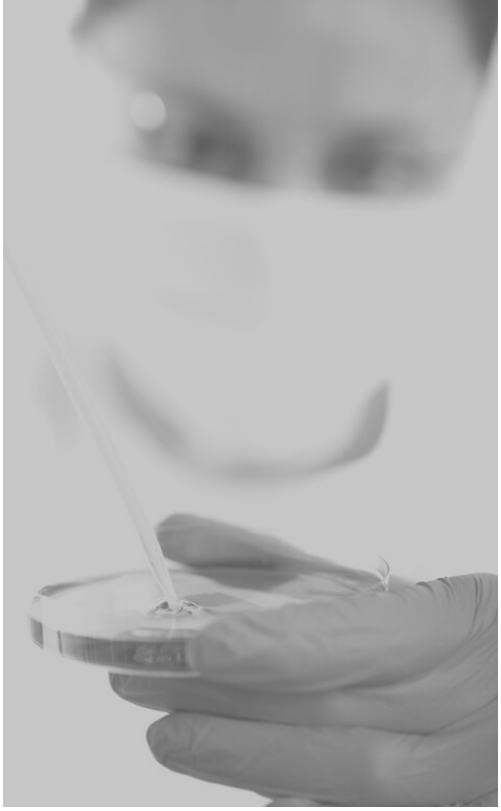

Transitioning From Academics to Industry

Pre-Meeting Workshop

Monday, May 10

10 a.m. – 2 p.m. ET

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Transitioning From Academics to Industry

Co-Chairs: Bartholomew Tortella, M.D. & S. Kaye Spratt, Ph.D.

Session 1: Working and Thriving in Industry: What You Need to Know to Prepare and Succeed

10 – 10:10 a.m.

The Journey From Basic Research: The Science & Discovery Perspective

Steven Gray, Ph.D., University of Texas Southwestern

10:10 – 10:30 a.m.

The Clinical Trialist Perspective: Working on the Other Side of the Clinical Trials Table

Gallia Levy, M.D., Ph.D., Spark Therapeutics

Kamal Bharucha, M.D., BridgeBio

10:30 – 11 a.m.

The Regulatory Perspective: Moving From Early Clinical Phase to Late Clinical Phase and Eventual Marketing Authorization

Adora Ndu, Pharm.D., J.D., BioMarin

Dan Takefman, Ph.D., Takefman Gene Therapy Advisors LLC

Nisha Jain, M.D., Takeda Pharmaceuticals

11 – 11:45 a.m.

Panel Discussion

Moderators:

- S. Kaye Spratt, Ph.D., BridgeBio Gene Therapy - Aspa and Adrenas Therapeutics
- Gregory LaRosa, Ph.D., Pfizer Rare Disease

Transitioning From Academics to Industry

Co-Chairs: Bartholomew Tortella, M.D. & S. Kaye Spratt, Ph.D.

Session 2: Learning From Experience: Case Studies of Transitions From Academia to Industry

12:15 – 12:25 p.m.
Finding That First Industry Job: Career Preparation and Timing, Rules of the Road, and Tricks of the Trade
Federico Mingozzi, Ph.D., Spark Therapeutics

12:25 – 12:35 p.m.
The Road Less Traveled: Transitioning Into Industry
Kevin Williams, M.D., J.D., Pfizer Rare Disease

12:35 – 12:45 p.m.
Academia to Medical Affairs: Understanding the World of Medical Affairs in Industry
Leonard Valentino, M.D., Hemophilia Foundation

12:45 – 12:55 p.m.
Thriving in Patient Advocacy Positions in Industry
Katherine Beaverson, Pfizer Rare Disease

12:55 – 1:05 p.m.

Moving From Academic Vector Production to Commercial Scale Manufacturing

Fred Porter, Ph.D., Taysha Gene Therapies

1:05 – 2 p.m.

Panel Discussion

Moderators:

- Eric David, M.D., J.D., BridgeBio
- Bartholomew Tortella, M.D., Spark Therapeutics

Katherine Beaverson
Pfizer Rare Disease

Katherine Beaverson, M.S., is Senior Director and Patient Advocacy Lead for the Rare Disease Research Unit (RDRU), at Pfizer Inc., leading the strategic planning and implementation of collaborations with patient advocacy groups in support of mutual areas of priority. She is external facing, engaging with rare disease patient advocacy groups to integrate their expertise into early medicines research and development. She is also internal facing, helping to facilitate alignment among cross-functional colleagues committed to advancing Pfizer science and programs with rare disease patient communities. Prior to joining Pfizer Inc., she held similar positions at Boehringer Ingelheim and Amicus Therapeutics. She is professionally trained as a Genetic Counselor, having spent 10 years at both New York Hospital-Weill Cornell Medical Center and Memorial Sloan-Kettering Cancer Center before entering industry. She received her B.A. from Swarthmore College and her Master of Science in Human Genetics from Sarah Lawrence College. Katherine is the current Chair of the Companies Constituent Committee of the International Rare Disease Research Consortium (IRDiRC) and a Member of the New York University Pediatric Gene Therapy Medical Ethics Working Group (PGTME).

TAYSHA GENE THERAPIES

WHO WE ARE

Gene therapies have proven to deliver transformational benefits to patients who suffer from devastating diseases. Our mission at Taysha Gene Therapies is to build upon these advancements to eradicate monogenic central nervous system (CNS) diseases for the thousands affected. Our gene therapy strategy and unrivaled partnership with UT Southwestern help fuel our development engine.

NEXT-GENERATION PLATFORM TECHNOLOGIES

We are developing next-generation technologies to optimize key components of our AAV-based gene therapies, including redosing, transgene regulation, and capsid development.

To learn more, visit us at **Taysha Gene Therapies** and read about our upcoming **R&D Day in June 2021**

OUR APPROACH TO GENE THERAPY

The fundamental components of our approach are based on recent success in gene therapy development and commercialization: an adeno-associated virus serotype 9 (AAV9) capsid, intrathecal delivery, and an efficient manufacturing process.

AAV9 CAPSID

We use an AAV9 capsid to deliver therapeutic genes engineered to replace a mutated gene, decrease the expression of a gene, or enhance the expression of a silenced gene. AAV9 has a unique ability to cross the blood-brain barrier, making it an ideal vector for gene therapies in the CNS, and since its discovery more than 50 years ago, AAV has been one of the most well-studied vehicles for the delivery of gene therapies.

INTRATHECAL DELIVERY

We use intrathecal administration, which directly delivers our gene therapies to the cerebrospinal fluid, to facilitate optimal biodistribution and cell transduction within the CNS. The procedure is routinely performed in an outpatient setting, and in comparison to intravenous administration, it allows for a lower dose of the therapy.

EFFICIENT MANUFACTURING

Taysha's manufacturing strategy will enable consistent production of commercial- and clinical-grade AAV gene therapies. Our flexible and productive manufacturing processes allow us to produce our gene therapy product candidates efficiently at scale. Through our partnerships with UT Southwestern and Catalent, we have access to clinical and commercial-ready production capacity that utilizes a suspension HEK293 process to produce AAV9. Our internal manufacturing facility designed to produce both clinical and commercial product is expected to be online in 2023.

UNPARALLELED GENE THERAPY PIPELINE FOCUSED EXCLUSIVELY ON MONOGENIC CNS DISORDERS

PROGRAM		INDICATION	DISCOVERY	PRECLINICAL	PHASE 1/2	PIVOTAL
NEUROGENERATIVE DISEASES						
TSHA-120	*GRT*	Giant Axonal Neuropathy				Regulatory Guidance YE 2021
TSHA-101	*GRT*	GM2 Gangliosidosis				Currently Open CTA
TSHA-118	*GRT*	CLN1 Disease				Currently Open IND
TSHA-119	*GRT*	GM2 AB Variant				
TSHA-104	*GRT*	SURF1-Associated Leigh Syndrome				IND/CTA Submission 2H 2021
TSHA-112	*miRNA*	APBD				
TSHA-111-LAFORIN	*miRNA*	Lafora Disease				
TSHA-111-MALIN	*miRNA*	Lafora Disease				
TSHA-113	*miRNA*	Tauopathies				
Visit Taysha's website to view 3 more programs in this franchise						
NEURODEVELOPMENTAL DISORDERS						
TSHA-102	*Regulated GRT*	Rett Syndrome				IND/CTA Submission 2H 2021
TSHA-106	*shRNA*	Angelman Syndrome				
Visit Taysha's website to view 8 more programs in this franchise						
GENETIC EPILEPSY						
TSHA-103	*GRT*	SLC6A1 Haploinsufficiency Disorder				
TSHA-105	*GRT*	SLC13A5 Deficiency				
TSHA-110	*mini-gene*	KCNQ2				
Visit Taysha's website to view 1 more program in this franchise						

Kamal Bharucha, M.D., Ph.D.
BridgeBio

Kamal Bharucha has both academic and industry research experience in the areas of pediatrics, endocrinology and rare diseases. He has a Ph.D. in Chemistry from UC Berkeley and subsequently obtained an M.D. from the Yale School of Medicine. He completed his clinical training in pediatrics at Johns Hopkins Hospital, followed by specialty training in pediatric endocrinology at UCLA (as a recipient of the Pediatric Scientist Development Program training grant). He then served as an assistant professor at UT Southwestern Medical Center, followed by his first industry position at Genentech, in which he was involved with regulatory approvals related to rare, life-threatening childhood diseases. Afterwards, he has worked at earlier stage, smaller companies and has helped launch several (now) clinical stage programs focused on rare genetic and pediatric diseases. He has also held positions at Ascendis Pharma, Spruce Biosciences and, most recently, at BridgeBio, where he is currently VP of Clinical Development. He maintains double-board certification in General Pediatrics and Pediatric Endocrinology and is an actively licensed physician in California.

Eric David, M.D., J.D.
BridgeBio

Eric Michael David is CEO of gene therapy at BridgeBio. He was a co-founder of Organovo, where he most recently served as Chief Strategy Officer and Executive Vice President of Preclinical Development. Prior to Organovo, Dr. David was an Associate Partner at McKinsey & Co, where he served stakeholders across the healthcare spectrum including biopharmaceutical companies, private equity firms, large public and private healthcare systems, academic medical centers, and foundations on topics ranging from operations to M&A and R&D strategy. He was also Assistant Professor at The Rogosin Institute, adjunct faculty at The Rockefeller University, and a lecturer in Medicine at Weil Cornell Medical College. Dr. David received his clinical training in internal medicine at New York Presbyterian Hospital / Weill Cornell, his M.D. from Columbia University College of Physicians and Surgeons, his J.D. from Columbia Law School and his B.A. in physics and fine arts from Amherst College. He is licensed to practice medicine in California and New York, and admitted to the Bar in New York.

Steven Gray, Ph.D.
University of Texas Southwestern

Dr. Steven Gray earned his Ph.D. in molecular biology from Vanderbilt University in 2006, after receiving a B.S. degree with honors from Auburn University. He performed a postdoctoral fellowship focusing on gene therapy in the laboratory of Jude Samulski at UNC Chapel Hill. He is currently an Associate Professor in the Department of Pediatrics at the University of Texas Southwestern Medical Center. Dr. Gray is the director of the UTSW Viral Vector Facility and maintains affiliations with the Department of Molecular Biology, the Department of Neurology and Neurotherapeutics, the Eugene McDermott Center for Human Growth and Development, and the Hamon Center for Regenerative Science and Medicine at UT Southwestern. Dr. Gray's core expertise is in AAV gene therapy vector engineering, followed by optimizing approaches to deliver a gene to the nervous system. His research focus has also included preclinical studies to development AAV-based treatments for neurological diseases, some of which have translated into clinical trials.

Nisha Jain, M.D.
Takeda Pharmaceuticals

Nisha Jain, M.D. is the Global Clinical Development Lead, Rare Genetic Disease and Hematology at Takeda Pharmaceuticals. She formerly served as Global Head LCM, Rare Blood Disorders at Sanofi Genzyme.

Gregory LaRosa, Ph.D.
Pfizer

Gregory LaRosa, Ph.D., is Vice President and Head of Scientific Research in Pfizer's Rare Disease Research Unit (RDRU). Prior to this role, Greg was the Chief Scientific Officer, and prior to that was VP, Head of Biology for the RDRU. Greg is responsible for RDRU portfolio strategies including external plans and monitoring the pre-clinical and clinical project progression. Greg received a Ph.D. from Harvard University (Division of Medical Sciences) in Molecular, Cellular, and Developmental Biology, and has 30 years of experience in rare disease and inflammation drug discovery and development. Prior to joining Pfizer in July 2012, Greg worked in several start-up and midsize biotechnology companies, most recently serving as President and CSO at BIKAM Pharmaceuticals, Inc., Cambridge, MA. At BIKAM, Greg led the internal team charged with the discovery and validation of novel small molecule pharmacologic chaperones for the rod cell visual pigment, with the goal to correct the misfolding and trafficking of mutant rhodopsin that causes Retinitis Pigmentosa.

Gallia Levy, M.D., Ph.D.
Spark Therapeutics

Dr. Gallia Levy is the Chief Medical Officer at Spark Therapeutics with responsibility for setting the global development strategy.Gallia was previously VP and Global Head of the Rare Blood Disorders Franchise at Genentech/Roche, where she was responsible for the clinical development of treatments for hemophilia A and other rare blood disorders. Gallia first joined Genentech in 2009, working in both early and late-stage clinical development. She later moved to Portola Pharmaceuticals, where she led the registrational program for ANDEXXA®. She returned to Genentech in 2014, to lead the global clinical development program for HEMLIBRA® from Phase 1 to global registration for adults and children with hemophilia A. Gallia is board-certified in hematology and earned an M.D. and Ph.D. in Molecular and Cellular Biology from the University of Michigan, during which time she discovered ADAMTS13, responsible for Thrombotic Thrombocytopenic Purpura. She completed her residency in internal medicine at Stanford University and fellowship in hematology at the University of California, San Francisco. She also has worked at the Pasteur Institute, where she received an M.S. in Molecular and Cellular Biology from the University of Paris, VI and holds a B.A. from the University of California, Berkeley.

Federico Mingozzi, Ph.D.
Spark Therapeutics

Dr. Federico Mingozzi is the Chief Scientific Officer of Spark Therapeutics. He obtained his his bachelor's degree in biology and his Ph.D. in biochemistry and molecular biology from the University of Ferrara, Italy. He spent several years in academia at the Children's Hospital Philadelphia (CHOP), in the United States, and the French National Institute of Health and Medical Research (INSERM) and Genethon, in France. He served as faculty at the Pierre and Marie Curie University in Paris, France, and Universitat Autonoma de Barcelona, Spain. His research is focused on the study of in vivo gene transfer and immunology. He contributed to the development of gene therapies based on the adeno-associated virus (AAV) vector platform all the way to the clinic. He also developed several strategies to modulate immune responses in gene transfer.

Adora Ndu, Pharm.D., J.D.
BioMarin

Adora Ndu, Pharm.D., J.D., is Group Vice President, and Head of Worldwide Research and Development Strategy, Scientific Collaborations and Policy. In this role she oversees BioMarin's strategic risk and opportunity assessment across programs, enterprise-wide scientific communications, collaboration strategy, and Global R&D and Regulatory Policy. Adora serves on the Board of Directors for the Alliance for Regenerative Medicine (ARM), the Board of Visitors for Howard University College of Pharmacy and is a member of DIA's North American Advisory Board. Adora chairs the American Society for Gene and Cell Therapy (ASGCT) Regulatory Affairs Committee, and she is the immediate past chair for the ARM Regulatory Committee. Prior to BioMarin, Adora served in multiple roles at the Food and Drug Administration (FDA), including as Commander in the United States Public Health Service, and Director for FDA's Division of Medical Policy Development where she led the development of a broad range of FDA guidances and regulations. At FDA she also held leadership roles in the Office of Prescription Drug Promotion (OPDP), and she was involved in FDA's pharmacovigilance program. Prior to FDA, Adora completed a PGY-1 residency at Georgetown University Hospital and subsequently worked at Procter & Gamble Pharmaceuticals as a medical science liaison. In 2016, Adora was recognized by the Maryland Daily Record as a Leading Woman in the state of Maryland. Adora received her Doctor of Pharmacy degree from Howard University and her J.D. from the University of Maryland.

Frederick Porter, Ph.D.
Taysha Gene Therapies

Frederick W. Porter is the Chief Technical Officer at Taysha Gene Therapies. Dr. Porter has held key scientific and executive management positions in academia and the biopharmaceutical industry including positions at BridgeBio, Duke University, GlaxoSmithKline and Novartis Vaccines. Immediately prior to joining Taysha, he held the position of SVP of Technical Operations for BridgeBio's gene therapy unit where he led the development and manufacturing strategy for their AAV product portfolio. His previous vaccine experience includes executive positions at the Duke Human Vaccine Institute where he oversaw vaccine and medical countermeasure development as well as the startup of its clinical manufacturing program and commissioning of its manufacturing facility and development laboratories. As Head of Drug Substance R&D at GSK, Dr. Porter led a global technical development team responsible for antigen manufacturing process development for the GSK Vaccine portfolio. His R&D expertise includes production and characterization of vaccines, gene therapy vectors (AAV, Adenovirus, VEE), nucleic acid (mRNA) recombinant protein therapeutics. His commercial product experience includes HUMIRA and FLUCELVAX. Dr. Porter received his Ph.D. in Biochemistry from The University of Wisconsin-Madison.

S. Kaye Spratt, Ph.D.

BridgeBio Gene Therapy - Aspa and Adrenas Therapeutics

Kaye Spratt, Ph.D. joined BridgeBio Gene Therapy in 2019 as Senior Vice President, Regulatory Affairs, bringing 30 years of experience in the pharmaceutical industry, including over 5 years specializing in Regulatory Affairs. Her regulatory efforts have focused primary on the clinical development of rare pediatric and neurodegenerative disease. Prior to joining BridgeBio Bene Therapy, she served as Senior Vice President of Regulatory Affairs at the clinical-stage gene therapy company Abeona Therapeutics, Inc. where she secured US and Ex-US orphan designations, FastTrack, RMAT and Breakthrough designations for clinical stage product and secured Scientific Advice from local and national regulatory agencies. Earlier in her career, Dr. Spratt served as Nonclinical Director/Assay Development and Quality Control Director, with increasing responsibilities for over 17 years at Sangamo Therapeutics. At Sangamo she was a major contributor to early discovery and development for several IND candidates in multiple therapeutic areas. Dr. Spratt has a B.S. degree in Biology from Langston University and a Ph.D. in Microbiology/Molecular Biology from Meharry Medical College.

Daniel Takefman, Ph.D.
Takefman Gene Therapy Advisors LLC

Daniel Takefman, Ph.D., is Principal of Takefman Gene Therapy Advisors. Dan provides expert regulatory advice for the development and commercialization of cell and gene therapies. Previously Dr. Takefman was SVP and Head of Regulatory Affairs at Spark Therapeutics for 5 years. At Spark, Dr. Takefman supervised the submission through to approval of the FDA and EMA Luxturna (voretigene neparvovec) marketing applications. Dan also supervised the regulatory process for multiple AAV based investigation products including two additional Breakthrough Designation products: SPK-9001 for the treatment of Hemophilia B and SPK-8011 for the treatment of Hemophilia A. Dan was also the Chief of the Gene Therapy Branch within the U.S. Food and Drug Administration (FDA). He supervised the Chemistry, Manufacturing and Control (CMC) review process for all gene therapy products and for a variety of therapeutic vaccine products. Dan began his career at FDA in 1999 as a Postdoctoral Fellow and became a Staff Fellow shortly thereafter. Dr. Takefman holds a Ph.D. in microbiology from Rush University and a B.S. in microbiology from the University of Iowa.

Bartholomew Tortella, M.D.
Spark Therapeutics

Dr. Tortella graduated summa cum laude from St. Joseph's University in Philadelphia, a Jesuit institution. He received his M.D. from the Harvard Medical School and a Master in Theologic Studies (MTS) Ethics concentration from the Harvard Divinity School. He received his M.B.A. from the Columbia University School of Business. Dr. Tortella was a General Surgery resident at Boston's Beth Israel Hospital and an Instructor in Surgery at Harvard. He completed an NIH research fellowship at the UC, San Francisco and a Trauma and Critical Care Fellowship at the NJ Trauma Center, Newark. He is Board Certified in both Surgery and Surgical Critical Care and is a Fellow of both the American College of Surgeons and the American College of Critical Care Medicine. He served as Medical Director of EMS & NorthSTAR Medical Helicopter and Director of the Hahnemann Trauma Center, Drexel University College of Medicine, in Philadelphia where he led both Trauma and Surgical ICU multidisciplinary teams. Joining the Industry in 2003, he was a Medical Affairs Associate Director at Merck. In 2005, he joined Novo Nordisk, Inc., where he was Senior Director and Global Project Director for Trauma (Phase 3 study), Cardiac Surgery (Phase 2 study), and global clinician in diabetes and obesity Phase 1 and 2 trials. Joining Pfizer in 2010, he was the Senior Director in USA Medical Affairs for Hemophilia, promoted to Hemophilia Global Development Leader in 2013 and then again to Global Medical Affairs Product Lead for Hematology and Transplantation in 2014. In 2017, Endocrinology and Inborn Errors of Metabolism were added to his Rare Disease portfolio. Bartholomew is currently at Spark Therapeutics as a Vice President and Head of Medical Affairs. He has served on two FDA Advisory Committees and as a grant reviewer for the Patient Centered Outcomes Research Institute (PCORI) in Washington, DC. He is a church organist and resides in Newtown Square, PA with his spouse Judge Maureen F. Fitzpatrick (retired) and their son Lucas, a Physics undergraduate at Saint Joseph's University, Philadelphia.

Leonard Valentino, M.D.
National Hemophilia Foundation

Leonard A. Valentino, M.D., is the President and Chief Executive Officer of the National Hemophilia Foundation. He is a board-certified pediatric hematologist oncologist and practiced at Rush University Medical Center where he was a Professor of Pediatrics, Internal Medicine, Immunology-Microbiology and Biochemistry and the Director of the Rush University Hemophilia and Thrombophilia Center in Chicago, IL, USA for more than two decades until he retired from academic medicine in 2013. Dr. Valentino then worked in the biopharmaceutical industry for seven years at Baxter Healthcare, Baxalta, Shire, and most recently at Spark Therapeutics, where he was Vice President and strategy lead for hematology. During his long career as a hematologist, he treated many patients with hemophilia, von Willebrand Disease, platelet disorders and rare bleeding disorders, as well as those with hereditary thrombotic disorders. He has published more than 160 peer-reviewed manuscripts and participated in phase 1, 2 and 3 clinical research trials as well as leading a basic science research laboratory investigating the molecular basis of joint disease in hemophilia patients. He joined the National Hemophilia Foundation in February 2020.

Kevin Williams, M.D., J.D.
Pfizer Rare Disease

Dr. Kevin Williams learned about patient centricity before it was a term from the best of the best - his father, one of the first African-American physicians in his hometown of Baton Rouge, LA. Be it nature or nurture, he has loved serving patients his entire life - from hands on interactions in an HIV medical practice after graduating from the UCLA School of Medicine to research and policy that addressed and advanced critical issues focused on access to care for patients and the impact of access on outcomes. Earning a Master's in Public Health from the UCLA School of Public Health and a Law Degree from Harvard Law School helped him see the need to serve patients in a different way. He joined Pfizer in 2004 working in the field medical organization to support Pfizer's efforts in HIV. Moving through various roles of increasing responsibility, Dr. Williams has been the Chief Medical Officer of Pfizer's Rare Disease business unit since May 2016 and now leads a global organization of more than 200 purpose-driven medical professionals. Collectively, his organization urgently and intentionally create the essential two-way communication between people living with and impacted by rare diseases and people working to discover and share the breakthrough science that will address their unmet medical needs. Dr. Williams loves his job and feels proud that he is living his purpose, like his dad taught him, serving patients one person at a time.

Disclosures

K. Beaverson
Pfizer, Inc.; Salary; Employee

K. Bharucha
BridgeBio; Salary; Employee

E. David
BridgeBio; Salary, stock; Full time management position

S.J. Gray
Taysha Gene Therapies; Possible royalties; Inventor
Asklepios Biopharma; Royalties; Inventor
Abeona Therapeutics; Royalties; Inventor
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Sarepta; Consulting fee; Advisory board membership
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G. Levy
Spark Therapeutics; Salary; Employee.
F. Hoffman-La Roche AG; Officer and shareholder

F. Mingozzi
Spark Therapeutics; Salary, equity holder; Employee

Disclosures

F. Porter
Taysha Gene Therapies; Salary and ownership interest; Chief technical officer
BridgeBio Gene Therapy; Salary and ownership interest; SVP technical operations

S.K. Spratt
BridgeBio; Employee

D.M. Takefman
Abintus Bio, Inc.; Scientific advisory board member
Paid consultant for several cell and gene therapy companies

B.J. Tortella
Spark Therapeutics; Employee

K.W. Williams
Pfizer; Salary; Employment