Summer 2019

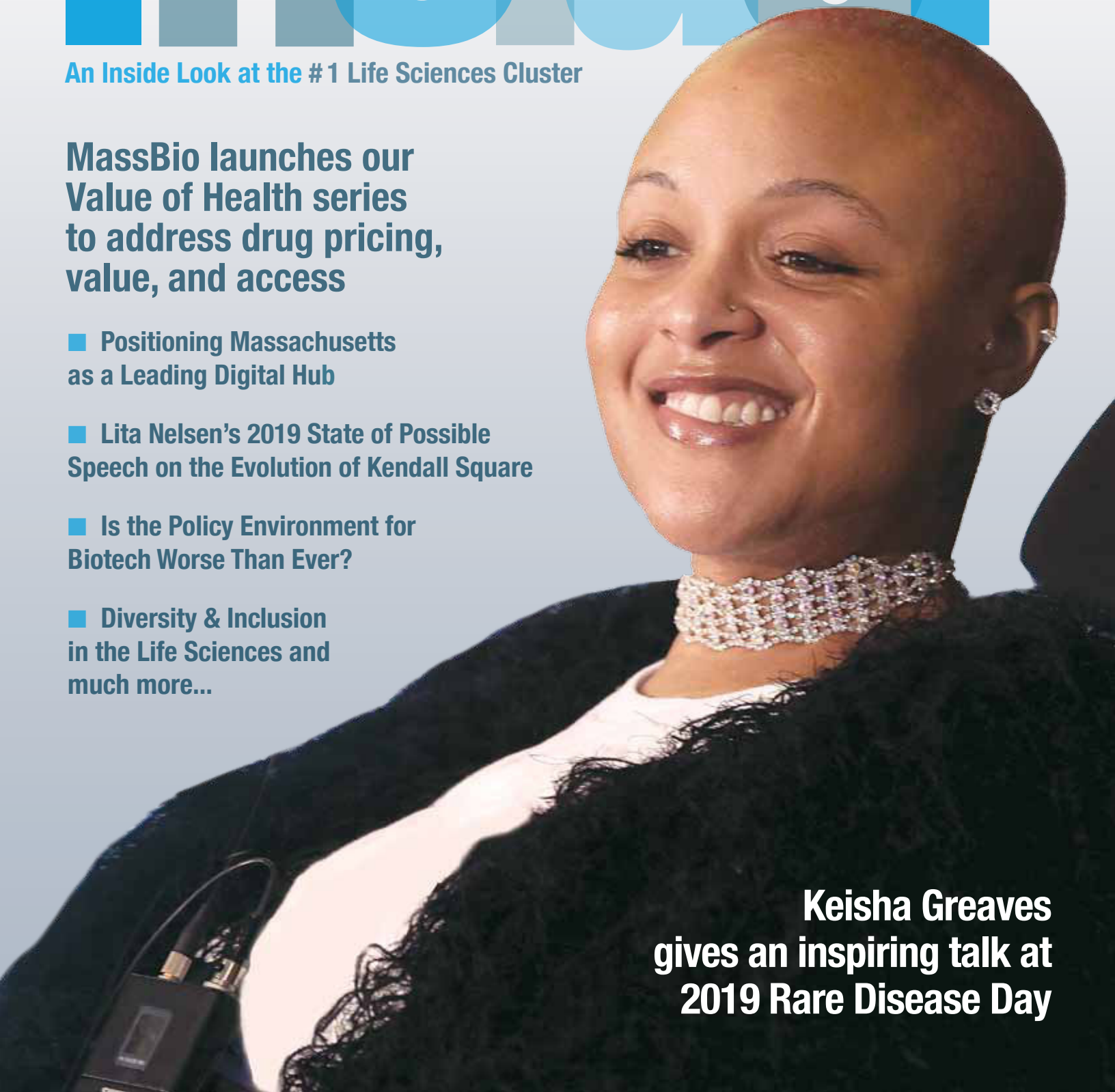
MassBio®

Insider

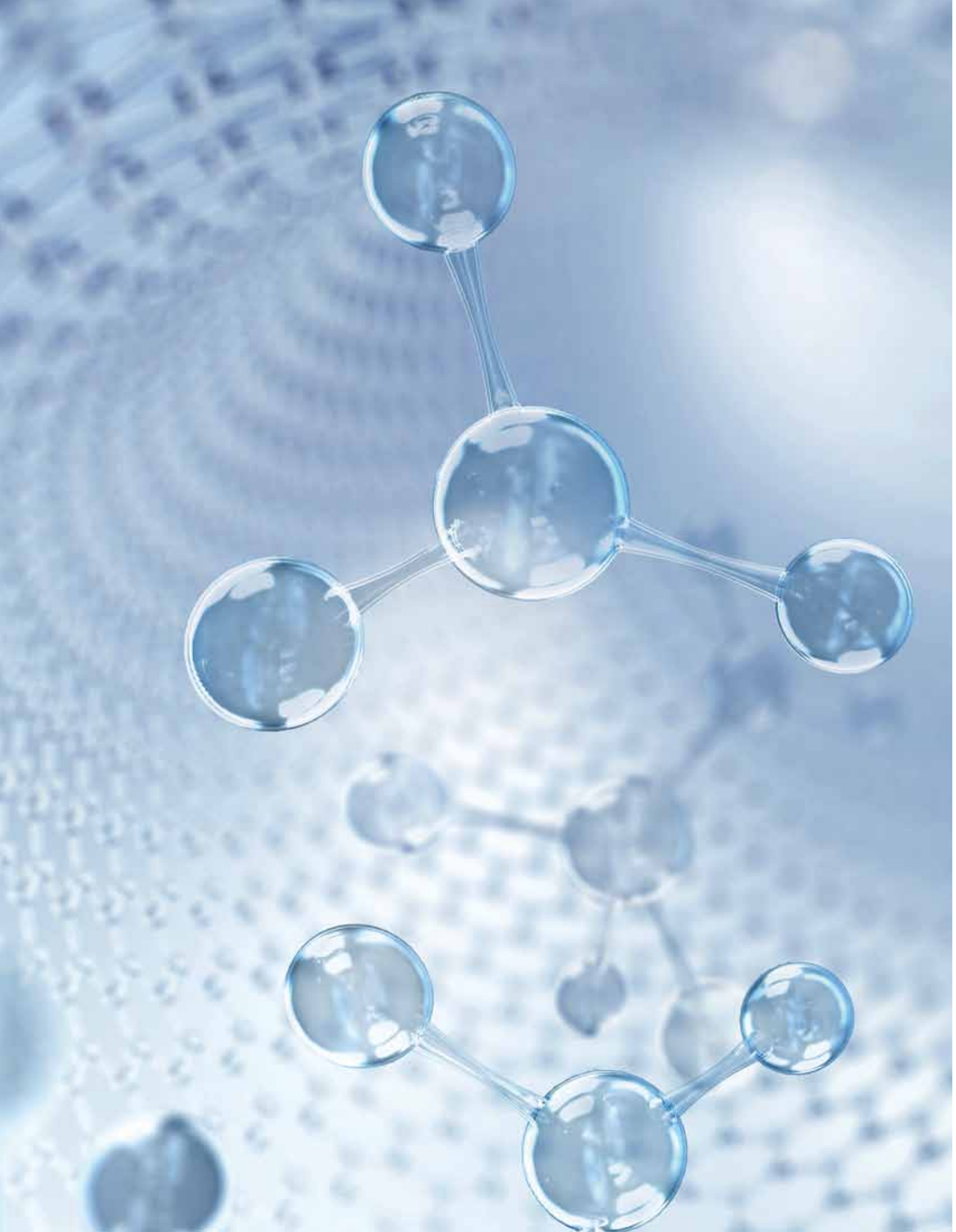
An Inside Look at the #1 Life Sciences Cluster

MassBio launches our Value of Health series to address drug pricing, value, and access

- Positioning Massachusetts as a Leading Digital Hub
- Lita Nelsen's 2019 State of Possible Speech on the Evolution of Kendall Square
- Is the Policy Environment for Biotech Worse Than Ever?
- Diversity & Inclusion in the Life Sciences and much more...



Keisha Greaves gives an inspiring talk at 2019 Rare Disease Day



MassBio

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An Inside Look at the #1 Life Sciences Cluster

Summer 2019

2019 Has Been a Transformative Year for MassBio.

MassBio's member services and offerings have expanded across the board, starting with the rebrand of our Purchasing Consortium and Employee Rewards—now MassBio *Edge*. This new platform offers our members and their employees increased value and ease of use. And I'm thrilled to announce that MassBio *Edge* will soon provide employee benefits to our member companies, allowing them to save money and reduce administrative burden.

Earlier this year, our Annual Meeting became the brand-new State of Possible Conference—a bigger, better event that truly reflects the greatness of our cluster. We also launched two new initiatives, one around strengthening the digital health ecosystem and another that addresses the drug pricing debate. Even our print newsletter is now a modern, more content-rich magazine.

As we look toward the remainder of 2019 and into the coming years, MassBio will continue to evolve in lockstep with our members' changing needs. We'll expand strategically into areas that offer our members, and the life sciences ecosystem as a whole, a better environment to operate and ultimately to create new tomorrows for sick people around the world.

words of welcome

Robert K. Coughlin, President & CEO, MassBio

MassBio

Upcoming events

Digital Health Impact 2019
September 9, 2019

Patient Advocacy Summit
November 6, 2019

MassBio Golf Classic to Benefit MassBioEd
September 13, 2019

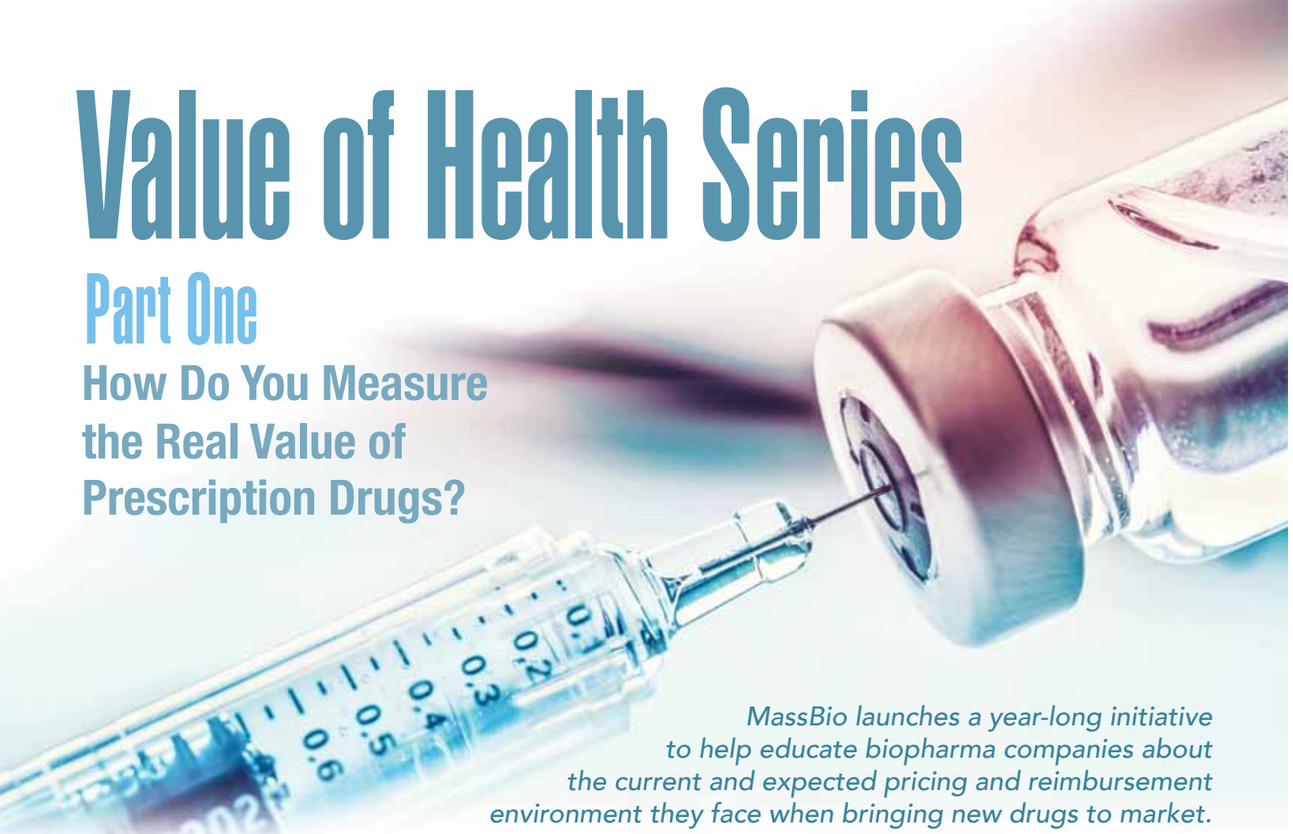
Holiday Party
December 5, 2019

Visit MassBio.org/events for details

Value of Health Series

Part One

How Do You Measure the Real Value of Prescription Drugs?



MassBio launches a year-long initiative to help educate biopharma companies about the current and expected pricing and reimbursement environment they face when bringing new drugs to market.

By Robert K. Coughlin, President & CEO, MassBio

We've all seen the headlines over the last few months, as the drug pricing debate becomes more inflamed and top of mind for both politicians and the public. Instead of celebrating the incredible advances in science, with biopharma companies coming out with cures for the first time, promising new hope and a healthier life for patients with debilitating and sometimes fatal diseases, we're questioning whether they are "too expensive" and if the healthcare system can afford them.

At its core, the argument is about how we establish the true value of these medicines. This is a serious and legitimate question that must be addressed. The answer will ultimately determine who, if anyone, has access to present and future "high priced" treatments.

As the head of the Massachusetts Biotechnology Council the value of prescription drugs is clear—they save lives, keep people healthy, make them productive members of society, and save costs across the healthcare system. As a dad with a son with a rare disease, it's even clearer: a new drug could mean he will live a long and healthy life.

My son Bobby has cystic fibrosis (CF)—a fatal, incurable genetic disease affecting about 30,000 Americans. As my wife and I learned about the disease and the seeming impossibility of a healthy life for him, we also discovered how many other children have diseases with few to no treatment options. In fact, 95% of rare diseases do not have one single FDA-approved treatment, and for those that do, many are just reducing the symptoms instead of treating the underlying cause of the disease.

My son is now 17 and for the first time I think he will outlive me, thanks to new treatments that are in the pipeline for his specific genetic mutation, and for that we are incredibly lucky. But even before these treatments are available, some are already claiming they will be "too expensive" and not offer enough value. This is where the existing debate about value falls apart. It ignores that therapies are first meant to make sick people healthy, in addition to reducing other healthcare costs. My son will no longer have an expiration date. As a parent, you can't put a number on that.

To better understand why new therapies like these offer immense value to our healthcare system, let's examine two factors: what someone like my son currently costs the healthcare system; and the incalculable difference they make to patients' and their families' lives.

Currently, my son takes dozens of pills a day along with multiple nebulizer therapies to counteract the lung-clogging buildup caused by his condition. He receives regular X-rays and chest physical therapy. Healthcare professionals come to the house to administer much of this. Yet, despite all of this, he still frequently ends up in the hospital. I haven't added up exactly what my insurer and my family pay annually, but a 2013 study found that the mean cost of hospital visits for someone with severe symptoms of CF, like my son, is as much as $94,664 per year—not even including all the other treatments listed above. My son has also been hospitalized several times this year, most recently for an episode of acute symptoms called pulmonary exacerbations. Treating patients with this issue can cost up to $119,862 annually in hospital costs alone.

Yet, this continual treatment cycle is not the end of the line for Bobby and many others like him. Cystic fibrosis worsens over time, and at some point in the future he will need a liver transplant. This is a huge expense—$812,500, on average—compounded by trying to find a donor liver and undergoing a major surgery and recovery. Lung transplants have been shown to extend and improve quality of life for CF patients, but they also come with a price tag of $500,000 – $800,000.

A therapy that treats the underlying cause of CF will avoid costs across the system for Bobby and others with CF. But we cannot be fooled into thinking that the value of prescription drugs is a 1:1 accounting equation. The new CF therapies also mean CF patients will be able to live a more normal life, free from the daily nurse visits, free from the fear of yet another hospitalization, and quite possibly avoiding a failed organ.

> **"Instead of restricting patient access to new treatments or saying innovation is too expensive, we need all pieces of the healthcare system to come together and agree about how to assess the value of prescription drugs."**

Eventually the drug will go generic, resulting in a dramatic price drop that will bring down the overall cost of his care. I'm even more hopeful that someday soon, there will be a cure for CF—and it'll be a one-and-done treatment.

The problem we face now is that determining a drug's value is not simply an academic exercise. Insurers are increasingly basing whether to cover a new drug based on its "value." If a drug is ultimately determined to deliver too little "value" insurers won't cover them or will create additional barriers for access. We also have an insurance system that is accustomed to paying for chronic therapies over time, and only considering the 12-month snapshot of a patient. While many of these payers are not arguing with the value or effectiveness of a one-time cure, they are still grappling with how to cover its costs.

Instead of restricting patient access to new treatments or saying, in effect, innovation is too expensive, we need all pieces of the healthcare system to come together and agree about how to assess the value of prescription

drugs. We need to break free from a one-size-fits-all approach to paying for therapies, meaning insurers and drug manufacturers must test new ways of covering drugs, whether that's reimbursing for drugs that do not work as expected, or coming up with some other cost-sharing model among insurers. If we do not address the value equation as an industry, government or other stakeholders will—and they will likely get it wrong because it's too complicated.

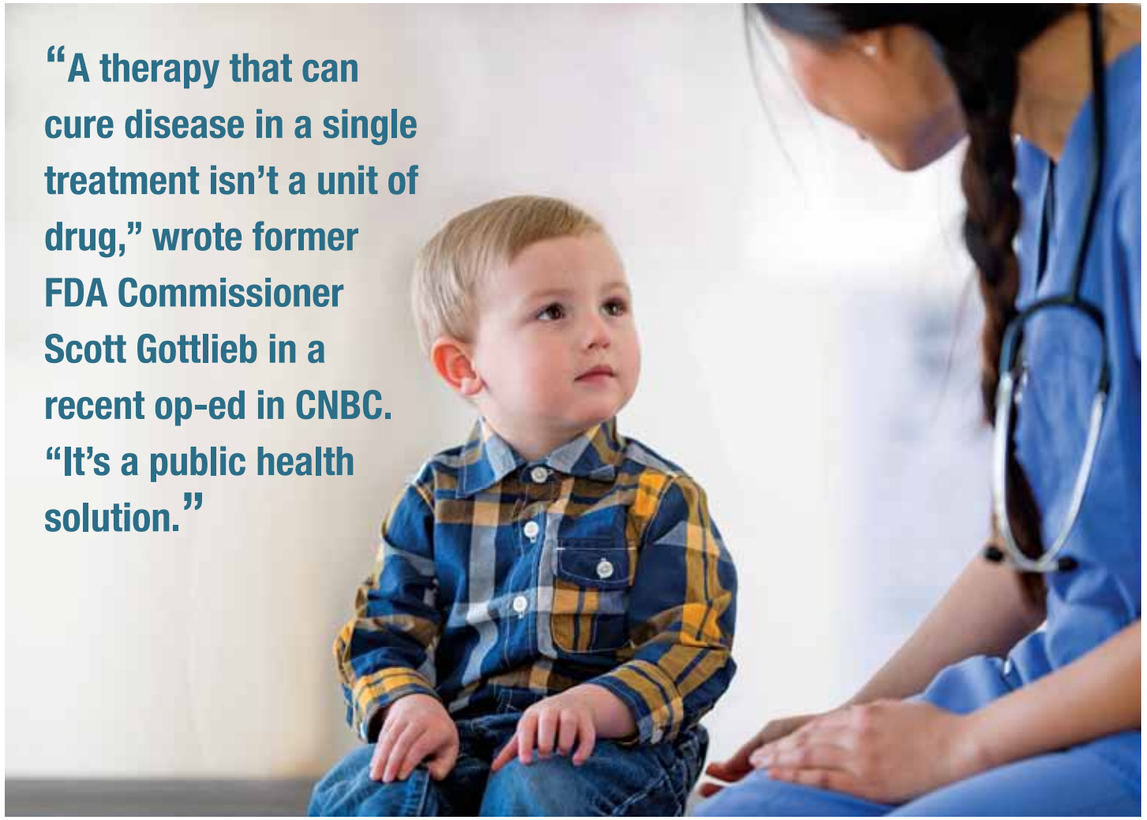
This is the impetus behind MassBio's Value of Health series, a major, new initiative to explore the future of the biotech industry through the prism of drug pricing. Guided by experts, we will produce a series of three whitepapers and related events in 2019 that together seek to answer the question: is the current biotech pricing model sustainable, and if not, what needs to change?

The series is a way for us to educate our members about the changing paradigm as it relates to value and access, and to get early and mid-stage biopharma companies thinking about value earlier and in a more actionable way. It is MassBio's belief that the sooner companies start thinking about value and how they will demonstrate it, the fewer hurdles to patient access will exist.

"A therapy that can cure disease in a single treatment isn't a unit of drug," wrote former FDA Commissioner Scott Gottlieb in a recent op-ed in CNBC. "It's a public health solution."

It's now up to us to prove that value. ■

Learn more about the Value of Health series and download the first whitepaper at MassBio.us/value-of-health



Positioning Massachusetts as a Leading Digital Hub

A stronger, more embedded digital health cluster will enable further convergence with the life sciences

By Kendalle Burlin O'Connell, Chief Operating Officer, MassBio

Digital technologies have infiltrated nearly every aspect of consumer life, from FitBit to Alexa, and are collecting data on our buying habits, fitness activity, and more. Now, we're seeing real potential for digital technologies to transform the life sciences and create new efficiencies within drug discovery and development, but we're still trying to figure out exactly what this looks like and how to accomplish it. That's why MassBio decided to tackle the issue last year, resulting in a digital health report, released in late February of 2019, "Making Massachusetts a Leading Global Destination for Digital Health."

The study's findings are clear: Massachusetts already has the core components of a leading digital health cluster—talent, capital, and data—along with a leadership commitment from government and other prominent stakeholders. However, there are missing pieces and structural problems that prevent it from being fully formed. For Massachusetts to become the leading hub for digital health nationally and for the life sciences industry here to benefit from it, it must focus on:

Talent & Academia

Massachusetts must foster a talent pool that understands both digital technologies and healthcare or life sciences, and must incentivize them to stay in the state.

Data Access

The current infrastructure platforms hosting the enormous amounts of valuable health-related data is archaic and difficult to access. Various platforms must be modernized and integrated, made possible by industry collaborations.

Leadership in the Life Sciences & Dense Customer Network

The prevailing culture in life sciences companies, payers and providers is to build digital solutions in-house, along with siloing and protecting digital health resources, which hampers cross-sector innovation.

Entrepreneurship & Anchor Firms

Massachusetts has a strong entrepreneurial ecosystem but must attract more digital health anchor firms to ensure digital health startups have the necessary partnerships and resources to flourish.

Firm Ecosystem & Digital Health Community

The ecosystem must actively support mentorship, robust incubators, and a thriving community for digital health startups and their counterparts to share knowledge and continuously interact and innovate.

Government

The private sector must support the Digital Health

Panelists at the 2019 State of Possible Conference discuss Massachusetts role in Digital Health

Council initiatives and ensure digital health remains a priority of state government.

We know we have the ingredients to make Massachusetts the leading hub for digital health, and as long as all of the pieces of our ecosystem can continue to work together, the full potential of digital health to the Massachusetts' life sciences industry will be realized.

So why is this so important? The convergence between digital health and the life sciences has already created opportunities to transform patient care as well as drug discovery and development. From wearables to machine learning, digital technologies are easing data collection from patients, increasing medical adherence, reshaping clinical trials, making drug discovery more efficient, and offering new insights into real-world applications of therapies. Combined digital health and life sciences efforts will also allow for development of new therapies that will better work within the growing value-based healthcare system that relies on data and measurable outcomes. This is especially important for new drugs. As more breakthrough, next-generation therapies are approved over the coming years, having measurable data on effectiveness is going to be critical to proving the therapy's value, and thus, ensuring patient access and payer coverage.

Many others including the Digital Health Council and the Massachusetts eHealth Institute (MEHI) are already doing well at tackling digital health broadly—and we don't want to duplicate those efforts. We want to support the ways in which digital technologies can converge with and strengthen our industry. In addition to supporting the state's efforts, MassBio will create a multi-year strategy to enable convergence between the life sciences and digital health to happen quickly and most effectively. This initiative will have three main pillars:

MassBio.DH

MassBio will coordinate the digital health cluster in Massachusetts so it's best positioned to support life sciences companies. This will include programs such as MassCONNECT.DH to support early-stage digital health companies through mentorship, similar to what we already do with MassCONNECT and early-stage biotech and med device companies; collaborating with and learning from the Israel digital health cluster; and convening a corporate investor working group.

Advocate for legislative action to support the Massachusetts digital health cluster

This will include activities such as advocating for new state funds to support the digital health cluster; mobilizing MassHealth to become a leading adopter of pilot digital health initiatives; and promoting digital health job creation incentives.

Differentiate Massachusetts through data liquidity and regulatory leadership

Our goal here is to build alignment and interoperability among current and future stakeholders, including enabling better access to customers and innovation; creating a distributed healthcare data framework; and supporting regulatory changes around data privacy, cyber security, and interoperability.

It will undoubtedly take the dedicated efforts of MassBio, its members, the public sector and Administration, educational institutions, and related and supporting industries to achieve this aggressive goal. It won't happen overnight, but I'm confident that with the right pieces and players, we'll become the number-one life sciences and digital health cluster in the world. ■

Leila Pirhaji, Founder & CEO of ReviveMed, talks about about leveraging artificial intelligence for drug discovery at the 2019 State of Possible Conference

the Magic Sauce of Kendall Square

Lita Nelsen, Retired Director of the MIT Technology Licensing Office

At MassBio's State of Possible Conference in March, we honored Lita Nelsen, Retired Director of the MIT Technology Licensing Office, with the Henri A. Termeer Innovative Leadership Award. This annual award was created to honor individuals who have contributed significantly to the growth and success of the life sciences industry in Massachusetts, and Lita's leadership at MIT exceeded our criteria in every way. Below is the speech Lita gave at the conference—one that perfectly encapsulates the growth, evolution, and "magic sauce" of Kendall Square.

During my 30-year tenure in the MIT Technology Licensing Office, I was visited by literally hundreds of people from throughout the US and from dozens of countries around the world. They came from governments, universities, and regional development organizations. Mostly they were interested to know not only how to do technology licensing, but how to bring about the extraordinary economic development that became Kendall Square as we know it now. They wanted to know, "What was the magic ingredient in the magic sauce?"

For a few of you old enough to remember Kendall Square in 1960, you know that it was the dying remnant of East Cambridge when it was a major industrial center of the US. The industrial part was occupied by decaying buildings, old warehouses, and a few small factories that made rubber products, metal fasteners, foodstuffs, and the like. The only place to get a meal was the F&T diner, which was no place to have a business meeting or take a date.

Change began with a new focus on entrepreneurship based on science. The end of World War II and the Vannever Bush Report led to massive increases in federal funding of basic research. Research laboratories in universities like MIT and Harvard grew quickly and kept growing—adding new useful knowledge to the world and turning out graduates educated in the leading edge of science and technology. And with a massive increase in funding from the NIH, hospital research laboratories grew apace.

By the late 1950s, a small number of research faculty members teamed with entrepreneurial business people to form new companies around university science—mostly in electronics. Thus grew the Route 128 "Massachusetts miracle", funded largely by government contracts and the beginning of technology-based, early-stage venture capital funds.

Lita shares her insights at the 2019 State of Possible Conference

American Research and Development Corporation, formed in 1946 by George Doriot of Harvard and Carl Compton, president of MIT at the time, was perhaps the first of these VC funds. In 1957, they invested $75,000 in an idea from a guy named Ken Olsen who worked in MIT's Research Laboratory of Electronics; Digital Equipment was born—and the computer revolution in Massachusetts began. But Kendall Square was still sleeping.

> **"Research laboratories in universities like MIT and Harvard grew quickly and kept growing—adding new useful knowledge to the world and turning out graduates educated in the leading edge of science and technology."**

Then came biology: the discovery of the double helix in the early 1950s followed almost 20 years later by Cohen and Boyer's gene splicing technology meant that practical use of biology for product development became possible, and the genetic engineering and biotechnology revolutions began. Cambridge was among the first cities to benefit, with Genzyme, Biogen, Repligen, and a few others, visibly led the way.

A very important, and perhaps surprising, event helped make Cambridge pre-eminent in the state as *the* place for new biotechnology companies. In the mid-1970s, there was a widespread global fear of "genetic engineering" per se. In Cambridge, people worried that "the bug that ate Cambridge" would emerge from MIT's laboratories.

To calm those fears, Mayor Vellucci assembled a team of leading scientists and others to draft regulations regarding the use of recombinant techniques in the city. The Cambridge Recombinant DNA Technology Ordinance was passed in 1977—fairly early in the game. The rules were straightforward and, if followed, permission for opening laboratories came rapidly.

As a result, at least in part, of this intelligent regulation, in the 1980s and '90s, the vast majority of biotechnology startups in the state were in Cambridge.

Kendall Square

Another important law for biotechnology, this time federal, was passed shortly thereafter: the Bayh-Dole Act of 1980, a remarkable piece of bipartisan legislation. The Act simplified the ownership and exploitation of patents arising from federal funding of research in universities, hospitals, and other non-profit research institutions (which I will now refer to in aggregate as "universities" since they comprise the majority). The Bayh-Dole allowed transfer of the title to such patents to the university itself, and allowed the universities to grant licenses to the patents and collect royalties—with a fraction of any royalties to be paid to inventors, thus providing some financial incentive to both the universities and the researchers to participate in the process. The regulations were quite simple and straightforward.

The express purpose of this Bayh-Dole Act was economic development. The federal government was spending over $100 billion a year (more now) in funding research in universities. But, with the federal government owning most of the patents arising from the research it sponsored, very few of the inventions from it were being taken up by industry. Transferring these patents to the universities meant that the patent administrators could work on the ground with the inventors (that is, the university tech transfer officers working hand-in-hand with the faculty) to translate their findings into companies.

Thus, the technology licensing profession grew—rapidly, after a few slow years in which the profession taught itself and a few universities had successes that others could follow. A 2015 survey by the Association of University Technology Managers showed results from 200 US research universities granting over 6,000 licenses in a single year and helping to start up over 1,000 new licensed companies in that year.

MIT is now starting up over 25 new companies a year, a good fraction of which are in biotech. Quite a large number of the companies represented here have origins from research and licenses from MIT, Harvard, and the other universities and research hospitals near us.

Success attracted more, and in turn built the infrastructure around it. When MIT licensed its first biotech startups in the late 1980s, the founding venture capital (VC) came, by necessity, from New York or California. The few early-stage VC firms in the region at the time did not invest in biotech. But early investment success soon led to new local venture firms, and established firms started to open offices in Massachusetts. By now, there are dozens of VC's looking to invest in promising biotech companies.

Real estate companies responded to the opportunities. The old warehouses became brick office buildings with the landlords willing to lease to small, high-risk companies with promise. And then the big pharmaceutical companies, almost totally absent from Massachusetts, began opening offices and laboratories to be close to the source of new products from the biotech community that could help fill their pipelines. This latter trend accelerated as many of the big companies radically pared down their internal R&D in the cause of short-term earnings.

The universities also responded, with incubators, mentoring services and other components of "entrepreneurial ecosystems". And independent

"The express purpose of the Bayh-Dole Act was economic development. The federal government was spending over $100 billion a year (more now) in funding research in universities. Thus, the technology licensing profession grew rapidly."

"And let us not forget the strength of networking. Cambridge and Boston biotech is one of the most dense clusters anywhere; there are hundreds of opportunities to get to know each other."

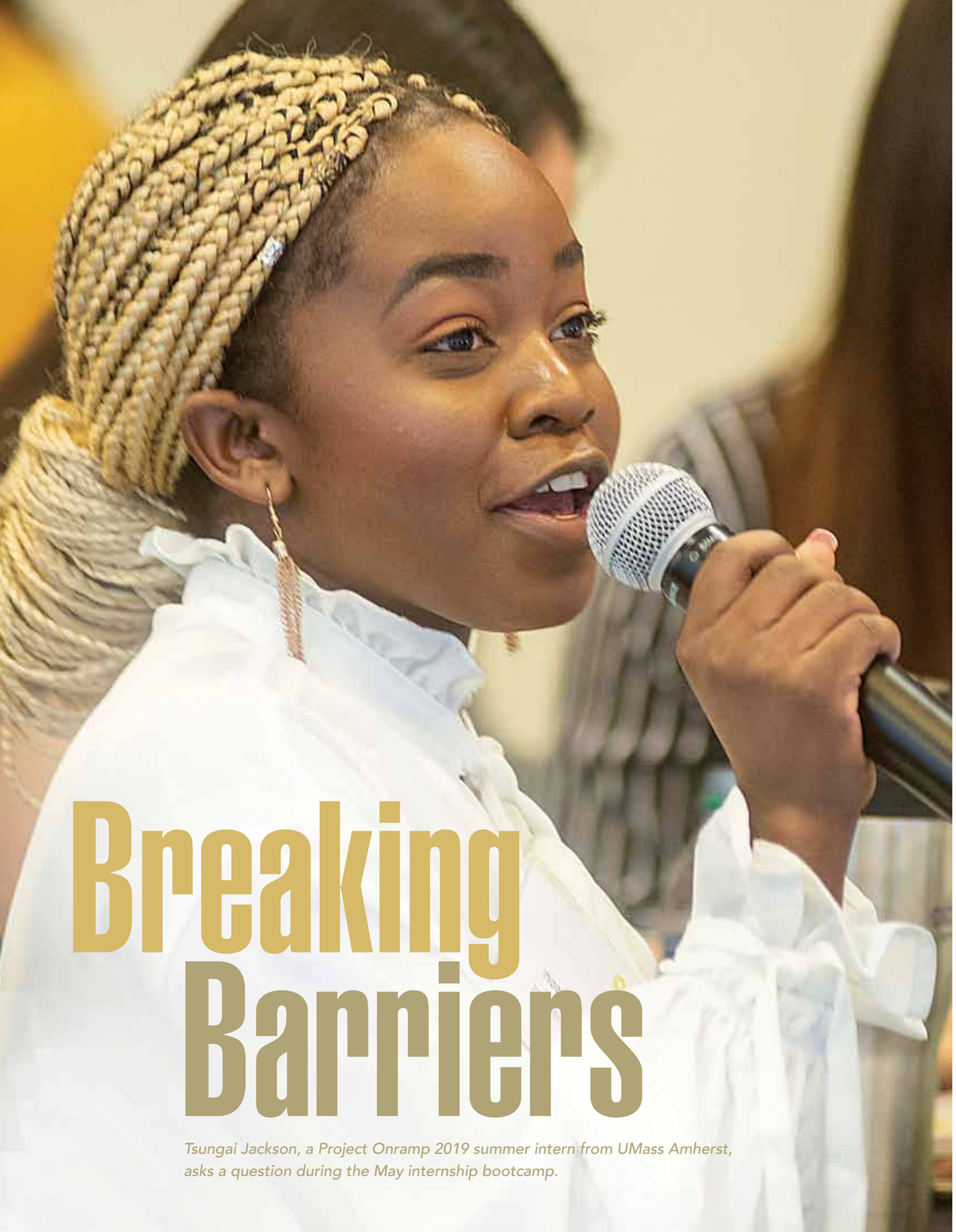
incubators and accelerators opened to house embryonic companies and help them grow.

And perhaps the most valuable component: people. Everywhere in the world that I've been invited to go where the local governments and universities want to accelerate biotech entrepreneurship in the cause of economic development, the scarcest resource is not money but talented managers: experienced entrepreneurs who can start new companies, manage science towards product development, and raise capital for it.

The density of biotech in Massachusetts means that we are raising our own scarce resource. Scientists and lower-level managers in the many companies of the region gain experience, insight, and personal connections that qualify them to become the next generation of CEOs. Essentially, clusters feed themselves.

And let us not forget the strength of networking. Cambridge and Boston biotech is one of the most dense clusters anywhere; there are hundreds of opportunities to get to know each other—and people understand that it's important to take the time to network. So everyone knows everyone. More seriously, ideas are exchanged, new ideas are catalyzed, and resources can readily be found if you have a strong proposal.

The "magic sauce" that built Kendall Square is a complex, interactive mixture that has been thoughtfully simmered and stirred by talented people over many decades. And is the envy of the world. I'm very grateful and proud to have been a small part of it. ■



Breaking Barriers

Tsungai Jackson, a Project Onramp 2019 summer intern from UMass Amherst, asks a question during the May internship bootcamp.

Welcoming Diversity & Inclusion Through Project Onramp

By David Lucchino, MassBio Board Chair, President & CEO of Frequency Therapeutics

When I started as the Chair of MassBio's Board of Directors in March 2018, the organization already had a strong and effective diversity and inclusive (D&I) initiative underway thanks to the leadership of our previous Chair, Abbie Celniker. Looking forward, I knew we had to build on this momentum and expand the initiative for the good of our industry and the people who work in it.

Our work around gender diversity provided a natural transition to allow MassBio to broaden its focus and understand the fact that not everyone has the same opportunities to gain access to work in our life sciences industry. Whether or not we, individually or collectively, are willing to admit it, it's clear this inequity is prevalent in our industry. For many who are considering a job in the life sciences, the deck can be stacked against them if they do not have the right connections or access to professional networks, the right college on their resume, or are of a diverse background.

To consider solutions to this inequity, I brought together our partners—MassBioEd, Massachusetts Life Sciences Center, and Life Science Cares—last year to determine where the biggest problems lay and how we could work together to solve them. Collectively, we agreed that our industry's internship programs were one of the clearest paths to create a more level playing field for all students, regardless of background, to gain an opportunity toward employment in the life sciences. Even more, internships can open eyes to the possibility of a career in the life sciences—something many students may assume is not for them for a variety of reasons, whether it's their background, major, or prior achievements.

This January, MassBio and our partners launched Project Onramp, a program focused on connecting high-performing, first-generation Massachusetts college students from underserved backgrounds to paid summer internships at leading life sciences companies. I am proud to say that we reached our initial goal of providing 50 paid internships for the summer of 2019. The enthusiastic response from leading life sciences companies in Massachusetts has been overwhelming. Moreover, many of the internships are not science-based roles but other critical positions in HR, communications, and accounting, for example. This was an important goal from the start: make clear that a job in the life sciences does not require a biology or chemistry degree.

Project Onramp is about breaking down barriers, generating equity where it did not exist, and building a more diverse workforce for the future of our life sciences industry in Massachusetts. I believe it has created a new model for extending opportunities in the thriving biotech industry for high-achieving students who don't have the personal or family connections that often play a big part in awarding internships.

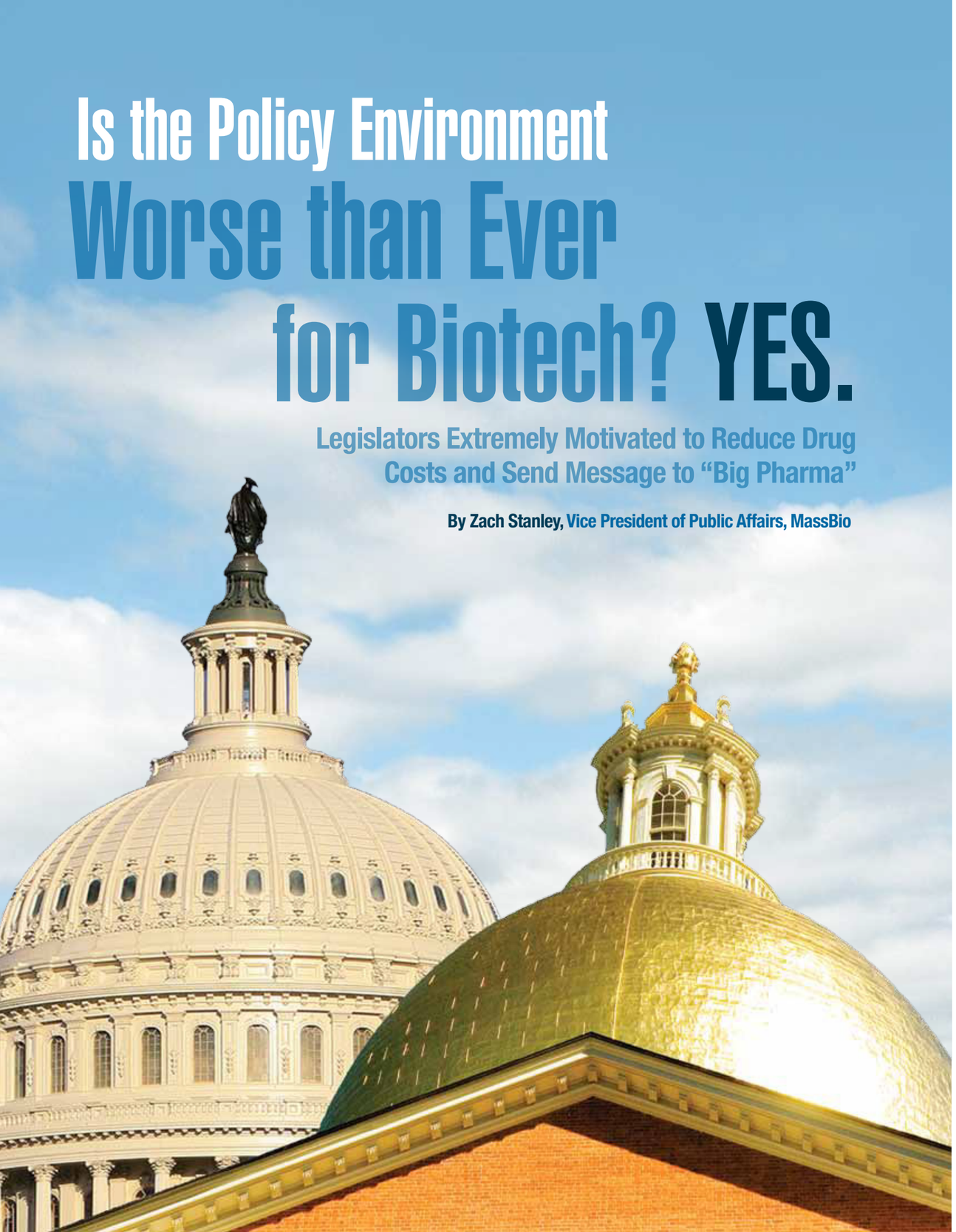
From a business standpoint, there are critical reasons we need to bring students of all different backgrounds into our companies. In fact, the immediate future of our industry depends on it. We expect there will be 12,000 new life sciences jobs to fill in Massachusetts by 2023 and we need to continuously work to identify the talent that will move our industry forward—regardless of where they live or whether they have a connection in the industry.

Moving forward, we are fully committed to making sure that highly motivated and accomplished students from underrepresented groups can find internship opportunities, and that we are able to get as many of our member companies as possible to participate in this program. If your company has a Project Onramp scholar this summer, thank you. If not, I challenge you to join in next year and see what Project Onramp students have to offer as interns, and potentially, as future employees. ■

Is the Policy Environment Worse than Ever for Biotech? YES.

Legislators Extremely Motivated to Reduce Drug Costs and Send Message to "Big Pharma"

By Zach Stanley, Vice President of Public Affairs, MassBio



A January 2019 poll showed voters' number-one healthcare priority for Congress this session is lowering prescription drug prices, with 94% of Democrats saying it is "Extremely Important" and 89% of Republicans saying the same. This mirrors previous polling that shows lowering prescription drug pricing is a top overall priority for voters. Judging by the number and scope of drug pricing legislation at the state and federal level this year, elected officials in both parties are not only listening but also acting.

Every year you've probably heard that legislation addressing drug pricing is more extreme and impactful than ever before. And every year, that has been accurate. This year is no exception. Yet, this year, significant legislation is actually being passed, and in more states than before. It also looks like Congress will pass various drug pricing related laws this session despite the usual partisan gridlock.

In Massachusetts, the issues are especially acute for the life sciences industry. Governor Baker proposed in his budget a policy that would allow the state's Medicaid program, MassHealth, to become a de facto price setter for drugs they deem too expensive. Through a series of negotiations, public hearings, and a threat of prosecution from the Attorney General, the Governor's proposal in effect forces manufacturers to agree to provide the state with supplemental rebates. Unfortunately, the proposal in various forms has passed through the House and the Senate and is now, as of this writing, subject to conference committee debate for what version will be included in the final state budget. MassBio and our members will continue to advocate for a final compromise solution that minimizes much of the policy's most harmful effects on innovation and drug development.

Yet, we know that more policy proposals are before us in Massachusetts and nationally. For years, MassBio has argued that if our industry doesn't work with other healthcare stakeholders to come up with common sense solutions, the government will do it for us – and they'll get it wrong. The leading proposals in states and Congress, from foreign reference pricing to compulsory licensing, to using value assessments for Medicaid supplemental rebate negotiations, are proof that government's impulses to control prescription drug costs are going to be ill-informed and ineffective.

"MassBio has argued that if our industry doesn't work with other healthcare stakeholders to come up with common sense solutions, the government will do it for us."

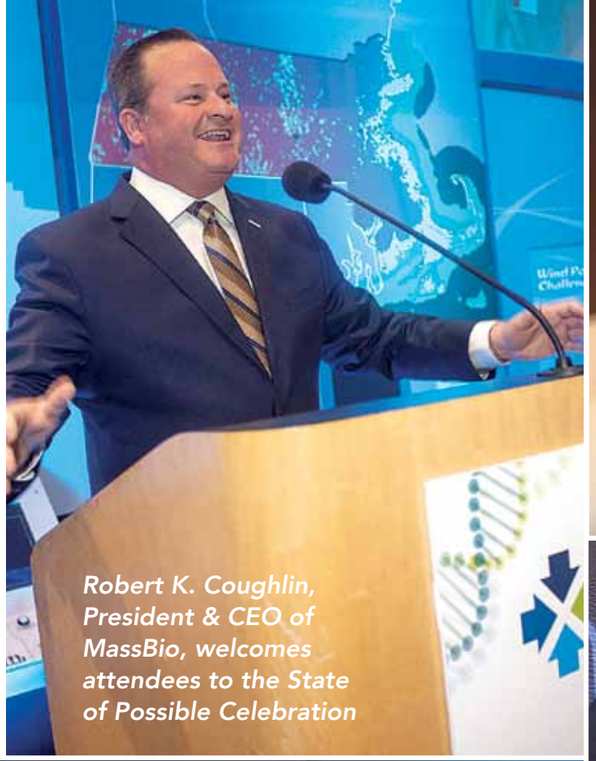
Yet, we know there is a willingness from government officials to seriously consider new, workable ideas, if we can bring them to the table. The question we face is what solutions are amenable for our industry and other healthcare entities. Can those proposals break through the political noise and be part of good-faith debate among both parties? Are those solutions actually solving the biggest problems for patients—access and out-of-pocket costs?

It's clear to us that these solutions must focus on the question of value. It's incumbent upon our industry and individual life sciences companies to clearly and accurately explain the value that therapies and cures bring to patients and the healthcare system through improved health outcomes and costs avoided in other parts of the system.

As an industry, our path forward is not clear, but we know the drug pricing debate is not going away. MassBio is committed to being part of the solution now and into the future. We look forward to working with you, our industry, payers, providers, and patients to get it right. ■

State of Possible Conference

MassBio's 2019 State of Possible Conference was a resounding success, bringing together the brightest minds in the life sciences to deliver invaluable insights to our ever-evolving industry.

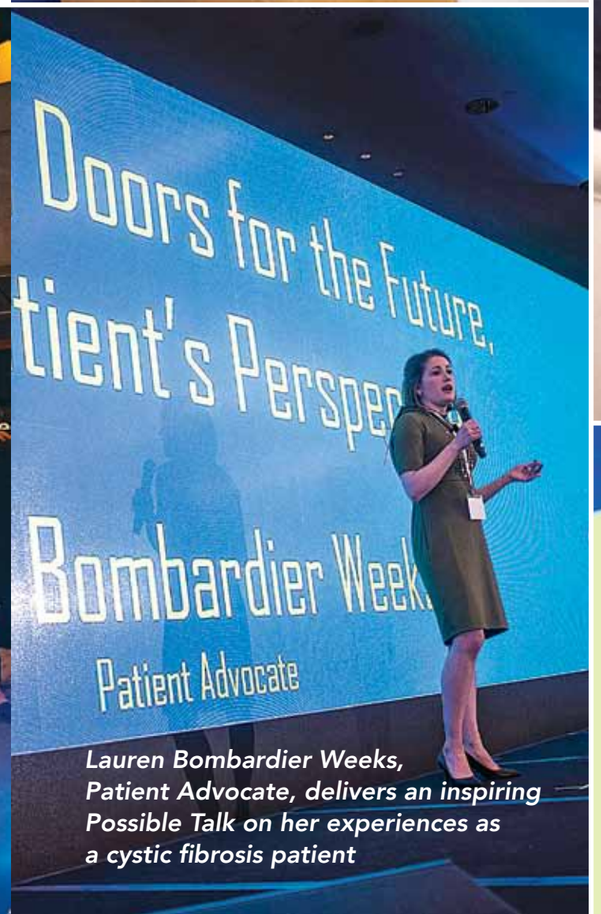


Robert K. Coughlin, President & CEO of MassBio, welcomes attendees to the State of Possible Celebration

Tamar Thompson, Executive Director, State Government Affairs & Federal Payment at Bristol-Myers Squibb, talks about solving the value equation to ensure patient access

Katrine Bosley, former CEO of Editas Medicine, and John Maraganore, CEO of Alnylam, talk RNAi and CRISPR with Mike Nikitas, the event MC

Boston Fire Commissioner Joseph Finn accepts the first-ever 2019 State of Possible Award at the State of Possible Celebration at the Museum of Science



Lauren Bombardier Weeks, Patient Advocate, delivers an inspiring Possible Talk on her experiences as a cystic fibrosis patient

Jeremy Levin, Chairman & CEO of Ovid Therapeutics, delivers the keynote on the state of biotech

The Evolving Landscape for Biotech Funding & Investment

An Interview with John Hallinan, Chief Business Officer, MassBio on how MassBio is Supporting Early-Stage Growth in the Life Sciences

How would you describe the investment landscape and how has it evolved in recent years?

More money than ever is flowing into the biotech industry, with venture capitalist (VC) investment in Massachusetts biotechs surpassing $4.8 billion in 2018 (MassBio Industry Snapshot). In addition, we're seeing other investors enter the scene, with angel investors, disease foundations, private equity firms, cross-over funds, and family offices supporting early-stage funding. At the same time, we're also seeing more money flowing to fewer companies and larger Series A rounds.

One explanation for this shifting landscape is the venture creation model. Ten or more years ago, it was more common to see a group of VC firms pool their money to invest in a company, sharing both risk and reward. The global economic recession of 2008/2009 helped to precipitate a change in the syndication model, and today many VCs are incubating and creating companies and investing larger sums of money to ensure that companies have enough capital to reach significant milestones.

The unmet medical need around the world is growing; 95% of rare diseases don't have a cure, presenting endless opportunities to invest in the industry. That is a big reason why more, and varying kinds, of investors are eager to invest—the returns are significant if the company successfully brings a therapy to market.

What do the new or non-traditional investors look like?

There are more types of investors active across different stages of development than there ever have been before, and they're wielding more influence than previously thought possible. These non-traditional investors include:

Angel Investors

Angel investors are more active in healthcare and the life sciences than ever before and play a critical role in the development of early-stage companies and especially those that do not need large amounts of capital but require smaller amounts of money to fund a discrete set of experiments that will de-risk/accelerate and demonstrate value for future investors. Angels invest their own money and have become an important component of early-stage funding, and by pooling their investments, they are now participating in later stages.

Large Pharma

In the past, early-stage funding was the province of VCs and many pharma companies would not invest until companies were at a later stage and more established. MassBio's Pharma Days® program has shown that external R&D is increasingly important to pharma companies and they have a keen interest in accessing, collaborating, and investing in early-stage companies.

Disease Foundations

The Cystic Fibrosis (CF) Foundation is one of the best and earliest examples of a disease foundation funding innovation. When the gene that causes CF was discovered in the late '80s, the CF Foundation began raising money to fund early-stage research. Other successful examples of venture philanthropy are The Leukemia & Lymphoma Society and Multiple Myeloma Foundation.

Family Offices

Family offices invest in areas they believe in or have a personal connection to and which can provide a double-bottom line with social impact and financial return. It is estimated that two-thirds of the wealth of family offices are being passed down to the next generation, and for this group, life sciences offers the rare opportunity to achieve ROI and impact human health.

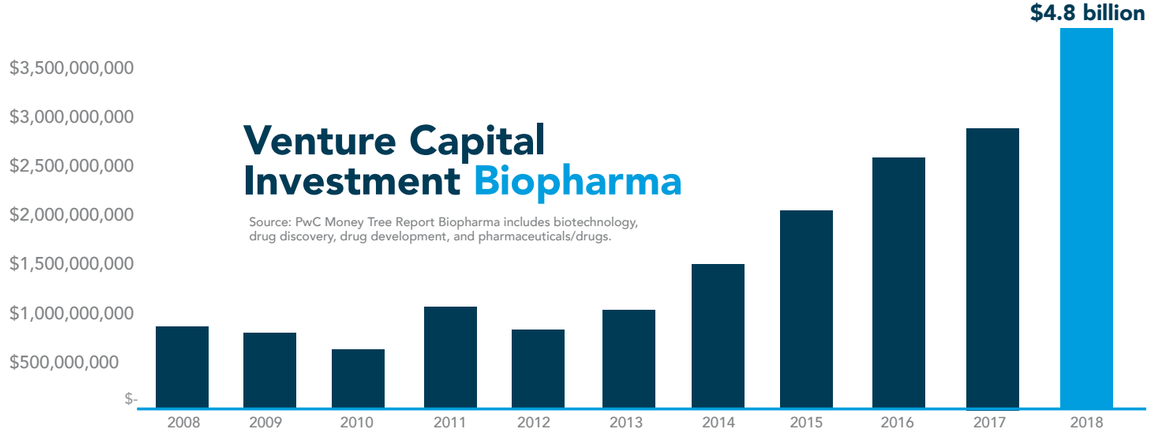
How do MassBio programs like MassCONNECT and Pharma Days help early-stage biotechs get the funding they need?

MassCONNECT de-risks and accelerates the ideas formulated by aspiring entrepreneurs. We match mentors, all of whom have 15+ years of industry experience, to the specific needs and objectives to the entrepreneur. By connecting entrepreneurs to the wisdom and lessons learned that have been created in MA—what we refer to as the "Wikipedia of Life Sciences"—innovators can tap into expertise that otherwise would not be available to them and gain industry exposure.

We have learned that first-time entrepreneurs often lack commercial experience and are bound to repeat the experiments and mistakes that our mentors have already made. Mentors help entrepreneurs define the commercial path by beginning with the end in mind, reverse-engineer the steps, and develop a go-to-market strategy to increase their chance of success. We are proud of the success metrics achieved by MassCONNECT graduates: Before enrolling in MassCONNECT, entrepreneurs had received about $7 million in grants. Post-graduation, they have raised over $100 million and secured 13 golden tickets to LabCentral along with 49 partnerships and collaborations with large life science companies. The success is a testimonial to the gift of time and perspective by the mentors, which totaled nearly 1,300 hours in 2018.

Pharma Days® is a premier partnering forum, which provides a significant ROI as we provide a one-stop shop and turnkey forum which connects pharma to companies and organizations they want to, or should, meet. It allows established and early-stage companies, entrepreneurs, tech transfer, clinicians, scientists, etc., to meet the senior R&D and commercial executives, and learn what pharma is working on, what they are interested in, and why.

Over the last 20 years we have seen a steady migration of pharma companies to MA, and they are coming here to access innovation and talent. Innovation Services programs at MassBio exemplify that evolution and are creating a unique portal to source, accelerate, partner, and fund innovation. The trends are favorable for MA as we have a unique mix of critical ingredients—education, innovation, industry expertise, investors, a strong public/private partnership—and the skilled chefs to masterfully blend those ingredients into a recipe that will help Massachusetts maintain its position as the leading biomedical cluster. ■



Unlocking Innovation by Embedding a Culture of Diversity & Inclusion in the Life Sciences

MassBio's Commitment to Leading by Example

By Edie Stringfellow, Director of Diversity & Inclusion, MassBio

In March 2018, as MassBio's new Director of Diversity and Inclusion, I made the commitment to examine our own actions, policies and practices as an organization so that we are leading by example. I also pledged to work with partners and stakeholders to create an inclusive and equitable Massachusetts life sciences ecosystem where all cultures, backgrounds and experiences are valued to drive patient innovation.

Since then we've made collective progress while building further awareness about how much more there is left to do and what actionable, intentional, measurable steps must be taken to get there.

Here is a snapshot of MassBio's current activities to address equity, diversity and inclusion (ED&I) in the industry:

Open Letter Follow-Up

In 2017, more than 100 life sciences executives signed our Open Letter committing to best practices to improve gender diversity in the industry. Two years later, we are holding signers accountable by tracking what they've done since then to improve diversity. We are also asking them about their current and future strategies for D&I, including recruitment, retention, promotion, culture, measurement, and sustainability; what obstacles and barriers are hindering implementation of D&I policies and best practices; how they leverage D&I to meet growth objectives; and how they are investing or nurturing a diverse STEM pipeline to sustain a future workforce in a globally competitive environment.

Project Onramp

Alongside MassBioEd, Massachusetts Life Sciences Center, Life Science Cares, and Bottom Line, MassBio co-created a first-in-nation program to open doors to biotech careers for those who don't have the social capital, parental networks or direct path to the biotech field. Project Onramp changes that with full-time, well-paid, summer internships for low-income, first-generation undergraduate college students. In the program's first year, 25 companies answered the call and placed 50 internships across the industry.

ERG Exchange

We are energized by the great work that our members' employee resource groups (ERGs) are doing every day to promote greater D&I within their companies. They enhance the employee experience for underrepresented demographics and meet company goals at the same time. Yet, ERGs are siloed within companies, stifling sharing of best practices and lessons learned. At the same time, executive sponsors are seeking ways to measure ERGs' impact on their companies' D&I. In mid-June, MassBio hosted an ERG Exchange for participants of ERGs across our membership to create a learning community and share best practices so that we can get the greatest impact of our initiatives collectively.

Affinity Group Partnerships

MassBio is committed to supporting organizations that share our values and objectives. Our industry's strength is powered by employees of all ages, backgrounds, cultures, faiths, schooling, upbringings, experiences and perspectives. Our vision is to elevate Massachusetts even higher as the top destination for all top talent. We know the important role that these groups have in providing quality development and networking opportunities. This year, we are offering programs to these associations to help spread their message and connect them with our members who can also benefit from the relationship.

Website Resources

Consistent engagement with the industry and our member community is very important to me. On our website, you will find several talent-sourcing opportunities; a list of partners that enhance the diversity of the biotech supplier landscape; members' D&I success stories; benchmark tools; and much more! I encourage anyone to visit massbio.org/diversity and familiarize themselves with our ongoing strategic commitments and initiatives.

MassBio is proud to be the driving force to increase D&I within the life sciences industry. We have made strides; however, we must become more aligned with the patient population that we serve as well as the next generation of science innovators and biotech leaders. I strongly believe that we must set our expectations clearly and measure our success regularly to give the patient community and society confidence in our progress.

I look forward to continuing this journey with you. ■

Learn more at MassBio.org/Diversity

Member Spotlights

Each month, MassBio spotlights a member company and the great work they do to advance the life sciences industry and support the patients we serve.

GE Q&A

In January, we spoke with Mohamed Fouda,

Executive Director at GE Healthcare Life Sciences, where he leads strategic initiatives and alliances focused on academia and pharmaceutical companies. Most recently, Mohamed executed a five-year precision cancer care partnership with Vanderbilt University Medical Center.

Tell us about your organization and your current initiatives.

GE Healthcare Life Sciences partners with pharmaceutical companies and academic centers to enable the research and development as well as the manufacturing of innovative therapies that are contributing to advancing standard of care in major life-threatening diseases. We have a unique position and experience in the ecosystem of hospitals, clinicians and pharma/biotech and academic research thanks to our broad range of diagnostics and enabling technologies and services for therapy innovation.

How do your organization's activities help patients now and into the future?

On top of the work that we do every day to provide healthcare providers and pharmaceutical companies with the diagnostics, technology and services needed to administer or manufacture therapies to patients around the globe, we are partnering with all the healthcare ecosystem stakeholders to help optimize patient access to innovative therapies. As an example, we have just announced an exciting 5-year partnership with Vanderbilt University Medical Center, focused on making cancer immune therapies more safe and precise. Through this partnership we will co-develop multiple diagnostic tools to help predict both the efficacy of an immunotherapy treatment and its adverse effects for a specific patient before the therapy is administered. This initiative has the potential to transform cancer therapy and patient lives by allowing clinicians to more accurately predict how patients will respond to a specific therapy.

What do you see as the biggest challenge facing the life sciences industry today?

It's hard to deem one challenge the biggest but if I must highlight only one I would highlight patient access. We as an industry have a lot of work ahead of us to commercialize new innovative therapies like cell and gene therapies. The question that comes to my mind always is how we can make these new transformative therapies accessible and affordable to a patient in Africa, for example? And how can we ensure we match the right patient with the right therapy? Currently these new life sciences tools, technologies and therapies are promising but we need to work on making them more precise, safe, affordable and scalable. This is a multifaceted challenge that requires significant industry collaboration. I personally see this as a moral obligation, not only a challenge.

What's next for your organization / what are you focused on in the coming year?

We will continue to partner with our customers to solve patient needs and deliver on our precision health vision. We are excited about the future but also humbled by the complexity and challenges—that's why we will double down on partnerships to combine our expertise and capabilities with various academic, clinical, industrial and technological partners to achieve this vision of delivering precision health. ■

KCR Q&A

In February, we spoke with Mike Jagielski,

President and CEO of KCR, who has over 20 years of experience in the global clinical trials operations industry and provides strategic leadership to a team of experienced project managers. Under his leadership, the company has grown into a full-service CRO, covering a wide range of therapeutic areas, with a multi-regional reach allowing for highly optimized delivery of trial execution strategies.

Tell us about your organization and your current initiatives.

KCR is a full-service contract research organization providing clinical development solutions for the biotechnology, pharmaceutical and medical devices industries. Our current focus is on oncology, CNS, immunology, pediatrics, imaging, and vaccines. KCR operates across four main regions: North America, Western Europe, Central Europe, and Eastern Europe, with hubs in Boston, Berlin, Warsaw, and Kiev. These geographical locations allow for optimized delivery of fully customized trial execution strategies. Our size of about 400+ employees allows us to adapt quickly to biotech company needs, which is the main development priority for our Boston operation. We want to bring European expertise close to Boston biotech companies and advance their clinical development internationally.

We are a 100% private company with PE investments. Our business focus is on achieving organic growth and being a choice partner for biotech companies who appreciate a speedy and customized trial execution. Our trial execution consulting service is a big part of that tailored delivery.

How do your organization's activities help patients now and into the future?

Two years ago, KCR launched the Human Behind Every Number (#HBEN) project. Recognizing that the CRO industry would not exist without patient involvement, KCR wanted to advance trial design with patients at the forefront. The project is based on the voices and perspectives of real patients who are past or present participants in clinical trials. We want to understand their incentives, concerns and opinions throughout the study enrollment. The results are used to engage stakeholders in a new discussion on improved patient experiences and the continued execution of highly optimized clinical trial design. Moreover, the project provides patients with an informative and supportive experience as they navigate the clinical trial space. For that reason, we decided to turn the project into a non-governmental organization (NGO)—Human Behind Every Number, Inc.

The research results will be shared with trial participants and industry stakeholders including patients, pharmaceutical companies, medical device companies, biotech companies, clinical research organizations and more. We welcome partners who would like to support the NGO and contribute to clinical trial design in the future.

What do you see as the biggest challenge or opportunity facing the life sciences industry today?

This is a big question, which I would like to answer with emphasis on trial execution in clinical development and new trends to watch. I am not sure what to think about AI in that context, so I will say that access to electronic health records on a large scale will have a permanent impact on trial design. Imagine for placebo-controlled studies that draw placebo data from available health records—opening a whole new world of possibilities for clinical trial designs and sample size calculations. Patient centricity is already a driving force, so I am eager to watch it evolve and to see its influence on real research results. Regardless, AI is here to stay, and it will improve patient comfort.

On the more practical operations side, the truly one-system technologies for CTMS/eTMF will have a significant impact on trial efficiency and trial oversight possibilities. We are not talking integration any longer, we are talking about a new generation of systems altogether. But don't worry, this industry doesn't have a reputation for early technology adaptation, so it will not be so fast.

What's next for your organization / what are you focused on in the coming year?

This year, we are focusing on two main goals. First, delivering great results in our project portfolio. It is the best challenge to have and we owe it to our customers to stay focused. Second, we are focused on further developing our Boston presence. Boston is a key biotech hub and with our north American operation right here, we are fully committed to be a competitive clinical development solution provider in this biotech ecosystem. If we deliver on these goals, we are good for 2020. ■

addgene the nonprofit plasmid repository Q&A

In March, we spoke with Aliyah M. Weinstein,

PhD, Marketing and Communications Manager at Addgene, the nonprofit plasmid repository. In this role, she works to ensure that scientists around the world know about Addgene's materials, services, and educational resources. Aliyah advocates for equitable access to STEM education and careers through writing and community outreach.

Tell us about your organization, its mission, and current initiatives.

Addgene is a global nonprofit plasmid repository. Our mission is to accelerate research and discovery by improving access to useful research materials and information. We organize the transfer of DNA-based reagents such as plasmids and ready-to-use viral preps between scientists in over 90 countries and have over 71,000 plasmids available in our repository. Over the past few months, Addgene has hit several memorable milestones. We shipped our 1 millionth plasmid in September, relocated to the LINX building in Watertown in November, and celebrated our 15th anniversary in January! With our new space comes the exciting opportunity to grow our team and expand the services that we can offer to the scientific community.

How do your organization's activities help patients now and into the future?

Clinical breakthroughs are fueled by basic science discoveries. The materials that Addgene distributes help basic science researchers easily access the DNA-based tools they need to make new discoveries. For scientists who develop new tools and deposit them at Addgene, we provide support by taking care of quality control, MTA compliance, reagent production and distribution, and record-keeping. Sharing speeds science, and Addgene empowers researchers worldwide to make an impact on the present and future of science and medicine.

What do you see as the biggest challenge facing the life sciences industry today?

The biggest challenge in the industry is the need for inclusive and diverse company cultures. It's the only way to ensure that every employee will feel welcomed, supported, and engaged—and ultimately for the organization to reach its full potential. Addgene is committed to fostering this kind of environment through our philosophy of supportive, radical flexibility; harassment awareness and unbiasing training for all employees; recruiting partnerships with local organizations such as Just a Start and community colleges; and as a founding sponsor of the Massachusetts LGBT Chamber of Commerce. As our CEO, Joanne Kamens, highlighted last year, we are engaged in at least half of the efforts to reach gender parity in the life sciences sector that were recommended in the MassBio report. We encourage other leaders to spend time understanding why taking these kinds of actions are important not only to their

company, but to the success of the industry as a whole.

What's next for your organization / what are you focused on in the coming year?
As always, we want to make it easy for scientists around the world to access the reagents they need. This year, Addgene is focused on filling gaps in our collection, expanding our distribution of plasmids and ready-to-use viral preps, and developing new services that further accelerate research. We'll continue working closely with the non-researchers in our pipeline, such as technology transfer offices and international distributors, to improve our processes for reagent sharing. We are also involved in the growing effort to enable scientific reproducibility. We will continue to provide open-access molecular biology protocols and educational resources, and plasmid sequence validation and associated information to the scientific community. ■

Boehringer Ingelheim

Q&A

In April, we spoke with Ioannis Sapountzis,

PhD, Global Lead of Business Development & Licensing (BD&L) at Boehringer Ingelheim Pharmaceuticals, Inc., with more than 16 years' experience in the pharmaceutical industry. Ioannis joined Boehringer Ingelheim in 2005 as a medicinal chemist and project leader in the oncology therapeutic area, and later transitioned to strategic roles in the corporate department of Research Networking. He currently serves on the MassBio Board.

Tell us about your organization, its mission, and current initiatives.
Boehringer Ingelheim is a family-owned, research-driven pharmaceutical company focused on therapeutic innovations that improve human and animal health by addressing unmet medical needs. Because we plan not for the short-term but rather for generations, we achieve long-term success via a thriving environment for research and development. We sustain and grow R&D via our internal efforts, as well as through our external partnerships and strategic alliances. Our three core businesses are human pharmaceuticals, animal health and biopharmaceutical manufacturing, and we have an independent subsidiary BI X that develops smart digital healthcare solutions.

Our human pharmaceutical business concentrates on developing novel and enhanced therapies for patients with diseases for which no satisfactory treatment option exists, particularly in the therapeutic areas of respiratory, immunologic, cardiometabolic, oncologic, and CNS diseases. To address these diseases, we expand our direct approach by applying synergies from our immune modulation and fibrosis expertise as well as harnessing emerging science, such as that of regenerative medicine, the microbiome and gene therapies.Such innovations enable us to target our medicines more precisely to individual patients, making our therapies more effective and increasing benefits to society.

How do your organization's activities help patients now and into the future?
Boehringer Ingelheim works continuously to help patients—efforts that encompass far more than drug discovery. We want to develop safe health solutions quickly and make them accessible to patients. We also want to operate in ways that are responsible to the communities in which our patients, colleagues, and families live, and that are respectful of the resources we all share.

We optimize life science innovation within our own R&D and outside our walls. Our own discovery and improvement of candidate agents is augmented by partnerships and alliances with experts and entrepreneurs based in academia, government or the private sector. Such projects enable us to accelerate development timelines with the goal to make new medicines available to patients faster. Additionally, through our BI Cares Foundation Product Donation and Patient Assistance Programs, we provide our medicines free of charge to patients in need in the US and around the world. We also have a robust Produce to Give Program that donates a committed inventory of medicines to clinics around the world to help build their capacity and improve health outcomes for underserved patients.

What do you see as the biggest challenge facing the life sciences industry today?
The life sciences industry faces many challenges today, and one which Boehringer Ingelheim is addressing that I would like to share with your readers is how we bring together the right talent and the best tools efficiently, and effectively work to get new therapies to patients faster. Our blueprint for innovation at Boehringer Ingelheim integrates research, pre-clinical and early clinical development, translational medicine and external partnering functions. To do so means having seamless and synergistic collaborations that excel at both sound science and smart risk-taking to generate the highest quality solutions. Because we value expertise both internally and externally, we mentor, foster and partner talent. For example, our Grass Roots programs address these three engagement channels by offering mentoring to small companies, bio-entrepreneurs and academics; networking for early-stage life-science companies to facilitate sharing of peer information and of industry perspective and feedback; and partnering initiatives. Furthermore, we have opnME.com, a platform offering scientists free access to first-class, pre-clinical molecules from Boehringer Ingelheim to validate new disease biology or collaborate with scientists on new ideas.

What's next for your organization / what are you focused on in the coming year?
Within our core therapeutic areas, we are investigating treatments based on small molecules, biologics and new modalities, such as oncolytic viruses and RNA therapeutics. We also have Research Beyond Borders (RBB), which is a part of our global research division specifically tasked with exploring emerging science and technologies for and beyond our current core therapeutic areas. RBB is on the lookout for exciting projects in areas as varied as regenerative medicine, gene therapy and the microbiome, for example. We select each project for its potential to have significant future implications for the health sector and patients, possibly delivering a candidate drug, technology or solution into our pipeline. We also will continue enhancing and expanding our partnerships and Grass Roots programs. ■

ELEMENTAL MACHINES

Q&A

In May, we spoke with Sridhar Iyengar,

CEO of Elemental Machines. Sridhar holds over fifty US and international patents and received his PhD from Cambridge University as a Marshall Scholar. A serial entrepreneur, he has started three companies that have revolutionized multiple industries.

Tell us about your organization and your current initiatives.
Elemental Machines is building a soup-to-nuts platform for automating data collection and analysis. Many of us know from our own experiences that R&D and manufacturing workflows, especially in the life sciences, are lengthy and complex. There are a lot of nuances that contribute to this: (1) managing and integrating different data types from different machines/instruments all made by different manufacturers, (2) poor user interfaces that are not designed for people of various skill levels and various disciplines, and (3) working in a regulated environment.

We are leveraging new technologies such as IoT (internet of things), informatics tools, machine learning (ML), and artificial intelligence (AI) to address many of these challenges and make scientific workflows faster and cheaper than ever before. With IoT data collection tools, we effortlessly get data from lab equipment and ambient lab environments. New informatics tools are readily avail-

able and capable of handling the big data sets collected by IoT. And lastly, ML and AI quickly and effectively recognize patterns and data trends to extract relevant information that would have traditionally taken weeks or months to uncover, or may possibly never even have been uncovered.

How do your organization's activities help patients now and into the future?

We know there are a lot of patients waiting for new therapies to treat some pretty debilitating diseases. Unfortunately, cures don't just happen overnight. From early stage R&D all the way through clinical trials, there are a lot of risks throughout the process, and hopes for new drugs may fall through because results are just not reproducible. Sometimes, despite our best efforts, it's difficult to pinpoint the root cause behind irreproducible data. But what if we had better tools to find and tease out the unknown unknowns that just may be the root cause behind the problem? Our platform specifically addresses this challenge. Much like how software engineers have tools to debug code, the technologies behind our platform help scientists 'debug' their work faster, the end result being finding the right treatment sooner for those who really need it.

What do you see as the biggest challenge facing the life sciences industry today?

There's a lot of new technologies out there that have been used by many industries outside of life sciences, that should be leveraged *within* life sciences. Unfortunately, there are additional challenges in our industry that make adoption of new tech more difficult (e.g., regulatory constraints). This completely makes sense given that there is so much at stake (i.e., the well-being of patients, the time/cost of clinical trials, etc.) that it's tough to be bold and try out new approaches, especially when you may not be an expert on the subject matter. That's why we are developing products in concert with regulatory requirements and with close partnership with industry leaders in our space. Ultimately, the coolest technology won't make any impact unless it can actually be used in a compliant and safe manner, and that's something we understand and embrace when we design our products.

What's next for your organization / what are you focused on in the coming year?

We have some ambitious projects in the pipeline for the coming year. We've spent the last few years building out a robust foundation for data collection from a number of different environments, machines, and instruments (and we're expanding that data collection network to have even more granularity) so that we can create a platform for aggregating and analyzing large amounts of heterogeneous process data. I'm most excited about now taking that large volume of data and coupling it with AI/ML models to help scientists and engineers optimize research and process outcomes. We're also building out features that are required for quality and regulatory compliance. These are a big deal in the life sciences, so we don't take this lightly. ■

In June, we spoke with Sarah T. Hogan,

Partner at McDermott Will & Emery. Sarah helps companies across the life sciences and digital health industries with structuring and negotiating strategic collaborations, licensing arrangements and other complex commercial transactions that drive their business and mission. She works closely with McDermott's regulatory lawyers to eliminate roadblocks and help her clients successfully deliver innovative solutions that improve health care.

Tell us about your organization, its mission, and current initiatives.

One of the most exciting things about working at the intersection of life sciences and health care is that the industry is constantly evolving and facing unique challenges. There are no established answers to some of the most pressing questions our clients face, so we dig in with our clients to tackle these issues together.

Data use is one of the most frequent issues our clients in the life sciences industry are grappling with today. Life sciences companies are sharpening their focus on data use practices, with emphasis on how they can use real-world evidence and other data to get therapies to market faster and drive patient adherence. Data use raises a myriad of complex regulatory issues, such as HIPAA and other data protection regulations, FDA and FTC regulatory concerns, and fraud and abuse laws, just to name a few. Our team at McDermott has a finger on the pulse of the ever-evolving regulatory framework in these areas, and as a transactional lawyer, I focus on bringing together the right specialists to develop a fully integrated approach to help our clients navigate these complexities.

How do your organization's activities help patients now and into the future?

The reason this practice is rewarding is that we partner with companies at the forefront of new therapies as they formulate their business plans. As I previously mentioned, there are a multitude of regulatory challenges that have an impact on how these companies build strategic partnerships and run their businesses. At McDermott, we work across practices including intellectual property, regulatory, transactional, litigation, tax and employment law to help our clients go further. We focus on strategies for clearing the obstacles so that our clients can focus on opportunities to improve health care delivery and patient outcomes, all in service of getting life-changing therapeutics to market sooner.

What do you see as the biggest challenge facing the life sciences industry today?

The health care industry as a whole—including life sciences stakeholders—continues to struggle with implementing a transition from the traditional fee-for-service model to a value-based care model. Upending the model for our entire health care system in the United States is obviously a considerable challenge, and I think we'll see the various stakeholders struggle with this for a long time to come. At the same time, this upheaval creates the opportunity for life sciences companies to help shape a new care model that focuses on patient wellbeing. And we're seeing our clients getting creative in building business models around this goal. That's where we come in—we thrive on helping companies seize opportunities while navigating the regulatory complexities and minimizing risk.

What's next for your organization / what are you focused on in the coming year?

As always, we'll continue to work with our clients to navigate the complex regulatory, business and legal issues that continue to proliferate across the life sciences and health care industries, and fuel the mission of life sciences companies large and small.

We're also highly focused on engaging with investors early to identify—and mitigate—potential regulatory, compliance and business risks before they arise. When a potential investment target does not have a solid compliance strategy, it can cause serious headaches for the investor down the road. We help investors make sure that the technology they are investing in actually makes it to market.

We'll also be maintaining our comprehensive global network and focus, which is vital in today's market, as many larger pharma companies have a global footprint and today's deals are cross-border more often than not. We have well-established practices in Europe and China, allowing us to deploy integrated global teams to deliver seamless solutions across geographies. ■

Cultivating the Next Generation of the Life Sciences Workforce

A Q&A with Michelle Mischke, Director of Biotechnology Education Programs, and Karla Talanian, Manager of Labor Market Research, MassBioEd

To learn more about the life sciences workforce and the future of hiring, we sat down with MassBioEd, whose mission is to build a sustainable life sciences workforce in the region through educational programs that inspire and propel students, engage and excite teachers, and illuminate the pathway from classroom to careers.

How would you describe the current hiring landscape?

The life sciences industry in Massachusetts is growing and innovating at an exponential rate, which is leading to amazing breakthroughs for patients, but is also putting an increased strain on hiring as job demand is superseding supply. According to our own data, it's predicted that by 2023 there will be 12,000 additional jobs that need to be filled, posing significant challenges in regard to hiring qualified candidates.

With 116 colleges and universities in the Commonwealth, we're at the epicenter of talent—Massachusetts' greatest resource. By getting students excited about life sciences careers, embracing foreign-born talent, and aligning academic programs with industry's needs for skills, we can harness future talent and address the forecasted hiring gap.

What are the biggest challenges to workforce development?

One of the largest barriers to workforce development is an inherent lack of awareness of the career opportunities available in the life sciences. It's critical to help students make connections between what they're learning in science classes and potential career opportunities—beyond becoming a doctor or a nurse. By exposing high school students to real-world opportunities in the life sciences, we are able to expand their visions of what a career in this industry might look like, as well as heighten their enthusiasm for pursuing college and career paths within the life sciences.

We do this through our Career Exploration Days, which bring students to biotech companies across the state to interact with employees from a wide range of scientific positions—as well as those who are in scientific support and professional roles—and our Biotech Futures events that connect students with life sciences departments at local colleges and universities. At these events, students engage in authentic lab-based activities and learn about the science at the heart of each company that drives their business model and shapes the values in their workplace. These efforts are critical to ensuring that Massachusetts remains the number-one life sciences cluster in the world, and that we can meet the industry's hiring needs so MassBio members and the industry at large—can continue to focus on delivering new breakthrough therapies and cures to patients.

As the fight for top talent continues, what should employers prioritize when looking to attract and retain workers?

Disease knows no boundaries, and neither should the workforce. To meet hiring needs and solve the toughest medical problems, biopharma companies are looking to the top colleges and universities in Massachusetts and are expanding their search across the country and even the globe. In fact, roughly 35% of the life sciences workforce is foreign-born, confirming the importance of immigrants to our industry.

Companies are striving to foster a diverse workforce, but immigration policies have a substantial impact on our ability to recruit talent. The larger companies have immigration specialists on board that can help employees navigate visa issues and complexities. However, there is a large proportion of companies that are so small, and in absence of a human resources professional, don't have the bandwidth to deal with issues of this nature.

With the various hurdles to obtaining and retaining work visas, you have to wonder what percentage of the talent pool is lost due to immigration policies and the number of students that are graduating in the US but can't stay here to work. The current political environment has not been conducive to hiring immigrants, something that we hope will change, as these experts are a critical part of our workforce.

What's next for MassBioEd?

We're thrilled to announce the appointment of our new Executive Director, Sunny Schwartz, who will help advance our impact and further our success. Under her leadership, we aspire to grow the number of schools engaged in science programs and develop a scope and sequence for what a high school biotechnology course would look like to better mold the workforce of the future. We also want to engage underserved populations and inner-city schools, supporting diversity among biotech companies.

Our major workforce initiative is to take all the information from the industry, job trends, and academia and translate that into digestible data for teachers and students. If we can disseminate the trends we're seeing, and what the industry is saying, colleges and universities, and even high schools, can adjust their training programs and ensure their curriculum matches the needs of the biopharma companies who are looking to hire these students. For 2019 and beyond, we hope to continue building industry excitement for students and expand our reach to ensure Massachusetts remains the best place in the world for life sciences. ■

Learn more at MassBioEd.org

Greater Value

MassBio Rebrands Purchasing Consortium and Launches New Online Platform to Offer Greater Value to Members

MassBio Edge to Serve as Umbrella for B2B Preferred Vendors and B2C Employee Rewards

By Jason Cordeiro, Vice President of Consortium Operations, MassBio

Our members today are operating in a different environment than they were 10 years ago and it's up to us to evolve in lockstep to support their changing needs. That's why in March, MassBio announced a rebrand and expansion of its savings and rewards programs to deliver greater value for members as they work tirelessly to bring lifesaving therapies to patients. Now called MassBio Edge, it will encompass those preferred B2B partners that have historically operated under the Purchasing Consortium, along with the B2C vendors under Employee Rewards, who offer over 125 individual employee discounts to members.

"Drug discovery is a capital-intensive business and the more companies are able to save on lab supplies, gases and other materials, the more money they're able to pour back into R&D for future innovations," said David Lucchino, Chair of the MassBio Board and President & CEO of Frequency Therapeutics. "The Purchasing Consortium has been instrumental in helping life sciences companies, especially those in early stages, find new efficiencies to do more with less—and ultimately to help patients in need."

The Purchasing Consortium was founded alongside MassBio in 1985 with the goal of aggregating the purchasing power of member companies to take advantage of competitive discounts and premier customer service. In the last 10 years, the Purchasing Consortium has grown exponentially, with 75% of members now participating in the program, resulting in more than $75 million in savings each year.

As part of this rebrand, MassBio also released a new online platform for members to market discounted services directly to other members, called the Edge Connector. The Edge Connector will also house MassBio Edge preferred vendors. ■

Learn more at Connector.MassBio.org

MassBio Opens Office

at UMass Amherst's Institute for Applied Life Sciences

Supporting the Life Sciences Throughout the Commonwealth

By Ben Bradford, Vice President of Membership, MassBio

Photo courtesy of UMass Amherst's Institute for Applied Sciences

In April, we announced the opening of our new office, MassBio West, at UMass Amherst's Institute for Applied Life Sciences (IALS), providing our members located in or around Western Massachusetts easier access to MassBio benefits and supporting further growth of the life sciences across the state.

As part of our collaboration with IALS, we're also offering members a discount at UMass Amherst Core Facilities, a collection of more than 30 cutting-edge equipment facilities available to researchers from government, academia and industry on a fee-for-service basis. More significantly, members who leverage these facilities for their research retain their intellectual property (IP). IP-free zones are a rarity in industry, making UMass a unique attraction that will help foster innovation and assist entrepreneurs with translating their research into companies.

In expanding the reach of life sciences in Massachusetts, Peter Reinhart, director of IALS notes, "IALS also facilitates industry collaborations and new ventures, and contributes to workforce development in the discovery, development, and manufacture of medical devices, biomolecules, and delivery vehicles." ■

Learn more about these unique benefits at MassBio.org/purchasing-and-rewards.

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300 Technology Square, 8th Floor • Cambridge, MA 02139 • MassBio.org • 617.674.5100

MassBio
Massachusetts Biotechnology Council
300 Technology Square, Ste 8
Cambridge, MA 02139-3520