



NOVEMBER 13TH 2014

NCI SBIR

Investor Forum

**Small Business Innovation Research (SBIR) &
Small Business Technology Transfer (STTR)
Programs of the National Cancer Institute**





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WELCOME

November 13, 2014

Welcome to the National Cancer Institute (NCI) Small Business Innovation Research (SBIR) Investor Forum. It is with sincere gratitude that I welcome you and thank you for participating in such an important event. Your presence today represents the power and promise of innovation and collaboration in a new era in the fight against cancer.

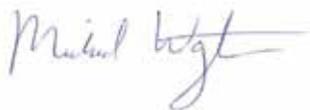
During this forum, you will have an opportunity to learn more about NCI SBIR & STTR priorities to address cancer and hear firsthand from the most promising SBIR-funded projects developing innovative technologies for the treatment, diagnosis, and prevention of cancer. The 28 presenting and poster companies were chosen from a highly competitive field of applicants based on their strength of research, product development, and market potential. These technologies have the potential to transform cancer care. We need your support and partnership to advance these projects into clinical use.

The NCI SBIR & Small Business Technology Transfer (STTR) Programs represent an active portfolio of more than 450 projects and an annual budget of more than \$119 million. These programs are one of the largest sources of early-stage, non-dilutive technology financing available in the United States enabling small businesses to develop promising cancer technologies. It is an exciting time to be involved with the SBIR & STTR Programs.

Today's Investor Forum is the result of an initiative of the NCI SBIR Development Center to further help companies and partners collaborate to accelerate the commercialization of novel therapeutics, diagnostics, devices, and digital health technologies. This year, we also introduced a new collaboration with the National Science Foundation (NSF) to develop the NIH Innovation Corps (I-Corps™) Team Training Pilot Program, a small business bootcamp that seeks to advance the development of new products and services arising from projects supported by currently funded NIH SBIR & STTR awards. Today we will also provide investors and strategic partners with an opportunity to learn more about the NCI Bridge Award. This award, a three-year, \$3 million funding opportunity, represents an innovative way for both the NCI and investors to work together to leverage their investments in the most promising companies.

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. These challenges can impede innovations and slow progress in translating research into clinical practice. By facilitating partnerships, we can catalyze the development of new tools that will ultimately help fulfill the mission of NCI to reduce the burden of cancer.

Today's agenda is designed to allow ample time for you to interact with the top-funded NCI-SBIR company project leaders 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 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

Agenda



8:00 a.m. – 8:30 a.m. Registration and Breakfast

8:30 a.m. – 8:45 a.m. Welcome Remarks

Speaker: Michael Weingarten, Director
NCI SBIR Development Center

8:45 a.m. – 9:00 a.m. Patient Perspective

Speaker: Peggy Devine, President, Cancer Information
& Support

9:00 a.m. – 9:45 a.m. Overview of the NCI SBIR & STTR Programs
and Key Initiatives

Speaker: Michael Weingarten, Director
NCI SBIR Development Center

Speaker: Andrew Kurtz, Program Director and Team
Leader, NCI SBIR Development Center

Company Presentations

9:45 a.m. – 10:00 a.m. Avidity Nanomedicines, LLC

10:00 a.m. – 10:15 a.m. G1 Therapeutics, Inc.

10:15 a.m. – 10:30 a.m. Annias Immunotherapeutics, Inc.

10:30 a.m. – 10:45 a.m. Modulation Therapeutics, Inc.

10:45 a.m. – 11:30 a.m. Poster Session/Networking Break



Company Presentations

11:30 a.m. – 11:45 a.m.	Bexion Pharmaceuticals, LLC
11:45 a.m. – 12:00 p.m.	KIYATEC, Inc.
12:00 p.m. – 12:15 p.m.	Accelerated Medical Diagnostics, Inc.
12:15 p.m. – 12:30 p.m.	Insight Genetics, Inc.

12:30 p.m. – 1:45 p.m.	Poster Session/Networking Lunch
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Company Presentations

1:45 p.m. – 2:00 p.m.	Weinberg Medical Physics, LLC
2:00 p.m. – 2:15 p.m.	Cynvenio Biosystems, Inc.
2:15 p.m. – 2:30 p.m.	Corvida Medical
2:30 p.m. – 2:45 p.m.	Lumicell, Inc.
2:45 p.m. – 3:00 p.m.	Delphinus Medical Technologies, Inc.

3:00 p.m. – 3:30 p.m.	Break/Partnering Sessions
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Company Presentations

3:30 p.m. – 3:45 p.m.	Cellsight Technologies
3:45 p.m. – 4:00 p.m.	StemMed, Ltd.
4:00 p.m. – 4:15 p.m.	DEKK-TEC, Inc.
4:15 p.m. – 4:30 p.m.	Senex Biotechnology, Inc.

4:30 p.m. – 4:45 p.m.	Closing Remarks
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4:45 p.m. – 6:00 p.m.	Reception
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SBIR & STTR Programs at NCI

Leading Small Business Innovation and Commercialization in the Fight Against Cancer

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.

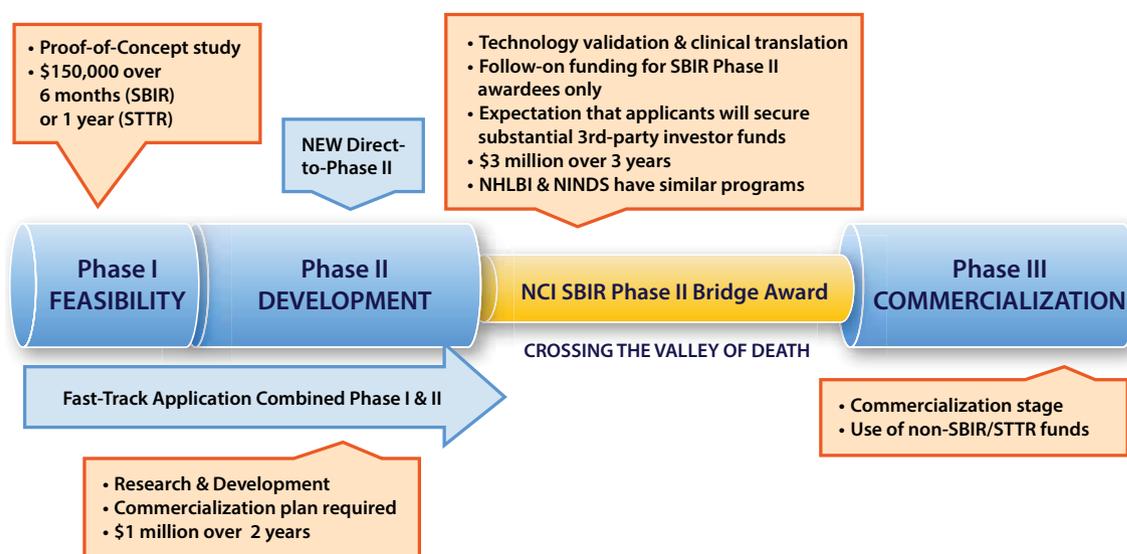
Program Goals

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, up to \$300K for Phase I and up to \$2M for Phase II, if appropriately justified.



Benefits of the NCI 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 many 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 toward 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.

For more information about SBIR's portfolio of projects and the small businesses leading them, please contact the NCI SBIR Development Center team.

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.

NCI SBIR Program

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

To participate in the NCI SBIR Program:

- The small business concern (SBC) must be an organized for-profit business located in the United States which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor.
- The Principal Investigator's primary employment must be with the SBC at the time of award and for the duration of the project period.
- The SBC must have no more than 500 employees, including its affiliates.
- The SBC must also be:
 - More than 50% directly owned and controlled by one or more individuals (who are citizens of or permanent resident aliens in

the United States), other business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States), or any combination of these;

OR

- More than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these. No single venture capital operating company, hedge fund, or private equity firm may own more than 50% of the concern;

OR

- A joint venture in which each entity to the joint venture meets the requirements above.

NCI STTR Program

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>.

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 mentors awardees in their technology development 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 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

The NCI SBIR Phase II Bridge Award

The NCI 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 NCI 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 a scientifically rigorous NIH peer review that complements due diligence performed by third-party investors. From FY 2009 – 2014, 18 Bridge Awardees have leveraged their total \$42.8 million of federal funding with \$86.3 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, innovative imaging devices that enable earlier cancer diagnosis to a device for expanding T-cells to improve outcomes in cellular immunotherapy.

There are two Bridge Awardees presenting at this year's Investor Forum: Bexion Pharmaceuticals, LLC and Corvida Medical.

The NCI SBIR Investor Forum

The 2014 NCI SBIR Investor Forum is the fourth 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.

The previous NCI SBIR investor forums have resulted in the closing of cumulatively ~\$300M in investments and partnership 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>.

NIH Innovation Corps (I-Corps™) Team Training Pilot Program

The I-Corps™ at NIH program seeks to accelerate the development and commercialization of new products and services arising from projects supported by currently funded SBIR & STTR awards. The nine-week boot camp supports training that will help teams at NIH-funded small businesses overcome key obstacles along the path of innovation and commercialization. For more information, visit <http://sbir.cancer.gov/resource/icorps>.

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>.

NCI SBIR & STTR Funding Opportunities

Contract Solicitations

Applications typically due: 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 toward commercialization. In FY 2014, NCI directed more than \$10 million to fund targeted areas of innovation through SBIR contract topics. This funding for small businesses supports the research and development of anticancer agents, biomarkers, health information technology, nanotechnology, proteomics, pharmacodynamic assays, and many other areas of interest to the NCI.

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.

Direct Phase II SBIR Grants to Support Biomedical Technology Development (PAR-14-088)

Applications due: April 5, August 5; December 5

The purpose of this funding opportunity announcement is to encourage applications to the newly authorized Direct-to-Phase II SBIR grant mechanism. The Direct-to-Phase II grant mechanism is

intended to facilitate SBIR-type R&D, to expand R&D opportunities for applicant small business concerns (SBCs), and to enhance the pace of technology development and commercialization.

Innovative Health Information Technology for Broad Adoption by Healthcare Systems and Consumers (PA-12-196)

Applications due: April 5, August 5; December 5

The purpose of this FOA is to facilitate the transition of SBIR-funded projects to the commercialization stage and to achieve broad scale dissemination of the products. This FOA is expected to promote partnerships between SBCs and large businesses or health-related organizations with the capacity to fully commercialize and disseminate the product.

Development of Highly Innovative Tools and Technology for Analysis of Single Cells (PA-13-14)

Applications due: April 5, August 5; December 5

This FOA encourages SBIR research grant applications to develop next-generation tools that distinguish heterogeneous states among cells and have commercial potential. These novel technologies will aid in obtaining a fine-grained, integrative, and dynamic view of heterogeneous cellular states/classes and will provide innovative platforms to transform research into the cellular basis of diseases.

Innovative Molecular Analysis Technology Development for Cancer Research and Clinical Care (PAR-13-327)

Applications typically due: May and November

This FOA encourages SBIR grant applications from SBCs proposing research for commercial development of novel cancer-relevant technologies. The proposed research projects are expected to focus on the development of highly innovative technologies that improve molecular and/or cellular analysis of cancer with a significant likelihood for either overcoming persistent challenges or obstacles or opening entirely new fields for cancer research or clinical care.

For information on the most current NCI SBIR & STTR funding opportunities:

- Visit sbir.cancer.gov/funding
- Sign up to receive e-mail notifications at sbir.cancer.gov/email_signup.asp
- Follow us on Twitter @NCIsbir

NCI SBIR Development Center Staff



Michael Weingarten, M.A.

Director

Phone: 240-276-5238

E-mail: weingartenm@mail.nih.gov



Greg Evans, Ph.D.

Program Director & Team Leader

Phone: 240-276-5245

E-mail: evansgl@mail.nih.gov

Cancer Biology, E-Health, and Epidemiology



Deepa Narayanan, M.S., C.C.D.M.

Program Director

Phone: 240-276-5229

E-mail: narayanand@mail.nih.gov

*Cancer Imaging, Clinical Trials, Radiation Therapy,
and SBIR Investor Forum*



Patricia Weber, Dr.P.H.

Program Director

Phone: 240-276-5240

E-mail: weberpa@mail.nih.gov

*Digital Health, Therapeutics, Biologics, and
SBIR Investor Forum*



Todd Haim, Ph.D.

Program Director

Phone: 240-276-5227

E-mail: haimte@mail.nih.gov

*Small Molecules, Biologics, Immunotherapeutics,
Theranostics, Cancer Prevention, and SBIR Investor Forum*



Andrew Kurtz, Ph.D.

Program Director & Team Leader

Phone: 240-276-5228

E-mail: kurtza@mail.nih.gov

*Biologics, Small Molecules, and Nanotherapeutics
and Molecular Diagnostics*



Amir Rahbar, Ph.D., M.B.A.

Program Director

Phone: 240-276-5230

E-mail: rahbaram@mail.nih.gov

*In-Vitro Diagnostics, Biologics, Therapeutics
and Proteomics*



Xing-Jian Lou, Ph.D.

Program Director

Phone: 240-276-5226

E-mail: loux@mail.nih.gov

*In-Vitro Diagnostics, Theranostics, Early-Stage Drug
Development, and Bioinformatics*



Ming Zhao, Ph.D.

Program Director

Phone: 240-276-5225

E-mail: zhaoming3@mail.nih.gov

*Cancer Diagnostics & Therapeutics, Cancer Control &
Prevention, Molecular Imaging, Bioinformatics, and Stem Cells*



Jonathan Franca-Koh Ph.D., M.B.A.

Program Director

Phone: 240-276-7622

Email: jonathan.franca-koh@nih.gov

Cancer Biology, Biologics, Small Molecules,
Cell Based Therapies



Brittany Connors

Scientific Editorial Assistant

Phone: 240-276-6474

E-mail: brittany.conners@nih.gov

Scientific Communications, SBIR Investor Forum,
Social Media, and Success Stories



Christie Canaria, Ph.D.

AAAS Science & Technology Policy Fellow

Phone: 240-276-5720

E-mail: christie.canaria@nih.gov

Scientific Communications and Special Initiatives



Tamar Boghosian

Program Analyst

Phone: 240-276-5231

E-mail: boghosiant@mail.nih.gov

Portfolio Analysis, Budget Tracking



Kory Hallett, Ph.D.

AAAS Science & Technology Policy Fellow

Phone: 240-276-5882

E-mail: kory.hallett@nih.gov

Program Analysis and Metrics



Julienne Willis

Program Specialist

Phone: 240-276-5235

E-mail: willisj@mail.nih.gov

**Small Business Innovation Research Development Center
National Institutes of Health
National Cancer Institute**

9609 Medical Center Drive
Rockville, MD 20850

Main phone number: 240-276-5300 | E-mail address: NCIlsbir@mail.nih.gov

Follow us on Twitter @NCIsbir and join the conversation #NCIsbirIF

SPEAKERS.....



Andrew J. Kurtz, Ph.D.

Program Director and Team Leader, NCI SBIR Development Center

Dr. Andrew Kurtz is Program Director and Team Leader in the Small Business Innovation Research (SBIR) Development Center at the National Cancer Institute (NCI), where he manages SBIR/STTR awards primarily in the areas of drug development and molecular diagnostics. Since 2009, he has managed the SBIR Phase IIB Bridge program designed to incentivize partnerships between federally-funded small businesses and third-party investors, in order to accelerate the commercialization of technologies seeded with SBIR/STTR funding. Dr. Kurtz also plays a key role in managing the recently-launched Innovation Corps (I-Corps™) at NIH Pilot Program, a training curriculum developed for NIH SBIR/STTR Phase I awardees that uses a hypothesis-driven method of customer discovery to gain insights into developing a repeatable and sustainable business model.

From 2005-2007, Dr. Kurtz served as an AAAS Science and Technology Policy Fellow at the NCI, during which time he helped to launch The Cancer Genome Atlas (TCGA) Pilot Project and also developed policy recommendations to enhance the NIH SBIR/STTR Programs. He also has prior industry experience developing high-throughput bioanalytical assays to support pharmacokinetic studies for the biopharmaceutical sector. Dr. Kurtz received a B.S. in Chemistry from The University of Texas at Austin and a Ph.D. in Biochemistry and Molecular Biology from The University of Texas Medical Branch (UTMB) at Galveston.



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 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 \$120M** 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. Mr. Weingarten has implemented a set of key initiatives for optimizing the performance of the NCI SBIR Program at the NIH. These include the establishment of a new model at the NCI for managing the programs – the SBIR Development Center.

Under Mr. Weingarten's leadership, the NCI SBIR Development Center has launched a range of new initiatives to facilitate the success of small businesses developing cancer-related technologies. Recent initiatives include the launch of the **NIH I-Corps™** pilot program in which teams of budding entrepreneurs engage in a hypothesis-driven approach to validate their proposed business models by conducting over 100 interviews with potential customers. Companies adjust their strategies based on direct customer feedback and analyze the information they collect to determine if there is a product/market fit. Other NCI SBIR initiatives introduced under Mr. Weingarten's leadership include the **NCI SBIR Investor Forum**, the **NCI SBIR Phase II Bridge Award**, and the workshop titled **Federal Resources to Accelerate Commercialization (FRAC)**. Thus far, NCI SBIR has held three investor forums that in total have facilitated the closing of deals valued at over \$300M. The NCI SBIR Phase II Bridge Award, which was launched in 2009, incentivizes partnerships between NIH's SBIR Phase II awardees and third-party investors and/or strategic partners to help small businesses bridge the funding gap between the end of their SBIR Phase II awards and the next round of financing needed to advance a promising cancer therapy or imaging technology.

Peggy Devine

President, Cancer Information & Support Network

Peggy Devine is a Medical Technologist with a B.S. in chemistry and biological science and a Clinical Laboratory Scientist (C.L.S.) license. She has worked in both clinical and research laboratories for over 25 years. She retired after her breast cancer diagnosis in 1994 and went to work at University of California, San Francisco as an assistant administrator of their breast oncology program to learn the world of breast cancer research from the inside. She quit after 6 years and formed a non-profit called Cancer Information & Support Network (CISN) and now serves as its President. Their focus is on providing information to patients as well as free e-course trainings online for advocates. CISN also conducts in-person trainings on clinical trials, personalized medicine, and cancer 101 around the country, and conducts trainings for staff on the patient perspective when asked to participate in a clinical trial.

Ms. Devine brings her love of science and research to her advocate work and focuses most of her volunteer as well as non-profit work on helping the general public and advocates better understand research. For Peggy the most challenging and rewarding aspects of advocacy is helping people understand the many aspects of cancer research and that to achieve a 'bench to bedside' approach, individuals must enter clinical trials and donate tissue. She is actively engaged in addressing the challenge of doing this so each person's best interests are served.

Ms. Devine has reviewed grants for Susan G. Komen, the NCI, the Department of Defense, Avon, the California Breast Cancer Research Program and the National Institute of Environmental Health Science. Peggy is a consultant for a Department of Defense team award "Catch it with Ultrasound." She also is a member of an NCI oversight committee for an Office of Biorepositories and Biospecimen Research study looking at the pre-analytical variables of collection, processing and storage on biomarkers. She is a NCI patient advocate, a UCSF SPORE member and an advocate for the Alliance clinical trial cooperative group.

Company Overviews

Reference to a 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.

Podium Presentations



Avidity Nanomedicines, LLC

www.aviditynano.com
11119 N. Torrey Pines Road
Suite 125
La Jolla, CA 92037

Kent Hawryluk
Chief Business Officer
317-989-3100
kent@aviditynano.com

Antibody siRNA Complexes (ARCs™)

9:45 a.m. – 10:00 a.m.

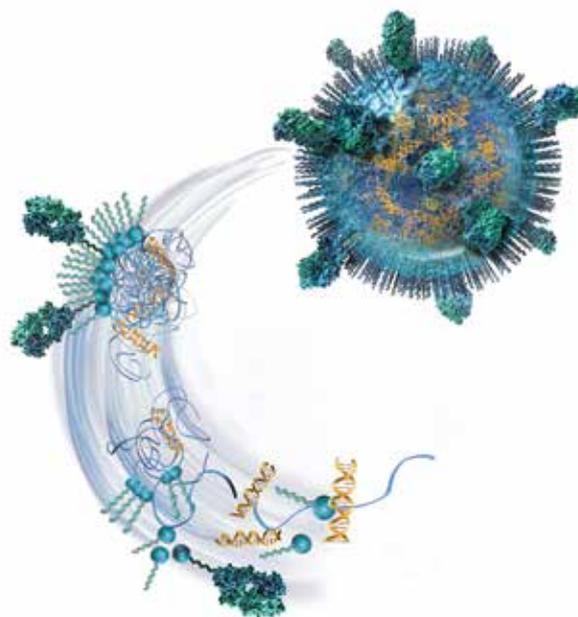
Company Background

Avidity NanoMedicines is pioneering a new class of therapeutics, antibody siRNA complexes (ARCs™), which draw on the best features of antibody-drug conjugates and nucleic acid-based medicines. Through partnerships with academic and industry experts, Avidity is applying its technology to the discovery and development of novel, targeted drugs. Founded in 2013, the company completed a \$9 million Series A financing in January 2014 and entered into a collaboration with a major pharmaceutical company.

Technology Overview

ARCs are self-assembling, polymeric nanoparticles that encapsulate one or more siRNA and are decorated with monoclonal antibodies for cell-specific binding and internalization. Avidity's core technology was invented by Mark Davis, professor

of chemical engineering at Caltech. ARCs represent the culmination of Professor Davis's nearly two decades of R&D in nanomedicines and are optimized for distribution, half-life, cell internalization, and tolerability. In the SBIR Phase I project, Avidity has assessed the feasibility of the ARCs via 1) identification of candidate siRNAs via bioinformatics and in vitro screening, 2) characterization of physicochemical properties of siRNA-containing ARCs, 3) demonstration of siRNA-mediated target knockdown and induction of apoptosis in cultured cells, and 4) evaluation of target knockdown and tumor regression in a xenograft tumor model.



Market Potential

By utilizing nano-scale self-assembly to combine the potency and specificity of biologics with siRNA payloads, ARCs create a disruptive approach to the treatment of cancer and other serious diseases. Preliminary results suggest that treatment with an ARC is superior to treatment with native antibody alone and results in profound tumor regression in mice. Avidity currently has a strategic collaboration with a top 10 pharmaceutical company and seeks to create exceptional collaborations around specific ARC products in cancer and other serious diseases based on its breakthrough technology. Importantly, Avidity plans to advance independent



programs through clinical proof-of-concept utilizing proceeds from collaborations in addition to venture financing.

Competitive Advantage

ARCs overcome the cell delivery barrier that has historically limited siRNAs to primarily targeting liver diseases. The physicochemical properties (e.g., size, charge, stability) of ARCs have been optimized for in vivo delivery of siRNAs to solid tumors. Thus, ARCs allow gene targets to be silenced with exquisite specificity and efficiency, and have the potential to exceed the efficacy of existing drugs.

Financial Overview

Avidity receives full-time equivalent (FTE) revenue and reimbursement of direct research expenses through an Evaluation Agreement with a large pharma company. Avidity was awarded a Phase I SBIR grant in December 2013 and completed a \$9 million Series A financing in January 2014. The company will close a \$5 million convertible note in fall 2014.

Avidity forecasts having adequate resources to allow for advancement of the candidate therapeutic through Investigational New Drug (IND)-enabling animal studies and for completion of a Phase I clinical evaluation in cancer patients.

The company intends to raise additional funding to support continued clinical development through Phase II and Phase III clinical studies, culminating with New Drug Application (NDA) submission.

Intellectual Property

Avidity licensed the intellectual property for the cMAP-based nanoparticle system from Caltech, including a patent issued in 2009. The company is filing provisional and non-provisional patent applications for specific candidate siRNAs and will seek and required licenses or agreements at an appropriate stage of product development.

Commercialization Strategy

Avidity plans to initiate a second pharma research collaboration, nominate 1-2 development candidates, close a convertible note and Series B financing, and have the first-in-human dose within the next two years.

Pipeline Products

Avidity is advancing multiple ARCs for the treatment of cancer, with a focus on solid tumors.

Management Team

- Troy Wilson, Ph.D., J.D., President and CEO, is also the president and CEO of Wellspring Biosciences and its affiliated company, Araxes Pharma.
- Kent Hawryluk, Chief Business Officer, has been an entrepreneur for 25 years and is also a partner of Twilight Venture Partners.
- Arthur Levin, Ph.D., Executive Vice President, R&D, has an immense background in nucleic acid-based therapeutics and previously held the same position at miRagen Therapeutics.



G1 Therapeutics, Inc.

www.g1therapeutics.com
 79 TW Alexander Drive,
 4401 Research Commons, Suite 105
 Research Triangle Park, NC 27709

Patrick Roberts, Ph.D.
 Director, Translational Medicine
 919-213-9862
 pjr@g1therapeutics.com

Reduction of Chemotherapy-Induced Myelosuppression (“Chemoprotection”) (G1 T28-1)

10:00 a.m. – 10:15 a.m.

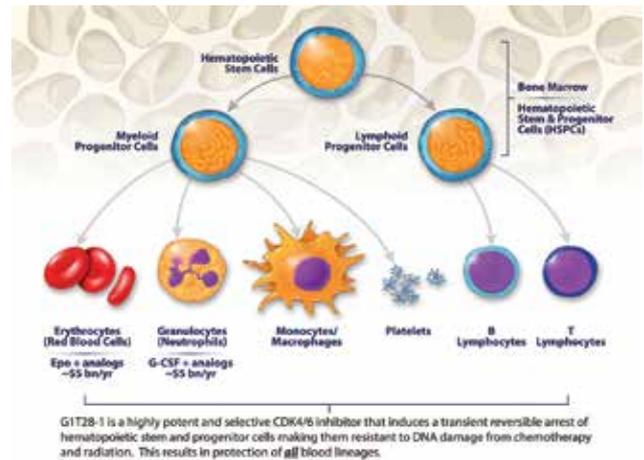
Company Background

G1 Therapeutics (G1, or the Company) is a clinical-stage oncology company using a small molecule-based approach to attenuate multi-lineage bone marrow suppression due to chemotherapy. G1 was founded by Ned Sharpless, M.D. (Director, UNC Cancer Center), and Kwok-Kin Wong, M.D., Ph.D., (Director, Belfer Institute/DFCI/Harvard), to capitalize on their research into how certain cyclin-dependent kinases (CDKs) control the production of blood cells by hematopoietic stem and progenitor cells (HSPCs) in the bone marrow. The Company’s lead program, G1T28-1, is a highly potent and selective CDK4/6 inhibitor that is currently in Phase 1 clinical trials. G1 has assembled a team of accomplished drug discovery and development scientists with extensive experience in bringing innovative oncology drugs to market. The Company has 10 full-time employees and is based in Research Triangle Park, NC.

Technology Overview

Bone marrow suppression (also known as myelosuppression) is a severe side effect of chemotherapy, resulting in the loss of red blood cells (anemia), white blood cells (neutropenia) and platelets (thrombocytopenia). Patients can experience fatigue due to anemia, infections due to neutropenia and bleeding due to thrombocytopenia. While oncologists expect chemotherapy to remain the standard treatment regimen for many kinds of tumors, the current treatments for myelosuppression have significant liabilities and shortcomings.

G1T28-1 induces a transient, reversible arrest of HSPCs, making them resistant to DNA damaging insults. Preclinical data has demonstrated that protecting the bone marrow from damage results in a quicker recovery of all blood lineages and mitigates bone marrow exhaustion. G1T28-1 has the potential to enhance antitumor efficacy by maintaining chemotherapy dose density and schedule, and to improve quality of life and to positively impact pharmacoeconomics by reducing transfusions, preventing hospital admissions due to infection, and attenuating the incidence of secondary hematological malignancies.



Market Potential

G1’s clinical candidate, G1T28-1, will enter the bone marrow supportive care market, which includes growth factors (biologics) such as Neulasta, Epogen, Procrit, Neupogen, and Aranesp with combined 2013 sales of \$8.4 billion in the United States alone. The Company has a target chemotherapy patient population of up to 300,000 per year in the U.S. alone.

Competitive Advantage

G1's first-in-class chemoprotectant, G1T28-1, is differentiated from current treatments for myelosuppression because it protects all hematopoietic lineages: red cells, platelets, granulocytes, and lymphocytes. While growth factors stimulate single-lineage bone marrow progenitor cells that have already been damaged by chemotherapy, G1T28-1 protects all hematopoietic stem and progenitor cells (HSPCs) before damage is done, potentially changing the treatment paradigm.

Financial Overview

Since inception, G1 has raised over \$5 million from non-dilutive sources and closed a Series A financing of \$12.5 million in October 2013. The Company is currently seeking a \$15 million Series B for conducting a Phase 1b/2a trial to demonstrate reduction of chemotherapy-induced myelosuppression in cancer patients.

Intellectual Property

G1 has broad freedom to operate for its novel compounds and their methods of use. G1 has five issued composition-of-matter US patents covering compounds (including G1T28-1) related to the Company's first proprietary scaffold. Additionally, G1 has multiple pending applications for composition-of-matter and methods-of-use on all three of its novel kinase inhibitor scaffolds.

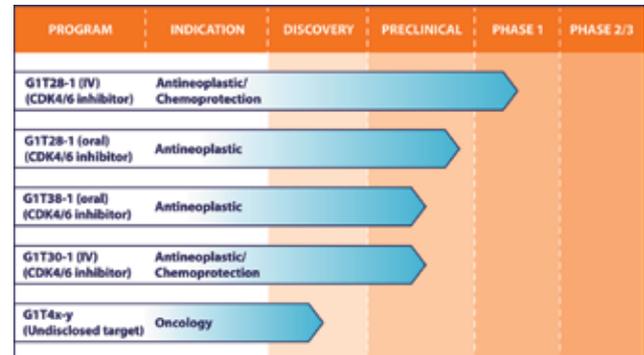
Commercialization Strategy

G1 is focused on developing G1T28-1 for chemoprotection. The Company plans to first demonstrate early proof of concept of bone marrow protection in a rapid and straightforward clinical trial in patients with small cell lung cancer. Following this trial, G1 plans to conduct additional Phase 2 trials to demonstrate efficacy in other cancer types.

Additionally, there has been heightened interest in drugs that target CDK4/6 as antineoplastic agents. The Company is currently in active discussion with several potential partners for G1's proprietary CDK4/6 inhibitors used as antineoplastics.

Pipeline Products

G1 Therapeutics is advancing a portfolio of proprietary drug candidates for both antineoplastic and chemoprotection indications. The Company's lead program, G1T28-1, is currently in Phase 1 clinical testing. PK/PD data from this trial will inform dose and schedule for Phase 1b/2a trials in cancer patients that are planned for Q2 2015. In addition, G1 has back-up/follow-on compounds for both chemoprotection (G1T30-1) and antineoplastic use (G1T38-1).



Management Team

- Mark Velleca M.D., Ph.D., Chief Executive Officer, was instrumental in founding, building, and leading CGI Pharmaceuticals. He forged a major drug discovery/development collaboration with Genentech and an acquisition of the company by Gilead.
- Raj Malik M.D., Chief Medical Officer, is an oncologist with more than 20 years of drug development experience in academics (University of Virginia), large pharma (BMS), and small biotech (Agennix).
- Greg Mossinghoff, M.B.A., Chief Business Officer, has extensive operational, financial, and deal-making experience in small biotech and big pharma. As President of Inspire (from inception through Initial Public Offering), he established significant corporate partnerships.
- Jay Strum, Ph.D., Chief Scientific Officer, brings more than 20 years of drug discovery experience to G1. He was a key leader of programs in cancer and metabolic diseases at GSK that led to marketed therapeutics such as Tykerb.



Annias Immunotherapeutics, Inc.

3 Sedgewood Road
Chapel Hill, NC 27514

Reiner Laus, M.D.

President/Chief Executive Officer
rlaus@anniasimmuno.com

Cytomegalovirus Therapeutic Vaccine – Glioblastoma and Other Cancers

10:15 a.m. – 10:30 a.m.

Company Background

Annias Immunotherapeutics, Inc., is a biopharmaceutical company focused on the development of novel immunotherapeutic approaches to treat cancer. The company was founded in 2009 by Senior Investigators at the Duke Medical Center and is led by CEO Reiner Laus, M.D. Its work on developing an immunotherapeutic vaccine is based on a patented and proprietary immunotherapeutic platform, discovered by John Sampson and Duane Mitchell at Duke University that targets human Cytomegalovirus (CMV). CMV is over-expressed in a variety of human cancers including significant and homogeneous expression in almost all glioblastoma (GBM) but not in normal brain tissue. Annias Immunotherapeutics is focused on this promising opportunity to utilize CMV proteins as tumor-specific targets. Additionally, the company has developed superior methods to immunize humans against cancer, and has already tested this approach in human clinical trials. This novel immunotherapeutic platform has shown extraordinary promise in eradicating GBM with virtually no toxicity experienced in the treated patients.

Technology Overview

Annias has exclusive rights to the next generation of proprietary immunotherapeutic platforms for peptide-based and dendritic cell approaches developed at Duke by Senior Investigators in the Preston Robert Tisch Brain Tumor Center. This team has completed two consecutive clinical trials using CMV pp65 loaded dendritic cells (DCs) in patients with GBM. The first of these trials was randomized and blinded and demonstrated the induction of CMV-specific immunologic responses along with remarkable

progression-free survival (PFS) exceeding 36.6 months vs. 10.8 months for the control group and a median overall survival (OS) exceeding 36.6 months vs. 18.5 months for the control group. The CMV vaccine is currently being reformulated into a cutting-edge rationally designed multi-epitope peptide conjugate, PEP-CMV. This proprietary technology platform combining chemotherapy and vaccination will be used to clinically evaluate the efficacy and immunologic effects of PEP-CMV vaccines in patients with newly diagnosed GBM. The poor prognosis for patients with GBM will enable Annias to obtain efficacy data from a randomized, controlled trial within two years of trial initiation. Product candidates based on this platform can be rapidly advanced in breast cancer, prostate cancer, and colorectal cancer.

Market Potential

Despite aggressive treatment, GBM remains uniformly lethal with median survival rates for patients with GBM being less than 15 months from the time of diagnosis. Thus, there is a large and urgent need for improved therapies for GBM. World-wide sales of the chemotherapeutic temozolomide (Temodar®) for GBM have reached one billion dollars in spite of its very limited efficacy. The markets for the products in the Annias pipeline for treatment of breast, colorectal, and prostate cancer present multi-billion dollar opportunities.

Competitive Advantage

The recent discovery and confirmation by five independent laboratories that CMV propagates within a high proportion of GBMs without infecting surrounding normal brain tissue provides an unparalleled opportunity to utilize the highly immunogenic antigens from CMV as tumor-specific targets. A distinct advantage of immunotherapeutic targeting of viral antigens is that the immune system is better equipped to target viral antigens compared to autoantigens. The frequency of CMV-specific T-cells is several orders of magnitude higher than what can be achieved with approaches targeting autoantigens.

Financial Overview

Annias secured \$246,000 in NCI Phase I SBIR funding in 2012 and has recently submitted a Phase II application for \$1.9 million. Through the Duke University Medical Center, several million dollars were secured in grant funding for CMV-targeted vaccine research. The company expects that taking PEP-CMV through a randomized Phase II program, developing its pipeline products, and operating the company over the next four years will require significant incremental investment.

Intellectual Property

The company has exclusive rights to the Duke University portfolio of immunotherapy patents. This portfolio includes both issued and pending patents, as well as published and as of yet unpublished patent applications. The issued patent includes claims that cover Annias approach both broadly (immunotherapy of cancer by targeting CMV) and narrowly (composition of PEP-CMV therapeutic).

Commercialization Strategy

Annias plans to start the next clinical trial for PEP-CMV this year. The initial capitalization of the company will serve to conduct and collect data from a large-scale, randomized controlled clinical trial for PEP-CMV. This trial will position the company well for product registration, partnering, and further development of its pipeline in additional diseases.

Pipeline Products

The company is developing PEP-CMV with GBM as the lead indication. Follow-on indications that can be targeted with the same product include the four leading cancers: prostate, breast, lung, and colorectal cancer.

Management Team

- Reiner Laus, M.D., CEO and President, has worked on developing cancer immunotherapeutics for over 20 years. He was most recently CEO of BN Immunotherapeutics and prior to that he was VP of R&D at Dendreon, where he was a co-inventor of Provenge.
- John Sampson, M.D., Ph.D., Chief Scientific Collaborator and founder, is leader of the Neuro-Oncology Program at Duke University and head of the Brain Tumor Immunotherapy Program there. He has published extensively on CMV as a tumor-specific antigen and immunotherapy approaches. His laboratory at Duke developed the EGFRvIII-targeted vaccine, which is now completing worldwide Phase III trials in patients with GBM.
- James Sheldon, Vice President and Corporate Secretary, was founder of Embrex, Inc. (acquired by Pfizer) and EnSys, Inc. (merged into SDOI).



Modulation Therapeutics, Inc.

www.modulationtherapeutics.com
3802 Spectrum Boulevard, Suite 124
Tampa, FL 33612

Lori Hazlehurst, Ph.D.

President and Co-founder

813-335-7401

hazlehurst@modulationtherapeutics.com

MTI-101, A Novel Peptidomimetic Drug for Cancer

10:30 a.m. – 10:45 a.m.

Company Background

Modulation Therapeutics is an early discovery and research startup company that has been spun out of the Moffitt Cancer Center as part of their initiative to commercialize the research being conducted at the research facility. Modulation is dedicated to the development of novel peptidomimetic drugs for multiple myeloma (MM) and other cancers that target bone. The company is currently focused on development of its lead candidate, MTI-101, a novel drug with a first-in-class mechanism of action.

Technology Overview

MTI-101 is a cyclic peptidomimetic that binds CD44 and induces an agonistic signal leading to toxic increases in the levels of intracellular Ca²⁺ that trigger cell necrosis in MM cells. Recent evidence indicates that metastatic tumors rewire their Ca²⁺ circuitry. We propose that rewiring of Ca²⁺ signaling renders tumor cells vulnerable to Ca²⁺ overload. The in vivo efficacy of Modulation's lead compound, MTI-101, has been demonstrated as a single agent and in combination with the proteasome inhibitor bortezomib using two independent MM in vivo models that considers the tumor microenvironment. Importantly, MTI-101 shows increased activity in primary MM specimens obtained from patients who have relapsed on therapy; a finding that has been used to develop predictive biomarkers to be further explored in early phase clinical trials.

Market Potential

MM is a disease that initially responds to therapy. However, inevitably all patients will relapse with disease that is refractory to standard of care agents. Thus novel treatment strategies are required to improve patient outcome. The market for MM is very large, and with improved diagnosis/detection combined with an aging population, is projected to exceed \$10 billion worldwide by 2018.

Competitive Advantage

There are no drugs on the market or in development that would provide direct competition to Modulation's lead candidate, MTI-101.

- MTI-101 induces necrotic cell death in myeloma cells and thus does not require the apoptotic machinery to induce cell death.
- Inhibits osteoclast formation and function and augments differentiation of osteoblasts using in vitro cultures and demonstrates decreased myeloma induced lytic bone lesions in vivo. MTI-101 uniquely targets the both the tumor and the bone marrow niche.
- Shows increased ex vivo activity in specimens obtained from patients relapsing on therapy.

The crucial unmet need in myeloma is for drugs effective in patients that have relapsed on existing therapies. Modulation Therapeutics is well positioned to develop MTI-101 for the treatment of drug refractory myeloma.

Financial Overview

Modulation is an early-stage, pre-clinical research organization and has not generated any company revenues to date, nor have they developed any revenue projects beyond understanding the potential size of the market opportunity.

The company has raised over \$1.7 million to date through a combination of research grants, foundation investments, and local commercialization debt.

Intellectual Property

Modulation Therapeutics has licensed MTI-101 and several analogs from the Moffitt Cancer Center. The composition of matter and use patent was filed in 2012. Additional filed patents include coverage of analogs, combination strategies as well as biomarkers of response.

Commercialization Strategy

Modulation is looking to raise \$3 million to build and fund the infrastructure and partnerships required to plan, manage, execute, and document the IND-enabling studies to include the IND application and approval process. Modulation expects to complete the IND approval process within 18 months of receiving the required funding. Currently, Modulation has been able to advance the development of MT-101 through initial PK studies.

Pipeline Products

The initial focus for Modulation is on MTI-101 for the treatment of MM. Additional indications currently being validated are EGFR-driven lung cancer, metastatic prostate and breast cancer. Targeting antibody conjugation strategies are in development and the patent has been filed for this strategy. Moreover a peptoid-peptide library is currently in development for covering additional chemical space surrounding MTI-101.

Management Team

- Lori Hazlehurst, Ph.D., Co-founder and Chief Scientific Officer, is an expert in defining strategies to target the tumor microenvironment and is the co-inventor of multiple patents, including MTI-101.
- Mark McLaughlin, Ph.D., Director of Synthetic Chemistry, is an experienced synthetic organic and peptide chemist with more than 100 publications, is a co-inventor of MTI-101, and a senior member of the Moffitt Cancer Center.
- William Dalton, M.D., Ph.D., Board Member, is the current CEO of M2GEN and former CEO of the Moffitt Cancer Center.
- Anne Cress, Ph.D., Board Member, is a professor of Cellular & Molecular Medicine at the University of Arizona, and Deputy Dean of Research.



Bexion Pharmaceuticals, LLC

www.bexionpharma.com
632 Russell Street
Covington, KY 41011

Ray Takigiku, Ph.D.

Chief Executive Officer and Co-founder
859-757-1611
rtakigiku@bexionpharma.com

SapC-DOPS Proteolipid Nanovesicles (BXQ-350)

11:30 a.m. – 11:45 a.m.

Company Background

Bexion Pharmaceuticals, LLC, is a clinical-stage company developing SapC-DOPS proteolipid nanovesicles (BXQ-350) as a therapy for glioblastoma multiforme (GBM). The company was founded in 2006 with technology licensed from Cincinnati Children's Hospital Medical Center. The distinctive tumor-targeting property of SapC-DOPS was discovered during Bexion's research on the function of saposin C, a lysosomal protein involved in sphingolipid catabolism, which is essential for tumor-targeting of nanovesicles.

Technology Overview

Bexion is developing a new molecular entity with a novel mechanism of action for targeting and eliminating GBM. The SapC-DOPS proteolipid nanovesicles specifically target and kill tumor cells in orthotopic xenograft models of glioma and have a high affinity for aberrant phosphatidylserine (PS)-rich membrane domains that occur on the surfaces of tumor cells and cells of tumor neovasculature, but not normal cells. The prolongation of life of tumor-bearing mice following BXQ-350 treatment was dramatic and statistically significant.

Market Potential

GBM is the most common and lethal primary brain tumor. The median survival time is still limited to less than 15 months under the standard treatment, comprised of surgery, radiation, and chemotherapy. Because of the high unmet need for a treatment for malignant glioblastomas, the market for an efficacious drug is very significant with estimates of as much as half a billion dollars for one year.

Competitive Advantage

BXQ-350 nanovesicles offer a new approach for targeting and killing cancer cells, potentially without harming normal cells and tissues. Current radio- and chemotherapies have low therapeutic indices, incur severe side effects, and in the case of brain tumors, also display neurotoxicity. BXQ-350 is expected to avoid the most debilitating side effects because its mechanism of action is significantly different. The efficient targeting of brain tumors by BXQ-350 was confirmed in a recent MRI study in which brain tumors were visualized using paramagnetic Gd-DTPA-BSA/SapC-DOPS vesicles. BXQ-350 targets PS, which multiple lines of evidence suggest is potentially a universal tumor target. Alternative PS-targeted therapeutics have been proposed but none have the ability to bypass the blood brain barrier (BBB).

Financial Overview

Bexion's projects have been supported over the last five years by almost \$6 million in SBIR grants (Phase I, Phase II + Kentucky Match Program, Phase IIb Bridge) and over \$15 million from combined founding equity, Series A financing, and private investments.

Intellectual Property

Bexion's technology is protected by two issued U.S. patents, several other pending applications, and trade secrets. Issued patents are for composition of matter and combinations. Recent filings by Bexion and its collaborators are focused on protecting additional new anti-cancer technologies, including novel chemistries, methods, and compositions. In conjunction with Bexion's overall business plan, the company plans to in-license complementary technologies as needed.

Commercialization Strategy

Bexion will explore additional funding options through acquisition, partnering, or licensing by major pharmaceutical companies who will carry on Phase III clinical development, product launch, and sales & marketing; or through an initial public offering (IPO).

Potentially and importantly, with further clinical studies, BXQ-350 could target the antineoplastics market for other types of cancers, both as the primary or adjuvant therapy.

Pipeline Products

Bexion's pipeline includes novel formulations and combination therapies for targeting a range of aggressive and lethal cancers, including pancreatic cancer; compositions to enable the imaging of invasive and hidden cancer cells' and very exciting methods to enhance the delivery of drugs across the BBB for targeting central nervous system (CNS) diseases.

Management Team

- Ray Takigiku, Ph.D., CEO, President, and Co-founder, is a former member of the leadership team at Procter & Gamble Pharmaceuticals that developed and marketed the blockbuster osteoporosis drug Actonel, and the market leader for ulcerative colitis, Asacol.
- Ellen Monson, Ph.D., Senior Vice President, has extensive knowledge of large molecule drug development experience from Eli Lilly and was formerly Director of Intellectual Property and Technology Transfer at the University of Cincinnati.
- Kevin Xu, M.D., Ph.D., M.B.A., Vice President and Co-founder, has been a PI on multiple SBIR grants and received in PhD training in tumor biology from the Mayo Graduate School.
- Tom Wei, Ph.D., Vice President, is the former Associate Director of the Research and Development and Quality Control labs at Coldstream Laboratories.
- Margaret van Gilse, M.B.A., Vice President of Business Development, has over 25 years of business development, strategic planning, governmental relations, communications, and fundraising experience with entrepreneurial companies in multiple healthcare segments.
- Olivier Rixe, M.D., Ph.D., medical advisor, is Associate Director for Clinical Research at the University of New Mexico Cancer Center.



Kiyatec, Inc.

www.kiyatec.com
900-B West Faris Road
Greenville, SC 29605

Matt Gevaert

Chief Executive Officer
864-502-2013
matt.gevaert@kiyatec.com

3-D Cell-based Cancer Diagnostic, 3DKUBE™

11:45 a.m. – 12:00 p.m.

Company Background

KIYATEC is a privately held company that has developed a platform to enable accurate *ex vivo* prediction of cancer patients' response to drug treatment. Incorporated in 2010 by co-founders David Orr and Matt Gevaert, the company has created novel 3-D cell-based models for drug response profiling that can generate information relevant to preclinical testing, clinical trials, and clinical diagnostics applications. By accurately predicting patient drug response without exposing patients to drugs, KIYATEC will enable informed drug selection that minimizes clinical trial failures and maximizes patient outcomes.

KIYATEC is located in Greenville, SC, and is based in the Greenville Health System's Institute for Translational Oncology Research (ITOR), which conducts phase I clinical trials and is a life science incubator for companies pursuing translational cancer therapeutics and/or diagnostics. KIYATEC currently has nine employees.

Technology Overview

KIYATEC's 3DKUBE™ is a technology platform that uses human clinical samples to generate 3-D microtumors to accurately predict human response to cancer drugs *ex vivo*. The 3DKUBE is a 3-D perfusion bioreactor that allows for co-culture of the different cell types found in tumors, and incorporates optimized 3-D scaffolds and media conditions. In addition to many cell lines, KIYATEC has tested clinically annotated, patient-derived primary ovarian and breast cancer cells in its drug response profiling and is expanding into primary glioblastomas (GBMs). KIYATEC's 3-D microtumors

can be used in preclinical drug evaluation, as a co-clinical trial patient selection tool, and as an *ex vivo* diagnostic for real time clinical decision making.

Market Potential

The global cancer/tumor profiling market was valued at \$13.3 billion in 2012, while the global market for cell-based assays for drug discovery was valued at \$6.2 billion in 2010. The U.S. total available market opportunity for cell-based ovarian cancer, breast cancer, and GBM cancer diagnostics is approximately \$1 billion. KIYATEC's live cell cancer diagnostics will enable response-based drug selection and will be offered via a laboratory service model.

Competitive Advantage

KIYATEC's drug response profiling platform uses a 3-D microenvironment to culture cells, enabling better prediction of clinical outcomes than 2-D microenvironments. In KIYATEC's Phase I contract, cells cultured in an actively perfused microenvironment had increased cell viability, richer paracrine interactions, and increased cell functionality compared to static cultures. The 3-D cultures are maintained as closed systems without manipulations, saving time and cost, decreasing contamination risk, and increasing scalability. KIYATEC's demonstrated ability to choose and utilize the best scaffold for a given cell type maximizes the number and type of tissues that can be effectively modeled and maximizes the potential for multi-cell interaction for better cell function. KIYATEC's exceptional clinical connectivity results in more effective procedures with the clinical partner and more successful translation of laboratory results back into the clinic, aspects not possible for competitors relying on third-party primary tissue sourcing.

Financial Overview

KIYATEC has secured over \$5.1 million in committed capital since 2008 (\$2.6 million in investment; \$2.5 million non-dilutive funding including a recently awarded NCI Phase II contract) and is currently working to raise a series B round of \$12.5 million, with an initial tranche of \$7 million to support company milestones.

Intellectual Property

KIYATEC's IP portfolio consists of an exclusive license to issued utility patents (product and method claims). The company has assignment of issued design patents and pending utility filings associated with the core technology for applications in drug screening, cancer diagnostics, and 3-D cell-based assays.

Commercialization Strategy

KIYATEC is currently generating revenue from late stage preclinical 3-D cell-based assay services for pharma, biotech, and contract research organization clients with potential to expand quickly into co-clinical trials. Future *ex vivo* cancer diagnostics that enable response based drug selection will be offered as a CLIA lab-based service offering either as a laboratory developed test (LDT) or as an FDA regulated diagnostic as required.

Pipeline Products

KIYATEC's first generation platform (3DKUBE) has been tested with patient derived ovarian and breast cancer cells/tissues; GBM studies will begin in the fourth quarter, , 2014. A second generation, higher throughput platform is under development. KIYATEC's platforms can be further expanded into additional solid tumor types (e.g., lung, colon, pancreas, and liver).

Management Team

- Matt Gevaert, Ph.D., Chief Executive Officer, has IP commercialization/technology startup experience as commercialization officer at Clemson University and has experience with Merck and 3M.
- David Orr, Ph.D., M.B.A., Chief Operating Officer, inventor of KIYATEC technology, has biomedical, industrial operations, and financial management experience at Cook Medical, Ingersoll-Rand, and Dwyer Instruments.
- Hal Crosswell, M.D., Chief Medical Officer, is a practicing oncologist and the lead investigator for more than 40 industry and NCI-sponsored clinical research studies.
- Bryce Chaney, M.B.A., Sr. Director of Business Development, has business development and technical experience at Cirrus Pharmaceuticals, Azopharma, Scynexis, and BD Technologies.
- Robert Silverman, Chairman of the Board, is a diagnostics industry veteran whose last company was acquired by Roche for \$270 million.

Accelerated Medical Diagnostics, Inc.

www.acceleratedmeddiagnostics.com
3347 Monaghan Street
Dublin, CA 94568

Paul Henderson, Ph.D.

Chief Executive Officer
925-570-1615
paul@acceleratedmeddiagnostics.com

PlatinDx

12:00 p.m. – 12:15 p.m.

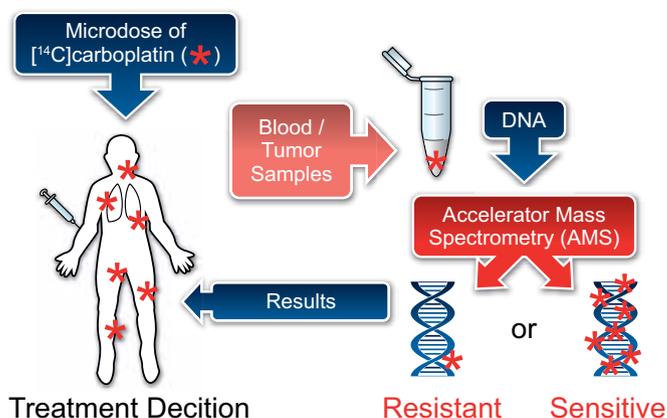
Company Background

Accelerated Medical Diagnostics, Inc. (AMD) is developing clinically validated tests that allow physicians to tailor cancer treatment to individual patients. Founded in 2008, AMD developed PlatinDx, a test for predicting response to platinum-based chemotherapeutics. The test works by directly measuring *in vivo* the patient's individual tumor susceptibility to platinum agents. We are presently conducting a multisite clinical feasibility study of PlatinDx for carboplatin/cisplatin in lung and bladder cancers, and a single site feasibility study oxaliplatin for advanced, metastatic breast cancer.

Technology Overview

The PlatinDx assay is a drug-device combination product that depends upon accelerator mass spectrometry (AMS) to analyze biopsy samples after patients are given microdoses of radiolabeled carboplatin or oxaliplatin. AMS is capable of detecting as little as one ¹⁴C atom per human cell, which enables administering humans with extremely low "microdoses" of labeled drugs for diagnostic purposes. Microdosing creates very low levels of a transient, radiolabeled biomarker that allows the *in vivo* measurement of the pharmacodynamic effect of this drug via the formation of drug-target complexes (adducts). The measurement of this label by AMS forms the basis for the ability of the PlatinDx test to predict response to subsequent full dose platinum-based therapy. The assay will identify those potential responders who have relatively high drug-DNA adducts and are likely to respond

to platinum-based chemotherapy, while potentially ruling out needless treatment for those patients who are unlikely to respond to those drug.



Market Potential

The addressable market for PlatinDx is \$500 million for the United States lung cancer market, \$250 million each for the U.S. bladder and breast cancer markets, and \$3-\$5 billion globally for multiple cancers and drugs.

Competitive Advantage

PlatinDx directly measures *in vivo* the patient's individual tumor susceptibility to specific chemotherapeutic agents, which will improve survival for one group and reduce acquired drug resistance caused by needless exposure of non-responders to platinum-based therapy. PlatinDx does not require patient or tumor genotype information or culturing of tumor cells. Other tests rely on quantitation of a single or a few gene mutations or expression levels, which is inadequate for prediction of platinum-based drug efficacy. FDA approval will lower barriers to reimbursement.

Financial Overview

AMD has been primarily funded through NIH/NCI contracts to develop PlatinDx for bladder and lung cancer. The company has raised over \$2 million since 2011. AMD is currently accruing patients for feasibility trials and has funding for operations through early 2015. The company will be raising \$32 million in additional capital over the next five years to complete the pivotal trials, establish the clinical and sales teams, develop the reimbursement and manufacturing processes, obtain CLIA certification, and gain FDA approval. Product launch is set for 2019.

Intellectual Property

AMD is presently refining and reducing practice-specific diagnostic methods for platinum-based chemotherapeutics through clinical evaluations. The company is pursuing protection of the PlatinDx platform via a series of patent filings for the global market, the first of which is a U.S. patent expected to be filed in November 2014. Microdose-based diagnostic applications to be covered include specifics of the microdose-based assay used for human studies, including useful drug concentrations, formulations, and specific activities, the resulting useful drug-DNA adduct frequencies in patients induced by microdosing, and sample processing methods optimized for AMS analysis. When issued, patent protection should extend until at least 2034. In addition to patent protection, FDA approval of the drug component as a "similar drug" will result in a period of market exclusivity for the drug component.

Commercialization Strategy

AMD is seeking regulatory approval for its diagnostic assays. AMD has key opinion leaders participating in the clinical trials and expects them to be early adopters upon launch. AMD plans to do a health economic study to justify reimbursement. AMD plans to develop regional laboratories that will serve U.S. and international markets. As an FDA approved test, AMD can license to large diagnostics companies.

Pipeline Products

The PlatinDX assays under development predict patient response for the three approved platinum chemotherapy agents (cisplatin, carboplatin, and oxaliplatin) in the lung, bladder, and breast cancer areas. The platform technology will be applied to other cancer drugs and tumor types.

Management Team

- CEO and founder Paul Henderson, Ph.D., CEO and founder, is a UC Davis faculty member with 15 years of experience in designing and implementing experiments to assess drug resistance, mostly with respect to accelerator mass spectrometry analysis.
- Vice George Cimino, Ph.D., Vice President of Development, is the co-founder and former Vice President of Development for Cerus Corporation. He has over 30 years of research experience with small molecules that interact with DNA and 25 years of experience in bringing regulated drug/device combination products to market, including CE Mark and FDA approvals.

- Chong-xian Pan, M.D., Ph.D., founder, is a UC Davis faculty member and practicing medical oncologist who led the clinical implementation of two trials for PlatinDx.



Insight Genetics, Inc.

www.insightgenetics.com
Two International Plaza Drive, Suite 510
Nashville, TN 37217

Eric Dahlhauser, C.P.A.

Chairman/Chief Executive Officer
615-255-8880
edahlhauser@insightgenetics.com

Insight ALK Resistance™ and Insight Resistance ID™

12:15 p.m. – 12:30 p.m.

Company Background

Founded in 2007, Insight Genetics is a full service precision medicine company. The company has a portfolio of proprietary Companion Diagnostic (CDx) assays that detect specific cancer biomarkers. The assays have potential to become new standards of care in the lung, breast, ovarian, and leukemia cancer markets. Together with its CLIA-certified laboratory, Insight Molecular Labs, the company also develops custom clinical trial assays and provides clinical trial testing services for the pharmaceutical industry, contract research organizations, and academic research institutions.

Insight Genetics lead product Insight ALK Screen™ was developed in collaboration with NCI to address an unmet need in the diagnosis of non-small cell lung cancer (NSCLC). The assay is exclusively licensed, manufactured, and distributed globally by commercial partner QIAGEN N.V. as an RUO kit (QIAGEN ALK RGQ RT-PCR™). The company and QIAGEN continue to co-develop the assay as a CE marked and FDA approved CDx for ALK inhibitors such as Pfizer's Xalkori®.

Technology Overview

Despite antitumor response to targeted cancer drugs such as Xalkori, most lung cancer patients eventually experience disease progression due to mechanisms that induce resistance to the inhibitor. In response, Insight Genetics has developed two resistance products: Insight ALK Resistance™, a qPCR test for ALK inhibitor resistance; and Insight Resistance ID™, a panel on both NGS and multiplex-qPCR platforms that comprehensively detects multiple mechanisms of targeted inhibitor resistance including EGFR and KRAS. As additional targeted therapies enter the lung cancer market, physicians will require these tests for patient monitoring to determine drug efficacy and combination therapies tailored to a patient's real-time genetic data. The next phase of development for these two products is non-invasive methodologies for using them (i.e., blood).

Market Potential

Insight ALK Resistance and Insight Resistance ID have potential to be the standard of care for diagnosing and characterizing therapeutic resistance in NSCLC patients (1.3 million annual incidence globally). As a CDx and patient monitoring tool, the global addressable market for the two products exceeds \$500 million. The addressable market for the company's complete product pipeline is estimated at over \$1 billion. Primary target customers include pharmaceutical companies, oncologists, pathologists, and academic research institutions.

Commercialization Strategy

Insight ALK Resistance and Insight Resistance ID are currently available to pharmaceutical companies and clinical researchers as CLIA-validated tests for (1) selection of patients for clinical trials, and (2) detection and monitoring of molecular-driven drug resistance in patients being treated with specific cancer therapies. The next step is to develop the assays in a non-invasive format with select multiplex-qPCR and NGS IVD platform companies, and together commercialize the assays as CLIA tests, RUO/CE marked kits, and FDA-approved IVDs. Insight Genetics revenue sources include: government contracts and grants; licensing, royalty and milestone payments; fees for custom assay development and clinical trial services, and clinical laboratory reference testing.

Competitive Advantage

In addition to a strong proprietary IP position, Insight Genetics will have first-to-market advantage. Patented platforms on which the assays will be offered ensure the best combination

of performance, ease of use, and cost for resistance detection and monitoring. Insight Genetics's competitive position will be strengthened through its commercial alliances with industry partners.

Intellectual Property

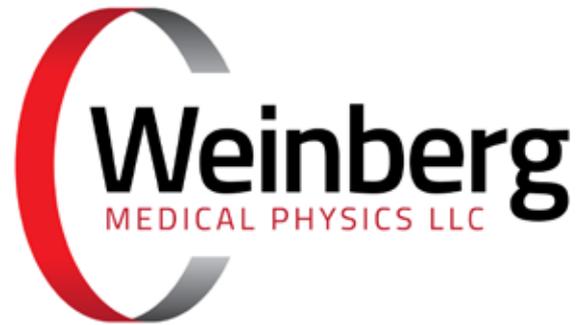
Insight Genetics's growing IP estate includes one awarded patent (ALK resistance mutations) and ten patents pending. The IP estate is filed and prosecuted globally.

Pipeline Products

Market Focus		
Non-Small Cell Lung Cancer	Triple Negative Breast Cancer	Select Other Malignancies
Product Categories		
First Line Molecular Test	Resistance Mutation Detection	Next-Gen Sequencing Panel
Selected Product Pipeline		
Biomarker	Description	Commercialization
ALK	Test to indicate which patients will respond to Pfizer's Xalkori and other ALK inhibitors	Exclusively licensed to QIAGEN; RUO kit 2014; PMA 2015
Other Lung Cancer Markers (ROS1, RET, DEPDC1)	Various other tests in development to be paired with existing/future therapies targeting genetic abnormalities	All 3 markers exclusively licensed to QIAGEN; Assay design and validation ongoing
ALK Resistance	Molecular test to identify known resistance mutations in ALK — can be used to monitor progress on Xalkori	Worldwide Exclusive License from St. Jude; Commercialization in progress
Insight Resistance ID	NGS panel that assesses the known ALK resistance mutations (above) as well as other common lung cancer markers	CLIA Validation & Commercialization in progress
TNBCtype	Suit of tests under development to classify sub-types of TNBC and match with best-available treatments	Worldwide Exclusive License from Vanderbilt; Sponsored research; Commercialization 2015
KIR	Genetic profiling assay to identify optimal donor in bone marrow transplantation	Worldwide Exclusive License from St. Jude; Commercialization 2014

Financial Overview

Insight Genetics has raised more than \$11.1 million since 2007 including \$5.3 million in NCI contracts. To fund growth, the company is seeking \$10 million from a combination of sources.



Use of Proceeds:

- \$3 million for further development and commercialization of lead product *Insight ALK Screen*.
- \$4.5 million to support the full development, regulatory approval, and commercialization of the resistance assays.
- \$2.5 million for working capital to further build and commercialize the company's total portfolio of novel assays.

Management Team

- Eric Dahlhauser, C.P.A., Chairman and Chief Executive Officer, has more than 20 years of clinical diagnostic laboratory experience and was previously the founder, Chairman, and CEO of Genetic Assays, Inc.
- Christopher Callaghan, D.P.A., M.B.A., President and Chief Operating Officer, co-founded Insight Genetics and has more than 20 years of senior management experience in startup and turnaround ventures.
- David Hout, Ph.D., Vice President of R&D, has extensive experience in the field of molecular diagnostics and served as a senior research microbiologist at Biomune.
- Stephan Morris, M.D., Scientific Founder and Chief Scientific Officer is an internationally recognized physician-scientist most known for the discovery of ALK.
- Robert Seitz, Chief Technology Officer, previously served as Senior Vice President of Clariant, Inc., after Clariant acquired Applied Genomics, Inc. (AGI). He served as AGI's Co-founder and CEO from 2000 to 2009.
- Pia Gargiulo, Ph.D., Managing Director of Pharmaceutical Partnerships, previously lead teams in the development and delivery of Companion Diagnostic Programs for the pharmaceutical industry. She has worked on eight PMA submissions resulting in three pivotal CDx offerings to breast, colorectal, and lung cancer patients.

Weinberg Medical Physics, LLC

www.weinbergmedicalphysics.com
5611 Roosevelt Street
Bethesda, MD 20817

Irving Weinberg, M.D., Ph.D.
President
301-346-7944
INWeinberg@gmail.com

Image-guided Therapy with Magnetic Nanoparticles

1:45 p.m. – 2:00 p.m.

Company Background

Weinberg Medical Physics LLC, (WMP) founded in 2008, is a privately-held company based in Bethesda, Md. WMP has special competence in medical imaging and image-guided therapy. Its mission is to introduce disruptive technologies that address compelling clinical indications. The company works closely with investigators at the University of Maryland. The company currently has eight employees and four university subcontracts.

Technology Overview

We have developed a new image-guided therapy system. The system has two properties that have never before been realized in therapeutics:

- It can deliver any drug to any location in the body non-invasively; and
- It can image any location in the body with cellular resolution (20 microns).

The system consists of two components: (1) an MRI-like set of electromagnetic (EM) coils and drivers that can steer magnetic

particles and rapidly image tissues; and (2) proprietary magnetic particles that can carry any drug or molecule, and can ablate tissues through rotational motion. The proprietary EM drivers are enabled through novel and energy-efficient application of pulsed power technology, which has been shown to have fewer bio-effects than conventional methods. The EM drivers alternately propel and image magnetizable particles as they are moved into and within solid organs (e.g., brain).

The company's particles are built with proprietary scalable nano-engineering processes to have specific magnetic and drug-eluting properties. These particles can deliver concentrated boluses of drugs or gene products to specific locations and can rotate rapidly to disrupt bio-films or ablate solid tumors. The system does not require liquid helium, and thus can be used portably and in sites without extensive infrastructures. The size of the body part to be targeted impacts product cost, and so we have selected diseases of the head/brain as first targets.

Market Potential

The system will be comparable in function to advanced radiation therapy and minimally-invasive devices, but with the advantage of being able to deliver molecular therapy non-invasively. The image-guidance component of the systems will be priced in the million-dollar range, lower than devices (e.g., robotic surgery, proton therapy) with similar therapeutic missions. We have selected chronic refractory sinusitis as the first clinical indication for FDA pre-market approval, because of the high prevalence of the disease (10 million patients in U.S.), lack of attractive surgical options, and likely device status of the application. Subsequent drug-device versions of the system will serve as minimally invasive alternatives to surgery for treatment of brain and head/neck tumors. Including renewable revenues from supplied unit-dose particle formulations, total revenues are expected to be several hundred million dollars per year within five years of FDA approval.

Competitive Advantages

Unlike prior systems for directing nanoparticles that could not concentrate assemblies of the particles at desired locations, our proprietary systems use pulsed fields to alternatively align, propel, and focus the particles. These fast and strong magnetic fields, which are interposed with imaging pulse sequences, have been proven to be well-tolerated by patients in clinical trials, and can realize spatial resolution at cellular levels. The particles used in the system have been shown to evade the blood-brain barrier by traveling in the interstitial spaces, and are made of biodegradable and biocompatible materials. Unlike other particle drug-delivery systems, the drugs in our system are not linked chemically to the

particles, but are contained in an inner chamber that releases the drug to the body through an aperture. As a result, the elution time of drugs carried by the particles can be adjusted in the nano-manufacturing process, which is massively scalable. Additionally, there is no constraint to the type of drug, for example whether it is a biologic, chemical compound, siRNA molecule, or a viral vector.

	No systemic side effects	Cellular spatial resolution	Deliver any molecule anywhere	Deliver to multiple sites at one time
WMP System	✓	✓	✓	✓
Radiation therapy	✓			✓
Image-guided/robotic surgery	✓			
Systemic therapy				✓

Financial Overview

WMP has received more than \$10 million in federal and state funding to develop the strong magnetic drivers that are at the heart of the system, and is currently licensing some of its technology in fields unrelated to this application. The company is seeking additional \$7 million from investors and/or foundations (to be partially matched by federal funds) to build a human-head-sized prototype that could be used in clinical trials, establish particle safety, submit an IDE to the FDA, and conduct the clinical trial

Intellectual Property

U.S. and foreign patents have been granted for the use of strong magnetic fields without bio-effects. As a result of this innovation, magnetic gradients that are orders of magnitude stronger and faster than in conventional MRI systems can be used *in vivo*. Other foreign patents and patents of additional innovations are pending. Company has out-licensed the application of its high-field low bio-effect magnetic technology for dental diagnostic imaging, a field with no overlap to the proposed interventional application that is the basis of this presentation.

Commercialization Strategy

To date, WMP has taken a licensing approach in order to further develop its core technology. Those licenses relate to niche diagnostic applications of strong/fast MRI (e.g., dentistry). Our preference would be to work with selected investors and/or strategic partners in order to develop and validate the therapeutic system. To this end, we will work with selected luminary sites

to validate the safety and efficacy of the magnetic delivery technology in a breakthrough clinical device indication with existing high reimbursements for competitive technologies (e.g., chronic sinusitis). Upon FDA premarket approval of this first indication, we will sell the company to a major medical device company, license the particle technology to a drug company, or raise financing necessary for commercialization through an initial public offering. Because of the large potential scope of the innovation, our preference would be to eventually go public.

Pipeline Products

The company has already demonstrated transport of drug-laden particles in rat brain, and will develop oncology and neurology products based on these particles. WMP's proprietary particle designs could be adapted to deliver most drug and/or gene products. Considering that the current roles for gene and RNA therapy have historically been delivery-limited, we anticipate that the new interventional system could play a role in advancing applications of these products.

Management Team

- Irving Weinberg, M.D., Ph.D., President, has been a serial medical device entrepreneur for 15 years. His designs that have helped over one million people with suspected or confirmed breast cancer, and have recently been acknowledged by manufacturers of medical imaging systems as addressing critical issues in the development of new high-field MRI systems. Dr. Weinberg is an experimental physicist and practicing radiologist who has worked at the Johns Hopkins Hospital, UCLA, and the National Institutes of Health. He has founded companies that have raised over \$50 million and initiated multi-center clinical trials. He will continue to lead the technical team, and assist in coordinating clinical trials.
- Pavel Stepanov, M.S., Chief Physicist, has been responsible for instrumentation design and implementation for the four FDA-approved products introduced by Dr. Weinberg. He will supervise quality and design control for the project, and assist in preparation of the premarket approval application to the FDA.
- Alek Nacev, Ph.D., lead bioengineer, has a doctorate in magnetic control, and has been key in demonstrating the capability to concentrate particles magnetically. He will manage the development of the coil, driver, and software.
- Lamar Mair Ph.D., bioengineer, has a doctorate and did post-doctoral work in nanoparticle fabrication at the National Institute of Standards and Technology. He is the designer of our nano-engineering processes. He will manage particle development

and transfer of the technology to a GMP-qualified supplier.

- Mika Shimoji, Ph.D., Senior Biologist has implemented preclinical studies of magnetic nanoparticles with GLP rigor. She will manage GLP-level animal studies.



Cynvenio Biosystems, Inc.

www.cynvenio.com
2260 Townsgate Road, Suite 2
Westlake Village, CA 91604

Paul Dempsey, Ph.D.
Chief Scientific Officer
1-805-214-6377
pdempsey@cynvenio.com

LiquidBiopsy® and ClearID™

2:00 p.m. – 2:15 p.m.

Company Background

Cynvenio is a commercial-stage diagnostics company providing a comprehensive, non-invasive blood test to match cancer patients with the best targeted therapy for their tumor. The company has developed and patented a unique technology to detect cancer cells circulating in the bloodstream. These invasive cells are responsible for the spread of disease in patients – or the metastatic process – which is the primary cause of death. Cynvenio's ability to capture these tumor cells in blood provides doctors the molecular evidence to characterize their patients' cancers, administer tumor-specific drugs, and measure response to treatment over time.

Technology Overview

Cynvenio's LiquidBiopsy® technology provides reliable access to rare populations of cancer cells in whole blood, with the ability to detect mutations in as few as one target cell per mL. LiquidBiopsy is capable of concurrently sampling DNA or RNA from circulating tumor cells as well as cell-free DNA (cfDNA) from a normal blood draw, and process up to four samples in under three hours. This technology enables faster, cheaper, and safer molecular analysis than traditional tissue biopsy approaches.



Market Potential

The rapid adoption of personalized medicine protocols is being fueled by the availability of new targeted therapies designed to fight cancer mutations that vary over time and from patient to patient. This has created a large unmet need for providing physicians with the patient- and-tumor-specific mutational information that forms the underpinning of evidence-based medical decisions. There are 235K new cases of breast cancer every year resulting in over 40,000 deaths. This presents a target of 3 million breast cancer patients and survivors in the United States. Cynvenio believes this is a \$350 million revenue opportunity that will validate the LiquidBiopsy approach and benefit large cohorts of patients.

Competitive Advantage

Cynvenio is the only company that offers a commercial test that allows sequence analysis of tumor cells recovered from blood. Legacy circulating tumor cell tests are all based on enumeration, a read out with prognostic value but no predictive molecular information. Cynvenio's LiquidBiopsy and ClearID™ blood tests can be used to complement traditional tissue biopsy analysis, or as standalone tests to find therapies for patients in which tissue biopsy is deemed difficult or too risky to harvest.

Financial Overview

Cynvenio has been privately funded since its inception in 2008. The company has raised \$14.5 million in equity capital and has generated approximately \$7 million in revenue.

Intellectual Property

Cynvenio has been issued patents protecting the core technology. These are also being pursued internationally, and already have been issued in Japan. Cynvenio has also pursued IP development around the platform and enabling consumables.

Commercialization Strategy

Cynvenio is seeking \$15 million in equity financing to fund the commercialization of its LiquidBiopsy system and the ClearID blood test for the genomic analysis of breast cancer.

Pipeline Products

Cynvenio's lead indication for LiquidBiopsy and ClearID is breast cancer because it has well-defined genetic alterations, the availability of multiple targeted drugs, and a large addressable patient population. The company will scale into other solid tumor indications including colorectal, prostate, and lung cancer.

Management Team

- André de Fusco, Chief Executive Officer, has 28 years of experience in high-tech development and financing as well as domestic and international experience in public companies and venture-backed startups.
- Paul Dempsey, Ph.D., Chief Scientific Officer, has 25 years of experience in immunology and biomedical research and was an assistant researcher professor at UCLA.
- Maureen Cullum, Chief Financial Officer, has more than 20 years of financial leadership positions specializing in medical device and pharmaceutical startup companies.
- Andreas Bakker, Ph.D., Vice President of Operations and CLIA Lab Services, has over 25 years of experience in laboratory, pharmaceutical, and biotechnology senior leadership positions.
- Leila Colgan, Vice President of Sales and Marketing, has over 20 years of sales and marketing leadership positions in the pharmaceutical, biotechnology, and oncology/diagnostic industries and specializes in strategy development for multichannel regional, national, and global marketing and sales plans.



Corvida Medical

www.corvidamedical.com
2261 Crosspark Road, Suite 127
Coralville, IA 52241

Kent Smith

Chief Executive Officer/President
800-651-6832 ext. 105
kent.smith@corvidamedical.com

Closed-System Drug Transfer Device (CSTD)

2:15 p.m. – 2:30 p.m.

Company Background

Corvida Medical provides innovative technologies that optimize the safe handling of hazardous medications. The Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH) confirm that over 5.5 million workers are exposed annually to chemotherapy and other hazardous pharmaceuticals during drug preparation and delivery, which studies have shown causes cancers, organ failures, reproductive toxicity, and genetic mutations. Corvida Medical is an emerging device company developing a disposable, Closed-System Drug Transfer Device (CSTD) that provides greater safety and significantly improved usability, enabling health care providers to safely deliver the highest quality care to patients. Corvida is led by a management team with experience leading multiple prior medical device companies from startup to successful exit. Corvida has scheduled the inaugural product unveiling to the public at a hospital pharmacy conference later this year and is on track for FDA 510(k) submittal of its initial CSTD product by end of 2014 and commercialization in 2015.

Technology Overview

Corvida's second generation CSTD products have new features that optimize containment effectiveness, simplify system configuration, and improve ergonomics. Preliminary data from Corvida's NCI-funded Phase II Small Business Innovation Research (SBIR) project shows the CSTD meets design and production quality criteria for product performance and has been validated against industry test standards.

Competitive Advantages

Corvida's innovative CSTD system consists of a set of proprietary disposable components incorporating key differentiators over existing technology that significantly improve safety, effectiveness, and usability.

Market Potential

The global CSTD market is valued at an estimated \$1 billion total available market, growing approximately 20 percent annually as cancer rates and use of chemotherapy continue to rise. The U.S. hospital segment includes 1,500 leading cancer centers that treat the most patient and are driving the adoption of CSTD technology. Sixty-eight of these facilities achieved an NCI Comprehensive Cancer Center or Cancer Center designation. Given both their high patient volume and prestige, these national Cancer Centers will be targets for Corvida's initial marketing and sales efforts, and many of these leading cancer centers have committed to collaborating with Corvida Medical on the NCI SBIR Phase II and Phase IIB projects. Beneficiaries of CSTD technology advances include pharmacists, pharmacy technicians, and nurses who prepare and/or administer chemotherapy, other health care workers who may be inadvertently exposed, and the patients who receive the drugs as well as their family/visitors.

Pipeline Products

Corvida has plans to introduce additional offerings to their CSTD product line. The company pipeline includes further feature development of the CSTD products as well as additional systems that can utilize the CSTD devices. Additional features of the CSTD will address drug administration (nursing) needs, alternate site needs, continued ergonomic improvements, and expansion to a wider category of hazardous drugs. The company is actively developing these pipeline products in tandem with the primary CSTD product offering scheduled to launch later this year.

Financial Overview

- Series B financing for 510(k) clearance and initial commercialization: Management has secured a lead investor and closed over half of this round of funding to date. Management is working to close the Series B by end of 2014. Management also plans to raise a Series C round to scale operations/manufacturing, which is planned for 2015.
- Series B financing for 510(k) clearance and initial commercialization: Management has secured a lead investor and closed over half of this round of funding to date.

Management is working to close the Series B by end of 2014. Management also plans to raise a Series C round to scale operations/manufacturing, which is planned for 2015.

Intellectual Property

Corvida maintains seven (7) issued/allowed utility patents domestically and in foreign jurisdictions, and has 15 PCT utility applications pending. The company also has multiple trademarks, protecting both the company and product brand. Additionally, Corvida has secured a clear freedom-to-operate analysis.

Commercialization Strategy

Corvida is in discussions with several potential strategic partners to distribute their CSTD product once it receives FDA 510(k) clearance. A partner will maximize sales penetration via use of their established sales and marketing organizations. Corvida will initially pursue direct sales and support, starting with pre-market launch in the fourth quarter of 2014 at the major pharmacy conference drawing over 20,000 hospital pharmacists, with a focus on a limited set of prestigious cancer centers. The early launch goal will provide an opportunity to establish reference accounts that will broaden the opportunity to sell to a wider audience. Corvida is collaborating with over 20 leading cancer centers that are participating in the Corvida NCI SBIR Phase II study and are likely to become customers upon completion of the study and receipt of FDA 510(k) clearance.

Management Team

- Kent Smith, M.S., CEO and President, has 30 years of successful global medical device commercialization and business leadership experience, and 10 years of experience in startups. He helped lead a medical device startup from \$0 to \$30 million with a \$310 million acquisition.
- Dana Schramm, M.B.A., Vice President of Manufacturing, has 20 years of experience in medical device manufacturing, working at companies ranging from \$1 million to over \$1 billion in sales, and was successful in developing and launching over 50 medical devices.
- Prasad Sunkara, Ph.D., Vice President of Research, has 35 years of corporate, financing, research, development, and management experience in corporate and startup environments. He has been an officer and/or founder in multiple life science companies, several of which were acquired.
- John Slump, Co-founder and Chief Financial Officer, has a BBA in Finance and a background in corporate accounting,

fundraising, financial modeling, and capital formation.

- Jared Garfield, Co-founder and Chief Technology Officer, has a BBA in Management Information Systems and a background in information technology, engineering, and business management experience.



Lumicell, Inc.

www.lumicell.com
80 William Street, Suite 2-260
Wellesley, MA 02481

David Lee
Chief Executive Officer
781-684-0258
dlee@lumicell.com

Intraoperative Cancer Imaging System

2:30 p.m. – 2:45 p.m.

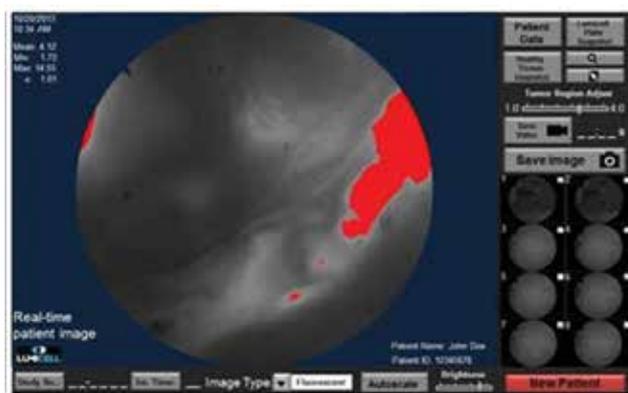
Company Background

The Lumicell Imaging System is addressing the number one challenge in cancer surgery: the need to remove all cancer cells within the tumor bed during the initial surgery. Lumicell combines a hand-held, single-cell detection imaging device and a cancer-specific molecular imaging agent (LUM015) for real-time identification of residual cancer in the patient's tumor bed. The system provides surgeons with visual information to perform a thorough removal of residual cancer cells, thus eliminating the need for repeat surgeries due to positive margins or local recurrence.

Technology Overview

The Lumicell Imaging System is a clinical-stage intraoperative technology for detecting and guiding the removal of all residual cancer during the initial surgery. Currently, after the initial breast cancer surgery, over 35% of patients undergo a second surgery due to residual cancer. LUM015, which is injected several hours prior to surgery, emits a fluorescence signal that is activated by

cancer enzymes in and around the tumor cells. Lumicell's imaging head is a hand-held device designed for maneuverability in the tumor bed providing seamless operation within the existing surgical workflow. The system uses Lumicell's proprietary detection algorithm to highlight regions containing residual cancer in a computer display.



Market Potential

Lumicell addresses the unmet need for locating microscopic residual cancer and guiding its removal during the initial surgery. Lumicell is in human clinical trials for breast cancer and sarcoma and has IRB approval to begin trials in esophageal and colon cancers. The U.S. market for Lumicell is a combined \$1.43 billion for breast, lung, prostate, colon, esophageal, ovarian, and brain cancers and sarcoma. Most large cancer practices are at risk for the cost of the second surgery and view Lumicell's product as an immediate financial benefit. The cost savings to the hospitals together with expected additional reimbursement for the guided surgery procedure ensures attractive revenues to Lumicell.

Competitive Advantage

A number of devices attempting to detect cancer without an imaging agent have shown poor sensitivity (below 60%) and specificity (below 40%) and struggled to be adopted. Other competitors are developing comparable technology using an imaging agent and device, but Lumicell is far along in the development process having successfully completed a Phase I clinical trial that demonstrates safety and preliminary efficacy (91% sensitivity and 86% specificity). In contrast with competitors' imaging agents, LUM015 is also specific to cells at the tumor margin, which reduces the dose requirement and increases the signal to background ratio. Unlike the same-day injection of LUM015, some competitors attempting to use antibody-based agents, which take days for clearance and require an extra visit to the clinic by the patient in advance of the surgery. The handheld device, which is insensitive to surgeon's and patient's motion, has

unprecedented detection of sub-millimeter residual cancer in a large field of view.

Financial Overview

Lumicell is very capital efficient and has raised \$6.7 million in Series A and B venture capital funding. Through National Science Foundation and NCI SBIR programs, Lumicell has been awarded \$2.4 million. The company has also received a \$1 million Massachusetts Life Sciences Accelerator Loan, and our academic and clinical collaborators have received about \$1.6 million in funding to support pre-clinical and clinical studies with the Lumicell system.

Intellectual Property

Lumicell has obtained an exclusive license from MIT for the use and commercialization of the imaging device. The company also has an expansive IP portfolio (U.S. and international) including specific architectures of imaging agents, methods for labeling the tumor margin, and a novel laser ablation technology for instantaneous and precise removal of residual cancer.

Commercialization Strategy

Lumicell has secured funds to finance operations through the pivotal trial (2015) and expects to raise \$10 million upon FDA product marketing approval (PMA) in late 2015 for product launch.

Regulatory Strategy and Pipeline Products

Lumicell's LUM015, combined with our first hand-held imaging device, has completed a Phase 1 safety study at Duke University Medical Center. Lumicell's combination product has been assigned to the FDA's Center for Devices and Radiological Health, (CDRH). Lumicell has completed a pre-Investigation Device Exemption meeting with the FDA to discuss upcoming trials in breast cancer. Lumicell aims for FDA approval under a Premarket Approval in breast cancer by late 2015. In parallel, Lumicell has developed a laser ablation module to perform precision surgeries required in brain and ovarian cancers. Lumicell has a pipeline of imaging agents offering further benefits including higher signal-to-background ratios, higher specificity for certain types of cancers and at lower doses.

Management Team

- David Lee, CEO and Co-Founder, has 25 years of demonstrated success in product development at Arthur D. Little and has experience running R&D groups and early commercialization of products. He is a co-Founder and the founding CEO of T2 Biosystems, Inc. (NASDAQ: TTOO) which is about to enter the market.
- Jorge Ferrer, Ph.D., Director of R&D, developed the original imaging system and LUM015. He has 8 years of experience in research, development, and project management.
- David Strasfeld, Ph.D., Senior Scientist, trained in physical chemistry, instrument design, and experimentation, and leads the device development efforts.



Delphinus Medical Technologies

www.delphinusmt.com
46701 Commerce Center Drive
Plymouth, MI 48170

Mark J. Forchette

President and Chief Executive Officer
817-296-2753
mforchette@delphinusmt.com

Ultrasound Tomography for Breast Imaging

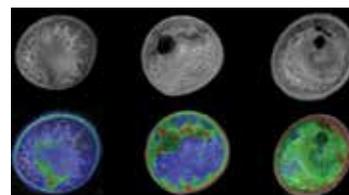
2:45 p.m. – 3:00 p.m.

Company Background

Delphinus Medical Technologies, Inc., is a privately held medical technology company headquartered in Plymouth, Mich., and was founded in 2010 as a spin-off of the Barbara Ann Karmanos Cancer Institute (KCI). Delphinus has succeeded in creating an innovative whole breast ultrasound imaging device called SoftVue that characterizes suspicious lesions for diagnostic applications using a safe (non-ionizing), comfortable (non-compressing), and reliable (operator independent) patented technology.

Technology Overview

The SoftVue system, designed and manufactured by Delphinus, utilizes ring transducer technology to transmit and receive ultrasound signals, and represents a first-ever innovation in automated whole breast ultrasound. The unique approach uses a dynamic new design to capture reflection echoes from all directions around the breast and leverages sophisticated algorithms to gather transmitted signals coming through the breast, and image a volumetric map with a single scan – something no other ultrasound system, currently available, can do. The end result of this approach is enhanced tissue characterization designed to deliver best in class specificity, improved sensitivity and a gentle patient experience. SoftVue has received 510(k) clearance from the FDA for diagnostic ultrasound imaging and is not a replacement for screening mammography.



Market Potential

Analysis from Frost & Sullivan in February 2013 reported the global breast imaging market is poised to grow at a CAGR of 15.37 percent from 2012 reaching approximately \$5 billion by 2017. The U.S. breast imaging systems market research finds that the market earned revenues of \$1 billion in 2011 and expects it to reach \$1.4 billion by 2016 at a compound annual growth rate of 5.8 percent. Due to growing legislation and advocacy around the issue of dense breasts and the ineffectiveness of mammography, whole breast ultrasound is gaining traction. SoftVue represents an innovative new technology and compelling alternative to improve women's health. The Delphinus business model includes SoftVue systems, consumables, and service contracts to hospitals and imaging centers throughout the U.S. and the rest of the world.

Competitive Advantage

Delphinus is committed to creating improved imaging methods that help medical professionals better define and diagnose breast disease, while establishing a better patient experience for all women, regardless of age, and without concern of radiation or discomfort. SoftVue's innovative transducer design, with its novel ring configuration, allows through transmission imaging of the whole breast, which allows tissue characterization over the entire breast. Furthermore, SoftVue scans the breast quickly (in 1 to 2

minutes) with no additional views required, unlike the other whole breast systems, which often require multiple positionings and up to 30-40 minutes per exam. Another competitive advantage is SoftVue's modular design, which allows the product to be configured easily for different markets and cost level and allows it to grow and evolve in performance by incorporating rapidly improving electronics and computing components.

Financial Overview

Delphinus has raised \$22.5 million since its inception in 2010 and is launching a process to raise a \$35 million series C round to cover the costs of the multicenter clinical trial to support a screening indication, and to support production and commercialization. Delphinus has no revenue to date. Potential sources of funding include venture capital firms and/or strategic partners.

Intellectual Property

Delphinus holds or has exclusive license to 14 patents covering broad aspects of its technology. In addition, the company has 12 additional patents pending including narrower aspects of the technology. As a result, Delphinus has broad coverage of the field of use while also covering specific aspects of core technology.

Commercialization Strategy

The Delphinus business model includes sales of SoftVue systems, consumables, and service contracts to hospitals and imaging centers throughout the U.S. and the rest of the world. The company plans to use a combination of direct and channel sales in the U.S. For the rest of the world, Delphinus will partner with large distributors and imaging Original Equipment Manufacturers looking for entry into the breast cancer imaging market. Delphinus will produce the devices through subcontracted manufacturing. Final assembly, testing, and quality assurance of the product has been contracted to an FDA- and ISO 13485-certified manufacturer located close to the facility in Michigan.

Pipeline Products

Delphinus secured its first 510(k) market clearance from the FDA in December 2013 for Softvue, indicated for use as a B-mode ultrasonic imaging system. The system is not intended to be used as a replacement for screening mammography but it is fully commercially developed for the diagnostic market. The initial clearance established a foundation for future submissions incorporating sound speed and attenuation measurements. Current

technical development is aimed at integrating color maps of stiffness tissue with the current imaging capabilities to expand the utility of SoftVue in the diagnostic market. Plans include additional 510(k) submissions over the next year, initial commercialization outside of the U.S., and a multicenter trial to gain an indication for screening, followed by global commercialization of a system with diagnostic and screening indications.

Management Team

- Mark J. Forchette, President & Chief Executive Officer, is an accomplished medical technology executive with more than 30 years of demonstrated success driving breakthrough medical technologies to market leadership with companies such as Abbott, OptiMedica, Alcon, and Grieshaber.
- Neb Duric, Ph.D., Chief Technology Officer and co-founder, has over 30 years of experience in imaging and is a key inventor of the SoftVue technology.
- Peter Littrup, M.D., Chief Medical Officer and co-founder, is a key inventor of the SoftVue technology and a renowned radiologist who has significant experience in breast imaging and has been instrumental in the conduct of ultrasound clinical studies.
- Chris Sanders, Vice President of Engineering, has over 20 years of global innovation expertise in medical ultrasound and has driven advancements in matrix array transducer design and led collaborative partnerships at companies such as Toshiba and Siemens.
- Shawn O'Brien, Vice President of Finance, has broad based financial operations experience and has served in senior financial leadership positions at Cyto-Pherex, Kux, and Advanced Material Process Corporation.
- Debra Saunders, Vice President of Sales and Marketing, has over 20 years of marketing and sales experience in women's health care with market changing breast cancer detection technologies and has been instrumental in advancing previous medical imaging companies including R2 Technologies, Naviscan, and Lorad.



CellSight Technologies

www.cellsighttech.com
185 Berry Street, Suite 350
San Francisco, CA 94107

Sanjiv Sam Gambhir M.D., Ph.D.

Founder
650-799-1589
agambhir@cellsighttech.com

[18F]FAraG PET Probe

3:30 p.m. – 3:45 p.m.

Company Background

CellSight Technologies is a privately held company with six employees located at the UCSF QB3 incubator in San Francisco. The company started operations in 2010 on the principle of providing innovative new positron emission tomography (PET) imaging technologies to accelerate therapy development and to leverage these imaging tools to personalize patient treatments. CellSight Technologies is combining fluorescence, bioluminescence and PET imaging within a single tri-fusion multimodality reporter gene, that will allow therapy developers to “barcode” and follow their cells or genes prior to introduction into living subjects, including human patients.

Technology Overview

CellSight is developing a PET probe, [18F]FAraG, for imaging anti-tumor immune response. [18F]FAraG is a fluorine-18 labeled analog of the lymphoblastic leukemia drug AraG, a guanosine analog. Since [18F]FAraG accumulates specifically in activated T cells, which is a major factor in anti-tumor immune response, detection of activated T-cells should enable early prediction of therapeutic efficacy, optimization of immunotherapeutic regimens, and personalization of immunotherapy. CellSight has other PET probes in various stages of development targeted at immunotherapy and cell therapy. In addition CellSight has reporter gene technology to determine trafficking of therapeutic cells in living subjects, including humans.

Market Potential

Immunotherapy is a rapidly expanding market segment due to demonstrated success in various hard-to-treat cancers such as melanoma and glioma. ClinicalTrials.gov shows that there are currently 90 industry-sponsored, cancer-specific cell-based immunotherapy trials actively recruiting, of which 60 trials are in the U.S. According to a June 2014 report by Citigroup, the immunotherapy market could exceed \$35 billion by 2023. There is currently no imaging technology on the market that is focused on imaging immune activation in humans. An imaging tool that can help predict a patient’s response to an immunotherapy early could enable patients to find effective therapies and reduce unnecessary medical costs.

Competitive Advantage

There are no commercially available imaging technologies that help visualize the biodistribution of activated T-cells. As immunotherapies gain traction based on their clinical success, there will be increased demand for a companion test to determine if an immunotherapy agent is effective with a particular patient. A scan that can be used to visualize immune cell activation post infusion or after treatment with immune modulating agents would provide invaluable information to guide future treatment options.

Financial Overview

CellSight has received over \$3 million in grants from NCI. The annual revenue from grants, product sales, and service contracts totaled \$377,045 in 2011, \$430,864 in 2012, and \$669,707 in 2013. Our estimated revenue for 2014 is \$ 1.1M.

CellSight is seeking a minimum of \$7 million in external funding beyond the nondilutive grant funding. The company plans to obtain \$10 million in grants and private funding in order to conduct a Phase I/II clinical trial for the [18F]FAraG imaging probe. CellSight will also continue to provide selective fee-based imaging services that have contributed about \$200,000 per year.

Intellectual Property

CellSight has exclusively licensed the [18F]FAraG PET probe from Stanford University and has two other patents focused on reporter gene technology. The patent from Stanford includes claims on the composition of matter, methods of synthesis, and methods of use. Also CellSight personnel are sponsors for an FDA Investigational New Drug (IND) for [18F]FHBG PET reporter imaging probe, which is used to image patients undergoing HSV1-tk gene therapy. In addition, the company founder is inventor of several other immunotherapy/cell therapy focused PET probes and has

expressed a strong desire to commercialize them through CellSight given the right opportunity and financial conditions.

Commercialization Strategy

CellSight is in the process of applying to the FDA for an IND approval for [18F]FAraG and expects approval by December 2014. The company's initial focus is the oncology market where we hope to fully partner with immunotherapy companies and offer the probe as a companion-imaging tool. We are in the early stages of partnering with two large pharma companies and are actively seeking additional partnerships. CellSight plans to expand the probe's use to other markets such as rheumatoid arthritis and diabetes mellitus where immunotherapy is in early stages.

Pipeline Products

CellSight intends to expand the probe for use in the rheumatoid arthritis and diabetes mellitus markets as the immunotherapy models for these applications mature and our company's capacity expands. In addition we will exclusively license two additional PET probes that our founder has developed for immunotherapy and cell therapy. The additional PET probes are specific to receptors on immune cells and could be used to image and monitor other processes affected by immunotherapies beyond T cell activation.

Management Team

- Sam Gambhir, M.D., Ph.D., founder, is Chair of Radiology at Stanford University and is a world-renowned pioneer in the field of molecular imaging.
- Aruna Gambhir, M.S., M.B.A., Chief Executive Officer, has over 25 years of broad experience in startups, R&D, sales, marketing, and operations.
- Shahriar Yaghoubi, Ph.D., Chief Scientific Officer, has over 18 years of experience in molecular imaging, including pre-clinical and clinical assessment of novel PET probes and FDA experience with IND.
- Sam Quezada, M.B.A., Chief Operating Officer, has over 30 years of experience in marketing, business development, and operations.



StemMed, Ltd.

www.stemmedcancer.com
7000 Fannin Street, Suite 1960M
Houston, TX 77030

David J. Tweardy, M.D.

President and Chief Executive Officer
713-798-8908
dtweardy@stemmedcancer.com

C188-9, First-in-class Drug for Targeted Treatment of Triple-negative Breast Cancer

3:30 p.m. – 3:45 p.m.

Company Background

StemMed is a pre-clinical stage drug discovery, development, and testing company is developing C188-9, a first-in-class, oral inhibitor of signal transducer and activator of transcription (Stat) 3, for treatment of ER-, PR-, HER2- (triple negative) breast cancer (TNBC). StemMed also provides state-of-the-art pre-clinical drug testing services using a panel of 44 breast cancer patient-derived xenograft (PDX) models developed from a diverse patient population, which includes 23 PDX models derived from patients with TNBC; 4 pancreatic cancer PDX models also are available.

Technology Overview

Stat3 plays a central role in breast cancer stem cell development and has been validated as a drug target in these cells, as well as in the treatment of TNBC, for which no targeted therapy exists. StemMed used computer-based docking to screen 920,000 compounds and identified three small-molecule probes that targeted the phosphotyrosyl peptide-binding pocket within the Src homology 2 domain of Stat3. The most active probe, C188, reduced TNBC PDX tumor volumes and improved tumor-free survival of engrafted mice fourfold when used in combination with standard chemotherapy. StemMed performed 2-D similarity screening, 3-D pharmacophore analysis, and three rounds of structure-activity relationship (SAR)-directed medicinal chemistry

to identify C188-9, its lead, first-in-class drug for targeted treatment of TNBC.

Market Potential

The first patients that will be targeted to receive C188-9 will be those patients with locally invasive, metastatic, or treatment-refractory TNBC. An estimated 230,480 new cases of invasive breast cancer were diagnosed in the United States in 2011. Of these, approximately 40,000 will suffer breast cancer recurrence including 50 percent of those with TNBC. Unfortunately, standard therapies cannot eradicate the disease and these patients succumb to metastatic disease with a median survival of 2 years. The size of the U.S. market for C188-9 for metastatic/refractory TNBC on a yearly basis is approximately 20,000 cases for 7 cycles, or a total of 140,000 cycles. C188-9 will be administered orally once daily in the interval between cycles of first-line chemotherapy. Using a conservative figure of \$2,000 per cycle, the income generated from 140,000 cycles of C188-9 would be \$280 million.

Competitive Advantage

There are two orally bioavailable, small-molecule competitors of C188-9 in development, BP-1-102 and HJC0123. BP-1-102's modest potency coupled with its low maximum tolerated dose will make it challenging to establish a safe and effective dose in humans. HJC0123's mechanism of action has not been established and the mouse toxicity data presented in the original report was very limited. Other oral agents under development have mechanisms of action that are not understood, substantial toxicity, and did not demonstrate an efficacy signal in Phase I studies.

Financial Overview

StemMed's drug testing revenue since 2010 totals \$913,000. Revenue from STTR grant awards totals \$417,000. StemMed also received \$100,000 from PDX licensing and \$213,000 from partner contributions.

StemMed needs \$1 million in external funds for investigational new drug (IND)-enabling safety and PK studies and for IND filing.

Intellectual Property

StemMed has an exclusive license to ten patents issued to, or filed by, BCM and ownership of composition for C188-9. StemMed also has an exclusive license to use all 48 PDX models for drug testing

services, as well as sublicensing to other companies for their in-house use.

Commercialization Strategy

StemMed's objectives for the next two years are to continue developing its lead product candidate C188-9 by taking it through various studies. StemMed is also in discussions with Atara Biotherapeutics regarding licensing C188-9 for use in cachexia in chronic kidney disease.

Pipeline Products

StemMed has compelling pre-clinical results in cancer cell line xenograft models that also support the use of C188-9 either alone or with radiation therapy in patients with non-small cell lung cancer and head and neck squamous cell cancer. In addition, results from mouse pre-clinical models support its use in patients with cachexia secondary to chronic kidney disease or cancer, and in patients with idiopathic pulmonary fibrosis, scleroderma, inflammatory bowel disease, asthma, and immediate-type hypersensitivity reactions.

Management Team

- David Tweardy, M.D., President, CEO, and director of drug discovery and development, discovered key molecular and cellular features of Stat3 during his 28-year research career supported by NIH and other extramural funding totaling over \$16 million as PI.
- Michael Lewis, Ph.D., Vice president and director of drug testing, is an expert in breast cancer biology and developer of 48 breast and pancreatic cancer PDX models whose 15 year research career has been supported by NIH and other extramural funding totaling over \$11 million as PI.
- Jeffrey Larson, Ph.D., Consultant and vice president of Texas BioAlliance, is a drug developer with extensive experience in pharmaceutical, biotechnology, and contract research industries, as well as a record of successful early- and late-stage regulatory meetings with the FDA.
- R. William Soller, Ph.D., Consultant and Principal of Soller Regulatory & Research Services, has extensive regulatory experience including serving as team leader and lead presenter for over 60 FDA or advisory committee meetings on drug development or postmarketing issues.



DEKK-TEC, Inc.

www.dekk-tec.com
725 Topaz Street
New Orleans, LA 70125

Lee Roy Morgan, M.D., Ph.D.

Chief Executive Officer and Medical Director
504-583-6135
lrm1579@aol.com

4-Demethyl-4-cholesteryloxycarbonylpenclomedine (DM-CHOC-PEN)

4:00 p.m. – 4:15 p.m.

Company Background

DEKK-TEC, Inc. was founded in 1983 and specializes in the research and development of novel anticancer and hormonal technologies to improve the management of cancer and allied diseases. DEKK-TEC was presented the 2000 National Tibbett's Award in recognition for its contributions to cancer research development in the SBIR program. The company is located in New Orleans, LA.

Technology Overview

DEKK-TEC, Inc., is developing a novel agent to treat primary and metastatic cancers. Its product, 4-Demethyl-4-cholesteryloxycarbonylpenclomedine (DM-CHOC-PEN) is a polychlorinated pyridine cholesteryloxycarbonate that is being evaluated in Phase II clinical trials in patients with advanced cancers of the lung and breast, melanoma, and primary cancers involving the brain/central nervous system (CNS) (IND 68,876).

DM-CHOC-PEN is an active and stable member of a larger series of carbonates and carbamates that has completed a Phase I clinical trial involving 26 patients with advanced cancer. Eleven of these patients had cancers involving the CNS, of which six demonstrated objective responses/progression-free survival (1 breast, 2 melanoma, 1 sarcoma, 1 lung, and 1 glioblastoma multiforme

(GBM)). Four of these patients had responses that lasted 1.3 to more than 3.5 years. These observations are supported by objective responses observed in pre-clinical studies with intracranial (IC) implanted human xenografts in mouse models.

The drug is currently being tested in a Phase II clinical trial for the treatment of primary and metastatic cancers (lung, breast, melanoma) involving the CNS. Objective responses are being verified in patients with lung cancer involving the brain. All trials support DEKK-TEC's goal to include DM-CHOC-PEN in the treatment of CNS cancers.

DM-CHOC-PEN's mechanism of action (MOA) is via alkylation of DNA at N7- guanine and cellular senescence, which means it could be used in combination with O6 - guanine alkylators.

To date, the DM-CHOC-PEN has demonstrated a favorable safety, toxicity, and pharmacokinetic/pharmacodynamics (PK/PD) profile. Although there have been demonstrated reversible hepatic toxicity in patients with prior liver disease/metastases, no hematologic, renal toxicities or neuro/psycho-performance abnormalities were noted in Phase I or in animal studies.

Market Potential

Primary brain cancer (notably GBM) is a dreaded cancer occurring in approximately 18,000 new patients annually in the U.S. In addition, approximately 20 percent of patients with all types of cancer will develop intracranial metastases. Approximately 150,000 patients will develop CNS metastatic cancers from primary lung and breast cancers and melanoma in 2014. The latter are the most common primary cancers responsible for brain metastases and generally correlate with the distribution of the neoplasia in the population.

The survival for advanced GBM remains less than one year. For anaplastic astrocytoma and low-grade glioblastomas, it varies from 18 months to five years. Thus there are a sufficient number of patients available to treat with the drug. For metastatic CNS cancer, survival is 4-6 months. There are just fewer than 200,000 patients annually in the U.S. that are potential candidates for such a drug.

Competitive Advantage

In general, since patients are living longer with cancer, there is an increased risk of developing metastases to the CNS and brain, which are notoriously impervious to systemic chemotherapy as these drugs generally do not cross the blood-brain barrier (BBB). Thus a product to manage primary and metastatic CNS cancers

has increasing demand. The prevalence of patients with these types of cancer presentations and the estimated markets make such a product worth developing.

DEKK-TEC's product delivers across the BBB into CNS cancer sites, potentially reverses hepatic toxicity in patients with hepatic disease, and can be used with other drugs.

Financial Overview

DEKK-TEC has raised almost \$5 million in NIH grants, \$2.2 million in licenses and milestone payments, and 1.8 million in Morgan personal funds; as well as \$500,000 in LA State Tax Credits.

Intellectual Property

To date, DEKK-TEC's products and technologies have been issued eight patents in the U.S.; fifteen issued worldwide patents and four worldwide patents pending. The patents cover DEKK-TEC's interest in penclomedine analogs, hormone delivery, phosphoramidate mustards, phenylhydrazones, and radiation devices.

Commercialization Strategy

In 2010, DEKK-TEC developed a c-GMP manufacturing facility (DEKK Pharmaceuticals, Inc.) to formulate and prepare unique and difficult delivery systems for Phase I drugs.

DEKK-TEC plans to raise \$5 to \$7 million to finish the Phase II trial and conduct the orphan drug trial. FDA funds are also a possible source of additional funding, though limited. The NCI Bridge Award is a possibility, but DEKK-TEC strives for a partner or financial associate.

Pipeline Products

DEKK-TEC is also developing 4-hydroperoxyifosfamide (HOOI) (pre-IND 381,783, US Pat 1,805,192) for use in the treatment of CNS cancers. The drug has a definite MOA (O6-guanine alkylation) and is also active in pre-clinical studies against IC xenograft brain human tumors. Phase I trial studies are pending.

Management Team

- Lee Roy Morgan, M.D., Ph.D., Chief Executive Officer and Medical Officer, is the founder who designed and synthesized DM-CHOC-PEN.

- Andrew Rodgers, Ph.D., Director of Research, developed the PK program.
- Lisa Stokes, B.S.R.N., Director of Clinical Research, is a nurse oncologist and has worked with DEKK-TEC since 1986.
- Edmund Benes, B.S., Scientist, works in the area of pharmaceutical and cell technology and has worked with DEKK-TEC since 1983.
- Gerard Bastian, Ph.D., Clinical Pharmacologist, collaborated with Dr. Rodgers to develop the PK program.
- David Adams, Ph.D., pharmacologist and biochemist, is a consultant who has worked in collaboration with DEKK-TEC since 2006.



Senex Biotechnology

www.senexbio.com
715 Sumter Street, CLS Room 513
Columbia, SC 29208

Igor B. Roninson, Ph.D.
President
518-727-5152
roninson@senexbio.com

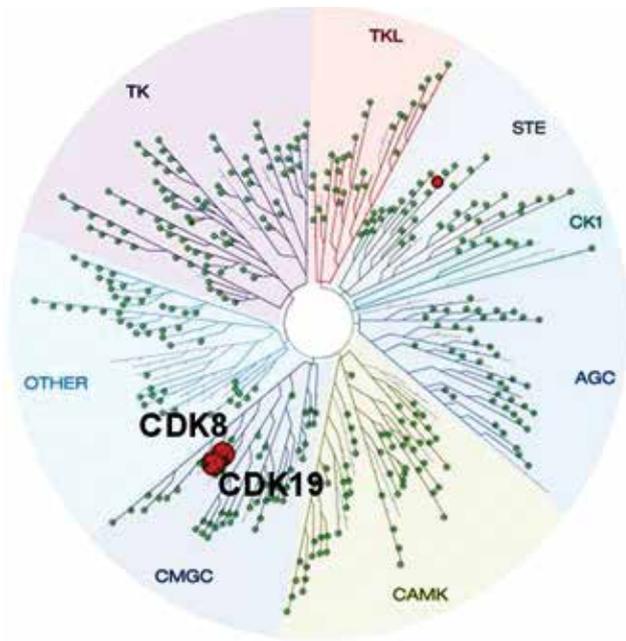
Small Molecule CDK8/19 Inhibitor, Senex B

4:00 p.m. – 4:15 p.m.

Company Background

The mission of Senex Biotechnology is to develop novel therapeutics for the treatment of cancer and other major diseases by targeting key disease-promoting pathways induced by cellular damage and aging, and by identifying and attacking novel cancer-specific molecular targets. Founded by Dr. Igor Roninson, on the basis of discoveries in his laboratory in 2002, the company is located in Columbia, S.C., and currently supports three scientists. Senex has won a series of grants, including two Phase II SBIR grants, and concluded a strategic licensing agreement with a

foreign pharmaceutical company in 2014. Senex has identified several novel targets and generated first-in-class small molecules against three of these targets. The drug for the most advanced program is about a year from clinical trials.



Technology Overview

Senex's most advanced program targets CDK8/19, a transcription-regulating oncogenic kinase. CDK8/19 inhibition has multiple anticancer effects at the molecular level, including the inhibition of oncogenic transcription factors, as well as stimulating immune surveillance by NK cells. The lead molecule, Senexin B, is fully optimized and exceptionally selective for CDK8/19. It is orally available, non-toxic, and extremely potent in numerous *in vivo* studies: Senexin B directly suppresses prostate and breast tumor growth, exhibits strong synergistic effects with several widely used drugs, and has antimetastatic activity in several cancer types.

Market Potential

Senex will initially develop Senexin B for treatment of metastatic castration-resistant prostate cancer (mCRPC), the second leading cause of cancer related death in the United States. Over 29,000 people die from prostate cancer every year; 1 out of every 36 men will die from prostate cancer. Median survival for mCRPC is less than 2 years. Although several new drugs have recently been approved, resistance to these drugs develops within several months so there is a large unmet need. Senexin B acts against those cancers that do not respond to any class of androgen receptor inhibitors, including cancers that are resistant to the newly approved drugs Xtandi® and Zytiga®.

Competitive Advantage

CDK8/19, Senex's primary target, belongs to the CDK family, but unlike better-known CDKs, CDK8/19 does not mediate cell cycle progression, and is not required by normal cells under homeostatic conditions. As a consequence Senexin B is extremely well tolerated. Senex is the only company to describe selective CDK8/19 inhibitors in a peer-reviewed article. Based on the known poster presentations and published patent applications, CDK8/19 inhibitors have been recently developed by Selvita (Poland), Bayer Pharma, and CNIO (Spain). Based on the available information, none of the competitors' compounds appear to be as selective as Senex's CDK8/19 inhibitors, and no comparable *in vivo* studies have been reported.

Financial Overview

Senex has received over \$2.8 million in NIH funding and over \$3.5 million from other sources, including angel investors, licensees, charitable foundations and the DOD. Senex is seeking \$10 million to fund additional pre-clinical and clinical studies through proof-of-concept in CRPC. The plans for this study have been developed with a NCI-designated cancer center.

Intellectual Property

The key issued patents for Senex's CDK8/19-related IP are U.S. patents 8,598,344 protecting the composition-of-matter of its CDK8/19 inhibitors and 8,592,147 protecting the general screening method for identifying inhibitors of transcriptional pathways including those regulated by CDK8/19. Senex also has several pending utility patent applications protecting other novel applications of CDK8/19 inhibitors that Senex and its collaborators have discovered.

Commercialization Strategy

Senexin B has been licensed to a foreign pharmaceutical company for minor markets. Marketing rights for all major markets are retained by Senex. The licensee will provide Senex with GMP manufactured Senexin B, the results of FDA acceptable preclinical safety studies, and clinical trials that will be conducted to international GCP standards. Senex will receive milestone payments and royalties from sales of drugs in the licensee's minor markets. These results will enable Senex to partner with a major pharmaceutical company to perform additional clinical trials and to market the drug. Anticipated milestone payments will fund other programs in Senex's pipeline.

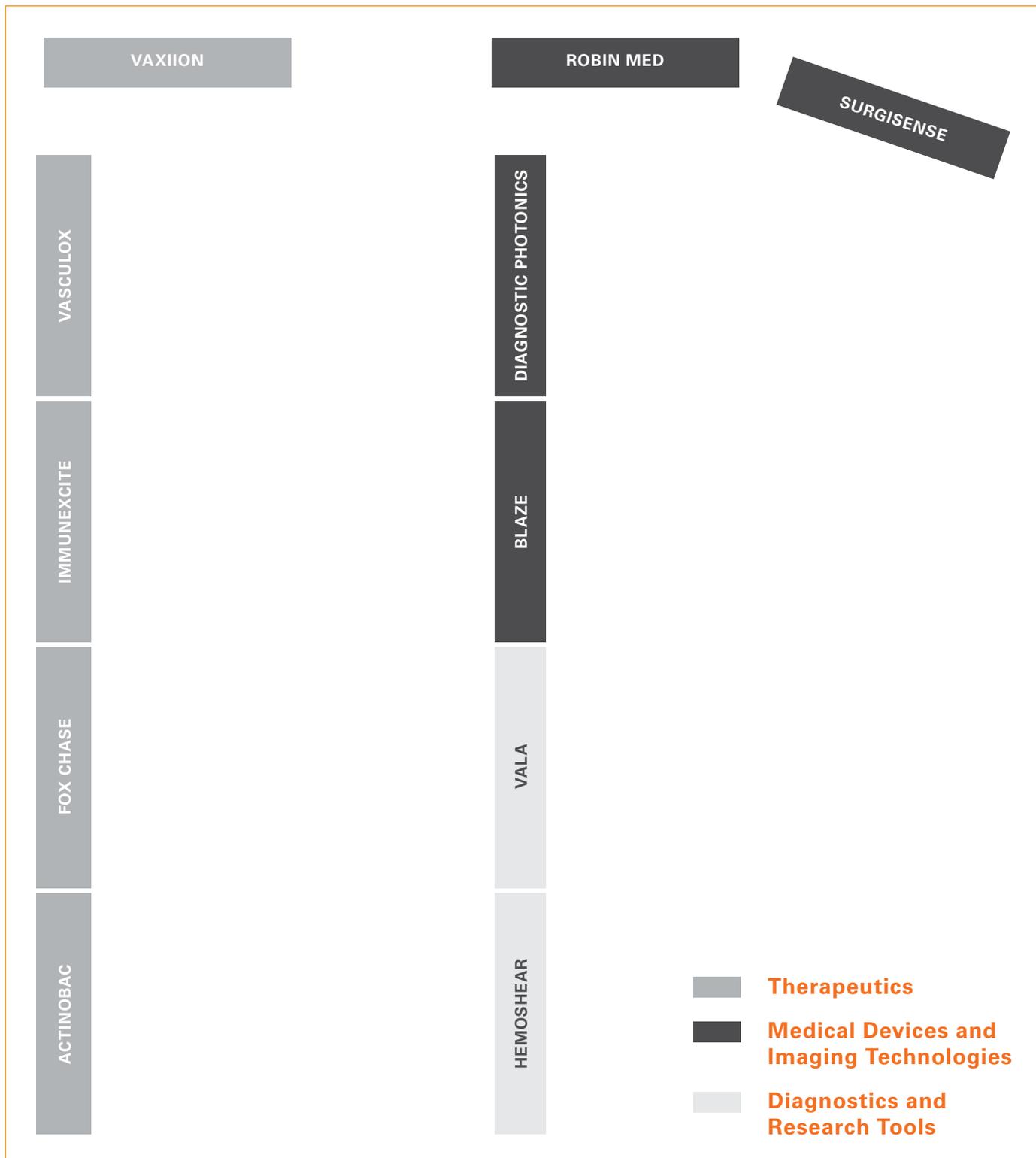
Pipeline Products

Senex also has programs targeting CDK3 and COPZ1. Senex has identified CDK3 as a cancer-specific target and is optimizing the first CDK3-selective small molecule inhibitors. COPZ1 is a component of the vesicle-coating complex and Senex has discovered the first COPZ1-targeting small molecules. COPZ1 inhibition should kill most types of tumor cells, including dormant cells and cancer stem cells, which are resistant to conventional therapy.

Management Team

- Igor Roninson, Ph.D., President and Chief Scientific Officer, is the founder of Senex and the inventor on 41 issued U.S. patents.
- Lawrence Friedhoff, M.D., Ph.D., Chief Executive Officer, has a long history of successful and rapid FDA approval of new drugs, including two blockbusters, one of which is Aricept®, the main drug used to treat Alzheimer's disease.
- Karthik Gopalakrishnan brings several years of experience in business development and negotiation skills to Senex. He has successfully concluded business transactions with several pharmaceutical companies. newly approved drugs Xtandi® and Zytiga®.

Poster Presentation Overview ..



Poster Presentations



Actinobac Biomed, Inc.

www.actinobac.com
15 Pelham Road
Kendall Park, NJ 08824

Scott Kachlany, Ph.D.

Founder and Chief Scientific Officer
908-295-1635
scottkachlany@actinobac.com

Executive Summary

Actinobac Biomed is conducting investigative new drug-enabling studies for their primary drug candidate, Leukothera™, a highly effective therapeutic for the treatment of hematological malignancies including B-cell lymphoma. Leukothera is a naturally derived biologic that specifically targets the subset of white blood cells (WBCs) expressing activated leukocyte function antigen-1 (LFA-1). Since LFA-1 is only present on WBCs and its activated form is uniquely expressed on cancerous and hyper-inflammatory WBCs, other cells and tissues are not affected, minimizing negative side effects.

Actinobac has exclusively licensed the patent portfolio established by Rutgers University covering the use of Leukothera for the treatment of multiple medical conditions including cancer, autoimmune/inflammatory diseases, and HIV infection. The company has raised \$960,855 since 2009 and is presently seeking funds to support the GMP production and formulation (\$700,000) of their drug candidate. This high quality material will be used to complete preclinical research and development activities (\$900k), stability and storage testing (\$500k), the assembly and filing of regulatory documentation and an IND application (\$1 million), and perform safety and preliminary efficacy clinical studies (\$1.5 million). Actinobac is presently in discussions with a number of major pharmaceutical companies and investment groups to provide scientific support and financing for these activities.

FCDC

FOX CHASE CHEMICAL DIVERSITY CENTER, INC.

Fox Chase Chemical Diversity Center, Inc.

www.fc-cdci.com
3805 Old Easton Road
Doylestown, PA 18902

Allen B. Reitz, Ph.D.

215-589-6435
areitz@fc-cdci.com

Executive Summary

Fox Chase Chemical Diversity Center, Inc. provides medicinal chemistry, target validation, *in vitro* pharmacology and chemical biology support to investigators at universities, and non-profit research organizations and foundations. Its goal is to transition innovative biomedical research technologies into full-fledged drug discovery and development programs of study. The metabotropic glutamate receptor 1 (GRM1, mGluR1) has recently been shown to play a significant role in the development and growth of melanoma tumors by Suzie Chen, Ph.D., and her colleagues at Rutgers University. They found that riluzole, the only drug approved by the U.S. FDA for the treatment of amyotrophic lateral sclerosis (ALS), which also blocks glutamate release from GRM1 cells, inhibits melanoma growth and proliferation both *in vitro*, in mouse xenograft models, and in limited human clinical trials in melanoma patients. However, the clinical use of riluzole for ALS, and potentially for melanoma, is severely limited by variable CYP1A2-mediated first pass metabolism. Fox Chase Chemical Diversity Center has developed novel and innovative prodrug derivatives of riluzole that avoid CYP1A2 *in vitro* metabolism and are expected to provide more regular pharmacokinetics and exposure in patients, with a longer half-life, allowing for once daily oral dosing versus the current twice daily dosing that is required, and potentially greater patient compliance.

The company has filed several patent cooperation treaty provisional U.S. patent applications on riluzole prodrugs, with additional composition of matter patent filings anticipated. Other than riluzole, there are no compounds that target the glutamate pathway for treatment of metastatic melanoma. The company has raised more than \$2.2 million specifically for this program since 2010, and is looking to raise an additional \$3 million by the third quarter of 2015, in order to perform the required IND-enabling studies for an IND application and enter Phase I clinical trials at the Cancer Center of New Jersey.



ImmuneXcite, Inc.

www.immunexcite.com
3 Forbes Road
Lexington, MA 02421

Yaniv Bejerano
President and Chief Executive Officer
781-674-4305
bejerano.y@immunexcite.com

Executive Summary

ImmuneXcite is a privately held biotech company developing the next generation of immune-activating therapies for cancer and infectious diseases utilizing a novel immunotherapy platform technology. ImmuneXcite's platform technology, mAbXcite, creates novel monoclonal antibody constructs that trigger a potent immune cell response selectively against disease targets. The mAbXcite technology is based on a unique polysaccharide that signals infection to the immune system. By linking this polysaccharide to monoclonal antibodies (or other targeting moieties like bi-specific monoclonal antibodies, aptamers, and peptides), a recruitment and activation of neutrophils/immune cells against the bound target is triggered, leading to its destruction. The mAbXcite constructs have demonstrated superior efficacy in resistant tumor xenograft models when compared to monoclonal antibodies. The company is currently developing lead therapeutic mAbXcite constructs for high unmet medical needs and breakthrough indications. IND-enabling studies have started and the company has developed an imaging assay that validates the mechanism of action and that can potentially be used as a pharmacodynamic marker for anti-tumor activity in Phase I clinical studies.

ImmuneXcite has a strong patent portfolio and has raised \$8 million from angel/private investors and non-dilutive sources (Massachusetts Life Science Center and a SBIR grant from NCI). The company is seeking to raise \$14 to \$16 million in its next financing in the fourth quarter, 2014, to support development of its lead compound through completion of Phase I clinical trials. ImmuneXcite's business development strategy is to establish partnerships/collaborations to maximize the therapeutic potential of its platform technology, and to build its internal pipeline through in-licensing. Active partnering discussions are ongoing.

Vasculox

www.vasculox.com
4320 Forest Park Avenue, Suite 304
St. Louis, MO 63108

George Capps, M.S., M.B.A.
Director of Business Development
314-932-4032, ext. 317
capps@vasculox.com

Executive Summary

Vasculox is a biotechnology company dedicated to developing CD47-targeting drugs for the treatment of cancer. CD47 is a checkpoint for the innate immune system, and tumor cells in numerous types of cancer upregulate CD47 to ward off the anti-tumor activities of macrophages. Vasculox's lead compounds are monoclonal antibodies (mAbs) against CD47 that not only promote phagocytosis of tumor cells but also have direct tumor-cell killing activity. Vasculox plans to develop one or more anti-CD47 antibody therapies through Phase II trials.

Although CD47 is recognized as a promising immuno-oncology target, no anti-CD47 products are currently on the market. Several entities are pursuing CD47 as a target preclinically or in early-stage clinical trials, but these competitors' compounds appear to lack the direct antitumor activity that provides the Vasculox mAbs with a competitive advantage. In animal models of lymphoma and pancreatic cancer, the Vasculox dual-function mAbs demonstrate superior efficacy compared to single-function mAbs, a distinction which has the potential to translate into improved efficacy in the clinic.

Vasculox's IP estate includes two U.S. patent filings and one PCT covering compositions of matter and uses of humanized anti-CD47 mAbs. The company has raised \$4.4 million since 2009 and is currently raising a Series A of \$8 million. Vasculox aims to achieve an exit by acquisition of at least \$300 million no later than 2019.



Vaxiion Therapeutics

www.vaxiion.com
11585 Sorrento Valley Road, Suite 105
San Diego, CA 92121

Matthew Giacalone

Vice President of Corporate Development & Research
858-792-0799, ext. 200
mjgiacalone@vaxiion.com

Executive Summary

Vaxiion Therapeutics is dedicated to the further development of VAX-IP, a promising investigational bacterial minicell-based biologic product initially intended for the topical intravesical treatment of Non-muscle Invasive Bladder Cancer (NMIBC). VAX-IP exerts rapid selective tumoricidal effects against human urothelial carcinomas in addition to synergistic secondary immunotherapeutic effects, a combination unlike that of any other product under development or on the market in the NMIBC space. With compelling pre-clinical efficacy data in several clinically relevant variations of the gold standard mouse model of NMIBC, Vaxiion is now committed to the commercial and clinical development of VAX-IP for initial use as an intravesical agent for the treatment of NMIBC. Currently, Vaxiion is initiating IND-enabling studies with the intention of filing an IND application with the FDA in Q1 of 2016. Clinical trials would focus on serving as a salvage therapy for BCG-refractory and BCG-intolerant NMIBC patients, and if successful, quickly be expanded to other areas of unmet need within the NMIBC treatment algorithm.

Vaxiion estimates the market size for an effective and reimbursable bladder cancer product addressing this admixed disease niche to be approximately \$937 to \$1.87 billion depending on the number of approved indications. The company feels that it will take approximately \$7 to \$10 million and 3.5-4 years to complete two Phase 2a efficacy studies and demonstrate human proof-of-concept, has raised about \$5 million for this effort to date, and is looking for \$3-\$4 million in addition to proceeds from a pending SBIR Phase II award to advance the program through this inflection point.

Blaze Bioscience, Inc.

www.blazebioscience.com
530 Fairview Avenue North, Suite 1400

Heather Franklin, M.S., M.B.A.

President and Chief Executive Officer
206-535-8144
heather.franklin@blazebioscience.com

Executive Summary

Blaze Bioscience, Inc., is a privately held biotechnology company focused on the development of guided cancer therapies. Blaze was founded in 2010 and is working to develop Tumor Paint™ products and optide-based guided cancer therapeutics. Tumor Paint products are designed to provide real-time, high-resolution visualization of cancer cells during surgery, enabling better detection and more complete and precise surgical removal of cancer, while sparing surrounding normal tissue. Precise illumination of cancer cells has been demonstrated in brain, lung, breast, prostate, colorectal, head and neck cancers, and in sarcomas. The first clinical candidate from the Tumor Paint platform, BLZ-100, is an intravenously (IV) delivered drug that is a combination of a cancer targeting peptide and a fluorescent beacon. The company's first Phase I clinical study of BLZ-100 is ongoing and initiation of a Phase 1b in brain cancer is anticipated in Q4 2014. Blaze has an ongoing collaboration with the Fred Hutchinson Cancer Research Center focused on the discovery and development of optide-based products for use as guided therapeutics.

Blaze has licensed patents and patent applications to the Tumor Paint and Optides platforms from the Fred Hutchinson Cancer Research Center and has filed additional patent applications related to Tumor Paint technology and BLZ-100.



Diagnostic Photonics, Inc.

www.diagnosticphotonics.com
200 S. Wacker Drive, 31st floor
Chicago, IL 60606

Andrew Cittadine

Chief Executive Officer
312-320-5478
acittadine@diagnosticphotonics.com

Executive Summary

Diagnostic Photonics is a medical imaging company formed from the University of Illinois to address the widespread and costly problem of repeat cancer surgeries due to incomplete tumor removal. The company's medical imaging system produces extraordinary images of tissue microstructure and reveals cancer missed during surgery. The Foresee (4C)TM Imaging System recently received CE-marking and initial FDA 510(k) clearance. The system pairs advanced optical coherence tomography with a novel physics-based image construction algorithm to create extraordinarily high resolution imaging using a compact, handheld probe.

The company's initial focus is on breast cancer lumpectomy surgery, where the repeat surgery rate from positive margins exceeds 25 percent. Lumpectomy surgery is performed on 1.6 million patients each year and represents an opportunity in excess of \$1 billion annually. The company has five issued patents and multiple patents pending. The company has established new CPT coding (Cat III) for breast imaging and successfully conducted a 50-patient, multicenter trial with excellent results. The company is working with leading academic medical centers to conduct a 460-patient multicenter pivotal clinical trial. Diagnostic Photonics has raised \$6.2 million to date and has a \$6 million Series B round pending to conduct the pivotal trial and generate initial commercial sales at leading medical centers in Canada, Europe, and the U.S.



Robin Medical, Inc.

www.robinmedical.com
P.O. Box 2414
Baltimore, MD 21203

Erez Nevo

Chief Executive Officer
443-450-4030
enevo@robinmedical.com

Executive Summary

Robin Medical, Inc., has developed and commercialized a wide range of medical devices since its formation in 1997. The ultimate goal of its newest cryopreservation technology is to collect biopsy tissue samples that retain the cells' viability, the *in vivo* biochemical profile, and the tissue ultrastructure by using a differential freezing profile that keeps part of the sample frozen (for biomarker analysis) and part unfrozen (for histology analysis). The cryogenic apparatus is either built into a cryobiopsy needle (CryoBxTM) to enable *in situ* freezing of the tissue, or in a disposable sample holder (the CryoSampTM) that maintains differential cryo temperature profile of samples acquired by any biopsy device.

The CryoBx will initially address the market of breast vacuum-assisted biopsy (VAB), estimated at \$300 million, as a competitive VAB device with tissue cryopreservation. We then plan to address the much larger market of biopsy devices for internal organs that require thinner biopsy needles. In parallel, the company plans to market the CryoSamp tissue holder to users of various brands of biopsy needles. A pending U.S. patent application for the cryogenic biopsy device and method has been filed and awaits Office Action. Robin Medical has raised \$13.5 million since its formation in 1997. The company plans to apply for an SBIR Phase IIB grant and it looks for an investment of \$2 million as matching funds for the grant. The funds will be used to continue the development and clinical testing of the device and to commercialize the biopsy cryopreservation line of products.



Surgisense Corporation

www.surgisense.com
5272 River Road, Suite 200
Bethesda, MD 20816

Jason Zand, M.D., M.B.A.
President & Chief Executive Officer
202-800-8071
jzand@surgisense.com

Executive Summary

Surgisense Corporation is a privately held C-corporation founded in 2006 with the mission of improving surgical care through intra-operative assessment of a patient's risk for surgical complications. The company is developing a new category of surgical instruments that integrate a novel oxygen sensing technology that directly measures tissue oxygenation. This enables surgeons to identify patients at risk of surgical complication due to alterations in blood flow and oxygenation through real-time assessment of tissue viability, and propensity to heal.

Surgisense's efforts initially target colorectal cancer for which surgical resection remains the mainstay of treatment. After removal of the tumor, the free ends of bowel are surgically joined to form an anastomosis. Surgisense's Stapled Anastomosis Viability Evaluation (SAVE) System strives to reduce the most dreaded complication: the anastomotic leak; a condition in which fecal material leaks into the abdominal cavity from the surgical junction. The technology integrates into the surgical workflow by replacing the anvil of commercially available, circular staplers with a sensing anvil that wirelessly transmits actionable data to the operative team. The System aims to reduce patient suffering while saving \$2 billion annually in excess health care costs.

Surgisense's core technology is protected in the largest medical device markets, and is extendable into many clinical applications. The company has been funded through a combination of federal grants and commercial revenue totaling \$2.3 million and is looking to raise \$6 million in Series A financing to support first-in-human clinical trials, U.S. and E.U. regulatory approval, and product launch.

HemoShear, LLC

www.hemoshear.com
501 Locust Avenue, Suite 301
Charlottesville, VA 22902

Vincent Aurentz
Chief Business Officer
434-872-0196
aurentz@hemoshear.com

Executive Summary

HemoShear is a privately held biotechnology company that is changing the way drugs are discovered and developed, departing from traditional and often misleading scientific methods and animal studies in favor of translational tissue systems that accurately replicate human disease biology. Its proprietary platform integrates best-in-class human disease systems, a comprehensive biorepository, interdisciplinary molecular and clinical disease expertise, and cutting-edge computational biology, together providing a unique and powerful lens to interpret biological mechanisms and human disease at a level not possible until now. Using its in vitro human tumor microenvironments, HemoShear's drug discovery collaborations uncover new targets, elucidate previously unknown mechanisms, differentiate drug candidates, and predict efficacy and safety of drugs before entering the clinic. HemoShear is collaborating to discover and develop new drugs with major pharmaceutical and biotechnology companies, five divisions of NIH and leading academic research institutions across several therapeutic areas, including oncology.

In November 2013, HemoShear announced a collaboration with NCI to initiate work to recreate the human tumor microenvironment in a physiologically relevant context that replicates human disease. HemoShear has successfully completed the first stage of the NCI contract to create a tumor system that incorporates three essential cell-types, restores molecular signaling pathways and responds to three cancer treatments at human concentrations. We know of no other systems that can assess drugs at human concentrations. HemoShear is seeking \$10 million from investors and/or pharmaceutical partners to engage in drug discovery collaborations and expand development of a wide range of tumor types and therapeutic approaches.



Vala Sciences, Inc.

www.valasciences.com
6370 Nancy Ridge Drive, Suite 106
San Diego, CA 92121

Jeffrey Price, M.D., Ph.D.

Chief Executive Officer
619-917-4633
jprice@valasciences.com

Executive Summary

Vala Sciences, Inc., is a life sciences company that develops and markets pathology diagnostics, in vitro alternatives to animal cardiac and neurological assays for early drug discovery, and related technologies to academia, pharmaceutical, and biotechnology companies. The company's multiplexed breast cancer assay includes quantitative fluorescent labels on a single slide for ER, PR, HER2/neu, and cytokeratin, and is read with an automated microscope that measures expression of all four biomarkers at the single cell level. Multiplexing speeds the pathologists' workflow over classical reading of one biomarker/slide at a time and by converting the current subjective scoring to an analytical test, Vala will eliminate the 15 to 25 percent error rates reported with the current standard of practice.

Vala holds a dozen issued patents and a total of 26 patents and patent applications encompassing the underlying enabling technological approaches and the key aspects of analytical biomarker testing and workflow optimization critical for this new diagnostic approach. This digital analytical pathology diagnostic approach can be adapted to pharmaceutical research, companion diagnostics and all cancer diagnostic tests that utilize biomarkers in tissue sections – the histopathology market – a global market that will surpass \$3 billion annually in 2015, according to a report by MarketsandMarkets.com. Vala has raised \$26.7 million since 2004 and is seeking \$10 million to create a suite of related pharmaceutical biomarker assays, carry out validation studies with CLIA-approved diagnostic laboratories, introduce a laboratory-developed test (LDT), obtain FDA 510(k) approval, and ramp marketing and sales.

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Visit: www.millennium.com

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