

JAN 0 7 2013

The Honorable Edward J. Kasemeyer Chair Senate Budget and Taxation Committee 3 West Miller Senate Building Annapolis, MD 21401-1991

The Honorable Norman H. Conway Chair House Appropriations Committee 121 House Office Building Annapolis, MD 21401-1991

RE:

2012 Joint Chairmen's Report, Page 57, M00F03.02 – In-state Development of Devices for the Treatment of Cancer

Dear Chair Kasemeyer and Chair Conway:

Pursuant to page 57 of the Joint Chairmen's Report of 2012, the Departments of Health and Mental Hygiene and Business and Economic Development respectfully submit this report on the status of research and development collaborations between Maryland companies and Maryland academic researchers that accelerate the development of devices, diagnostics, and therapeutics that improve cancer outcomes.

I hope this information is useful. If you have any questions regarding this report, please contact Ms. Marie Grant, Director of Governmental Affairs for the Department of Health and Mental Hygiene, at 410-767-6481.

Sincerely,

Joshua M. Sharfstein, MD

Secretary

Department of Health and Mental Hygiene

Christian Johansson

Secretary

Department of Business and Economic

Development

Enclosure

cc:

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MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE MARYLAND DEPARTMENT OF BUSINESS AND ECONOMIC DEVELOPMENT

Research and Development Collaborations to Improve Cancer Outcomes in Maryland

December 2012

Joshua M. Sharfstein, MD Secretary Department of Health and Mental Hygiene

Christian Johansson Secretary Department of Business and Economic Development

Background

Pursuant to the 2012 Joint Chairmen's Report (page 57) the Department of Health and Mental Hygiene (DHMH) in conjunction with the Department of Business and Economic Development (DBED) have developed this report to identify research and development collaborations between companies and academic researchers in Maryland that accelerate the development of devices, diagnostics, and therapeutics that improve cancer outcomes. Both DHMH and DBED have a history of working with researchers and/or companies to advance cancer research in Maryland. This report provides information about collaborations between academic research and Maryland biotechnology companies, and an overview of other programs in Maryland aimed to increase commercialization of research technology in the State.

Maryland is home to more than 500 bioscience companies, as well as federal agencies including the National Institutes of Health (NIH) and the U.S. Food and Drug and Administration (FDA). In order to utilize this immense research potential and help translate the technologies developed in labs into commercialized products, in 2009 Governor O'Malley unveiled BioMaryland 2020 – the State Strategic Plan for Life Sciences, which calls for an investment of more than \$1.3 billion in ten years. This initiative supports innovation, translation, and commercialization of technologies in a variety of fields including therapeutics, diagnostics, devices, and agricultural biotechnology. Maryland's commitment to biotechnology has propelled the State to become one of the largest bioscience clusters per capita. Of the State's 500 bioscience companies, 91 are actively engaged in research and development of products for cancer (Table 1).

University Collaborations with Maryland Companies

Since the start of the Maryland Industrial Partnerships (MIPS) program in 1987, the State has been committed to the development of collaborative relationships between companies and universities. In the last 25 years, there have been a number of fruitful collaborations between academic cancer researchers and companies interested in commercializing the technology developed through these partnerships. Tables 2 and 3 document these collaborations initiated during FYs 2011 and 2012 with both the Johns Hopkins University and the University of Maryland.

Johns Hopkins University and the University of Maryland are involved in nearly 30 cancer-related research projects with companies based in Maryland. Though some of these projects have been funded through the Cigarette Restitution Fund (CRF)'s component that allocates money to the academic health centers in Maryland, the vast majority have not. Cumulatively, these projects represent nearly \$10 million in funding. The majority of the collaborations and clinical studies involve evaluation of cancer drug therapies and protocols for treatment related to cancer. Treatment regimens range from small molecule to biologics, including cellular therapies and vaccines. Some collaborations involve biomarker studies or diagnostic imaging markers.

Some of these university collaborations have been based on or resulted in technology transfer activities. Examples include A&G Pharmaceutical, Gliknik, Xcision, and Profectus, who

licensed their technologies from the University of Maryland, and Biomarker Strategies who licensed their technology from Johns Hopkins University. Collaborations like these facilitate the translation of the fruits of laboratory science to private companies with the expertise to apply these new technologies.

Maryland Funded Resources for Research

A variety of programs to promote collaborations between academic researchers and biotechnology companies in Maryland are administered through State agencies. While all of these programs are open to research and collaborations focused on cancer, only the Cigarette Restitution Funding to the Academic Centers is specifically targeted at cancer.

Cigarette Restitution Funding to Academic Centers

Health-General Article §13-1116 establishes the provision of grant funds from DHMH through the CRF Program to two academic centers; the University of Maryland Medical Group (University of Maryland), and the Johns Hopkins Institutions. The purpose of these funds is to enhance cancer research activities that may lead to a cure for a targeted cancer, and to increase the rate at which cancer research activities are translated into treatment protocols in Maryland. Seven cancers are targeted by the CRF Program: lung, breast, cervical, prostate, skin, oral, and colorectal cancer. Detailed research activities funded by the CRF are reflected in the "Cigarette Restitution Fund, Funds and Expenditures, Fiscal Year Annual Report" prepared by DHMH and provided annually to the Department of Budget and Management.

CRF statute also requires each academic center to enter into a Memorandum of Understanding (MOU) with the following three State agencies: DHMH, DBED, and Maryland Technology Development Corporation (TEDCO). The purpose of the MOU as outlined by the statute is to:

- Establish a plan for expediting the translation of cancer research activities into treatment protocols and clinical trials;
- Establish the scope of the State's ownership or other financial interest in the commercialization and other benefits of the results, products, inventions, and discoveries of cancer research activities funded by a statewide academic health center cancer research grant under the CRF; and
- Reflect the intellectual property (IP) policies of the statewide academic health center; specifically, the MOU stipulates the following related to university commercialization:
 - For each invention assigned to the university, the university shall make best efforts to commercialize each invention through a license of similar arrangement with an entity in Maryland; and
 - The university shall consult with DBED and TEDCO to identify potential licenses.

The academic centers' commitment to cancer research reaches beyond the scope of activities funded by the CRF Program. Each academic center attempts to develop, license, and commercialize all viable IP related to the development of devices for cancer treatment. TEDCO

and DBED work alongside academic centers to forge collaborations with Maryland bioscience companies through referrals, mentoring, funding programs, and provision of additional resources.

Maryland Biotechnology Center Translational Research Award

The Maryland Biotechnology Center's Translational Research Award seeks to stimulate the movement of early stage bioscience research into the development of viable products or services. For projects involving collaborations between the State's private companies and academic research programs, the company is the applicant and recipient of the award, which may be shared with the university under a service contract. University submissions that advance research discoveries toward development of a product may also be submitted without a company partner, provided that a letter of support from the university's technology transfer office indicating that the technology has IP protection is included with the application.

Biotechnology Investment Incentive Tax Credit (BIITC) Program

The BIITC Program provides income tax credits equal to 50 percent of an eligible investment for investors in qualified Maryland biotechnology companies. This tax credit program offers incentives for investment in seed and early-stage biotechnology companies for up to \$250,000. Total credit certificates issued in a fiscal year cannot exceed the budgeted amount (\$8 million in FY 2013). Applications are reviewed and approved on a first-come, first-served basis.

In addition to receiving the BIITC tax credit, investors making qualified investments in Maryland biotechnology companies in Montgomery County may receive a payment from the county's Supplemental Program.

InvestMaryland (Maryland Venture Fund)

Through a premium insurance tax credit auction sale, where future tax credits are sold to insurance companies at a discount, the State of Maryland raised \$84 million in venture capital funding to invest in early stage technologies in the areas of life sciences, software, communications, and cyber-security. These venture capital dollars can be used to develop technologies such as cancer therapeutics, cancer vaccines, devices, and diagnostics.

Two-thirds of the funds raised will be apportioned to venture capital firms. The Maryland Venture Fund Authority, a public-private partnership chaired by Peter Greenleaf from MedImmune, is managing the selection process, and will recommend award recipients to DBED's Secretary. Investment awards began in July 2012, and will end by December 2013.

The remaining one-third of funds will be apportioned to the existing Maryland Venture Fund, the State's early stage equity fund within DBED, to invest in emerging companies.

Maryland Industrial Partnerships (MIPS) Program

The MIPS Program accelerates the commercialization of technology in Maryland by funding collaborative research and development projects between companies and University of Maryland faculty. MIPS provides funding, matched by participating companies, for university-based research projects that help companies develop new products. MIPS projects help companies find solutions to technical challenges, as well as develop products, processes or training materials, and are conducted by university faculty and graduate students in conjunction with company researchers.

While not exclusive to cancer research, MIPS funding is available for collaborations between universities and private companies involving cancer research. More than 400 Maryland companies have participated in project awards worth more than \$160 million since 1987. MIPS-supported products have generated more than \$23 billion in sales, added jobs to the region, and infused state-of-the-art technology into the global marketplace. MIPS celebrated its 25th anniversary in 2012, recognizing Maryland's long-term commitment to collaboration between companies and the university system. MIPS' 25 Anniversary Commemorative Collection can be viewed at http://dl.dropbox.com/u/1392738/mips_25th_anniversary_book_highres.pdf.

TEDCO Funding

Maryland Technology Transfer Fund (MTTF) - Provides funding for Maryland companies working to develop technology-based products and/or services in collaboration with the universities and/or federal laboratories in Maryland.

Johnson and Johnson Joint Investment Program - A component of the MTTF, a seed stage fund for companies working with universities or federal laboratories in Maryland.

Innovate Maryland - Launched in July 2012, Innovate Maryland has \$5.8 million in State funding to facilitate universities partnering with each other on commercialization proposals, strategies, and funding. This initiative represents an historic partnership between the State and its world-renowned research universities that unites researchers with entrepreneurs across disciplines and institutions to strengthen Maryland's economy, start new businesses, and create jobs.

Conclusion

Maryland has an established record of supporting collaborations between companies and academic researchers in the State. These collaborations have led to the development of cutting-edge technologies, including those technologies aimed at reducing the burden of cancer. The State's continued support of programs like those listed in this report will help to further expedite the translation of cancer research into new technologies that can be commercialized for wide-spread use and benefit in Maryland, nationally, and globally while fostering new biotechnology companies within the state.

Table 1

Maryland Companies Engaged in Cancer Research

Company Name	County	Website
20/20 GeneSystems, Inc.	GeneSystems, Inc. Montgomery www.2020gene.com	
A&G Pharmaceutical, Inc.	Howard	www.agrx.net
AllTranz, Inc.	Baltimore City	www.alltranz.com
Alper Biotech	Montgomery	www.alperbiotech.com
Ambiocore, Inc.	Baltimore City	N/A
American Gene Technologies International, Inc.	Montgomery	www.americangenetechnologies.com
Amplimmune, Inc.	Montgomery	www.amplimmune.com
AnGes, Inc.	Montgomery	www.anges-mg.com
Avanti Therapeutics	Baltimore	www.at-gc.com
Bacilligen, Inc.	Montgomery	www.bacilligen.com
Bartron Medical Imaging, Inc.	Prince George's	www.bartron.ws
Biological Mimetics, Inc.	Frederick	www.bmi-md.com
BioMarker Strategies, LLC	Baltimore City	www.biomarkerstrategies.com
BIOQUAL, Inc.	Montgomery	www.bioqual.com
Brassica Protection Products, LLC	Baltimore City	www.brassica.com
BriJen Biotech, LLC	Baltimore	www.brijenbiotech.com
Cangen Biotechnologies, Inc.	Baltimore City	www.cangenbio.com
Cato Research, Ltd.	Montgomery	www.cato.com
CCC Diagnostics, LLC	Baltimore City	www.cccdiag.com
Celek Pharmaceuticals, LLC	Montgomery	www.celekpharma.com
Cellona Therapeutics	Montgomery	www.cellonatherapeutics.com
CervoCheck, LLC	Baltimore	www.cervocheck.com
Champions Oncology, Inc.	Baltimore City	www.championsbiotechnology.com
Chiesi Pharmaceuticals, Inc.	Montgomery	www.chiesigroup.com
Chikujee Therapeutics	Montgomery	www.chikujee.at-gc.com
ConverGene, LLC	Montgomery	N/A
Correlogic Systems, Inc.	Montgomery	www.correlogic.com
Creaty MicroTech, Inc.	Montgomery	www.creatvmicrotech.com
CSA Medical, Inc.	Baltimore City	www.csamedical.com

Company Name	County	Website	
CytImmune Sciences	Montgomery	www.cytimmune.com	
DP Clinical, Inc.	Montgomery	www.dpclinical.com	
Emergent BioSolutions, Inc.	Montgomery	www.emergentbiosolutions.com	
Emmes Corp.	Montgomery	www.emmes.com	
EntreMed, Inc.	Montgomery	www.entremed.com	
Eisai, Inc.	Baltimore City	www.eisai.com	
ExonHit Therapeutics, Inc.	Montgomery	www.exonhit.com	
Expression Pathology, Inc.	Montgomery	www.expressionpathology.com	
FASgen, Inc.	Baltimore City	www.fasgen.com	
Fisher BioServices, Inc.	Montgomery	www.fisherbioservices.com	
Foligo Therapeutics, Inc.	Montgomery	www.foligotherapeutics.com	
Genomics and Bioinformatics Group	Montgomery	discover.nci.nih.gov	
GenVec, Inc.	Montgomery	www.genvec.com	
Gliknik, Inc.	Baltimore City	www.gliknik.com	
GlycoMimetics, Inc.	Montgomery	www.glycomimetics.com	
Human Genome Sciences	Montgomery	www.hgsi.com	
ImQuest Biosciences	Frederick	www.imquestbio.com	
InfraTrac	Montgomery	www.infratrac.com	
Intrexon Corporation	Montgomery	www.dna.com	
Lentigen Corporation	Montgomery	www.lentigen.com	
MacroGenics, Inc.	Montgomery	www.macrogenics.com	
MarkPap Pacific, LLC	Montgomery	www.bioscicon.com	
MaxCyte, Inc.	Montgomery	www.maxcyte.com	
MedImmune Oncology, Inc.	Montgomery	www.medimmune.com	
Medigen, Inc.	Frederick	www.medigen-usa.com	
Meso Scale Discovery	Montgomery	www.mesoscale.com	
Micromet, Inc.	Montgomery	www.micromet-inc.com	
NeoDiagnostix, Inc.	Montgomery	www.cervicaldnadtextest.com	
Neuren Pharmaceuticals	Montgomery	www.neurenpharma.com	
New Horizons Diagnostics	Baltimore	www.nhdiag.com	
Corp.	City		
NexImmune, Inc.	Montgomery	www.neximmune.com	
Noble Life Sciences, Inc.	Montgomery	noblelifesci.com	
Northwest Biotherapeutics, Inc.	Montgomery	www.nwbio.com	
OncoImmunin, Inc.	Montgomery	www.phiphilux.com	
OncoPlexDX	Montgomery	www.oncoplexdx.com	
OriGene USA	Montgomery	www.origene.com	
Osiris Therapeutics, Inc.	Howard	www.osiris.com	

Company Name	County	Website	
Otsuka Maryland Medicinal	Montgomery	www.otsuka-us.com	
Laboratories, Inc.			
Panacea Pharmaceuticals, Inc.	Montgomery	www.panaceapharma.com	
Pearl LifeScience Partners, LLC	Baltimore	www.pearllifesciencepartners.com	
Profectus BioSciences, Inc.	Baltimore	www.profectusbiosciences.com	
Prolias Technologies, Inc.	Frederick	www.proliastechnologies.com	
ProMetic BioTherapeutics, Inc.	Montgomery	www.prometic.com	
(United States)			
Protein One	Montgomery	www.proteinone.com	
QIAGEN	Montgomery	www.qiagen.com	
QioMed	Montgomery	www.qiomed.com	
RAFAGEN, Inc.	Montgomery	www.rafagen.com	
Rexahn Pharmaceuticals, Inc.	Montgomery	www.rexahn.com	
Royer Biomedical, Inc.			
SAIC Life Sciences Operation -	Frederick	www.saic.com/health/life-sciences/	
Frederick			
SAIC-Frederick, Inc., National	Frederick	www.saic-frederick.com	
Cancer Institute at Frederick			
Sigma-Tau Pharmaceuticals,	Montgomery	www.sigmatau.com	
Inc.			
Sirnaomics	Montgomery	www.sirnaomics.com	
Synergy BioSolutions, Inc.	Montgomery	www.synergybiosolutions.com	
Tengen Biomedical	Montgomery	www.tengen-biomed.com	
Theranostics Health, Inc.	Montgomery	www.theranosticshealth.com	
Trevigen, Inc	Montgomery	www.trevigen.com	
TrimGen Corp.	Baltimore	www.trimgen.com	
TriStar Technology Group,	Montgomery	www.tristargroup.us	
LLC			
Trophogen, Inc.	Montgomery	www.trophogen.com	
United Therapeutics	Montgomery	www.unither.com	
Corporation			
Valens Therapeutics, Inc.	Baltimore	www.valenstherapeutics.com	
VARNISS, LLC	Frederick	www.varniss.com	
VectorLogics, Inc.	Montgomery	www.vectorlogics.com	
VIRxSYS Corporation	Montgomery	www.virxsys.com	
Wellstat Diagnostics, LLC	Montgomery	www.wellstatdiagnostics.com	
Wellstat Immuno Therapeutics,	Montgomery	www.wellstatimmunotherapeutics.com	
LLC			
Westat, Inc.	Montgomery	www.westat.com	
Xcision Medical Systems	Howard	www.xcision.com	
Zyngenia, Inc.	Montgomery	www.zyngenia.com	

Johns Hopkins University Cancer Related Research Collaborations with Maryland Companies Initiated in FYs 2011 and 2012

	Company Name
1	BioMarker Strategies, LLC
2	Otsuka Pharmaceuticals Co., Ltd.
3	Otsuka Pharmaceuticals Co., Ltd.
4	Eisai, Inc.
5	Ambiocore, Inc.
6	Eisai, Inc.
7	Emmes Corp.
8	Medimmune Oncology, Inc.
9	Eisai, Inc.
10	Emmes Corp.
11	Westat, Inc.
12	GlycoMimetics, Inc.
13	Medimmune Oncology, Inc.
14	Medimmune Oncology, Inc.

Table 3

University of Maryland Cancer Related Research Collaborations with Maryland Companies Initiated in FYs 2011 and 2012

	Company Name
	Company Name
1	A & C Phormocoution! Inc
1	A&G Pharmaceutical, Inc.
2	20/20 GeneSystems, Inc.
3	AllTranz, Inc.
4	Convergene, LLC
5	Creaty MicroTech, Inc.
6	Gliknik, Inc.
7	Medigen, Inc.
8	NexImmune, Inc.
9	Otsuka America
10	Profectus BioSciences, Inc.
11	Rexahn Pharmaceuticals, Inc.
12	SAIC-Frederick, Inc.
13	New Horizons Diagnostics Corp.
14	Xcision Medical Systems