ReGen Valley Tech Hub – Overarching Narrative

I. Executive Summary

Chronic illness affects more than 6 in 10 Americans, fuels health inequity and socioeconomic burden, and causes billions in lost productivity each year, even as rising healthcare costs approach one fifth of GDP. U.S. health outcomes trail other developed countries despite the highest per capita spend on the globe. Further, the endpoint of chronic illness is organ failure, and the U.S. supply of donor transplants is egregiously short of need and inequitably distributed; 17 Americans die each day waiting for a transplant. The potential to solve these challenges with curative regenerative medicine therapies has been known to academia, industry, and government for decades, but not until now has the field of biofabrication had a proven commercialization model to make it a reality. Globally, the market for biofabricated medical products (cell therapy, tissue engineering) is $15B and projected to reach $62B by 2034. The ReGen Valley Tech Hub capturing a conservative 10% of the global market represents a $6B opportunity – and a life-saving revolution in healthcare. However, global competition is rapidly intensifying, and *this moment is exigent*. Future decades of market share in health technology, and thus military readiness, economic and national security, and responsible deployment of these technologies, depend on action today. The U.S. must win the global race to lead this new industry and keep American innovation, intellectual property, manufacturing jobs, and supply chains on-shore. ReGen Valley is poised to execute with speed, and Tech Hubs Phase II funding is essential for the U.S. to secure the lead.

II. Synopsis. Vision for ReGen Valley 10 Years from Tech Hubs Investment. In the ReGen Valley of the mid 2030s, once-bustling textile mills lost to the Great Depression thrive anew. The Millyard, once the largest industrial complex in the world, again plays a critical role in the Nation's economic and national security. Key Technology Focus Areas such as biotechnology, medical technology, genomics, synthetic biology, robotics, automation, and advanced manufacturing combine in this global epicenter to produce life-saving cell-based therapies, measurably advance health equity, and bend what once seemed an intractably accelerating healthcare cost curve. National and international demand for cell-based therapies and the equipment used to manufacture them expands with each successful clinical trial and patent, and healthcare systems across the country deliver restorative therapies developed and manufactured in ReGen Valley to all who need them, finally overcoming intransigent disparities and socioeconomic burden. These life-saving technologies are tangible assets that strengthen relationships with allies and potential allies, as well as military readiness, and America's leadership of this industry has enabled the U.S. to lead global policy, ethics, quality standards, and responsible distribution. Manufacturing these technologies on-shore and sustaining supply chain resiliency ensure Americans and allies do not face the scarcity that has occurred with other industries. The concentration of companies anchoring in ReGen Valley for access to its unique and comprehensive continuum of commercialization capabilities, trained workforce, and accessible capital stack has created thousands of good jobs, and economic opportunity is more equitably distributed, driving intergenerational economic growth. Training and education institutions in the region are world-class and operate as a 'Common Campus', offering complementary, stackable, modular curriculum informed by trusted relationships with industry. Clear and accessible career pathways into biofabrication ensure inclusion and drive the retention, development, and attraction of a capable, job-ready workforce. Local residents, with the stability of affordable housing, accessible childcare, public transportation,

and smart policy, have pride in their contribution to the health, economy, and security of the Nation and world. ReGen Valley represents more than 10% of global market share ($6B) and serves as the export center for the globe. The Consortium looks back on the Tech Hubs place-based investment in capacity as the keystone that sealed the story arc of the region.

ReGen Valley: A Vibrant, Capable Consortium. The Designation of ReGen Valley as a Tech Hub served as a pivotal affirmation of the acknowledgement first made with the City of Manchester's Build Back Better award: this region has the foundational assets to become the global epicenter of the biofabrication industry. Small groups of dedicated community leaders have long been working together to better their community and establish this foundation, and ReGen Valley's Designation synthesized these efforts into a powerful, diverse team united by a common, inclusive vision of the future. This collective vision has driven consistent engagement since the Designation was announced, and members have devoted hundreds of hours to architecting ReGen Valley's growth and impact. This vision has also attracted essential new partners (*Figure 1).*

Consortium Members	Primary Role
UNH, SNHU, Community College System of NH, Dartmouth College, UMass Lowell (*an MSI*), Saint Anselm College*, Franklin Pierce*	Academia
Manchester, Nashua, State of NH	State and local govt.
ARMI, Rockwell Automation, DEKA, Advanced Solutions Life Sciences, Catholic Medical Center, United Therapeutics/Lung Bio*, NH Hospital Assoc, Safi, VitroLabs, Merrimack Manufacturing, Get Tech Smart*	Tech/Innovation/ Manufacturing Industry
NextGen Manchester Resiliency Council, SNHPC, NPC*, Business Finance Authority	Economic Development Orgs
NH AFL-CIO, NH Building, Construction and Trades Council	Labor and Workforce Training Orgs
Manchester School District, Spark Academy*	Elementary/secondary/ career & technical schools
FIRST NH, Business Alliance for People of Color	Diversity in STEM and Entrepreneurship
Granite YMCA, NH Businesses for Social Responsibility*, YWCA*, NH Center for Justice and Equity*	Economic stability, opportunity, and childcare
NH Small Bus Development Center (through UNH), Amoskeag Ventures, NH Tech Alliance*	Venture Development Organization
NH Community Development Finance Authority, Community Loan Fund	Underserved communities economic development
NH MEP*	Mfg Ext Center

Figure 1: ReGen Valley Consortium (* = new member)

Component Projects: Building Capacity to Fuel Inclusive Economic Growth. Upon Designation, the Consortium focused immediately on the design of a tightly-knit complement of Component Projects (*Figure 2)* that will launch ReGen Valley from burgeoning biofabrication industry epicenter to leading global competitor. ReGen Valley has a solid technical foundation and proven *capability* for commercialization and workforce development. However, but for Tech Hubs implementation funding, the region cannot build *capacity* with the speed and agility required to meet this moment of intensifying international competition. While the U.S. Department of Defense (DoD) provided vital foundational capabilities, critical-path efforts to build commercialization capacity and place-based resources are

Project	Description
Consortium Coordination & Impact Assessment	Hub-wide coordination, including policies and training, impact assessment, DEIA
ReV/Up: Creating a Pipeline of Talent & Businesses	Building a diverse and connected network of entrepreneurs & local businesses; matching diverse entrepreneurs with BioFab Startup Lab & other companies; building a Supplier Diversity Database
ReGen Valley Common Campus: Attracting, Building, & Retaining Critical Workforce	Creation of a multi-institution Common Campus model to bring synergy and agility to biofabrication workforce needs, expand, inclusive opportunities, and retain, develop, and attract talent
Scaling Commercialization Capacity	Scaling a proven model to meet skyrocketing industry demand and keep U.S. innovation and good jobs on-shore
Strengthening Demand Generation and Clinical Readiness	Understanding baseline clinician and public knowledge of regenerative therapies to inform training and engagement and fuel demand
Sustaining & Expanding Childcare for Existing and Future Workers	Apprenticeship program to expand supply of childcare workers and ensure capacity for biofabrication workforce
Transportation Management Association	Strategic management of transportation needs and opportunities in ReGen Valley, bringing workers to good jobs
Closing the Capital Gaps	Catalyzing commercialization by establishing infrastructure to raise venture and philanthropic funds; building a ReV/Up Capital Program for local entrepreneurs

Figure 2: ReGen Valley Component Projects

not within their mandate (*letter enclosed*). **Urgency has never been higher. U.S. national and economic security depends on U.S. innovators, intellectual property, manufacturing jobs, and supply chains staying on-shore – and the U.S. claiming the lead.**

Commitments. Since Designation, every member of the Consortium – including each major industry leader - has affirmed additional commitments to the future of ReGen Valley. New entities joining the Consortium are taking action to amplify impact, as are State, Local, and Federal leaders.

Entity	Description
Rockwell Automation, DEKA	Providing critical services and expertise: $10M in automated manufacturing and $30M in engineering services over the next 5 years
Safi, VitroLabs, ARMI Members	Commitments to use expanded commercialization capacity & manufacture with the BBBRC-funded CDMO; inform workforce programming; create jobs
Community Loan Fund, Cities, NH AFL-CIO, NH Housing	Commitments of more than $60M in housing investments and trusts; changing zoning policies; co-convening affordable housing summits
St. Anselm, Dartmouth, UNH; Franklin Pierce, UMass Lowell, CCSNH	Adding biofabrication-relevant capabilities: biotechnology ethics; express licensing pathways; creation of a rural sim lab; equitable clinical trials; state of the art workforce training center co-created with ARMI
Amoskeag Ventures, Rockwell, New North Ventures, Woods Capital	Commitments to raise venture capital (Amoskeag & NNV); co-invest alongside ARMI BioVentures fund (Rockwell, NNV); applied for SBICCT license through SBA's joint program with DoD on critical technologies
NH BFA, NH BEA, NH CDFA	Implementing biofabrication-specific student loan reimbursement; supporting NH Life Sciences strategy & workforce retention; building capacity for underrepresented institutions and entrepreneurship
DOD, VA, NH MEP	Commitments to strengthen supply chain resiliency; guide the Consortium on national security and Servicemember & Veteran needs
Dept of Ed, Spark Academy, Manchester SD, FIRST NH	Commitments to broaden biofabrication programming to every grade band, implement industry-recognized credential and curricula in high school, and clarify career pathways

Figure 3: Illustrative ReGen Valley Commitments.

Additionally, entities outside ReGen Valley, including biomaterials and services supplier ATCC and international (NATO member country) companies, are reaching out to join the momentum and establish a presence in ReGen Valley.

Competitive Advantage: Winning the Biofabrication 'Place Race'. The potential to manufacture curative regenerative medicine therapies has been known to academia, industry, medicine, and government for decades. However, attempts to commercialize these promising technologies have historically fallen short due to fragmentation between disciplines, inconsistent and expensive manual manufacturing approaches, and fluctuations in funding. In the dawning days of the industry, breakthrough American technologies were routinely lost to foreign interests, and this led the DoD to invest $80M in ARMI to establish a Manufacturing Innovation Institute, part of the Manufacturing USA network. ARMI immediately began removing industry barriers, translating research into products that would restore injured warfighters to form and function and securing U.S. leadership of the industry. ARMI established defense-relevant manufacturing, robotics, and automation capabilities focused on Technology Readiness Levels (TRLs) 4-7, regulatory and translation expertise, and workforce development programming. Seeing so many critical needs met in one place, companies began to concentrate around ARMI's campus. In 2022, the City of Manchester received a Build Back Better Regional Challenge (BBBRC) award that funded pilot scale manufacturing capacity for TRL 8-9 including commercial market entry, an adjacent Workforce Training Facility (*future home of the Common Campus' Center for Biofabrication and Automated Manufacturing*), the BioFab Startup Lab, equity-based workforce and transportation efforts, and a novel product transport network. ***This is the first time the complete biofabrication technology commercialization continuum had existed in one place, and the industry took notice.*** Before it was officially announced, the BioFab Startup Lab had triple the number of applications it was designed to support, and ***demand for ReGen Valley's proven capability to move products through to commercialization now outpaces capacity by two orders of magnitude***. Importantly, it is not just startups who are waiting in suspense on ReGen Valley's doorstep; leading corporations

with commercialized technologies, including those in Boston, need the analytic and manufacturing expertise that exists here, as well as a trained and capable workforce, to grow.

Proposed component projects and commitments will unlock additional private and philanthropic capital, establishing a flywheel that leads to the sustainment of ReGen Valley and fuels its ascent to global leadership (*Closing the Capital Gaps*). At the core of ReGen Valley's approach is *urgent and essential* Tech Hubs investment in commercialization capacity. Without an immediate increase in commercialization capacity, life-saving technologies will fail to reach patients, American intellectual property will continue to be lost to foreign interests, and the U.S. may permanently lose the lead of this industry – harming our national security and missing the opportunity to fuel the creation of good manufacturing jobs here at home. Demand for curative regenerative medicine therapies is already clear, and ReGen Valley will further accelerate demand generation by proactively engaging the healthcare workforce to support training opportunities and operational readiness (*Clinical Readiness*).

As demand grows, residents of ReGen Valley seeking a fulfilling, family-sustaining career in biofabrication must have equitable access to jobs and entrepreneurial opportunities. ReGen Valley proposes to invest in accessible, multi-level career pathways (*RVCC*), a thriving, connected startup ecosystem focused on meeting the business and C-Suite talent needs of the biofabrication industry *(ReV/Up; Closing the Capital Gaps)*, and increased access to childcare (*Childcare*) to enable businesses and workers in ReGen Valley to grow and thrive here long-term.

Climate & Environmental Responsibility. Executive Order 14008 – Tackling the Climate Crisis at Home and Abroad, describes the importance of reducing climate pollution in every sector of the economy. ReGen Valley approaches this imperative with the utmost seriousness and is taking multiple steps in alignment. Consortium member NH Businesses for Social Responsibility (NHBSR) will train Consortium members on social and environment responsibility and will work with the ReGen Valley Governance Committee to track and report outcomes. ReGen Valley's technical vision also inherently advances environmental responsibility and employs an approach that will be essential to prevent climate impacts as the industry expands. Shipping is the primary source of the industry's carbon footprint, and the Consortium is working on multiple approaches to reduce materials consumption, including the reconstitution of dry cell culture media in place of shipping large quantities of liquid. The ability to analyze a cell-based product at each process stage also enables process efficiencies – using fewer materials to achieve the same product yield. Automated manufacturing with in-line, non-destructive quality monitoring further reduces materials consumption, achieving a similar end. Further, climate and environmental responsibility is the driving purpose of key technologies in development within the Consortium, including VitroLabs' lab-grown leather. Of note, sourcing and shipping materials from abroad also threatens supply chain resilience and risks dependence on foreign adversaries; climate responsibility and supply chain resilience are, for biofabrication, highly interdependent. As set forth in *Scaling Commercialization Capacity,* ReGen Valley will seek to work with the U.S. Department of Commerce's (DOC) new Supply Chain Center, described by the Department as an analytic engine for supply chain resilience policy action and a partner to industry in building resilient supply chains, supporting U.S. businesses to lead the industries of the future. This will build on ARMI's prior supply chain work with HHS' Essential Medicines program and ensure the biofabrication supply chain is resilient, climate responsible, and within the U.S. and its allies' control. Notably, ARMI has also been in conversation with the National Security Council in recent months on this topic, and the White House attention on securing U.S. advantages in biotechnology and biomanufacturing is evidence of the issue's salience.

Equity & Inclusion. ReGen Valley is the most populated and most diverse area of New Hampshire, and the Consortium attests to the human and economic imperative that diversity, equity, inclusion, and access (DEIA) be foundational to every activity. The Consortium is engaging underrepresented community voices in governance, including Unions, workers, and minority-owned businesses and entrepreneurs, and has strengthened representation from equity-focused organizations and collaborators. ReGen Valley will implement an Impact Dashboard (*Consortium Coordination and Impact Assessment*) to measure progress with inclusive growth as the guidepost. The President and CEO of the New Hampshire Center for Justice and Equity holds the seat on the elected Consortium Governance Committee permanently reserved for an equity-focused representative. The accomplished founder of Get Tech Smart, a long-time diversity advocate, will be the Consortium's Chief Impact Officer and will lead Consortium metrics reporting, including tracking the advancement of equity in every component project. NHBSR has been working to help companies measure their sustainability impact, including DEIA, and is bringing these skills to the Consortium.

The Consortium will also build upon underrepresented community engagement established through the BBBRC award, ensuring the future of ReGen Valley benefits from diverse business and entrepreneurial strengths. Specifically, the Consortium will work with the Business Alliance for People of Color (BAPOC) and the Small Business Development Center (SBDC)'s community outreach programs to create a Community Access Coalition of trusted community partners (*ReV/Up*). Lessons learned from NH CDFA's Community Navigator Program will also inform the creation of the Consortium's Community Engagement Strategy, connecting historically underrepresented constituents with the Hub's activities.

In addition to economics, the impact of U.S. leadership in biofabrication on health equity cannot be overstated. More than 6 in 10 Americans live with at least one chronic health condition; marginalized populations face disproportionate healthcare access barriers and socioeconomic burden; and U.S. health outcomes trail other developed countries despite the highest per capita spend on the globe. Efforts to alleviate U.S. healthcare disparities have achieved insufficient progress to date, and the technologies developed in ReGen Valley will finally change this trajectory. As described in commitment letters from clinical partners, ReGen Valley will strive for equity in clinical trials, as well as in therapy distribution and access.

Outcomes & Impact Assessment. ReGen Valley's component projects and commitments are designed to: 1) increase commercialization capacity by two orders of magnitude and prevent the loss of U.S. IP and biofabrication companies to foreign acquisition or investment; 2) increase the number of U.S. companies accessing manufacturing, regulatory, and commercialization capacity in ReGen Valley, thereby increasing the success rate for clinical trials with cell-based products and decreasing time-to-market for novel therapies; 3) increase clinical trial safety and therapy efficacy by correlating analytics with clinical outcomes (*Scaling Commercialization Capacity*); 4) increase good jobs in ReGen Valley and equitable participation at every level of the workforce; 5) increase private and philanthropic investment in biofabrication technologies; 6) increase regional GDP by 5% by 2032; 7) advance health equity; 8) drive down U.S. healthcare spend while improving outcomes; 9) secure U.S. leadership of the biofabrication industry.

Timeline. Demand for commercialization capacity in ReGen Valley is pressing, and with foundational assets already in place, the Consortium is poised to execute with speed. In Year 1 of award, the Consortium will expand commercialization capacity, establish and raise a seed fund, raise philanthropic funding, expand the capabilities of the BioFab Startup Lab to include grants, establish a *Common Campus*, launch programs to expand childcare capacity, increase diverse

entrepreneurship, and establish a Transportation Management Association. These Year 1 achievements will catalyze demand, investment, and revenue - the flywheel of industry growth. By Year 5, the Consortium will self-sustain with commercial revenue and philanthropic funding.

III. Maturing an Industry

Companies of every size and at every stage of the cell-based product development cycle have a critical need for specific capabilities, including: product and process analytics to determine the critical characteristics of an effective therapy; consistent, quality-controlled, scalable manufacturing to reduce costs and speed the advancement through U.S. Food and Drug Administration (FDA) regulatory milestones and clinical trials; a capable, skilled workforce; access to regulatory, business, intellectual property, legal, reimbursement, and commercialization expertise; supply chain resiliency sufficient to support manufacturing; and access to capital. These companies face a quandary: they must either attempt to build internal capabilities - at high risk and tens of millions in expense, or navigate a convoluted landscape of geographically-dispersed consultants and service providers, some of which are foreign-owned – similarly at high risk and tens of millions in expense. For individual startups, this barrier is often insurmountable, and promising technologies are either shelved within academia or lost to foreign acquisition, moving critical American intellectual property to foreign interests. Even for large corporations, building the necessary set of capabilities and expertise internally to commercialize cell-based products can be prohibitively expensive and time-consuming. Large companies that do proceed to clinical trials without analytical product and process data, or a scalable manufacturing plan in place, often see their technology struggle in early clinical trials and have little ability to characterize the underlying reason or find a bridge forward. Meanwhile, patients, and the U.S. economy, continue to endure the burden of chronic illness and missed opportunities.

ReGen Valley is the first and only place in the Nation to establish complete commercialization capabilities for biofabrication, the first and only to apply those capabilities in support of a true Quality by Design (QbD) approach (*Scaling Commercial Capacity*), and the first and only to prove its efficacy – assisting companies in achieving TRL advancement, novel regulatory breakthroughs, investment, and market entry. As above, the DoD investment that launched ARMI established defense-relevant proof-of-concept capabilities focused on TRL 4-7, and the 2022 BBBRC award

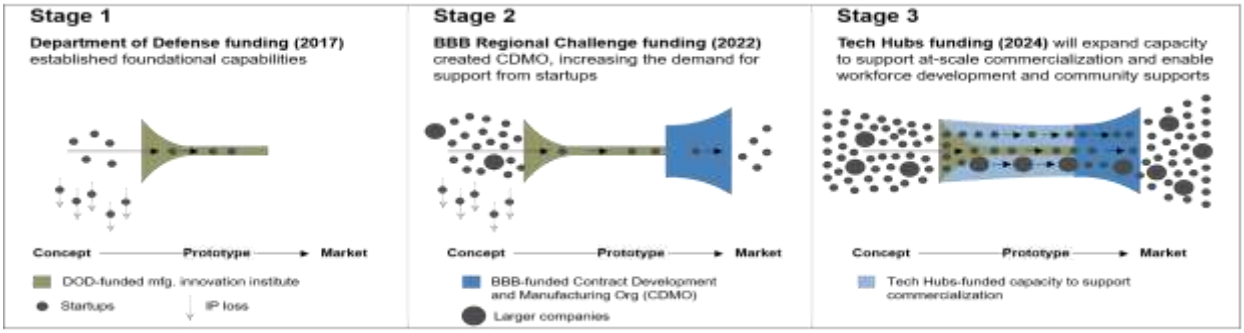

Figure 4: Demand and Capacity

to the City of Manchester funded pilot scale and commercial manufacturing capacity for TRL 8-9. **This marked the first and only complete set of capabilities in a single geographic location, a watershed moment for the industry, which unleashed unprecedented demand** *(Figure 4)*.

The majority of ARMI's nearly 200 industry members are technical entrepreneurs, and through ARMI's long-standing, member-driven Leadership Advisory Council, they have reaffirmed the same need: commercialization capacity (*see letters*). Companies large and small are waiting on ReGen Valley's doorstep in desperate need of demonstrated capabilities and wrap-

around expertise. Without the capacity to accommodate them, ARMI is forced to be selective – collaborating specifically on technologies that are appropriate for DoD funding and show commercialization promise. The DoD also desires a capacity solution, as this will speed the production of dual-use technologies, but the DoD funding mandate does not include commercialization capacity *(letter enclosed)*. The current capacity bottleneck threatens national security, with far too many breakthrough technologies falling into the hands of foreign adversaries and the U.S. at risk of losing the race to control responsible access and distribution. Further, with commercialization capacity solved, job creation will soar. As workforce demand could then become the next bottleneck, complementary component projects and commitments are designed to ensure workforce development keeps pace with industry - and that affordable housing, childcare, transportation are timed to meet the increase (*Common Campus, Childcare, Transportation*).

IV. Biofabrication Meets National Health, Security, and Economic Imperatives. One year after the CHIPS and Science Act, the Biden-Harris Administration celebrated progress in bringing semiconductor supply chains home to the U.S. – the result of billions in national security and workforce investments. In a related announcement, the Administration also announced the creation of a new White House Council on Supply Chain Resilience and new cross-governmental supply chain data-sharing capabilities, in part focused on addressing foreign dependency vulnerabilities and points of failure for critical therapeutics. The biofabrication industry represents the next wave of critical healthcare technology and is every bit as relevant to the security of the Nation - strengthening military readiness; restoring wounded Warfighters and Veterans; finally amending the trajectory of U.S. healthcare inequity and soaring costs; and with purposeful management, alleviating foreign supply chain dependence. Its value to Americans is unprecedented, and the U.S. must secure the opportunity to lead. Foreign adversaries are racing to claim market share and to build U.S. reliance on services and products manufactured abroad. **This time, America's breakthrough technologies – and the good manufacturing and supply chain jobs they create – must stay at home.**

The work of ReGen Valley Consortium member Safi Biotherapeutics, a cell therapy company focused on the development of bio-manufactured red blood cell products, is a key example of the direct national security relevance of these technologies. Commercialization of blood products like Safi's will address and transform critical, persistent gaps in the transfusion supply chain to life-saving effect. A major challenge in the development of such products is scale; there are approximately 2 trillion red blood cells in a single unit of blood, and roughly 36,000 units are needed in the U.S. each day. Manufacturing this immense volume by hand is infeasible and cost-prohibitive; the manufacturing process must be automated to achieve commercial scale, and ReGen Valley needs the commercialization capacity to propel the technologies developed by companies like Safi to market – and to patients. Further, with commercialization capacity created by Tech Hubs, Safi and dozens of others companies would anchor operations in ReGen Valley and manufacture here, taking advantage of the BBBRC-funded pilot-scale manufacturing facility coming online in 2025 and creating good jobs. This pipeline of companies ready to use ReGen Valley's pilot-scale cGMP facility (*see letters*) as it comes online will generate commercial revenue and accelerate financial sustainment.

V. Role of the Private Sector. At the technical foundation of ReGen Valley is inventor and entrepreneur Dean Kamen, Chair of ARMI's Board of Directors, who has been investing in the region for decades. Additionally, industry leaders like Rockwell Automation, United Therapeutics Lung Bio, 3D Systems, and Advanced Solutions Life Sciences (ASLS) have put down roots in ReGen Valley on the evidence-based premise that this is the epicenter of the new American

industry of biofabrication. Before launching ARMI with the competitive investment from the DoD, Dean created DEKA Research & Development Corp - a mission-driven company with nearly 1,000 engineers, and FIRST- a U.S.-based global STEM education nonprofit bringing hands-on robotics experience to millions of underrepresented youth each year. DEKA has contributed more than $30M in cost-share (engineering services and personnel) to ARMI to kick-start the formation of ReGen Valley, and is committing another $30M to the Consortium. DEKA continues to develop category-defining medical and defense-relevant products that have saved the lives of countless Americans, including Servicemembers and Veterans. On this foundation, new ventures in the Millyard have raised more than $500M in recent months and are fueling job growth – demonstrating the ability of this environment to draw capital and sustain beyond government funding once technologies are de-risked to the point of venture investment.

In 2017, Rockwell Automation opened a Customer Demonstration Center on ARMI's campus and provided $10M in manufacturing software, training, consulting, and equipment to build automation infrastructure and train the next generation biofabrication workforce. The company is a key partner in BBBRC-funded workforce training efforts and has permanent personnel working alongside Consortium member innovators and training institutions. Rockwell is committing another $10M to ARMI and the efforts of the Consortium and will contribute an additional $300K as cost-match for the *Common Campus* – contributing to the design of workforce training for automated manufacturing. Rockwell will also invest alongside ReGen Valley's seed/growth fund.

Innovation luminary Martine Rothblatt, CEO of Consortium member United Therapeutics (UT), is surging the company's presence from a single lab to an 88,000 ft^2 building steps from ARMI's campus, dedicated to the manufacture of UT's 3D-printed lungs. UT plans to double its workforce in ReGen Valley in the next 2 years, as does Merrimack manufacturing (*see letters*), creating good jobs for skilled workers coming through apprenticeships and other *Common Campus* training programs. Consortium member ASLS, which provides cutting edge robotics solutions to cell-based therapy developers, operates from labs and offices on ARMI's campus – adjacent to Rockwell Automation, the BBBRC-funded BioFab Startup Lab, and other innovators preparing to manufacture with ARMI. ProKidney is working with ARMI to advance the company's renal therapy, shown in late-stage clinical trials to delay the need for dialysis by up to three years. With the commercialization and workforce capacity that Tech Hubs implementation funding will create, ProKidney intends to build out full-scale automated manufacturing in ReGen Valley, creating thousands of jobs and hiring local talent as demand for their product grows post FDA-approval. Microsoft Health intends to partner with ARMI to speed development and commercialization of the technologies manufactured in ReGen Valley. New collaborators like ATCC, a major biomaterials and life sciences services provider, are exploring expansion into ReGen Valley, desiring to engage a growing customer base and understand how ARMI's technical approach may lower production costs while exceeding quality standards. Cell-based therapy and enabling technology companies from other NATO countries are also approaching the Consortium by the dozens, looking to found U.S. branches in ReGen Valley.

The desire and commitment of these major industry players to invest in ReGen Valley, along with a dense concentration of novel startups, comes down to a single truth: **ReGen Valley's technical vision has realized a proven, multi-disciplinary, systems-integration model for biofabrication, de-risking novel cell-based technologies and speeding commercialization.** Just this year, ARMI has facilitated multiple industry breakthroughs: CMFlex™ became the first-ever 3D-printed regenerative bone graft product cleared by the FDA and achieved investment and market entry; Aruna Bio achieved Investigational New Drug (IND) for a novel biotherapeutic

designed to treat acute ischemic stroke and ameliorate a $56.5B annual strain on the U.S. economy; Theradaptive achieved Investigational Device Exemption (IDE) for a novel biotherapeutic for spinal conditions that affect 40% of adults over the age of 40; and Miromatrix achieved IND for a bioengineered liver organoid. Further, the many defense-relevant companies who have engaged in product development and automation with ARMI have advanced their TRLs and are better positioned to attract private investment and achieve commercialization; several are joining the BioFab Startup Lab. Companies across the country – and world – are taking notice of ReGen Valley's track record and driving up demand for ARMI's capabilities. *Capacity is what stands between ReGen Valley and global leadership.*

VI. Federal, State and Local Investment in Biofabrication

Along with the private sector, Federal, State and local entities are paying attention to ReGen Valley's exemplary record. Highlights from this quarter include: the FDA requested a proposal to place a Tissue Foundry on-site in its facilities; the U.S. Department of Labor approved a novel Biofabrication Technician Registered Apprenticeship Program that was subsequently elevated in two separate White House Fact Sheets and is engaged in the launch of an Advanced Manufacturing program; and the Advanced Research Projects Agency for Health (ARPA-H) approached ARMI to conduct independent validation and verification of cell-based technologies relevant to its program focused on implantable therapeutics. The DoD and the U.S. Department of Veterans Affairs (VA) are also permanent members of ARMI's Leadership Advisory Council and have made new commitments to the Consortium. The Consortium appreciates this whole-of-government engagement. However, prior investments carry only the resources to complete corresponding scopes of work; this does not solve ReGen Valley's urgent capacity challenges.

At the State level, multiple agencies have made new commitments to ReGen Valley's future (*see letters*). The NH Business Finance Authority recently implemented a student loan forgiveness program specific to the biofabrication workforce, and the NH CDFA will implement a $10M childcare program, augmenting ReGen Valley's *Childcare* project. The Cities of Manchester and Nashua are driving important infrastructure efforts, including housing development, zoning policy changes, and transportation (*see letters*) that will enable workers to access good jobs.

VII. Sustainment. The design of ReGen Valley's capital stack is purposeful and is meant to generate a flywheel of investment, commercialization, job creation, and inclusive, intergenerational economic growth. The establishment of a low-barrier fund, complemented by philanthropic funding, grants, and micro-loans - as well as separate venture funding focused on biofabrication - will provide the phase-appropriate capital necessary to drive commercialization.

VIII. Union Engagement. The NH AFL-CIO is a decisional member of the Consortium Governance Committee and is committed to advising ReGen Valley on the incorporation of strong labor standards, as well as coordinating resources and support with the national AFL-CIO. ARMI is constructing BBBRC-funded facilities with the benefit of a Project Labor Agreement (PLA) informed by consultation and collaboration with NH Building and Construction Trades Council, and the NH AFL-CIO is already assisting ReGen Valley in ensuring its Registered Apprenticeship Programs, including the recently launched Biofabrication Technician program and the forthcoming Advanced Manufacturing Technician program, meet Good Jobs Principles.

IX. Inclusive, Intergenerational Impact. To ensure that the benefits of the Tech Hub are equitably shared, the ReGen Valley Consortium is holding itself accountable for ensuring equity and inclusion are measured and advanced in every activity. Equity and inclusion are core responsibilities of the entire team and are thus embedded in the Consortium's SMART Goals. The

Consortium will work cross-functionally, and with the Community Access Coalition, to ensure policies, practices, structure, and operations are measurably advancing these aims.

X. ReGen Valley SMART Goals

SMART Goals	Stretch Goals
Triple the number of technologies at/beyond TRL 6 by Year 5	Quadruple the number of technologies at/beyond TRL 6 by Year 5
Triple the number of technologies progressing through regulatory milestones by Year 5	Quadruple the number of technologies progressing through regulatory milestones by Year 5
Double private and philanthropic investment by Year 3	Triple private and philanthropic investment by Year 3
Exceed BBBRC projected direct job creation in ReGen Valley by Year 3	Exceed BBBRC projected direct job creation (6,913) in ReGen Valley by Year 2
Exceed BBBRC projected direct job creation in ReGen Valley by Year 5	Exceed BBBRC projected direct job creation in ReGen Valley by Year 4
Increase diversity by 50% at all job levels, including C-suite, by Year 5	Increase diversity by 75% at all job levels, including C-suite, by Year 5
Increase regional GDP by 5% by Year 10	Increase regional GDP by 6% by Year 10
Decrease product time-to-market by 20% by Year 5	Decrease product time-to-market by 30% by Year 5

Figure 5: SMART Goals.

XI. The Home of Biofabrication

The Consortium is aligned with the Cities of Manchester and Nashua and the State of NH in ensuring housing capacity will accommodate biofabrication workforce demand, as well as ensuring growth is achieved without displacement. Housing is a foremost priority of the City of Manchester, which is making zoning policy changes to accommodate growth, and the State recently approved a bipartisan budget that dedicated and additional $50M to housing development. Permits issued for residential construction have doubled, and New Hampshire is now on track to bring thousands of new units online this year – many of these in ReGen Valley. New Hampshire Housing has financed the creation of more than 16,000 multifamily housing units and helped more than 55,000 families purchase their own homes, and its leaders are committed to implementing grant programs and convening stakeholder summits on workforce housing, co-hosted with the Consortium, chambers of commerce, municipalities, and broader industry (*see letters*).

XII. Progress Since Designation

Underpinning the multinational corporations and novel startups betting on ReGen Valley is a committed network of interdisciplinary civic and community leaders who have been striving – some for decades – to rebuild community vitality, resiliency, and infrastructure after the prolonged economic blight caused by the loss of the local textile mills. When the COVID-19 pandemic further impacted local small businesses, affordable housing, and childcare in the region, these resilient, capable leaders redoubled their efforts and positioned the area to grow anew; their efforts were especially vital for low-income residents. Now united with major industry players in the Consortium around a common mission, there is a palpable surge of confidence and pride. Consortium meetings began shortly after Designation, with the development of the Consortium Charter and election of its rotating Governance Board. As component projects were sourced directly from Consortium members, existing partnerships were strengthened and new ones were formed. For example, a representative of Dartmouth College suggested putting forth a Bioethics Institute for Biofabrication as a component project. Although it was deemed not a likely fit for Tech Hubs, St. Anselm's College offered expertise in this area and is now partnering with Dartmouth and UNH to pursue the project. The Consortium also welcomed the NH Manufacturing Extension Partnership (MEP), which is working with Consortium members to host manufacturing career fairs and conduct supply chain assessments in support of ReGen Valley, which are further informed by DoD, HHS, and VA. Robust federal engagement demonstrates the critical importance of US leadership in biofabrication and the urgent imperative for Tech Hubs funding to catalyze commercialization and protect national security.