Biotech M&A and Partnerships: Innovation and Deal-Making in Challenging Markets



As part of Goodwin's exclusive programming during the BIO International Convention in Boston, we invite you to join us for a session spotlighting the evolving world of M&A and strategic partnerships in a rapidly shifting biotech landscape.

Through a dynamic fireside chat and expert panel discussions, we'll uncover innovative deal-making strategies, explore how biopharma companies are forging smart alliances, and reveal the pivotal decisions driving growth in unpredictable times.

Don't miss this opportunity to gain actionable insights, hear from industry insiders, and connect with the leaders shaping the future of biotech. This event is in partnership with PJT Partners.

Please RSVP **here** and see below for more details!

Date & Time: Wednesday, June 18 from 12:00 PM – 2:30 PM ET

Location: Goodwin's Boston Office, 100 Northern Avenue, Boston, MA 02210

12:00 – 12:30 PM | Registration and Lunch
12:30 PM – 12:40 PM | Opening Remarks
12:40 PM – 1:15 PM | Fireside Chat: Biopharma Strategy in Volatile Times

- Rob Masella, Partner, Goodwin
- Daniel Lee, Partner, Healthcare Group, PJT Partners

1:15 PM – 2:00 PM | Panel Discussion: Current Perspectives on M&A and Partnering: Finding Strategic Alignment

- Erini Svokos, Partner, Goodwin (Moderator)
- Rajeev Dadoo, PhD, COO & Managing Partner, SR One
- Daniel Rosan, Chief Financial and Business Officer, Ascidian Therapeutics
  2:00 PM – 2:10 PM | Audience Q&A & Closing Remarks

From Europe to the US: Crossing the Atlantic for Capital & Strategic Growth

As part of our week of premier programming during the BIO International Convention in Boston, we're bringing together industry leaders, investors, and strategic advisors for an engaging session on how European biotechs can successfully expand into the US market.

This dynamic lunchtime event will dive into unlocking US capital, driving strategic growth, and navigating the critical legal, business, and partnering pathways that fuel transatlantic success. Hear firsthand lessons from seasoned dealmakers and biotech executives in our expert panels and fireside chat and seize the opportunity to connect with key players shaping the future of global life sciences. This event is in partnership with Danforth Advisors.

Please RSVP **here** and see below for more details!

Date & Time: Tuesday, June 17 from 11:30 AM – 1:30 PM ET

Location: Goodwin's Boston Office, 100 Northern Avenue, Boston, MA 02210

11:30 AM – 12:00 PM | Registration and Lunch

12:00 PM – 12:45 PM | Panel: Unlocking US Capital: Legal and Business Pathways – The Mindset for European Biotechs

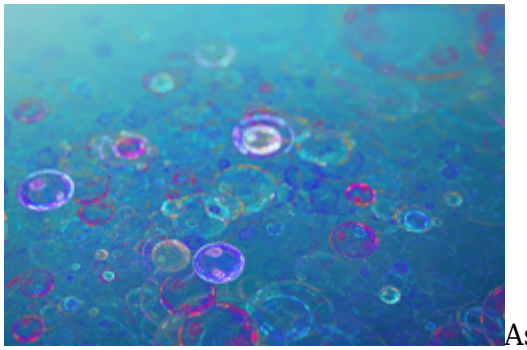
- Gregg Beloff, Co-Founder and Managing Director, Danforth Advisors
- Robert Puopolo, Partner, Goodwin
- Henry Capper, Managing Director, Head of EMEA BioPharma, J.P. Morgan

12:50 PM – 1:30 PM | Fireside Chat: Partnering and M&A for European Biotechs: Lessons from the Zealand/Roche Experience

- Tim Worden, Partner, Goodwin
- Eric Cox, Chief Commercial Officer, Zealand Pharma

Navigating China-Related Transactions:

Legal and Strategic Considerations

As part of Goodwin's week of exclusive programming during the BIO International Convention in Boston, we're excited to invite you to a session focused on China-based NewCos and the dynamics of cross-border dealmaking. China continues to be a dynamic hub for biotech innovation, and companies operating in this space are navigating new opportunities and evolving challenges.

Join us for a morning of insightful conversations exploring what it takes to launch, grow, and expand China-based NewCos—and how to successfully pursue international transactions in a rapidly changing environment. From legal and regulatory foundations to cross-border growth strategies, our expert panels will share practical perspectives and real-world experience to help guide your next move.

Please RSVP **here** and see below for more details!

Date & Time: Tuesday, June 17 from 8:30 AM – 10:30 AM ET

Location: Goodwin's Boston Office, 100 Northern Avenue. Boston, MA 02210

8:30 AM – 9:00 AM | Registration and Breakfast

9:00 AM – 9:05 AM | Welcome Remarks

9:05 AM – 9:45 AM | Panel: China NewCos – Strategic and Legal Insights

- Josha Berlin, Head of Corporate Alliances & Business Development, BioCentury Inc. (Moderator)
- David Chen, Partner, Goodwin
- Sue Yao, Executive Director of Licensing and Business Development, Kelun Biotech and Klus Pharma
- Regina Salvat, PhD, Principal, Forbion

9:50 AM – 10:30 AM | Panel: New Challenges and Opportunities in Cross-Border Transactions

- Wendy Pan, Partner, Goodwin (Moderator)
- Alan Wang, Partner, Goodwin
- Jimmy Zhuang, Assistant General Counsel – Business Development, Novo Nordisk
- Tim Opler, Managing Director, Healthcare, Stifel Institutional
- Jon Kiburz, VP Transactions, R&D Business Development, GSK
- Jesús Baena, Director BD&L Oncology, Novartis

AI & Drug Discovery Symposium: Revolutionizing the Future of Medicine



Jumpstart your week with a deep dive into the future of medicine as part of Goodwin's exclusive programming during the BIO International Convention in Boston. Join us for a dynamic symposium where industry leaders and AI pioneers come together to unveil how artificial intelligence is revolutionizing drug discovery. Don't miss this chance to explore groundbreaking technologies and connect with the minds shaping tomorrow's healthcare.

RSVP **here** to attend and see below for more details!

Date & Time: Monday June 16 from 1:00 PM – 4:30 PM ET

Location: Goodwin's Boston Office, 100 Northern Avenue. Boston, MA 02210

1:00 – 1:30 PM | Registration & Lunch

1:30 – 2:00 PM | Panel: AI Governance and AI Security

- Kaitlin Betancourt, Partner, Goodwin
- Jud Welle, Partner, Goodwin
- Tom Doughty, Chief Information Security Officer, Generate:Biomedicines

2:05 – 2:40 PM | Panel: Diligence Considerations with Tech Acquirers and IP Risks from AI in Drug Discovery and Development

- Marty Gomez, Partner, Goodwin
- Sarah Solomon, Partner, Goodwin
- Robert Carroll, Partner, Goodwin
- Hilary Eaton, CBO, Profluent
- Jen Asher, PhD, Founder and CEO, 1910 Genetics

2:40 – 3:00 PM | Networking/Coffee Break

3:00 – 3:30 PM | Fireside Chat: Advancing a New Era of Programmable Biology Through AI

- Joe Theis, Partner, Goodwin
- Mike Nally, CEO, Generate:Biomedicines

3:35 – 3:45 PM | FDA Insights on AI in Drug Development

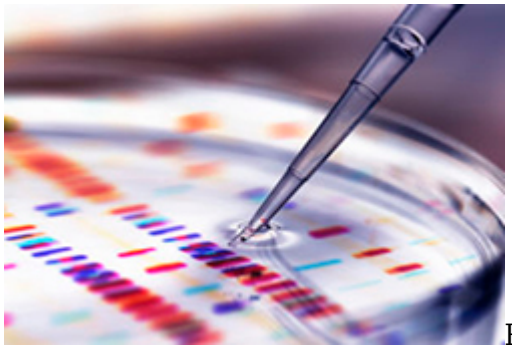
- Qi Liu, Co-Chair of CDER AI Council; Lead of CDER AI Review Rapid Response Team, U.S. Food and Drug Administration (*virtual*)

3:50 – 4:30 PM | Panel: Smarter Drug Development – The Role of AI in Regulatory Strategy

- Julie Tibbets, Partner, Goodwin
- Alexander Morgan, MD, PhD, Partner, Khosla Ventures
- Tracey Sikora, Vice President of Research & Clinical Programs of the National Organization for Rare Disorders (NORD); Co-Founder of Every Cure

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2nd BCLT Advanced Life Sciences Institute



Rapid advancement in life sciences technologies has made keeping up with the legal implications more important than ever. Join the **Berkeley Center for Law and Technology** for the **2nd BCLT Advanced Life Sciences Institute**, where you will learn from the experts about cutting-edge issues impacting your life sciences practice.

The programming will share key insights and best practices related to the rapid rise of AI in the life sciences and new trends for licensing, deals, and life sciences funding models. Expert will review key developments in the law (Section 112, obviousness-type double patenting), anti-counterfeiting and patient safety, and the ever-complex interplay of regulatory and IP exclusivities. Finally, don't miss in-depth discussions on future pandemic preparedness and use of trade secrets v. patents for portfolio protection!

The Advanced Life Sciences Institute will be launched virtually through **B-CLE** on May 21 and 22.

Registration is free and available to all, and CLE will be offered.

Goodwin Invites You to a Conversation with Rare Disease Community Leaders



In global observance of Rare Disease Day, Goodwin invites you to join us for a special awareness event on March 1, 2023 in our Boston office or virtually for those attending remotely to spotlight the critical work being done to address over 7,000 rare diseases that impact more than 300 million people globally.

Goodwin's Life Sciences Regulatory & Compliance team is bringing together global leaders in the rare disease community for a series of three fireside chats to discuss what inspires them, what challenges continue to face the rare disease community and rare disease patients, the work ahead in the global effort against rare disease, and what we can do to help. Our registration links and full agenda are below, and a networking reception will follow the in-person event in Boston.

A Conversation with Rare Disease Leaders (March 1, 2023) Agenda:

12:00 PM – 12:30 PM EDT | Welcome & Networking Lunch

12:30 PM – 1:00 PM EDT | Fireside Chat – The CEO View

- Justin Klee and Josh Cohen, Co-CEOs & Co-Founders Amylyx (via Zoom)
- Julie Tibbets, Moderator

1:00 PM – 1:30 PM EDT | Fireside Chat – The Patient View

- Bob Coughlin, Managing Director, JLL and Cystic Fibrosis Patient Advocate
- Julie Tibbets, Moderator
- Matt Wetzel, Moderator

1:30 PM – 2:00 PM EDT | Fireside Chat – The Policy View

- Tom DiLenge, Senior Partner, Global Public Policy, Regulatory & Governmental Strategy, Flagship Pioneering (formerly of BIO)
- Matt Wetzel, Moderator

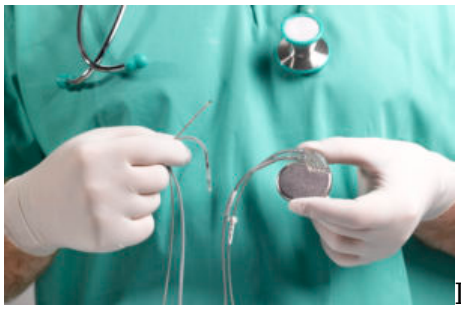
2:00 PM – 2:30 PM EDT | Networking Reception

Click **here** to register for the in-person event in our Boston offices.

Click **here** to register for the virtual event.

Planning For The End: Goodwin FDA attorneys Steve Tjoe and Susan Lee highlight key takeaways From FDA's draft guidances

proposing transition plans for medical devices marketed under EUAs or enforcement policies during the COVID-19 Public Health Emergency

During the COVID-19 public health emergency, the United States Food and Drug Administration (FDA) has issued hundreds of Emergency Use Authorizations (EUAs) and numerous enforcement policies to facilitate the availability of important medical devices. On December 23, 2021, FDA published two draft guidances setting forth the Agency's proposed process for transitioning the multitude of devices brought to market under these circumstances to full compliance with FDA requirements:

- Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "EUA Transition Draft Guidance"); and
- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "Enforcement Policies Transition Draft Guidance").

In our **recent Alert**, we summarize some key takeaways from FDA's proposed transition plan for manufacturers of devices marketed under a COVID-19 EUA ("EUA Devices") and devices marketed under one of more than 15 COVID-19 enforcement policies listed in the guidance ("Enforcement Policy Devices"). **Read More**

Federal Audits and Enforcement Actions of Telehealth Providers: Future Trends and Mitigating Risk

As the COVID-19 pandemic progresses and the expanded use of telehealth has appeared to stabilize over the past year according to a **July report from McKinsey & Company**, Federal agencies have continued the recent trend of enforcement actions and audits of telehealth providers.

On September 17, 2021, the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) and U.S. Department of Justice (DOJ) **announced their latest enforcement action**, totaling $1.4 billion, with approximately $1.1 billion involving alleged telehealth fraud. This is the latest action taken by enforcement agencies, with a **$143 million COVID-19 enforcement action announced in May 2021** and a **$4.5 billion telehealth enforcement action announced in September 2020**. These actions have focused in part on the use of telehealth to submit fraudulent claims to private payors as well as Federal health care programs. The May 2021 enforcement action involved fourteen defendants in seven Federal judicial districts and the September 2020 enforcement action involved over three-hundred defendants in fifty-one Federal judicial districts.

This most recent round of enforcement actions from September 2021 targeted telemedicine executives who were alleged to have paid physicians the nurse practitioners in exchange for ordering durable medical equipment, genetic testing, other diagnostic tests, and pain medications that were considered unnecessary. The government charged that items were ordered without patient interactions or minimal telephonic conversations, and that the physicians and nurse practitioners at issue had never even met or seen their patients. Additionally, in January 2021, HHS OIG announced a **series of audits** reviewing Medicare Part B payments to telehealth providers during the public health emergency to determine whether Medicare requirements were met. The first phase of audits focus on whether services such as evaluation and management, opioid use disorder, end-stage renal disease, and psychotherapy met Medicare requirements. The second phase includes additional audits regarding distant and originating site locations, virtual check-in services, electronic visits, remote patient monitoring, use of telehealth technology, and annual wellness visits.

While the long-term effects of Federal agency actions remain unclear, so long as telehealth is utilized at a substantial level, government agencies will likely continue to scrutinize telehealth industry practices to mitigate fraud, waste and abuse. Telehealth providers and others in the industry can decrease the likelihood and impact of being audited or charged in an enforcement action by structuring their compliance programs and operations to abide by Federal health care program requirements such as provider credentialing, sufficient medical necessity documentation, program integrity requirements and other coverage and reimbursement issues.

2nd Virtual Goodwin + KPMG @ JPMorgan Symposium – Day Two Recording



Goodwin's 2nd Annual Goodwin + KPMG @ JPMorgan Symposium kicked off Day Two of our Symposium with an overview of the effects of the pandemic on the biopharma market by Dale Raine, Managing Director and Co-Head of the European Healthcare Investment Banking at Lazard in conversation with Goodwin Life Sciences Corporate partner, Graham Defries. This chat was followed by a panel discussing global life sciences outlook, partnerships and M&A opportunities, and whether Europe will continue to be a focus for 2021 and beyond. The Symposium wrapped up with a fireside chat featuring the Carl Hansen, CEO and Tryn Stimart, CLO of AbCellera in conversation with Goodwin Life Sciences partner Deepa Rich, discussing drug discovery and the accelerated adoption of AI and machine learning in our new reality, and their path to one of the largest IPOs in biotech history.

View the Video

2nd Virtual Goodwin + KPMG @ JPMorgan Symposium – Day One Recording



Goodwin held the 2nd Annual Goodwin +KPMG @ JPMorgan Symposium on Wednesday, January 27th and Thursday, January 28th. The Symposium kicked off with industry luminary, Noubar Afeyan, Chairman and Co-Founder of Moderna sitting down for a fireside chat with Vice Chairman, Global Chair of M+A and Goodwin partner, Stuart Cable.

Following the fireside chat, there were three industry focused panels. The first panel, "The COVID Catalyst: Driving Innovation Mainstream," discussed how COVID-19 boosted innovation across the continuum whether it be devices, therapeutics, diagnostics, supply chain, or the dissemination of

needed products and services on a worldwide scale. The second panel, “COVID Gives Digital Health a Shot in the Arm,” addressed how digital health came into the spotlight in 2020 as a result of increased demand for virtual health. The first day wrapped with the panel, “How the 2020 SPACs Revolution Will Impact the IPO Market for 2021 and Beyond,” focused on the rise of SPACs in 2020 and how that will affect the IPO market moving forward.

View the Video: