LIFE SCIENCES
Securities Litigation
Annual Report

BAKER BOTTS

PARTNER TO THE INNOVATORS

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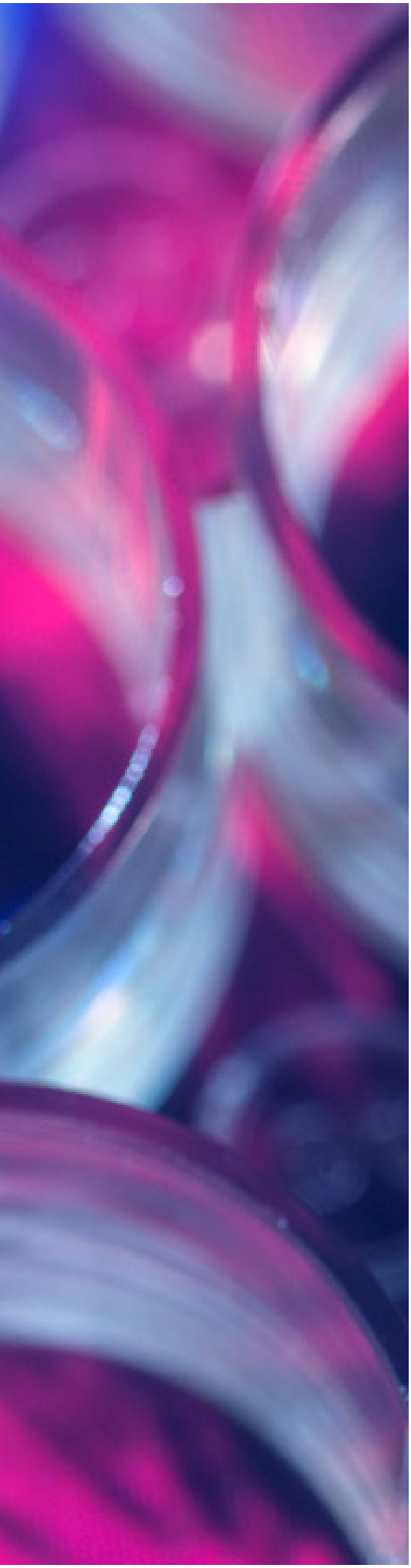


INTRODUCTION

We are pleased to present Baker Botts's 2023 Review of Securities Litigation in the Life Sciences Industry, summarizing significant developments during the past year in federal securities class action litigation against publicly traded biotechnology, pharmaceutical, and medical device and product companies.

Part I provides background on class action litigation under U.S. securities laws and discusses recent trends in U.S. securities litigation.

Part II summarizes the allegations in each of the new securities class action complaints filed against life sciences companies in federal courts in 2023.

Part III reviews significant federal court decisions issued in 2023 in securities class actions against life sciences companies, highlighting the common themes and arguments raised in defense of those claims.

We hope this Review will help management and in-house counsel for public life sciences companies to better understand the securities litigation landscape, the business activities that most commonly generate shareholder litigation, steps they can take to reduce litigation risk, and the strongest defenses to securities claims.

PART I: BACKGROUND

OVERVIEW OF SECURITIES CLASS ACTION LITIGATION

The Exchange Act, the Securities Act, and the Reform Act

Two foundational New Deal securities statutes—the Securities Exchange Act of 1934 (the Exchange Act) and the Securities Act of 1933 (the Securities Act)—remain the principal federal securities laws. The Private Securities Litigation Reform Act of 1995 (the Reform Act) amended both the Exchange Act and the Securities Act, creating various unique procedural and substantive rules in federal securities litigation.

Exchange Act Claims. Most securities class action claims are brought under the general anti-fraud provisions of Section 10(b) of the Exchange Act and its enabling rule SEC Rule 10b-5, which prohibit fraud in connection with any domestic securities transaction.[1] To prevail on a Section 10(b) claim, a plaintiff must prove that the defendants (1) made a false statement or misleading omission of material fact, (2) with *scienter* (i.e. a "wrongful state of mind"), (3) in connection with the purchase or sale of a security, (4) on which the plaintiff relied (i.e. reliance or "transaction causation"), and (5) which caused an economic loss (i.e. "loss causation").[2]

In addition, Section 20(a) of the Exchange Act imposes secondary liability on any "control person"—such as a senior executive or a controlling shareholder—who participates in a company's primary Section 10(b) violation.

Securities Act Claims. The Securities Act regulates securities offerings, i.e., the initial sales of securities to the public. Section 11 of the Securities Act provides purchasers of securities issued under false or misleading registration statements with a private right of action against the issuers of the securities and other actors in the offering process. Section 12 provides purchasers of securities sold under false or misleading prospectuses with a private right of action against the seller of the securities. Sections 11 and 12(a)(2) impose "strict liability" for misstatements in securities offering materials: Plaintiffs need only prove a material untrue statement of fact in the registration statement or prospectus. Securities Act plaintiffs are not required to prove the misstatement was made with *scienter*, that they relied on the false statement, or that the false statement caused an economic loss.

While Securities Act claims are easier to plead and prove than Exchange Act claims, the class of potential Securities Act plaintiffs is strictly limited. Section 11 plaintiffs must prove that they purchased securities issued pursuant to the allegedly misleading registration statement. To do so, they must either prove that they purchased securities directly in the offering or otherwise "trace" their shares back to the challenged offering.[3] The Securities Act also has a one-year statute of limitations and a three-year statute of repose. Due to the tracing requirement and the repose period, Securities Act class action claims generally must be asserted within three years of an issuer's initial public offering.

1 While neither Section 10(b) nor Rule 10b-5 expressly provide a private right of action for defrauded investors, courts have long-recognized an "implied" private right of action for securities fraud under Section 10(b) and Rule 10b-5.
2 *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005).
3 *Slack Technologies LLC v. Pirani*, 1435 S.Ct. 1433(2023).

The Reform Act. Congress passed the Reform Act in 1995 to curb "abusive practices committed in private securities litigation."[4] Among other provisions, the Reform Act imposes an automatic stay of discovery pending any motion to dismiss and imposes various heightened pleading requirements on federal securities complaints, raising the bar for federal securities claims to survive a motion to dismiss. Federal securities complaints must "specify each statement alleged to have been misleading" and the "reasons why the statement is misleading." And complaints in fraud cases must plead facts raising a "strong inference" that the defendants acted with *scienter* (i.e. fraudulent intent). Finally, the Reform Act provides a "safe harbor" for "forward-looking statements." Under the Reform Act safe harbor, defendants will not be liable for an allegedly false forecast, projection, or other statement about future events if the statement is identified as forward-looking and accompanied by meaningful cautionary language or if the complaint fails to plead facts showing the speaker had actual knowledge that the statement was false when made.

Federal securities complaints must "specify each statement alleged to have been misleading" and the "reasons why the statement is misleading." And complaints in fraud cases must plead facts raising a "strong inference" that the defendants acted with scienter (i.e. fraudulent intent).

4 H.R. Rep. No. 104-369, at 41 (1995) (Conf. Rep.), reprinted in 1995 U.S.C.C.A.N. 730.

Motions to Dismiss Securities Class Action Complaints

Because of the Reform Act's heightened pleading requirements and automatic discovery stay, defendants move to dismiss in virtually every securities class action.[5] Motions are granted (either with or without prejudice) roughly half the time.[6] When securities claims survive the motion to dismiss phase, however, defendants may face years of expensive and burdensome litigation, including fact discovery, expert discovery, class certification proceedings, and summary judgment motions, before facing the uncertainty of trial. The cost and uncertainty of litigating securities class action claims to judgment places tremendous pressure on defendants to settle those securities class actions that survive motions to dismiss.

Between the relatively high dismissal rate and the settlement pressure in those cases that are not dismissed, the overwhelming majority of securities class actions end either in dismissal or settlement.[7] As a result, motions to dismiss are considered the "main event" in securities class action litigation.[8]

RECENT DEVELOPMENTS IN LIFE SCIENCES SECURITIES LITIGATION

The most significant trend in federal securities litigation over the past decade has been the continued growth of so-called "event-driven" securities litigation—that is, securities fraud claims based solely on adverse news or events causing a public company's stock price to fall.[9]

Before this development, most securities class action complaints were filed after accounting charges or restatements or disappointing earnings announcements from public companies. Complaints in those cases typically focused on allegations of accounting fraud, misstated financials, or false projections. Over the past decade, however, shareholder plaintiffs have filed securities complaints after virtually every significant drop in the stock price of a large public company, regardless of the cause.

Many of these "stock-drop" cases involve "event-driven" fraud claims, alleging fraud based on adverse developments or outside events unrelated to financial reporting, including accidents involving company products, product recalls, data breaches, explosions or accidents at company facilities, or announcements

5 According to NERA's analysis of securities class actions filed and resolved between January 2014 and December 2023, motions to dismiss were filed in 96% of cases. ***See*** Edward Flores and Svetlana Staryk, NERA, "Recent Trends in Securities Class Action Litigation: 2023 Full-Year Review" ("NERA Report") at 16 (available at nera.com/insights/publications/2024/recent-trends-in-securities-class-action-litigation--2023-full-y.html).

6 According to NERA's analysis of securities class actions filed and resolved between January 2014 and December 2023, motions to dismiss were granted with prejudice in 54% of those cases in which a motion was filed. NERA Report at 16.

7 According to Cornerstone, 46% of "core" securities class actions filed in federal court from 1997 through 2023 settled, 43% were dismissed, 10% remain ongoing, and only 0.4% (21 total cases) reached trial. ***See*** Cornerstone Research, "Securities Class Action Filings - 2023 Year in Review" ("Cornerstone Report") at 19 (available at https://www.cornerstone.com/wpcontent/uploads/2024/01 /Securities-Class-Action-Filings-2023-Y ear-in-Review. pdf).

8 See Stephen J. Choi and A. C. Pritchard, The Supreme Court's Impact on Securities Class Actions: An Empirical Assessment of Tellabs, Journal of Law, Economics, & Organization, Vol. 28, No. 4 at 851 ("The [Reform Act] makes the motion to dismiss the main event in securities fraud class actions, charging district courts with the task of gatekeeping: screening out meritless class actions at an early stage. . .").

9 See, e.g., Gideon Mark, Event-Driven Securities Litigation, 24 U. Pa. J. Bus. L. 522 (2022), available at https://scholarship.law.upenn.edu/jbl/vol24/iss3/1.

of regulatory enforcement actions.[10] As one commentator put it, "everything everywhere is securities fraud."[11]

Life sciences companies are particularly susceptible to the types of adverse, market-moving company events that generate "event-driven" securities litigation. Pharmaceutical companies frequently face setbacks in the development of new drugs, in clinical trials, in obtaining regulatory approval for their products, and then manufacturing, marketing, and selling their products under regulatory scrutiny. If these setbacks result in declining stock prices, event-driven securities complaints soon follow.

For example, if a publicly traded pharmaceutical company speaks positively about a new drug candidate but the FDA later denies the company's application for approval to sell the drug and the stock price falls on the news, then a securities complaint will likely follow, alleging that the company's positive statements about its newest product were fraudulent simply because the FDA later declined to approve the drug.[12]

In addition to the inherent risk of event-driven claims given the nature of the life sciences industry, many life sciences companies have in recent years faced event-driven complaints related to the global COVID-19 pandemic and to the opioid abuse crisis in the United States.

Given the risk of operating in the life sciences and healthcare industries, the recent spike in COVID-related securities cases, and the persistence of event-driven securities class action filings, it is no surprise life sciences companies consistently have been among the most frequent targets of securities class action complaints.

For the past decade, the number of new securities class action complaints filed in federal courts each year has hovered around 200.[13] There were 209 new securities class action complaints filed in federal courts during 2023, slightly higher than the 201 filings in 2022 and roughly in-line with recent years.

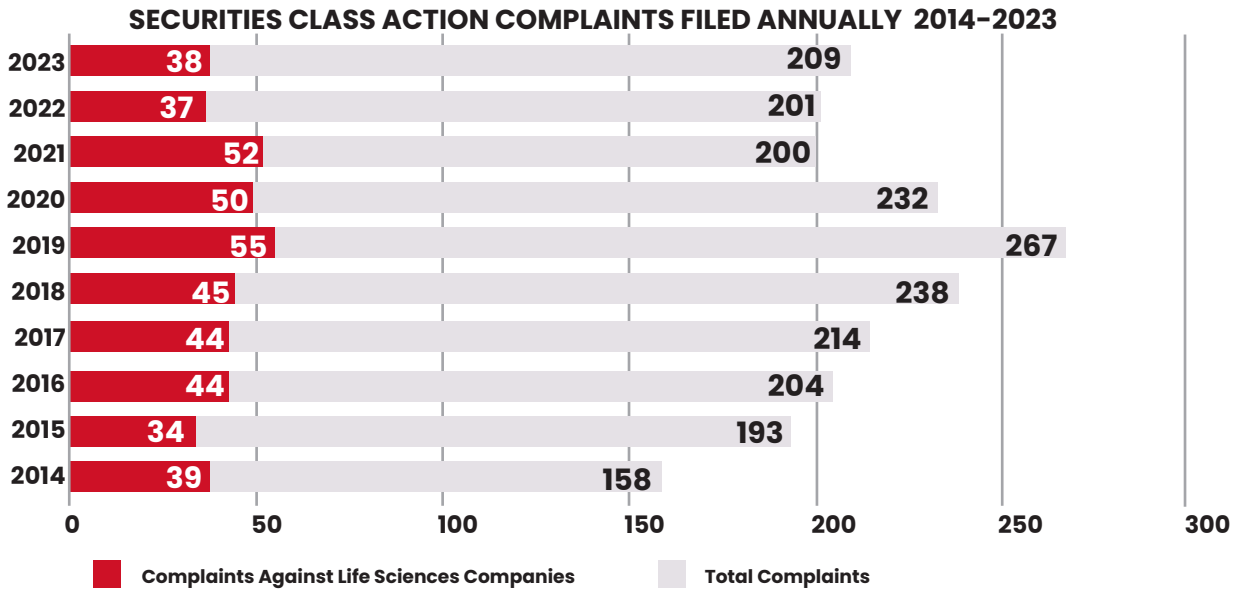
10 *See, e.g., In re Tesla Motors Inc. Sec. Litig.*, 75 F. Supp. 3d 1034 (N.D. Cal. 2014) (securities fraud complaint premised on explosion of faulty car battery); *In re BP p.l.c. Sec. Litig.*, 843 F. Supp. 2d 712 (S.D. Tex. 2012) (securities fraud complaint premised on off-shore oil rig explosion)

11 Matt Levine, "Everything Everywhere is Securities Fraud," Bloomberg (Jun. 26, 2019), available at https://www.bloomberg.com/opinion/articles/2019-06-26/everything-everywhere-is-securities-fraud.

12 Federal courts have long recognized the frequency of shareholder class action complaints following "the all-but-inevitable decline in a company's stock price following the company's announcement that the FDA has not approved" the company's application for approval of a new drug. *Fort Worth Employers' Retirement Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 229 (S.D.N.Y. 2009).

13 Aggregate securities class action filing data is drawn from Stanford Law School's Securities Class Action Clearinghouse (SCAC), a collaboration between Stanford Law School and Cornerstone Research. *See* www.securities.stanford.edu. The total number of filings are for "core" filings—that is, Exchange Act and Securities Act class action claims excluding those challenging M&A transactions.

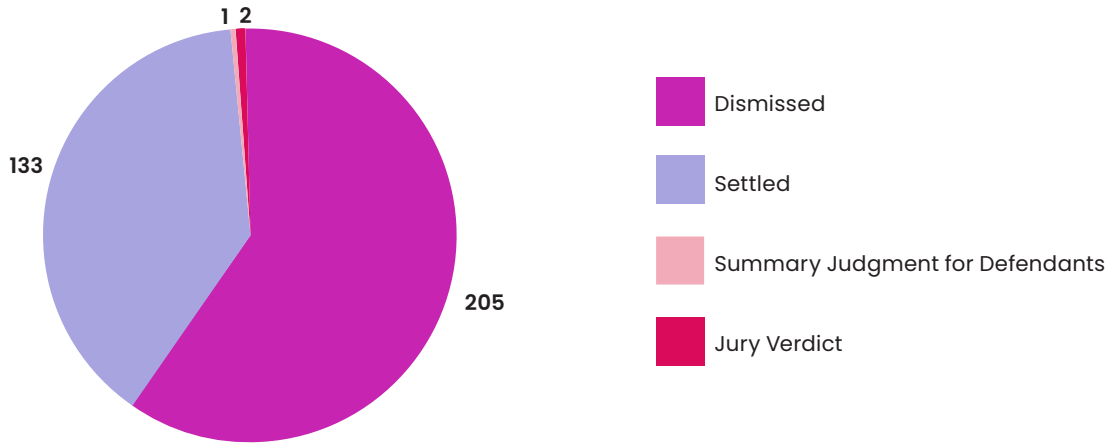
The most frequent targets of those complaints have been companies in the healthcare sector—which includes biotechnology & drugs, medical equipment & supplies, and other life sciences-related industries—named as defendants in roughly 20% of new federal securities class action complaints each year. That trend continued in 2023 with just under 20% of new federal securities complaints targeting healthcare companies.



Most securities complaints against life sciences companies follow the disclosure of unfavorable developments in applications for FDA approval, such as disappointing clinical trial results, a negative recommendation from an FDA advisory committee, or FDA denial of a new drug application. Securities complaints also frequently follow regulatory action related to the manufacturing, marketing, or sale of FDA-approved and -regulated drugs and announcements of issues related to reimbursement from third-party payers, like Medicare and private health insurance companies. In recent years, life sciences companies have also faced securities fraud claims based on the effects of the global COVID-19 pandemic and the opioid crisis in the United States.

While life sciences companies are frequent targets of securities class action complaints, they also successfully defend against those claims more frequently than other companies. As noted above, most cases in general end in dismissal or settlement. But cases against life sciences companies specifically end in dismissal more often than those against other defendants. Life sciences companies prevailed—achieving either dismissal or a favorable summary judgment—in 60% securities class actions filed and resolved in the past ten years.

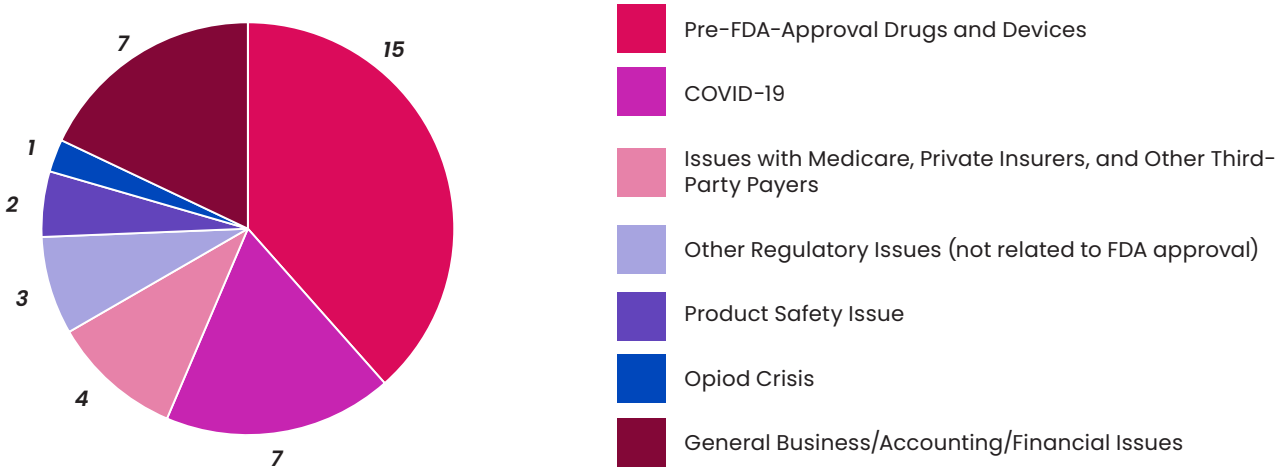
OUTCOME OF RESOLVED SECURITIES CLASS ACTIONS AGAINST LIFE SCIENCES COMPANIES (2014-2023)



The decisions and complaints we review in this report bear out these trends.

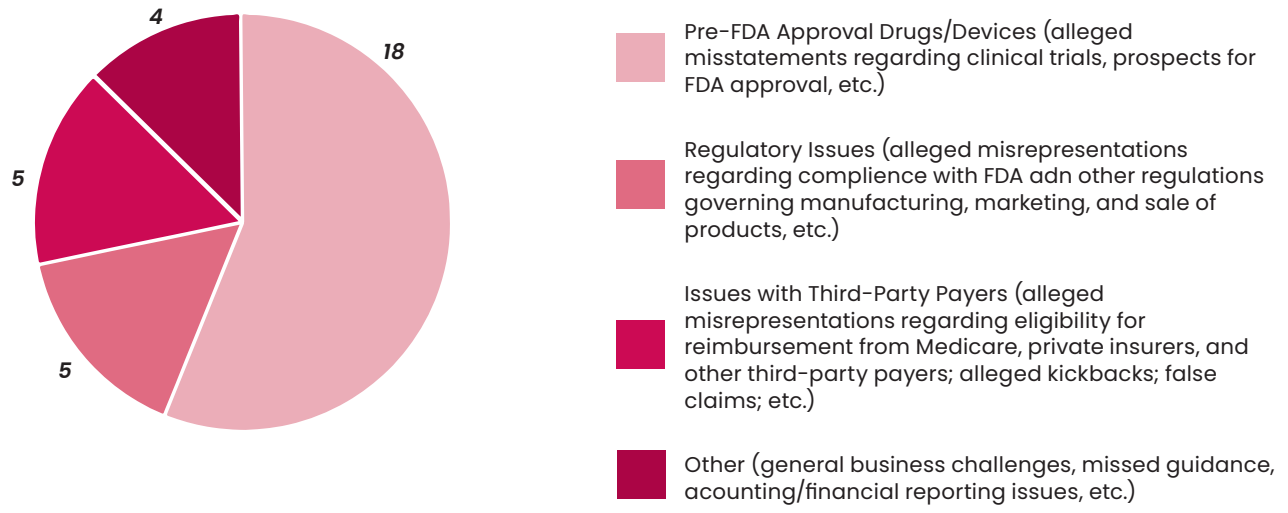
In ***Part II***, we summarize 37 new securities class action complaints filed against life sciences companies in 2023. Of those, 15 involved allegations related to pre-approval drugs, including alleged misstatements about preclinical and clinical study results and the prospects for FDA approval; 7 related to the COVID-19 pandemic, involving either companies' statements about their COVID-19 vaccines or treatments or about the pandemic's effects on their businesses; 4 related to issues with third-party payers, including both government payers and private insurers; 3 related to regulatory issues other than FDA new drug/product approval; 2 related to product safety issues or product recalls; 1 related to the business fallout from the opioid crisis; and 7 related to accounting and financial reporting issues, missed projections, or general business challenges unrelated to the life sciences industry.

ALLEGATIONS IN NEW COMPLAINTS FILED IN 2023



In ***Part III***, we review 32 federal court decisions in 2023 in securities class actions against life sciences companies. In most of these cases, the claims involved alleged misstatements about either (i) applications for FDA approval of new drugs or devices, (ii) compliance with FDA regulation of post-approval drugs and devices, or (iii) reimbursements from Medicare and other third-party payers.

MOST COMMON CLAIMS IN 2023 LIFE SCIENCES SECURITIES DECISIONS



Life sciences company defendants fared well in these cases: 18 of 27 district court decisions either granted motions to dismiss or granted summary judgment in favor of the defendants, and four out of five court of appeals decisions affirmed dismissal.

In many of the decisions we examine, life sciences companies successfully invoked the Reform Act's heightened pleading standards to win dismissal of claims, arguing successfully that the complaints against them failed to specify how the challenged statements were misleading or failed to plead a strong inference of *scienter*. Notably, courts granting dismissal frequently cited the defendant corporations' risk factors, confirming that the substance of public companies' securities disclosures matter.

These decisions should provide some comfort that life sciences companies can express optimism about their businesses (while appropriately disclosing the risks) without undue fear of liability should they face unexpected business or regulatory challenges in the future.

For example, federal courts in 2023 held that:

- FDA denial of a new drug application does not render the applicant's earlier positive statements about clinical trial results false because "a mere dispute about the proper interpretation of data" cannot support a securities fraud claim;[14]

- A development-stage drug company can disclose encouraging top-line clinical trial results—and express positive views about those results—without disclosing full, subject-level data, even if some of the more detailed information might conflict with the positive top-line results;[15]

- A company that tells investors that it expects federal health insurance to cover its product—while also cautioning investors about the risk from its "unique" and "disruptive" new sales model—will not be liable for fraud-by-hindsight if insurers later conclude that the product is not eligible for reimbursement;[16] and

- A developmental drug company's statements about the prospects for FDA approval of a new drug candidate "'are classically forward-looking"—and, thus, entitled to safe harbor under the Reform Act—"because 'they address what defendants expect to occur in the future.'"[17]

Nonetheless, our review also confirms the need to speak with appropriate nuance and caveats, particularly when discussing the prospects for an inherently uncertain FDA approval process or drawing conclusions from complex clinical trial data.

For example, a biotechnology company released top-line Phase III clinical trial results (but not sub-group-level results from the trial) and told investors that the results showed "the high dose reduced clinical decline." The FDA later released a briefing book with a statistical analysis finding that "the totality of the data does not seem to support the efficacy of the high dose." The court of appeals affirmed dismissal in part, finding that the conflict between the company's conclusions and the FDA reviewer's conclusions reflected mere disagreements about competing interpretations of data. But the court reversed the dismissal order as to the CEO's statement that the data was "**all** consistent with" the company's view that the high dose was effective.[18] Thus, while corporate executives can express positive views of clinical results, broad categorical statements about large bodies of complex clinical data can create unnecessary litigation risk.

14 *See Zhou v. NextCure, Inc.*, No. 20-CV-7772, 2023 WL 4493541 (S.D.N.Y. July 12, 2023); *Emps.' Ret. Sys. of the City of Baton Rouge & Par. of E. Baton Rouge v. MacroGenics, Inc.,* 61 F.4th 369 (4th Cir. 2023).
15 *Lewakowski v. Aquestive Therapeutics, Inc.*, No. 21-CV-3751, 2023 WL 2496504 (D.N.J. Mar. 14, 2023).
16 *In re Eargo, Inc. Sec. Litig.*, 656 F. Supp. 3d 928 (N.D. Cal. Feb. 14, 2023).
17 *In re Bristol-Myers Squibb Co. CVR Sec. Litig.*, 658 F. Supp. 3d 220 (S.D.N.Y., 2023).
18 *Shash v. Biogen, Inc.*, 84 F. 4th. 1 (1st Cir 2023).

PART II – SECURITIES CLASS ACTION COMPLAINTS FILED AGAINST LIFE SCIENCES COMPANIES IN 2023

First Circuit

Invivyd, Inc.

Invivyd, formerly known as Adagio Therapeutics, Inc., is a clinical-stage biopharmaceutical company formed in 2020 to develop treatments for COVID-19. Adagio went public through an initial public offering in August 2021. Its lead product candidate was ADG20, an investigational monoclonal antibody treatment for COVID-19. The complaint alleges that Adagio misrepresented ADG20's effectiveness in treating the Omicron variant of COVID-19 when Omnicron emerged in November 2021. In December 2021, Adagio released clinical studies revealing that ADG20 was significantly less effective in treating Omicron than it was in treating earlier COVID-19 variants. Adagio's stock price fell on the news and shareholder plaintiffs sued. The complaint asserts Section 10(b) and 20(a) claims against Adagio and its senior executives. The case is *Brill v. Invivyd, Inc.* (D. Mass.) (filed Jan. 31, 2023).

Charles River Laboratories International, Inc.

Charles River Laboratories is a non-clinical drug development company that assists drug developers in developing new products. Charles River is the U.S.'s largest commercial user of non-human primates, including long-tailed macaques, 60% of which it imported from China pre-COVID. Exports of long-tailed macaques from China to the U.S. ceased during the COVID-19 pandemic; at the same time, demand for long-tailed macaques increased due to an increase in COVID-19 related drug research. The complaint alleges that, in response to the loss of Chinese imports, Charles River "engaged suppliers that were under criminal investigation for sourcing long-tailed macaques from the wild (not captive or purpose-bred) in Southeast Asia, specifically Cambodia." Charles Rivers' revenues (and its stock price) increased substantially during the COVID-pandemic due to the increased business from COVID related drug research. While Charles River has not been accused of any wrongdoing, the company's stock price fell when the DOJ announced indictments of several of Charles River's suppliers as part of an alleged "international primate smuggling ring." The complaint asserts Section 10(b)and 20(a) claims against Charles River and its senior executives. The case is *State Teachers Ret. Sys. of Ohio v. Charles River Laboratories Intern., Inc.* (D. Mass.) (filed May 19, 2023).

Aldeyra Therapeutics, Inc.

Aldeyra is a biotechnology company focused on treatment of immune-mediated diseases, which are conditions that result from an imbalance of the immune system. The complaint arises from Alderya's application for FDA approval of reproxalap (a topical ophthalmic solution that Aldeyra was exploring for the treatment of dry-eye disease and allergic conjunctivitis) and ADX-2191 (an injectable formulation that Aldeyra was exploring for the treatment of primary vitreoretinal lymphoma, a rare eye cancer). Ultimately, Aldeyra's stock price fell when the FDA denied approval for reproxalap and ADX-2191. The complaint asserts Section 10(b) and 20(a) claims based on Aldeyra's positive statements about the prospects for its two clinical stage drugs. The case is *Paice v. Aldeyra Therapeutics, Inc.* (D. Mass.) (filed July 31, 2023).

Infinity Pharmaceuticals, Inc.

Infinity Pharmaceuticals is a clinical-stage biopharmaceutical company focusing on developing novel cancer treatments, including eganelisib, a clinical trial stage breast cancer treatment. The complaint asserts Section 10(b) and 20(a) claims and alleges that Infinity "pushed the false narrative that eganelisib was proceeding apace in its clinical studies" and that those statements were revealed to be false when Infinity announced a failed merger and significant layoffs. The case is *Dilbarian v. Infinity Pharmaceuticals, Inc.* (D. Mass.) (filed Aug. 15, 2023).

Second Circuit

Y-mAbs Therapeutics, Inc.

Y-mAbs is a clinical-stage biopharmaceutical company focused on developing antibody cancer treatments. Its lead product was omburtamab, designed to treat pediatric neuroblastoma. The company's stock price fell when the FDA released its briefing book for an advisory committee meeting regarding Y-mAbs' application for approval of omburtamab and when the advisory committee later voted that the company had not provided sufficient evidence to conclude that omburtamab improved overall survival. The complaint alleges that the briefing book disclosed concerns about the adequacy of Y-mAbs' clinical study data. The complaint asserts Section 10(b) and 20(a) claims based on alleged misstatements about the company's discussions with the FDA. The case is *In re Y-mAbs Therapeutics, Inc. Sec. Litig.* (S.D.N.Y.) (filed Jan. 18, 2023).

NovoCure Ltd.

NovoCure is a global oncology company that developed and markets a proprietary cancer therapy called Tumor Treating Fields ("TTFields"). TTFields therapy is administered through a wearable device and employs electrical pulses to disrupt the ability of cancer cells to divide and proliferate. TTFields is FDA-approved to treat a type of brain cancer. NovoCure sought to expand TTFields' approved usage to treatment of other forms of cancer. The complaint arises from NovoCure's statements about clinical trials conducted to support its application for approval of TTFields to treat non-small cell lung cancer. NovoCure accurately disclosed the trials' positive top-line results, but the complaint alleges that NovoCure concealed "serious flaws and missing data that rendered the purportedly favorable results unreliable, uninterpretable, and clinically meaningless." According to the complaint, the company's stock price fell when it disclosed more detailed results of the study. The complaint asserts Section 10(b) and 20(a) claims based on alleged misstatements and misleading omissions about the TTFields clinical study results. The case is *Bazzelle v. NovoCure Ltd.* (S.D.N.Y.) (filed June 19, 2023).

BioXcel Therapeutics, Inc.

BioXcel is a biotechnology company that employs artificial intelligence to identify new therapeutic uses for pre-existing chemicals. According to the complaint, BioXcel focused on development of four chemical compounds: BXCL501 and BXCL502, which are used to treat agitation in various patient populations, and BXCL701 and BXCL702, which are potential cancer treatments. After securing FDA approval for BXCL501 to treat agitation in patients with schizophrenia and bipolar disorders, BioXcel sought approval for BXCL501 to treat agitation in patients with dementia and Alzheimer's Disease. According to the complaint, BioXcel's stock price fell when it disclosed that the FDA had raised concerns about the conduct of the principal investigator conducting Phase 3 clinical trials in support of the application. The complaint asserts Sections 10(b) and 20(a) claims based on alleged misstatements about the BXCL501 Phase 3 clinical trials. The case is *Martin v. BioXcel Therapeutics, Inc.* (D. Conn.) (filed July 7, 2023).

Syneos Health

Syneos provides contract clinical research services to pharmaceutical and biotechnology companies. Like many companies, Syneos experienced disruptions in its business at the outset of the COVID-19 pandemic in March 2020, as existing clinical trials and new customer projects were delayed. After these initial disruptions, Syneos's business recovered and it experienced strong demand as a result of COVID-related clinical trials. After many months of robust COVID-related demand, Syneos announced disappointing financial results in September 2022, and Shareholder plaintiffs sued. The complaint asserts Section 10(b) and 20(a) claims alleging that Syneos's statements about its increased demand were false or misleading. The case is *United Ass. of Plumbers and Pipefitters v. Syneos Health, Inc.* (S.D.N.Y.) (filed July 27, 2023).

Brainstorm Cell Therapeutics Inc.

Brainstorm Cell Therapeutics is a biotechnology company that develops and commercializes autologous cellular therapies for the treatment of neurodegenerative diseases. In August 2022, Brainstorm applied for FDA approval of NurOwn to treat amyotrophic lateral sclerosis. During the application process, Brainstorm made various statements about the status of the application and the company's communications with the FDA. In September 2023, Brainstorm disclosed that the FDA's Cellular, Tissue, and Gene Therapies Advisory Committee voted that there was not substantial evidence to establish NurOwn's effectiveness. Brainstorm's stock price fell in reaction to the news. Shareholder plaintiffs sued. The complaint asserts Section 10(b) and 20(a) claims based on allegations that Brainstorm Cell Therapeutics' statements about it application for FDA approval of NurOwn were false and misleading The case is *Sporn v. Brainstorm Cell Therapeutics Inc.* (S.D.N.Y.) (filed Nov. 1, 2023).

Third Circuit

BioLineRx Ltd.

BioLineRx is a pre-commercial-stage biopharmaceutical company. It develops various cancer therapy programs, including its lead program Motixafortide. In May 2021, BioLineRX announced that its Phase 3 study for Motixafortide achieved its primary and secondary endpoints. The company also announced that it believed that it had sufficient cash to bring Motixafortide through approval and commercialization while also advancing its other clinical programs. By mid-2022, however, BioLineRx determined that it would need additional financing to fund Motixafortide's commercial launch. In September 2022, the company announced a financing transaction with a private equity firm. The complaint alleges the transaction was dilutive and caused the company's stock price to fall. Shareholder plaintiffs sued. The complaint alleges that BioLineRx's statements about its ability to finance approval and commercialization of Motixafortide were misleading in violation of Sections 10(b) and 20(a). The case is *In re BioLineRx Ltd. Sec. Litig.,* (D.N.J.) (filed Jan. 5, 2023).

Catalent, Inc.

Catalent, an outsourced drug manufacturer for pharmaceutical and biotech companies, benefited from the COVID-19 pandemic initially, but by mid-2021, demand for vaccine products decreased significantly. The complaint asserts Section 10(b) and 20(a) claims, alleging that, to mask falling demand for its vaccine products, Catalent engaged in an accounting scheme, artificially inflating reported revenues while cutting corners on safety and quality control at its facilities. The case is *City of Warwick, Ret. Sys. v. Catalent, Inc.* (D.N.J.) (filed Feb. 24, 2023).

Fulcrum Therapeutics, Inc.

Fulcrum Therapeutics is a clinical-stage biopharmaceutical company focused on genetically defined rare diseases. One of its lead product candidates is FTX-6058, a treatment for sickle-cell disease and other hemoglobinopathies. In 2022, Fulcrum submitted preclinical data to the FDA in connection with a planned application for FDA approval of FTX-6058. During the application process, Fulcrum made various statements about clinical results and its views about the prospects for FDA approval. In March 2023, Fulcrum disclosed that the FDA had placed a clinical hold on FTX-6058, requesting that Fulcrum "further define the population where the potential benefit of continued treatment with FTX-6058 outweighs potential risk." The company's stock price fell. Shareholder plaintiffs sued under Sections 10(b) and 20(a) alleging that the company's prior positive statements about FTX-6058 were fraudulent. The case is *Celano v. Fulcrum Therapeutics, Inc.* (D.N.J.) (filed Apr. 28, 2023).

Viatris Inc.

Viatris was created in 2020 as a combination of Mylan, the world's largest generic drug maker, and Upjohn, Pfizer's off-patent brands division. In February 2022, Viatris announced plans to restructure and sell non-core assets, including its biosimilars business. The company's stock price fell in response to the announcement. Shareholder plaintiffs sued under Sections 10(b) and 20(a), alleging that Viatris' prior statements about the benefits of its diversified portfolio of businesses (including its biosimilars business) were fraudulent. The case is *In re Viatris Inc. Sec. Litig.* (W.D. Pa.) (filed May 12, 2023).

Mallinckrodt Pharmaceuticals

Faced with billions of dollars of potential liabilities from lawsuits arising from the U.S. opioid crisis, Mallinckrodt filed for bankruptcy protection in 2020. The bankruptcy plan provided the company releases from all opioid-related claims in exchange for $1.725 billion in payments to an opioid claimant trusts—an initial $425 million payment and annual $200 million payments for the next eight years. Ultimately, Mallinckrodt filed a second bankruptcy case after failing to make scheduled payments under the settlement. The complaint asserts Section 10(b) and 20(a) claims, alleging that Mallinckrodt falsely assured investors that its first bankruptcy plan resolved all outstanding opioid litigation risk while leaving the company with a capital structure that would allow it to operate profitably in the future. The case is *Continental General Ins. Co. v. Olafsson* (D.N.J.) (filed Jul. 7, 2023).

Bausch Health Companies Inc.

After a large settlement in an earlier securities class action case, Bausch Health Companies, a pharmaceutical company and majority owner of Bausch + Lomb Corporation, announced plans to spin-off B+L. The complaint asserts Section 10(b) and 20(a) claims, alleging that Bausch Health's statements about the spin-off's benefits were misleading because they allegedly failed to disclose that B+L would retain its most valuable assets, while Bausch Health would be saddled with potential liabilities from the securities case, and because Bausch Health allegedly failed to disclose that an important product would be subject to generic competition. The case is *Kelk v. Bausch Health Companies Inc.* (D.N.J.) (filed July 26, 2023).

Apellis Pharmaceuticals, Inc.

Apellis is a commercial stage biopharmaceutical company. One of its leading products is SYFOVRE, a treatment for geographic atrophy (GA), a leading cause of blindness. In early 2021, Apellis presented results from a completed Phase 2 trial and ongoing Phase 3 trials for SYFOVRE, reporting that safety was "in line with other studies of intravitreally administered agents," i.e. treatments administered by injection into the vitreous cavity at the back of the eye. As the Phase 3 trials continued, Apellis reported that SYFOVRE "demonstrated a favorable safety profile" and that no cases of vasculitis or occlusive vasculitis—a dangerous form of inflammation in blood vessels in the eye—had been observed. In February 2023, the FDA approved SYFOVRE. Then, in July 2023, the American Society of Retina Specialists published reports of vasculitis in patients treated with SYFOVRE. Apellis confirmed the reports and disclosed that some of the cases were occlusive. The company's stock price fell. Shareholders sued, asserting Section 10(b) and 20(a) claims and alleging that Apellis's statements regarding SYFOVRE's safety profile were false and misleading. The case is *Soderberg v. Apellis Pharmaceuticals, Inc.* (D. Del.) (filed Aug. 2, 2023).

Integra LifeSciences

Integra develops regenerative tissue technologies, many of which it makes in a manufacturing plant in Boston. In October 2018, the FDA inspected Integra's Boston plant and found violations of FDA safety regulations. Integra told investors it took steps to address the identified violations and that there were "no patient safety issues." The company continued to sell products made at the Boston plant and applied to expand FDA approval for SurgiMed, one of the products made at the Boston plant. But, in April 2023, the FDA identified additional violations at the Boston plant and Integra paused production there. The next month,

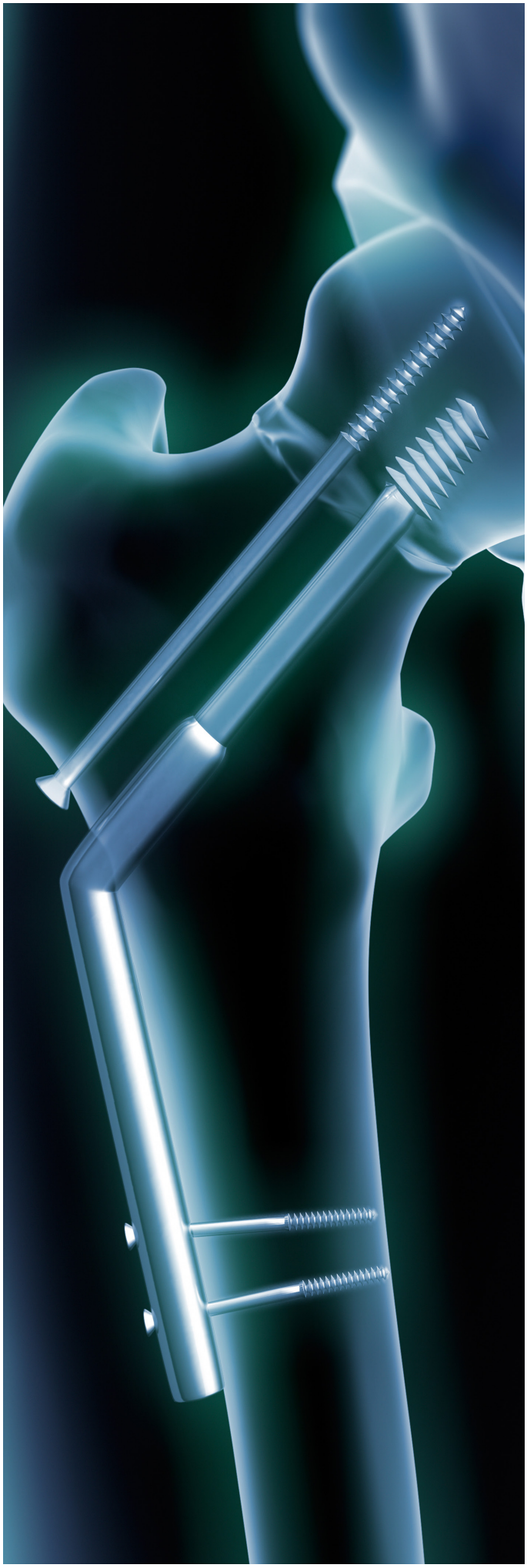
Integra recalled all products made at the Boston plant since March 2018. Integra's stock price fell on the news. Shareholders sued, asserting Section 10(b) and 20(a) claims and alleging that Integra's statements that it had taken steps to correct the issues identified during the 2018 inspection and that the Boston plant presented "no patient safety issues" were false or misleading. The case is *Pembroke Pines Firefighters & Police Officers Pension Fund v. Integra LifeSciences Holdings Corp.* (D.N.J.) (filed Sept. 12, 2023).

Kenvue, Inc.

In May 2023, Johnson & Johnson spun off its consumer health division as a stand-alone company, Kenvue. Kenvue's products included Johnson & Johnson's iconic consumer brands, including Tylenol, Neutrogena, Listerine, and Band-Aid, and several nasal decongestants containing phenylephrine, including Sudafed PE, Benadryl Allergy Plus Congestion, and Tylenol Sinus + Headache. Soon after Kenvue's IPO, the FDA declared phenylephrine ineffective as a nasal decongestant. Kenvue's stock price fell. Shareholders sued, asserting both Section 11 and Section 10(b) and 20(a) claims and alleging various statements in Kenvue's IPO offering documents were misleading because Kenvue failed to disclose that phenylephrine was ineffective. The case is *Hammond v. Kenvue Inc.* (D.N.J.) (filed Oct. 9, 2023).

AdaptHealth Corp.

AdaptHealth sells medical equipment to patients and bills insurance providers. After achieving record financial results, the company announced a surprise loss for the fourth quarter of 2022. The stock price fell and investors sued. The complaint asserts Section 10(b) and 20(a) claims, alleging that AdaptHealth concealed from investors that its record numbers allegedly resulted from a scheme to overcharge the Centers for Medicare and Medicaid Services and other insurance providers



by submitting improper billing codes for diabetes equipment. The case is *Allegheny County Employees' Retirement System v. AdaptHealth Corp.* (E.D. Pa.) (filed Oct. 24, 2023).

Outlook Therapeutics, Inc.

Outlook Therapeutics is a late clinical-stage biopharmaceutical company that focuses on antibodies to treat ophthalmic indications, including its lead product candidate, ONS-5010. The company's stock price fell when the FDA announced it would not accept Outlook's application for approval of ONS-5010. The complaint asserts Section 10(b) and 20(a) claims and alleges that Outlook misled investors by failing to disclose alleged manufacturing issues with ONS-5010, which purportedly precluded FDA approval. The case is *Alsaidi v. Outlook Therapeutics, Inc.* (D.N.J.) (filed Nov. 3, 2023).

Scynexis, Inc.

Scynexis, a biotechnological company primarily engaged in the development of ibrexagungerp, received FDA approval to sell ibrexafungerp tablets under the brand name BREXAFEMME. But, after sales began, the company conducted a recall due to possible cross-contamination in the manufacturing process. Scynexis's stock price fell. Plaintiffs sued, asserting Section 10(b) and 20(a) claims and alleging that Scynexis misled investors about the safety of its manufacturing facilities. The case is *Feldman v. Scynexis, Inc.* (D.N.J.) (filed Nov. 7, 2023).

Eagle Pharmaceuticals, Inc.

Eagle Pharmaceuticals, an integrated pharmaceutical company, has several commercialized products, including PEMFEXY, a metabolic inhibitor used in the treatment of genomic tumor aberrations. Plaintiffs allege that the company failed to disclose material adverse facts about the company's business related to PEMFEXY, including allegedly misreporting PEMFEXY sales and allegedly failing to disclose lower than expected sales to a significant wholesale purchaser of PEMFEXY. The case is *Miller v. Eagle Pharmaceuticals, Inc.* (D.N.J.) (filed Dec. 11, 2023).

Fourth Circuit

Bioventus Inc.

Bioventus is a medical device and drug company focusing on orthobiologics. It went public through an IPO in February 2021. As part of its business model, Bioventus sold products to wholesalers and then provided significant rebates on retail purchases funded or reimbursed by Medicare and other third-party payers. As a result, when accounting for sales revenue, Bioventus had to estimate potential future rebates. In November 2022, Bioventus announced that it would not be able to timely file its Q3 2022 financial statements, in part because it was "seeking resolution related to the validity of" a large rebate claim. Bioventus also disclosed that "[t]he recognition of additional rebates may impact Bioventus' recently announced revenue guidance" and that "its internal controls related to the timely recognition of quarterly rebates were inadequate." Bioventus shareholders sued following this announcement asserting Section 11 and Section 10(b) claims. The case is *Ciarciello v. Bioventus Inc.* (M.D.N.C.) (filed Jan. 12, 2023).

Sixth Circuit

Sotera Health Co.

Sotera Health provided sterilization services for medical products using high volumes and concentrations of ethylene oxide ("EtO"), a highly regulated substance. Sotera's stock price fell after an Illinois jury awarded $363 million to a woman who alleged that a Sotera medical equipment sterilization facility contributed to her cancer. Sotera's investors sued, asserting Section 10(b) and 20(a) claims and alleging that

Sotera misrepresented its commitment to safety, its compliance with safety regulations, and its potential exposure to EtO-related ligation. The case is *In re Sotera Health Co. Sec. Litig.* (N.D. Ohio) (filed Jan. 24, 2023).

Seventh Circuit

Baxter International, Inc.

Baxter International, a biotech and pharmaceuticals company, focuses on products designed to treat kidney diseases and other chronic and acute medical conditions. In February 2023, Baxter announced that it would not meet its prior financial guidance due to supply chain problems related to the COVID pandemic and the Russian invasion of Ukraine. The company's stock price fell and investors sued, asserting Section 10(b) and 20(a) claims and alleging that Baxter should have disclosed its supply chain issues earlier. The case is *Kelley v. Baxter International, Inc.* (N.D. Ill.) (filed July 12, 2023).

Eighth Circuit

Inspire Medical Systems, Inc.

Inspire develops minimally invasive products for patients with obstructive sleep apnea. Patients seeking insurance reimbursement for Inspire's products generally need prior doctor's authorization. The complaint asserts Section 10(b) and 20(a) claims and alleges that Inspire concealed problems with its Acceleration Program, a pilot program through which Inspire assisted customers in scheduling doctor appointments and submitting prior authorizations for reimbursement. The case is *City of Hollywood Firefighters' Pension Fund v. Inspire Medical Systems, Inc.* (D. Minn.) (filed Dec. 22, 2023).

Ninth Circuit

Fate Therapeutics, Inc.

On April 2, 2020, clinical biopharmaceutical company Fate Therapeutics entered a collaboration agreement with Janssen Biotech, a unit of Johnson & Johnson, for cell-based cancer immunotherapies, under which Fate was eligible to receive milestone payments and royalties on any net sales from collaboration. In January 2023, Fate announced it had terminated the Janssen agreement because it was not able to align with Janssen on two product candidates. Investors sued, asserting Section 10(b) and 20(a) claims and alleging that Fate overstated the impact its agreement with Janssen was likely to have on the company's commercial profitability. The case is *Hadian v. Fate Therapeutics, Inc.* (S.D. Cal.) (filed Jan. 20, 2023).

Caribou Biosciences, Inc.

Caribou Biosciences—a clinical stage biopharmaceutical company focused on development of cell therapies to treat blood cancers—conducted an IPO in July 2021. One of its new drug candidate is CB-010, a cell therapy for non-Hodgkins lymphoma. At the time of Caribou's IPO, a Phase 1 clinical trial for CB-010 was ongoing. Caribou released interim results as the trial progressed in 2022. Those results suggested that CB-010's effects were not as persistent as hoped. Caribou's stock price fell and a shareholder class action was filed asserting both Section 10(b) and Section 11 claims. The complaint alleges that Caribou's IPO offering documents misled investors about CB-010's clinical and commercial prospects. The case is *Greenhalgh v. Caribou Biosciences, Inc.* (N.D. Cal.) (filed Feb. 10, 2023).

Cutera, Inc.

Cutera is a medical aesthetic device company that provides equipment for beauty treatments. In February 2023, Cutera disclosed that it would not be able to timely file its 2023 financial report because it had identified material weaknesses in its internal control over financial reporting related to inventory accounting. In March, Cutera announced it would not meet the extended filing deadline and disclosed additional material weaknesses in internal controls related to stock-based compensation. In April, Cutera's Executive Chairman and CEO both called for five of the company's directors to resign. The board responded by firing them both. In May, Cutera's CFO resigned. As a result of these developments, the company's stock price declined. Investors sued, asserting Section l0(b) and 20(a) claims. The case is *Erie County Employees' Retirement System v. Cutera, Inc.* (N.D. Cal.) (filed May 24, 2023).

ImmunityBio, Inc.

ImmunityBio, Inc. is a clinical-stage biotechnology company that develops immunotherapy and cell therapy platforms, including a product called Anktiva. ImmunityBio contracts with third-party manufacturers to produce Anktiva. In May 2022, ImmunityBio applied for FDA approval of Anktiva. ImmunityBio told investors it had "established Good Manufacturing Practice (GMP) manufacturing capacity at scale" to produce Anktiva. ImmunityBio's stock price fell when problems with the third-party manufacturing facilities came to light. Shareholders sued, asserting Section 10(b) and 20(a) claims and alleging that ImmunityBio misled investors about the extent and quality of its due diligence into manufacturing contractors and the prospects for FDA approval of the Anktiva BLA. The case is *In re ImmunityBio, Inc.* (S.D. Cal.) (filed June 30, 2023).

Rain Oncology Inc.

Rain Oncology is a clinical-stage oncology company. When Rain went public in July 2021, it told investors that it was on the verge of launching a "pivotal Phase 3 trial" for a new treatment for liposarcoma, a rare and dangerous fatty tissue cancer. At the time, Rain was completing a preclinical Phase 1 trial and determined to proceed directly from that stage to a Phase 3 clinical trial. Ultimately, Phase 3 trial results were disappointing and Rain's stock price fell. Shareholders sued, asserting Section 10(b) and 20(a) claims and alleging that Rain's IPO offering documents misled investors about the risk associated with bypassing a Phase 2 trial and proceeding directly to a Phase 3 trial. The case is *Thant v. Rain Oncology Inc.* (N.D. Cal.) (filed July 26, 2023).

Masimo Corporation

Masimo is a global technology company. Its healthcare business sells patient-monitoring technologies, hospital automation and connectivity solutions, remote monitoring devices, and consumer health products to hospitals, emergency medical providers, home care providers, physician offices, veterinarians, long-term care facilities, and consumers. Its non-healthcare business sells high-end consumer audio products direct-to-consumers or through authorized retailers and wholesalers. In February 2023, Masimo announced its 2022 financial results and provided forward-looking guidance about its expected 2023 performance. The company reported that it expected the recent acquisition of consumer audio company Sound United would allow the company to "realize the tremendous potential of the hearables, wearables and telemonitoring markets unlocked by our unique combination of healthcare and consumer technology capabilities." Based on this expectation, Masimo projected 2023 revenues in the range of $2.415 billion to $2.460 billion. In May, Masimo reported first quarter results in line with its projections. But second quarter results released in July fell short. Masimo's stock price fell on the news and a shareholder complaint was filed. The complaint asserts Section 10(b) and 20(a) claims and alleges that Masimo's 2023 guidance was inflated and that the company misled investors about its ability to predict future revenues based on its customer pipeline. The case is *Vazquez v. Masimo Corp.* (S.D. Cal.) (filed Aug. 22, 2023).

Tandem Diabetes Care Inc.

Tandem Diabetes Care is a global medical technology company focused on at-home diabetes care products. In August 2022, Tandem released its Q2 2022 financial results and projected 2022 annual sales "in the range of $835 million to $845 million," representing approximately 20% growth over 2021 results. Then, in November, Tandem announced its third quarter results and revised its forecast downward, projecting 2022 sales revenue of $800-$805 million, citing increased competition in the diabetes-care sector, complications arising from the COVID pandemic, and macroeconomic factors. The company's stock price fell on the news. Shareholders sued, asserting Section 10(b) and 20(a) claims and alleging that Tandem's August 2022 announcement misled investors about the potential risk from competition from other diabetes-care companies. The case is *Lowe v. Tandem Diabetes Care Inc.* (S.D. Cal.) (filed Sept. 8, 2023).

DermTech, Inc.

DermTech is a molecular diagnostic company that develops and sells non-invasive genomics tests targeted at skin diseases. In August 2022, DermTech announced second quarter results and disclosed a "lower average selling price" for its melanoma test due to "Medicare billing code edits" and "less favorable collection patterns from commercial payers." In November, DermTech announced its

third quarter results, reporting flat growth due to "headwinds caused by limited commercial payer coverage" and "commercial payer collection challenges." The stock price fell. Shareholders sued, asserting Section 10(b) and 20(a) claims and alleging that DermTech misled investors about the likelihood that issues with collections from third-party payers would affect the company's financial results. The case is *Bagheri v. DermTech, Inc.* (S.D. Cal.) (filed Oct. 16, 2023).

Acelyrin, Inc.

Acelyrin is a clinical-stage biopharma company. Its lead product candidate is izokibep, designed to treat Hidradenitis Supperativa, a painful skin condition. In 2023, izokibep was in Part B of a Phase 2b/3 clinical trial. Acelyrin went public through an IPO in May 2023. In September, Acelyrin announced disappointing top-line results from Part B of the izokibep Phase 2b/3 trial. Acelyrin's stock price fell. Shareholders sued, asserting Section 10(b) and 20(a) claims and alleging that Acelyrin misled investors about izokibep's effectiveness and its clinical and commercial prospects. The case is *Aramouni v. Acelyrin, Inc.* (C.D. Cal.) (filed Nov. 15, 2023).

The Beauty Health Co.

The Beauty Health Co. is a health and beauty company and provider of "skin health experiences." Its flagship brand is Hydrafacia, which sells goods and services related to hydradermabrasion, a dermatological procedure involving mechanical exfoliation. In March 2022, Hydrafacial launched Syndeo, a data-connected hydradermabrasion machine. In its Second and Third Quarter 2023 financial reports, Beauty Health announced (i) lower than expected revenues caused by lowered margins on Syndeo sales and "restructuring charges related to device upgrades of early generation Syndeo devices," (ii) lowered guidance for future Syndeo revenues, and (iii) the departure of the company's CFO. Shareholders sued, asserting Section 10(b) and 20(a) claims and alleging that Beauty Health's earlier financial reports misled investors about the prospects for Syndeo. The case is *Alghazwi v. The Beauty Health Company* (C.D. Cal.) (filed Nov. 16, 2023).

D.C. Circuit

Danaher Corporation

Danaher, a manufacturer of diagnostic medical tests, generated strong financial results during the COVID-19 pandemic. As the pandemic subsided and demand for Danaker's products fell, the company's stock price fell as it reported reduced revenues and lowered its forward-looking guidance. The complaint asserts Section 10(b) and 20(a) claims and alleges that Danaher misled investors about the sustainability of the growth the company experienced during the pandemic. The case is *Hawkinds v. Danaher Corp.* (D.D.C.) (filed July 17, 2023).

PART III – NOTABLE 2023 DECISIONS IN LIFE SCIENCES SECURITIES CLASS ACTIONS

COURT OF APPEALS DECISIONS

MOTION TO DISMISS – AFFIRMING DISMISSAL

Nandkumar v. AstraZeneca PLC, No. 22-2704-CV, 2023 WL 3477164 (2d Cir. May 16, 2023)

During Phase 2/3 trials for a development-stage COVID vaccine, AZD1222, AstraZeneca told investors that initial results showed similar responses to the vaccine in both younger and older adults and that the inflammatory response to vaccination was lower in older adults. In December 2020, however, the company published trial results, disclosing that the trial had not established that AZD1222 was effective for older adults. AstraZeneca's stock price fell. Investors sued.

The complaint alleged that AstraZeneca's statements about the AZD1222 clinical trials were misleading because, although the company accurately reported the initual trial results, the company did not disclose allegedly adverse facts about the trials, including that the trials allegedly "failed to include a substantial number of patients over 55 years of age … despite this patient population being … a high priority target market for the drug."

The trial court dismissed the complaint. The U.S. Court of Appeals for the Second Circuit affirmed the dismissal. The court of appeals concluded that the complaint failed to state a securities fraud claim because it failed to show how the alleged omissions rendered AstraZeneca's statements misleading. The court also found that the complaint failed to plead a strong inference of *scienter*, noting that AstraZeneca's voluntary disclosure of negative information about the trial results undercut any inference of fraudulent intent.

In re Philip Morris Int'l Inc. Sec. Litig., 89 F.4th 408 (2d Cir. Dec. 26, 2023)*

Between December 2016 and March 2017, Philip Morris International (PMI) applied for FDA authorization to market IQOS, a smoke-free electronic tobacco device, in the U.S, either generally (unaccompanied by any claims about health benefits relative to conventional cigarettes), as a "reduced-exposure" tobacco product, or as a "reduced-risk" tobacco product. PMI submitted various studies assessing IQOS's effects on users and relative health risks compared to traditional cigarettes. PMI told investors these studies had been "conducted according to Good Clinical Practice ('GCP')," an international quality standard for clinical trials, and that the studies supported PMI's conclusion that "IQOS has the potential to reduce the risk of smoking-related diseases in adult smokers."

In December 2017, *Reuters* reported a former PMI scientist's criticisms of the IQOS studies. The next month, the FDA's Tobacco Products Scientific Advisory Committee recommended that the FDA grant IQOS a "reduced-exposure" order but deny a "reduced-risk" order. The *New York Times* reported that "F.D.A. Panel Rejects Philip Morris's Claim That Tobacco Stick Is Safer Than Cigarettes." PMI's share price fell. PMI investors sued.

After the complaint was filed, the FDA authorized PMI to market IQOS with "reduced-exposure" claims. In doing so, the FDA found that PMI's

* Although this case did not involve a life sciences company, the decision includes an important discussion of the proper treatment of securities fraud claims based on alleged misstatements about scientific studies conducted in connection with an FDA application.

studies showed "switching completely from conventional cigarettes to the IQOS system significantly reduces … exposure to harmful or potentially harmful chemicals." Thus, the FDA concluded "a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely…."

The district court dismissed the complaint. The Second Circuit affirmed the dismissal.

In In re Philip Morris, the Second Circuit confirmed that "a mere dispute about the proper interpretation of data" cannot support a securities fraud claim. Rather, so long as the defendants' interpretation is "reasonable," it is not "false."

The Second Circuit explained that vague positive statements about scientific study methodology—i.e., that studies were "rigorous," "extensive," and "thorough" and that the scientists involved were "expert" and "world-class"—were "precisely the type of puffery that [courts] have consistently held to be inactionable." And the court extended this reasoning to PMI's statements that its studies followed "Good Clinical Practice." The court explained that determining compliance with GCP—which requires studies to be "scientifically sound" and those performing them to "qualified"—involves "inherently subjective assessments that do not lend themselves to resolution as a matter of objective fact."

The court also affirmed dismissal of claims based on PMI's characterization of the studies' results—including that the studies "indicate that IQOS is likely to present less risk of harm compared to smoking." The court explained that "a mere dispute about the proper interpretation of data" cannot support a securities fraud claim. Rather, so long as the defendants' interpretation is "reasonable," it is not "false." Finally, the court held—as a matter of first impression — that any interpretation the FDA ultimately accepts is per se reasonable.

Golla v. Neovasc, Inc., No. 22-361-CV, 2023 WL 2469770 (2d Cir. Mar. 13, 2023)

Neovasc developed the Reducer, a device to treat refractory angina. After the Reducer became commercially available in Europe in 2015, Neovasc had regular discussions with the FDA about marketing the device in the U.S. In February 2019, Neovasc disclosed that an FDA review team recommended that the company collect additional blinded data before submitting a pre-market approval application. Rather than conduct additional pre-approval studies, Neovasc sought pre-market approval based on a proposal for an additional post-approval clinical study. The FDA advisory panel expressed concerns about the lack of an additional pre-approval study, ultimately recommending against approval. The FDA followed the panel's recommendation and denied the application. Neovasc's stock price fell. Investors sued.

The complaint alleged that Neovasc misled investors about "(1) . . . communications with the FDA, (2) the strength of the clinical data already collected to demonstrate efficacy, and (3) whether there was a sound basis to approve a pre-market application for the Reducer, which would allow Neovasc to market it in the United States." The district court dismissed the complaint. The Second Circuit affirmed the dismissal.

The Second Circuit found that the complaint failed to plead a strong inference of *scienter*. The complaint's scienter theory rested heavily on the FDA advisory panel's statements to Neovasc about the lack of an additional pre-approval study. The plaintiff argued that these statements showed that the company knew the application would not be approved. But the court found the more compelling inference was that Neovasc decided—given the expense and time involved with conducting a new study—that submitting a proposal for a post-approval study alongside its application was preferable. The court also noted that Neovasc disclosed the substance of the advisory panel's concerns when it told investors that the FDA recommended "collection of further pre-market clinical data."

Emps.' Ret. Sys. of the City of Baton Rouge & Par. of E. Baton Rouge v. MacroGenics, Inc., 61 F.4th 369 (4th Cir. 2023)

A breast cancer treatment called Margetuximab was MacroGenics' first treatment to reach a Phase 3 trial. MacroGenics designed the trial to compare Margetuximab with the current standard-of-care treatment based on two endpoints: "prolongation of progression free survival" and "prolongation of overall survival."

In early 2019, MacroGenics announced that the study had "met the primary endpoints of prolongation of progression-free survival." The company also told investors that collection of data for the "overall survival" endpoint was ongoing and that full study results would be presented at the upcoming American Society of Clinical Oncology (ASCO) conference in June.

The next week, MacroGenics raised more than $120 million through a secondary stock offering. The offering documents cautioned that "[w]e may publicly disclose topline or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial."

In the following weeks, MacroGenics made additional positive statements about the "progression-free survival" results, while noting that those results "d[id] not indicate whether the co-primary endpoint of overall survival will be achieved."

In MacroGenics, the Fourth Circuit concluded that general positive statements concerning interim clinical study results—describing those results as "positive" and "promising"—were inactionable puffery, noting that those statements were qualified with warnings that the final data could still fail to achieve the study's primary endpoint.

In June 2019, MacroGenics presented the full Margetuximab study data at the ASCO conference. While the study results showed a statistically significant increase in progression-free survival, market analysts were disappointed in the overall survival data, concluding that the study would not meet its overall survival endpoint. MacroGenics' stock price fell and investors sued.

The complaint alleged that MacroGenics' discussion of the promising progression-free survival results was misleading because it omitted discussion of the overall survival results.

The district court dismissed the complaint and the Fourth Circuit affirmed. The court of appeals found that MacroGenics' statements about the trial's progression-free survival results did not trigger a duty to disclose interim overall survival results. The court noted MacroGenics' discussion of overall survival results stressed that the study was ongoing and that the progression-free survival results did not guarantee that the overall survival endpoint would be met. In addition, the court concluded that MacroGenics' general positive statements concerning the interim overall survival results—describing those results as "positive" and "promising"—were inactionable puffery, while noting that those statements were qualified with warnings that the final data could still fail to achieve the study's primary endpoint.

MOTION TO DISMISS – AFFIRMING IN PART AND REVERSING IN PART DISMISSAL

Shash v. Biogen, Inc., 84 F.4th 1 (1st Cir. 2023)

In late 2015, Biogen began two Phase III studies for an application for FDA approval of an Alzheimer's disease treatment, aducanumab. The trials each included placebo, low dose, and high dose dosage arms. In March 2019, Biogen announced

that it had terminated both studies following a futility analysis. After a post-hoc review of the study data, Biogen concluded that the high dosage groups' results supported FDA approval. In its announcement of this conclusion, Biogen released top-line study data but not subgroup-level data.

Over the next several months, Biogen repeatedly told investors that it believed the study data showed "the high dose reduced clinical decline." During a company earnings call, Biogen's CEO told an equity analyst, "you really need to get to the higher dose" and "I think our data are all consistent with that."

In November 2020, the FDA released its briefing book in advance of the aducanumab advisory committee meeting. While otherwise "overwhelmingly favorable," the briefing book included an FDA reviewer's opinion that "the totality of the data does not seem to support the efficacy of the high dose" and included his subgroup-level analyses of the study data in support of this conclusion. The advisory committee then voted that it was unreasonable to consider the Phase III results as "primary evidence of effectiveness of aducanumab for the treatment of Alzheimer's disease." Biogen's stock price fell. Investors sued.

The complaint alleged that Biogen's statements about aducanumab's efficacy were misleading because they failed to disclose allegedly contradictory Phase III subgroup data that allegedly undermined Biogen's stated position. The district court dismissed the complaint.

The First Circuit affirmed dismissal with respect to all but one of Biogen's statements. Assuming that the Phase III subgroup data undermined Biogen's public statements, as the complaint alleged, the court of appeals held that the complaint failed to plead scienter because it was "not evident or inferable from the complaint" that Biogen "knew or believed that [subgroup] data undermined their statements about aducanumab's general efficacy." The court noted that conclusions about aducanumab's efficacy involved subjective interpretation of significant amounts of data requiring complex statistical analysis and that the complaint failed to allege facts showing that Biogen did not actually believe its analysis and judgments.

But the court reversed dismissal as to the CEO's statement that "I think our data are all consistent with" the conclusion that "you really need to get to the higher dose." Unlike Biogen's other, more general statements, the court found the complaint pleaded falsity and scienter as to this statement by alleging that the omitted subgroup data undermined Biogen's views and, thus, necessarily conflicted with the statement that available data were "all consistent with" Biogen's conclusions.

DISTRICT COURT DECISIONS

GRANTING MOTION TO DISMISS

Quinones v. Frequency Therapeutics, Inc., No. CV 21-10933-WGY, 2023 WL 2693901 (D. Mass. Mar. 29, 2023)

Frequency Therapeutics developed FX-322 to treat a form of severe hearing loss. After a promising Phase I clinical trial, Frequency announced a Phase 2a trial, with participants receiving weekly injections of either FX-322 or a placebo. Frequency told investors the Phase 2a trial "was conducted on an unbiased and appropriate sample population" and that all participants had "meaningful word recognition deficits."

Several months later, Frequency disclosed that the Phase 2a trial was "unlikely" to "support the efficacy of the FX-322." Frequency explained that

"interim results" showed "an unexpected apparent level of hearing benefit in the placebo group that did not occur in previous trials and exceeded well-established published standards, potentially suggesting bias due to trial design." Market analysts understood this to mean that "patients may have been faking worse hearing than they actually had to make sure they could enroll." Following this announcement, Frequency's stock price fell 78%. Investors sued.

The complaint alleged that Frequency defrauded investors by saying that (i) the study's admission criteria "required all subjects have meaningful word recognition deficits;" (ii) Frequency had not publicly disclosed the study's admission criteria in order "to minimize any bias" and (iii) "all" study subjects had "meaningful word recognition deficits." The complaint included statements from Frequency's former Senior Manager of Clinical Operations, who claimed "multiple patients … simply 'faked being deaf' in order to enroll" and that the defendants were "well aware" the admission criteria "were being disseminated online."

The district court dismissed the complaint. The court found Frequency's statements that "Phase 2a's entrance criteria required all subjects have meaningful word recognition deficits" were not misleading because they accurately described the trial's enrollment criteria. As to scienter, although the court found that complaint adequately alleged that the statement that "all subjects have meaningful word recognition deficits" was false, the court found that the complaint failed to plead scienter as to this statement because it failed to establish that the individual defendants knew there were enrolled patients who did not meet the stated admissions criteria. The decision is now on appeal to the First Circuit.

Luongo v. Desktop Metal, Inc., No. 1:21-cv-12099, 2023 WL 6142715 (D. Mass. Sept. 20, 2023)

In February 2021, Desktop Metal acquired EnvisionTEC, a 3D-printing company that sold materials for printing custom medical and dental devices. One of EnvisionTEC's products, Flexcera, is a resin that can be formed into removable denture bases using 3D printers and "curing boxes," which harden the resin after it is printed. The next month, Desktop Metal applied for FDA approval to market Flexcera. The company produced the final hardened resin product used in its application with an EnvisionTEC 3D-printer and a curing box made by a competitor. The FDA approved the application.

After selling Flexcera as an FDA-approved product for several months, Desktop Metal disclosed a whistleblower complaint alleging that EnvisionTEC had been manufacturing Flexcera at a non-FDA compliant facility and had been selling Flexcera with the company-made "PCA 4000" curing box rather than the third-party curing box used for the FDA application. Desktop Metal announced an internal investigation and that EnvisionTEC's CEO had resigned.

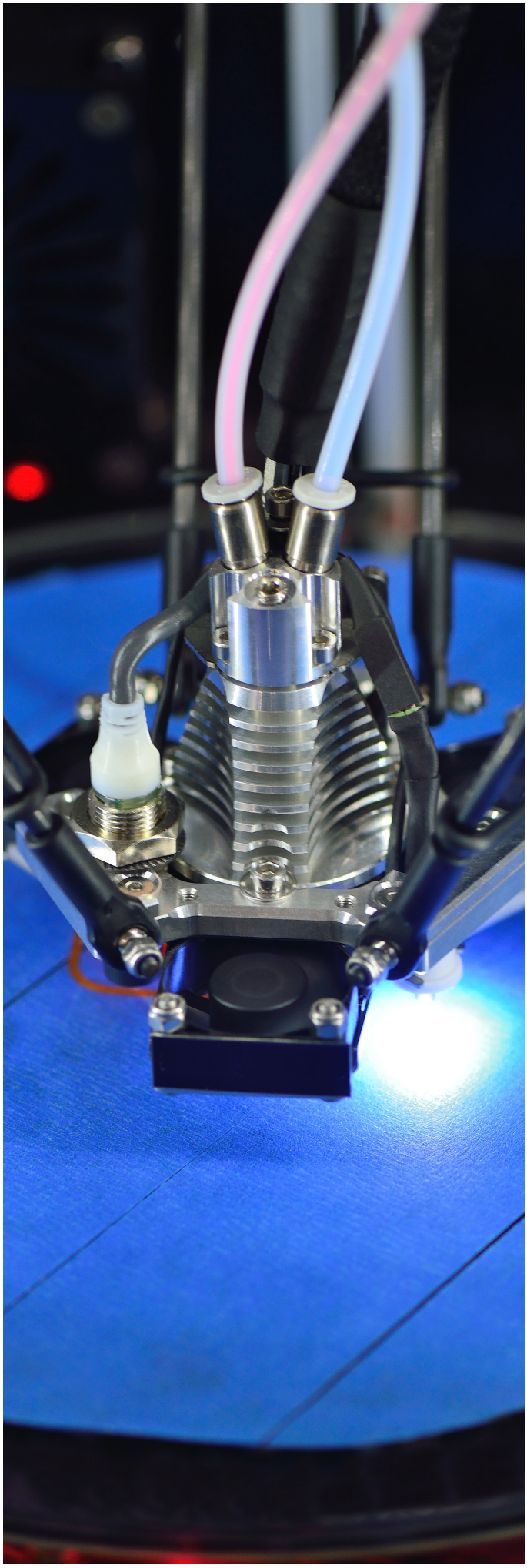
Following the investigation and consultation with the FDA, Desktop Metal recalled Flexcera resin manufactured between April 1 and September 15. Desktop Metal's stock price fell. Investors filed a Section 10(b) class action complaint.

The complaint identified four general categories of alleged misstatements: (i) Desktop Metal's pre-acquisition statements about the company's due diligence into EnvisionTEC; (ii) statements about the application for FDA approval of Flexcera; (iii) general statements about EnvisionTEC's regulatory compliance; and (iv) statements about the PCA 4000 curing box's capabilities.

The court dismissed the complaint. As to Desktop Metal's pre-acquisition due diligence statements, the court found that the complaint failed to allege facts showing Desktop Metal's due diligence was inadequate. As to statements about the application for FDA approval of Flexcera, the court found that the complaint failed to allege that Desktop Metal falsified data for its FDA application or that the FDA's approval was invalid. In other words, the complaint did not plead falsity because Desktop Metal accurately disclosed the basis for its application and the fact that the FDA had approved it. As to the company's general statements about regulatory compliance, the court found that Desktop Metal disclosed that its business was subject to FDA regulation, adequately warned of the risk of potential non-compliance, and then promptly disclosed allegations that EnvisionTEC used non-complaint manufacturing facilities when it received the whistleblower complaint. Finally, while Desktop Metal and EnvisionTEC had made statements touting their PCA 4000 curing box, the complaint did not identify any public statements suggesting that the PCA 4000 curing box could be effectively used in the production of Flexcera.

In re Bristol-Myers Squibb Co. CVR Sec. Litig., 658 F. Supp. 3d 220 (S.D.N.Y. Mar. 1, 2023)

In connection with its 2019 acquisition of pharmaceutical company Celgene, Bristol-Myers Squibb (BMS) issued contingent value rights (CVRs)—securities promising payments tied to occurrence of specified future events—to Celgene shareholders, tied to FDA approval of Celgene's three new drug candidates, including Liso-cel, by specified deadlines. BMS was to pay $9 per CVR—a total of $6.4 billion—if, and only if, the FDA approved all three Celgene drugs by their respective deadlines. The deadline for approval of Liso-cel was December 31, 2020.



Because Liso-cel is a biologic drug, it could be approved only after the FDA reviewed BMS's biologics license application (BLA), conducted facility inspections, and concluded that Liso-cel was safe, efficacious, and appropriately labeled. Less than a month after the Celgene merger closed, BMS submitted the final portion of the Liso-cel BLA on December 18, 2019. On February 13, 2020, the FDA granted Liso-cel "Priority Review," with an August 17, 2020 target approval date.

On March 23, 2020, the FDA directed BMS to supplement the Liso-cel BLA and BMS promptly did so. After reviewing the supplement, the FDA concluded that it constituted a "Major Amendment" of the application, triggering a 3-month extension of the target approval date, until November 16, 2020. Due to internal scheduling issues, the FDA did not complete required inspections of Liso-cel manufacturing facilities until early December. The FDA inspections identified regulatory violations requiring remediation. Although BMS provided a remediation plan by the FDA's deadline, the FDA did not approve Liso-cel until February 2021, a few weeks after the December 31, 2020 milestone deadline. As a result, the CVRs expired worthless.

Acquirers of the CVRs sued under both Section 10(b) and Section 11, alleging BMS made misstatements about ''the 'diligent' efforts" it would make to meet the milestone deadlines and the likelihood that it would meet the milestone deadlines.

The district court dismissed the Exchange Act claims for failure to plead scienter. The plaintiffs sought to plead scienter based on BMS's alleged "missteps" during the Liso-cel approval process, including "delays in filing and supplementing information with the FDA and not adequately preparing the two Liso-cel manufacturing facilities for their inspections." The plaintiffs argued it was ''simply implausible" that the various "missteps" "all happened in such a way as to delay the FDA approval of Liso-Cel just enough to save [BMS] $6.4 billion, accidentally.'' The court disagreed, concluding that "the more compelling inference to be drawn from the pleaded facts is that both BMS and the FDA experienced embarrassing, but not 'extreme' setbacks during an unprecedented pandemic."

The district court also dismissed the Securities Act claims under the Reform Act safe harbor for forward-looking statements. Plaintiffs premised the Securities Act claims on statements in the CVR offering documents about the likelihood of FDA approval for the three drugs. But the court explained that "'statements about FDA approval . . . are classically forward-looking' because 'they address what defendants expect to occur in the future.'"

Zhou v. NextCure, Inc., 20-CV-7772, 2023 WL 4493541 (S.D.N.Y. July 12, 2023)

In the fall of 2018, NextCure announced that it had initiated a Phase 1 trial for NC318, a new drug candidate designed to block the immunosuppressive properties of a protein present on some cancerous tumors. NextCure designed the Phase I trial "to assess the safety and tolerability of NC318, define the maximum tolerable dose, … and to assess preliminary efficacy." NextCure also announced an agreement with Eli Lilly to develop new treatments using FIND-IO, a three-dimensional imaging platform that NextCure used to develop immune-oncology therapies.

In May 2019, while the Phase 1 trial was ongoing, NextCure went public. The IPO prospectus described FIND-IO as a "novel," "proprietary" platform for the development of immunotherapies that NextCure developed based on "a predecessor platform" invented by NextCure's founder, Dr. Lipeing Chen.

On November 5, 2019, NextCure published an abstract in a medical journal summarizing "interim results" from the NC318 Phase 1 trial, which NextCure planned to present at an industry conference a few days later. The abstract described interim data "as of August 2019"—i.e. from two months earlier. Summarizing this data, the abstract explained that forty-three cancer patients, including ten with non-small cell lung cancer, had been given doses of NC318. Of those forty-three patients, thirty-two were "evaluable" and eleven had not yet "reached their first assessment," as of August. Based on results from the thirty-two "evaluable" patients, NextCure reported that NC318 had been "well-tolerated across multiple dose levels" and had "shown encouraging anti-tumor activity." A few days later, on November 9, NextCure presented the current to-date study data at the industry conference.

Later that month, NextCure conducted a secondary stock offering. The offering materials described NC318's "potential to treat multiple cancer indications," while reiterating that the Phase 1 study was "designed to determine the pharmacologically active dose" and "maximum tolerable dose of NC318."

In 2020, a series of negative developments drove down NextCure's stock price. In January, NextCure announced that Eli Lilly had canceled their agreement. In February, another biopharma company, Immunaccel Labs, sued NextCure's CEO, alleging that FIND-IO "effectively copied" Immunaccel's 3D imaging platform. Finally, in July, NextCure released another interim update on the NC318 Phase 1 trial and announced that the lung and ovarian cancer cohorts would not continue to the trial's second stage because data for those cohorts was "disappointing."

In In re Bristol-Myers Squibb, the court explained that "'statements about FDA approval . . . are classically forward-looking' because 'they address what defendants expect to occur in the future.'"

NextCure's stock price declined on the news. Investors sued, asserting Section 10(b) and Section 11 claims against the company and alleging that NextCure's statements about the promising early NC318 Phase 1 trial results, NC318's "potential" to treat "multiple" cancers, and FIND-IO's "unique" and "proprietary" nature were misleading.

The district court dismissed the complaint.

As to NextCure's statements about the early Phase 1 trial data, the court stressed that NextCure repeatedly explained that the trial was designed to evaluate safety and dosage, not efficacy. While NextCure told investors that preliminary data from the early-stage trial showed encouraging signs about NC318's efficacy, the company cautioned both that "initial success in clinical trials may not be indicative of results obtained when such trials are completed" and that "early-stage clinical trials may not be predictive of the results of later-stage large-scale efficacy clinical trials." The also court noted FDA guidelines providing that Phase 1 trials are meant to "determine the metabolism and pharmacologic actions of the drug in humans" and "the side effects associated with increasing doses."

Thus, the court concluded that complaint's theory of liability as to NC318—that accurate disclosures of interim Phase 1 study results misled investors about the drug's efficacy and the likelihood of FDA approval—failed because it "ignore[d] both the regulatory context" and "NextCure's own disclosures." In "the Phase 1 context," the court explained, NextCure's statements were neither false nor misleading.

As to statements about FIND-IO's "unique" and "proprietary" nature, the court first found that mere repetition of unproven allegations in Immunaccel's lawsuit failed the Reform Act's heightened pleading standard. In any event, even if FIND-IO "effectively copied" Immunoaccel's technology, the plaintiff could not show how that contradicted NextCure's statement that FIND-IO was "proprietary."

Shapiro v. TG Therapeutics, Inc., 652 F. Supp. 3d 416 (S.D.N.Y. Jan. 25, 2023)

TG Therapeutics focuses on treatments for B-cell malignancies and autoimmune diseases, including cancer and multiple sclerosis. As of February 2021, the company had developed two drugs, Umbralisib (known commercially as "UKONIQ"), to treat Lymphoma, and Ublituximab, to treat multiple sclerosis. TG was also studying joint use of both UKONIQ and Ublituximab together (in a package called "U2") to treat leukemia. In addition to the respective applications for approval of UKONIQ and Ublituximab, the FDA required the company to submit a supplemental application for approval of the two drugs taken together as U2.

While the trials were ongoing, TG announced that the FDA had placed UKONIQ on an accelerated approval timeline. The company also expressed its view that UKONIQ was safe and effective, while publicly reporting (through the FDA's Adverse Event Reporting System) that some patients in the U2 trials suffered serious adverse events.

In November 2021, TG announced that the FDA Oncologic Drugs Advisory Committee would be reviewing the U2 application. But, in April 2022, before the ODAC meeting, TG announced that it had voluntarily withdrawn the application and would be closing its oncology division. A few weeks later, the FDA pushed back the schedule for the Ublituximab application and denied the UKONIQ application due to safety concerns. TG's stock price fell. Investors sued.

The complaint alleged that TG's statements about its expectations and plans for its application for FDA approval of UKONIQ —including that the company expected to complete a regulatory submission in

the coming year, that it believed its actions would "support, if approved," the drug's launch, that it believed the evidence warranted FDA approval, and that it was working towards obtaining approval—were misleading because, when it made the statements, TG did not disclose the adverse events some clinical trial patients had experienced.

The court dismissed the complaint. In doing so, the court found that alleged omission of information about adverse events in clinical trials was not misleading because TG publicly disclosed the information through the FDA Adverse Event Reporting System. In addition, the court found that statements about potential future developments in the FDA application process were forward-looking statements protected by the Reform Act safe harbor.

Lewakowski v. Aquestive Therapeutics, Inc., No. 21-CV-3751, 2023 WL 2496504 (D.N.J. Mar. 14, 2023)

Aquestive applied for FDA approval for Libervant, a diazepam-based anti-seizure medication. The FDA directed the company to conduct a study comparing Libervant to Diastat, an FDA-approved diazepam-based anti-seizure medication. Aquestive released top-line study results, which, Aquestive reported, showed Libervant performing comparably to Diastat. As the FDA application process progressed, Aquestive executives made various positive comments about the process, including that the pre-NDA meeting was very positive and that the FDA told Aquestive it was close to the end of the approval process.

But the FDA ultimately denied approval for Libervant based, in part, on results of the study comparing Libervant and Diastat. While the FDA concluded that, overall, Libervant "achieved comparable absorption [of diazapem] compared to Diastat," it found diazepam absorption rates "too low" for some patients taking Libervant. Following this announcement, Aquestive's stock price fell.

Investors sued, alleging that Aquestive's positive statements about the Libervant study and the prospects for FDA approval were misleading because the company only disclosed positive top-line study data while omitting more detailed—and allegedly contrary—underlying data. The district court dismissed the complaint.

In its decision, the court noted that the reported topline data was accurate and found that the complaint failed to plead any facts suggesting Aquestive did not believe the reported data was valid. Though the FDA ultimately denied approval based on results for a sub-set of patients, the court explained that differences of opinion between an applicant and the FDA about interpretation of clinical data do not suffice to plead securities fraud. The court also noted that Aquestive repeatedly cautioned investors about the "inherently uncertain" FDA approval process. Finally, the court found that the Reform Act safe harbor for forward-looking statements protected Aquestive's statements about the prospects for FDA approval of Libervant.

In re Ocugen, Inc. Sec. Litig., 659 F.Supp.3d 572 (E.D. Pa. Mar. 3, 2023)

In December 2020, Ocugen announced a letter of intent to partner with Indian pharmaceutical company Bharat Biotech to develop COVAXIN—a COVID vaccine then under development in India—for the U.S. market.

In January 2021, the Indian government granted COVAXIN expedited approval. In March, Bharat announced initial Phase III trial results suggesting COVAXIN had 81% efficacy against COVID.

In dismissing the complaint in Aquestive Therapeutics, the court noted that the supposedly misleading topline clinical study data was accurate and, though the FDA ultimately denied approval based on results for a sub-set of patients, differences of opinion between an applicant and the FDA about interpretation of clinical data do not suffice to plead securities fraud.

In February, Ocugen announced a definitive agreement with Bharat for U.S. commercialization of COVAXIN. Ocugen told investors that it had begun conversations with the FDA about expedited approval of COVAXIN under an emergency use authorization (EUA) and that it planned to file an EUA application for COVAXIN in the first half of 2021. Based on this projected timeline, Ocugen said COVAXIN had "potential for significant revenues" in 2021. Over the next several months, Ocugen continued to speak optimistically about the prospects for expedited approval of COVAXIN on this timeline.

In June 2021, however, Ocugen announced that—at the FDA's recommendation—it would seek approval for COVAXIN under a biologics licensing application (BLA) rather than an EUA, which would significantly extend the approval timeline. Ocugen's stock price fell following the announcement.

Investors sued, alleging that Ocugen's statements about the timeline for submitting an EUA and the prospects for expedited approval were false or misleading. The district court dismissed the complaint.

The court found that the complaint failed to plead that Ocugen's statements about its expected timeline for submitting its emergency use application were misleading when made because the complaint failed to allege any facts suggesting that Ocugen did not intend to meet the timeline or that the FDA had told Ocugen not to proceed with an EUA at the time the statements were made. The court concluded that the most likely inference from the facts alleged was that Ocugen sincerely intended to apply for an EUA and was making plans to do so until the FDA recommended against it.

Turnofsky v. electroCore, Inc., No. CV1918400ZNQTJB, 2023 WL 4527553 (D.N.J. July 13, 2023)

electroCore, Inc. is a bioelectronic medicine company. Its flagship product is gammaCore, a small, handheld electronic device that treats cluster headaches and migraines by electronically stimulating the Vargus nerve, blocking pain signals to the brain.

In April 2017, the FDA approved sales of electroCore's original gammaCore product to treat cluster headaches on a thirty-one day prescription basis. In December 2017, the FDA approved sales of gammaCore Sapphire, intended for multi-year use. Finally, in January 2018, the FDA approved gammaCore to treat acute migraine pain.

In June 2018, electroCore went public through an IPO. The IPO Registration Statement represented that electroCore had "agreements in place with commercial payers" that "we believe, based on our estimates, will provide reimbursement of gammaCore as a pharmacy benefit for approximately 17 million commercial lives with such number expected to increase to as many as 45 million lives." The Registration Statement also represented that electroCore was engaged in negotiations at "the active clinical review stage with more than a dozen additional insurance plans covering approximately 120 million additional commercial lives." But the Registration Statement warned that, "[w]hile some commercial payers may provide coverage under their pharmacy benefit plans," other payers, "including governmental and private insurers, may not be willing or authorized to provide coverage for our therapy under pharmacy plans that more commonly cover prescription drug products." And the Registration Statement explained that payers who did not cover gammaCore under pharmacy plans might "require us to seek coverage for gammaCore as a medical supply or item of durable medical equipment," which could result in "different pricing, reimbursement, and patient cost-sharing policies."

In the months after the IPO, electroCore's senior executives continued to discuss ongoing negotiations with third-party payers, stating that the company remained on track to reach the agreements contemplated in the IPO Registration Statement, including an agreement for reimbursement for gammaCore for approximately 30 million people covered under CVS pharmacy plans.

In May 2019, however, electroCore disclosed that difficulties obtaining commercial insurance coverage for gammaCore were negatively affecting the company's financial results. On May 29, electroCore announced a cost reduction plan. On June 10, it announced that its CEO was stepping down. The company's stock price declined. Investors sued, asserting both Securities Act and Exchange Act claims.

The court granted electrocCure's motion to dismiss, finding that the complaint failed to plead a material misstatement as both Section 10(b) and Section 11 require.

First, the court concluded that the complaint failed to establish that the Registration Statement's statements about payer agreements that electroCore had in place were false or misleading, in light of the cautionary language about the risk that payers would not cover gammaCore under their pharmacy benefit plans, including warning of the risk that "[i]f third-party payers do not provide adequate coverage and reimbursement for the use of gammaCore, we will be unable to generate significant revenues."

Second, the court rejected the plaintiff's argument that electroCore's statement that it had "agreements with commercial payers" falsely implied it had agreements in place with insurance companies, when, in fact, it had only two "limited" agreements with pharmacy benefits managers (PBM). The court noted that the Registration Statement made clear that "payers" was an umbrella term that included all third-party payers, including commercial insurance companies, PBMs, government payers, and others. And, when it wished to refer specifically to commercial insurance companies, it did so.

Third, the court rejected the plaintiff's challenges to electroCore's disclosures about its agreement with CVS, including that it overstated the number of "commercial lives" covered under the agreement and that it misleadingly omitted to disclose various limitations on coverage under the agreement. The court noted that electroCore's disclosed the number of commercial lives that it "believed" would be covered "under its estimates," making clear that the statement was a subjective opinion, not a statement of fact. As for the omission of information about limitations on coverage under the agreement, the court concluded that sophisticated investors understand that coverage and reimbursement under insurance and benefit plans are typically subject to some limits and conditions.

In re Eargo, Inc. Sec. Litig., 656 F. Supp. 3d 928 (N.D. Cal. Feb. 14, 2023)

Eargo makes hearing aids and sells them directly to people with mild-to-moderate hearing loss. It was founded in Silicon Valley in 2010 as a "disruptor" to the traditional hearing aid sales model, in which customers must visit an audiologist for an in-person hearing test and then test and hearing aid fitting. Eargo developed a telecare model through which Eargo's in-house team of licensed hearing aid dispensers interacted directly with customers online, selling them hearing aids based on "do-it-yourself" hearing tests. Thus, Eargo customers can buy hearing aids without an in-person audiologist visit or a professional hearing test.

Initially, Eargo primarily marketed to customers paying out-of-pocket. But, in 2017, Eargo began targeting customers with Federal Employees Health Benefits Program ("FEHBP") insurance. FEHBP is the largest employer-sponsored health program, covering over eight million federal employees and their families. It provides benefits through various insurance carriers, the largest of which is the Blue Cross Blue Shield Federal Employee Plan ("BCBS FEP").

Unlike most insurance plans, FEHBP offers hearing aid benefits. FEHBP carriers require hearing aid claims to include a hearing-loss-related diagnosis code, typically based on a professional hearing test. FEHBP generally does not cover "over-the-counter" hearing aids.

Eargo had success targeting customers with FEHBP benefits, which allowed Eargo to expand beyond customers with the financial resources to pay cash for hearing aids. With the benefit of FEHBP insurance reimbursements, Eargo's revenues doubled from 2019 to 2020. By the end of 2020, 45% of Eargo's customers had FEHBP benefits.

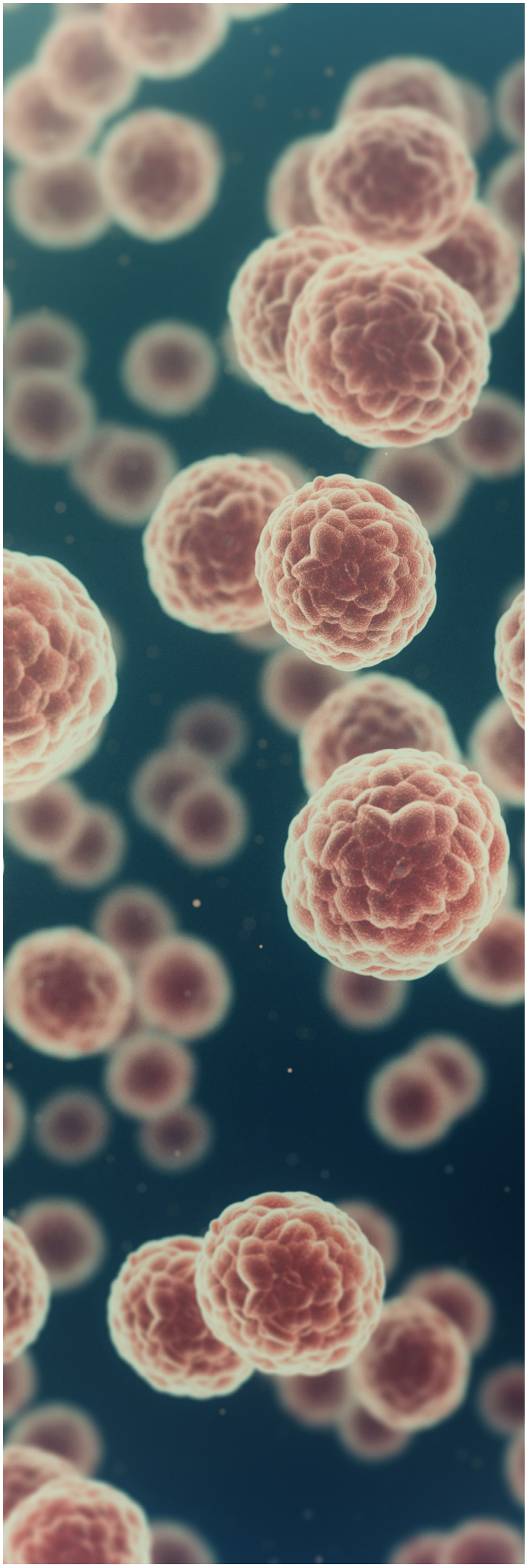
Eargo went public in October 2020. The IPO offering materials discussed Eargo's strategy of targeting customers with hearing aid insurance benefits, explaining that "the increase in customers with insurance has been a significant driver of our growth in 2020," that Eargo "intend[ed] to pursue additional coverage in the future," and that there were approximately 12 million adults in the United States over 50 years of age with both hearing loss

and access to an existing hearing aid benefit" under FEHBP plans. But Eargo also cautioned investors that its products were primarily sold "on a cash-pay basis" and that "[t]hird party coverage and reimbursement . . . could decrease," which "could reduce our market share."

In March 2021, BCBS—Eargo's largest third-party payer—asked Eargo to provide "office/medical records" and "all supporting documentation" for a small number of BCBS FEP members. BCBS explained that it was requesting the documentation pursuant to federal regulations requiring BCBS to conduct audits and reviews of claims. Two weeks later, BCBS told Eargo that it had found "irregularities" in Eargo's billing and that, going forward, BCBS would require Eargo to submit supporting documentation with all claims.

In its first quarter 2021 Form 10-Q (filed in May 2021), Eargo disclosed it was "subject to a routine audit" with BCBS. Then, in its second quarter 2021 Form 10-Q (filed in August), Eargo disclosed that BCBS had not paid any claims submitted since March 2021 and that claims submitted to another insurance company were "also currently undergoing an audit." While Eargo reported that it believed the claims submitted were valid, it also cautioned that "an unfavorable outcome of the ongoing audits could have a material adverse effect" on its financial results. Eargo also warned that insurers might "seek recoupments of previous claims paid and deny any future claims." But Eargo executives also told investors that the audits were "pretty routine" and that BCBC was "not denying claims," but trying to "define a process that allows for them to approve our claims in a more streamlined manner."

Then, in September 2021, Eargo disclosing that the Justice Department had opened a criminal investigation into its claims to federal employee



health plans. Eargo's stock price fell 68% following this announcement. Eargo investors sued, asserting Section 11 and Section 10(b) claims.

A few months later, Eargo disclosed that the criminal investigation was no longer active and had been referred to the Justice Department's Civil Division. Ultimately, Eargo reached a $34 million civil settlement of fraud and False Claims Act allegations. The announcement of the settlement summarized the government's allegations—that Eargo knowingly included unsupported diagnosis codes on claims and invoices submitted to FEHBP and FEHBP beneficiaries. The announcement also explained that the claims were "allegations only," that there had been "no determination of liability," and that Eargo denied any wrongdoing.

The shareholder complaint alleged that, before its IPO, Eargo and its executives knew its telecare model was inconsistent with FEHBP reimbursement policies and knowingly overstated revenues by failing to reserve for denial of insurance reimbursements, falsely touted federal insurance markets as a growth opportunity, and misleadingly downplayed the significance of the BCBS audit. The complaint also alleged that Eargo's IPO offering materials misleadingly failed to disclose that the telecare model conflicted with FEHBP insurance billing standards.

The district court granted Eargo's motion to dismiss. The court first held that Eargo's reported revenues—which were calculated based on subjective judgments about whether insurers would accept reimbursement claims—were statements of opinion, which are only "untrue statements of fact" if the speaker does not actually hold the stated opinion, and the court found that the complaint failed to plead facts showing that Eargo did not actually believe its claims would be approved. As to Eargo's business model, the court noted that Eargo extensively disclosed that its telecare model was unique and "nontraditional" and held that the complaint failed to allege facts showing Eargo knew its telecare business was "seriously incompatible with FEHBP insurance policies."

Dresner v. Silverback Therapeutics, Inc., 21-CV-1499, 2023 WL 2913755 (W.D. Wash. April 12, 2023)

Silverback Therapeutics is a biopharmaceutical company that developed SBT6050, designed as an anti-tumor therapy for patients who had failed to see results from other available therapies. In July 2020, Silverback initiated a Phase 1 clinical trial to evaluate SBT6050's safety and tolerability through a series of studies of different doses of SBT6050 in monotherapy (with patients receiving SBT6050 alone) and combination therapy (with patients receiving SBT6050 along with prempro, an FDA-approved anti-tumor therapy).

In December 2020, Silverback went public through an IPO. The IPO offering materials disclosed initial results from the first, lowest-dose monotherapy cohort of the SBT6050 Phase 1 study. Silverback told investors that six patients had been enrolled to date; one patient had shown stable scan results after 8 and 16 weeks; another patient's lesions had reduced in size after 8 weeks; and two enrolled patients had later withdrawn. Silverback also reported that "changes in PD [pharmodynamics] markers" that were "consistent with the potential mechanism of action" had been seen "in the first cohort" and that those same changes in PD markers had been associated with tumor regression in earlier preclinical and non-human primate studies. The IPO offering materials also discussed SBT6290, a second, anti-tumor drug candidate related to SBT6050.

In March 2021, Silverback reported its 2020 annual results. Silverback again discussed the same initial results from the first monotherapy cohort, noting the observed changes in PD markers and the potential association of those changes with tumor regression. Silverback also discussed safety data from the first monotherapy cohort, disclosing the most common side effects: flu-like symptoms and swelling and redness at the injection site. Silverback told investors that it planned to provide an update on interim study results in the second half of 2021. Silverback' s first and second quarter 2021 reports-released in May and August-included similar disclosures about the initial results for the first low-dose monotherapy cohort and the company's plans to provide a further update later in the year.

In September, Silverback presented interim Phase 1 results at a European Society for Medical Oncology (ESMO) conference. A few days before the conference, Silverback released an abstract of its presentation based on Phase 1 trial results through April 4, 2021. The abstract disclosed that-as of the April 4, 2021 cut-off date-eighteen patients had received various doses of SBT6050 in either monotherapy or combination therapy; fourteen patients were evaluable; three patients demonstrated stable tumors; and one patient showed a partial anti-tumor response. The Abstract also discussed safety data from the trial, reporting that flu-like symptoms were the most common side effects and that some toxicities had occurred at higher doses, but were resolved with supportive care. Based on this preliminary safety data, Silverback concluded that SBT6050 had a "manageable safety profile."

At the ESMO conference, Silverback presented more detailed interim results through August 1, 2021. Silverback's presentation focused on results for six specific patients, which Silverback said showed SBT6050's clinical benefits for some patients with advanced tumors that had not responded to other treatments. The presentation also revealed that only thirteen of the forty patients who had participated in the study remained on SBT6050 treatment as of the August 1, 2021 cut-off date. Of those patients no longer receiving treatment, seventeen discontinued treatment because of disease progression; seven chose to discontinue treatment without identifying the reason; and five had died.

In November 2021, Silverback released its third quarter 2021 results and disclosed that three patients in higher dosage combination treatment cohorts experienced serious toxicities, including one who died. As a result, Silverback discontinued testing of combination treatment at higher dosages. But the company reported that it would continue combination therapy at a lower dose.

Finally, in March 2022, Silverback released its 2021 results and announced it had discontinued the SBT6050 trial because the full study data showed only limited anti-tumor activity from monotherapy and adverse events limiting the dosage in combination with pembro. In addition, because of the similarity of SBT6050 and SBT6290, Silverback also discontinued SBT6290 based on this data. After this announcement, Silverback's stock price fell and investors sued.

The complaint asserted Section 11 claims based on statements in Silverback's IPO offering materials and Section I0(b) claims based on various statements about SBT6050 and SBT6290 from the IPO through the March 2022 announcement. The district court granted Silverback's motion to dismiss.

The court dismissed the Section 11 claim for failure to plead a material misstatement in Silverback's IPO offering materials.

First, the court rejected the plaintiffs' arguments that the IPO offering documents' discussion of initial results for the first monotherapy dose cohort

In dismissing the complaint in Silverback Therapeutics, the court explained that "[a] reasonable investor able to follow and understand the technicalities of a cancer drug's development would not construe statements that discuss the 'potential mechanism of action' and 'associations with tumor regression' as claims of efficacy."

was misleading. The plaintiff did not contest the literal truth of Silverback's statements that (i) of the first six patients in the study, one had been disease stable for 16 weeks and another had seen reduced lesions after 8 weeks; (ii) changes in patients' PD markers had been seen in the first cohort, and (iii) those same changes in PD markers had been associated with tumor regression in preclinical and non-human primate studies. But the plaintiff argued these statements were nonetheless misleading because Silverback allegedly knew but failed to disclose that the patients in the first cohort showed limited anti-tumor activity.

In support of this argument, the complaint pointed to data as of April 2021, which Silverback disclosed in the ESMO presentation abstract in September 2021. Plaintiffs argued that this data showed that, by April, all six of the initial patients had withdrawn from the study because of disease progression.

The court rejected this theory as impermissible fraud-by-hindsight pleading. The court found that, even if Silverback had known the April 2021 results immediately, that still would not suggest the company was misleading investors when it spoke about initial results four months earlier, in the December 2020 IPO documents. In any event, the court concluded that, even if the company did have data showing disease progression in December 2020, this would not have rendered Silverback's otherwise accurate statements misleading.

In reaching this conclusion, the court agreed with Silverback that reasonable investors would not be surprised by a report of disease progression in the initial cohort, given that they were on the lowest dose and all the patients had advanced metastatic tumors and failed to see results from other therapies. The court noted that "Silverback's statements repeatedly ma[d]e clear that the changes in PD markers [we]re 'consistent with the

potential mechanism of action' and the changes 'had been associated with tumor regression."' And the court explained that "[a] reasonable investor able to follow and understand the technicalities of a cancer drug's development would not construe statements that discuss the 'potential mechanism of action' and 'associations with tumor regression' as claims of efficacy." To the contrary, the court recognized that "it is likely a reasonable investor" would "expect to see limited anti-tumor activity in patients with advanced diseases on the lowest dose of a trial drug."

Second, the court also rejected the plaintiffs' argument that the IPO offering documents' statements about SBT6290 were misleading because Silverback did not adequately disclose that prospects for SBT6290 were tied to the success of the SBT6050 trial. The court explained that a holistic view of the IPO offering materials showed that "Silverback properly disclosed the relationship between SBT6050 and SBT6290, and the risks associated with SBT6290's future." The court noted specific language in the offering materials discussing the similarities between the two drugs and Silverback' s extensive risk factors warning about the possibility of failed clinical trials.

The court also dismissed the Section 10(b) claims for failure to plead a misstatement.

The plaintiff alleged that Silverback's discussions of the initial results for the first monotherapy cohort in its first and second quarter 2021 reports-filed in May and August-were misleading based on the results disclosed in the September 2021 abstract. While those results were from data with an April 4, 2021 cut-off date, the court found that the plaintiff failed to allege facts showing when Silverback learned of the results. The plaintiff argued that the defendants learned of the results in real-time because the Phase 1 study was an "open label" study. But the court explained that this the plaintiffs' theory "conflate[d] data cutoff dates to mean the data had been gathered and reviewed by no later than that cutoff date," but that "is not generally what data cutoff means." In essence, the plaintiff argued that the court "should infer from the trial's open label that the twelve clinical sites located in the three countries were continuously cleaning and aggregating data, reviewing it, and summarizing it, and making it available before the data cutoff date, and that … Silverback's CEO and CFO[ ] had access to that information at any given moment." The court rejected a theory of liability based on such an implausible and unsupported inference.

In any event, regardless when Silverback learned of those results, the court found the April 2021 data would not have rendered Silverback's statements misleading because, like Silverback's IPO disclosures, "Silverback's statements [in May and August] regarding changes in the PD markers ma[de] clear that these changes had been associated with tumor regression in preclinical studies, not that these changes meant tumor regression occurred."

The plaintiff also alleged that Silverback's statements about SBT6050's safety profile were misleading because Silverback allegedly knew, but failed to disclose, that SBT6050 could not be safely used in high doses in combination with prempro. But the court found that the complaint lacked "any allegations or facts that the [defendants] knew this at the time" the alleged misstatements were made. While the plaintiff argued that "the Abstract and ESMO presentation show[ed] these adverse events were demonstrated by the data collected by the cutoff dates," the court noted, "again," that "cutoff dates alone do not demonstrate Defendants had that information at the time the statements were made."

Plumbers & Pipefitters Loc. Union #295 Pension Fund v. CareDx, Inc., No. 22-CV-03023-TLT, 2023 WL 4418886 (N.D. Cal. May 24, 2023)

CareDx sells diagnostic tests for transplant patients, including AlloSure Kidney, a test to detect signs of kidney transplant rejection. At the outset of the COVID pandemic, CareDx introduced RemoTraC, a program through which at-risk transplant patients could have blood drawn at their homes. Under the program, when doctors ordered at-home blood collection for AlloSure tests, RemoTraC phlebotomists could collect blood for other routine blood tests as well. Driven by at-home testing through the RemoTraC program, CareDx's testing volume and revenue—and its stock price—grew substancially during the pandemic.

In the fall of 2021, CareDx disclosed DOJ, SEC, and state regulatory investigations of allegedly improper bundling of AlloSure tests and blood tests in the RemoTraC program. CareDx's stock price fell following this and a series of later disclosures about the allegations and the resignation of several senior executives of the company. Investers sued.

The court dismissed for failure to plead either a material misstatement or scienter.

The complaint asserted claims based on two categories of alleged misrepresentations: (i) CareDx' s representations (in publicly filed securities underwriting agreements) that it complied with health care laws and (ii) its statements that the RemoTraC program met an ''unmet need." According to the complaint, these statements misled investors in violation of Section 10(b) because CareDx concealed that the company allegedly "relied on billing unnecessary AlloSure tests to Medicare, facilitated by illegal kickback schemes, to boost its testing services."

The court dismissed claims based on CareDx's contractual representations to its underwriters that it was "in material compliance with" all applicable healthcare laws, finding that CareDx's securities underwriting agreements could not be reasonably interpreted as communications to investors. The court highlighted disclaimers in the agreements explaining that (i) representations in the underwriting agreements were "solely for the benefit of the parties" and "not meant to provide investors with . . . factual information regarding the Company" and (ii) while the agreements were filed publicly due to regulatory requirements, investors considering purchasing shares should rely on the formal offering documents.

The court also dismissed claims that CareDx false represented that RemoTraC met an ''unmet need," while concealing that RemoTraC allegedly "was built on giving patients tests that were not medically necessary." The court explained that it was undisputed that there was "a need for a mobile phlebotomy service" during the COVID pandemic. Thus, even if it were true, as alleged, that doctors "were ordering AlloSure only because they had to do so in order to complete the other home tests," RemoTraC was filling the need for mobile blood tests.

The court also found the failure to plead scienter an independent basis for dismissal. The complaint sought to plead the required "strong inference" of scienter based on the so-called "core operations" doctrine (which argues that senior executives should be presumed to know material facts about a company's "core operations"), the resignations of some senior executives, and allegations in a whistle-blower complaint against the company. The court explained that neither the individual defendants' senior positions at the company, executive departures following announcements of bad news at the company, nor unproven and unverified allegations in an unrelated legal

In CareDX, the court dismissed claims based on the company's representations in contracts with its underwriters that it was "in material compliance with" all applicable laws, finding that contractual representations made "solely for the benefit of the parties" to the agreements were not communications to investors.

proceeding brought by a disgruntled former employee met the heightened scienter pleading standard without some particular factual allegations suggesting the defendants knew or should have known their statements were false.

In re Acutus Medical, Inc. Securities Litigation, No. 22-cv-206-RSH-DDL (S.D. Cal Sept. 27, 2023)

Acutus Medical makes a heart mapping device called the AcQMap System. The AcQMap System maps patients' hearts to allow their doctors to effectively target treatments for irregular heartbeats. Acutus makes money both by selling AcQMap consoles and workstations and by selling disposable products used with the system. Thus, its long-term success depends on installing AcQMap consoles and workstations in hospitals and clinics-increasing the "installed base" of AcQMap systems-and increasing doctors' use of the systems to generate revenue from sales of products used with the system.

Acutus commercially launched the AcQMap System in early 2020 and went public in August 2020. In its first earnings release as a public company, Acutus reported an increased installed base of AcQMap consoles and expressed "cautious optimism[ ]" that "trends will continue to improve," but also noted that the company had faced operational "struggles," that "there [was] work to be done," and that the company continued to face "COVID-related headwinds." The next quarter, Acutus warned investors that it had "a limited history operating as a commercial company" and that future performance could suffer if the company failed to effective train its sales force or increase its sales and marketing capabilities." And Aculus again reminded investors of COVID-related challenges, including that restricted access to hospitals and customer sites "negatively impacted our ability to install our AcQMap consoles and workstations in new customer accounts."

In May 2021, Acutus released its first quarter 2021 financial results, reporting "improved … commercial execution" and that the company was "encouraged" the business was "gaining momentum." But Aculus again noted uncertainty relating to COVID-19 and reported that the company "anticipated continued … headwinds" going forward. Aculus projected full year 2021 revenues between $22 million and $30 million. Over the next several months, in its financial reports and in offering materials for a secondary stock offering, Aculus continued to report both operational progress and continued challenges and uncertainty, while confirming its prior full year revenue projection. Then, in its third quarter earnings announcement, Aculus reported a net increase of only one new installed AcQMap console during the quarter and told investors the company now expected full year revenue of only $17 million to $17 .5 million. Aculus' s stock price fell and investors sued.

The complaint alleged that Aculus misled investors about the company's commercial challenges by telling them it was "executing on our plan," had a "strategy to be more targeted," and was "working to convert" more sales. The court dismissed these claims, finding such "highly generalized statements about progress, strengthening, or gaining momentum" were nonactionable puffery. And the court found the complaint failed to plead falsity in any event. For example, the court found that "the [c]omplaint's allegation that the company was not in fact 'working' to convert AcQMap system placements into revenue implies the company was literally doing nothing," which the court found implausible.

The court also rejected the claim that Aculus's full year 2021 revenue guidance was misleading, finding the company's forward-looking guidance protected by the Reform Act safe harbor.

In reaching these conclusions, the court noted that "[t]he statements at issue must [] be considered in light of the Defendants' ongoing disclosures of the challenges associated with its commercial execution, including specific challenges related to the pandemic." In light of the company's repeated discussion of operational challenges, no reasonable investor was misled by vague statements that the company was "focused" on improving results. Nor were investors misled into thinking that the company's projections for its future performance were guarantees.

Berlinger v. Bienaime, No. 21-CV-08254-MMC, 2023 WL 322899 (N.D. Cal. Jan. 19, 2023)

In November 2018, BioMarin announced it was developing BMN 307, a gene therapy to treat a rare disease called phenylketonuria. In the announcement, the company presented data from a preclinical mouse study and described mouse models used to develop BMN 307. In January 2020, BioMarin announced that BMN 307 had been approved for clinical trials. And, in April 2020, BioMarin announced that BMN 307 had progressed to "Clinical Phase 1/2" trials.

Then, in September 2021, BioMarin revealed that it had "observed liver tumors in a preclinical mouse study." As a result, the FDA shut down the BMN 307 Phase 1/2 trials. BioMarin's stock price fell and investors sued.

The complaint alleged that BioMarin's statements in 2020 about the progress of clinical studies for BMN 307 were misleading because BioMarin failed to disclose its observation of liver tumors in preclinical mouse studies. While BioMarin's September 2021 disclosure did not say when the company observed the liver tumors, the complaint noted that BioMarin first discussed the results of preclinical mouse studies in 2019 before announcing in 2020 that it had begun clinical studies. According to the complaint, this suggested that the preclinical study in which the liver tumors were observed must have been conducted—and the company must have known about the observation of liver tumors—in 2019 before BioMarin moved from the preclinical study phase to the clinical study phase.

The court found this theory too speculative to meet the Reform Act's heightened pleading standard. The court noted that while BioMarin told investors that it had progressed to "clinical stage" studies, it also said that it might continue preclinical testing, negating any inference that the preclinical study must have been conducted before the company began clinical studies. In the face of BioMarin's disclosures that it might continue conducting preclinical mouse trials in 2020, the complaint failed to allege any concrete facts about the timeline, such as "when the study that prompted the clinical hold started, when dosing concluded, when BioMarin received data from the study, when BioMarin began analyzing the data, how long that analysis took, when and how BioMarin learned that mice in the highest dose arm developed liver tumors, and when and how that information was communicated to the individual defendants."

In AcelRX Pharmaceuticals, the court dismissed the complaint for failure to plead scienter, finding that "[t]he fact that [the company] was aware that the FDA was regulating its marketing [did] not give rise to an inference that Defendants would be aware that any particular marketing material was misleading."

Sneed v. AcelRx Pharms., Inc., No. 21-CV-04353-BLF, 2023 WL 4412164 (N.D. Cal. July 7, 2023)

AcelRx is a pharmaceutical company that develops pain medications, including an opioid painkiller called DSUVIA. DSUVIA is administered sublingually—under the tongue—rather than swallowed or injected intravenously.

In 2018, the FDA approved the sale of DSUVIA, subject to a Risk Evaluation and Mitigation Strategy (REMS)—a drug safety program the FDA requires for approval of some medications raising serious safety concerns.

In February 2021, the FDA warned AcelRx that some of its marketing materials included "false or misleading claims" about DSUVIA's "risks and efficacy," violating the Food, Drug, and Cosmetics Act's prohibitions on selling "misbranded" drugs. The FDA's Warning Letter said the alleged violations were "particularly concerning considering that a REMS program was required for DSUVIA." A few days later both AcelRx and the FDA publicly disclosed the FDA's warning. The FDA's press release said AcelRx's promotional materials "undermine[d] key subscribing conditions required for the safe use of this opioid product." AcelRx's stock price fell and investors sued under Section 10(b) and 20(a).

The complaint alleged that certain of AcelRx's statements about DSUVIA (including the marketing materials the FDA identified) misled investors about DSUVIA's use and safety and that AcelRx's statements about its efforts to market DSUVIA (including statements that the company had worked to increase awareness of benefits of sublingual administration of pain medicine and to develop its sales and marketing organization)

were misleading because AcelRx allegedly failed to disclose that its marketing materials misbranded DSUVIA.

The complaint's challenge to AcelRx's marketing materials focused on statements about administration of the drug, including advertisements featuring the slogan "Tongue and Done" and executives' statements that, to administer DSUVIA, you "simply" tell the patient to "tilt their head back, lift up their tongue, you inject it under, and you're done." The FDA concluded that these statements misleadingly implied that "the administration of DSUVIA consists of simple, one-step process, when that is not the case." The complaint alleged that AcelRx's marketing statements were misleading because they omitted information about dosing, administration, and limitations of use for DSUVIA, which showed administration of DSUVIA was not as simple as the company's marketing materials suggested.

AcelRx argued that the FDA's warning letter—based on subjective judgments and issued months after the materials were prepared—could not establish that the company's statements were false when made. The company also argued that it had disclosed the information about dosing, administration, and limitations of use that the plaintiff claimed had been omitted. And the company argued that, in the full context of the company's public disclosures, "no reasonable investor would have viewed these statements as providing comprehensive instructions for use."

The court found it a "close determination whether these statements were false or misleading." The court was not convinced by the defendants' argument that an FDA warning issued months after AcelRx's statements could not show those statements were false when made, noting that "facts about DSUVIA's proper use, limitations, and administration were known at the time the statements were made, as c[ould] be gleaned from . . . allegations about the extensive and iterative process that AcelRx went through to obtain approval for DSUVIA." And, while the court recognized that "the full information about the use and administration of DSUVIA was publicly available" and that this fact "weaken[ed] Plaintiffs' allegations," the court "decline[d] to find that the statements were not false or misleading on this basis at the motion to dismiss phase."

Nonetheless, the court dismissed the complaint for failure to plead scienter. The plaintiff argued that AcelRx had access to information undermining its public statements because AcelRx executives "had multiple interactions with the FDA regarding DSUVIA" and put AcelRx "on notice that [it] would be subject to FDA scrutiny if it failed to adhere to the REMS." But the court found that "[t]he fact that Defendants were aware that the FDA was regulating its marketing does not give rise to an inference that Defendants would be aware that any particular marketing material was misleading or otherwise not in compliance with the FDCA."

Abady v. Lipocine Inc., **No. 2:19-cv-906, 2023 WL 2938210 (D. Utah Apr. 13, 2023)**

Lipocine is a biopharmaceutical company primarily focused on developing oral alternatives for drugs with poor bioavailability—i.e. drugs that are difficult for the body to absorb when taken orally. Lipocine's lead product candidate was TLANDO, an oral testosterone replacement therapy designed to enable better absorption of testosterone undecanoate ("TU") than other forms of TU delivery. The case arose from Lipocine's long and winding road seeking FDA approval for TLANDO.

In August 2015, Lipocine submitted its first new drug application for TLANDO based on Phase 3 clinical study results. A year later, the FDA told

Lipocine that it would not approve the application in its current form and that Lipocine would have to conduct additional clinical trials to validate TLANDO's proposed dosing regimen before submitting a new application.

In response, Lipocine conducted two additional studies to validate TLANDO's dosing regime. The FDA established a primary endpoint for the study to evaluate efficacy and secondary endpoints to evaluate safety. The primary endpoint required at least 75% of TLANDO-treated subjects to achieve testosterone levels within a pre-determined range after 24 days of treatment. The secondary endpoints set different maximum testosterone levels after 24 days of treatment.

In June 2017, Lipocine announced the studies' results and its plan to resubmit the TLANDO NDA. Lipocine disclosed that TLANDO met the primary endpoint evaluating efficacy, with 81% of TLANDO-treated subjects showing testosterone levels in the predetermined range. Lipocine also published raw study data showing that TLANDO had failed one of the secondary endpoints because some subjects exceeded max testosterone limits.

In August 2017, Lipocine resubmitted the TLANDO NDA. The FDA scheduling an advisory committee meeting for January 2018. Before the meeting, Lipocine released briefing materials, arguing that TLANDO's failure to meet the secondary endpoints should not preclude approval because instances of excessive max testosterone were transient, isolated, and not correlated with adverse effects.

The advisory committee voted 13-to-6 against recommending approval. But only one committee member identified TLANDO's failure to meet the secondary endpoints as a reason for a negative vote. Several others expressed concern about the lack of a study evaluating TLANDO's cardiovascular safety. The FDA then denied the resubmitted NDA based on both the lack of any cardiovascular safety study and failure to meet the secondary endpoints.

Lipocine promptly announced it would conduct cardiovascular safety studies and perform additional analysis of existing data regarding subjects with excessive testosterone levels. A year later, Lipocine announced that the FDA had accepted the third TLANDO NDA. In the next months, Lipocine spoke positively about the prospects for FDA approval, continuing to express its view that TLANDO's failure to meet the secondary endpoints should not be considered significant in evaluating its safety.

Finally, in November 2019, the FDA again denied approval of the TLANDO NDA. Lipocine disclosed that the FDA's response letter "identified one deficiency," that the efficacy trial did not meet the "secondary endpoints for maximal testosterone concentrations." Lipocine's stock price fell on this news. Lipocine investors sued, alleging that Lipocine's statements about TLANDO's safety and about the prospects for FDA approval were false and misleading.

The district court dismissed the complaint. First, the court held that Lipocine's statement that the TLANDO met a "key secondary endpoint" in the clinical trial was not false or misleading in the context of Liponcine's full presentation of the trial results. TLANDO had, in fact, met one of the secondary endpoints and Lipocine's accurate disclosure of the study subjects' max testosterone concentrations revealed that it had failed another one. The court also noted that Lipocine's supposedly misleading statement that TLANDO met a key secondary endpoint was followed immediately in the presentation by a discussion of the company's response to FDA concerns about the failure to meet another secondary endpoint. As to Lipocine's argument that the failure to meet

one of the secondary endpoints should not be a basis for denying approval, the court found that the complaint failed to allege facts showing Lipocine did not sincerely believe its argument. The court noted that Lipocine never suggested the FDA agreed with its view.

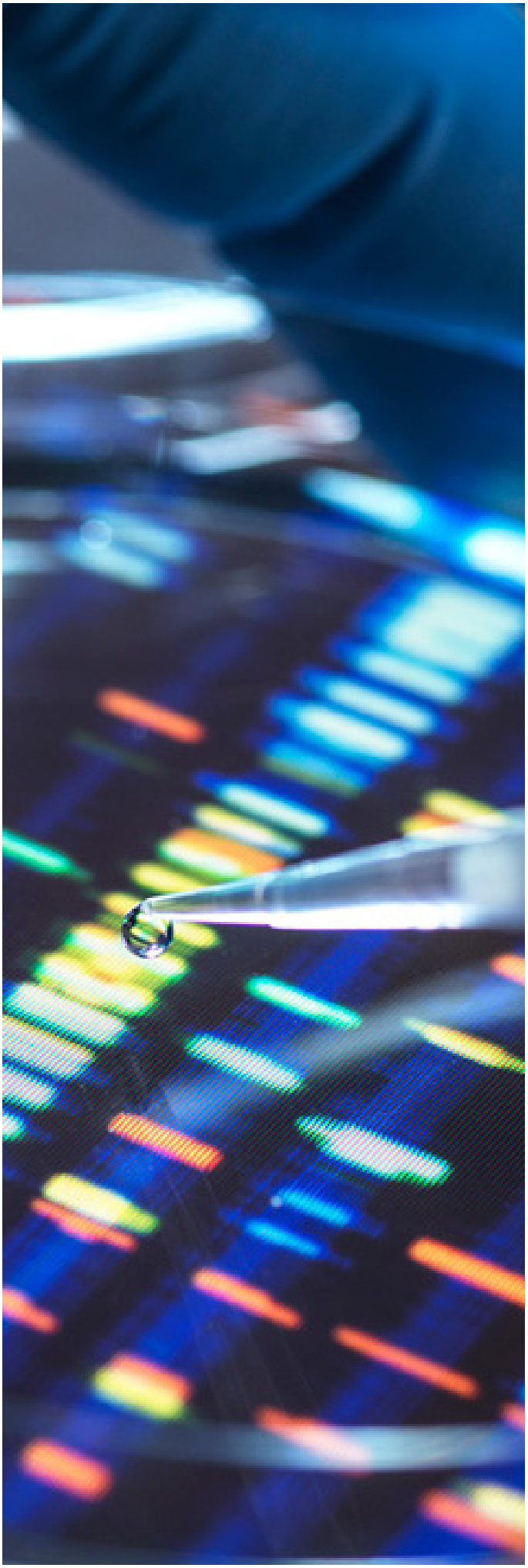
The court also concluded that the complaint failed to plead a misleading omission about the dosage study results, holding that Lipocine's accurate disclosure of some study data did not trigger a duty to disclose the complete results.

Finally, the court held that omission of specific study data from some SEC filings and public statements was not misleading because the allegedly omitted information had been publicly disclosed in the advisory committee meeting briefing books.

In Lipocine Inc., the court dismissed claims based on allegedly misleading omission of certain study results, holding that a company's accurate disclosure of some study data did not trigger a duty to disclose the complete results.

***Richfield v. PolarityTE, Inc.*, No. 2:21-CV-00561-BSJ, 2023 WL 3010208 (D. Utah Apr. 19, 2023)**

PolarityTE is a biotechnology company that develops regenerative tissue products. Its first product was SkinTE, designed to repair skin in patients with chronic wounds, burns, and scars. SkinTE is regulated as a human cell and tissue product (HCT/P), i.e. a product containing human cells or tissues intended for use by human recipients. To be sold in the U.S., HCT/Ps must be registered with the FDA. There are two ways to register: If the manufacturer determines that the product is "minimally manipulated" and that it meets other criteria, it can self-register the product under Section 361 of the Public Health Services Act; if the product does not meet the requirements for self-registration under Section 361, then the manufacturer must seek registration under Section 351, conduct clinical trials, and obtain FDA approval to market the product under either an investigational new drug ("IND") application or a new drug application ("NDA").



In 2017, PolarityTE self-registered SkinTE under Section 361. PolarityTE told investors that it "believe[d]" SkinTE was "appropriately regulated" as a Section 361 HCT/P but warned that regulators could disagree.

In 2020, PolarityTE announced that it would submit an IND to register SkinTE under Section 361. The company explained that it "still believe[d] that SkinTE is appropriately regulated as a Section 361 HCT/P" but it "believe[d] that the SEC might disagree with our interpretation." The company said that it would discuss with the FDA the possibility of continuing to market SkinTE as a Section 361 HCT/P pending approval of its NDA, but cautioned that "it not customary for the FDA to allow wide-spread commercial sales of a product subject to a pending" application.

In 2021, PolarityTE submitted its IND application for SkinTE. Later in the year, PolarityTE announced that the FDA had placed a clinical hold on the application pending resolution of certain "chemistry, manufacturing, and control" items. PolarityTE's stock price fell in response to this announcement and investors sued under Section 10(b). After PolarityTE responded to the identified items, the FDA lifted the hold in early 2021.

The complaint alleged that PolarityTE misled investors by saying that SkinTE was properly classified as a "minimally manipulated" HCT/P under Section 361. In dismissing this claim, the court first noted that PolarityTE's statements on the topics were expressions of opinion- the company repeatedly told investors that it "believe[d]" SkinTE was a Section 361 HCT/P. The court found that the complaint failed to plead facts showing that Polarity did not, in fact, "believe" this statement. While the complaint included statements from some former employees disagreeing with the company's view, the court found that "alleg[ations] that

unnamed employees may have believed that SkinTE was registered under the 'wrong' section" were "not sufficient to plead falsity" because "debate among employees … does not show that PolarityTE lacked a reasonable factual or legal basis for its [] opinion."

Hattaway v. Apyx Medical Corp., 22-cv-1298, 2023 WL 4030465 (M.D. Fla. June 15, 2023)

Apyx makes "Helium Plasma Technology" systems, which are designed "to offer surgeons and physicians a unique ability to provide controlled heat to tissue so as to 'operate with a high level of precision and virtually eliminat[e] unintended tissue trauma" in certain procedures." Apyx markets these systems as "J-Plasma" in the hospital surgery market and as "Renuvion" in the cosmetic surgery market.

In 2012, Apyx obtained FDA clearance to market Renuvion for "cutting, coagulation, and ablation of soft tissue during open and laparoscopic surgical procedures." Other uses-including for cosmetic surgery-were not cleared and, thus, considered "off label."

By 2021, Apyx was generating substantial revenue through sale of its J-Plasma/Renuvion system, including for off-label use in cosmetic dermal resurfacing procedures.

In its first quarter 2021 earnings announcement, Apyx reported strong growth and expressed optimism about the company's future prospects, while also warning investors that "the FDA has taken the position that device manufactures are prohibited from promoting their products other than for the uses and indications set forth in the cleared product labeling" and that "[a]ny failure to comply could subject us to significant civil or criminal exposure, administrative obligations and costs, other potential penalties from, and/or agreements with, the federal government." During this announcement, Apyx also disclosed to investors that "it had received a number of requests from the FDA concerning 'changes to Apyx's messaging on its website labeling, and training materials with respect to the off-label use of its products[,]' 'stronger statements in A pyx's labeling to warn of any specific procedure … which had not yet been reviewed or cleared' by the FDA, and the removal of 'instances of language or imagery that might imply intended use outside the cleared general indications.'" During Apyx's first quarter earnings call, an investor asked whether J-Plasma/Renuvion was used in dermal resurfacing procedures and the company's CEO responded, "[y]es, it is an off-label procedure. We cannot promote it and we do not promote it. So it is being done. You're correct, because the clinician can decide to use the technology any way they want to … it is something that we as an organization do not promote[.]" In the second and third quarters, Apyx again reported strong growth while warning of the risks from off-label use of its products. Apyx also disclosed that it had applied for FDA approval to expand the label for J-Plasma/Renuvion to include cosmetic dermal resurfacing procedures.

In March 2022, the FDA issued a release "warn[ing] 'consumers and health care providers against the use of the Renuvion/J-Plasma device by Apyx Medical for certain aesthetic procedures,' including those 'intended to improve the appearance of the skin through dermal resurfacing … or skin contraction[.]'" The FDA reported that it was "working with [Apyx] to evaluate all available information about the use of Renuvion/J-Plasma for aesthetic skin procedures and to inform patients and providers that the device has not been determined to be safe or effective for these procedures." Apyx's stock price fell and investors sued.

The complaint alleged that Apyx's statements about the company's "financial position, future prospects, and current risks were materially misleading due to [Apyx's] omission of information concerning healthcare providers' off-label use of Renuvion." The court dismissed for failure to plead a material misstatement. As to the plaintiffs' claim that Apyx's reported financial results-i.e. its "raw financial numbers"-were misleading, the court noted that the complaint "d[id] not dispute the numerical accuracy of the general financial figures . . . or otherwise explain why these figures themselves are materially misleading." As to the plaintiffs' challenge to Apyx's "optimistic comments concerning future growth," the court noted that Apyx expressly disclosed that future results were uncertain and "repeatedly disclosed that health care providers were using Apyx's products off-label." The court also found that Apyx's statements touting its "exceptional growth" and "impressive execution" were puffery, i.e. the "kind[] of talk which no sensible man takes seriously."

DENYING MOTION TO DISMISS (IN WHOLE OR IN PART)

In re Mylan N.V. Sec. Litig., 2:20-cv-955-NR, 2023 WL 3539371 (W.D. Pa. May 18, 2023)

Mylan was one of the world's largest generic drug makers. During the relevant period (2016-2019), it manufactured drugs in fifty facilities around the world, including one in Nashik, India, and another in Morganstown, West Virginia, where Mylan made roughly 85% of the tablets and capsules it sold in the U.S.

The Food, Drug, and Cosmetics Act requires drug makers to follow "current good manufacturing practices," including safety testing drugs made in their facilities. The FDA also periodically inspects drug manufacturing facilities. If an FDA inspector believes conditions at a manufacturing facility may violate the FD&C Act, the FDA may issue a "Form 483," listing the "inspectional observations" of potential violations. The FDA encourages manufacturers to respond and address any issues identified. The FDA may then issue a Warning Letter, warning of potential enforcement action; take some further regulatory enforcement action, including issuing a fine or penalty; or issue a Closeout Letter if it finds the manufacturer has addressed the violations identified.

In September 2016, the FDA inspected Mylan's Nashik, India factory; issued a Form 483 identifying data and safety issues at the factory; and, ultimately, issued a Closeout Letter, stating that the FDA had "completed an evaluation" and concluded that Mylan "addressed the violations." Mylan disclosed these letters.

In November 2016, the FDA inspected the Morganstown factory and issued a Form 486. The FDA said the inspection "raised questions" about quality control at the Morganstown facility but the FDA did not issue a Warning Letter or take any further action.

In Spring 2018, the FDA again inspected the Morganstown facility and issued another Form 483, identifying operational safety issues, including issues with cleaning manufacturing equipment. Mylan submitted a detailed response and worked with the FDA to address the issues. Mylan disclosed to investors that (i) it had received a Form 483 raising issues at Morganstown, (ii) it was planning a "restructuring and remediation program" at the Morganstown facility, and (iii) this program would negatively affect the company's financial results.

In November, the FDA issued a Warning Letter finding "significant violations" at the Morganstown facility. Mylan disclosed the letter and Bloomberg reported the FDA's findings. Mylan halted production at the Morganstown facility and recalled some of the drugs made there.

In January 2019, Bloomberg Law reported on alleged quality control issues at Mylan manufacturing facilities. The article quoted a Mylan spokesperson saying that "any suggestion that Mylan employees circumvented data and quality systems" was "simply false."

Finally, in February 2019, Mylan reported disappointing 2018 financial results, including a decline in North American sales and over $250 million in remediation costs. Mylan's stock price fell and investors sued under Section 10(b).

Relying heavily on the two Bloomberg articles and reporting from "Bottle of Lies," a book about the generic drug industry, the complaint alleged that Mylan misled investors about the risk from safety and regulatory issues at its manufacturing facilities. The alleged misstatements included (i) general positive statements about Mylan's business and operations; (ii) Mylan's statements about its regulatory compliance, (iii) statements in Mylan's financial statements about the "suitability" of its manufacturing plants, (iv) Mylan's statements about plans to restructure operations at the Morganstown facility, and (v) Mylan's statement in the January 2018 Bloomberg Law article denying that Mylan circumvented quality control systems.

The district court dismissed the claims, except as to Mylan's statement in the Bloomberg Law article.

The court found most of the alleged misstatements—such as Mylan's statements on its public website that it "utilize[d] state of the art monitoring systems"—were puffery, the kind of "loosely optimistic" statements that were "so vague, broad, and non-specific that a reasonable investor would not rely on them."

The court likewise found that Mylan's warnings of the risk from regulatory noncompliance—such as, that "'there is no guarantee' that its compliance program . . . will prevent instances of non-compliance"—were not materially misleading. The plaintiff argued that these statements were misleading because they only identified the possibility that regulatory violations "might occur in the future when, in fact, Mylan had already received notices of significant violations." The court found that this claimed failed, "ironically, because of what it selectively omitted from its quotation" of Mylan's securities disclosures. Mylan did not merely identify the possibility of future regulatory issues, it expressly disclosed that, "from time to time, we receive notices of . . . observations following inspection by regulatory authorities" and "official agency correspondence regarding compliance." Accordingly, the court found that Mylan's risk factors "disclosed the very thing that Plaintiff claims was left out—that Mylan had already received 'quality-related observations following inspections by regulatory authorities.'"

The court also rejected the plaintiff's challenge to Mylan's statement in its quarterly SEC filings that "[w]e believe that all of our facilities are in good operating condition, . . . the facilities are suitable for their intended purposes and they have capacities adequate for the current operations." The plaintiff argued this statement was misleading because Mylan's facilities were allegedly "rife with serious, repeat [good practices] and data integrity violations." The court disagreed. The court noted that statements of Mylan's "belief" were statements of opinion. The court explained that "alleging an actionable opinion is 'no small task' because 'a reasonable

investor understands that opinions sometimes rest on weighing of competing facts.'"[19] In this case, the district court concluded that the complaint's allegations failed to meet the "rigorous benchmark" for pleading a false opinion.

Finally, the court addressed Mylan's statement to Bloomberg Law that "[a]ny . . . suggestion that Mylan employees circumvented data and quality systems that jeopardized the quality of the medications we manufacture . . . is simply false." Unlike the other alleged misleading statements, the court found this statement wasn't corporate puffery, opinion, aspirational, or qualified, but, rather, "a declaration" that Mylan employees had not circumvented data and quality systems. And the court found the complaint sufficiently alleged "circumvention of quality controls at Mylan to cut corners for time pressure." As a result, the court found Mylan's statement to Bloomberg Law could form the basis for a Section 10(b) claim.

In re Emergent Biosolutions Inc. Securities Litigation, Civ. No. DLB-21-955, 2023 WL 5671608 (D. Md. Sept. 1, 2023)

Emergent BioSolutions provides contract drug manufacturing services to biopharmaceutical companies and government agencies, including contract vaccine manufacturing at its Bayview facility in Baltimore. In 2012, the U.S. Department of Health and Human Services awarded Emergent a $163 million contract to prepare Bayview for mass production of vaccines in the event of a pandemic.

Soon after the COVID-19 pandemic began, the federal government launched Operation Warp Speed to fund rapid development, manufacturing, and distribution of COVID-19 vaccines. As part of the initiative, Emergent obtained contracts with both Johnson & Johnson and AstraZeneca to manufacture their vaccines at Bayview and a contract with HHS to expand Bayview to "ensure capacity" to "manufacture third-party COVID-19 vaccines." In total, these contracts awarded Emergent more than $875 million to provide manufacturing facilities for COVID-19 vaccines. Emergent began manufacturing AZ and J&J vaccines in August and November 2020, respectively.

At the same time, evidence emerged of quality control problems at Bayview. Beginning in April 2020, an HHS audit found "substantial evidence of . . . noncompliance" with good drug manufacturing practices and "failure of quality systems"; an FDA inspection found "multiple deficiencies with data integrity and general [drug manufacturing] practices"; an Operation Warp Speed adviser reported that "most of Bayview's existing equipment was 'not suitable'" and that Bayview had "significant" compliance risks; and J&J and AZ audits found a "persistent problem with mold in areas required to be kept clean."

In the Spring of 2021, the New York Times reported that millions of doses of J&J and AZ vaccines had been destroyed because of either contamination or worker error and tens of millions more had been quarantined. In April 2021, the House Oversight Committee began an investigation into Emergent. Its report found, among other things, that (i) nearly 40 million COVID vaccine doses had been destroyed due to Emergent's failure to meet quality standards; (ii) Emergent hid evidence of contamination from investigators; (iii) Emergent executives promoted the company's manufacturing capabilities despite knowing of quality problems; and (iv) Emergent failed to remediate deficiencies that J&J, AZ, and the FDA identified.

Emergent investors brought Section 10(b) claims based on alleged misstatements about the company's contract manufacturing operations. The court sustained the complaint in large part.

19 The court quoted the U.S. Supreme Court's 2015 decision setting the standard for pleading a false or misleading opinion statement under the securities laws, *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015).

The court dismissed claims that Emergent's reported financial results and its senior executives' Sarbanes-Oxley certifications were false or misleading. The court found that the complaint failed to establish that accurate reporting of revenue earned from COVID-19-related contracts or certifications of internal controls "over financial reporting" were misleading. But the court otherwise sustained the plaintiffs' claims.

The court found that Emergent's statements about its vaccine production capabilities—including that the Bayview facility had "the capacity to produce tens to hundreds of millions of doses of vaccines"—were "not necessarily false on their face" but were nonetheless misleading in light of the alleged extensive, undisclosed quality issues at the facility. The court similarly found that Emergent's response to the New York Times' reporting on cross-contamination and other vaccine production problems at Bayview—acknowledging that "a single batch of drug substance was identified that did not meet specifications" and that Emergent had "isolated this batch and it will be disposed of properly"— was misleading because Emergent allegedly concealed the widespread quality control and production issues, which ultimately resulted in destruction of more than 400 million vaccine doses.

Ciarciello v. Bioventus Inc., No. 1:23-CV-32, 2023 WL 7300081 (M.D.N.C. Nov. 6, 2023)

Bioventus is a medical device and pharmaceutical company that sells drug therapies, including hyaluronic acid injections. A substantial portion of its revenues come from third-party payers, including private insurance companies and the Centers for Medicare and Medicaid Services (CMMS).

Bioventus's contracts with private insurers generally required the company to pay rebates to insurers that paid for Bioventus injections. Thus, under generally accepted accounting principles (GAAP), Bioventus had to estimate expected future rebates and deduct them from its reported revenues. In its 2021 and 2022 financial statements, Bioventus told investors it followed GAAP and estimated expected future rebates based on historical data, buying trends, and other appropriate variables.

In the summer of 2021, Bioventus received a large, unexpected rebate request. In response, the company conducted an internal audit of its processes and controls over accounting for and estimating rebates. According to the complaint, the audit was highly critical Bioventus's process for estimating future rebates, finding at least twelve "severe" action items needing "immediate attention and correction." But, according to the complaint, Bioventus failed to make any changes to its rebate estimation process. Nonetheless, Bioventus continued to tell investors that it followed an appropriate process for estimating rebates and complied with GAAP.

In 2022, Bioventus was also facing unfavorable changes in CMS's reimbursement process. Before 2022, CMS reimbursed Bioventus based on wholesale acquisition cost to other payers, that is, the price other third-party payers were charged before rebates or other discounts granted to large private insurers. As a result, CMS paid significantly higher rates than private insurers paid. But Congress passed legislation, effective January 1, 2022, requiring manufacturers seeking reimbursements from CMS to report average sales price (after rebates and discounts) rather than wholesale acquisition cost. Use of discounted prices to set CMS reimbursement rates would result in CMS paying Bioventus significantly less.

According to the complaint, Bioventus repeatedly assured investors that the company had prepared for the change by securing agreements with private payers for lower rebates and that the company had calculated that the lower rebates—which would increase revenue both from private payers and from CMS—would results in the change in calculation of CMS reimbursements having a "net-neutral" effect on Bioventus's financial results. According to the complaint, this was false because Bioventus had neither "carefully calculated" the effect of the change in CMS reimbursement nor obtained any agreements with private payers to reduce rebates.

In November 2022, Bioventus reported lower than expected revenue. The company attributed its disappointing results to a large, "unexpected" rebate request from an insurer and to the change in CMS's method for calculating rebates. Bioventus's stock price fell on the news and investors sued.

In a cursory analysis, the court denied Bioventus's motion to dismiss.[20] The court found that the complaint adequately pleaded that Bioventus misstated its revenue by alleging that Bioventus learned of serious problems with its accounting for expected rebates through the 2021 internal audit but failed to address the problems. As a result, the court concluded, even if the second large rebate request was "unexpected," it was a foreseeable result of the alleged failure to address known issues with accounting for future rebates. The court similarly concluded that the negative effects of the CMS reimbursement change reflected in the November 2022 earnings announcement showed that the company's earlier statements that it was prepared for the change and expected a "net-neutral" effect were false.

Schneider v. Natera Inc., 2023 WL 958265, 22-cv-398-DAE (W.D. Tx. Sept. 11, 2023)

Natera is a genetic testing company. Among other products, it makes Prospero (a kidney transplant-rejection test) and Panorama (a pre-natal test that screens for genetic abnormalities).

Prospero. When Natera launched Prospero in mid-2020, the dominant test in the market was CareDx, Inc.'s AlloSure. Natera touted published studies finding Prospero more accurate than Allosure. From the launch through 2022, Prospero sales and revenue increased steadily as the test gained market share from AlloSure.

Panorama. As of early 2020, Natera had recently added to Panorama screening for microdeletions—"small, missing parts of a chromosome that can adversely impact a baby's health and development." Panorama revenues increased in 2021 and 2020, driven, in part, by revenues from microdeletion screenings.

Natera's stock price more than tripled from 2020 to late 2021. Natera conducted two stock offerings during that time. Natera's stock price then fell in March 2022, following two negative developments.

First, short-seller Hindenburg Research issued a negative report alleging that increased demand for Panorama was driven by deceptive business practices, including (i) allegedly "inappropriate" reliance on a third-party company to submit prior authorizations on Natera's behalf for insurance coverage of microdeletion screenings and (ii) allegedly employing a requisition form that "automatically opted patients in for screening for one microdeletion," which allegedly

20 The court dismissed Section 11 claims for lack of statutory standing, unrelated to the merits of the claims.

"created the impression that demand growth for microdeletion testing was organic, rather than the result of a default order form."

Second, a few days later, a jury found that Natera "misled the public by falsely marketing Prospera as more accurate than, and superior to, AlloSure."

Natera investors sued, asserting both Section 11 and Section 10(b) claims. Natera moved to dismiss. The court dismissed the claims related to Natera's statements about Prospera but sustained the claims related to statements about Panorama.

Natera's statements comparing Prospera to AlloSure were based on a published study—the "Sigdel study"—which found that Prospera showed "greater sensitivity" (percentage of accurate positive tests) and "a higher AUC value" (a measure of overall accuracy) "in comparison" to the results for AlloSure in another study called the "Bloom study." The plaintiffs argued that Natera's statements that "published studies" found Prospera more accurate than AlloSure were misleading because some Natera employees allegedly believed the Sigdel and Bloom studies were not "apples to apples." But the court explained that, "where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology." This was true even if "some at Natera may have interpreted the results differently than the Sigdel study's authors." As a result, the plaintiffs' criticisms of the Sigdel study did not suffice to allege that Natera's statements about Prospera were misleading.

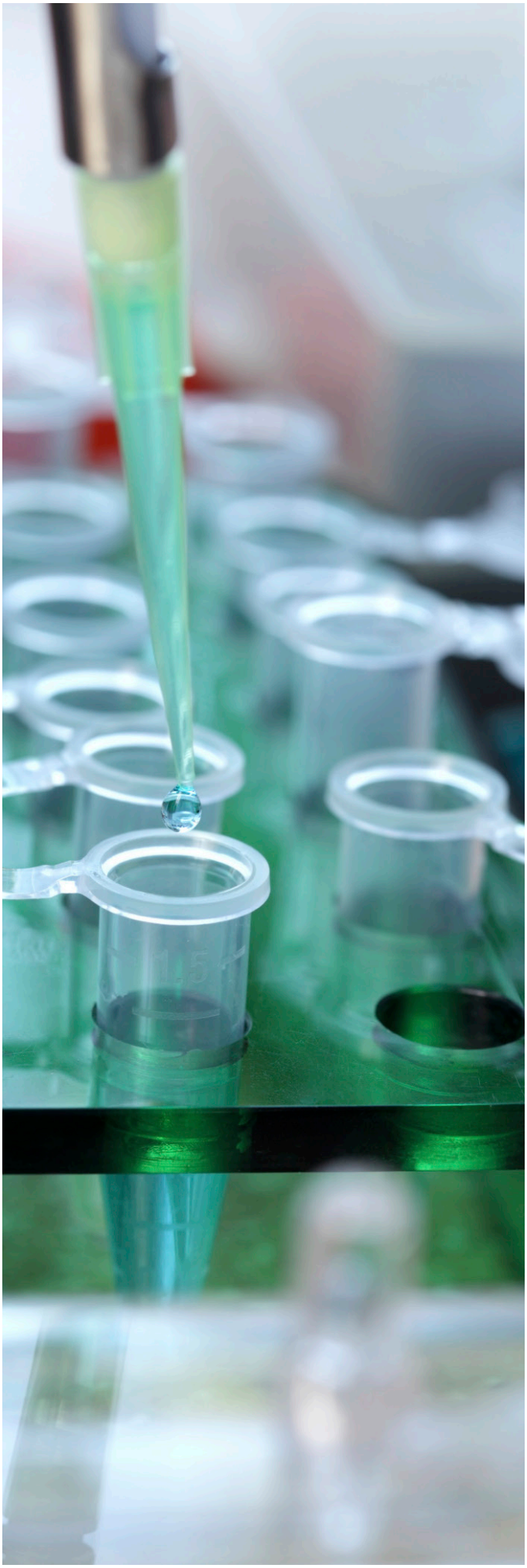
But the court found the Hindenburg short-seller report sufficient to plead that Natera's statements about Panorama were misleading. As a threshold matter, while many courts have found unverified allegations from short-sellers—who have a financial interest in driving down the company's stock price—presumptively unreliable, the Natera court concluded that the reliability of short-seller reports was a question of fact that could not be resolved on a motion to dismiss. Assuming for purposes of the motion that Hindenburg's allegations were true, the court found that Natera's statements that the increase the company's revenues "was primarily driven by sales of Natera's Panorama" would be misleading if, as Hindenburg alleged, Natera "conceal[ed] that Panorama revenues were inflated by deceptive practices."

In re Cassava Scis., Inc. Sec. Litig., No. 1:21-CV-751-DAE, 2023 WL 3442087 (W.D. Tex. May 11, 2023)

Cassava Sciences' primary drug candidate was simufilam, an Alzheimer's disease treatment. Dr. Hoau-Yan Wang (a professor at CUNY Medical School and consultant at Cassava) invented simufilam based on research that he and Dr. Lindsay Burns (Cassava's senior vice president of Neuroscience and the wife of Cassava's founder) conducted at the company and published in peer-reviewed journals between 2008 and 2016. In July 2017, Cassava announced that the FDA had approved an investigative new drug application to study simufilam in Alzheimer's patients.

After successful Phase 1 and Phase 2a trials, Cassava launched a Phase 2b trial in September 2019. But Cassava announced in May 2020 that the Phase 2b trial failed to meet its primary endpoint because the results did not show lowered biomarkers of Alzheimer's. Cassava's stock price fell in response to this news.

After this stock drop, Cassava adopted an incentive bonus plan under which senior executives would receive cash bonuses tied to increases in the company's stock price.



A few weeks later, in September 2020, Cassava announced "final results" of the Phase 2b trial based on a "reanalysis" by an outside academic lab. Based on the reanalysis, Cassava told investors that (i) the "initial bioanalysis"—which found no showing of lowered biomarkers of Alzheimer's—was "highly anomalous" and of questionable validity and (ii) the new "final results" showed simufilam "significantly improved an entire panel of validated biomarkers" of Alzheimer's.

In February 2021, Cassava reported results from another trial, which suggested simufilam might renew cognitive function in some Alzheimer's patients, and that the company had reached an agreement with the FDA on key elements of a Phase III trial for simufilam. Cassava's stock price climbed higher on this news and the company sold four million shares of stock at $49 per share on February 10, 2021.

On July 26, 2021, Cassava presented a poster prepared by Dr. Wang and Dr. Burns summarizing the reanalyzed Phase 2b trial data at the Alzheimer's Association International Conference. Following the presentation, Cassava's stock price climbed to a high of $149 per share on July 29, 2021. At that point, Cassava's executives had earned millions of dollars in bonus compensation as a result of the increase in Cassava's stock price since the release of the reanalyzed Phase 2b results.

On August 18, 2021, two scientific researchers filed a Citizen Petition with the FDA, raising "grave concerns about the quality and integrity of the laboratory-based studies" involving simufilam. The petition noted that all the foundational research supporting simufilam came from articles co-authored by Dr. Wang and Dr. Burns and revealed that Dr. Wang's lab at CUNY Medical School—which received funding from Cassava—was the "outside academic lab" that generated the Phase 2b final results. In addition,

the petition alleged that the data published in Dr. Wang and Dr. Burns' academic articles contained "anomalies that are strongly suggestive of data manipulation" and that Cassava's presentation of the Phase 2b results for simufilam, including the poster presented to the Alzheimer's Association, suggested "data anomalies or manipulation." Within hours, Cassava responded that the petition was "false and misleading" and that the company stood behind "its science, its scientists, and its scientific collaborators." But, within days, an independent expert in identifying manipulation of biomedical images posted online that, after reviewing the images in the Citizen Petition, she "agreed with most of those concerns" and "at least five other articles from the Wang lab at CUNY appear to show image concerns." Cassava's stock price fell sharply following these developments

Cassava's stock price continued to fall as further evidence of potential data manipulation and research misconduct emerged over the next several months. On August 30, 2021, the Citizen Petition authors filed a supplement claiming to have identified "new instances of scientific misconduct by Cassava and Dr. Wang." In response, Cassava again denied the petition's allegations but acknowledged "visual errors" in "one publication and one poster presentation." Then, in November 2021, Cassava disclosed that it had received information requests from regulators and the Wall Street Journal reported that the SEC and the NIH were investigating potential data manipulation by Cassava and that CUNY was investigating Dr. Wang's lab. The Citizen Petition authors published additional supplements in November and December, raising additional allegations of misconduct. In 2022, several medical journals retracted papers by Dr. Wang and Dr. Burns and *Reuters* reported that the Justice Department had opened a criminal investigation into Cassava's research results.

Cassava's investors sued. The plaintiffs alleged that Cassava's statements about the Phase 2b study results were materially misleading because Cassava failed to disclose that Dr. Wang's lab conducted the reanalysis, that the reanalysis "suffered from highly anomalous baseline measurements" and that the company "intentionally removed unfavorable data" from its presentation of the study results. More broadly, the plaintiffs alleged that Cassava misleadingly touted simufilam based on research published in peer-reviewed journals without disclosing that the research was "rife with manipulated data."

Cassava moved to dismiss, arguing that the alleged omissions were not actionable because Cassava's statements were true and the company had no affirmative duty to disclose the omitted information. Cassava also argued that allegations about mere regulatory or criminal investigations were insufficient to show that Cassava had engaged in wrongdoing and that the complaint improperly adopted the allegations in the Citizen Petition and supplements without any independent knowledge or verification of their accuracy.

The court denied Cassava's motion.[21] The court acknowledged that public companies have "no duty to 'confess' unadjudicated allegations of wrongdoing" and that "corporate officials need not present an overly gloomy or cautious picture of the company's current performance." But the court stressed that a company's public statements must be "reasonably consistent with reasonably available data" and that "a duty to speak the whole truth" arises when a company chooses to speak. Under these principles, the court concluded that the omission of information about Dr. Wang's role in the Phase 2b study reanalysis and of information about alleged data manipulation by Dr. Wang and Dr. Burns rendered the company's statements materially misleading,

21 The court dismissed claims against one individual defendant because he passed away while the case was pending, and the plaintiffs failed to take timely action to substitute his estate as a party.

even if some of them were "literally true." Finally, as to Cassava's objections to the plaintiffs' reliance on the Citizen Petitions' allegations and reports of government investigations, the court explained that the Reform Act's particularized pleading standard did not require that the plaintiff have personal knowledge of every allegation in the complaint and noted that, in addition to allegations about the Citizen Petitions and the government investigations, the complaint identified specific alleged instances of data manipulation in Cassava's studies, supported by photographic evidence.

Homyk v. ChemoCentryx, Inc., No. 21-cv-3343, 2023 WL 3579440 (N.D. Cal. Feb. 23, 2023)

ChemoCentryx is a pharmaceutical company specializing in drugs to treat rare diseases. During the alleged class period in the case, ChemoCentryx had four developmental drugs in its pipeline, the most advanced of which was avacopan, a treatment for ANCA-associated vasculitis. The existing standard-of-care vasculitis treatment (prednisone) included corticosteroids, long-term use of which can present various safety risks. ChemoCentryx developed avacopan to be an alternative ANCA-associated vasculitis treatment that would not require long-term steroid use.

In November 2019, ChemoCentryx announced results of the Phase III trial for avacopan. The company told investors that these results showed avacopan was safer than standard-of-care steroid therapy; that avacopan demonstrated non-inferiority versus prednisone; and that chronic steroid use was not needed to achieve remission. The company also told that communications with the FDA about the avacopan new drug approval application had been "straightforward" and that, if approved, avacopan had "$1 billion plus revenue potential per year" in the U.S.

In May 2021, the FDA published a briefing book in advance of an upcoming advisory committee meeting to discuss the avacopan application. The briefing book expressed various concerns of FDA staff about the Phase III trial's design, including that it included patients receiving steroid treatment, which meant that the trial was inadequate to evaluate avacopan's relative safety and efficacy compared to steroid treatments. The briefing book also revealed that some patients in the trial experienced serious adverse liver events. And the briefing book revealed that the FDA had shared these concerns with ChemoCentryx on multiple occasions in the past.

The advisory committee was evenly split on whether to recommend approval of avacopan, with all of those in favor of approval voting to recommend that the label be limited, if approved. ChemoCentryx's stock price fell 79% on this news and investors sued. The FDA ultimately approved avacopan for use only in conjunction with steroids by adult patients with severe ANCA-associated vasculitis. The FDA also required ChemoCentryx to include warnings for liver toxicity on the label.

The court found that the complaint sufficiently pled that ChemoCentryx's statements about the trial's safety results were misleading, because they would give a reasonable investor the impression that the trial results could support a safety comparison between avacopan and the standard-of-care therapy.

The court likewise found ChemoCentryx's statements about the trial's efficacy results misleadingly suggested the results were stronger

and more meaningful than they actually were due to omissions facts about deviation from the trial protocol and the widespread use of steroids by study participants.

But the court found that statements that the company submitted an FDA approved application based on "positive" trial results did not suggest a state of affairs different in a material way from reality. The statements generally conveyed that ChemoCentryx submitted an NDA based on the trial results and a reasonable investor would assume an NDA to be based on whatever positive results were achieved in the Phase III trial.

Zaidi v. Adamas Pharms., Inc., 650 F. Supp. 3d 848 (N.D. Cal. Jan. 13, 2023)

Adamas is a pharmaceutical company focused on developing treatments for chronic neurological disorders, including Parkinson's disease. On August 24, 2017, the FDA approved Adamas's drug GOCOVRI for treatment of dyskinesia, "involuntary and uncontrolled movements" that occur as a side effect of a popular Parkinson's treatment, levodopa. Before the FDA approved GOCOVRI, the standard treatment for levodopa-induced-dyskinesia had been off-label use of a generic, immediate-release version of a drug called amantadine IR, taken in multiple doses throughout the day.

Because GOCOVRI was significantly more expensive than generic immediate-release amantadine, Adamas' commercial success depended on physicians and payers differentiating GOCOVRI from amantadine IR. Before it began marketing GOCOVRI, Adamas conducted surveys of payers and physicians to understand the likelihood that physicians would prescribe GOCOVRI and that payers would cover it at various price points. According to the complaint, the payer surveys showed that payers favored the lowest price range and that some payers said that, regardless of price, they would impose restrictions on GOCOVRI, including a step-through—i.e., requiring patients to first try amantadine IR before they could be reimbursed for GOCOVRI. The physician survey allegedly showed that some physicians did not see a meaningful difference between GOCOVRI and amantadine IR. The complaint also alleged that, after GOCOVRI launched, Adamas' sales force reported to senior executives that patients were experiencing negative side effects with GOCOVRI, causing prescriptions to drop.

The complaint challenged Adamas' pre-launch statements that physicians and payers did not "see [GOCOVRI's] profile as really having much to do with the amantadine IR profile," that "there is no anticipation of requiring a step-through of amantadine IR to get to" GOCOVRI; and that "the payers were willing to support us at . . . the GOCOVRI list price." The complaint also challenged the post-launch statements that "we're hearing loudly and clearly from these patients about the successes they are seeing with GOCOVRI treatment" and that "I'm not aware of any plan that has a hard step for us through IR amantadine."

The district court granted in part and denied in part Adamas' motion to dismiss. The court found that the complaint adequately alleged that the pre-launch statements that there was "no anticipation of requiring a step-through" and that physicians and payers did not see GOCOVRI's profile as "having much to do" with amantadine IR were materially false and misleading in light of

the information from physician and payer surveys that Adamas allegedly had access to. The court also found that the complaint adequately pleaded falsity of Adamas's statement that it was hearing "loudly and clearly" about patients' successes with GOCOVRI in light of the allegations that the sales force was reporting negative side effects were driving down prescriptions. On the other hand, the court found that the complaint failed to plead falsity as to the statement that the company was "not aware of any plan" requiring a step-through given the absence of any particular allegation that anyone at Adamas in fact knew of such a plan at the time the statement was made.

In re Talis Biomedical Securities Litigation, No. 22-CV-00105-SI, 2023 WL 3167844 (N.D. Cal. Apr. 28, 2023)

Biotechnology company Talis Biomedical was developing a rapid diagnostic testing system—the Talis One System—consisting of a testing instrument and single-use cartridges. Before the COVID-19 pandemic, Talis was working to develop rapid tests for sexually transmitted infections. In early 2020, the company shifted focus to developing a COVID-19 test.

Talis sought FDA approval for its Talis One COVID-19 test under an Emergency Use Authorization (EUA). The FDA required any applicant for approval of a COVID-19 test to submit data comparing their test's accuracy to that of a prior test—called a "comparator assay"— and required use of "high sensitivity" comparator assays.

In February 2021, Talis conducted an initial public offering. The Registration Statement described the company's comparative studies—reporting that it had tested the Talis One System against "two 'FDA-authorized' comparators tests" and that the results "exactly matched." The Registration Statement also described steps Talis had taken to prepare for production of its COVID-19 tests, stating that Talis had "ordered 5,000 instruments" to be delivered "beginning in the first quarter of 2021," had "manufacturing lines . . . scheduled to begin to come on-line in the first quarter of 2021," and that the company expected to "scale to full capacity through 2021."

In March 2021, less than a month later, Talis announced that the FDA had told the company it "could not ensure" its comparator assay had "sufficient sensitivity to support" Talis' application. In response, Talis withdrew the application and "announced plans to submit [a new] EUA application" based on a study "designed with a different comparator assay, which Talis believes will address the FDA's concerns."

In May, Talis told investors the company expected to "be in a position to ship product in a timely manner following [FDA] approval." Talis submitted the second EUA in July. In August, it disclosed that its "development timelines ha[d] been extended by delays in the launching of our COVID-19 test and manufacturing scale." In November, the FDA approved the Talis One COVID-19 test and Talis announced that it planned a "controlled product rollout" using a "measured approach."

In March 2022—months after obtaining FDA approval—Talis disclosed that it "ha[d] not started its phased launch of the Talis One COVID-19 Test System due to challenges with manufacturing." Finally, in May 2022, Talis reported that it did not expect the Talis One System to make a "significant revenue contribution" in 2022.

Talis investors sued, asserting Section 11 claims (based on alleged misstatements in Talis's IPO Registration Statement) and Section 10(b) claims (based on the same statements from the Registration Statement and various alleged post-IPO misstatements). In a December 2022 order, the court dismissed the complaint but granted leave to amend.

The court held that the complaint failed to plead facts showing that Talis's statement that it had "ordered 5,000 instruments . . . to be delivered beginning in the fourth quarter of 2020 through the first quarter of 2021" was false when made, The plaintiffs argued that Talis had "admitted" this statement was false when it said in March 2022 that it had ordered "components for up to 5,000 instruments" "to be delivered through the third quarter of 2021." But the court did not find the distinction between ordering "instruments" and ordering "components for instruments" misleading, particularly given Talis's disclosure that it engaged a "contract manufacturer that provisions the parts and assembles our instruments." And the court concluded the change in the description of the timing of delivery—"through the first quarter" vs. "through the third quarter"—could simply reflect a change in the timing of delivery rather than an admission that the earlier statement was false when made.

The court also held that the complaint failed to plead that Talis's statements about its comparator assay were false or misleading. While the plaintiffs argued that Talis concealed that it used "a comparator assay that lacked sufficient sensitivity," the court rejected this theory because the complaint neither identified any "objective criteria for the sensitivity of a comparator assay" nor alleged that the FDA had told Talis at the time of the IPO that its comparator assay lacked

sufficient sensitivity. As a result, the plaintiffs merely alleged a "disagreement . . . about the appropriate [ ] methodology."

And the court found that the complaint failed to show Talis's statements about its test's accuracy—that the test was "designed . . . to provide highly accurate results" and had "demonstrated" "accuracy and reproducibility"—were false when made. While the complaint included statements from former employees reporting high invalid rates and design issues, the complaint failed to show that these issues existed at the time of the IPO.

Finally, the court found Talis's post-IPO statements about the prospects for the Talis One System and the expected production timeline following FDA approval were either inactionable puffery or forward-looking statements subject to the Reform Act safe harbor.

In early 2023, the plaintiffs filed an amended complaint, abandoning their Section 10(b) claims and adding new allegations bolstering their Section 11 claims. The court found these new allegations sufficient to plead falsity of certain statements in Talis's IPO Registration Statement and denied Talis's motion to dismiss the amended complaint. In particular, the court noted "new allegations about the Talis One's high invalid rates at the time of the IPO" and "new allegations about how the comparator assay did not meet objective criteria for 'high sensitivity' as well as about management's knowledge at the time of the IPO."

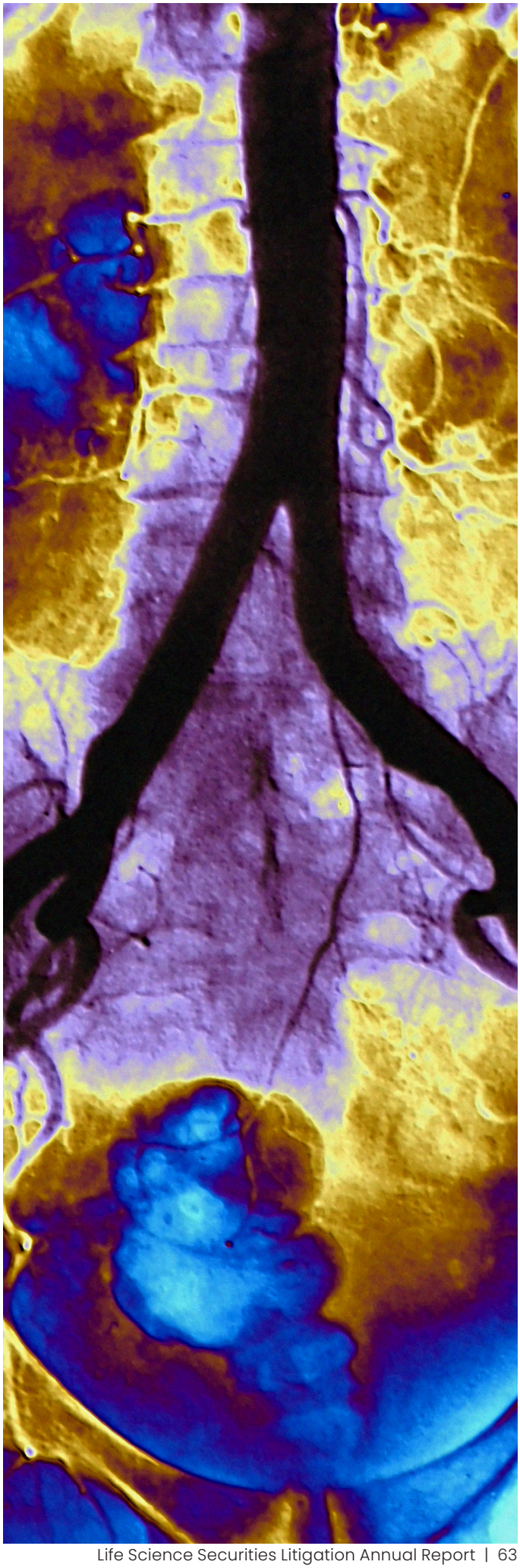
GRANTING SUMMARY JUDGMENT FOR DEFENDANT

In re Mylan N.V. Sec. Litig., 16-CV-7926, 2023 WL 2711552 (S.D.N.Y. Mar. 30, 2023)

Mylan faced a series of claims and government enforcement actions for alleged antitrust violations and anticompetitive behavior related to sales and marketing of Mylan's EpiPen product and to alleged price-fixing in the generic drug markets. After Mylan's stock price fell in response to the announcement of these claims, investors filed a securities class action alleging that Mylan misled investors by concealing the company's alleged violations of antitrust law.

After multiple motions to dismiss, discovery, and class certification, the parties cross-moved for summary judgment. The court entered summary judgment in Mylan's favor. Because the complaint alleged that Mylan fraudulently concealed its illegal behavior, the court concluded that the plaintiff had to—and could not—prove Mylan's underlying antitrust violations. The court found that exclusive-dealing contracts between Mylan and pharmacy benefit managers ("PBMs") did not substantially foreclose competition, as necessary to constitute monopolization under the Sherman Act, and that the pro-competitive nature of exclusive-dealing contracts precluded an inference that Mylan made any fraudulent misrepresentations about whether its contracts restrained trade in violation of the Sherman Act. The court also found that Mylan's rebate payments to PBMs did not constitute commercial bribery.

The court similarly found that the evidence did not support an inference that Mylan conspired to allocate the market for any particular generic drug.



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