BIO BUZZ

THE OFFICIAL SHOW DAILY

ISSUE 3

JUNE 3-6, 2019 | PHILADELPHIA, PA | #BIO2019

BIO International Convention
The Global Event for Biotechnology

MEET OKLAHOMA BIO

Linear Health Sciences

Oklahoma City's Linear Health Sciences has developed the Orchid Safety Release Valve (Orchid SRV) – a quick-release IV valve that protects against accidental dislodgement that results in pain to the patient and loss of medication. The Orchid SRV is currently pursuing FDA clearance and prepairing for a commercial launch.

Linear Health Sciences was chosen as a semifinalist in the 2016 Medtech Innovator competition and received a scholarship to participate in the Medtech Innovator Virtual Accelerator Program to focus on their product concept for the Orchid SRV.

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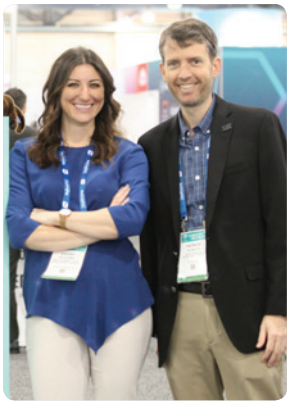


THURSDAY

REGISTRATION	BIO BUSINESS FORUM	BIO EXHIBITION HOURS
6:30AM TO 4:30PM	7:00AM TO 4:30PM	10:30AM TO 4:30PM

MUST-SEE EDUCATIONAL PROGRAMMING

For a complete list of sessions and events please visit convention.bio.org/sessions

TODAY'S SUPER SESSION

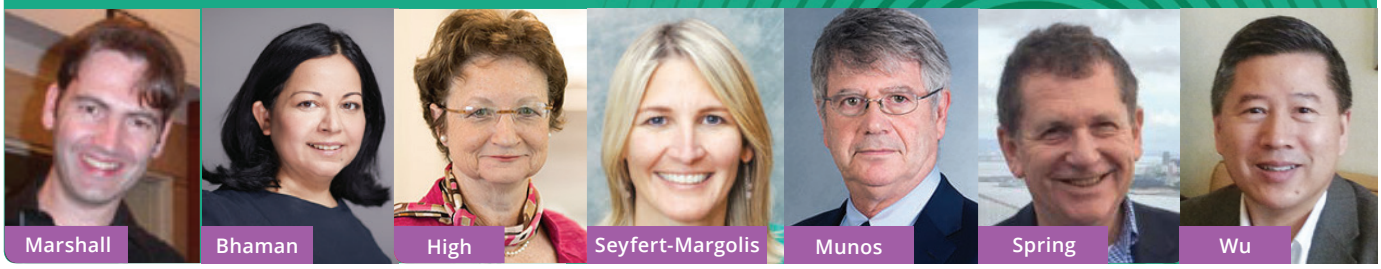
NATURE BIOTECHNOLOGY AND SCIENTIFIC AMERICAN WORLDVIEW: BIOTECH INNOVATION IN A FASTER FUTURE

12:00PM TO 1:30PM | ROOM 113ABC, LEVEL 100

MODERATOR: Andy Marshall, *Chief Editor, Nature Biotechnology*

SPEAKERS: Maina Bhaman, *Partner, Capital Funds, Sofinnova Partners*
Kathy High, *President and Head of Research and Development, Spark Therapeutics*
Vicki Seyfert-Margolis, *Founder and CEO, MyOwnMed*
Bernard Munos, *Senior Fellow, FasterCures; Founder, InnoThink Center for Research in Biomedical Innovation*
Nick Spring, *Partner, Life Sciences US, Alten Calsoft Labs*
Jinzi J. Wu, *PhD, Founder, Chairman, and CEO, Ascletis Pharma Inc.*

DON'T FORGET..... There are more than forty dynamic presentations open to all attendees running from 10:45-12 and 1-3. The company presentation theaters are located in Hall B next to the entrance of the Business Forum.



MERCK CEO FRAZIER: SOLVING DRUG ACCESS PROBLEM IS KEY

By Chris Morrison

In a wide ranging discussion that touched on the drug pricing debate, cutting edge biotechnologies, and his own obituary, Kenneth Frazier, chairman and CEO of Merck & Co., discussed the future of his company and the future of the biopharmaceutical industry during a fireside chat at the BIO International Convention on Wednesday morning.

Frazier, an attorney and native of BIO 2019 host city, Philadelphia, has been with Merck since 1992 and CEO since 2011. During the session he lauded Merck's medicines including its experimental Ebola vaccine, new antibiotics, the "revolutionary" early HIV medicine Crixivan as well as the juggernaut immuno-oncology therapy Keytruda.

"Keytruda clearly is a transformative medicine with evidence that it works across 25 tumor types," he said, noting that Merck is moving into new tumors and combination therapies to increase the amount of patients who can benefit from the drug, and has 20 new oncology drug candidates in its pipeline.

But Frazier was most animated when defending the system that makes taking on the risk to create those medicines in the first place possible. "We try to do the responsible thing in pricing and marketing," he said. But at the same time, he doesn't "apologize for being [part of] a profit-driven industry. We have to defend capitalism as well."

"It's capitalism that has lifted billions of people out of poverty and that allows us to develop these drugs," he said. The discussion about drug prices is an important one, and even if 80% of people want industry to lower drug prices, "100% of people want new cures," he said. Those cures cannot be discovered and developed without access to the capital markets. "You can't get access to capital without a return on investment that is commensurate with the huge risks we take in this business," said Frazier. "Our business has a noble purpose, but the capital markets don't go to church on Sunday or to synagogue on Saturday."

Ultimately the question is how do we get today's patients access to today's medicines without hindering the drug industry from developing the next generation of medicines, he said. No company that's just driven by maximizing profit could stay in business for 130 years, as Merck has, and "I see my goal to optimize return on investment and optimize patient access."

Society must recognize that biopharmaceutical companies take on risk well before the advance is evident, Frazier said. The fundamental question becomes "If we are successful, will there be a functioning market out there?" For the market to remain functional, we must address the problem of out-of-pocket costs for American patients, he said. "People are paying too much for their drugs, and this is largely a function of a reimbursement system that in my view is highly inappropriate," said Frazier. Merck's discount to various players in the drug supply chain was on average 45% last year, he said, but patients pay co-pays at the pharmacy counter that don't reflect those rebates. "We think rebates should be passed through to the patient at the pharmacy counter," he said.

Frazier held up the biopharmaceutical industry as one of three industries where the US leads the world, alongside high tech and entertainment (he name-checked Beyonce). "We need to make sure we don't destroy that when we're trying to solve the problem of affordability."

The CEO declined to describe what Merck might look like in ten years, only that it would certainly have a different CEO. But "we're committed to pushing the frontiers of human biology and research," said Frazier. "If we stick with the science we will have great opportunities down the line."

RECOGNIZING A FEW WHO HAVE HELPED SHAPE THE INDUSTRY

By Michael Eisenstein

Before the start of Wednesday morning's Keynote Address by Jamie Dimon, Chairman & CEO at JPMorgan Chase & Co., BIO President and CEO James Greenwood took the opportunity to mark the midpoint of this year's BIO International Convention and to honor the achievements of some leading figures in the biotechnology world.

He began with a tribute to Janet Woodcock, Director of the Center for Drug Evaluation and Research at the Food & Drug Administration, and recipient of this year's Biotechnology Heritage Award from the Science History Institute. "Janet oversaw the transition from the 'safety-first' era of the 90s to the embrace of the patient's voice," said John Maraganore, Alnylam CEO and outgoing chairman of BIO.

Maraganore subsequently took the stage to offer BIO's highest honor, a prize named for the late Genzyme founder and orphan disease drug development pioneer Henri Termeer. This year's recipient of the Henri A Termeer Biotechnology Visionary Award was Emil Kakkis, president and CEO of Ultragenyx, a company specializing in rare disease indications. Kakkis is also founder of the Every Life Foundation, an organization designed to mobilize patient-advocates, and Kakkis spoke of his and Termeer's shared vision of the role of biotechnology in transforming patients' lives. "We agreed that the reputation of a biotech company is sometimes not based on saving hundreds or thousands of lives, but what the company is willing to do for one patient," said Kakkis.

Finally, Maraganore took the opportunity to welcome his successor as BIO Chairman, Ovid Therapeutics CEO Jeremy Levin. Levin spoke of the industry in terms of its covenant with patients and its compact with society, and pledged to help steer the organization towards continuing innovation even in the face of political and public furor over drug pricing and access.

Celebrating Leaders Reception

More than 250 leaders *in biotechnology came together for an evening of networking including biopharma CEOs and BIO board members. During this reception, the Governor of the Year award was presented to Governor Phil Murphy of New Jersey.*

JAMIE DIMON TACKLES RISING HEALTH CARE COSTS, DIVERSITY CHALLENGES AND MORE

By Renee Morad

Jamie Dimon, chairman and CEO of JPMorgan Chase & Co., headlined a keynote address this morning at the 2019 BIO International Convention. He chatted with Jim Greenwood, president and CEO of BIO, about what drives him, what he learned from fighting throat cancer and how he would fix some of our nation's most pressing challenges, from rising health care costs and climate change to boosting diversity in the workplace.

"The root of you comes from your parents and the values you have," Dimon said. Raised to believe that he should do his part to make the world a better place, he has always sought opportunities to make a larger contribution to society, he shared.

In 2014, Dimon was diagnosed with throat cancer, and he said his experience fighting cancer taught him to live more deliberately. "I eat better, exercise more and am more thoughtful about certain things," he said. "After you've had cancer, you know there's an end date to life and you treat things a little differently."

He urged all of America's youth—including boys—to get the HPV vaccine, which is one of the main causes of some types of throat cancer.

With healthcare spending expected to hit 19.4% GDP in the next decade, Dimon acknowledged that we have the best pharma, biotech, innovation and treatment centers in the world, but also some of the worst outcomes, including rising health care costs for patients, an opioid epidemic and an obesity problem that drives cancer, depression, stroke and diabetes.

To tackle rising health care costs, Dimon recently partnered with Amazon's Jeff Bezos and Berkshire Hathaway's Warren Buffett on health care venture Haven that aims to improve health care for employees, using a model similar to Amazon's small-scale operation during its beginning stages. A major component of this initiative is to advocate for the patient and serve as an ally to clinicians, industry leaders, innovators and policymakers to improve patient care and costs.

Dimon recently eliminated health insurance deductibles for all JPMorgan Chase & Co. employees earning less than $60,000 per year.

When BIO's Greenwood asked Dimon what he would do differently if he were to become president—though he said he has no plans to run for presidential nomination—Dimon detailed dreams of inner cities that do not leave poor children behind, a push for more affordable education and greater efforts to tackle climate change.

Dimon is also committed to increasing diversity in the workplace, with many diversity and inclusion initiatives successfully at play at JPMorgan Chase & Co. "Wall Street is way ahead of everybody else," he said. "If you're the boss, you have to sit with people at the table who are different than you."

"American innovation is unbelievable," Dimon said, adding that it's time to acknowledge the problems in our country and do a better job of taking care of the American public.

U.S. AS A GLOBAL LEADER FOR PATIENT ACCESS

By Renee Morad

Some 95 percent of cancer drugs launched around the globe are available in the U.S. Given that the U.S. is a global leader in ensuring patients have access to the newest therapies, the country has a profound impact on patient treatment and outcomes around the world. During the panel, Global Perspectives on Patient Access, speakers emphasized the U.S.'s role on access and the need for transparency in drug pricing at the global level.

"The U.S. has led the way in drug approvals and drug development, and now we have a change in administration and new ideas," said Pam Traxel, vice president for alliance development and philanthropy for the American Cancer Society Cancer Action Network. "There's a much more global role to think about in terms of access."

There are a number of proposed solutions, from reference pricing to boards that would enable states to set "allowable rates" for certain high-cost drugs and other ways to reduce drug costs. While there's no clear solution, it certainly remains clear that drug pricing—with an emphasis on improving patient access—should be at the forefront of conversations moving forward.

The panel also touched on what patient access actually means, and how it can take on different meanings for different people. In cancer, there is a lot of data about what access to drugs and treatments means for patients. In breast cancer, women with triple negative breast cancer are 53 percent more likely to die if they have to wait 90 days to get chemotherapy. "Without quick access in the cancer space, people die," Traxel said. "Now, a lot of people are benefitting from having quick access in the U.S."

The panelists agreed that there's an enormous need to continue innovating, but it could be helpful to remain laser-focused on the people who will need these drugs and what they can truly afford. There was a shared hope among the speakers in the room: by recognizing and expanding on the U.S.'s role as a global leader, perhaps patient access will also grow and more lives will be saved around the world.

BUILD-A-BEAR WORKSHOP

BIO partnered with Rubye's Kids (rubeyskids.org) to include Teddy Bears in duffle bags that are distributed to children entering shelters. BIO attendees dressed teddy bears from the Build-A-Bear Workshop (King of Prussia Mall). 500 personalized bears will be delivered!


Nordic

THE VIKINGS ARE BACK!

Four years since the halls last echoed to the sound of Abba, the Nordic Pavilion is back. Sweden, Norway, Finland and Denmark have joined forces to highlight their respective strengths.

Iris Ohn, who is responsible for life science investments in the west of Sweden is particularly happy “Digitilisation and precision medicine are now the buzzwords in the Nordics and BIO International convention gives us the perfect showcase for the host of new companies springing up in these areas. “

NEW PAVILIONS

Uraguay

New Zealand

Poland

Rendering from BizJournal

IT STARTS WITH ONE: STEPHEN TANG AND THE FUTURE OF BIOTECHNOLOGY IN PHILADELPHIA

By Sara Reisert, Science History Institute

A native of Wilmington, Delaware (Philadelphia's neighbor to the south), and the child of two scientists, Stephen Tang was well aware of Philly's University City Science Center, the nation's first and largest urban research park. Little did he know that he would serve as its CEO for 10 years and in the process change Philadelphia's scientific research landscape and set it up for major growth well into the 21st century.

Tang's impact on the Science Center's growth from 2008 to 2018 cannot be overstated. Under his tenure the center transformed from a traditional real estate–focused research park to an innovation powerhouse. Perhaps most vitally, the Science Center's campus in Philadelphia's University City neighborhood expanded from 17 to 27 acres and creating a new complex named uCity Square. The innovation-focused development springing to life under Tang's vision promises to be a game changer: "The kind of vibe we'd like to have here is similar to what they have in Mission Bay, San Francisco, where they have a residential component tied to the actual office and lab for innovation," said Tang. "It's actually something that goes beyond what iconic places like Kendall Square have. Kendall Square has great space for labs and offices, but not much in terms of residential or retail. I think that we're hoping to bring all that together."

In addition to living and retail space the project includes: 3711 Market, a 154,845-square-foot building with offices and wet labs; 3737 Market, which at 14 stories has 334,000 square feet of clinical, medical, wet lab, and office spaces. It's anchored by Penn Presbyterian Medical Center of University of Pennsylvania's Health System (as well as Spark Therapeutics before they sold to Roche earlier this year); and 3675 Market, where the Science Center will occupy 20,000 square feet of office space for its headquarters. Another 5,000 square feet are set aside for First Hand (an educational initiative that combines STEM and the arts) and 127,000 square feet for offices and labs for the Cambridge Innovation Center.

Also joining the fun at 3675 Market is Amicus Therapeutics. Amicus's commitment in the building totals 75,000 square feet of office and lab space over three floors and is expected to be open in the second half of 2019. The space will eventually accommodate up to 200 employees. "We're thrilled to welcome Amicus Therapeutics to 3675 Market," says the Science Center's new president and CEO Steve Zarrilli. "The establishment of the Global Research and Gene Therapy Center of Excellence is a testament to the vitality of the vibrant community here at uCity Square and Philadelphia as a leader in biotechnology and gene therapy research."

But uCity Square is about more than just big players moving in. "Over the past couple of years we've spoken about the pillars of not just innovation but access and inclusion," said Tang. "Because 3675 [Market] will be the physical manifestation of our connection to the neighborhoods, my hope is that we can be an inspiring place for entrepreneurs to participate and find their way into well-paying jobs and participate. If we do that, we'll begin to chip away at the disparity. I believe we're ideally situated to make that happen."

Between uCity Square, Schuylkill Yards (a 20-year, $3.5 billion project to create a hub for technology and life sciences), and Penn Center for Innovation (created in 2014 and has facilitated at least 24 start-up spinoffs), Philadelphia's University City neighborhood may be the most exciting biotech region in the country.

Stephen Tang: it starts with one.

To learn more about the history of biotechnology, visit the Science History Institute at 315 Chestnut Street while you're in Philadelphia! Or visit us online at sciencehistory.org.

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Catalent Biologics provides advanced technologies and integrated solutions for biologic and biosimilar development and manufacturing, from DNA to aseptic fill/finish and commercial supply, through its extensive biologics network including: Bloomington, Indiana, where the company recently announced a twentieth commercial launch of a fill/finish product, and Madison, Wisconsin, home of Catalent Biologics' proprietary GPEx® technology for stable, high-yielding mammalian cell lines, with eleven approved molecules. Through the services offered across the two sites, Catalent is able to provide biopharmaceutical firms with a single, integrated partner supporting a wide range of clinical and commercial needs.

In January 2019, the company announced that it had commenced a $200 million capital investment in the Biologics business to expand drug substance manufacturing capacity and drug product fill/finish capacity due to projected growth among existing and future customers. The investments, phased over a three-year program, are being undertaken at both the Madison and Bloomington sites. This announcement followed an earlier announcement that it was to invest $14 million in packaging capabilities at Bloomington.

Mammalian cell culture capacity will be increased at Madison with the build out of two new suites, each with a 2 x 2,000-liter single-use bioreactor system, providing additional clinical and commercial production capacity at the 2,000 or 4,000-liter batch scale. Work is expected to be completed by mid-2021 and will double Catalent's commercial biomanufacturing capacity.

Additionally, fill/finish capacity at the Bloomington site will be expanded by 79,000 sq. ft., with both GMP and non-GMP capabilities. A high-speed flexible vial line, utilizing both ready-to-use (RTU) components and bulk filling, at a filling speed of 300 units per minute, will be installed along with a high-speed flexible syringe/cartridge line with a filling speed of over 300 units per minute, and a fully automated vial inspection machine. The previously announced $14 investment in packaging will be completed in 2019 and complements the new investments to enable one of the most comprehensive packaging offerings for a Contract Development and Manufacturing Organization in North America.

Commenting at the time, Barry Littlejohns, President, Catalent Biologics and Specialty Drug Delivery said, "The expansions at both sites will support our customers' development programs and commercial launches,". He added, "Catalent's continued investments in innovative technologies and flexible capacity allow us to offer the most comprehensive solutions to bring important and innovative treatments to market faster."

Opened in April 2013, Catalent Biologics' Madison facility specializes in development, biomanufacturing and analytical services for new biological entities and biosimilars. The facility was designed for cGMP production from 10 to 4,000-liter scale, providing flexibility in batch size to meet customers' needs.

In 2018, the site celebrated a significant milestone when the eleventh biologic therapy utilizing the GPEx technology was approved for commercial use.

Catalent's 875,000-square-foot biologics development and manufacturing facility in Bloomington employs a growing staff of 900 employees, with deep expertise in sterile formulation and extensive biomanufacturing and drug product fill/finish capacity across liquid and lyophilized vials, prefilled syringes, and cartridges. The site also recently achieved regulatory approval for a twentieth commercial product.

MORE ABOUT CATALENT BIOLOGICS

Catalent Biologics has 20+ years' experience in development, manufacturing, and analytical services for new biological entities, biosimilars, and antibody-drug conjugates. Catalent has worked with 600+ mAbs and 80+ proteins, and more than 115 clinical trials. 11 marketed products have used GPEx® cell line engineering technology, and a further 20 commercially-approved products that have employed Catalent Biologics' capabilities through to aseptic fill/finish. Using advanced protein improvement technology and tailored solutions from DNA through to clinical and commercial supply, Catalent Biologics brings better biologic treatments to patients, faster.

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AMPLIFYING THE VOICES OF RARE DISEASE PATIENTS

By Michael Eisenstein

Every patient matters. But this is especially true when developing medicines for rare diseases, where published research is scarce and there may be just a few thousand or even a few hundred patients scattered around the world. At Wednesday morning's session "Telling the Story – Collaborative Research Models for Rare Diseases," Anne Pariser, Director of the Office Rare Diseases Research at the National Center for Advancing Translational Science, moderated a discussion on opportunities for rare disease patients to take the helm in guiding research into their conditions.

Vanita Sharma, Executive Director of Patient Advocacy and Public Policy at Strongbridge Pharma, described her efforts in developing a clinical program around an acquired drug for periodic paralysis. This condition affects 4–5,000 patients in the US, although Sharma suspects more remain undiagnosed—and after bringing patient-advocates to the table, she recognized that even patients with a formal diagnosis had to struggle to get there.

Many rare diseases have advocacy groups and patient networks, but it can still be a challenge for these communities to connect with clinical researchers and companies interested in developing treatments. Vanessa Boulanger, Director of Research Programs at the National Organization for Rare Disorders (NORD) described a solution developed by her nonprofit. NORD uses their 'IAMRARE' platform to help these communities set up disease-specific registries, where patients can share their own data, symptoms and experiences. "This is designed to capture patient-reported, research-grade data on the natural history of rare conditions to support and inform the design of patient-centered clinical trials," said Boulanger.

NORD has also collaborated with Trio Health, a healthcare analytics company, on a newly-published book called "The Power of Patients". Panelist Brent Clough, Trio's CEO, described how his company helped collect individual patient experiences for this book, as well as broader data on rare disease symptoms, diagnosis, and treatment. "They told their stories from their eyes—and it's heartbreaking," said Clough. "But this is all about creating awareness."

THE FUTURE IS BRIGHT FOR SOMATIC CELL GENOME EDITING

By Renee Morad

Scientific advances in human genome editing have proven that somatic cell genome editing holds great potential to treat or maybe even cure genetic diseases. During the panel, Scientific Advances in Genome Editing: Where Are We Today?, panelists shared insights on how recent advances are accelerating innovation, some of the challenges that stand in the way and how genome editing will become a mainstay in the future.

Biotech company CRIPSR Therapeutics is developing gene-editing therapy in treating rare blood diseases beta thalassemia and sickle cell disease using its proprietary CRISPR/Cas9 platform. It also hopes to use the technology to potentially treat cancer patients. The CRISPR-Cas9 gene editing tool is a breakthrough technology that gives researchers the ability to change an organism's DNA, so that they are able to remove or alter certain genetic material.

Caribou Biosciences was also represented in the discussion by chief scientific officer Steve Kanner. The company uses proprietary technologies to develop an internal pipeline of off-the-shelf CAR-T cell therapies, other gene-edited cell therapies and engineered gut microbes.

The panelists spoke of a sense of urgency to cure diseases but also a sense of responsibility to lead the patient down the right path. Sandy Macrae, CEO of Sangamo Therapeutics, said it's important on the path of innovation to identify areas where "the benefit is clear and the risk is as small as possible."

The panelists agreed that developing any medicine has a specific set of challenges tied to pharmacology, biology, engineering, manufacturing, and so on, but the bigger picture is: can we then apply those tools in the right way to the right biology to treat rare disease and other diseases?

Some of the more pressing challenges that genome editing innovators currently grapple with is delivery, or the sending of the technology to the organ of interest in the body, which depends on the modality you're using and what organ you're going to. It also becomes a challenge to determine how high the bar for editing should be. For some diseases, it's five percent, whereas other diseases may require 30 or 40 percent editing. Safety, of course, is also of utmost importance.

The panelists reaffirmed that the era of genome editing has arrived, and innovation will continue to accelerate. Someday in the future, these groundbreaking innovations will become a mainstay.

GoodDay BIO

Check out this week's episodes from our new morning show program, Good Day BIO, to see news and highlights from the BIO International Convention.

This fast-paced variety show will give you a behind-the-scenes look at the event's most talked about panels and exhibits, feature interviews with biotech leaders, patients and others including Halozyme's Helen Torley, Emily Kramer-Golinkoff of Emily's Entourage, BIO's new board Chair Dr. Jeremy Levin, and provide an engaging and shareable recap for your teams and coworkers back home.

View the playlist at convention.bio.org/gooddaybio/

TIPS FOR ALLIANCE SUCCESS: BUILDING URGENCY AND RELATIONSHIPS

By Chris Morrison

A panel of veteran biopharma deal makers offered strategic advice on how to avoid alliance pitfalls during a panel discussion on Wednesday afternoon at the BIO International Convention. The executives drew on both lessons learned from successful deals and, just as importantly, the ones that never made it over the finish line.

So much of a deal's eventual success depends on how it's struck in the first place, said Aradhana Sarin, chief business and strategy officer at Alexion Pharmaceuticals, referring to the hard work of relationship building. "You make the deal work after you sign it, before you sign it," echoed Sophie Kornowski, senior partner at Gurnet Point Capital and former head of BD at Roche. She said the best deals are when you can take the contract, put it in the drawer, and never take it out again. "Because you only take out the contract when there's a problem."

Sometimes the deals that fall apart at the eleventh hour are the ones that impart the most lasting lessons, the panelists agreed. In recalling one such negotiation, Rachna Khosla, VP business development at Amgen, said that while "none of us regret the decision to walk away, we continue to recognize the impact that the asset could have had on our organization."

Paul Biondi, head of strategy and BD at Bristol Myers Squibb advised business development executives to "act with a sense of urgency, because time kills all deals." If a negotiation drags on, that opens up a greater possibility that strategic alignment or company leadership might change. Competitive data could emerge. "Even inconsequential issues" that might add a week or so to a negotiation could put a deal at risk, he said.

Among the kernels of wisdom for small biotechs were practical guidelines for making sure your product candidate was ready for prime time and admonishments to think like the buyer when it comes to striking a deal. Deals can be scuttled with an unexpected problem related to the asset. For example, if you need to take an additional year of process engineering to scale up manufacturing, time is money. And failing to think through market access for an eventual product will sabotage your commercial forecasts.

But several panelists also described abandoning negotiations due to poor chemistry with the other deal party - "when the dating was so bad that you just knew how bad the marriage would be," said Sarin. "This is a people business," said Kornowski. "The first skill you want in the BD team is that they can read people."

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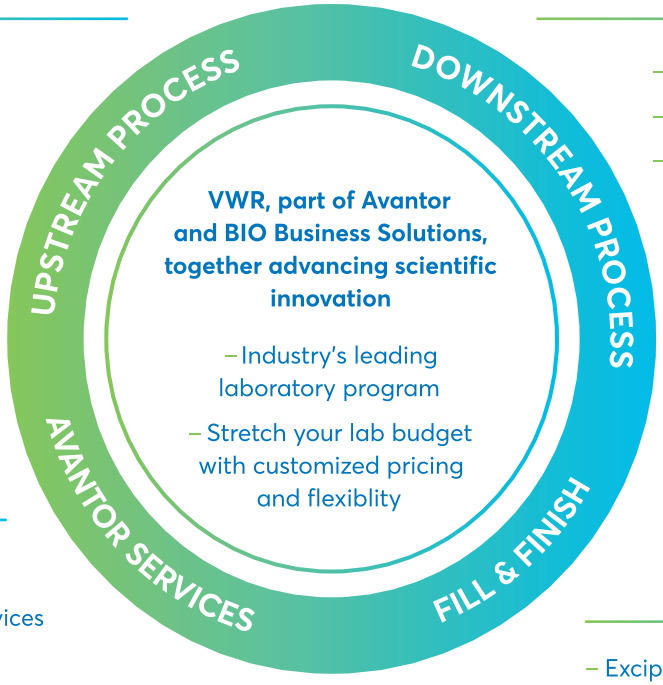

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THE CHALLENGES OF INTERCEPTING EARLY-STAGE CANCER

By Michael Eisenstein

There's no question that bringing a drug to market is difficult—but developing and launching an effective test for early detection can be even more daunting. In Wednesday's session, aptly-named "Climbing Cancer's North Face: The Challenges of Developing and Clinically Validating Biomarkers for Early Cancer Detection", panelists discussed their experiences on this front.

The appeal of early detection is undeniable, particularly for malignancies like lung cancer that are often diagnosed far too late. "Between 75 and 80% of lung cancers are diagnosed at stage 3 or later," said Mike Fisher, commercial director at Oncimmune. "These are very expensive to treat, and for stage 4 it's mainly palliative care." He noted that in Scotland, a test that shifts diagnosis to a more-treatable stage 1 or 2 could save the healthcare system £40,000 per patient.

But these trials are costly and complicated. Biomarker development typically entails a five-stage process: discovery, validation, retrospective testing, initial prospective testing, and finally, demonstration of mortality benefit. These latter trials are typically immense and long-lasting. In lung cancer, for example, the current gold-standard is the National Lung Screening Trial, which lasted nine years and required 50,000 participants. And the results were a mixed bag; although the low-dose CT scan tested in that trial offered good sensitivity, the specificity was poor. "Of all the positive tests, 96% of those were false positives," said Duncan Whitney, Head of the Early Detection Lung Cancer Initiative at Johnson & Johnson. Such false-positives could result in harm due to over-treatment.

his poor specificity does create opportunities for additional biomarkers to be introduced that boost testing accuracy, and the panelists were enthusiastic about the under-explored possibilities of multi-biomarker testing regimens. But it can be difficult to get buy-in from the private sector for development of early-detection tests, particularly since such tests must be priced low to achieve broad uptake. "We're talking, say, a $20 million investment for a product that you can charge $150 and it's going to take you ten years—try taking that to a VC," said Fisher.

But the panelists also offered signs of hope and progress. Wendy Alderton of Cancer Research at UK Cambridge described a plethora of projects underway at her institution for early diagnosis of lung, prostate, esophageal and other cancers. And Oncimmune is now moving into the final stage of testing for a promising lung cancer biomarker test, with a liver diagnostic test following close behind. "There certainly are a lot of challenges," said Whitney, "but I am extremely hopeful about what can be done in terms of survival in lung cancer."

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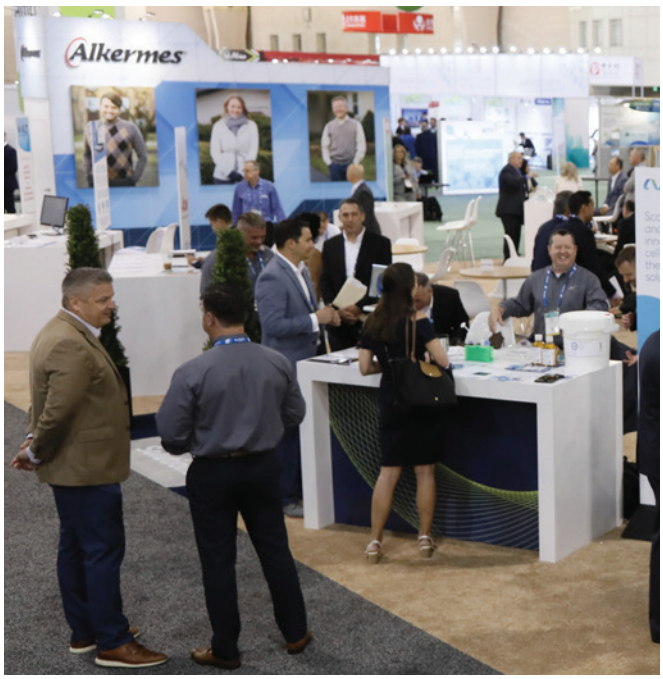

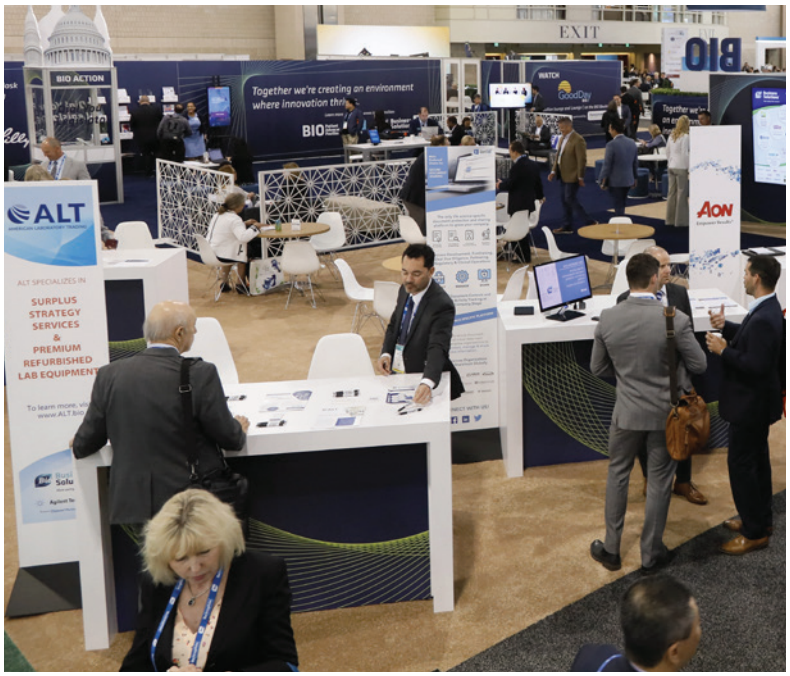

Max Schill is a passionate advocate for rare disease.
Max Schill, It Starts With One.

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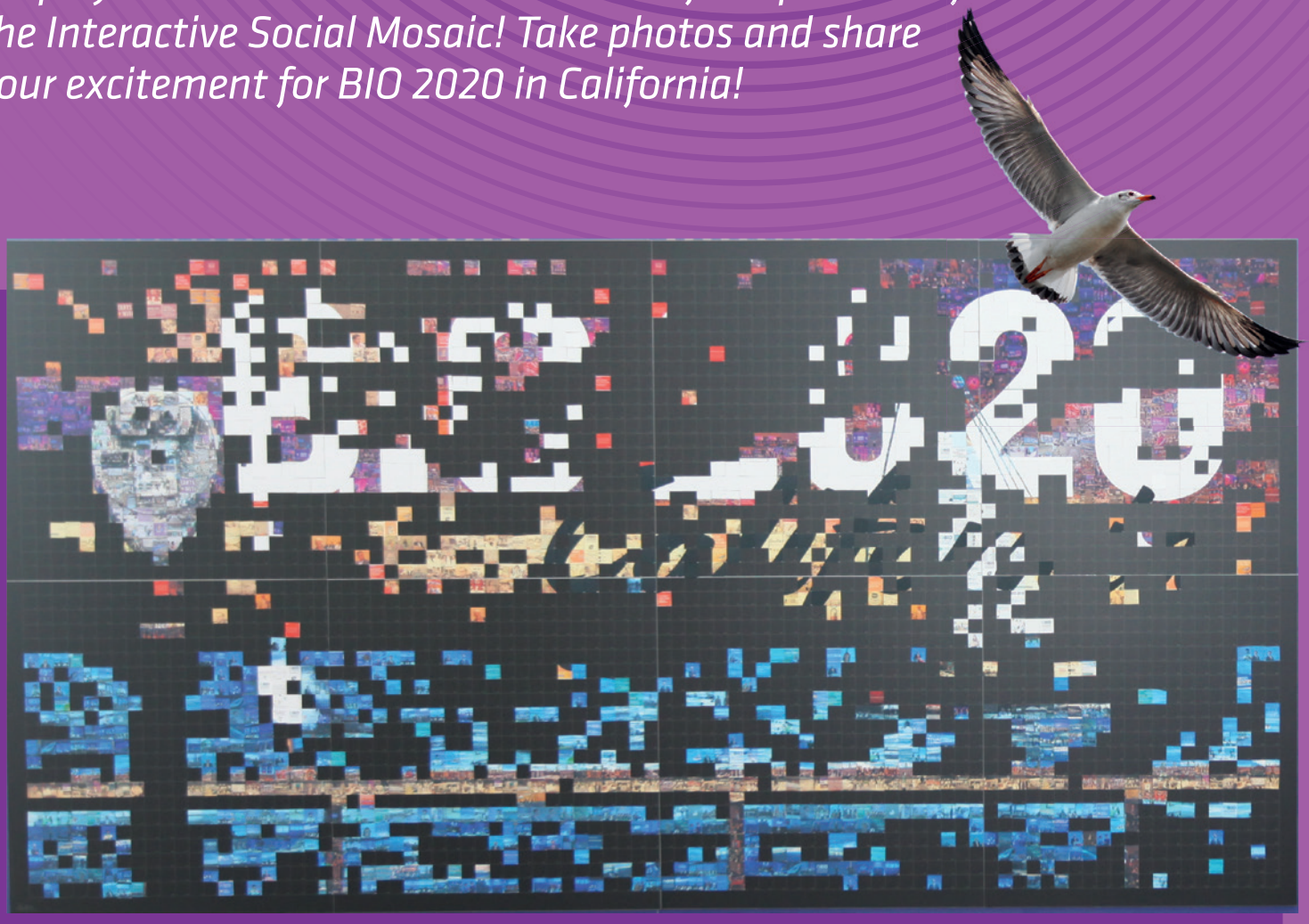

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