COMMONWEALTH of VIRGINIA

Peter Blake
Director

STATE COUNCIL OF HIGHER EDUCATION FOR VIRGINIA
James Monroe Building, 101 North Fourteenth Street, Richmond, VA 23219

(804) 225-2600
www.schev.edu

November 1, 2018

The Honorable Ralph S. Northam
Governor, Commonwealth of Virginia
Patrick Henry Building, Third Floor
Richmond, VA 23218

The Honorable Thomas K. Norment, Jr.
Co-Chair Senate Committee on Finance
P.O. Box 2
Mount Solon, VA 22843-0002

The Honorable Emmitt W. Hanger, Jr.
Co-Chair Senate Committee on Finance
P.O. Box 6205
Williamsburg, VA 23188

The Honorable S. Chris Jones
Chair, House Committee on Appropriations
P.O. Box 5059
Suffolk, Virginia 23435

Re: Virginia Research Investment Committee

Dear Governor Northam, Senator Norment, Senator Hanger and Delegate Jones,

As Chair of the Virginia Research Investment Committee (VRIC or the Committee), and on behalf of its members, I write to update you on the Committee's work over the past year, per Va. Code § 23.1-3132.E.

Since my report to you last November, the Committee has awarded three research grants from the Virginia Research Investment Fund (VRIF) and issued a Call for Concept Papers for a second competition for VRIF grants. We also have received guidance from a team of experts regarding prioritization and implementation of the recommendations contained in last year's assessment of the Commonwealth's research assets. This guidance likely will result in requests for statutory, budgetary and policy changes in the 2019 legislative session to improve Virginia's innovation ecosystem and public universities' research-to-commercialization pipelines. We also continue to monitor progress on the Global Genomics and Bioinformatics Research Institute (GGBRI) and the new Commonwealth Cyber Initiative (CCI). I am pleased to share the following details with you on these important fronts.

1. Virginia Research Investment Fund (VRIF): Initial Grant Awards, Early Outcomes and Second Grant Competition

In December and January, the Committee approved three proposals from public universities for VRIF grants to fund applied-research projects with strong potential for commercialization, company formation and/or job creation. These proposals had advanced from an initial pool of 10 that received critical review by a panel of scientific experts, industry leaders, entrepreneurs and venture capitalists. The trio of grant awards totaled just over $2.5 million, with an additional $3.8 million in matching funds committed by the universities and their private-sector partners.

- An artificial pancreas that uses smart phones, insulin pumps and the online cloud to reduce blood-sugar variation in people with diabetes (University of Virginia): $255,855 ($291,952 in matching funds).
- Two product lines based on patented algorithms that use machine learning to improve the safety and security of wireless communications from cyberattacks (Virginia Tech): $1,181,030 ($2,362,74 in matching funds).
- A medical device that will use low-energy electric fields to treat brain tumors (Virginia Tech): $1,111,758 ($1,236,872 in matching funds).

All grantees consistently have met their 2018 timeline milestones and have remained in full compliance with the terms and conditions of their grants.

You will be pleased to learn that, beyond these minimum thresholds and in less than one year, the three projects collectively have: (i) leveraged almost $3 million in addition to their 1:1 matches; (ii) created (or will create in the coming months) an estimated 25 new jobs over and above their grant-funded personnel; and (iii) resulted in the filing of one patent application. Please see the attachment for additional details on these projects and their progress in furthering the Commonwealth's reputation for creating state-of-the-art technologies.

Earlier this month, VRIC members approved the issuance of a Call for Concept Papers for a new VRIF grant competition that will support collaboration between public universities on capacity building for translational research centers in targeted growth-opportunity areas. We issued the Call on October 26; we will invite full proposals in early 2019, and we expect to make awards prior to June 30. This capacity-building program will ensure that university-industry partnerships are strengthened and that the winning grantees will be more competitively positioned for future funding opportunities from federal, state, non-profit and private entities.

2. 2017 Research-Asset Assessment and 2018 Implementation Guidance

Item 255A.2. of Chapter 836 of the 2017 Acts of Assembly authorized SCHEV to assist VRIC by contracting for an assessment of the research assets in the Commonwealth's universities, companies and federal facilities. Via the competitive procurement process, SCHEV negotiated a contract with

TEConomy Partners, LLC. The consultant conducted a four-phase study that began in August 2017 and delivered to VRIC in January a final report and three detailed sub-analyses. These documents are available on the VRIC webpage here: http://schev.edu/index/institutional/grants/va-research-investment-fund

Given the depth of the consultant's analyses and the insights elicited from the underlying data, VRIC members suggested in January that we assemble a group of stakeholders to provide additional, front-line guidance on prioritizing next steps and developing an implementation plan for the study recommendations. I tapped Dubby Wynne to recruit and chair this Implementation Advisory Team (IAT), and SCHEV negotiated a sole-source contract with TEConomy Partners to conduct additional analyses and provide technical support. The 14-member IAT worked from March through October to identify strategies through which to achieve transformational change for Virginia's innovation ecosystem. Mr. Wynne refers to these strategies cumulatively as an investment prospectus, which we will bring forward for the 2019 legislative session.

In October, the Committee received the stakeholder group's preliminary guidance, which recommended activities under four interconnected sub-goals: (1) generate more new high-growth potential commercialization ideas; (2) focus on strategic domain areas; (3) launch and scale-up high-growth, product-oriented startups; and (4) coordinate a statewide network of innovation services. The guidance describes Virginia's competitive advantages and innovation assets in five strategic innovation domain areas: (i) cybersecurity technologies; (ii) big data (leveraging fiber and data center assets); (iii) unmanned autonomous systems applications (leveraging test and demonstration facilities); (iv) space and satellite development and applications; and (v) life sciences. A sixth domain allows for state investment in significant, differentiated, new (i.e., unforeseen) opportunities unfolding in the future. In December, VRIC will review for approval the final guidance, which will be an actionable plan to nurture a more productive and efficient innovation ecosystem in the Commonwealth.

3. Global Genomics and Bioinformatics Research Institute (GGBRI): Update and Expectations

Pursuant to Item 478.20 of Chapter 836 of the 2017 Acts of Assembly, in May 2017 the Committee approved the release of the capital funds associated with the bonding authority for the Global Genomics and Bioinformatics Research Institute (GGBRI), which is a collaborative public-private partnership between INOVA Health and Virginia's public research universities. At that time, the partner institutions withdrew their request for the $8 million in general funds appropriated for GGBRI operations. In June 2018, VRIC received a progress update from INOVA and its university partners. VRIC members expect to receive a GGBRI briefing from the partner organizations in December; we likewise expect a request for some or all of the general-fund operating dollars to accompany this briefing.

4. Commonwealth Cyber Initiative (CCI)

The Committee has received two status reports from personnel of Virginia Tech on their efforts to facilitate development of the "blueprint" for the Commonwealth Cyber Initiative (CCI). The document is due by December 1 to VRIC, which the CCI budget language tasks with: (i) establishing a

process for public higher-education institutions to seek certification as CCI "spoke" sites; (ii) receiving requests for matching funds from the CCI "hub" and certified "spoke" sites; and (iii) approving or denying these requests for allocations of funds.

In August, VRIC members provided considerable input and feedback on the university's initial planning and work groups. In October, members responded to requests for guidance regarding the initiative generally and the "spoke" certification process specifically. Jim Dyke and I represent the Committee on the CCI Blueprint Advisory Council; Mr. Dyke is a member of its Executive Committee as well. We believe that the CCI Council is on schedule to deliver the "blueprint" report to VRIC by the deadline.

The Committee will meet on December 11, with an agenda that we expect to include discussion of the CCI blueprint, update on (and potential action to release funds for) the GGBRI and action on the investment prospectus to change the trajectory of Virginia's innovation ecosystem.

I conclude by noting that SCHEV recently hired a coordinator to facilitate development of the next Commonwealth Research and Technology Strategic Roadmap, for which responsibility moved on January 1 from the Center for Innovative Technology (CIT) to the State Council. The new statute directs SCHEV to develop and, at least every three years, update the Roadmap; then VRIC is to review and, upon approval, forward it to you and the Joint Commission on Science and Technology. On behalf of SCHEV staff and our Council, including chairman Heywood Fralin (who is also a member of VRIC), thank you for your confidence and trust in us in this endeavor.

And thank you for reviewing this annual report of the Committee's work and progress. Please contact me at any time with questions or requests for updates or other information.

Sincerely,

Peter Blake

Peter Blake
Chair, Virginia Research Investment Committee

cc: Heywood Fralin, Chair, State Council of Higher Education for Virginia
Members, Virginia Research Investment Committee

Attachment

ATTACHMENT
First-year Progress of Projects Awarded by VRIC in VRIF Round 1

Summary

All three grantees have met the milestones on the timeline promised in their applications.

Collectively, the three projects have leveraged almost $3 million, in addition to the 1:1 match committed in their proposals.

In addition to the personnel funded by the grants, collectively the three grantees have created (or will create in the coming months) an estimated 25 new jobs.

One project already has resulted in the filing of a new patent application.

Virginia Tech
Machine Learning for Cyber Awareness and Defense
Timothy O'Shea
Collaborating start-up: DeepSig, Inc.

Virginia Tech and DeepSig together are leveraging cutting-edge research on a type of artificial intelligence (AI) known as deep learning, applied to the rapid understanding and optimization of wireless systems to greatly enhance the security and performance of wireless systems and users. By rapidly maturing and incorporating these new techniques into mature software products tested under real world conditions, this team and program stands poised to provide an order of magnitude leap in both the security and performance of next generation wireless systems.

DeepSig attracted a private venture capital investment of $1.5M from a collection of industry veterans, led by Scout Ventures of New York. A news article in *Techcrunch* characterizes DeepSig as "a startup working to improve wireless technology by applying deep learning to radio signal data" and added "The firm has become increasingly interested in frontier technology, with investments in its core sectors of AI, machine learning, autonomy and mobility, and a big focus on data and cybersecurity." This investment, along with initial sales, has enabled DeepSig to grow from four to eight full-time employees in Arlington. The research funding at the university continues to support research faculty as well as at least three graduate students.

A Virginia Tech news release quotes Co-PI Charles Clancy: "DeepSig is one of eight start-up companies founded by Virginia Tech faculty affiliated with the Hume Center for National Security and Technology. These companies have raised over $120 million in venture funding since 2012 and currently employ nearly 200 people, the majority in the Commonwealth of Virginia. We are proud of the tremendous work of our faculty in commercializing technologies invented at Virginia Tech."

The team reported new collaborations with early adoption partners including the silicon valley graphics and AI company NVIDIA, as well as the academic/industry organization, Institute for Electrical and Electronics Engineers (IEEE), and SETI, DARPA and GNU Radio.

Technical progress includes the development of novel state-of-the-art AI algorithms (machine learning and probabilistic models) for rapidly making sense out of wireless activity (to characterize "normal" wireless behavior) and to rapidly identify deviations from this, enabling autonomous detection and reaction to a wide variety of wireless device failures or anomalous or malicious cyber intrusion activity. This core wireless sensing capability has gone from laboratory experiments to efficient, mature software implementation.

Several conference and journal papers from the work were submitted to and are currently under review in peer-reviewed scientific venues.

University of Virginia
Eliminating the Neurocognitive Consequences of Diabetes: The Virginia Hypoglycemia Safety Project
Daniel Cherñavvsky
Collaborating start-up: TypeZero Technologies

This project is a continuation of more than a decade of work on biobehavioral monitoring and control methods in the treatment of type 1 diabetes (T1D). It builds on the technology being tested in two large-scale ongoing clinical trials at the University of Virginia to evaluate the neurocognitive impact of the artificial pancreas, in particular its dedicated Safety System that automatically adjusts insulin levels to achieve better blood sugar control.

The Diabetes Safety System is an integral part of inControl software, developed by TypeZero Technologies, Inc. While trials of the artificial pancreas (AP) (or automated insulin delivery [AID]) are ongoing at several U.S. institutions, including three studies led by the UVA Center for Diabetes Technology, no studies have directly tested the neurocognitive impact of this emerging technology. Thus, this investigation is the first to bridge this substantial knowledge gap.

TypeZero Technologies, Inc., the partnering Charlottesville-based start-up company, has licensed the inControl AP software to Tandem Diabetes Care, which subsequently embedded the software on an insulin pump rather than a cellphone. This change in device is much easier for users. This achievement prompted an increase in the value of TypeZero, that resulted in its acquisition by Dexcom (the maker of a leading continuous glucose monitor, also used in the study). The terms of the transaction were not publicly disclosed. TypeZero will remain in Charlottesville and increase employees from 12 to 20 in the upcoming year, thus creating at least eight new jobs in the Commonwealth.

Two UVA students in the fields of biomedical engineering and applied sciences have joined the project, as has a postdoctoral physician scholar from Berkeley Center for Social Medicine and a registered nurse clinical research coordinator.

Tandem Diabetes Care is now providing in-kind the insulin pumps with the embedded inControl software for this trial, increasing the in-kind match for equipment to $90,000 (cost of each insulin pump is approximately $3,000) rather than the $30,000 originally proposed.

The research team has submitted an NIH grant application to expand the cognitive study in T1D to a larger population. If awarded, it will bring $1.5 million in direct cost to UVA.

Technical progress includes successful attainment of regulatory approval to conduct the clinical trial (FDA approval for an Investigational Device Exemption (IDE)) and UVA Institutional Review Board (IRB) approval. The team is on track to complete enrollment of study subjects on time, with the enrollment of two of the first 15 subjects. In addition, the team has designed and developed a unique data collection system, which allows cognitive testing, as well as assessment of mood and other indicators of emotional well-being, in real time in participant's normal environment and routine. This data collection strategy, known as Ecological Momentary Assessment, represents a novel and powerful method for assessing the impact of the Diabetes Safety System on individuals' daily lives and function.

Virginia Tech
Brain Cancer Treatment with High-Frequency Electroporation
Rafael Davalos
Collaborating start-up: VoltMed, Inc.

Brain and spinal cord tumors account for one out of four childhood cancers and are the second most common cancers in children, after leukemia (American Cancer Society). The most common and aggressive type of brain cancer is glioblastoma multiforme (GBM). Only 25% of children diagnosed with high-grade gliomas live longer than five years; while in adults, the five-year survival drops to 10%. A major reason for poor survival is migration of glioma cells beyond the margins of the visible tumor. The research team is developing a minimally invasive medical device to ablate and target invasive cells beyond the tumor margin through the Integrated Nanosecond-Pulsed Irreversible Electroporation (INSPIRE™) system. Within one minute and a single treatment protocol, low-energy, high-frequency pulsed electric fields ablate the bulk tumor mass while selectively killing cancer cells that are present beyond the "visible" margin -- sparing the surrounding healthy brain tissue. The grant-funded project activities include critical steps on the path to regulatory approval and market entry by fabricating a pulse generator and electrosurgical probes and performing Good Laboratory Practice (GLP) compliant in vivo studies. The INSPIRE™ device is geared towards commercialization and will comply with Good Manufacturing Practices (GMP) and all pertinent ISO, IEC and ASTM standards. The team has submitted a patent application on methods for improving the safety of electroporation in neurological tissue. These methods include a new procedure for inserting treatment electrodes into the brain (which was discovered in accordance with the development of an MRI-compatible electrode), as

well as methods for improved timing of the electrical pulses and modification of the tissue electrical properties to maximize the treatment volume.

The team has been awarded an NIH SBIR Phase I grant for $244,000 to support this effort and has partnered with Plastics One (Roanoke, VA) to finalize the construction of an MRI-compatible probe. This brings the total amount of funding raised for this project to $4.644 million. They have also applied to the Center for Innovative Technology GAP Fund, are in ongoing discussions with Virginia Tech Carilion Innovation Fund, plan to submit an administrative supplement to their SBIR grant designed to promote diversity in research and are targeting an NIH SBIR Phase 2 application for fall of 2019.

The team projects that 13 new jobs will be created in the next three years, adding to the eight jobs created to date.

The team has published two papers and a book chapter. Dr. Davalos gave an invited presentation on INSPIRE™ as a Plenary Speaker at the 24th International Symposium on Bioelectrochemistry and Bioenergetics of the Bioelectrochemical Society in Lyon, France. Christopher Arena of VoltMed gave a presentation on INSPIRE™ at the Washington, DC Health Impact Forum organized by Cavendish Global.

Technical progress includes critical planning for FDA approval of INSPIRE™ for an investigational device exemption (IDE). The team has contracted with consultants who have scientific backgrounds and extensive knowledge in medical device development and FDA regulations to provide guidance on the optimal regulatory pathway to market and the development of preclinical and clinical studies. They are on track to achieve IDE approval in 2019.

The team partnered with Sterling Medical Device (Rochelle Park, NJ) to build the INSPIRE™ pulse generator in compliance with GMP and other standards. The initial design documentation has been completed and the team is entering the development phase. VoltMed engineers observed a neurosurgeon at Wake Forest School of Medicine during operation of a different brain tumor device to guide the design to ensure proper fit within the existing clinical workflow.