadership. She has developed, implemented, and managed large, diverse, multidisciplinary scientific programs and projects in areas including infectious diseases, cancer and genomics, has established research resources and enhanced their utilization, has promoted training and career development, and has developed strategic alliances between academic, healthcare and commercial organizations to leverage resources and capacity across institutions. As Deputy Director, Division of Extramural Research Activities (DERA), National Heart Lung and Blood Institute (NHLBI), National Institutes of Health, she provides scientific and management leadership and oversight of extramural research and training programs that are remarkable in their diversity, scope, and funding. DERA scientific activities span the Institute's entire $2.8 billion research portfolio involving cardiovascular, lung, blood diseases, sleep disorders, and blood resources and encompass basic, clinical, and population-based research and training. Dr. Black currently also serves as the Acting-Director of the Office of Translational Alliances and Coordination, providing leadership and coordination to accelerate the translation of basic discoveries and innovations into new diagnostics, devices, and therapeutics. The Office facilitates identification of emerging areas of translational opportunities and provides functional integration by developing interdependent teams that leverage resources and intellect across the NHLBI and with other ICs, agencies, and organizations.

Dr. Black was previously VP of Research Administration at the Translational Genomics Research Institute (TGen) where she developed, implemented, managed and directed the policies and processes of the pre-award and departmental research administration functions. She oversaw the activities of the Office of Sponsored Research, the Office of Special Scientific Programs and the Office of Research Compliance. She was responsible for interdisciplinary scientific program coordination and oversaw the scientific and technical development of proposals, working directly with faculty and administrative staff to identify relevant funding opportunities, facilitate interactions between TGen faculty and funding organizations and track status of all proposals. She developed and led high priority initiatives in both the national and international arena.

Previously, Dr. Black served as the Director of the Office of the AIDS Malignancy Program, National Cancer Institute (NCI), where she developed and maintained a diverse portfolio of AIDS oncology initiatives that included clinical trials, biospecimen resources, epidemiology cohort studies, centers programs and investigator-initiated awards. She simultaneously held a position in the NCI Office of International Affairs as an International Project Officer and introduced an international research agenda that included training and capacity building for AIDS, viral oncology and cancer research in developing countries. Dr. Black also served as the NCI AIDS Coordinator where she coordinated AIDS and cancer efforts across the NCI, facilitated management of the NCI AIDS budget allocation and served as the NCI representative and liaison to the NIH Office of AIDS Research (OAR) to develop the AIDS Malignancy priorities, objectives and strategies for the annual NIH Plan for AIDS Research on behalf of the NCI.

Session Description

NHLBI Initiatives to Enhance the Commercial Potential of Innovations

1:35 p.m. – 1:45 p.m.

The National Heart, Lung, and Blood Institute (NHLBI) recently established the Office of Translational Alliances and Coordination (OTAC) to facilitate the translation of basic research discoveries into products that improve patient care and public health. OTAC develops, implements and leads programs that help create recognizable commercial value for innovations that could lead to novel diagnostics, devices, therapeutics and tools for heart, lung, blood, and sleep diseases and disorders. The Office is also charged with identifying emerging translational opportunities, serving as a focal point for extramural researchers for information on NHLBI-wide small business technology development opportunities and developing public private partnerships. These activities are in part accomplished through the following new programs:

1. **The Centers for Accelerated Innovations** will foster both the development of high priority early-stage technologies within the NHLBI's mission and the innovator in a manner consistent with business case development and regulatory requirements by providing (A) funding for the scientific feasibility studies required to advance the technology through the product definition stage (e.g. prototype development, validation, or proof of concept studies), (B) unified and coordinated access to expertise in areas required for early technology development, including scientific, regulatory, business, legal, and project management, (C) access to existing NIH resources, and (D) training and hands-on experience in entrepreneurship.
2. **The NHBLI SBIR Bridge Award** will fill the funding gap that often exists between the end of an SBIR Phase II award and the next round of financing needed to advance a promising technology toward commercialization.
3. **The NHLBI SBIR-TT Award** enables transfer of NHLBI intellectual property from the intramural labs to the small business community.

Speakers

Melinda Richter, M.B.A.

Founder & CEO, Prescience International

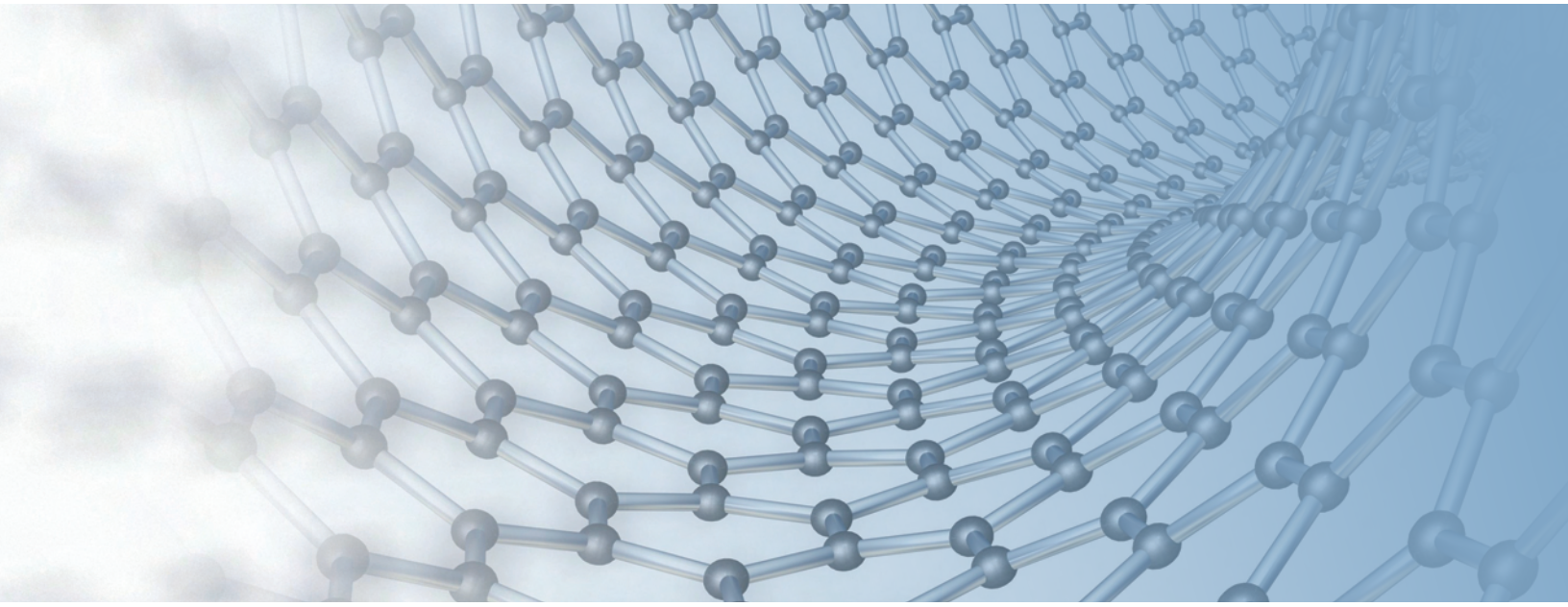
With over 15 years of global experience in creating, financing and managing innovative companies in emerging and convergence technologies, Melinda Richter specializes in accelerating the development of products-to-market, and companies-to-investment. She is the Founder and CEO of Prescience International, a full-scale management firm which focuses on accelerating the commercialization of science and technology by starting and operating life science and cleantech centers of innovation, including incubators, institutes and foundations. Prescience centers of innovation include, Janssen Labs, the San Jose BioCenter and the Environmental Business Cluster.

For Janssen Labs, located at Janssen Research & Development in San Diego, she guides an operations management team to enable innovative life sciences companies to rapidly deliver better solutions to the healthcare challenges faced today.

In addition to Janssen Labs, the Prescience innovation center portfolio includes the San Jose BioCenter. Under Ms. Richter's leadership, the San Jose BioCenter—a $15 million state-of-the-art 40,000 square-foot life science research center and incubator—was named one of the best life science incubators in the U.S. by CNN, was honored by the National Business Incubation Association with its 2009 Incubator of the Year Award, and was granted the Harvard's Bright Ideas Award.

Also in San Jose is the Environmental Business Cluster (EBC)—one of the first cleantech incubators ever to be established in the U.S. Ranked as one of the "Top 10 Incubators Changing the World" by Forbes.com, one of the "Top 10 Start Up Incubators to Watch" by Inc.com, one of the top incubators in the country by CNN, and named by Popular Science Magazine as one of three Places Where Inventors Are Born, the EBC has successfully attracted more than 180 cleantech companies and continues to lead the way in pushing forward innovative emerging green technologies.

Ms. Richter has served on the governing board of the National Business Incubation Association and currently sits on boards of University of California Berkeley's Haas School of Business Center for Executive Education BioExec Institute, the San Jose State University's Masters of Biotechnology Program, and UC San Francisco's School of Dentistry. She holds a Bachelor of Commerce from the University of Saskatchewan in Canada and an M.B.A. from INSEAD in France.



Keynote

Keynote Speaker

Ed Harlow, Ph.D.

Special Advisor to the Director, NCI

Ludwig Professor of Cancer Research and Teaching

Professor of Biological Chemistry and Molecular Pharmacology, Harvard Medical School

Dr. Harlow and his laboratory study the mechanisms that underlie the early stages of cancer development. He is best known for advances in our understanding of how cells determine when it is appropriate to divide. In 1988, his lab discovered how some viruses alter cell proliferation by using viral proteins to interact with and inactivate negative regulators of proliferation. Loss of these "brakes" on proliferation leads to cell division at inappropriate times. This model is widely applicable to cancer, and the discovery of how these viruses subvert cell regulation led to major advances in our knowledge of how cells control cell division. These contributions have been recognized by many awards, including the Sloan Prize from the General Motors Research Foundation, Bristol-Myers Squibb Award for Distinguished Achievements in Cancer Research, and Medal of Honor from the American Cancer Society. Dr. Harlow was elected to the National Academy of Sciences in 1993 and the Institute of Medicine in 1999. He is currently a Professor of Biological Chemistry and Molecular Pharmacology at Harvard Medical School where he holds the Virginia and DK Ludwig Chair for Cancer Research and Teaching.

Dr. Harlow did his undergraduate training at the University of Oklahoma and received his Ph.D. from the Imperial Cancer Research Fund Laboratories (London, England) in 1982. Much of his early work on the function of viral proteins was performed while on staff at Cold Spring Harbor Laboratory from 1982 to 1990. In 1990 he moved to Boston to become the Scientific Director of the Massachusetts General Hospital Cancer Center. From 1995 until 1998 he led the planning efforts for the nation's cancer research efforts while an Associate Director at the National Cancer Institute, and he currently serves as a Senior Advisor to the Director of the National Cancer Institute. From 2009 to 2011, while on leave from Harvard, Dr. Harlow was the Chief Scientific Officer of Constellation Pharmaceuticals, a biotechnology company in Cambridge, MA, that is developing small molecule inhibitors for cancer therapeutics. He is also co-author of one the most widely used manuals for biology research, entitled Antibodies, A Laboratory Manual, and he has published extensively in distinguished peer-reviewed journals.

Keynote Description

Provocative Questions: Identifying Perplexing Problems to Drive Progress Against Cancer

9:00 a.m. – 9:30 a.m.

During this session, Dr. Harlow will share insights and updates on the NCI's Provocative Questions Initiative. This initiative has pooled the collective imaginations of the cancer research community to join in a new effort to fight cancer. Engaging a diverse range of scientists to define and then solve the major unstudied or underappreciated problems in oncology, the Provocative Questions Initiative excites curiosity, stimulates new ideas and technologies, and inspires progress. As part of this effort, the cancer community (including scientists from academia and industry, patients, advocacy groups, and health professionals) was asked to pose intriguing research questions in areas that are still unsolved or neglected. Questions were solicited through town hall workshops at NIH and various locations across the U.S. and via a public-access website (http://provocativequestions.nci.nih.gov). So far, over 35,000 community members throughout the world have participated.

Dr. Harlow will discuss the questions that have been solicited to-date, highlighting the 24 questions included in a Funding Opportunity Announcement entitled "Research Answers to NCI's Provocative Questions," that is currently nearing funding decisions. For these key priority areas, NCI has set aside $15 million for fiscal year 2012 to support the best ideas for answering any of these provocative questions. Another funding opportunity will be released in 2012, with submissions planned for later this year. The applications are judged on a competitive basis to assess the relative power of the proposed ideas and solutions to address them.

A few examples of provocative questions include:

- How does obesity contribute to cancer risk?
- Are there new technologies to inhibit traditionally "undruggable" target molecules, such as transcription factors, that are required for the oncogenic phenotype?
- Can tumors be detected when they are two to three orders of magnitude smaller than those currently detected with *in vivo* imaging modalities?

Panel

Panel Moderator

Michael J. O'Donnell

Partner, Morrison Foerster

Michael O'Donnell is a partner in Morrison Foerster's Palo Alto office, specializing in corporate and securities law. He has more than 25 years of experience providing general corporate representation to biopharmaceutical and other life sciences companies. He offers particular expertise in venture capital financings, public offerings, mergers and acquisitions, strategic alliances, technology licensing, and corporate spin-out transactions. He represents numerous public and private biopharmaceutical, medical device, diagnostic, and instrumentation companies.

Michael was the founding attorney and lead attorney on the initial public offerings for companies such as Illumina, Pain Therapeutics, Cytokinetics, NeurogesX, Neurocrine Biosciences, Sequana Therapeutics, Ciphergen Biosystems, Argonaut Technologies, and Microcide Pharmaceuticals.

He also has extensive experience with negotiating strategic alliances, representing clients in major collaborations with GSK, Amgen, Schering-Plough, J&J, Daiichi, Astellas, Valeant, and King Pharmaceuticals and most recently with Pfizer and Eisai.

Michael was also the lead attorney responsible for negotiating a number of notable biopharmaceutical spin-outs, including Onyx Pharmaceuticals (Chiron-Cetus), Tularik (Genentech), X-Ceptor (Ligand Pharmaceuticals), Metabasis (Gensia Sicor), and Iconix (Microcide Pharmaceuticals) and as well on the reverse merger of Transcept Pharmaceuticals with Novacea, creating a new publicly traded entity.

Michael did his undergraduate training at Bucknell University, and received his J.D. from Harvard Law School. Michael has published several articles and is a frequent speaker on corporate strategic alliances and creative financing techniques for life science companies.

Panel Description

Investor Perspectives on the Next Big Thing in Cancer Research

4:30 p.m. – 5:15 p.m.

What is it that VCs or strategic partners look for when investing in early-stage cancer companies these days? The financing of early-stage cancer technologies has changed dramatically over the past few years. Yet, with the appropriate fit, the right deal can still be struck and a mutually beneficial relationship formed. This panel will discuss some of the emerging new trends in the financing of early stage cancer companies – what kind of deals are getting done, and what promising new research areas are corporate investors pursuing? Panelists will also provide insight about how non-dilutive funding sources, such as SBIR, fit into the overall paradigm. Panel members, including VCs and corporate investors, will discuss what is coming next, and how we can all work together to advance the progress of cancer research and technology development.

Panelists

- Alex DeWinter, Ph.D., Partner, Mohr Davidow Ventures
- Armen Shanafelt, Ph.D., Venture Partner, Lilly Ventures
- Brian Atwood, M.B.A., Managing Director, Versant Ventures
- Jeff Settleman, Ph.D., Senior Director, Oncology Discovery, Genentech

Company Overviews

Reference to an specific disease statement, commercial product, process, service, manufacturer, and/or company does not constitute an endorsement by the NCI SBIR & STTR Programs or any other part of the U.S. Government.

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Stephen Cary, Ph.D.
Chief Executive Officer
510-333-9296
scary@omnioxinc.com

Tumor Re-Oxygenating Chemo-Radiosensitizers
9:30 a.m. – 9:45 a.m.

Company Background
Omniox is a biotechnology company commercializing a breakthrough oxygen delivery technology called H-NOX for a broad range of peripheral hypoxia diseases including cancer, acute cardiovascular ischemia, wounds, and trauma. The H-NOX technology directly overcomes key reasons for the failure of prior efforts in this area. The technology was originally developed in the laboratory of Michael Marletta, currently President and CEO of The Scripps Research Institute. Omniox currently employs seven full-time scientists and has laboratory operations in Mission Bay, San Francisco, and Sunnyvale, Calif.

Technology Overview
Omniox is a preclinical/IND-stage company initially focused on developing an H-NOX product that sensitizes hypoxic tumors to radiation and chemotherapy. Preclinical data with the lead H-NOX candidate demonstrate substantial re-oxygenation of hypoxic tumors. When combined with radiation, there is a significant delay in tumor growth and enhanced survival in relevant mouse models of human cancer including glioblastoma, with a promising safety profile.

The University of California, San Francisco Neuro-Oncology Clinical Site Committee has approved H-NOX for parallel Phase IB clinical trials in recurrent and newly diagnosed glioblastoma. A real-time pharmacodynamic biomarker for hypoxia has been validated in the clinic and will be used to identify appropriate patients and measure the biological effects of H-NOX in reducing tumor hypoxia.

Market Potential
Radiation therapy is the most common non-surgical treatment for cancer patients (more than chemotherapy and targeted therapies combined). Needham & Company estimates that an oxygen-delivery therapy to improve chemo-radiation would command $4,000 to $20,000 per round of chemo-radiation treatment and may represent a market of $3 to $5 billion per year. The competitive, regulatory, clinical, and reimbursement landscapes for this indication are compelling.

Competitive Advantage
Omniox's H-NOX oxygen carriers are designed to penetrate deep into the tumor tissue, beyond the reach of red blood cells. This approach is a major improvement over prior clinical efforts relying on manipulating red blood cells: this only succeeded in hyper-oxygenating normoxic tissues with minimal effects on hypoxic tumors. H-NOX is an entirely new approach to re-oxygenating hypoxic tumors to enhance chemo/radiosensitiation.

Financial Overview
Omniox has secured more than $4 million in NIH SBIR funding since 2009. We are actively seeking equity financing to match the NCI Phase IIB $3 million Bridge Award to advance a lead candidate through Phase IB clinical trials. This clinical milestone will create a significant value inflection for investors joining at this stage of development.

Omniox has received firm commitments for $1 million from high net worth investors, and is seeking a minimum of $2 million in additional investments to match the NCI Bridge Award.

Intellectual Property
In 2006, UC Berkeley filed broad patent claims to protect the core technologies, and Omniox continues to file for further protection of specific applications. Omniox holds an exclusive option to negotiate (with capped financials) for an exclusive worldwide license for all therapeutic and industrial uses of these technologies. The company has retained the law firm of Morrison & Foerster to oversee IP matters and the firm of Latham & Watkins for corporate affairs. More details on the current status of national filing phases of the core patents are available upon further request.

Company Overviews

Commercialization Strategy
Omniox expects to partner with or be acquired by a pharmaceutical company to successfully commercialize H-NOX for peripheral oxygen delivery. All major pharmaceutical companies are currently conducting clinical trials with chemotherapeutics or targeted therapies in combination with radiation, with the goal of enhancing the efficacy of radiation.

The lead H-NOX product will be best utilized by medical oncologists who oversee patient treatment plans as part of a team of oncology professionals, including a radiation oncologist. More than 90 percent of radiation oncologists practice within two blocks of medical oncology clinics, therefore, radiosensitizers can be infused at the medical oncology office prior to transport of the patient for radiation treatment.

Pipeline Products
H-NOX oxygen carriers have the potential to reduce tissue loss during myocardial infarctions and stroke, as well as in acute and chronic wound settings, a range of transplant surgeries, and ultimately may function as part of a resuscitation fluid in emergent situations. There is tremendous life cycle potential for H-NOX proteins beyond their utility in oncology.

Management Team
- Omniox is led by CEO and co-founder Stephen Cary, formerly in Research and Development/Market Strategy at Genentech.
- The Chair of the Scientific Advisory Board is co-founder, Michael Marletta, currently President/CEO of The Scripps Research Institute, member of the SAB of HHMI, and member of NAS and IOM. He has extensive experience in advising pharmaceutical companies in drug development.
- The business co-founder is Ajit Shah, who has a combined 24 years of experience as an entrepreneur, operating executive, and venture capitalist. He is active in Silicon Valley as an outstanding scientific and strategic advisor to start-ups.
- The IND Core Team is made up of experienced drug development veterans from Genentech, Quintiles, and Baxter Healthcare.

Altor BioScience Corporation

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Hing C. Wong, Ph.D.
President and CEO
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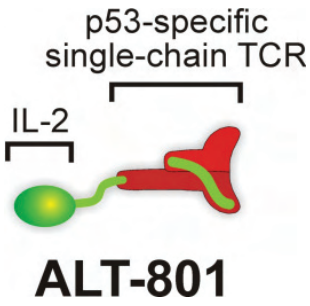
STAR™ Therapeutics for Cancer
9:45 a.m. – 10:00 a.m.

Company Background
Altor BioScience Corporation is a privately held, venture-backed, development-stage company engaged in the discovery and development of high-value, targeted immunotherapeutic agents for the treatment of cancer, viral infection, and inflammatory diseases, based on three revolutionary technology platforms. Altor was formed in 2002 by Hing C. Wong, Ph.D., and is based in Miramar, Fla., with 22 employees.

Technology Overview
Altor, a clinical-stage biopharmaceutical company with multiple on-going Phase II trials, has developed technology to produce biologically active, soluble T-Cell-Receptor molecules in a single-chain format (scTCR). These scTCRs can be modified into STAR™ fusion agents, which retain the ability of the TCR to specifically recognize novel targets on cancerous or virus-infected cells, including intracellular antigens that are not accessible to therapeutic antibodies. STAR molecules are ideally suited to deliver anti-cancer and anti-viral drugs, such as immunomodulatory cytokines, cytotoxic drugs, radioisotopes, and imaging agents, directly to diseased cells. Altor has developed a high-affinity scTCR that recognizes a peptide antigen derived from p53, which is over-expressed in roughly 50 percent of all human cancers. ALT-801 is a fusion of this p53-specific scTCR and the approved anti-cancer drug, Interleukin-2 (IL-2). ALT-801 is designed to deliver the IL-2 directly to the tumor site providing greater efficacy, lower toxicity, and better quality of life for patients.

Company Overviews



Market Potential

ALT-801 would benefit patients with bladder cancer, multiple myeloma, and melanoma. In 2010 in the U.S., 68,130 new cases of melanoma were diagnosed and 8,700 deaths occurred due to melanoma. In 2008, there were approximately 822,770 people alive in the U.S. who had a history of melanoma. It also estimated that 70,530 new cases of bladder cancer were diagnosed and 14,680 deaths occurred due to bladder cancer in the U.S. in 2010, and that there were approximately 537,428 people alive in the U.S. who had a history of bladder cancer in January 2008. In addition, an estimated 64,615 people in the U.S. were alive in 2008 with a history of multiple myeloma. This represents a market opportunity of over $3 billion in the U.S. alone. Bladder cancer, a major unmet medical need, is currently Altor's main development focus.

Competitive Advantage

STAR agents significantly broaden the spectrum of tumor- and virally-specific antigens that can be targeted for therapeutic intervention. Altor has demonstrated scTCRs can be used to create targeting molecules to recognize antigens that cannot be targeted by monoclonal antibodies for diagnostic or therapeutic purposes. Although there are no TCR-based products on the market, monoclonal antibodies for cancer had sales of $24 billion in 2010.

Financial Overview

Altor has raised $35.5 million in paid-in capital from institutional investors, including Sanderling Ventures and Florida Growth Fund, as well as from high net worth, private individuals. The company has been awarded $14 million in SBIR awards from NIH, FDA, and Gates Foundation grants. Altor is seeking $20 million in financing to support and complete the pivotal trial using ALT-801 for locally advanced and metastatic bladder cancer to gain accelerated approval.

Intellectual Property

STAR technology and ALT-801 are the subjects of 37 issued patents and 51 pending applications, including USP #7,456,263, EP 1,546,188.

Commercialization Strategy

Altor's short-term objectives are to continue clinical development of its lead product candidates, ALT-801 and ALT-803, through proof-of-principle Phase II clinical trials and then license these to a major biopharma/pharma partner for further development/commercialization. On a case-by-case basis, Altor will consider conducting a registration trial for FDA product approval.

Pipeline Products

- ALT-801 (p53-TCR/IL-2 fusion protein)
  - Phase II for treating metastatic melanoma (NCT01029873)
  - Phase II for locally-advanced/metastatic bladder cancer (NCT01326871)
  - Other Phase IB/II trials for superficial bladder cancer, multiple myeloma - supported by $3 million SBIR Bridge grant
  - Phase I/II Adonor lymphocyte infusion to treat Acute Myeloid Leukemia (NCT01478074)
- ALT-836 (anti-Tissue Factor Antibody partnered with Genentech)
  - Phase II for treating ALI/ARDS (NCT00879606) and Phase I/IIA for solid tumors (NCT01325558)
- ALT-803 (non-targeted IL-15 super agonist/IL-15Rα-Fc fusion complex)
  - Pre-IND for treating solid and hematological tumors

Management Team

- Hing C. Wong, Ph.D., President and CEO, is a 28-year veteran providing leadership, overall direction, fundraising, IND filing, and oversight of multiple products in clinical trials/commercialized. He has raised $65 million in private capital.
- Dean Taylor, Ph.D., Chief Business Development Officer, has 30 years of experience and is responsible for business development, contracts, strategy, and concluding deals.
- Peter Rhode, Ph.D., Vice President, R&D, leads product development, supervises R&D and manages the manufacturing and IP portfolio, and oversees IND filings.
- Jeff Weber, M.D., Ph.D., Consulting Medical Director, supports clinical development strategy and planning, and is a renowned clinical research oncologist and senior member of Moffitt Cancer Center.

Company Overviews

A&G Pharmaceutical, Inc.
www.agpharma.com
9130 Red Branch Road
Columbia, MD 21045

Ginette Serrero, Ph.D.
President and CEO
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gserrero@agpharma.com

GP88 Antibody for Treatment of Cancer
10:00 a.m. – 10:15 a.m.

Company Background
A&G Pharmaceutical (A&G), founded in 2000, is a privately held company based in Columbia, Md. A&G uses proprietary technology for rapid development of monoclonal antibodies (mAB) to unique cancer-specific theranostic targets, to develop novel therapy/diagnostic combination products that address a broad range of cancers. A&G holds a proprietary position on the detection and treatment of diseases related to the growth factor GP88 (progranulin). The company is currently developing a therapeutic mAB to treat lung and breast cancer. A&G has also developed clinically validated proprietary companion diagnostic products to identify and monitor patients treated with mAB. The company employs 22 people.

Technology Overview
Several peer reviewed studies have demonstrated that glycoprotein GP88 has a critical role in the proliferation and survival of cancer cells. A&G has developed a recombinant therapeutic anti-GP88 to treat cancers overexpressing GP88. Direct validation of GP88, as a novel therapeutic target, was provided by inhibition of GP88 expression and function in breast carcinoma cells resulting in both reduced proliferation *in vitro* and reduced malignancy *in vivo*. Xenograft data demonstrates that anti-GP88 is useful for the treatment of breast and lung cancers as a single agent. When used in combination with Tamoxifen in Tamoxifen-resistant tumors, anti-GP88 restores Tamoxifen sensitivity, leading to significant tumor reduction. Restored sensitivity to Tamoxifen and other anti-estrogen therapies is a major breakthrough, more than 50 percent of all patients on anti-estrogen develop resistance de novo or during treatment. Similar results were obtained with chemo resistant lung cancers. A&Gs pre-clinical candidate is ready to enter IND-enabling acute and repeat dose toxicology studies in primates.

Market Potential
GP88 therapy can address two leading cancers in the U.S., including: breast (220,000 new cases; 40,000 deaths annually) and lung (200,000 cases;160,000 deaths) cancers. More than 50 percent of lung cancer patients die within 5 years. There is an unmet need for targeted lung cancer therapies, especially among cancers that are chemo resistant. In the case of breast cancer even for Tamoxifen, a leading drug used to treat breast cancer, 40-50 percent of patients do not respond to initial treatment, while the majority of those patients that do respond can have the cancer become resistant during treatment. A&G has developed diagnostic kits to identify patients who are de novo resistant or who are becoming resistant and thus identify patients that are suitable for anti-GP88 therapy.

Competitive Advantage
GP88 is uniquely placed as a novel biological target for development of products for oncology:

- GP88 is a critical biological player in development, proliferation and survival, and drug resistance for several cancers.
- GP88 expression in tumor tissue has been statistically shown to be a prognostic indicator of poor patient outcome (disease-free and overall survival).
- GP88 is secreted by cancer cells and detectable in blood, making it an important target for therapeutic and diagnostic product development.
- Inhibiting GP88 with mAB reduces tumor growth and reverses resistance to hormone therapy in breast cancer.
- 2 GP88 Diagnostic tests have been clinically evaluated: (1) Tumor levels are prognostic, (2) Blood levels are linked to tumor growth and can be used to monitor treatment.

Herceptin remains the last major combination therapeutic and companion diagnostic co-development in oncology. GP88 is positioned to be the next major theranostic product.

Company Overviews

Financial Overview
A&G Pharmaceutical's financial overview includes:

- Seed capitalization of $1.5 million in 2002
- Closed a Series A round of $2 million in 2005
- Raised a total of $6.4 million in 2006 in form of strategic investment. As part of license agreement with Celltrion they agreed to provide cash and candidate development including initial manufacturing process development and materials for toxicology.
- Completed Series B prime financing of $4 million 2008.
- Profits from sales of custom monoclonal antibodies (www.precisionantibody.com); anticipated revenues for 2012 are more than $2.8 million.
- Seeking a $5.0 million investment to fund toxicology and first-in-human clinical studies.

Intellectual Property
Fifty patent applications and 49 patents (15 U.S. patents) granted worldwide covering therapy and diagnostic use of GP88.

Commercialization Strategy
A&G will enter safety/efficacy clinical studies of anti-GP88 in lung/breast cancer. During early clinical trials, A&G will pursue agreement(s) with key player(s) in the pharmaceutical/biotech industry active in the field of oncology. Such agreement(s) will dictate the commercialization strategy for anti-GP88.

Pipeline Products
GP88 has been implicated in several cancers and as such A&G is interested in developing its proprietary theranostic pipeline for use in cancers of the GI, prostate, and brain. Using A&G's proprietary antibody development technology the company is researching other cancer biomarkers for development along the theranostic pathway.

Management Team

- A&G's CEO, Ginette Serrero, Ph.D., has 25 years of experience in cancer research and 10 years in biotech management and has been instrumental in directing A&G's vision and assembling the management team.
- VP of Drug Discovery, Randy Barton, Ph.D., was previously the director of drug discovery, Boehringer Ingelheim, and has 20 years of experience validating small-molecule and biological drug candidates.
- VP of R&D Jun Hayashi, Ph.D., is an immunologist and inventor of A&G's proprietary mAB technology.
- COO Michael Keefe, MBA, is seasoned in raising capital and managing the growth of start-ups.
- VP of Product Management, David Hicks, has more than 20 years of experience with diagnostic products and clinical development.

NovoMedix

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Cathy A. Swindlehurst, Ph.D.
President and CEO
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Novel Small Molecule Anticancer Therapies
10:15 a.m. – 10:30 a.m.

Company Background
NovoMedix specializes in the development of small molecule inhibitors of multiple biological pathways that are critical drivers of disease and are relatively inactive in normal tissues and housekeeping processes, with an initial focus on cancer. NovoMedix targets underserved markets with unmet clinical needs, including triple negative breast cancer (TNBC), high risk B-cell acute lymphoblastic leukemia (B-ALL), and melanoma.

Technology Overview
NovoMedix has developed two new classes of small molecule translation initiation inhibitors with unique mechanisms of action as targeted therapies for high risk TNBC (estrogen and progesterone receptor, and HER2/neu-negative breast cancer). Lead compounds are currently in the preclinical stage and have been tested in an animal model of TNBC in which they significantly reduced tumor growth (better than paclitaxel) with no apparent toxicity. These novel compounds are promising clinical candidates and represent first-in-class small molecule therapeutics aimed at reducing recurrence and increasing survival rates for TNBC. Since these drug candidates are small molecules, they will be less expensive and easier to administer than biologics and should fit easily within the current treatment regimen.

Company Overviews

Market Potential

Breast, prostate, and colorectal cancer account for more than half of cancer patients in the United States. One in eight women in the U.S. will develop breast cancer during her lifetime. Although the overall survival rate for early stage breast cancer is high, triple negative breast cancers are particularly aggressive and are more likely to recur than other subtypes, resulting in a significantly increased risk of death. Currently, no targeted therapies exist for TNBC. Since more than 60 percent of triple negative breast tumors overexpress eIF4E (a critical factor in translation initiation), and high levels of eIF4E are correlated with recurrence and death, inhibitors of protein translation initiation should prove to be a viable targeted therapy for TNBC with high eIF4E.

Competitive Advantage

NovoMedix's most advanced drug candidates for the treatment of TNBC represent two new classes of translation initiation inhibitors with unique mechanisms of action. Besides the anti-viral drug, ribavirin, there are no viable drug-like inhibitors of translation initiation have been reported to date. More importantly, there are virtually no novel therapies in clinical trials for TNBC. Most ongoing trials for TNBC are on various combinations of existing chemotherapy drugs. Recent data suggests that at least one of these "first-in-class" compounds has the potential to enter into a Phase I clinical trial for TNBC.

Financial Overview

NovoMedix was established as a partnership in 2001 and converted to an LLC in 2010 in anticipation of angel or VC funding and/or corporate partnerships. NovoMedix is currently privately owned and has no venture capital investment. NovoMedix has raised $1.75 million in equity, government grant, and tax credit revenue. SBIR funding has allowed the company to increase its value without dilution. NovoMedix is seeking a strategic investment of $5 million to complete preclinical studies and file an IND for TNBC within 24 months. NovoMedix would then partner with a larger pharmaceutical company for clinical development and commercialization of a novel therapy for TNBC.

Intellectual Property

NovoMedix has filed a composition of matter patent application (PCT/US2011/039377) for the NM043 series of compounds for the treatment, prevention, and/or amelioration of various disorders, including cancer. In addition, NovoMedix is in the process of filing provisional patents on several other lead series.

Commercialization Strategy

NovoMedix's commercialization strategy is to design and execute an IND-enabling nonclinical safety program to support a Phase I clinical trial in patients with advanced metastatic disease and enter into partnerships with pharmaceutical companies for the clinical development and ultimate commercialization of novel small molecule drugs. NovoMedix plans to license its compounds in exchange for licensing fees, milestone payments, and royalties.

Pipeline Products

The NovoMedix pipeline contains several novel compounds in various stages of development. Most relevant to this project are follow-up studies that are planned to determine the efficacy of previously identified lead compounds for the treatment of metastatic breast cancer. In addition, several different novel lead compounds are currently under development for the treatment of high risk pediatric B-ALL. These compounds have demonstrated *in vitro* safety and efficacy and preliminary safety in animals. *In vivo* studies in mouse models of high risk B-ALL are the subject of a recently submitted Phase I SBIR proposal.

Management Team

- Cathy Swindlehurst, Ph.D., Founder and CEO, has 22 years of experience in biotechnology. Former V.P. at PanCel, MagneSensors, and NovaDx.
- Leah Fung, Ph.D., Founder and Exec. Director, Drug Discovery, has 20 years of experience in medicinal chemistry. Management positions at Structural Genomics, Structural Bioinformatics, and Celgene.
- Sabine Ottilie, Ph.D., Director, Molecular Oncology, has 20 years of molecular oncology research experience in academia and biotechnology.

Reference to an specific disease statement, commercial product, process, service, manufacturer, and/or company does not constitute an endorsement by the NCI SBIR & STTR Programs or any other part of the U.S. Government.

Company Overviews

Centrose, LLC
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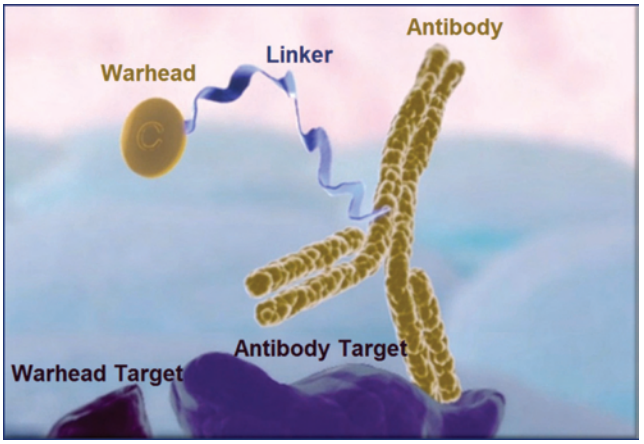
Stephen Worsley, M.B.A.
Chief Business Officer
650-814-5590
Worsley@centrosepharma.com

Extracellular Antibody Drug Conjugate Technology (EDC)
11:30 a.m. – 11:45 a.m.

Company Background
Centrose is a biotechnology company formed in 2006 and is focused on developing a novel antibody-drug conjugation (ADC) technology that targets a wide variety of diseased cells. Centrose discovered the first-ever synergistic drug targeting system called the Extracellular Drug Conjugate System (EDC). Centrose has 10 employees and projects to grow to 25 staff.

Technology Overview
Centrose is a preclinical stage company developing a novel ADC technology that targets a wide variety of diseased cells. Centrose discovered the first-ever synergistic drug targeting system called the EDC System. EDCs are like (ADCs), but are safer and more effective because they are not pro-drugs and only affect diseased cells. To modulate cell growth and activity, EDCs use antibodies (specific to diseased cells) attached to Centrose's proprietary modulating drugs to work in concert together – the two must be attached to work. Currently, Centrose has four EDC lead drug candidates. As a platform, the EDC system allows for the construction and development of targeted drugs that can be developed for multiple indications including cancer, inflammation, and diabetes.



Market Potential
Currently, Centrose has four lead programs that it anticipates moving into clinical trials in the next 24 months. The company's lead program, EDC1, is focused on the lung and metastatic cancer markets; specifically non-small cell lung cancer (NSCLC) and pancreatic cancer.

Competitive Advantage
There are limitations with regards to traditional antibody drug conjugates technologies:

- First, ADC cell internalization is inefficient and requires the use of very toxic drugs;
- Second, to become activated, the drugs must be released from the antibody;
- Third, once released, the drugs can interact with normal surrounding tissue leading to toxicity concerns.

In combination, these requirements present formidable design challenges and seriously limit the power of traditional antibody drug conjugates.

To address these problems, Centrose discovered and developed a revolutionary new type of ADC, called EDC. The Centrose EDC system is composed of three parts: a binding component that specifically targets diseased cells, a proprietary drug, and a linker that connects them. This is similar to the ADC system except that the EDC never requires drug dissociation or cell internalization, negating the three major problems of the ADC system.

Financial Overview
Centrose has raised $3.5 million from individuals and $1.5 million from government grants. The company is currently looking to raise $20 million under a Series A round to move Centrose's lead compound into and through Phase I clinical trials.

Company Overviews

Intellectual Property
Centrose technology is the sole property of Centrose. Centrose has applied for multiple U.S. and worldwide patents covering EDC technology. Centrose also has the freedom-to-operate in the space.

Commercialization Strategy
Centrose's business strategy is focused on producing the next generation of targeted therapies and to out-license these assets to select pharmaceutical companies. Strategic partnering is therefore critical to advance Centrose's novel therapeutics programs into clinical development and then to the market.

Pipeline Products
In addition to EDC1, Centrose has four other EDC programs:

EDC2: The antibody target is CD147 and is highly expressed on cancer cells where it facilitates invasion and metastasis. CD147 is also a biomarker for wide range of cancers. As proof of efficacy, Centrose has tested EDC2 and with gemcitabine on pancreatic cell line and demonstrated that EDC2 shows picomolar activity on PANC1 cell line verses gemcitabine, which demonstrated only micromolar activity. Gemcitabine is approved for the treatment of pancreatic cancer.

EDC3: The antibody target is CD44v6 and is associated with tumor progression, metastasis, and specifically with NSCLC lymph node metastasis. Centrose studies show Na,K-ATPase-and CD44v6 complexes on certain cancer cells, yet EDC3 is not toxic to human skin cells in culture (warhead target is low on normal skin).

EDC7: The antibody target for EDC7 is CD56 (aka NCAM-Neural Cell Adhesion Molecule). The mAB target, CD56, is also the target of ImmunoGen's lead internal program: IMGN-901. CD56 is highly expressed on the following human tumors SCLC, multiple myeloma, ovarian, and other related indications such as leukemia and Wilms' Tumor. Studies show Na,K-ATPase-and NCAM, form a complex on SCLC cells. EDC7 demonstrated low picomolar level activity when cancer cells express CD56; thus EDC7 may be an excellent candidate for SCLC.

Management Team
Dr. James Prudent is the CEO and founder of Centrose and brings more than 20 years of biotechnology. Before Centrose, Dr. Prudent served as Chief Scientific Officer and on the Board of Directors at EraGen Biosciences (sold to Luminex). Dr. Prudent received his doctorate in chemistry from the University of California at Berkeley.

Steve Worsley is the Chief Business Officer and brings 25 years in the biotechnology industry to Centrose. Mr. Worsley has executed numerous transactions in the mAB market; most notably with the companies Abgenix and Raven Biotechnologies. Mr. Worsley out-licensed Vectibix®, the first fully human mAB specific to the EGFr (HER1). He received his MBA from the University of Washington.

The technical staff at Centrose includes two managers, Dave Marshall, Director of EDC Technologies, and Dr. Mohammed Shekhani, Director of Chemistry, who manage the biotechnology and chemistry groups respectively.

The technical group is provided consultation by Dr. Homer Pearce who developed gemcitabine (Gemzar) and has numerous years of experience in oncology while at Eli Lilly and numerous other technical advisors.

CELEK PHARMACEUTICALS

Celek Pharmaceuticals, LLC
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Graham Allaway, Ph.D.
President and CEO
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gallaway@celekpharma.com

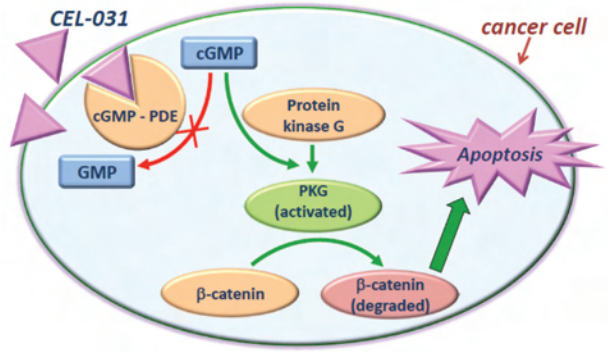
CEL-031, a Targeted Anticancer Drug
11:45 a.m. – 12:00 p.m.

Company Background
Celek Pharmaceuticals is addressing the need for new medicines to help patients suffering from cancers that are poorly served by current therapies. The company's strategy is to enhance the value of in-licensed drug candidates by advancing them through proof-of-concept clinical trials. Formed as a Delaware LLC in 2009, Celek's two founders, Graham Allaway, Ph.D., and Gary Robinson, Ph.D., are currently the sole employees.

Company Overviews

Technology Overview

Celek's lead product, CEL-031, is a clinical-stage targeted anticancer drug that selectively induces apoptosis in tumor cells by inhibiting cyclic GMP phosphodiesterases, which are overexpressed in human tumors. Currently in preclinical development for non-muscle invasive bladder cancer (NMIBC), CEL-031's mechanism of action involves the degradation of β-catenin, a cell signaling protein that plays a key role in bladder cancer tumorigenesis. In clinical studies against advanced cancers, orally-administered CEL-031 showed evidence of efficacy and a good safety profile. CEL-031 should have greater clinical efficacy against NMIBC, where it will be administered intravesically (i.e., instilled transurethrally), the standard drug delivery route for this indication.



Inhibition of cGMP Phosphodiesterases (PDE) leads to apoptosis via degradation of β-catenin.

Market Potential

Bladder cancer is the fifth most common cancer in the U.S., with 70,000 new cases annually and 600,000 individuals living with the disease. Worldwide, there are approximately 400,000 new cases annually and the incidence is rising.

About 70 percent of new bladder cancer diagnoses are made at the non-muscle invasive stage. Current NMIBC treatments involve transurethral resection (TUR), often followed by intravesical chemotherapy using non-specific cytotoxic drugs such as mitomycin C, or immunotherapy with Bacillus Calmette Guerin (BCG). These treatments often fail, with five-year recurrence and progression rates of 50-70 percent and 20-30 percent, respectively. Current drugs also cause adverse side-effects and are hazardous to health care workers.

Since NMIBC is a chronic disease requiring lifelong monitoring and treatment, the lifetime cost per patient of treating bladder cancer is the highest of all cancers.

Despite the pressing need, few new drugs are in development for NMIBC. Celek is developing CEL-031 for two NMIBC indications: (i) perioperative administration following TUR, and (ii) BCG-refractory NMIBC. CEL-031's estimated peak annual sales in these indications range from $510 million to $660 million.

Competitive Advantage

As the first targeted drug for NMIBC, CEL-031 represents a potential breakthrough in the treatment of patients with this disease. It should be possible to deliver CEL-031 safely at higher, more effective doses than current cytotoxic chemotherapies, resulting in dramatic reductions in rates of recurrence and progression. CEL-031's favorable safety profile should also result in a substantial increase in the number of patients treated with CEL-031 compared to current drugs.

Financial Overview

Celek has raised more than $700,000 in funding, including investments by the principals and federal and state grants. The NCI awarded Celek a $176,000 Phase I SBIR contract supporting preclinical studies on CEL-031 for NMIBC. Celek is currently seeking to raise $3 million to support preclinical studies of CEL-031 in bladder cancer and acute myeloid leukemia (AML), and the initiation of a Phase I/II clinical trial in non-muscle invasive bladder cancer.

Intellectual Property

Celek obtained exclusive rights to CEL-031 from OSI Pharmaceuticals. CEL-031 as a composition of matter and methods of treating cancer with CEL-031 are covered by four issued U.S. patents (plus foreign equivalents). Additional patents cover analogs, methods of identifying anticancer compounds and combination therapies.

Commercialization Strategy

Celek plans to complete a proof-of-concept clinical trial of CEL-031 in NMIBC patients, then partner for later stage development/ commercialization. Recent partnering deals in this therapeutic area have had attractive financial terms. Celek has already met with potential partners who indicated interest in the product.

Pipeline Products

Celek is also developing CEL-031 to treat advanced cancers using novel formulation and delivery technologies to increase concentrations of the drug in the body, thereby maximizing efficacy. The company is focusing on: (i) advanced bladder cancer, and (ii) acute myeloid leukemia (AML). A recently published independent study reported that CEL-031 has potent activity against tumor cells from AML patients, including those resistant to current drugs, and recommended clinical testing of CEL-031 against AML. CEL-031 would be eligible for Orphan Drug status in this indication.

Company Overviews

Management Team

Graham Allaway, Ph.D., President and CEO, has spent 22 years in the biotechnology industry. As founding CEO of Panacos Pharmaceuticals, he played a key role in building that company from a private venture-backed start-up to a public company, while raising more than $125 million in private and public equity financing. Dr. Allaway also led Panacos' drug discovery and development programs. Prior to Panacos, Dr. Allaway was CEO of Manchester Biotech and he previously led therapeutic R&D at Progenics Pharmaceuticals.

Gary Robinson, Ph.D., Chief Business Officer, has 20 years of experience in research, development, and commercialization of technologies and products in the physical and life sciences. Most recently, he was Senior Director of Business Development at Panacos Pharmaceuticals, where he led partnering, contracting, intellectual property and pre-launch marketing activities. Prior to Panacos, Dr. Robinson held business and corporate development positions at IGEN.

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Jay Schwartz, Ph.D.
Chairman and CEO
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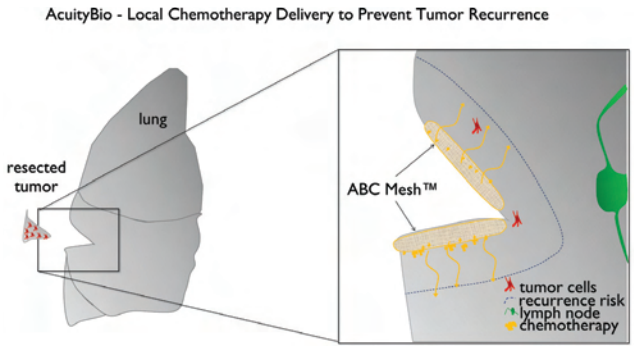
ABC Mesh™- a drug delivery platform technology
12:00 p.m. – 12:15 p.m.

Company Background

AcuityBio is a preclinical stage company focused on the commercialization of the company's unique biocompatible, biodegradable drug delivery platform technology to prevent post-surgical locoregional tumor recurrence in early-stage lung cancer patients. AcuityBio's formation in 2010 stemmed from a collaboration between lung cancer thoracic surgeon Dr. Yolonda Colson (Brigham and Women's Hospital) and Professor of Chemistry/Biomedical engineering Mark Grinstaff (Boston University). Together with Drs. Grinstaff and Colson, AcuityBio was co-founded in 2010 with CEO Jay Schwartz, Ph.D., and co-inventor of the technology and Director of Research, Jesse Wolinsky, Ph.D. AcuityBio currently has two full-time employees.

Technology Overview

AcuityBio has developed chemotherapy-eluting ABC Mesh™ based on their proprietary slow-release, biodegradable ABC Polymer™ for the prevention of locoregional lung cancer recurrence. It functions by delivering paclitaxel locally at a slow and predictable rate directly at the resection site following lung cancer tumor removal surgery. This maintains a localized high level of drug while minimizing side effects without affecting healing, which will result in better patient outcomes. AcuityBio is currently evaluating applying ABC Mesh to select soft tissue orphan oncology indications that have a high recurrence rate. This will allow a shortened time through a first-in-human trial as an "orphan" indication and accelerated FDA approval. AcuityBio has developed ABC Mesh to the preclinical stage, focusing on Chemistry Manufacturing and Control, engineering, and securing key manufacturing and supplier CMO/CRO vendor relationships.



Market Potential

Lung cancer is responsible for more deaths annually in the U.S. than breast, colorectal, and prostate cancers combined. Surgical removal of the tumor (resection) is the standard of care for early-stage lung cancer patients, yet lethal, locoregional tumor recurrence continues to afflict about half of the 50,000 patients per year who receive surgical treatment with curative intent.

Each year in the U.S., 221,000 new lung cancer cases are reported. Roughly one-quarter of these patients (about 50,000/year in the U.S.) will be considered candidates for surgical resection (the standard of care). The cost to the health care system resulting from the 50 percent endemic cancer treatment failure in the U.S. alone is a staggering $1 to $2 billion per year. Other early stage cancers also suffer from high locoregional recurrence rates, including stage II colorectal cancer (50,000 patients) and breast cancer lumpectomy patients (71,000). Several soft tissue "orphan" oncology indications more than 50,000 patients per year.

Company Overviews

Competitive Advantage
Existing drug-eluting polymer products on the market do not possess the properties that are required for the development of an ideal soft tissue compliant, biocompatible, biodegradable drug-eluting implant with tunable drug release. ABC Mesh has all these features. ABC Mesh is an easy-to-manufacture, widely applicable drug delivery platform, which can predictably and locally deliver insoluble and water-sensitive drugs to soft tissue for more than 50 days. The implant has already been proven to be biocompatible (ISO10993), biodegradable, and physically compliant and capable of slow, controlled drug delivery.

Financial Overview
AcuityBio has received almost $3 million in non-dilutive capital through NIH, SBIR Phase I and II, and government and Coulter Foundation grants, which will be sufficient to advance their ABC Mesh program to a first IND. The company seeks $3.5 million to help propel its first product through preclinical and to Phase I safety trials for early-stage non-small-cell lung cancer and to support the clinical development of its orphan drug first-in-human trials.

Intellectual Property
AcuityBio has negotiated with Boston University and Brigham and Woman's Hospital-Harvard/Partners to obtain exclusive world-wide rights to issued patent (U.S. 7,671,095) and three pending patents covering compositions and methods of use. The company has determined it will have a freedom to operate clear of prior art.

Commercialization Strategy
The value proposition of ABC Mesh is that it combines clinical differentiation, ease of use, and positive patient impact at lower overall cost per patient. Thoracic surgeons, hospital purchasing agents, group purchasing organizations will be the company's main customers. Customers will be compelled to choose ABC Mesh because of its strong clinical data, key opinion leader, and contract sales channels.

Pipeline Products
ABC Mesh is a platform technology that has been specialized to deliver water-insoluble or water-sensitive drugs that are traditionally difficult to formulate for administration. The company can tune the drug release rate and the implant's degradation rate depending on the application. AcuityBio is actively pursuing other clinical indications including orphan indication that would benefit from their localized delivery technology.

Management Team
John 'Jay' Schwartz, Ph.D., Co-Founder, CEO, and Chairman, has more than 20 years in life sciences technology development. He was research faculty at MIT working on drug delivery, is experienced in private equity fundraising, and has succeeded in securing multiple U.S. government grants. He co-founded the venture-backed engeneOS, bought by ADNEXUS, which was acquired by Bristol-Myers Squibb in 2007. Jay received his Ph.D. in Biochemistry and Molecular Biology from New York Medical College and pursued postdoctoral work at Harvard and MIT in drug delivery, protein engineering, and cardiovascular medicine.

Jesse Wolinsky, Ph.D., Co-Founder and Director of Research, is a co-inventor of the ABC Mesh. He holds a doctorate in Biomedical Engineering from Boston University and a Bachelor of Science in Materials Science and Engineering from the University of Florida where he specialized in Polymer Chemistry.

THERMEDICAL

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Michael G. Curley, Ph.D.
President and Founder
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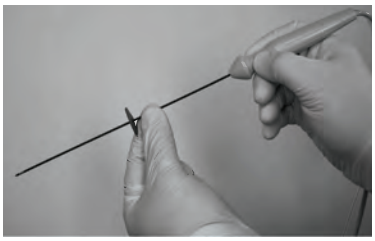
Saline-Enhanced Radiofrequency (SERF™) Ablation
12:15 p.m. – 12:30 p.m.

Company Background
Michael Curley, Ph.D., and Patrick Hamilton, Ph.D., incorporated Thermedical in Delaware in 2008 to develop, manufacture, and sell thermal therapy devices. They have been collaborating since they met at the Massachusetts Institute of Technology's Hyperthermia Center, and they have a unique and detailed understanding of biologic heat transfer. The company has seven employees.

Technology Overview
Thermedical's first product, SERF Ablation therapy for liver cancer, has a 510(k) application pending with the FDA. Thermedical is taking a revolutionary approach to tumor thermal ablation by altering the physics of heat transfer in tissue. SERF Ablation transports thermal energy deep into tissue using convection of warm saline, which carries

Company Overviews

the heat through the extracellular space. The tissue is transformed from having the insulating properties of wood to conducting heat as efficiently as bronze. Radiofrequency (RF) energy then heats the transformed tissue, and can thereby treat 100 times the volume of tissue that conventional RF can heat. Thermedical has demonstrated that SERF Ablation can treat an 8-cm diameter liver tumor in five minutes.



Market Potential
SERF Ablation for Liver Cancer will extend a treatment therapy for small tumors—RF Ablation—to the 80 percent of patients with tumors larger than 3 cm. The 1.3 million patients annually diagnosed with these large tumors have no cure available to them and live less than one year. This market is significant, with $1.8 billion spent annually on palliative therapies for these patients.

The markets for follow-on products are even more substantial. SERF Ablation will be curative for Ventricular Tachycardia (VT), and will be a disruptive technology for the $7 billion Implantable Cardioverter Defibrillator market. SERF Ablation for fibroids is an alternative to hysterectomy and may restore fertility in the 300,000 women who present with fibroids annually in the U.S.

Competitive Advantage
Thermedical's competitive advantage is their expertise on biologic heat transfer and their techniques for increasing heat transfer in tissue. Tissue does not conduct heat well, so existing ablation systems overheat tissue near the energy applicators. These products create hot-spots, islands of therapy in a sea of untreated tissue. SERF Ablation addresses the source of the problem. Warm saline transport increases the heat transfer capacity of tissue by a factor of more than 20, and can quickly and uniformly heat very large volumes of tissue — up to 8 cm diameter — using a single RF applicator. SERF Ablation is uniquely capable of treating conditions that require ablation of large volumes of tissue.

Financial Overview
Thermedical has been funded through NCI and NHLBI grants ($9.0 million) and a grant from the Massachusetts Life Sciences Center ($500,000). With these funds the company has brought SERF Ablation to a 510(k) application. Thermedical has just received its Series A investment from Dr. Samuel H. Maslak, the founder and former CEO of Acuson, the pioneering developer of modern ultrasound imaging systems, acquired by Siemens in 2001. These funds will be used for expanded regulatory clearances. Thermedical seeks funds for human clinical trials of their liver cancer ablation system.

Intellectual Property
Thermedical's technique is protected by U.S. Patent #6,328,735. The company has filed four additional patents and two trademarks.

Commercialization Strategy
Thermedical will sell direct in the U.S., building a strong training program to ensure that physicians understand the technology. The company will use this approach in Europe for product introduction, but will shift to distributors once the product is established. Thermedical plans to use distributors in the rest of the world.

Pipeline Products
New SERF Ablation therapies will be built around the company's SERF Ablation system, which can be used to treat a variety of conditions using therapy-specific applicators. The SERF Ablation system and needle for treating liver cancer are undergoing FDA 510(k) review. The company has also completed a preclinical prototype of their VT ablation catheter, which is undergoing successful preclinical testing. The gynecological application for treating fibroids is in design development. Clinical collaborators for all three applications are enthusiastic about bringing these new tools into the clinic.

Management Team
Michael Curley, Ph.D., President, is the inventor of SERF Ablation Therapy. Dr. Curley previously founded Acuson's Interventional Devices Business Unit and was its Vice President and General Manager with full profit and loss responsibility. He invented the AcuNav™ Diagnostic Ultrasound Catheter and led its successful introduction to the electrophysiology and interventional cardiology markets; the AcuNav has accumulated more than $1.0 billion in sales to date. His graduate research focused on thermal therapy for cancer. He holds S.B., S.M, and Ph.D. degrees from MIT.

Katharine M. Stohlman, Chief Operating Officer and VP Regulatory and Clinical Affairs was VP of QA and Regulatory Affairs for Viacor, Inc., from 2002 to 2011 and held operational management positions with HP Medical Products Group from 1983 to 2002, with direct reports of more than 200 employees. She holds an S.B. from MIT and an M.B.A. from Harvard Business School.

Company Overviews

Patrick S. Hamilton, Ph.D., Founder and VP Engineering, has considerable experience designing and implementing hardware and software for diagnostic and therapeutic medical systems. Dr. Hamilton holds an S.B. from MIT and M.S. and Ph.D. degrees from the University of Wisconsin.

Oncoscope, Inc.
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Perry A. Genova, Ph.D.
President and CEO
919-251-8030
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a/LCI – Angle Resolved Low Coherence Interferometry
12:30 p.m. – 12:45 p.m.

Company Background

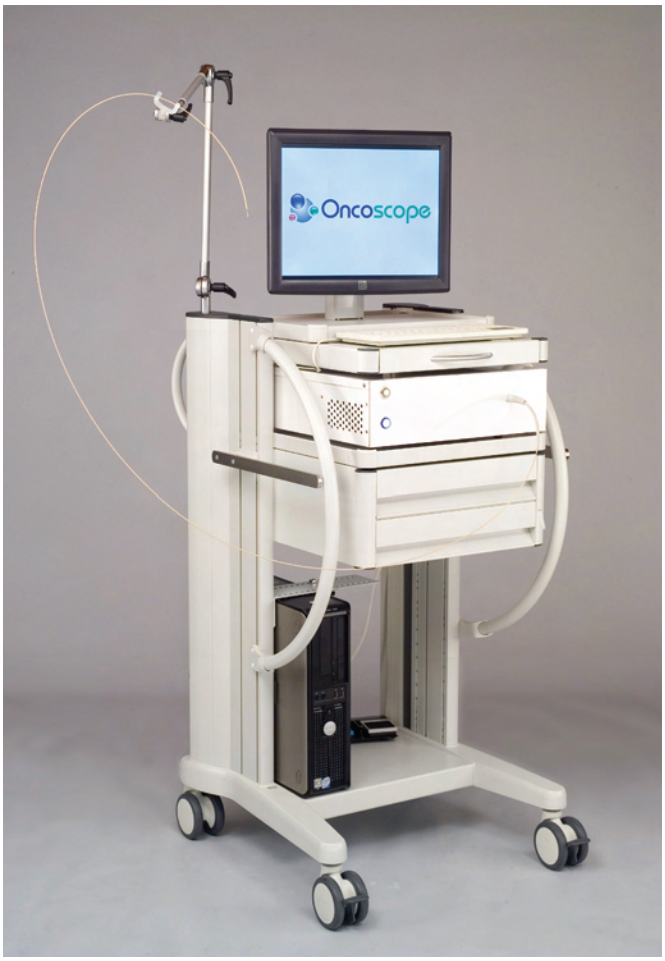
Oncoscope, founded in June 2006 by Dr. Adam Wax, employs optical imaging technologies developed at Duke University. Oncoscope has been supported by grants from NCI, NIH, the National Science Foundation, and the Wallace H. Coulter Foundation. The company resides in Durham, N.C., maintains eight full-time employees, and manages close relationships with Duke University and regional service providers.

Technology Overview

Oncoscope develops diagnostic devices that use proprietary a/LCI optical technology to locate abnormal epithelial tissue, where 85 percent of all cancers begin. These devices are fast, accurate, non-invasive, and allow real-time examination of large tissue areas *in vivo*. They detect early pre-cancerous dysplasia, a breakthrough over existing diagnostic methods, and have demonstrated 100 percent sensitivity in human studies to date. These devices leverage the biological premise that the primary early marker of cancer examined by pathologists is enlarged cell nuclei. The system examines scattered light to determine average cell nuclei size using a technology called angle-resolved low coherence interferometry (a/LCI). Oncoscope's first product targets the rapid *in vivo* identification of pre-cancerous tissue in the esophagus during standard esophageal endoscopy. The device consists of a base unit, a probe compatible with current esophageal endoscopes, and a disposable single-use probe cover. The company has collected clinical pilot data from over 200 patients and is presently preparing for its pivotal trial for FDA approval.

Market Potential

More than 12 million invasive biopsy procedures costing $25 billion are performed annually in the U.S. to detect cancerous epithelial tissue. Many cancers cannot be reliably detected at early stages with current techniques. For example, early detection in esophageal cancer could significantly improve the abysmal nearly 95 percent mortality rate. The esophagus is of particular concern given an estimated 43 million adults with Gastro-Esophageal Reflux Disease, 10 percent of which develop Barrett's Esophagus leading to an estimated 16,000 cases of esophageal cancer and 15,000 deaths annually. Oncoscope's device targets 1.6 million annual esophageal endoscopy procedures, each averaging 35 randomly selected biopsies. Oncoscope's first product addresses this market by: (1) improving accuracy in the early detection of dysplasia, (2) eliminating unnecessary biopsies, (3) decreasing procedure time and cost, and (4) combining diagnosis with immediate treatment.



Company Overviews

Competitive Advantage
Of the many different cancer detection technologies in use or in development, none employ a/LCI or other proprietary technologies used by Oncoscope. Only two of the many devices attempting to detect epithelial cancer can see early stage growth. Of these, only Oncoscope examines deep tissue layers where cancer begins, works in real time, is non-invasive, does not require patient pre-treatment with a contrast agent, and does not require a pathologist to interpret the data.

Financial Overview
Oncoscope has been funded by SBIR grants and $5.1 million in equity financing. The company is looking to raise a $10.0 million series B to support U.S. and EU regulatory approval, product validation, manufacturing development, clinical trial support for regulatory filings, and commercial product launch.

Intellectual Property
Oncoscope has three issued patents and has developed six patent families directed to devices and methods for various optical systems. The first two cover key innovations for determining cell nuclei size in multiple tissue layers from a single data collection event using scattered light. Broad patent claims have been recently issued by the USPTO for the core technology involved in determining cell nuclear size.

Commercialization Strategy
Oncoscope will focus on marketing a product and the procedure in which the product is employed with a small, dedicated, and focused sales force. A key objective is to expand to both the earlier stage of lower risk patient monitoring and later-stage treatment. Physician customers are interested in assessing Oncoscope's a/LCI device to improve detection and treatment in all stages of cancer. The company plans to capture as much of these investigations as possible in a number of clinical studies aimed at expanding the clinical range of use for Oncoscope's a/LCI. On the therapeutic end of the clinical spectrum, studies will be pursued to evaluate the utility of "see-treat" methods and for post-ablation margin analysis. Thus, the initial marketing will entail an active parallel development program to capture the array of clinical use concept testing that will inevitably occur once physicians have access to a powerful new tool that provides critical insight on the condition of tissue.

Pipeline Products
Oncoscope's device is applicable to screening for a wide spectrum of cancers with little adaptation. The company is exploring product development opportunities in colon IBD, cervix, and gastric cancers. Additionally, Oncoscope is developing product enhancements for wide area and trans-nasal scanning to further improve screening paradigms.

Management Team
- Perry A. Genova, Ph.D., CEO, is a serial entrepreneur, who has held Global VP positions with GSK, KOS. He has more than 25 years developing medical devices and drug products.
- Adam Wax, Ph.D., CTO, is Professor of biomedical engineering at Duke. He is a recognized biophotonics expert.
- Micki Lew, Director Regulatory Affairs has significant domestic and foreign experience in clinical operations.

GAMMAMEDICA

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James Hugg, Ph.D.
Chief Technology Officer
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Molecular Breast Imaging (MBI)
1:45 p.m. – 2:00 p.m.

Company Background
Gamma Medica (GMI) is a revenue-stage company that develops and utilizes advanced solid-state digital detectors in health care imaging systems with leading-edge technology. GMI was founded in 2001. GMI acquired in 2005 IDEAS of Oslo, Norway, and in 2006 Advanced Molecular Imaging of Sherbrooke, Quebec. GMI and GE Healthcare entered a joint venture in preclinical imaging in 2008, and then Gamma Medica acquired the entire business in 2011. GMI has 60 employees and leverages contract engineers, contract manufacturers, and distributors. Projected 2012 sales will be $24.7 million, comprising 75 percent preclinical, 20 percent clinical, and 5 percent industrial electronics.

Company Overviews

Technology Overview
GMI's FDA-approved Molecular Breast Imaging (MBI) device is installed in 20 clinical sites and uses mild immobilization of the breast between two digital, solid-state gamma photon detectors that image cancer lesions regardless of breast density. The patient is injected intravenously with a tracer amount of Tc-99m-sestamibi, avid for tumor cells, and imaging begins within five minutes. The company has lowered radiation dose to equal screening digital mammography.

Market Potential
Clinical revenues were $1.8 million in 2010, $1.9 million in 2011, $4.9 million projected in 2012, and growing to $50 million in 2015. GMI recalibrated several market analyses using actual equipment sales and constructed Rogers/Bass diffusion models to predict market potential. The company divided the market for breast cancer imaging into three segments: general screening, high-risk screening (dense breasts, BRCA genes, family history), and secondary diagnosis. The primary application for MBI will be screening of radiographically dense breasts (40 percent of European and American population; 70 percent of Asian population). The Mayo Clinic and GMI predict that MBI utilization will grow to 10.5 million high-risk screening and 5 million secondary diagnostic procedures per year.

Competitive Advantage
Women with radiographically dense breasts carry a sixfold increased risk for breast cancer. However, mammography fails to detect most cancers in these women. In a Mayo Clinic 1,700-patient dense-breast screening trial, digital mammography detected only 2 of 20 tumors, while MBI found 18 of 20.

MBI has a clear advantage in specificity over competing technologies: a Mayo Clinic 1,000-patient study demonstrated 91 percent sensitivity and 93 percent specificity in dense-breasted women, much better than mammography and with similar sensitivity to MRI but better specificity (fewer negative biopsies). The GMI LumaGEM® system is 1.5 to 2.0 times more efficient than competing MBI systems, which results in the lowest dose.

Financial Overview
Gamma Medica has been supported by $13.2 million in grants, including NCI STTR and SBIR Bridge grants, $82.4 million in product sales, $18.2 million in venture capital, and $16.3 million in debt financing. GMI is seeking $15 to $20 million to grow its Clinical Division by developing a mobile gantry, to conduct dense-breast MBI screening trials required for PMA, to develop international distribution capabilities, and to promote reimbursement, accreditation, and ACR/SBI clinical use guidelines.

Intellectual Property
The GMI technology is protected by eight patents for electronic detector readout and MBI with mild breast compression. In addition, GMI has licensed exclusively all Mayo Clinic patents and know-how related to MBI.

Commercialization Strategy
GMI has developed a commercially successful (19 installations) MBI system (LumaGEM) for breast cancer secondary diagnosis. The company is expanding usage of MBI for breast cancer screening, treatment monitoring, and guidance of biopsy and surgery.

The cost of the MBI system hardware and procedure is less than one-third that of MRI. Average reimbursement is $450 (plus professional component and radiotracer cost) and most payors have positive reimbursement policies or approve MBI with prior authorization.

Pipeline Products
GMI is developing an MBI-guided biopsy procedure (2012 commercial release). The company expects to introduce a mobile gantry in 2013, and plans to combine ultrasound with MBI in 2014-15. The same detector technology can be applied to prostate, brain, and other small organ cancer imaging.

Company Overviews

Management Team

The seasoned management team has a combined 150 years of professional experience with 110 years in management, 100 years in health care, and 60 years focused on women's health.

- James Hugg, Ph.D., VP R&D, CTO: GE Healthcare and Global Research, Henry Ford Health, University of Alabama - Birmingham, British Petroleum, Shell.
- Debbie Thomas, VP Marketing: Aurora Imaging Technology, WebMD, SAP America.
- Sharon Smith, VP Sales: Aurora Imaging, Naviscan, Hologic, Procter & Gamble.
- Deborah Matthew, VP Operations: Paragon Business Systems, Delphi Information Systems.

Guided Therapeutics™

Early Detection, Better Outcomes®

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Mark L. Faupel, Ph.D.
President and CEO
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LuViva® Advanced Cervical Scan
2:00 p.m. – 2:15 p.m.

Company Background

Guided Therapeutics (OTCBB & OTCQB: GTHP) is developing a rapid and painless testing platform for the early detection of cancer based on its patented biophotonic technology. Guided was founded in 1994 and went public via an IPO in 1997 as SpectRx, Inc. The company is the developer of the BiliChek® Non-invasive Bilirubin Analyzer, which uses spectroscopy to measure bilirubin in infants. That product is now sold by Philips Medical. The company changed its name to Guided Therapeutics in 2007 to focus on developing its cancer detection platform. Guided Therapeutics has 38 employees.

Technology Overview

LuViva® is a diagnostic device that scans the cervix with light and uses spectroscopy to measure how light interacts with the cervical tissue. Spectroscopy identifies chemical and structural indicators of precancer that may be below the surface of the cervix or misdiagnosed as benign. Unlike Pap, HPV tests, or biopsies, LuViva does not require laboratory analysis or a tissue sample, and is designed to provide results immediately, which eliminates costly, painful, and unnecessary testing. LuViva is currently approved for use in Canada and is under PMA review in the U.S. and CE mark review in the European Union.

Market Potential

LuViva is designed for use in women who have undergone initial Pap test screening and are called back for follow up with a colposcopy examination, which in many cases, involves taking a biopsy of the cervix followed by histopathological examination of the biopsy specimen. LuViva is designed to triage patients to help physicians determine if a woman should undergo a colposcopy exam. About 55 million American women undergo Pap tests with 5 percent to 10 percent requiring follow up. The device is used in conjunction with the LuViva Cervical Guide single-use patient interface and calibration disposable.

Reference to an specific disease statement, commercial product, process, service, manufacturer, and/or company does not constitute an endorsement by the NCI SBIR & STTR Programs or any other part of the U.S. Government.

Company Overviews

Competitive Advantage
LuViva's advantages over existing methods include immediate results, no painful tissue samples and no lab-based infrastructure required. In addition to detecting precancerous cells up to two years earlier than the current standard of care, LuViva has been shown to reduce the number of unnecessary procedures.

Financial Overview
In addition to grants from NCI, the company raises additional funding through partnering, contract work and the sale of equity. In 2011, the company raised $6.2 million through these methods. Since its inception in 1993, the company has raised approximately $78 million. The company anticipates requiring approximately $3 to $5 million for an initial product launch.

Intellectual Property
Guided Therapeutics has 16 issued patents pertaining to the technology platform.

Commercialization Strategy
In the U.S., Guided Therapeutics plans a mix of dedicated sales force and selected regional distributors. Internationally, the company is employing country-specific or regional distributors with an established presence in the gynecological market.

Pipeline Products
Guided Therapeutics has entered into a partnership with Konica Minolta Opto to develop a non-invasive test for early esophageal cancer in patients with Barrett's Esophagus using the biophotonic technology platform.

Management Team
Mark L. Faupel, Ph.D., President, Chief Executive Officer and Director has more than 25 years of experience as a senior executive developing non-invasive alternatives to surgical biopsies and blood tests, especially in the area of cancer screening and diagnostics. Prior to coming to SpectRx in 1998 as Vice President of Business Development and then co-founding Guided Therapeutics, Dr. Faupel was a senior executive and co-founder of Biofield Corp. In 2007, he became President and CEO of Guided Therapeutics.

Richard L. Fowler, Sr. Vice President, Engineering is responsible for identifying new technical and business opportunities for Guided Therapeutics. These opportunities include new technologies, product lines, or business acquisitions that are strategic to the company's business. Mr. Fowler was formerly VP of Engineering at Guided Therapeutics where he oversaw the successful development of the BiliChek Non-invasive Bilirubin Analyzer.

Shabbir Bambot, Ph.D., Vice President, Research and Development, is a co-founder of Guided Therapeutics. He has 20 years of experience in developing medical diagnostic products and is co-inventor of the technology behind the company's cancer diagnostic products. He currently manages the development of the company's esophageal cancer surveillance product in partnership with Konica Minolta Opto, Japan.

METABOLOMX

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Paul Rhodes, Ph.D.
Chief Executive Officer
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Breath Test for Cancer
2:15 p.m. – 2:30 p.m.

Company Background
Metabolomx is commercializing a non-invasive, rapid, and inexpensive breath test for cancer with the potential to revolutionize cancer diagnosis.

Technology Overview
Metabolomx has developed technology enabling the identification of lung cancer from its metabolomic fingerprint in exhaled breath. Currently it is in a second round of efficacy trials at Cleveland Clinic and other distinguished clinical centers. At the heart of the system is a high dimensional array of diversely reactive chemical indicators that change color upon interaction with volatile species or mixtures.

Using the first generation of the Metabolomx sensor a recent Cleveland Clinic study (Mazzone et al., 2012, *Journal of Thoracic Oncology*) reported 85 percent specificity and sensitivity for lung cancer detection, comparable to a CT scan, the present gold standard. In the first quarter of 2012, the Cleveland Clinic and the National Jewish Health Center in Denver (led by Dr. Jim Jett, Editor-in-Chief of JTO) began testing a Metabolomx sensor over 100 times more sensitive than the version used in the Journal study. The Mayo Clinic, led by Dr. David Midthun, is scheduled to begin testing in the second quarter of this year. Metabolomx's technology will be in the clinic at the country's three top-

Company Overviews

ranked lung care centers (U.S. News and World Report), reflecting the promise of this new paradigm for lung cancer assessment.

Market Potential

First indication: A companion diagnostic to CT scan
Metabolomx's first FDA indication will be as a diagnostic adjunct to an inconclusive CT scan. Results from the 53,000 patient National Lung Screening Trial (NSLT) indicate that a CT scan screening of high-risk patients extends life expectancy over 20 percent (NEJM, June 2011). The study has already prompted a powerful shift toward widespread use of CT, with Wellpoint recently announcing it will cover CT screening of the enormous at-risk population (more than 55 years of age, more than 30 pack years) identified in the study. However, CT generates a large number of false positives (the NLST found 27 percent of the high-risk group had a positive CT). Millions of people who have a positive CT are faced with the difficult decision of whether to monitor with follow-up CT or submit to an invasive and expensive biopsy, magnifying the need for a diagnostic adjunct to inconclusive CT. The estimated market size of this first indication is 10 million units per year in the U.S., with revenue of $1 billion.

Pre-screen of high-risk population to triage who should receive CT: The financial costs of CT, risks involved with radiation exposure, and the enormous size of the at-risk population defined in the NLST calls for a non-invasive, inexpensive initial test to better triage who should be screened by CT. Metabolomx expects to gather data on more than 1,000 patients to confirm that the breath test is a candidate pre-CT screen of the high-risk population. The estimated market size to pre-screen the high-risk population is 25 million units per year in U.S., with revenue of $2 billion.

Monitor efficacy of chemotherapy: Metabolomx is gathering data to confirm that the breath signature declines when chemotherapy is effective in curtailing tumor growth. The estimated potential market to monitor treatment is 15 million units per year in the U.S., with revenue of $1.5 billion.

Correlation between metabolomic breath fingerprint and effective treatment: Metabolomx is compiling an unmatched database allowing the post-hoc assessment of whether there is a predictive correlation between the metabolomic breath fingerprint and the efficacy of a particular treatment. With each treatment often tailored to intervene in a particular metabolic pathway, Metabolomx predicts that the metabolomic fingerprint in exhaled breath will allow individualized selection of treatment.

Competitive Advantage

The technology is a five minute, inexpensive (less than $100), non-invasive test for lung cancer and other cancers, based on the VOC profile present in the bloodstream and picked up in exhaled breath. Each cancer has its own "smell," and canines have been documented more than a 95 percent accurate in detection across stages, signaling the extraordinary promise of this new paradigm.

Financial Overview

Metabolomx has received several government development contracts, including a NCI Phase I/Phase II Fastrack award of $1.135 million. The company seeks a $5 million Series A round to reach clinical quantification of the level of accuracy of the second generation lung cancer detection system (building on the 85 percent accuracy of the first generation system) and submission to the FDA. Financial information on Metabolomx is available to interested parties under NDA.

Intellectual Property

The company holds exclusive, worldwide rights to an estate of fundamental enabling technology, including both the sensor itself and application IP. Additional private information is available to interested parties under NDA.

Commercialization Strategy

The Metabolomx breath analysis instrument will be sold or leased to the same hospitals and testing centers that use CT. The bulk of the company revenue is from the disposable sensor arrays and the balance from equipment and support. The company's first FDA indication will be as a diagnostic adjunct to indeterminate CT scan.

Pipeline Products

The first product is a breath test for lung cancer, but tests for other cancers will follow.

Management Team

- Paul Rhodes, Ph.D., CEO leads a diverse group of technology companies, which have received $13 million in DARPA contracts to develop next-generation sensory systems.
- Ray Martino, COO, who, during a 20-year career at Symbol Technologies was General Manager of its mobile business ($500 million in division sales) and then CTO of Symbol prior to its acquisition by Motorola for $3.9 billion in 2007.
- Sung Lim, Ph.D., Chief Scientist, is a co-inventor of the company's proprietary nanoporous pigment array optical sensing technology, along with Metabolomx' co-founder, University of Illinois Professor Ken Suslick.

A Clinical Advisory Board has been formed, and includes deep practical expertise in FDA approval processes.

Company Overviews

ARBOR VITA

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Peter S. Lu, M.D.
Founder and CEO
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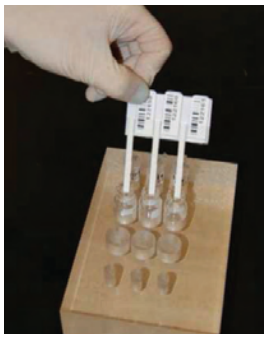
HPV E6 Oncoprotein Detection Platform
2:30 p.m. – 2:45 p.m.

Company Background

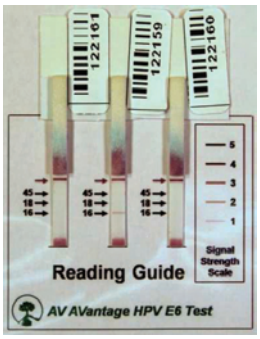
Arbor Vita Corporation (AVC) was founded in 1998, based on technology initiated at Howard Hughes Medical Institute (HHMI) at Stanford University. AVC focuses on the development of novel diagnostics and therapeutics using the proprietary PDZ platform to improve health care worldwide. AVC was the first to obtain FDA clearance for a rapid test for H5N1 Avian Flu in 2009, and it is now moving into commercialization of the HPV E6 Test. AVC also maintains a program to develop a treatment for HPV-induced cancers. Currently the company has 30 employees and several consultants.

Technology Overview

PDZ protein domains play important regulatory roles in the cell. The AVC PDZ proteome platform combines informatics and chemistry to identify and validate important biological targets for development. Using its PDZ proteomic technology, AVC has developed one diagnostic product (H5N1 rapid test) 510(k) cleared by the FDA, a suite of diagnostics for HPV malignancy (one of which just completed a successful clinical trial), and a companion therapeutic for HPV cancer currently in pre-clinical development. The HPV E6 oncoprotein test platform addresses HPV neoplasia like cervical cancer, anal cancer, and oral cancers. In the clinical trial conducted by PATH (Seattle) and CICAMS (Chinese Academy of Medical Sciences, Beijing) the AVC E6 test achieved analytical sensitivity of less than 1,000 transformed cells, 99 percent specificity, and a positive predictive value (PPV) of 33 percent in a general screening population. In contrast current screening technologies (like Pap and HPV DNA/RNA) achieved lower specificity and a 5 percent PPV. The AVC HPV E6 rapid test that completed the clinical trial is suited for use in near point-of-care settings in developing countries and also physician's offices.



HPV E6 Test unit
- Three tests per unit
- Multiple units can be run in parallel



Test interpretation
- Visible red test line for positive E6 oncoprotein
- Built in test control line

Market Potential

The current cervical cancer screening market is more than $1 billion in the U.S. Current screening technologies lack specificity which leads to over treatment and more testing. The AVC E6 test addresses this concern with a test that is 99 percent specific. In addition, the improved analytical sensitivity permits earlier detection of cervical cancer (and potentially anal and head-and-neck cancers) that is crucial for survival and to decrease morbidity associated with surviving cancer. AVC plans to commercialize the HPV E6 Test within the next two years.

Competitive Advantage

Current cervical cancer screening (Pap and HPV DNA/RNA tests) suffers from low specificity, best captured by the term PPV. The 5 percent PPV typically seen in screening technologies means only 5 percent of the positives have disease and 95 percent do not. Low PPV leads to more testing, higher cost and greater morbidity. The HPV E6 Test achieves a 33 percent PPV for high-grade disease in the same general screening population. The improved PPV means better screening efficiencies, lower costs, and better outcomes for the patient.

Financial Overview

The HPV E6 oncoprotein detection platform is supported by SBIR grants and private investments. To accelerate the commercialization of this new technology, AVC will require an infusion of $10 to $20 million in new investments.

Intellectual Property

Most IP associated with the technology was developed by AVC and is patent protected in the U.S., Europe, and Asia. Ancillary patents to enable commercialization of this product have been licensed.

Company Overviews

Commercialization Strategy

AVC's HPV E6 oncoprotein detection platform can be used in point-of-care settings, high-throughput reference labs, and as augmentation to traditional pathology lab assays. The initial focus will be non-U.S. countries, with an emerging middle class, that have not invested in the health care infrastructure that exists in the U.S. and Europe. This approach favors new technologies able to bypass current practices to provide improved care at a lower cost. AVC also plans to introduce its technology in the U.S. initially through specialty labs, and then to established medical communities.

Pipeline Products

AVC's initial focus is to commercialize the HPV E6 Test, followed by adapting the E6 platform to fit various environments. AVC also has a drug in pre-clinical development to address HPV-related cancer treatment and prevention.

Management Team

- Peter Lu, M.D., Founder and CEO, trained at Caltech, Stanford, and University of Washington with a background in medicine, molecular biology, and oncology.
- Johannes Schweizer, Ph.D., VP of Research and Development, trained at Institute Pasteur and Stanford with a background in genetics, molecular biology.
- Olga Petrauskene, Ph.D., Director of Commercialization, formerly at ABI.
- Charles Trimble, Chairman, founded Trimble Navigation and is a successful entrepreneur who has brought new technology into practical use, such as GPS.

APOCELL
molecular profiling
& diagnostics

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Darren Davis, Ph.D.
President and CEO
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ApoCell and the ApoStream™ Rare Cell Capture System
2:45 p.m. – 3:00 p.m.

Company Background

ApoCell was founded in 2004 by Darren W. Davis to commercialize biomarker technologies that monitor the effectiveness of cancer drugs by measuring biomarker expression patterns in tumor biopsy specimens. ApoCell provides molecular analytical services supporting clinical trials for pharmaceutical/biotechnology companies, government, and academia. The company mission is to be in the forefront of scientific and technological developments for providing highly effective molecular diagnostic services and products to significantly improve the treatment and outcomes for people afflicted with cancer and other chronic diseases. ApoCell scientists have investigated and developed laboratory techniques that provide highly accurate mechanistic, predictive, and prognostic cancer information.

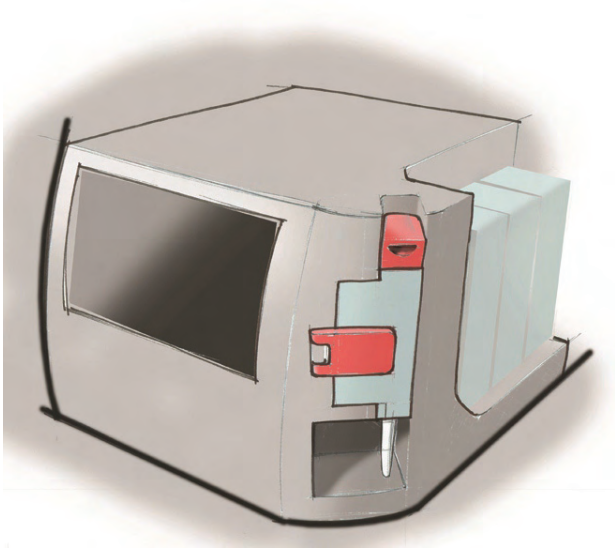
ApoCell has seen continued growth in revenue from its service business since its inception. In 2011, ApoCell made the Inc. Magazine's 500/5000 list with more than a 400 percent growth rate over the past three years and ranked the 13th fastest growing company in Houston, Texas. ApoCell has 41 employees and continues to hire additional staff to support the continued growth of its service and product development businesses.

Reference to an specific disease statement, commercial product, process, service, manufacturer, and/or company does not constitute an endorsement by the NCI SBIR & STTR Programs or any other part of the U.S. Government.

Company Overviews

Technology Overview

The ApoStream™ system uses dielectrophoresis field-flow fractionation (DEP-FFF) technology to capture rare circulating tumor cells (CTCs) from blood. Growing evidence suggests that capture of CTCs from a blood sample may allow reliable early detection and molecular characterization of cancer for diagnosis or relapse and provide a minimally invasive method to guide and monitor the efficacy of cancer therapy. CTCs represent a potential alternative to tumor biopsy as a real-time 'liquid biopsy' and have been shown to be a prognostic indicator of survival.



The ApoStream point-of-care (POC) is currently in the alpha prototype stage and will be launched as a Research Use Only Device (RUO) in the fall of 2012. ApoCell anticipates the final POC device will become a foundational platform for several next-generation diagnostics based on molecular profiling of CTCs for tailoring patient-specific therapy.

Market Potential

A report by BCC Research indicates that the total global annual market for next-generation cancer diagnostics was $776 million in 2010, and is growing at a compound annual growth rate (CAGR) of 47 percent, to reach a forecast market size of $5.3 billion in 2015. Current clinical applications of CTCs have been shown to predict overall survival in breast, prostate, and colorectal cancer.

Competitive Advantage

The ApoStream rare cell capture technology is an improved approach from current marketed technology, in that it is the first device that enables antibody-free capture of viable cancer cells from a wide range of human cancers, including non-epithelial cancers or cancers with low or negative epithelial expression. The captured cells are not modified (no labeling or fixing) thereby enabling the cancer cells to be cultured and allowing RNA/DNA and protein analysis for complete cell characterization.

ApoStream's ability to capture viable, unlabeled CTCs from cancer patients will contribute to significant improvement for diagnosis, prognosis, and discovery of biomarkers associated with cancer progression and treatment, thereby advancing the clinical application of personalized medicine.

Financial Overview

Currently, ApoCell has funded the majority of its operations from its pharmaceutical and clinical trial services business.

In 2009, a private equity investment of $5 million was raised for the development/commercialization of the ApoStream technology, and to expand the capabilities of the services business.

In January of 2010, ApoCell was awarded a $2.9 million contract from the NCI/SAIC for development and delivery of 12 alpha research use only (RUO) prototypes along with several pre-clinical diagnostic applications. Subsequently, a SBIR Phase I grant for $200,000 was awarded to begin conversion of the RUO device into a clinical POC device.

ApoCell is currently looking for $10 to $15 million to further implement the technology into the ApoCell research services business and to fund the next development and commercialization stage of the ApoStream POC device.

Intellectual Property

ApoCell has an exclusive license from the University of Texas MD Anderson Cancer Center to commercialize the ApoStream technology. There are five patent families and 22 patents included in the license agreement. In addition, the company continues to file its own intellectual property (IP) and has several agreements with major pharma/biotech companies that permit ApoCell additional diagnostic rights.

Company Overviews

Commercialization Strategy

ApoCell plans to establish strategic partnerships with companies that can provide appropriate distribution channels for each stage of the device. Discussions are ongoing with several larger companies to target the RUO and clinical *in vitro* diagnostics (IVD) markets.

ApoStream will be rolled out in the following three phases during its development:

- Research Only Device (RUO) – Academic, pharma/biotech research environment, and fee-for-service work
- Clinical Sample Device (IUO) – Internal services, diagnostics development, and analytical instruments markets
- *In Vitro* Diagnostic Device (IVD) – For use as a clinical instrument providing diagnostic assays

Pipeline Products

The ability to capture viable CTCs from various cancer types will allow researchers to culture these rare cells to advance scientific knowledge, including discovery of novel drug targets on these metastatic cells. Further, capturing adequate numbers of CTCs will allow for RNA/DNA molecular characterization and protein expression analysis.

Management Team

- Darren W. Davis, Ph.D., President and CEO/CSO, is a world-recognized cancer researcher who has published 40 scientific articles and edited the book *Antiangiogenic Cancer Therapy*.
- David K. Hasegawa, M.S., is Vice President of Product Development.
- Kenna Anderes, Ph.D., is Vice President of Scientific Affairs.
- Glen A. Ferguson, MBA, is Vice President of Molecular Biomarkers.
- Jim M. Walther, MBA, is Vice President of ApoStream Business Development and Strategic Partnerships.
- Natalie Gassen, C.P.A., is Chief Financial Officer.
- Vlada Melnikova, M.D., Ph.D., is Director of Molecular Biology.

VALA SCIENCES

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Jeffrey Price, M.D., Ph.D.
Chief Executive Officer
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Quantitative Multiplex Biomarker Imaging
3:30 p.m. – 3:45 p.m.

Company Background

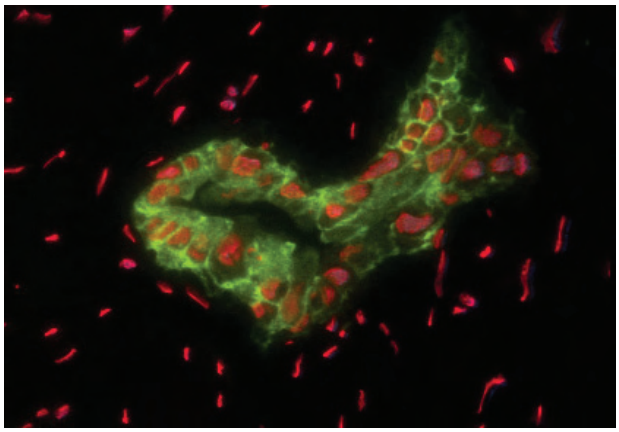
Vala Sciences was incorporated in March 2004 as a C corporation in Calif. Many members of the core team have worked together as part of similar business ventures at Q3DM, Inc., and Beckman Coulter. Vala was spun out from Q3DM, Inc., a venture- and grant-financed company purchased by Beckman Coulter in December 2003. In August 2009, the company reacquired the Q3DM patent portfolio. The Q3DM-Vala intellectual property combination creates a substantial patent portfolio, which helps solidify Vala's place in the marketplace. The aggregate successful experience of managing Q3DM from start-up to acquisition by Beckman Coulter, positions Vala well for long-term commercial success.

Technology Overview

Vala's multiplex technology, currently in preclinical development, brings quantitative innovation to diagnostic and prognostic clinical testing. The company's technology uses haptens and quantum dots to enable multiple biomarkers to be simultaneously localized and quantified on a cell-by-cell basis, on a single-tissue section. This unique approach greatly enhances the data that can be generated from single-tissue sections, thereby allowing a much richer data set to be obtained than is possible using current standard immunohistochemical (IHC) techniques. Multiplex

Company Overviews

imaging on a single slide means that more data can be obtained from a very small tissue sample, such as a needle biopsy, compared with traditional techniques. Vala's breast cancer biomarkers of interest include estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor (HER2).



Quantum dot conjugated secondary antibodies

Market Potential

The increasing incidence of cancer in an aging population and the growing use of targeted cancer drugs requiring companion diagnostics drives the rising need for automated testing and standardization that Vala's tools provide. The world microscopy market is expected to grow from $2.7 billion in 2010 to $4.5 billion in 2015, at an estimated CAGR of 10.8 percent from 2010 to 2015. Quantum dot nanotechnology in microscopy is a growing area of interest and is expected to drive the future growth of microscopy market. Nanotechnology currently accounts for a meager 10 percent of the market; however, it is expected to grow the fastest pace during the forecasted 2010 – 2015 period at a CAGR of 17.9 percent (reportlinker.com World microscopy market 2011).

Vala's technology is at the cutting edge of multiplex biomarker imaging and, when combined with their state of the art whole slide scanning and image analysis technology, Vala is well positioned to become an industry leader in predictive and prognostic cancer diagnostics.

Competitive Advantage

Vala's multiplex biomarker technology utilizes hapten-conjugated antibodies to allow antibodies from the same species to be used simultaneously, a major restriction in traditional IHC techniques. The company is combining that advantage with quantum dot conjugated secondary antibodies due to their enhanced fluorescence and lack of photo bleaching. Slides labeled with quantum dots will remain fluorescent after at least a year, making them suitable for archiving; this is not possible using many other fluorescent dyes. Vala's assays localize multiple biomarkers in the same slide, therefore reducing the amount of human tissue needed. This is a real problem when patients have needle biopsies, for example, as the volume of tissue biopsied is very small, meaning that the number of slides that can be generated from that sample is extremely limited.

Financial Overview

To date, Vala Sciences, Inc., has raised a total of $17 million from a combination of private equity, federal and state grants/contracts, and commercial revenue. Vala is seeking to raise an additional $5 million to allow the company to complete development, obtain regulatory clearance, and introduce its product to the market.

Intellectual Property

Vala's 19 patents and patent applications are thought to comprise one of the largest, most competitive patent portfolios in the High Content instrumentation market.

Commercialization Strategy

Vala is developing strategic partnerships to commercialize the breast cancer assay as a Laboratory Developed Test (LDT). The company will then obtain FDA approval for the assay, whole slide scanning image capture, and image analysis system as a Class III medical device. Vala also plans to market FDA-approved diagnostic reagent kits to clinical labs.

Pipeline Products

Vala's technology currently focuses on multiplex imaging in breast cancer; however, it is readily adaptable to address questions in a wide range of cancers, including prostate cancer.

Management Team

Vala Sciences has a strong leadership team with combined experience in molecular pathology, cell biology, and bioengineering. Key members include:

- Jeff Price, M.D., Ph.D., is the former Chief Executive Officer of Q3DM, Inc. Dr. Price is also an Associate Professor at The Sanford-Burnham Medical Research Institute.
- Patrick McDonough, Ph.D., has more than 25 years of experience in cell biology and a history of success developing commercial products.
- Randy Ingermanson, Ph.D., has more than 20 years of algorithm and software engineering experience.
- James Evans, Ph.D., has a background in molecular cell biology and imaging informatics and is the former Assistant Director of the Whitehead MIT BioImaging Center.

Company Overviews

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Thomas Neumann, M.D.
President and CEO
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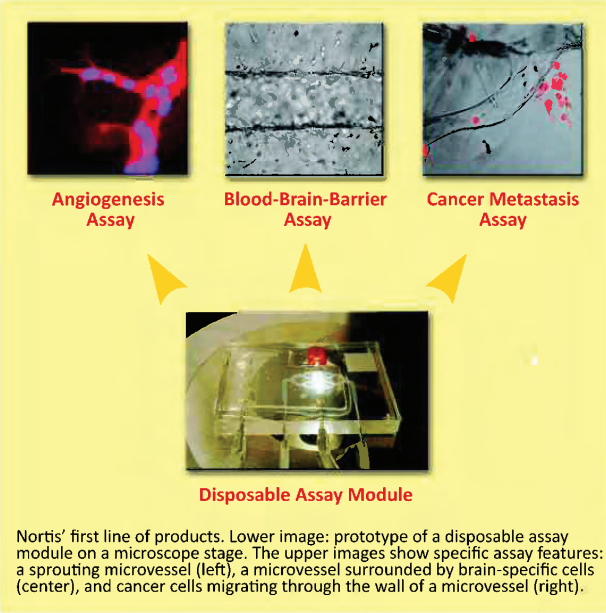
Tissue-Engineered Microenvironment Systems (TEMS)
3:45 p.m. – 4:00 p.m.

Company Background
Nortis is dedicated to developing a new generation of *in vitro* systems that are based on small segments of tissues and organs grown from human-derived cells in disposable, chip-like devices. Such human "body-on-a-chip" systems represent urgently awaited alternatives to laboratory animals and are expected to become the gold standard for the testing of drugs, vaccines, toxic compounds, cosmetics, and warfare countermeasures.

The Nortis project started in 2005 as a division within VisionGate, a bio-imaging company. In 2011, Nortis, Inc., was officially spun-off and subsequently moved into its new facilities at a biotech incubator on the University of Washington campus. As of January 2012, the Nortis team consists of 10 full- and part-time employees and consultants.

Technology Overview
Nortis is developing products that will overcome a crucial bottleneck in the development of therapeutic drugs and vaccines. Due to the lack of reliable *in vitro* assays, drug development depends heavily on animal testing for predicting efficacy, safety, and pharmacokinetics in humans. This is problematic for several reasons. Testing in animals is expensive and fraught with ethical concerns. Most importantly, the results obtained with animals often don't translate to humans.

Nortis has pioneered proprietary techniques for the *in vitro* creation of human tissues and organs in disposable chip-like devices. These organ microenvironments are designed as disposable modules, to be used as single assays or integrated in fluidic circuits that connect several different organ modules in various configurations as needed for the testing of drug/vaccine efficacy, toxicity, and pharmacokinetics. Nortis established proof-of-principle for their technology through a completed SBIR Phase I grant. Nortis anticipates their first products to enter the market within two to three years.



Nortis' first line of products. Lower image: prototype of a disposable assay module on a microscope stage. The upper images show specific assay features: a sprouting microvessel (left), a microvessel surrounded by brain-specific cells (center), and cancer cells migrating through the wall of a microvessel (right).

Market Potential
Market analysis for the first two Nortis assays, a model of the blood-brain-barrier assay and an angiogenesis assay, were prepared by Foresight Science & Technology, a leading technology commercialization and transfer firm. The combined yearly revenue potential for the two assays was predicted to exceed $400 million. The market potential of the other tissue/organ assays has not yet been evaluated, but is expected to have the same magnitude.

Competitive Advantage
Nortis' tissue and organ models differ significantly from other body-on-a-chip approaches. The competitive advantage of Nortis' technology arises from the integration of living vasculature, which can be directly perfused to mimic blood flow. This unique feature allows for the study of vascular growth and function in real time, reducing the need for expensive and laborious animal testing. Vasculature is a structural and functional key element of almost every tissue. Thus, Nortis' assays are

Company Overviews

poised to produce test results that better replicate *in vivo* conditions and predict clinical outcome. Notably, the Nortis system is ideally suited for administering test compounds either through the vessel lumen or through the surrounding microenvironment. This is especially important for the testing of drugs, toxins, and vaccines. Nortis' assays are modular and can be set up in flexible configurations with anticipated widespread adoption in various research areas, including high-throughput drug screening.

Financial Overview
The development of Nortis's first commercial assays were supported by three NCI SBIR Phase I grants. The company aims to raise an additional $1 million in private investment this year to support R&D efforts until SBIR Phase II grants are secured in 2013.

Intellectual Property
Nortis owns two issued U.S. patents, and two U.S. applications that were filed on this technology to cover additional features and techniques. International patent applications in important global markets are currently undergoing the examination process. Nortis is the sole owner of all related IP.

Commercialization Strategy
Nortis plans to introduce the first assays and basic perfusion platforms into the scientific research market during the second half of 2014 — ideally by partnering with a company with established sales structures in this area. Nortis anticipates that the success in the scientific research market will translate to adoption in the area of commercial drug development.

Pipeline Products
The first line of products will include a blood-brain-barrier assay, an angiogenesis assay, a metastasis assay, as well as a perfusion platform in which the assay modules can be inserted.

Management Team
Thomas Neumann, M.D., is President and CEO of Nortis. His career path includes clinical work, academic appointments, and leadership positions in industry, where he has gained extensive experience in directing multidisciplinary teams. He and Dr. Nelson are the founders of Nortis.

Alan Nelson, Ph.D., Chairman, held multiple prestigious academic positions. He is a dynamic serial entrepreneur. His first biomedical company, Neopath, won landmark FDA approval in 1995, had an initial public offering (IPO) in 1996 and was sold to Becton Dickinson in 2000.

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Davide Marini, Ph.D.
Co-founder and CEO
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Universal Multiplexing
4:00 p.m. – 4:15 p.m.

Company Background
Firefly is introducing a universal technology platform for biomarker detection with a broad range of applications in life sciences, agriculture, veterinary medicine, and human diagnostics. Firefly BioWorks is a spin-out of the Chemical Engineering Department at the Massachusetts Institute of Technology (MIT), where the founders developed a novel method for high-throughput production of complex microparticles. The company began operations in 2010 and grew to seven full-time employees through a combination of SBIR awards and angel funding. The company is focused on developing multiplexed assays for biomarker detection that scale from discovery to clinical diagnostics. The company has adopted a lean startup approach. The first minimum viable product is being launched and operations will be scaled according to demand.

Technology Overview
Firefly develops and manufactures next-generation microparticles for biomolecule detection. The company's first product, a kit for detecting microRNA aimed at the research market, has just been launched commercially. Firefly's core technology, Optical Liquid Stamping, was developed by combining photolithography (typically used in microchip production) with microfluidics. This method allows fabrication of microparticles with virtually any shape, chemistry, and biofunctionality. Using Optical Liquid Stamping, Firefly developed a barcoded particle architecture that enables multiplexed biomarker detection on standard laboratory instrumentation. Through the support of the NCI SBIR Program, Firefly developed a particle-based assay for high-throughput profiling of microRNAs, a class of molecules with enormous potential for early diagnosis of cancer.

Company Overviews

Market Potential
Firefly operates in the global market for biotechnology tools, a market that generates approximately $70 billion in worldwide sales. Firefly developed its first product for microRNA profiling, a market currently estimated at approximately $100 million and expected to grow very rapidly. Several market surveys indicate that bead-based assays for high-throughput/mid-multiplexing profiling are expected to address a critical need in the industry and grow at the fastest rate, especially in the area of microRNA.

Encoded, bio-functional microparticles

Competitive Advantage
The Firefly platform enables detection of clinically relevant biomolecules with an unprecedented combination of performance, flexibility, throughput, and cost. Additionally, the assay developed by Firefly allows direct detection of miRNA in clinical samples without purification. This eliminates protocol discrepancies in RNA purification and will likely lead to more reliable diagnostics.

Beyond microRNA, Firefly's platform has been used for the detection of disease-related proteins, mRNAs, and genomic DNA. The technology naturally lends itself to simple bedside or handheld devices that can be used in routine screens for early disease detection or point-of-care diagnostics.

Financial Overview
Initial funding was provided by two Phase I SBIR awards, for a total of about $500,000, followed by a seed round of $1 million from angel investors. In August 2011, Firefly was awarded a $2 million NCI SBIR Phase II award that catalyzed a $2 million second round of angel funding used for commercial development in the research market.

Firefly seeks an industry partner to adopt the company's technology and estimates additional funding in the $10 to $20 million range is required to expand its diagnostics capabilities.

Intellectual Property
Firefly has obtained an exclusive license from MIT for use of its technology in any research or clinical diagnostics application. The company's current IP portfolio comprises four issued patents and 16 pending applications, covering the entire value chain of Firefly products from particle fabrication, encoding and bio-functionalization, to custom microRNA assays and readout in standard instrumentation.

Commercialization Strategy
Firefly's long-term goal is to become a trusted provider of reliable and cost-effective solutions for clinical diagnostics. The company plans to first establish a presence in the research market and eventually enter the diagnostics field. Firefly intends to grow the company in three phases:

- Selling initial products to leading academic laboratories.
- Partnering with flow cytometry manufacturers for co-marketing of products.
- Expanding the product offering to include diagnostic applications by partnering with content developers in the cancer space.

Pipeline Products
Firefly's first product is a custom 25-plex microRNA profiling kit that can be used on standard benchtop cytometers. The next generation of products will offer expanded multiplexing, a larger set of supported cytometers, and sensitivity that rivals polymerase chain reaction (PCR). Once the company has proven the technology in the field of microRNA, it will enter the protein market, with a set of companion products with relevance in both research and diagnostics.

Management Team
Firefly has built a team of executives and business advisors with deep expertise in molecular assays, microfluidics, materials, computer science, flow cytometery, and protein science, with roots in both start-ups and large life-science corporations. The team includes:

Operational Team:

- Davide M. Marini, Ph.D., Co-founder, Chief Executive Officer
- Daniel C. Pregibon, Ph.D., Co-founder, Chief Technology Officer
- Andreas Windemuth, Ph.D., Chief Information Officer
- Isaac B. Stoner, Vice President of Product Development
- Andrea K. Bryan, Ph.D., Director of Engineering

Company Overviews

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David P. Bartel, Ph.D., and Patrick S. Doyle, Ph.D.

BioMarker STRATEGIES

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Douglas P. Clark, M.D.
CMO/Acting CEO/Co-founder
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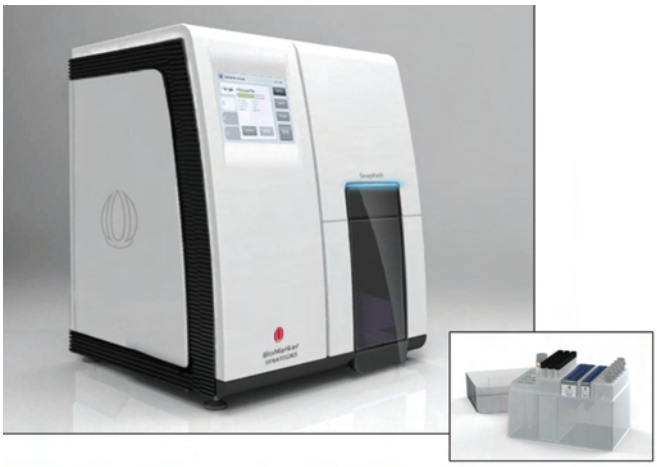
dpclark@biomarkerstrategies.com

SnapPath™: Live-Tumor-Cell Testing System
4:15 p.m. – 4:30 p.m.

Company Background
BioMarker Strategies was founded in 2006 by Dr. Douglas Clark, a Professor of Pathology at Johns Hopkins, to improve the treatment of cancer by developing first-in-class, live-tumor-cell-based predictive tests to guide targeted drug therapy selection. Today the company is based at the Johns Hopkins Science + Technology Park and employs 10 people. BioMarker Strategies has successfully developed the SnapPath™ testing platform, and is engaged in pre-clinical and clinical studies with two major academic medical centers.

Technology Overview
The SnapPath biomarker testing system is an automated live-tumor-cell processing platform that enables next-generation, ex vivo biomarker tests to guide targeted drug therapy selection. A small portion of a patient's live tumor (from a biopsy or surgical excision) is placed into a disposable cartridge and inserted into the SnapPath instrument. The SnapPath uses onboard robotics and fluid handling systems to expose a patient's live tumor cells to drugs and/or growth factors to evoke a phosphoprotein-based Functional Signaling Profile (FSP) of the signal transduction network that is not possible using static biomarkers from dead, fixed tissue. These FSPs generated by the SnapPath device can be utilized by oncologists to guide targeted therapy for cancer patients. To date, the company completed proof-of-mechanism studies with human melanoma samples using a prototype device, produced and verified several SnapPath alpha units, and placed two of these alpha units at academic medical centers for clinical research studies.



Market Potential
With approximately 1.5 million solid tumor cancer patients in the U.S., the total addressable market for live-tissue testing exceeds $5 billion, assuming value-based reimbursement. Within this population, the initial target markets include:

- Melanoma (BRAF V600E)
- Lung carcinoma (EGFR wt)
- Colorectal carcinoma (KRAS wt)
- Breast (Triple Negative)
- Renal cell carcinoma

Competitive Advantage
Most current molecular profiling strategies rely on the analysis of static DNA or protein-based biomarkers, but this tells little about the actual functioning of the complex signal transduction network within tumor cells. By interrogating living solid tumor cells from cancer patients using the SnapPath testing platform, the resultant predictive tests will contain

Company Overviews

novel information content — such as pathway bypass mechanisms and feedback loops — that will enable oncologists to select better targeted therapies, including drug combinations, for their patients.

Financial Overview
To date, BioMarker Strategies has obtained the following funding:

- $9 million from private investors
- $2.3 million SBIR Fast Track Phase I/II contract for SnapPath instrumentation development
- $200,000 Phase I SBIR contract for companion diagnostic development
- Additional funding from the Federal Therapeutic Discovery Tax Credit Program, MD TEDCO, and Johnson & Johnson

BioMarker Strategies is currently seeking investors for an initial institutional investment round of $7 million to achieve the early-stage commercialization goals outlined below.

Intellectual Property
BioMarker Strategies is using a combination of patent filings, trade secrets, and trademarks to protect its proprietary interest in the SnapPath testing system. To date, the company has filed three patent applications that focus on the platform, the process of ex vivo stimulation, and the resultant ex vivo test content.

Commercialization Strategy
The company's long-term commercialization strategy is focused on developing SnapPath-deployed predictive tests to guide therapy for solid-tumor cancer patients in the U.S., Europe, and Asia. BioMarker Strategies will use the following steps to bring its products to market:

Early-stage commercialization

- Place first-generation SnapPath units at comprehensive cancer centers
- Achieve 510(k) approval for the platform
- Expand academic and pharma collaborations

Later-stage commercialization

- Increase SnapPath placements at additional cancer centers
- Expand sales and marketing infrastructure
- Validate and clinically qualify tests
- Establish Clinical Laboratory Improvement Amendments (CLIA) lab and launch Laboratory Developed Tests (LDTs)
- Transition LDTs to pre-market approval (PMA)

Pipeline Products
BioMarker Strategies' proof-of-concept studies have focused on characterizing resistance to BRAF inhibitors in advanced melanoma. This will be followed by the development and launch of tests to guide targeted drug use in larger markets such as non-small-cell lung, colorectal, breast, and renal cell carcinomas. Given the ability to test specific drugs in the device, SnapPath also has the potential to become a platform to improve early drug development, provide more effective clinical trial design through patient stratification, and enable companion diagnostics. To this end, the company was awarded a SBIR grant in September 2011, to support the development of a pathway-based companion diagnostic test to use in conjunction with the SnapPath platform.

Management Team
Douglas Clark, M.D., Chief Medical Officer/Acting CEO, is an entrepreneur and a Professor of Pathology at The Johns Hopkins Medical Institutions, who brings over 20 years of experience in diagnostic pathology, laboratory management, and biomarker discovery.

Scott Allocco, co-founder, brings 15 years of business development, pharmaceutical drug management, and public-sector reimbursement experience to the company, having most recently served as the Vice President of State Government Affairs and Business Development for Coventry Health Care.

Adam Schayowitz Ph.D., M.B.A, Senior Director of Operations and Business Development, brings nearly a decade of experience in tumor cell biology with a focus in targeted cancer therapeutics, preclinical, and early clinical drug development, and leads the company's strategic partnerships and collaborations with external collaborators.

Board of Directors
Glenn Miller, Ph.D., Chairman, VP/Head of Personalized Medicine at AstraZeneca; Dr. Samuel Broder, former Director of the National Cancer Institute; Dr. Paul Beresford, VP of Business Development at Biodesix and former VP of Translational Diagnostics at Ventana Medical Systems; Skip Klein, Managing Member at Gauss Capital Advisory and founder of the T. Rowe Price Health Sciences Fund; and Christy Wyskiel, former Managing Director at Maverick Capital and Life Sciences Equity Analyst at T. Rowe Price.

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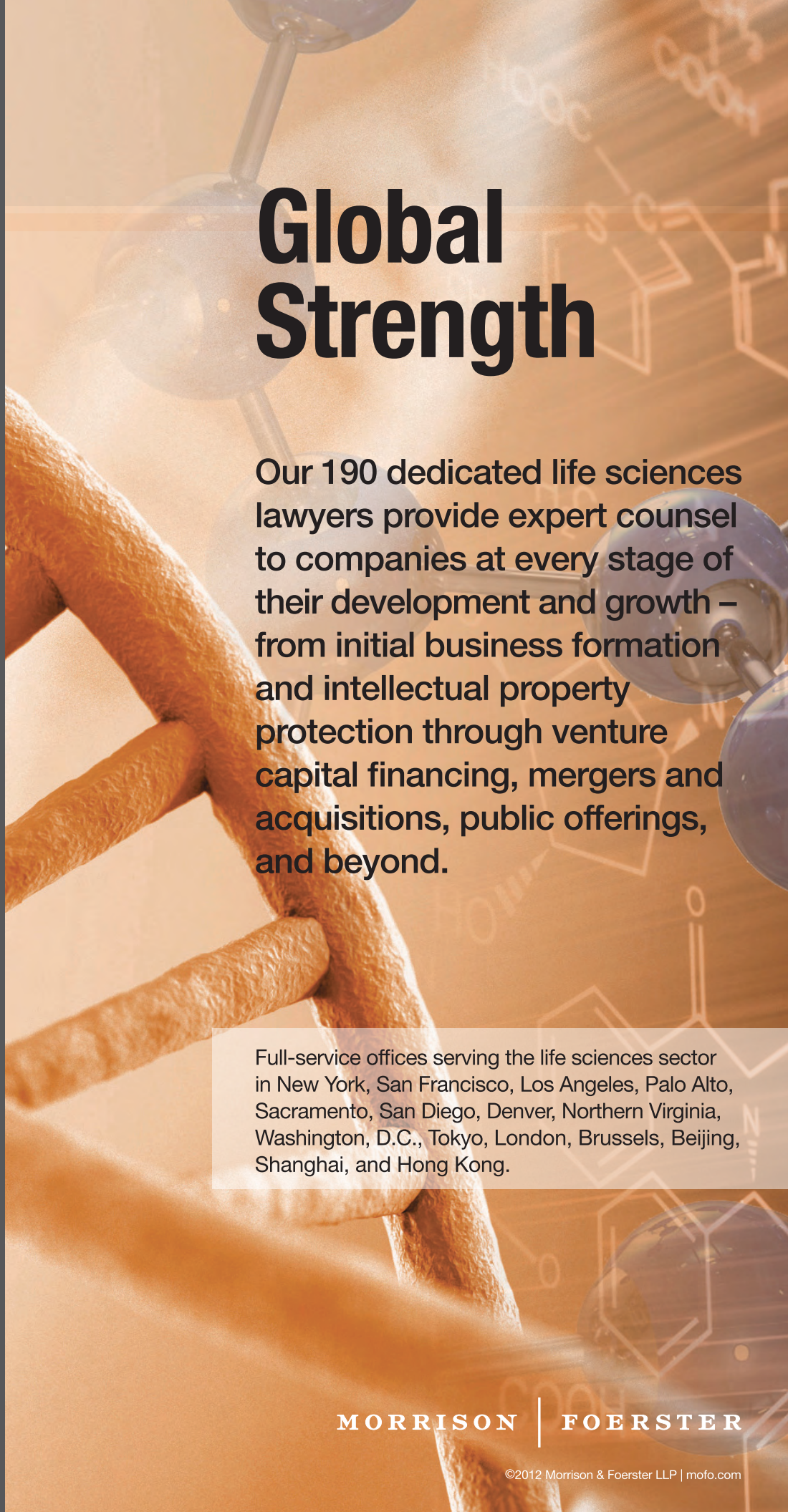

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