FDA's Push for "Radical Transparency": Key Takeaways from the Agency's Publication of Complete Response Letters

On July 10, 2025, the U.S. Food and Drug Administration (FDA) **announced** publication of over 200 complete response letters (CRLs) issued in response to applications submitted to FDA for approval of drugs or biologics between 2020 and 2024. The FDA has described this move as a step toward the Agency's "broader initiatives to modernize and increase transparency."

CRLs are formal communications sent to applicants when the FDA has completed its review of an application but determined that it cannot approve the application in its current form. Until now, the Agency has only made CRLs available as part of larger approval package files on the Drugs@FDA online database (i.e., after product approval). While the CRLs released this week continue to be limited to approved products—and have been redacted to remove trade secrets and confidential commercial information—the FDA has, for the first time, provided these documents in a central database on **openFDA**. A few key highlights:

- While many of these CRLs have already been disclosed as part of the "Other Action Letters" section of publicly posted drug approval packages, some have not.
- There are multiple CRLs for supplemental New Drug Applications (sNDAs) that had not yet been disclosed, reflecting the fact that approval packages for sNDAs are not consistently posted in the same manner as original NDA approvals.
- Some of these CRLs were issued for products approved before 2020, suggesting that the CRL database scope may exceed the time frame identified in the FDA's announcement.
- At least one CRL has been posted for a product approved as recently as June 2025. For this product, no other portions of the approval package (beyond the label and approval letter) have yet been posted on Drugs@FDA.

Notably, the FDA's announcement references a 2015 analysis conducted by FDA researchers, which found that sponsor disclosures of CRLs did not consistently provide full detail regarding the Agency's specific concerns. The FDA's highlighting of this finding, coupled with the Agency's statement that it plans to publish additional CRLs from its archives, warrants attention from sponsors, especially public company sponsors.

Sponsor disclosures regarding CRLs are always closely scrutinized, and the FDA's move to (1) centralize and regularly release CRLs, and (2) publish additional CRLs (e.g., those for sNDAs, or very recently approved products) is likely to invite further scrutiny—by investors, analysts,

competitors, and patient communities. Sponsors should prepare disclosures around receipt of a CRL with the expectation that the CRL itself will become public upon approval of an application. Even where a product is ultimately approved, third parties may make comparisons between a sponsor's characterization of a CRL and the later-posted CRL itself.

According to the FDA, publication of CRLs is just one step in the Agency's broader transparency push. Our team will continue to monitor the frequency and scope of additional releases, as well as any opportunities for interested stakeholders to provide comments or feedback to FDA on its plans.

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

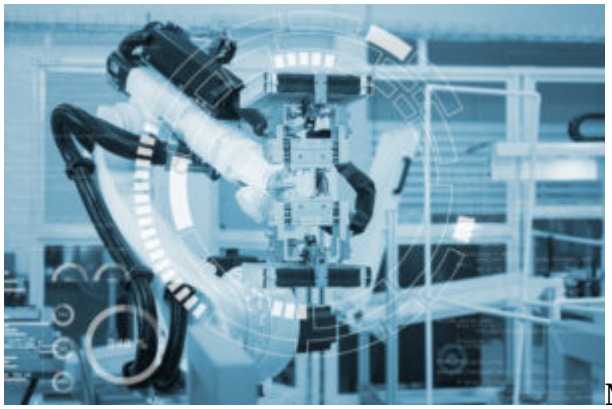
12:00 – 12:30 PM | Registration and Lunch
12:30 PM – 12:40 PM | Opening Remarks
12:40 PM – 1:15 PM | Fireside Chat: Biopharma Strategy in Volatile Times

- 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

Medtech M&A and VC Signal Positive Momentum Entering 2025


Medtech mergers and acquisitions (M&A) and venture capital (VC) showed signs of life in 2024, contributing to an overall optimistic outlook for the sector this year despite lingering headwinds.

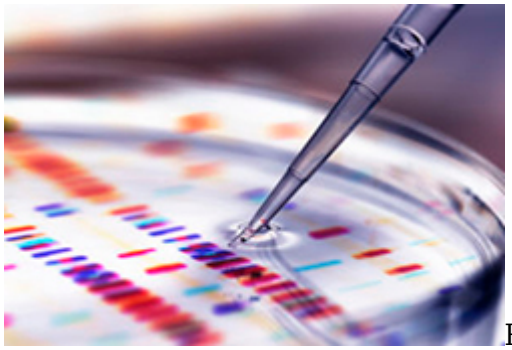
Strategic investments are expected to continue as medtech companies innovate, particularly in areas such as AI-driven diagnostics, wearables and remote monitoring devices, and advanced surgical technologies.

Private, venture-backed M&A activity for medical devices—which picked up in the second half of last year and started 2025 strong with two ten-digit acquisitions and two spin-offs by strategics—could continue rising amid a more deregulatory backdrop under the new presidential administration.

Still, challenges persist that could slow growth. Early-stage VC deals in the sector have faced difficulties, and private M&A exit timelines have increased. Uncertainty regarding the path of interest rates and the broader economy also muddy the outlook.

Read the full insight **here**.

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.

California Law Requiring Female Directors on Public Company Boards Held Unconstitutional

 A California court has **held** that California **Senate Bill 826**, which required that "publicly held" corporations that listed a California address for their principal executive offices on the cover page of their Form 10-K reports must have specified numbers of female directors by certain dates, violates the California constitution and has enjoined the use of California taxpayer funds to carry out the 2018 law. This ruling follows the **decision** of another California court in April 2022 holding that California **Assembly Bill 979** violated the California constitution and the issuance of a similar injunction preventing California from using taxpayer funds to implement that law. Assembly Bill 979 was enacted in 2020 to add a requirement that publicly held corporations that were already subject to Senate Bill 826 also have specified numbers of directors from "underrepresented minorities," as defined in the law, by certain dates. If the state

does not appeal these decisions and California appellate courts do not overturn these decisions, it appears that both of these legislative initiatives to promote more diverse representation on public company boards will have come to an end.

Read the **client alert**.

European Life Sciences Deal Trends

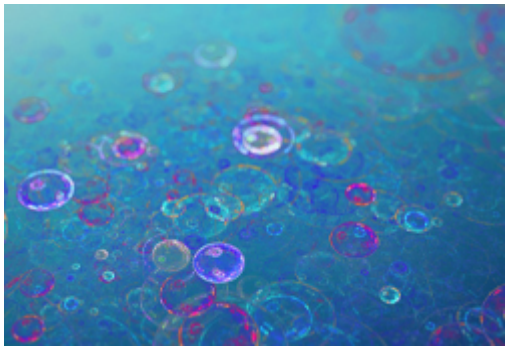
In Europe, life sciences deals increased over the last few years with a strong acceleration in 2021. As a result, the market wonders whether this is just a pick or rather a steady trend which will impact our market in the future as well. Analyzing the reasons of such growth and comparing it with more mature markets such as the U.S. comfort us in thinking that it is just the beginning for continental Europe.

The U.S. life sciences market has been very strong over the past decades and is seen as very mature. The level of venture investments, which are now very much standardized, licensing, M&A and IPOs is very high, both in volume and in number.

For the last ten years or so, the life sciences UK market attracted U.S. investors and an increasing number of growth funds. After a first step of development through venture investments, such companies are now ready for licensing, M&A and IPOs. This is also the trend that we anticipate for the European market even if each country or region still has its own specificities (in particular UK, Germany, France and the Nordic Countries).

Read the **client alert**.

Survival Guide to Structuring Life Sciences Partnering and M+A Agreements



The life sciences space is ever-growing and dynamic as the industry witnesses more companies and, therefore, more collaboration, licensing and M&A agreements, come into the spotlight. While these deals are exciting opportunities for life sciences companies at all stages, they can also be daunting when it comes to their legal structure.

In order to best leverage assets, align incentives, allocate risk and draft agreements to position your partnership for success, Goodwin recommends considering the following business, legal and litigation perspectives as you navigate these type of agreements.

Read the **full insight**.

SEC Chairman's Comments Signal Likely Changes to Rule 10b5-1 Trading Plans

Rule 10b5-1 trading plans have faced increased scrutiny since the onset of the COVID-19 pandemic and the corresponding public focus on stock sales by executives of public **life sciences companies**. On June 7, 2021, SEC Chairman Gary Gensler continued that scrutiny when he delivered prepared **remarks** to the *Wall Street Journal*'s CFO Network Summit concerning Rule 10b5-1 trading plans and his view that "these plans have led to real cracks in our insider trading regime." Mr. Gensler outlined four potential reforms that the SEC staff is considering to address those "cracks".

Read the full insight **here**.

Conducting Internal Investigations – In-House Counsel's Guide

Whether you are a director, or a member of an in-house legal, human resources, or internal audit team, there are sensitive scenarios that occur daily in life sciences companies that trigger the need for an internal investigation.

Goodwin has crafted an "In-House Counsel's Guide" that sets forth a framework of best practices and key considerations for effective internal investigations, including special subject matter and industry-specific considerations; preserving the attorney-client privilege and attorney work product protection; the need for disclosure to and coordination with auditors, regulators, and others; and conducting investigations remotely.

Read the **In-House Counsel's Guide — Conducting Internal Investigations**

The Rise of SPACs in Biotech

The use of special purpose acquisition companies, or SPACs, as an alternative to the traditional IPO process has gained significant traction over the past few years and in 2020 in particular. While these transactions have historically focused more on the tech space, with top-tier biotech investors such as Perceptive Advisors, RA Capital, RTW Investments, Foresite Capital and 5AM Ventures serving as SPAC sponsors, SPACs have gained more popularity in the biotech industry.

A SPAC is a blank check company that goes through the standard IPO process to raise capital with

the purpose of using the proceeds to acquire one or more business targets or their assets. The IPO proceeds are placed in a trust account to be used at a later date to fund the De-SPAC transaction (the process through which a private target combines with the SPAC and begins trading as a public company).

The use of De-SPAC transactions to bring a private company public is gaining in popularity due to the benefits that such transactions offer. These benefits can include:

- **More Streamlined**: a De-SPAC transaction typically involves both a merger with the SPAC and a concurrent private investment in public equity, or PIPE, which raises additional capital from outside investors and potentially existing investors of the target company and SPAC. Both the SPAC merger and the PIPE are signed and announced simultaneously, which allows for a more streamlined process than the typical two-step crossover financing followed by an IPO.
- **Mitigate Risk**: because valuation is agreed towards the beginning of the De-SPAC process, a De-SPAC transaction helps to mitigate the potential market volatility risk that is inherent with traditional IPOs.

Given the success of recent De-SPAC transactions in the biotech space, with eight (8) De-SPAC transactions with biotech companies closed in 2020, coupled with the peaked interest of biotech investors, the use of De-SPAC transactions by private biotech companies to go public will likely continue to grow in 2021.