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SECURITIES CLASS ACTIONS IN THE LIFE SCIENCES SECTOR

2024 ANNUAL SURVEY

TALENT. TEAMWORK. **RESULTS.**

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Securities Class Actions in the Life Sciences Sector

2024 Annual Survey

INTRODUCTION AND OVERVIEW

In our eleventh annual year-in-review survey, we address developments in securities class actions brought against life sciences companies in 2024. We begin with an overview and analysis of trends in federal district court and appellate decisions in these cases. We then provide summaries of the 49 decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2024.

At the most basic level, the cases analyzed share a common feature. In each, a life sciences company has suffered a setback that, when publicized, was followed first by a stock price decline and then by litigation initiated by shareholders seeking to recover investment losses. Such setbacks can, of course, occur at any stage of a company's development, but in the life sciences sector—given particular issues relating to drug development, regulatory approval, and continued regulatory oversight of manufacturing, marketing and sales activities—the setbacks are clustered in two obvious stages of a company's life cycle.

We believe that analyzing legal developments by reference to the stage of drug or device development at which the setback occurs may yield useful insights and assist in risk mitigation. Accordingly, we have structured this survey around the following stages:

Pre-Approval: Clinical Trials and Pre-Clinical Studies
Post-Approval: Launch and Marketing of the Product

PRE-APPROVAL: CLINICAL TRIALS AND PRECLINICAL STUDIES

PRECLINICAL DEVELOPMENT

CONDUCT OF PHASES 1–3

of clinical trials and analysis and report of trial results.

SUBMISSION OF APPLICATION FOR REGULATORY APPROVAL OF PRODUCT

for pharmaceutical products, the New Drug Application; for Class III medical devices, the Premarket Approval Application; and for non-exempt Class I or II medical devices, Premarket Notification under 510(k) of the Food, Drug and Cosmetic Act.

COMMERCIALIZATION AND LAUNCH OF THE NEW DRUG OR DEVICE

POST-APPROVAL: MATURE PRODUCT

LAUNCH STAGE

CONTINUED MONITORING BY AND INTERACTION WITH THE FDA AND OTHER REGULATORS IN THE FOLLOWING AREAS:

Marketing — regulatory monitoring of marketing efforts, and FDA or other government action if issues arise concerning off-label marketing, Medicare/Medicaid fraud, Foreign Corrupt Practices Act, anticompetitive activities or other statutory or regulatory violations.

Adverse event reporting — reporting of adverse events to the FDA as required by regulation; FDA response and further developments.

Inspection of facilities — routine inspection by the FDA, followed by various communications should issues arise and not be resolved — Forms 483, Establishment Inspection Reports, Warning Letters.

Other regulatory issues — new label indications; changes in label or product design that may trigger regulatory obligations.

NON-REGULATORY ISSUES

Financial forecasting and performance

Financial reporting

Other issues not specific to life sciences companies

A setback at any stage will present disclosure issues, and a company will be required to determine when and how best to inform the financial markets of the negative development. Assuming a company's stock price declines following the disclosure, members of the plaintiffs' securities bar will review the company's past statements relevant to the issue and will search for inconsistencies between past positive representations and the current negative development. Plaintiffs' counsel will then seek to attribute any such inconsistencies to fraud. Given the heightened pleading standards of the Private Securities Litigation Reform Act, plaintiffs' allegations will be tested at an early stage in the litigation. In nearly all cases, the company will move to dismiss, arguing that plaintiffs have failed to allege facts that create a "strong," "cogent," and "compelling" inference that the company made deliberately false statements.[1]

1 *Tellabs, Inc. v. Makor Issue & Rights, Ltd.*, 551 U.S. 308, 310 (2007).

DECISIONS ISSUED IN 2024: TRENDS AND ANALYSIS

In this section (pages 3–17), we discuss trends in the reported federal decisions issued in securities actions at the pleading stage (or in three cases, at summary judgment). Unless otherwise noted, these decisions concern class actions brought under Section 10(b) of the Securities Exchange Act of 1934.[2]

In the district courts, companies prevailed more often than not in 2024. Companies' success rate in 2024 was 59%, a decrease compared to last year but in line with previous years. There were also significantly more decisions this year than in prior years.

2021: Companies won dismissal in 19 of the 33 decisions issued by the district courts, or 58%.

2022: Companies won dismissal in 15 of the 29 decisions issued by the district courts, or 52%.

2023: Companies won dismissal in 17 of the 25 decisions issued by the district courts, or 68%.

2024: Companies won dismissal in 24 of the 41 decisions issued by the district courts, or 59%.[3]

Unlike in previous years, the success rate was similar between companies with pre-approval drugs or devices and those with post-approval drugs or devices—indeed, the latter prevailed slightly more frequently. Specifically, companies prevailed in 57% of the pre-approval cases (13 out of 23) and in 61% of the post-approval cases (11 out of 18).

Companies fared well in the appellate courts in 2024, with affirmance of dismissal in six cases and affirmance of the district court's grant of summary judgment in the remaining two cases. Five out of the eight appellate decisions were not reported in the Federal Reporter; none of them broke new ground in terms of their analysis of the issues.

As we discuss more fully in the Table of New Filings section of this survey, the volume of new cases filed also rose in 2024 to the mid-40s range, more in line with what we saw before 2022.

2020–45 new complaints
2021–49 new complaints
2022–37 new complaints
2023–34 new complaints
2024–44 new complaints

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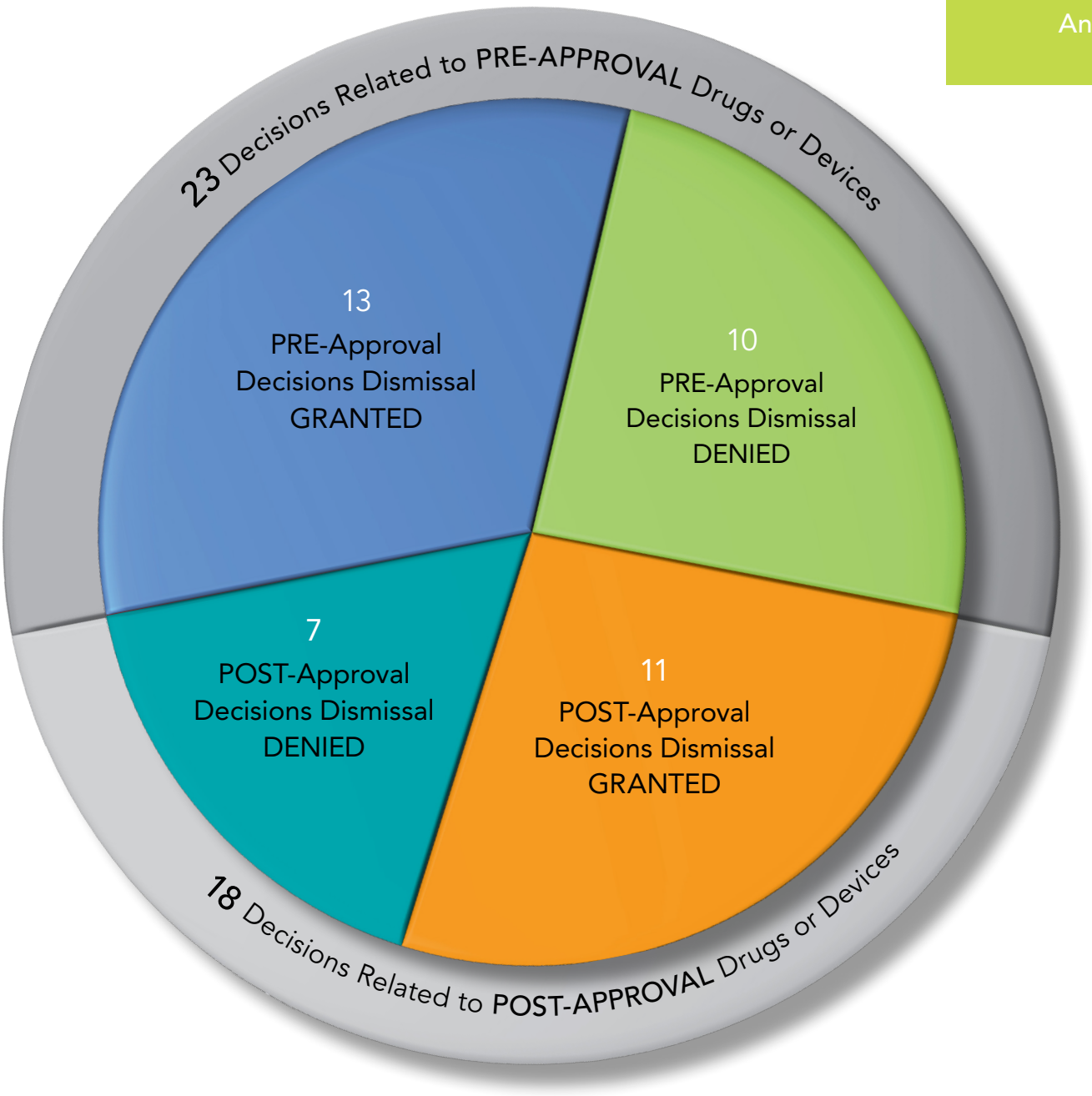
2 Under Section 10(b) (15 U.S.C. § 78j(b)), life sciences companies and their officers may be liable for consciously false or misleading statements they make in virtually any public context, including press releases, earnings calls, investor conferences, and SEC filings. Defendants may also be liable for participating in a "scheme" to defraud, although successful scheme claims asserted by private plaintiffs are rare. Several cases discussed in this review also include claims under Sections 11 and 12 of the Securities Act of 1933 in addition to Section 10(b) claims (15 U.S.C. §§ 77k, 77l). Sections 11 and 12 apply only to statements made in connection with new securities offerings—generally, statements in the prospectus and registration statement for an offering. In contrast with Section 10(b), Sections 11 and 12 do not have a scienter requirement.

3 In this section and throughout this review, we use the term "company" to refer collectively to the defendants in securities litigation—both the company and individual officers or directors.



DISTRICT COURT DECISIONS

In the five pieces that follow, we address a range of trends from the 2024 decisions.

We first consider two areas in which companies received unfavorable communications from the FDA. Synthesizing the disclosure issues presented in these cases yields some practical guidance for companies determining how best to discuss such communications with investors. It also suggests that companies need to review their routinely issued and repeated statements about risk in order to ensure that those statements are not misleading in light of the recent unfavorable development.

In the first set of decisions, companies received negative feedback while an NDA or BLA was pending. The guidance that emerges from the decisions is that once this has occurred, companies are on safer ground when they stick to discussing trial results, the strength of the application, and approval prospects generally. Companies are in more dangerous territory when they directly characterize the FDA's position, and in particular when they say that the FDA is aligned with their own views of outstanding issues.

In the second set of decisions, companies received Forms 483, either before or after products had been approved. The decisions are almost entirely unified in holding that companies have no standalone duty to disclose a Form 483. But the decisions also strongly suggest that a company faces peril if it does not review and revise its risk disclosures and other statements it routinely makes about contingent events after receiving the Form 483.

We then discuss three decisions dealing with setbacks at the product launch stage, related both to early coverage hurdles and to product acceptance generally. The results in the launch cases were mixed. The companies prevailed in two cases. But Biogen suffered an eleventh-hour reversal of fortune in litigation arising from the launch of its controversial Alzheimer's disease drug, Aduhelm.

In the post-approval area, we discuss three cases in which profitable lines of business were threatened by regulatory or other setbacks. In such cases, plaintiffs will claim that the company misled investors by not revealing the problem earlier—but may have difficulty identifying an affirmative statement even arguably inconsistent with the existence of the problem. In all three cases, the companies won dismissal because the plaintiffs could not match any statement with the allegedly undisclosed issue.

We finally discuss three decisions in which courts demonstrated an appropriately nuanced view of scienter and dismissed on that basis. In all three cases, the courts concluded that plaintiffs had adequately alleged falsity. In all three cases, plaintiffs also established that defendants were aware of facts purportedly inconsistent with the challenged statements. But in all three cases, the courts held that this was not enough. Scienter requires an intent to defraud, and that is more than simply knowledge of purportedly contrary facts. To plead scienter, plaintiffs must establish what defendants believed and intended. Risk disclosures may show that a company did not intend to hide the truth from investors. And defendants may be aware of problems with a product but still believe their optimistic statements about it are true—because they have confidence the problems can be addressed, even if others at the company believe otherwise.

DECISIONS ON INTERIM FDA COMMUNICATIONS AFTER SUBMISSION OF AN NDA PROVIDE POINTERS ON RECURRING DISCLOSURE ISSUES

In five of the 2024 decisions, courts faced a familiar narrative. A drug developer meets with FDA representatives in connection with the submission of an NDA or BLA. In written materials, the FDA, as is its wont, emphasizes obstacles to approval rather than the positive features of the application. Later, the FDA denies the application. Plaintiffs' counsel are able to obtain some greater or lesser volume of information about what the FDA said in its interim communications. Pointing to what they have obtained, plaintiffs allege either that the company's statements about the FDA's communications were false, or that the company's positive account of the likelihood of approval or the strength of underlying clinical data was misleading in light of the FDA's undisclosed negative comments.

Companies prevailed at the pleading stage in two of the five 2024 cases (*Ardelyx* and *Spero*) and lost in part in three (*Y-mAbs, Spectrum,* and *Tricida*).

Plaintiffs' success in defeating dismissal is linked to their access to FDA documents

One possible way to account for the differences in outcome is to look at the volume of FDA materials available to plaintiffs when they drafted their complaints. In both *Y-mAbs* (page 30) and *Spectrum* (page 28), the FDA convened an advisory committee. As is standard, FDA staff prepared a briefing document for the committee and released it publicly shortly before the committee met. Such briefing books typically include the FDA's summary of its past communications with the company. These regulatory summaries can provide plaintiffs with a treasure trove of negative-seeming or ambiguous FDA commentary, which plaintiffs then allege contradict a company's public statements. The court in *Spectrum* concluded that the briefing book showed that "FDA officials had repeatedly expressed concerns to Defendants about [the drug's] safety profile, delayed enrollment…and [the company's] inadequate dosage data." The court in *Y-mAbs* similarly concluded, based on briefing materials, that plaintiffs had "plausibly alleged conflicts between [the challenged statements] and the FDA's immediately preceding feedback." At the pleading stage, it can be difficult for companies to put FDA commentary in context, or to explain to courts that apparently negative comments are at times simply the work product of an agency striving to create a record that emphasizes diligence, skepticism, and concern with public health.

In *Ardelyx* and *Spero*—where the companies prevailed—the plaintiffs had far less to work with. In both cases, the FDA halted review by issuing a deficiency notice in the course of considering the NDA. Such notices are generally short and cryptic, and the FDA does not release them to the public in any event. In cases with deficiency notices, plaintiffs are consequently left to speculate about the FDA's position and the specific content of the agency's communications with the company. That was fatal for plaintiffs in both *Ardelyx* and *Spero*. The court in *Ardelyx* (page 26) explained that the plaintiff "asks the Court to infer that the FDA had expressed that the [clinical] trial evidence presented would not be sufficient for approval," and to "further infer that the FDA's statements convinced Defendants that the [drug's] review process was not actually proceeding in an ordinary manner, that the clinical data [were] not robust or clinically relevant, and that the approval was thus in jeopardy." The court declined to draw any of these inferences—because the plaintiffs had failed to allege supporting facts. Similarly, in *Spero* (page 25), the court rejected plaintiffs' allegations about the FDA's position notwithstanding allegations attributed to a confidential witness who attended FDA meetings. Plaintiffs' "conjecture as to the FDA's 'thinking' does not amount to a specific concern that the agency communicated to *Spero*."

In *Tricida*, as in *Ardelyx* and *Spero*, the FDA issued a deficiency notice. As an initial matter, therefore, plaintiffs lacked the fuller record that comes with an advisory committee briefing book. But the *Tricida* plaintiffs, having survived an initial motion to dismiss, issued a document subpoena to the FDA before filing their amended complaint. By means of that subpoena, they obtained copious documents. And with those documents in hand, the *Tricida* plaintiffs, like the *Y-mAbs* and *Spectrum* plaintiffs, were able to avoid dismissal in part when defendants filed a second-round motion to dismiss. The court concluded that the company's account of a late-cycle meeting with the FDA reflected only part of what the FDA documents showed had happened at the meeting.

Leaving aside the *Tricida* plaintiffs' early discovery, the situation reflected in the other four cases is a curious one. As a matter of drug development, the further a company gets through the FDA review process, the stronger its candidate is. All things being equal, a company that progresses to an advisory committee meeting and vote has done better than a company that receives a deficiency notice mid-review. But from a litigation perspective, the company with the deficiency notice is generally in a better position, simply because plaintiffs will be unable to exploit a fuller regulatory record to their own ends.

How can a company seek to avoid the situation in which plaintiffs have a fuller record in hand when drafting a complaint? Unfortunately, companies have little control in this area. Perhaps the best course is to bear in mind that a substantial number of FDA communications may find their way into plaintiffs' grasp before discovery, either through a summary in a briefing book or otherwise. A briefing book summary will reflect the FDA's perspective. More than that: In any FDA review process that results in securities litigation, the FDA's perspective is that of

officials who are not unreservedly recommending approval. Such a summary, which the court will see out of context at the pleading stage, is unlikely to be favorable for defendants' litigation purposes. Knowing that plaintiffs may come to obtain such a summary—or the FDA documents themselves—suggests that companies should be extremely conservative in speaking about what the FDA has communicated during the review process.

Statements directly characterizing FDA communications present greater peril than statements about approval or underlying data

In the three cases in which plaintiffs survived dismissal, they did so only in part. Comparing the statements that survived the motion to dismiss with those that did not shows which kinds of statements place companies in greatest peril. The results are consistent across the three cases.

In all three cases, the companies failed to win dismissal of statements that directly addressed FDA communications. In *Spectrum*, the company stated that it was "obviously aligned with the FDA" on a particular dose; plaintiffs were able to cite FDA communications that appeared to be contrary. In *Y-mAbs*, the company told investors that it had in its possession all of the information the FDA had requested and that it had resolved all concerns. Again, plaintiffs were able to draw apparently contrary facts from the briefing book. In *Tricida*, the company said that it had addressed the FDA's outstanding review issue, which the court inferred to mean that the FDA had raised only one such issue. Plaintiffs adequately pled that two review issues had been in play at the relevant time.

A fourth decision not listed above is similar. This is *Owlet* (page 33), which is a device case and therefore does not follow the FDA review process for drugs discussed above. But the issues related to FDA communications are the same. In *Owlet*, the company told investors that it believed its product, a "Sleep Sock" for babies, was not a Class II device and thus did not require premarket notification. Owlet said this even though the product had an alarm feature, which the company had initially disclosed *would* bring it within the Class II designation. The FDA told the company in a series of communications beginning in 2016 that it believed the product fell within Class II. In a 2021 de-SPAC offering document, the company made legal compliance statements, representing that it had marketed all products in compliance with FDA rules and had received no communication from any government entity regarding material noncompliance with FDA rules. After the offering, the FDA issued a warning letter in which it chronicled its past communications with the company on the issue (in other words, the functional equivalent of the briefing book communication summaries discussed above). Plaintiffs obtained the warning letter. The court denied the company's motion to dismiss based on the apparent conflict between the legal compliance statements and the description of past interactions in the warning letter.

All four decisions suggest that companies should be exceedingly cautious when they describe FDA communications, and in particular when they state that they have reached agreement or alignment with the FDA on a given issue. One approach, although it may not always be satisfying to investors, is to describe FDA communications in only generic terms.

Outside direct commentary about the FDA's position, however, companies have significant leeway. In *Y-mAbs*, the court dismissed plaintiffs' challenge to the company's statements about resubmitting its BLA (after receiving an initial refusal to file letter) as well as statements interpreting clinical trial results. In *Spectrum*, the court rejected plaintiffs' challenge to the company's opinion statements about its progress in optimizing dosing, as well as the statement that the product was "on the cusp of approval." The court also rejected an attack on the company's risk disclosures. Plaintiffs alleged that the risk the company identified—that approval might be delayed—had already come to pass, as certain trials were behind schedule in enrollment. But the court distinguished carefully between the two delays: The risk of delayed *trials* had come to pass, but the risk of delayed *approval* had not.[4] Finally, in *Tricida*, the court dismissed plaintiffs' challenge to a host of statements discussing the substance and strength of the company's NDA, including opinion statements.

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4 As discussed on pages 9-10, below, courts are currently divided on this approach to analyzing risk disclosures.

The divided outcomes in these decisions suggest that companies may do well by seeking to respond to investor interest in the progress of an NDA or BLA with information about the content of the application and their confidence in approval—and by trying to avoid as much as possible direct characterizations of the FDA's position or communications.

Framing statements as opinions can help, and so can risk disclosures

Ardelyx, one of the cases in which the company prevailed, also suggests some preferred practices. The company there framed certain statements as opinions; the court also seemed willing to characterize any statement reflecting "assessment of and judgment about the underlying circumstances" as an opinion. Opinion statements are of course not immune from challenge, but plaintiffs must come within one of the three narrow channels the Supreme Court carved out ten years ago in *Omnicare*.[5] The *Ardelyx* court also drew on the company's risk disclosures in concluding that plaintiffs had failed to adequately allege falsity, concluding that the risk disclosures actually revealed the purportedly omitted fact that the FDA could interpret clinical trial results differently than the company did, as well as the heightened risk faced by first-in-class drugs. This use of risk disclosures is distinct from the safe harbor protection they can provide, and also distinct from *plaintiffs'* targeting of such disclosures as affirmatively misleading statements (as discussed above in connection with *Spectrum* and below in connection with Form 483 disclosure issues). Risk disclosures can furnish companies with strong responses to claims that critical information has been omitted. Risk disclosures can also be powerful tools in rebutting inferences of scienter. Companies should bear all of these uses in mind when drafting and updating their risk disclosures.

As a matter of litigation and analysis (as opposed to pre-litigation practice in drafting disclosures), *Ardelyx* also suggests an interesting way around one of the Ninth Circuit's most difficult decisions for defendants. In its 2016 *Arena* decision, the Ninth Circuit reversed dismissal based on negative FDA commentary even where the company had refrained from directly characterizing FDA communications.[6] The company in *Arena* stated that *all* trials to date supported approval of its weight-loss drug. A rat study, however, suggested that the drug could be linked to cancer at very high doses, and the FDA had raised concerns about this. The Ninth Circuit concluded that plaintiffs had adequately made out a fraud claim by omitting the FDA's concerns—which showed that at least in the regulator's view, at least one trial did *not* support approval. *Arena* suggests that even a company that avoids discussing FDA feedback may face a fraud claim when its positive statements are characterized as inconsistent with that feedback.

Ardelyx, however, distinguishes *Arena*. The *Ardelyx* court noted that the FDA's requests for information about the rat study and carcinogenicity in *Arena* were "unusual"—the agency asked for that information repeatedly, every two months, out of cycle. Finding no comparable allegations, the *Ardelyx* court concluded that *Arena* had little bearing on the case before it. This focus on the particular facts related to the FDA's interactions with the company in *Arena* may be helpful in limiting the reach of that plaintiff-friendly Ninth Circuit decision in future cases.

DECISIONS ARISING FROM ISSUANCE OF FORMS 483 PROVIDE ADDITIONAL DISCLOSURE GUIDANCE

Six of the 2024 decisions address disclosure issues related to Forms 483. When a company receives a Form 483 and does not disclose it, plaintiffs will claim that the omission rendered other statements misleading. When a company does report the Form 483, plaintiffs will argue the company's discussion was incomplete or insufficiently negative, and that statements on other ostensibly related subjects suffer from the same defects.

The 2024 decisions span the pre-approval and post-approval categories. Results for defendants were mixed. Plaintiffs survived motions to dismiss (at least in part) in three cases (*Verrica*, *ImmunityBio*, and *Catalent*). Defendants prevailed in the other three cases (*BioXcel*, *Revance*, and *Medtronic*). But that 50/50 split may understate the peril for companies in connection with

5 *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015).

6 *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698 (9th Cir. 2016).

Forms 483. In every case except *Medtronic*, plaintiffs were able to adequately allege materially false or misleading statements. Defendants in *BioXcel* and *Revance* prevailed only because plaintiffs were unable to establish a strong inference of scienter.

The decisions are largely united in holding that companies have no standalone duty to report receipt of a Form 483. They accordingly raise and partially answer next-level disclosure issues: What kinds of statements may be rendered misleading in light of an undisclosed Form 483? And how can companies avoid making such statements?

The starting point: No standalone duty to disclose

Several of the 2024 decisions repeat and discuss the rule that companies have no affirmative duty to disclose receipt of a Form 483. The court in *BioXcel* (page 24) agreed with the defendants that "there is no standalone duty to disclose a Form 483 in and of itself"—but then immediately added that "it is equally clear that the failure to disclose a Form 483 can render a statement materially misleading, depending on the circumstances of the statement at issue." Similarly, the court in *Revance* (page 27) stated in connection with a Form 483 that "[a]lthough Defendants were under no obligation to discuss the FDA process, once they chose to discuss the process, they were required to do so in a way that was not misleading."

Two reasons undergird the lack of an affirmative disclosure duty in this area. First, Section 10(b) law as a whole does not impose disclosure duties: There is no liability for omissions unless they can be shown to render an identified statement misleading.[7] Second, courts recognize that Forms 483 do not reflect final agency determinations.

ImmunityBio (page 29) contains language suggesting that a sufficiently sweeping and adverse Form 483 could give rise to a duty to disclose. Reviewing case law, the court stated that "disclosure of Form 483's observations may be necessary depending upon the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA." But that result would contradict controlling law holding that Section 10(b) imposes no independent disclosure duties. The better reading of the case law discussed in *ImmunityBio* is that companies are required to report non-trivial Forms 483 when their omission would render another statement misleading. A Form 483 below a certain level of severity will be immaterial regardless of the nature of a company's affirmative statements. That, indeed, is the reading of the same case law adopted by the court in *Medtronic* (page 39), which stated that a duty to disclose a sufficiently serious Form 483 may arise if a company has made affirmative (and positive) statements about its regulatory compliance.

The absence of a standalone duty to disclose a Form 483 is only the starting point. The six 2024 decisions illustrate the vulnerability to attack, once a Form 483 is in the mix, of several kinds of commonly made statements.

Risk disclosures

In securities litigation against life sciences companies, as in securities litigation generally, plaintiffs argue that risk disclosures—intended by companies to ensure that investors are not misled—are themselves misleading if a company characterizes as a contingency an event that has already occurred. Courts broadly accept this theory.

Risk disclosures about manufacturing and related compliance issues are obvious targets for plaintiffs when a company ultimately reports a previously undisclosed Form 483. Plaintiffs will argue that every such risk disclosure issued between receipt of the Form 483 and the date the "truth" is revealed constitutes fraud. Plaintiffs adequately pled falsity based on this theory in *BioXcel* and *ImmunityBio*—although, as noted, the *BioXcel* defendants ultimately prevailed on scienter grounds.

The company in *BioXcel* warned that if the clinical research organization (CRO) conducting its trial "fail[s] to comply with applicable CGPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials." At the time it issued the disclosure, the company had received a Form 483 listing issues with the CRO's

7 *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 260 (2024); *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011).

documentation of medical histories and patient consents, as well as its failure to report a serious adverse event. The company was also working to determine whether the trial's principal investigator had falsified adverse event documentation. The court held that the plaintiff had adequately alleged that the risk disclosure was misleading: The warned-of risk had already materialized. Interestingly, the court rejected the company's argument that the warned-of risk was delay in FDA approval—not a Form 483 in itself—and that the risk of delay had *not* in fact materialized. In the court's view, this argument "confuses the risk for its consequences."

The court's analysis in *ImmunityBio* is very similar. The company there warned that it could "encounter difficulties in production," and that if it did, its "ability to provide adequate supply…could be delayed or stopped." At the time it issued the risk disclosure, the company's contract manufacturer had received a Form 483. As in *BioXcel*, the company argued that the warned-of risk had not occurred: Plaintiffs did not allege that the company was ever unable to provide adequate supply. And again as in *BioXcel*, the court was not persuaded, reasoning that the company was confusing the materialized risk with the (unmaterialized) consequences.

The analysis in *Medtronic* is quite different. *Medtronic*, again, is the only one of the six Form 483 cases from 2024 in which plaintiffs failed to plausibly allege falsity. The company there, which was seeking approval of a next-generation insulin pump, had received a Form 483 pertaining to its facilities generally (which also produced earlier-model pumps as well as other medical devices). Plaintiffs challenged a variety of statements, including risk disclosures. As usual, they argued that the risk disclosures misleadingly described a materialized risk as a mere contingency. But in contrast to the courts in *BioXcel* and *ImmunityBio*, the court in *Medtronic* focused on the risk of delay and did not consider the receipt of a Form 483 itself to constitute a materialized risk. Drawing on Second Circuit law, the court reasoned that at the time of the challenged statement, delay was not a certainty, and that failure to disclose the Form 483 was accordingly not misleading.

As significantly, the *Medtronic* court did not appear to seriously consider the company's risk disclosures as independent bases for liability. The court considered only whether the disclosures were sufficient to protect forward-looking statements under the PSLRA's cautionary language safe harbor (and it concluded that they were). The court strongly suggested that the *only* kind of affirmative statement that may be rendered misleading by virtue of an undisclosed Form 483 is a statement about regulatory compliance.

Although favorable, that result is not one companies should rely on prospectively. A company that receives a Form 483 and chooses not to disclose it in the short term should review (and if necessary amend) its risk disclosures. Disclosures about manufacturing risks should obviously be of concern. But so should more general disclosures about the possibility of regulatory setbacks or interventions, in the context of both clinical-stage and approved products.

Statements about regulatory compliance

The plaintiffs in *ImmunityBio* survived the pleading stage as to both risk disclosures and the company's multiple statements that it had "established GMP manufacturing at scale." At the time of the statements, the company's contract manufacturer had received a Form 483, which plaintiffs claimed showed that the manufacturer was not complying with GMP. In moving to dismiss, the company argued that the challenged statements were not properly read as representations about regulatory compliance; they simply referred to the standard under which the company was operating. The court disagreed: "The argument requires the Court to ignore the plain meaning of the language, and is not persuasive at this stage of the litigation." The decision suggests that companies in receipt of Forms 483 should review their standard disclosures about manufacturing practices with a high degree of conservatism.

On the other side of the ledger, *Catalent* (page 45) provides a model for qualifying statements about regulatory compliance that may protect companies in this area. Although the *Catalent* court allowed plaintiffs to proceed into discovery with respect to certain statements, it held that plaintiffs had failed to plead falsity as to the company's statement that it operated its business in compliance with cGMP. In light of the context provided by the following language, that statement was not misleading:

> In addition, our facilities are subject to periodic inspection by the FDA, the DEA, and other equivalent local, state, and foreign regulatory authorities as well as our customers. All FDA, DEA and other regulatory inspectional observations have been resolved or are on track to be completed at the prescribed timelines provided in commitments to the applicable agency in all material respects.

This formulation could be made even more broadly protective by removing the references to "on track" and "prescribed timelines."

To summarize: Statements about risk and regulatory compliance are often formulas repeated from one SEC filing to the next. The case law strongly suggests that a company should review its standard formulations in these areas after receiving a Form 483.

Statements about regulatory approval or commercial activity

A company's more targeted statements about FDA approval or the manufacture and sale of approved products can also open the way to fraud claims when a company has received a Form 483. In *Revance*, the company's executives said they "felt very good" about their pending BLA submission. Several weeks before they made those statements, the FDA had issued a Form 483, and an inspector had informed the company that manufacturing changes it had made were inconsistent with the BLA. The court recognized that the challenged statement was an opinion but concluded that plaintiffs had plausibly pled falsity. They had shown, under *Omnicare* and its progeny, that the company was "aware of undisclosed facts tending seriously to undermine the statement's accuracy."

The company in *BioXcel* also made favorable statements about its path to approval, noting that its Phase 3 trials were "complete." Plaintiffs alleged that an open Form 483 meant that the trial was *not* complete. Here, too, the court concluded that plaintiffs had plausibly alleged falsity.

Catalent involved drugs that had already been approved: The company manufactures approved products (including COVID-19 vaccines) for pharmaceutical and biotech companies. After receiving a Form 483, the company closed its Brussels facility for several months. It nevertheless stated that it had "not experienced any slowdown in our commercial activity." The court concluded that plaintiffs had adequately pled falsity: "By discussing commercial activity at the Brussels location… Defendants put that specific issue 'in play,' entitling investors to know that, in fact, Brussels experienced 'zero commercial revenue' after its shutdown, contrary to what Defendants portrayed." Plaintiffs also adequately pled falsity as to a more detailed opinion statement: "We believe that our sites and equipment are in good condition, are well maintained, and are able to operate at or above present levels for the foreseeable future." The court concluded that findings of contamination in Forms 483 plausibly undermined the basis of this opinion.

Statements about inspection

An outstanding Form 483 may also cause problems when a company refers to the underlying inspection. The company in *Verrica* (page 29), which had an NDA pending during the COVID-19 pandemic, stated that an FDA inspection would take place "according to plan." Five days before it made the statement, Verrica's contract manufacturer had received a Form 483. The court held that because the inspection had already occurred, and because issues had emerged that could jeopardize timely approval, plaintiffs had adequately alleged falsity. The court declined to adopt the company's interpretation of the challenged statement—that "according to plan" simply meant that the FDA was working through its backlog of inspections stalled by the pandemic.

Following the issuance of the Form 483, Verrica received a CRL citing manufacturing deficiencies. The company resubmitted its NDA, and the FDA again inspected the contract manufacturer's facilities and again issued a Form 483. The company subsequently referred to a "successful resolution" of inspection issues in the CRL—but then received a second CRL. With respect to the "successful resolution" statement, too, the court held that plaintiffs had adequately alleged falsity. The undisclosed second Form 483 showed that the issues in the first CRL had not been resolved.

Disclosing the Form 483

Given the variety of statements that plaintiffs will claim are rendered false when a company declines to disclose a Form 483, one option is to disclose it. But that may not dispose of all issues. The company in *Revance* chose this route, but the court still found that plaintiffs had plausibly pled falsity as to certain statements. The decision does not make the company's disclosure chronology entirely clear, but it appears that at some point between the FDA's issuance of a Form 483 in July 2021 and a CRL in October 2021, the company told investors that it had received and responded to a Form 483. The court *rejected* plaintiffs' attack on the company's related statement that it remained confident in timely approval of its BLA. Although not a part of the court's analysis, subsequent events supported the company's view of the interplay between a Form 483 and approval. After it received the CRL, the company resubmitted its BLA. The FDA again conducted an inspection and again issued a Form 483. But the FDA then approved the drug, notwithstanding the second Form 483. The subsequent events show that receipt of a Form 483 does not necessarily undermine the basis of confidence in approval.

But while the court rejected plaintiffs' attack on Revance's statement about the Form 483 itself, it concluded that plaintiffs had plausibly alleged falsity as to a slightly more general statement about the approval process. After it received the first Form 483, the company stated "our BLA may receive a Complete Response Letter *or another response from the FDA identifying deficiencies that must be addressed,* rather than an approval." The court held that plaintiffs had adequately alleged falsity. The court's reasoning was similar to that in the decisions addressing risk disclosures discussed above: It was plausibly misleading for the company to refer to the *possibility* of a response identifying deficiencies when it had already received a Form 483 that did just that. The court's analysis is again a reminder for companies to reassess standard formulations addressing risk after receiving a Form 483.[8]

DECISIONS IN PRODUCT LAUNCH CASES YIELD MIXED RESULTS

Courts issued three decisions in 2024 stemming from challenges related to the commercial launch of recently approved products. In two cases—*electroCore* (page 36) and *Aurinia* (page 38)—the company defeated plaintiffs' claims at the pleading stage. In a third, *Biogen* (page 43), the court took the uncommon step of allowing plaintiffs to amend after issuing a judgment against them, which permitted the case to move forward.

Biogen's drug, Aduhelm, had an unusual history. In 2015, Biogen began two Phase 3 trials for Aduhelm—Engage and Emerge. In 2019, the company discontinued the trials on futility grounds. A post hoc analysis disaggregating the data from the two trials showed that Emerge met its primary endpoint, while Engage did not. The analysis appeared to show that at a sufficiently high dose, Aduhelm was effective.

The FDA encouraged the company to submit an NDA. In November 2020, the FDA scheduled an advisory committee meeting, and the company and FDA submitted a joint briefing document advocating approval. The company's stock price rose the day the briefing document was released, and fell the next trading day, possibly in delayed response to a dissenting section of the document written by an FDA statistician.

The FDA approved Aduhelm under its Accelerated Approval pathway, but the approval was controversial, and the subsequent launch was not a success. A contract with the VA fell through. The launch sites Biogen had targeted were slow to work through pharmacy and therapeutics committee reviews. Medicare decided to cover the drug only in the clinical trial setting. Biogen cut the price of the drug in half. In 2022, the company largely abandoned commercialization.

This saga generated two major pieces of securities litigation, one arising from statements the company made before the November 2020 advisory committee meeting and the other from statements about the launch. Biogen prevailed in the district court in the first action. But in 2023, the appellate court reversed in part, as we discussed in last year's review. In the second

8 As noted above and discussed further below, *Revance* ultimately won its motion to dismiss, as well as winning FDA approval. While plaintiffs adequately alleged falsity, they fell short on scienter.

case, concerning the launch, Biogen initially prevailed in the district court, but that court then allowed plaintiffs to amend post-judgment, reviving the case in March 2024.

Plaintiffs in the launch case challenged statements about the readiness of sites to begin prescribing, about Medicare coverage, about the VA contract, and about Biogen's collaboration with the FDA leading up to approval. In its first ruling, the court carefully parsed the challenged statements and concluded that there was no inconsistency between those statements and the truths plaintiffs alleged the company had concealed. Post-judgment, however, plaintiffs moved for leave to amend based on purportedly new evidence derived from a congressional committee report. The court held that the report showed management discussing a high likelihood of a longer process and narrower coverage for Aduhelm than the company had suggested in its public statements about Medicare—and that this supported an inference of knowing falsehood. While the court denied the motion to amend the judgment as to other categories of statements, the survival of the challenge to statements about Medicare coverage allowed the plaintiffs to move forward. This series of events, while atypical, underscores the need for particular care around oral statements. The challenged statements that prompted the court in *Biogen* to revive the case were all made on investor calls.

By contrast, in *electroCore*, the Third Circuit affirmed dismissal of plaintiffs' challenge to statements about coverage issues. In 2017, *electroCore* launched gammaCore, a treatment for pain associated with cluster headaches. The company conducted its IPO in 2018, and advised investors in its offering documents that securing reimbursement was a "key element" of its strategy. In the same documents, the company stated that it had agreements with "commercial payers" in place, which would provide reimbursement for gammaCore for "approximately 17 million commercial lives." Plaintiffs alleged that these disclosures were misleading because investors would understand "commercial payer" to mean insurance companies, not pharmacy benefits managers (PBMs). According to the plaintiffs, the company therefore misrepresented the reimbursement situation. The district court rejected this argument, and the appellate court agreed, reasoning that the company used "commercial payers" as an umbrella term referring to both PBMs and insurance companies. The appellate court also affirmed dismissal of plaintiffs' challenge to the company's statement about covered commercial lives, describing the statement as a "heavily caveated statement of opinion" that was not rendered misleading merely by a contrary opinion held by a confidential witness.

In the third case, *Aurinia*, the company also succeeded in defeating plaintiffs' challenge to statements related to its commercial launch. *Aurinia* sells Lupkynis, a treatment for lupus nephritis (LN). Plaintiffs alleged that the company's statements about plans for the launch were misleading by omission. According to plaintiffs, the company misleadingly failed to disclose that it had targeted rheumatologists rather than nephrologists, that the patient population for LN was hard to reach and often noncompliant with drug regimens, and that some providers had concerns over insurance coverage limitations that deterred them from prescribing the drug. The court granted the company's motion to dismiss on falsity grounds, emphasizing the ways in which the allegedly omitted information was actually disclosed.

For example, plaintiffs were simply wrong in claiming that the company omitted the fact that the patient population was hard to reach. In its risk disclosures, the company repeatedly stated that LN patients came from "underserved and under-resourced communities" and that the company was seeking to "improve access" for the LN community. The company also disclosed that LN patients "were not receiving healthcare services at an appropriate level during the pandemic." In light of these disclosures, the court reasoned that the company was not obligated to say more:

> It is true that Defendants did not explicitly say that "[t]he social and economic backgrounds of LN patients[] made them hard patients to reach."…But this they were not required to do. Defendants were not required to state every obstacle facing them in the most specific language possible.

This does not break new ground as a statement of the law, but it may be a useful soundbite for companies arguing that an omission theory fails in light of information presented in risk disclosures.

IN POST-APPROVAL CASES, COURTS REJECT FRAUD CLAIMS WHERE PLAINTIFFS CANNOT MATCH A REGULATORY OR OTHER SETBACK WITH ANY CHALLENGED STATEMENT

In 2024, several decisions addressed the recurrent situation in which regulatory incidents or other issues with a company's product threaten a previously profitable line of business. In this area as in others, plaintiffs will claim that because the company did not disclose the issue earlier, its statements were misleading by way of omission, and that the statements the company did make created a duty to disclose the issue. But plaintiffs can face a matching problem in these cases. The company may not have publicly discussed the area in which the setback occurred. Or its statements may be too general and too far removed from that area to create a duty to disclose the setback. In three decisions, defendants won dismissal on these grounds: *Organogenesis* (page 38), *Medtronic* (page 39), and *Berkeley Lights* (page 42).

Organogenesis sells skin substitute products for wound care. For a time, two of the company's products, Affinity and PuraPly XT, had not been assigned an average sales price (ASP) under the Centers for Medicaid and Medicare Services' pricing formula. In accordance with government guidance, the amount physicians were reimbursed for these products was determined by individual Medicare Administrative Contractors (MACs). Plaintiffs alleged that the company improperly marketed a "spread" physicians could earn if their costs were less than the MACs' reimbursement rate, and that revenue declined after Affinity received an ASP. Plaintiffs challenged the company's statements about growth, sales, performance, and compliance. Dismissing with prejudice, the court held that plaintiffs had failed to allege that any statement was false or misleading, concluding that none of the company's statements "g[a]ve rise to a duty to disclose." The statements "do not detail any specific marketing strategies or efforts with respect to Affinity and PuraPly XT, do not suggest that the undisclosed improper activity alleged by Plaintiffs was not occurring, do not suggest that reimbursement status did not affect Affinity and PuraPly XT's success, and do not otherwise conceal the importance of reimbursement with respect to those products."

The analysis in *Berkeley Lights* was similar. Berkeley Lights (now Bruker Cellular Analysis) sells a lab instrument—the Beacon—that processes cell data used in biotherapeutics and other cell-based products. The company's stock price fell after a disappointing earnings release, and after a short seller claimed that the Beacon was too expensive and that customer complaints would further limit sales growth. Plaintiffs challenged the company's statements about the Beacon's capabilities and growth prospects. The court granted the company's motion to dismiss because plaintiffs could not identify a statement rendered misleading by the omitted information. The court held that the company "was not required to disclose that its product had experienced defects or recite the specifics of all customer complaints every time it described the Beacon."

In *Medtronic* too, plaintiffs struggled to connect regulatory scrutiny and product challenges with the company's statements. As noted above, Medtronic received a Form 483, and plaintiffs argued that the company's failure to disclose this rendered its statements about the financial performance of its insulin pumps misleading. Among other things, plaintiffs challenged the company's statement that it was facing increased competition in the U.S. diabetes care market. According to plaintiffs, that statement was misleading because the company was losing customers as a result of quality issues, not increased competition. The court dismissed the claim. Here too, the claim suffered from a fatal mismatch problem: The challenged references to competition were general, and did not suggest that competitors' advancements were the *sole* source of the company's challenges. (The court also noted that Medtronic had revealed the purportedly omitted information.) Similarly, the court held that the company's statements attributing growth in its diabetes business to overseas sales of its pumps did not create a duty to disclose customer complaints, quality issues, or other reasons for concern about the product.

Of course, defendants do not always win motions to dismiss in cases where successful products hit snags. As noted, defendants lost motions to dismiss in seven of the 2024 post-approval cases. But the rulings in *Organogenesis*, *Berkeley Lights*, and *Medtronic* show that courts understand that the foundation of a fraud claim in such cases has to be a challenged statement

sufficiently closely related to the setback that it is plausibly rendered false or misleading in the absence of earlier disclosure.

SEVERAL 2024 DECISIONS DISPLAY COURTS' APPROPRIATELY NUANCED VIEW OF SCIENTER

Scienter requires an intent to defraud—that is, to mislead investors. Securities plaintiffs often seek to establish scienter by alleging facts that they say contradict the company's statements. Whether through confidential witness allegations or otherwise, plaintiffs then endeavor to show that the defendants were aware of those facts. But as several courts recognized in 2024 decisions, such awareness does not in itself equate to an intent to defraud. Making a statement that turns out to be wrong is not fraud. Awareness of problems within a company is not fraud, particularly if those problems can be addressed. Nor is it fraud to make a statement with which other employees disagree. Applying these principles, courts have dismissed complaints on scienter grounds even after concluding that plaintiffs adequately alleged both falsity and the defendants' awareness of purportedly contradictory facts.

The company in *BioXcel* (page 24) received a Form 483 during the Phase 3 trial of a drug treating agitation in dementia patients. The company did not initially disclose the Form 483, and plaintiffs alleged that defendants' statements about clinical trial results and prospects for approval were misleading in light of the omission. As discussed above, the court concluded that plaintiffs had adequately alleged falsity as to two challenged statements—a risk disclosure and a statement that the trial was complete. But the court dismissed the complaint on scienter grounds, and did so even though defendants did not dispute that they knew about the Form 483 at the time of most of the challenged statements. After first disposing of plaintiffs' allegations about stock sales and funding-related motives, the court rejected the argument that "awareness of the Form 483" demonstrated recklessness. "Even if, in hindsight, two of Defendants' statements were misleading by omission due to the failure to disclose the Form 483, this alone does not support an inference that they were intentionally or recklessly so."

That analysis appropriately separates knowledge of an underlying fact from an intent to defraud. Ascertaining a defendant's intent requires more than determining whether he or she knew a given fact. In *BioXcel*, the court's analysis of intent included the company's risk disclosures. The court found that the risk disclosures cut against an inference of fraud—even after ruling that plaintiffs had adequately alleged that one of the same disclosures was misleading. The court held that the risk disclosures "strongly negate[d]" an inference of scienter, reasoning that a company that puts investors on notice of the consequences of failing to comply with good clinical practices is not "deliberately hiding" a Form 483.

A Form 483 was also at issue in *Revance* (page 27). The company in that case received the Form 483 after it had submitted a BLA for a drug treating frown lines. The company initially said it expected approval by late 2020, but delays caused by COVID-19 complicated the inspection chronology. Plaintiffs challenged 29 statements about the likelihood and timing of FDA approval, most of which the court ruled were puffery or came within the PSLRA's safe harbors. But plaintiffs adequately alleged falsity as to two statements. One was a risk disclosure (as in *BioXcel*), stating that the company "may" receive a Form 483. The other was the company's statement that it "felt good about its preparedness for approval." Plaintiffs alleged that an FDA inspector had told the company that its assumption that its manufacturing changes were consistent with the BLA was "incorrect," and for pleading purposes, that was sufficient to show that the statement was misleading.

Also in *BioXcel*, after concluding that plaintiffs had adequately alleged falsity, the court granted the motion to dismiss on scienter grounds, and did so notwithstanding allegations that the defendants were aware of purportedly contradictory facts. The court rejected plaintiffs' theory that the company "knew of the existence of various deficiencies, and therefore [] statements about FDA approval were misleading." What was missing, the court explained, was "any evidence that [the company] *believed* that FDA approval was unlikely or would be delayed because of the deficiencies." Benign inferences outweighed inferences of fraud because "even if [the company's] projections or statements of confidence were overly optimistic, Plaintiffs have not alleged facts

showing that [the company] *believed* manufacturing issues could not be resolved quickly," or that the FDA would not approve the BLA. In the court's analysis, knowledge of purportedly underlying facts does not equate to scienter because *in a defendant's mind,* those facts may not render the challenged statements false or misleading. "[E]ven if a company knows that a problem exists, it could still honestly and in good faith report that the company will continue to perform as expected. Management simply may have been confident that they could overcome the problems or merely underestimated the severity of such problems."

The court in *AcelRx* (page 39), had a similarly nuanced view of scienter, and again rejected the simplistic formulation that knowledge of purportedly contradictory underlying facts equates to an intent to defraud. The company in that case, which sold an opioid taken sublingually, received a warning letter from the FDA asserting misbranding in its promotional materials. The FDA told the company that its "Tongue and Done" tagline "dangerously undercut" the conditions of use for which the FDA had granted approval. On the basis of the warning letter, plaintiffs challenged both the promotional materials and other statements the company had made about administering the drug. The court held that plaintiffs had adequately pled falsity, although it was a "close call."

But as in *BioXcel* and *Revance*, the court dismissed on scienter grounds. The court credited certain of plaintiffs' confidential witness allegations, but those allegations showed only that the company's CEO and chief health officer "were aware of the Tongue and Done slogan in promotional materials and their use at conferences." Knowledge of that underlying fact was not enough to establish scienter. "[T]he fact that [those executives] were aware of or even signed off on the use of the Tongue and Done slogan in marketing [the drug] is not enough to raise a strong inference that either Defendant intended to deceive investors or to engage in Misbranding Violations through the use of the materials." The same was true of confidential witness allegations showing that defendants knew about applicable FDA regulations. That knowledge did not "strongly imply that [defendants] knew any specific [challenged] statement…was false at the time it was made."

Plaintiffs' confidential witness allegations in *AcelRx* were more complete than those in many cases, in which plaintiffs are unable to find witnesses who interacted with the defendants. One of the *AcelRx* witnesses had not only interacted with the defendants but had purportedly told them that the "Tongue and Done" slogan put the company at risk of a warning letter. But that too was insufficient to establish scienter. Plaintiffs did not allege that the defendant *agreed* with the witness's concerns. Plaintiff had accordingly shown only internal company disagreement about the propriety of a marketing approach, and that did not equate to an intent to defraud investors.

RECENT SUPREME COURT DEVELOPMENTS

Before turning to summaries of individual pre-approval and post-approval decisions, we briefly touch on Supreme Court activity in 2024 in two pieces of securities litigation outside the life sciences field.

In both cases—*Facebook* and *NVIDIA*—the Supreme Court granted certiorari to review the Ninth Circuit's reversal of company victories on motions to dismiss.[9] But in both cases, the Supreme Court in late 2024 dismissed the writs of certiorari as improvidently granted.

In *Facebook*, plaintiffs challenged the company's risk disclosures in the aftermath of revelations of Cambridge Analytica's misuse of Facebook user data, alleging that those disclosures identified *potential* harm from data misuse, but did not reveal that actual misuse had already occurred. The plaintiffs argued that the disclosures implied that no such misuse had occurred in the past. Disputing the plaintiffs' characterization of the risk disclosures, Facebook (now Meta) argued that the disclosures carried no implied assurance about past misuse. The company further argued that the Ninth Circuit's approach would require companies to over-disclose previous materializations of risk, which would be burdensome and potentially lead to more generic, less helpful disclosures. As noted above, the district courts are divided on certain issues in the

9 *Facebook, Inc. v. Amalgamated Bank*, 604 U.S. 4 (2024); *NVIDIA Corp. v. E. Ohman J:or Fonder AB*, 604 U.S. 20 (2024).

analysis of risk disclosure. Some courts have held that a risk disclosure is not misleading unless the warned-of *consequences* have come to pass, while other courts reject that approach.

In *NVIDIA*, plaintiffs challenged the company's statements about the extent to which its revenue depended on cryptocurrency miners (and was therefore subject to risks associated with the crypto market). To support their falsity allegations, plaintiffs relied on an expert report. To support their scienter allegations, plaintiffs relied on purported internal documents whose contents they were unable to identify. At the Supreme Court, the company argued that the expert allegations were based on speculation and did not comply with the PSLRA's factual particularity requirements, and that reliance on unidentified documents similarly falls short of the required particularity. As we noted in our 2022 review, both the Ninth Circuit and the Second Circuit have previously rejected expert allegations in complaints against life sciences companies, although in neither case did the court issue a blanket ruling that expert allegations will always be out of bounds.[10]

At both oral arguments, the Justices showed skepticism toward the companies' positions, and questioned whether they should wade into the fact-specific inquiries the cases presented. Ultimately, in dismissing the writs as improvidently granted, the Court declined to do so. In the absence of Supreme Court guidance on the issues, the favorable Ninth and Second Circuit decisions on expert allegations remain good law, and companies may continue to build arguments from the plain language and logic of risk disclosures.

10 *In re Nektar Therapeutics Sec. Litig.*, 34 F.4th 828 (9th Cir. 2022); *Ark. Pub. Emps. Ret. Sys v. Bristol-Myers Squibb Corp.*, 28 F.4th 343 (2d Cir. 2022).

Trends and Analysis

DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 19–33), we provide detailed summaries of decisions in cases arising from setbacks life sciences companies experience at the pre-approval stage.

As discussed in the "Trends and Analysis" section above, companies won dismissal in 13 out of 23 development-stage cases in the district courts.

In the appellate courts, companies won affirmance of dismissal in all four cases.

APPELLATE DECISIONS

Local 282 Pension Tr. Fund & Local 282 Annuity Tr. Fund Dist. No. 9 v. Biomarin Pharm., Inc., 2024 WL 637491 (9th Cir. Feb. 15, 2024), affirming dismissal. **IND**

Biomarin develops a gene therapy drug for the treatment of a metabolic disorder. In November 2018, the company presented preclinical data for the drug and described some of the mouse models used in development. One year later, Biomarin announced that it would soon file an IND application with the FDA. In January 2020, Biomarin stated that the FDA had approved the drug for clinical trials. Later that year, the company reported that it was in the Phase 1/2 testing stage. But in September 2021, Biomarin disclosed that it had observed live tumors in a preclinical mouse study known as the Highest Dose Study, and that the FDA had placed a clinical hold on Phase 1/2 testing. The stock dropped 8%.

Investors sued, challenging the company's statements that the drug had yielded safe testing data and showed significant promise. According to plaintiffs, the tumor results from the Highest Dose Study predated the challenged statements. The district court dismissed on falsity grounds. Plaintiffs failed to allege facts showing when the company commenced the Highest Dose Study, when and how it learned that mice in the study developed tumors, and when and how that information was communicated to the individual defendants. Plaintiffs claimed that the company had admitted to having the relevant knowledge at the relevant time, but the purported admissions plaintiffs identified did not relate to Highest Dose Study or did not show that the study was complete at the relevant time.

The Ninth Circuit affirmed in a brief decision. Plaintiffs' falsity claims depended on a specific chronology of events, but plaintiffs failed to allege particularized facts sufficient to support that chronology.

Quinones v. Frequency Therapeutics, Inc., 106 F.4th 177 (1st Cir. 2024), affirming dismissal. **Phase 2**

Frequency Therapeutics developed FX-322, an injectable treatment for severe hearing loss. The company conducted a Phase 2a clinical trial in late 2020. In discussing inclusion criteria, the company stated that all participants had "meaningful word recognition deficits." In March 2021, the company reported disappointing top-line trial results: The treatment group did not perform discernibly better than the placebo group. The stock fell 78%. In reporting the top-line results, Frequency noted that the placebo group had performed better than expected based on previous trials. The company stated that the results may have been influenced by bias in the trial design, and some analysts speculated that patients may have exaggerated hearing loss in order to qualify for enrollment. When the company reported complete trial results at an investor conference in June 2021, the data suggested that at least one patient may have done just that.

Investors sued, challenging the company's statements about enrollment criteria and trial design. The district court dismissed with prejudice, as we reported in last year's review. Most notably, plaintiffs did not allege that the company knew or recklessly disregarded that patients who failed to meet the enrollment criteria were included in the trial.

The First Circuit affirmed. The appellate court agreed with the district court that plaintiffs had pled falsity as to the company's statement that "all subjects have meaningful word recognition deficits." But plaintiffs failed to adequately allege scienter—that any individual defendant knew about possible patient exaggeration or other problems at the time of the challenged statements. Plaintiffs' core operations allegations did not cure the shortfall.

In a subsequent decision, *Quinones v. Frequency Therapeutics, Inc.,* 347 F.R.D. 560 (D. Mass. 2024), the district court denied plaintiffs' motion to vacate dismissal. The motion was untimely and also failed on the merits. Plaintiffs did not demonstrate reasonable diligence in obtaining new confidential witness statements, and those statements did not support a strong inference of scienter in any event.

In re Ocugen, Inc. Sec. Litig., 2024 WL 1209513 (3d Cir. Mar. 21, 2024), affirming dismissal.
COVID-19 vaccine development; EUA

In 2020, Ocugen, a struggling pharmaceutical company, announced a partnership with Bharat, an Indian biotech developing an inactivated whole-virion COVID-19 vaccine called Covaxin. While Bharat conducted clinical trials in India, Ocugen took steps to prepare for an EUA application with the FDA based on the Indian trial data. Between February and May 2021, Ocugen spoke optimistically about submitting the EUA in the first half of the year, distributing 100 million doses, and earning significant revenue in 2021. Ocugen's stock price rose from $1.81 to $15.81 during this period. In June 2021, Ocugen reported that the FDA had recommended that it pursue a BLA rather than an EUA, and its stock fell 28%.

Investors sued, claiming that Ocugen never had a chance of obtaining an EUA for Covaxin and that the company concealed that fact. According to plaintiffs, various guidance documents the FDA issued about EUAs for COVID-19 vaccines foreclosed success. As we reported in last year's review, the district court dismissed all claims with prejudice. The court held that the FDA guidance was just that—nonbinding guidance—and nothing suggested that a vaccine could not succeed on the EUA pathway unless every factor in the guidance was satisfied.

The Third Circuit affirmed. Because the relevant information about FDA guidance and the company's efforts was readily available to investors, the purportedly misleading statements were immaterial. Various statements were also opinions, and plaintiffs failed to satisfy *Omnicare's* requirements, *i.e.,* demonstrating subjective disbelief, identifying false embedded statements, or identifying material omissions about the bases of the opinions. Plaintiffs' challenge was also impermissibly based on hindsight.

In re Sorrento Therapeutics, Inc. Sec. Litig., 97 F.4th 634 (9th Cir. 2024), affirming dismissal.
COVID-19 vaccine development

Sorrento developed a monoclonal antibody, STI-1499, for the treatment of COVID-19. On May 15, 2020, while the drug was in the early stages of preclinical testing, a news article quoted Sorrento's CEO saying "We want to emphasize there is a cure. There is a solution that works 100%…if we have the neutralizing antibody in your body, you don't need the social distancing. You can open up a society without fear." Sorrento's stock price rose over 200%. On May 20, 2020, two short sellers published reports questioning the company's claims of a "cure" for COVID-19. The stock fell 33%. The same day, the company's CEO stated that "you have the antibody that can prevent the virus from infecting healthy cells," and the stock rose again. On May 22, 2020, the company responded to short-seller criticism, stating that STI-1499 "might be" a cure, and that the drug could not cure late-stage patients. The stock fell 13%.

Investors sued, claiming that the company had misled the market by describing the antibody as a cure while testing was still in the preclinical stage. The district court dismissed on falsity and scienter grounds in a decision we previously reported. The statements at issue were either accurate or mere puffery, and the company disclosed that STI-1499 was still in preclinical stages and had not yet received FDA approval.

The Ninth Circuit affirmed. The company did not promise an immediate cure, and its enthusiastic statements were qualified by its acknowledgement that STI-1499 had undergone only laboratory tests. The fact that STI-1499 was not ultimately approved did not render this enthusiasm false. As to scienter, plaintiffs alleged no facts showing that the company did not believe its positive statements. Plaintiffs claimed that Sorrento's dire financial situation supported a strong inference of scienter, but the company had taken steps to address its finances well before it made the challenged statements.

DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

Hadian v. Fate Therapeutics, Inc., 2024 WL 4246083 (S.D. Cal. Sept. 19, 2024), granting motion to dismiss without prejudice. **IND**

Fate Therapeutics develops cellular immunotherapies using a technology that programs stem cells to fight disease. In particular, Fate used its technology to create "natural killer" cells (which can kill tumor cells) and T-cells (which play a vital role in immunity). In April 2020, Fate entered into a collaboration agreement with Janssen Pharmaceuticals to develop its natural killer and T-cell product candidates. Under the agreement, Fate was required to demonstrate efficacy. Milestones included obtaining IND approvals. In late 2021, Janssen declined to proceed with the first product because the treatment had not demonstrated efficacy against solid tumors. As a result, Fate could not move forward with its IND application. In January 2023, Fate announced that the collaboration agreement had been terminated. The stock fell 61%.

Investors sued, challenging the company's statements about the Janssen collaboration and IND applications. Plaintiffs alleged that Fate misleadingly failed to disclose that (1) it was experiencing difficulties in replicating earlier favorable efficacy results and in producing cell quantities sufficient for use in a clinical setting, and (2) Janssen had declined to proceed with the first IND candidate. The court dismissed on falsity and loss causation grounds. Plaintiffs' claims failed as to the first omission theory on falsity grounds alone. Fate did not conceal but repeatedly warned of the difficulties plaintiffs identified, explicitly stating that it was still developing reproducible processes for clinical-scale manufacturing. Plaintiffs cleared the falsity hurdle on the second omission theory—that the company implied that it was moving toward submitting its IND application when Janssen had already rejected the first candidate. Plaintiffs' scienter allegations as to this theory were also adequate. Plaintiffs cited a confidential witness who purportedly told them that one of the individual defendants knew about and reacted negatively to Janssen's rejection (which prevented Fate from meeting a milestone). This was buttressed by the core operations inference. Ultimately, however, plaintiffs' second omission theory failed on loss causation grounds. Plaintiffs failed to relate the termination of the collaboration agreement (which triggered the stock drop) to the challenged omissions.

Merritt v. Molecular Partners AG, 2024 WL 495140 (S.D.N.Y. Feb. 5, 2024), granting motion to dismiss. **Phase 1**

Molecular Partners develops protein therapeutics. In December 2018, the company entered into a licensing agreement with Amgen to develop a treatment for fibroblast activation protein positive cancers. The company conducted its IPO in 2021, while a Phase 1 clinical trial for the cancer drug was underway with Amgen. Meanwhile, an Amgen competitor, Roche, commenced three clinical trials for similar cancer treatments. In April 2022, Molecular Partners announced that Amgen had terminated the licensing agreement. The stock fell 37%.

Investors sued under Section 11, challenging statements about (1) the company's cancer drug, (2) the terms of the Amgen agreement, including that Amgen could terminate it, and (3) expectations for the drug and the use of IPO proceeds. Plaintiffs claimed that the statements were misleading because Roche was further along in developing similar drugs, putting the value of the Amgen agreement at risk. Plaintiffs also alleged that various of Molecular Partners' patents were about to expire. The court dismissed the action. The IPO registration statement repeatedly disclosed the patent expiration date and warned of associated risks. The company did not specifically disclose information about the Roche drug candidates, but that did not render any statements misleading: Plaintiffs failed to allege any "serious conflict" between Roche's progress and the company's statements about its own drug or the Amgen agreement. Notably, plaintiffs did not allege that Amgen terminated the agreement because of Roche's progress. (Although this did not affect the result, the court declined to credit at the pleading stage the company's argument that the relevant information about the Roche trials was in the public domain.) Plaintiffs also failed to allege that the Amgen agreement was already in jeopardy at the time of the challenged statements. Amgen did not terminate the agreement until a year after Roche had pulled ahead in its trials. The company also disclosed the risks of significant competition and termination of the Amgen contract.

Pizzuto v. Homology Meds., Inc., 2024 WL 1436025 (D. Mass. Mar. 31, 2024), granting motion to dismiss without prejudice. Phase 1

Homology develops a gene therapy for a disorder that causes an amino acid to build up in the body. In June 2019, Homology launched a two-part Phase 1 clinical trial and enrolled four patients. The first part of the trial evaluated safety and efficacy. The second part—dose expansion—was designed to evaluate a specific dosage across a larger number of randomized patients. In December 2019, Homology reported favorable initial clinical data from three of the four patients in the trial and recruited two more patients. In November 2020, Homology presented additional data showing that the two newer patients had not responded to the treatment. Homology explained that it believed the patients were not responding because they were being treated with steroids for elevated liver enzyme levels, which were in turn caused by pre-existing immune conditions. The company reported that it was advancing to the dose-expansion part of the trial, from which patients with such conditions would be excluded, and that the second part might be converted into a registrational trial. In February 2022, Homology disclosed that the FDA had placed a clinical hold on the trial due to the need to modify the risk mitigation measures related to liver enzyme levels. Homology announced that it would propose a more specific immunosuppressive regimen, which would delay the trial. Homology's stock fell 33%.

Investors sued, arguing that the company downplayed negative clinical data, concealed safety issues posed by the steroid regimen, and falsely suggested that the clinical data supported advancing to the dose-expansion part of the trial. The court dismissed on falsity, scienter, and loss causation grounds. The company had no duty to disclose "in real time" the unfavorable data from two patients simply because it discussed the preliminary positive data from three other patients. Statements limited to data collected before a specified cutoff date are not rendered misleading by less favorable data collected thereafter. The company's interpretations of the data, meanwhile, constituted opinion statements as to which plaintiffs had failed to satisfy applicable pleading requirements. As to the steroid regimen, the company never promised that it would eliminate side effects, and indeed it had warned about the risk of liver toxicity and associated regulatory issues. The company's statements about the dose-expansion phase were forward looking and appropriately accompanied by meaningful cautionary language. In the absence of facts contradicting the company's statements, as well as the company's transparency, plaintiffs failed to establish a strong inference of scienter. Finally, plaintiffs failed to allege a corrective disclosure. The FDA's clinical hold was the materialization of a known risk.

Pitman v. Immunovant, Inc., 2024 WL 964258 (E.D.N.Y. Feb. 25, 2024), recommending dismissal with prejudice, 2024 WL 1342737 (E.D.N.Y. Mar. 29, 2024), adopting report and recommendation. Phase 2

Immunovant develops a drug for autoimmune disorders. A potential risk of the treatment was decreased albumin levels, which may be linked to elevated cholesterol levels associated with an increased risk of vascular disease and overall mortality. In February 2021, Immunovant halted its Phase 2b clinical trial after receiving reports of increased cholesterol levels. The company also announced that it had not included cholesterol monitoring in its Phase 1 and Phase 2a clinical trial designs. The stock price fell 42%.

Investors brought Section 11 and Section 10(b) claims, claiming that statements about safety and efficacy were misleading in light of the company's undisclosed failure to monitor cholesterol in the earlier trials. The court dismissed the complaint with prejudice. The court noted at the outset that a disagreement as to the interpretation of scientific data is not a permissible subject of a securities fraud action—particularly where plaintiffs do not allege facts sufficient to support the conclusion that a challenged interpretation is rendered misleading in light of available scientific literature. Plaintiffs' Section 11 claim failed on falsity grounds. The company's statements about the safety and viability of the drug and the design and progress of the trials were not misleading by omission, given plaintiffs' inability to plead contrary facts substantially undermining the statements. The Section 10(b) claim failed on falsity grounds for the same reason, and several statements were non-actionable puffery in any event. As to scienter, plaintiffs' motive and opportunity allegations could have been made against any company, while their references

to purportedly contrary medical literature amounted to a non-justiciable dispute over the interpretation of clinical trial data.

Fernandes v. Centessa Pharms. PLC, 2024 WL 3638254 (S.D.N.Y. Aug. 2, 2024), granting motion to dismiss without prejudice. **Phase 3**

Centessa worked to develop lixivaptan, a kidney disease treatment. The FDA had already approved a treatment for the disease, but that treatment carried a significant risk of liver toxicity. Centessa therefore sought to show that lixivaptan was safer; this was critical to marketability and profitability. In May 2021, Centessa conducted its IPO while the drug was in Phase 3 trials. The company noted in its registration statement that it was seeking a differentiated safety profile for the drug. In June 2022, Centessa announced that it was discontinuing development: A patient in the trial had experienced the same liver chemistry abnormalities that beset the existing treatment. The stock fell 28%.

Investors sued under Section 11, challenging the company's statements about lixivaptan's comparative safety profile and clinical and commercial prospects. The court granted the company's motion to dismiss. The challenged statements were opinions as to which plaintiffs had failed to meet *Omnicare's* requirements; among other things, the company was not required to disclose every fact cutting the other way. The court also rejected plaintiffs' argument that statements about safety were misleading in light of allegedly undisclosed issues with trial design. The company disclosed the purportedly omitted information, and disagreements about trial design are not justiciable in any event. Many of the challenged statements about the trial were also forward looking and accompanied by appropriate warnings, including the warning that the company could decide to terminate development if a patient experienced an adverse liver toxicity event. The company's statements about commercial prospects were similarly forward looking and accompanied by relevant warnings. Although the PSLRA safe harbors do not apply to forward-looking statements in IPO registration statements, the pre-PSLRA bespeaks caution doctrine does, and the court concluded that it shielded the company's statements. Plaintiffs argued that the doctrine did not apply because the risk of under-enrollment allegedly had already materialized: Only two patients were enrolled at the time of the IPO. The court disagreed. The registration statement made clear that the Phase 3 study was ongoing and that enrollment challenges could arise.

Hills v. BioXcel Therapeutics, Inc., 2024 WL 3374145 (D. Conn. July 11, 2024), granting motion to dismiss without prejudice. **Phase 3; inspection**

BioXcel works to find new therapeutic uses for preexisting compounds. In December 2021, the company announced that it was launching two Phase 3 clinical trials to support FDA approval of BXCL501 for dementia and Alzheimer's. The drug was currently used to treat agitation. In April 2022, the company reported that its access to certain financing was contingent on achieving milestones, including FDA approval for BXCL501. In December 2022, the FDA inspected a site used for one of the clinical trials (Tranquility II) and issued a Form 483 detailing instances of noncompliance, including failure to properly document consent and medical history and failure to report a serious adverse event. The company disclosed the Form 483 in June 2023. At the same time, the company reported that the FDA inspection remained open and that it had determined that the principal investigator in Tranquility II may have fabricated a serious adverse event report in an effort to show compliance. The stock fell 64%. In August 2023, the company reported that it was unlikely to meet the financing milestones and expressed doubt about its ability to continue as a going concern. The stock fell 41%.

Investors sued, challenging the company's statements about its financial health and Tranquility II. Plaintiffs' theory was that the statements were misleading because the company did not disclose the Form 483 between December 2022 and June 2023. The court dismissed as to most statements on falsity grounds and the remaining two for shortfalls in pleading scienter. On falsity, many statements were too vague to be actionable or were not contradicted by the Form 483. Plaintiffs adequately pled falsity as to (1) a statement that FDA approval *could* be delayed if third parties did not comply with applicable protocols, which the company made when the risk had already materialized through the issuance of the Form 483, and (2) a statement that

Tranquility II had been completed, when the FDA inspection was still open. But plaintiffs failed to adequately plead scienter as to either statement. As to the risk factor, the company's awareness of the Form 483 did not equate to knowledge that its statement was false or misleading, and the fact that the company alerted investors to the risk cut against an inference of scienter. As to the statement that Tranquility II was complete, the question of whether an open inspection renders a trial incomplete is a technical one—not the stuff of fraud. The court also rejected plaintiffs' allegations that the company had a motive to commit fraud to obtain financing. Financing depended on FDA approval, and the company did not say that it had obtained such approval. Stock sales made under pre-class period trading plans did not support an inference of scienter either.

In re Spero Therapeutics, Inc., Sec. Litig., 2024 WL 4593422 (E.D.N.Y. Oct. 28, 2024), granting motion to dismiss with prejudice. NDA

Spero developed an antibacterial pill to treat complicated urinary tract infections. Treatment for such infections typically requires hospitalization and intravenous medication. Spero's drug was designed to be administered orally, which would be more cost-efficient. Spero launched a Phase 3 trial in February 2019, and announced a month later that the FDA had granted the drug Fast Track Designation. During the Phase 3 trial, the trial's data review committee recommended that Spero enroll the maximum sample size to ensure adequate power for the primary endpoint. In May 2020, Spero announced that it would proceed with a below-maximum number of patients. Also during the trial, the FDA raised concerns about gram-positive patients. Unless the trial included those patients, it would not be able to show noninferiority compared to an already approved medication. In August 2021, the company reported that it had submitted its NDA. But in March 2022, Spero announced that the FDA had identified deficiencies that precluded discussion of labeling and post-marketing requirements. The stock fell 18%. In May 2022, Spero disclosed that it would defer plans for the commercial launch of the drug based on further FDA feedback. The company explained that while review was ongoing, the data package might be insufficient to support approval. Spero also announced workforce cuts and an operational restructuring. The stock fell 64%.

Investors sued, challenging the company's statements about the drug's statistical noninferiority and approval prospects. The court dismissed on scienter grounds. The company's decision to enroll fewer patients than recommended by the data review committee was made in consultation with the FDA to navigate COVID-19-related challenges, undercutting plaintiffs' theory that the alleged under-enrollment was highly unreasonable. Plaintiffs also failed to plead facts suggesting the company knew that enrollment would present an issue. On the subject of gram-positive patients, plaintiffs pled no facts showing what, if anything, the FDA had told the company at the time of the challenged statements. Plaintiffs' allegations about personnel turnover did not support a strong inference of scienter, and neither did executive stock sales or salary increases. Plaintiffs failed to show that any of that activity was suspicious as to timing. The relevant time would have been between March and May 2022, and that is not when the conduct occurred.

In re Athenex, Inc. Sec. Litig., 2023 WL 7690175 (W.D.N.Y. Sept. 29, 2023), recommending granting motion to dismiss with prejudice, 2024 WL 2725609 (W.D.N.Y. May 28, 2024), adopting report and recommendation. NDA

Athenex, which develops cancer treatments, pursued approval of Oraxol, a combination of an existing intravenous cancer drug and an inhibitor that enables oral administration. In 2015, Athenex began a Phase 3 clinical trial in Latin America. The primary endpoint was confirmed tumor response rate. Athenex hired clinical research organizations to monitor the trial. In 2017, while the Phase 3 trial was ongoing, the company conducted its IPO. Throughout 2018, the company reported that the Phase 3 trial was going according to plan and that Oraxol was on track to receive FDA approval. The company also conducted a secondary public offering. The Phase 3 trial concluded in 2019, and the company subsequently filed an NDA. In March 2021, the company reported that the FDA had issued a CRL denying its NDA based on concerns about the validity of the Phase 3 trial primary endpoint, the patient population, and safety risks. The stock dropped 55%.

Investors sued, challenging the company's statements about an agreement between the company and the FDA as to the primary endpoint of the Phase 3 trial, as well as optimistic statements about the Phase 3 trial results. The court dismissed on scienter grounds. Plaintiffs' motive allegations were generic. Plaintiff claimed that two of the company's directors had interests in the clinical research organization, which was accordingly a related party, but identified no particular motive to commit fraud arising from that relationship. The clinical research organization was also eligible for payments when the trial reached certain milestones, but those never materialized. And none of plaintiffs' confidential witness allegations showed that individual defendants knew contradictory facts at the time of the challenged statements.

Strezsak v. Ardelyx Inc., 2024 WL 1160900 (N.D. Cal. Mar. 18, 2024), granting motion to dismiss without prejudice. **NDA**

Ardelyx develops tenapanor, a treatment for a condition resulting from high levels of phosphate in the blood. The company conducted Phase 3 clinical trials using a surrogate endpoint. The surrogate endpoint was the level of serum phosphate in trial participants' blood; a clinical endpoint would have been reduced mortality. The FDA provided the company with feedback in November 2017, in a December 2018 Advice Letter, and at a March 2020 meeting about the NDA. In its feedback, the FDA indicated that if the decrease in serum phosphate was not sufficiently large—that is, if it was no larger than that provided by other treatments—the company would need to demonstrate clinical relevance and otherwise justify approval. The company publicly continued to express confidence in its interactions with the FDA, its trial data, and the eventual approval of tenapanor. In June 2021, the company announced that the FDA had identified deficiencies in the NDA that prevented the review process from moving forward. The stock fell 74%.

Investors sued, arguing that in its optimistic statements, the company misleadingly omitted information about the concerns the FDA had expressed. The court granted the company's motion to dismiss on falsity and scienter grounds. The company's optimistic statements were opinions as to which plaintiffs failed to meet *Omnicare's* requirements. Plaintiffs did not allege facts sufficient to show that the FDA's feedback convinced the company that tenapanor's approval was in jeopardy, and thus failed to allege that the company did not hold its optimistic beliefs or that such beliefs were objectively untrue. At most, the FDA's statements constituted views contrary to the company's opinions, and the company had no duty to disclose such views. The court further noted that the company *did* disclose general clinical trial risks, including the risk that the FDA could conclude that the clinical data were insufficient for approval. Plaintiffs also failed to allege facts sufficient to create a strong inference of scienter. The FDA concerns plaintiffs cited were not sufficiently serious to show that the defendants' optimistic statements were knowingly false. Insider selling allegations did not support an inference of scienter either. Plaintiffs did not connect cited stock sales with particular items of nonpublic information, and allegations about a single individual's purportedly unusual trades were insufficient.

Strezsak v. Ardelyx Inc., 2024 WL 4194797 (N.D. Cal. Sept. 12, 2024), granting motion to dismiss with prejudice. **NDA**

In a subsequent decision, the court dismissed the complaint, with prejudice, on falsity grounds. Plaintiffs' only new factual allegation related to a company official who purportedly believed that approval was in serious jeopardy following the March 2020 FDA meeting. The allegation was insufficient because plaintiffs neither identified the official nor otherwise pled facts showing reliability or personal knowledge. Plaintiffs challenged two new statements from the company's risk disclosures, arguing that these warnings failed to inform investors that the trials did not yield the results necessary for FDA approval. But these were the same statements the court had previously held adequately *disclosed* the relevant risk, and plaintiffs failed to allege facts showing that the risk identified had already materialized.

In re Bristol-Myers Squibb Co. CVR Sec. Litig., 2024 WL 873436 (S.D.N.Y. Feb. 29, 2024), granting motion to dismiss with prejudice. **BLA; contingent value rights**

In connection with its 2019 merger with Celgene, Bristol-Myers (BMS) issued $6.4 billion in contingent value rights (CVRs). The CVRs would pay out if the FDA approved three legacy Celgene products by specified deadlines. Two were approved on time, but the third, Liso-cel, missed the December 31, 2020 approval deadline by five weeks. That rendered the CVRs worthless.

Investors sued, challenging BMS's statements about its efforts to meet the deadlines and the likelihood of timely FDA approval. Plaintiffs' theory was that BMS deliberately slow-rolled approval and concealed this from investors. The court granted the company's motion to dismiss in a decision we reported in our 2023 review, concluding, among other things, that plaintiffs failed to establish a strong inference of scienter. The court dismissed plaintiffs' amended complaint in 2024. In an effort to improve their motive allegations, plaintiffs pled that both the merger and the approval of Liso-cel had enterprise-level significance for BMS; the court held that this was insufficient. The court also rejected plaintiffs' allegations that the company's oversight committees and direct lines of communication showed scienter. New confidential witness allegations were similarly inadequate, as they did not bear on the individual defendants' knowledge. Plaintiffs finally cited an "FDA Biologics Expert" for the proposition that the expected approval timeline for Liso-cel was a "statistical anomaly," but this supported at most an inference of corporate or agency mismanagement, not a strong inference of scienter.

Aramic LLC v. Revance Therapeutics, Inc., 2024 WL 1354503 (N.D. Cal. Apr. 2, 2024), granting motion to dismiss without prejudice. **BLA; manufacturing issues**

Revance develops a skin treatment for frown lines. In November 2019, the company announced that it had submitted a BLA for the drug and expected FDA approval at the end of 2020. In July 2021, following COVID-19-related delays, the FDA completed its inspection of Revance's manufacturing facility and issued a Form 483 containing several observations the company needed to address. Revance provided a written response to the Form 483 later that month, disagreeing with some of the FDA's observations. Revance then publicly announced in August 2021 that the FDA had conducted its pre-approval inspection and that it anticipated approval by the end of 2021. In October, the FDA issued a Complete Response Letter denying the BLA. The stock fell 39%.

Investors sued, challenging the company's statements about readiness for the inspection and confidence in FDA approval, including statements the company made after the FDA had issued the Form 483. The court dismissed on falsity grounds, save as to two statements, and on scienter grounds as to all. On falsity, plaintiffs adequately alleged that the company's post-inspection opinions about its preparedness for approval were misleading in light of omitted facts about an FDA inspector's contrary feedback. Plaintiff also adequately alleged falsity as to the company's post-inspection statement that it "may" receive a response from the FDA identifying deficiencies. At that point, the company had already received the Form 483 and unfavorable feedback from the inspector. While the company had no standalone duty to disclose that feedback, it was not entitled to discuss the FDA process in a misleading way. But plaintiffs' claims ultimately failed on scienter grounds. The company's knowledge of manufacturing issues did not in itself equate to an intent to deceive or recklessness about investor deception. Plaintiffs pled no facts about the individual defendants' states of mind. The most compelling inference was that the company believed it was on the path to approval even after the FDA issued the Form 483. That inference was buttressed by the FDA's post-class period approval of the BLA.

In re BioLineRx Ltd. Sec. Litig., 2024 WL 3409800 (D.N.J. July 15, 2024), granting motion to dismiss without prejudice. **Financing to support product development**

BioLineRx, an Israeli company, develops stem cell treatments for patients with blood cancer. From February 2021 through early September 2022, the company told investors that it believed its current financing would be sufficient to fund projected cash requirements into the first half of 2024. In mid-September 2022, the company reported that it had entered into a $40 million loan

agreement and was making a direct securities offering to certain institutional investors at a 30% discount. The stock fell 34%.

Investors sued, challenging the company's statements that it believed it had sufficient capital through the first half of 2024. The court dismissed on falsity grounds. The court rejected plaintiffs' assumption that the company must have lied about having enough cash on hand to last into 2024 simply because it raised capital more than a year earlier. Plaintiffs alleged no facts showing that the company was in dire need of cash, nor that it had misstated the amount of cash on hand in the challenged statements. Those statements were also forward looking and accompanied by sufficient cautionary language.

DISTRICT COURT DECISIONS: MOTION TO DISMISS DENIED

In re RenovaCare, Inc. Sec. Litig., 2024 WL 2815034 (D.N.J. June 3, 2024), denying in part motion to dismiss. **Stock promotion**

RenovaCare develops stem cell therapies. Its stock trades on an OTC market. In the summer of 2017, the company engaged StreetAuthority, a financial research firm, to promote its stock. StreetAuthority disseminated materials stating that the FDA would approve the premarket submission for one of RenovaCare's medical devices. In reality the company had not yet made any such submission. In January 2018, RenovaCare was told by the authorities regulating the OTC market to disclose the stock promotion campaign. The company did so, and it further disclosed that it had paid $90,000 for costs incurred by unnamed investor relations firms relating to the StreetAuthority publications. But the company also maintained that the promotional materials were accurate, and it denied that its executives or controlling stockholder participated in creating the materials. Associates of the company then traded stock in a coordinated fashion. The next month, the OTC market downgraded the company's stock to its lowest tier. The stock price fell 30%. In April 2019, the company announced that its disclosure controls were ineffective and that it had identified material weaknesses in its internal controls. In May 2021, the SEC announced that it was charging the company with securities fraud based on its undisclosed role in the stock promotion campaign and on false statements in the promotional materials. The stock fell 25%.

Investors sued, challenging the company's statements denying involvement in the stock promotion campaign. The court largely denied the company's motion to dismiss. Plaintiffs adequately alleged that the company's controlling stockholder was a maker of the January 2018 statements, and that he had failed to disclose the whole truth about the company's promotional activities. Plaintiffs also adequately alleged a "pump-and-dump" scheme liability claim, as well as a market manipulation claim under Section 9(f) against certain individual defendants.

Luo v. Spectrum Pharms., Inc., 2024 WL 4443323 (D. Nev. Oct. 7, 2024), denying in part motion to dismiss. **Phase 2; BLA**

Spectrum developed Pozi to treat certain lung cancers and Rolontis to treat a side effect of chemotherapy. In 2017, Spectrum launched two Phase 2 clinical trials of Pozi—the MD Anderson trial and the ZENITH20 trial. Spectrum intended to use data from the MD Anderson trial to secure a breakthrough therapy designation. In 2018, Spectrum announced that the FDA had declined to grant breakthrough therapy status for Pozi and that the trial did not achieve the targeted objective response rate for approval. Spectrum's stock fell 39%. One year later, Spectrum announced that the ZENITH20 trial also failed to meet the FDA's target objective response rate. The stock fell 60%. As to Rolontis, Spectrum submitted a BLA in December 2018 but withdrew the application in March 2019 so it could provide additional manufacturing-related information. Spectrum then resubmitted the BLA, but the FDA rejected the application after an inspection revealed numerous deficiencies. The stock fell 26%.

Investors sued, challenging the company's statements about Pozi's approval prospects, the efficacy of existing treatments, the FDA's target objective response rate, and interim results. The court held that plaintiffs had adequately pled that the company misled investors about the objective response rates of existing treatments. The company cited rates in the 6-10%

range, but that reflected only drugs of the same type of Pozi—not the standard of care overall. Plaintiffs also adequately alleged that the company misled investors by suggesting that a drug with a 20-30% objective response rate would be approved; the threshold was actually higher. The company's statement that it was in regular discussions with the FDA bolstered plaintiffs' allegations that the company knew the FDA's views about the required objective response rate. The court also held that plaintiffs had adequately alleged that expressions of confidence were misleading where the company referred to earlier trial data in optimistic terms despite unpromising interim results. But plaintiffs' challenge to other optimistic statements failed; plaintiffs could not identify with particularity contradictory data the company knew about when it made the statements. The court also dismissed plaintiffs' attack on the company's statements about Rolontis. The company accurately stated that it had withdrawn its BLA, and plaintiffs pled no facts showing that the company knew it would fail the inspection. As to scienter, plaintiffs established the necessary inference with allegations about the CEO's stock sales (among other things). Although the CEO made the sales pursuant to trading plans or tax withholding obligations, the sales were dramatically out of line with prior trading practices. The CEO's retirement just months after the class period ended also supported a strong inference of scienter.

Salzman v. ImmunityBio, Inc., 2024 WL 3100274 (S.D. Cal. June 20, 2024), denying in part motion to dismiss. **BLA; manufacturing**

ImmunityBio develops cancer treatments. Its flagship product candidate is Anktiva, a biologic drug. Anktiva's active ingredient was produced by a contract manufacturer, which had agreed to tell ImmunityBio about findings made in FDA inspections. In March 2021, the FDA issued a Form 483 to the manufacturer, citing numerous deficiencies. In July 2021, the FDA again cited the manufacturer for violations. ImmunityBio's CEO began meeting monthly with the manufacturer's executives to discuss these issues, but the deficiencies remained. ImmunityBio submitted its BLA in May 2022. The FDA conducted another inspection in February 2023, attended by ImmunityBio's CEO and other representatives, and issued another Form 483. The FDA rejected the BLA in May 2023, and the company's stock fell 55%.

Investors sued, alleging that the company had misleadingly suggested that no manufacturing difficulties existed. The court denied the company's motion to dismiss. Plaintiffs adequately alleged falsity as to the company's statements that it had established compliant manufacturing at scale. The fact that the manufacturer rather than the company was out of compliance did not change the analysis, given the company's acknowledgement that it was ultimately responsible for manufacturing. Plaintiffs also adequately alleged that risk disclosures about manufacturing difficulties were misleading; at the time of the challenged statements, the risks had already materialized. By contrast, plaintiffs failed to allege falsity as to the company's statements about compliance in the context of its plan to vertically integrate and develop its own manufacturing process. The same was true of the company's risk disclosures about FDA approval, as negative interim findings about manufacturing issues did not preclude approval. As to the statements that survived, plaintiffs established a strong inference of scienter based on specific facts about what the company learned from the manufacturer about its violations, as well as the company's failure to timely disclose the Forms 483.

Gorlamari v. Verrica Pharms., Inc., 2024 WL 150341 (E.D. Pa. Jan. 11, 2024), denying in part motion to dismiss. **NDA; manufacturing**

Verrica develops a drug-device product to treat a skin disease. In April 2021, Verrica announced that the FDA would inspect the facility of its contract manufacturer, Sterling Pharmaceutical, as part of the NDA review process. The FDA issued a Form 483 containing several observations of noncompliance with current good manufacturing practices, though none related to Verrica's product specifically. Verrica told investors "we fully anticipate that we'll have our inspections take place according to plan." In September 2021, the FDA issued a Complete Response Letter denying the NDA because of Sterling's manufacturing noncompliance. The stock fell 8%. Verrica then resubmitted its NDA and told investors it had reached "successful resolution" of the manufacturing deficiencies. The FDA inspected Sterling a second time in February 2022 and again provided observations of noncompliance that did not directly concern Verrica's product. In public filings over the next several months, Verrica again referred to "satisfactory resolution" of

the Sterling deficiencies. In May 2022, Verrica announced that Sterling's second inspection had been classified as "Official Action Indicated," and that Verrica had received a second Complete Response Letter denying its NDA. The stock fell 64%.

Investors sued, challenging the company's statements about the inspection and purported successful resolution of issues at Sterling. The court denied the company's motion to dismiss in part. Plaintiffs adequately alleged that the statement that inspection of Sterling would go forward "according to plan" was misleading, given that the inspection had already occurred and had revealed problems that would prevent timely approval. While the company was not required to disclose interim feedback, it had a duty to not falsely imply that the FDA's inspections were on track for a timely approval when this was not the case. As to scienter, the company's relationship with Sterling, the importance of the product to Verrica's core business, and allegations attributed to a confidential witness established a strong inference that the company knew its statements were misleading. The court also noted the "evasive phrasing" of some of the statements. Conversely, while plaintiffs adequately alleged falsity as to the "successful resolution" statements, they failed to plead scienter: They established neither that the company knew about the outcome of the second inspection at the time of the challenged statements nor that the company recklessly disregarded the risk that measures taken to remedy the manufacturing issues were insufficient. Plaintiffs satisfactorily pled loss causation in connection with the FDA's September 2021 denial of the NDA.

Gorlamari v. Verrica Pharms., Inc., 2024 WL 4026176 (E.D. Pa. Sept. 3, 2024), denying in part motion to dismiss. **NDA**

The court subsequently denied in part the company's motion to dismiss plaintiffs' amended complaint. In that complaint, plaintiffs sought to show through confidential witness allegations that the company knew Sterling would fail the second inspection when it made the challenged statements. At the outset, the court declined to consider two declarations submitted by confidential witnesses recanting their statements. As a procedural matter, the declarations were "off limits on a motion to dismiss." The court then credited allegations from another confidential witness who purportedly stated that the CEO traveled to the Sterling site during the second FDA inspection and received regular updates about persistent problems identified by the FDA. But the court dismissed the claims against the CFO. Plaintiffs did not allege he was made aware of the significance of the inspection for the company's prospects, and the only connection between him and the challenged statements was that, as CFO, he signed financial reports attaching a press release with the challenged statements.

In re Y-mAbs Therapeutics, Inc. Sec. Litig., 2024 WL 451691 (S.D.N.Y. Feb. 5, 2024), denying in part motion to dismiss. **BLA**

Y-mAbs develops omburtamab, a treatment for cancer in nerve tissue. The company submitted a BLA in August 2020. The FDA issued a Refusal to File letter in October 2020, identifying problems with one of the clinical trials and concluding that the company had failed to establish safety and efficacy. In reporting the letter, the company expressed confidence that it could address the issues the FDA had raised and planned to resubmit the BLA before year-end. The FDA continued to raise concerns in 2020 and 2021. The company resubmitted its BLA in March 2022. The FDA convened an advisory committee, and in October 2022 it released a briefing document identifying various issues with the BLA. The stock fell 27%. Later in October, the company reported that the advisory committee had voted unanimously that the BLA did not contain sufficient evidence that omburtamab improved overall survival. The stock fell 60%.

Investors sued, challenging the company's statements about the timing of the BLA resubmission, progress toward that resubmission, trial results, and its interactions with the FDA. The court denied the company's motion to dismiss as to a subset of statements in the latter category—specifically, statements that the company had provided the FDA with all the information it had requested and had resolved all of the FDA's concerns. Plaintiffs plausibly alleged that these statements were contradicted by the FDA's feedback. For example, plaintiffs adequately alleged falsity as to statements that meetings with the FDA confirmed the company's path toward resubmission, given plaintiffs' allegations that the FDA continued to

voice concerns with trial data at those meetings. While interim FDA feedback is not necessarily material, the company's decision to report on that feedback suggested that defendants themselves believed it was material. Plaintiffs sufficiently pled recklessness based on individual defendants' involvement in the BLA process and FDA communications, as well on omburtamab's status as the company's lead product candidate. Plaintiffs adequately pled loss causation based on the FDA briefing document, which contained information contradicting the challenged statements. But the court dismissed plaintiffs' claim as to other challenged statements. Some were protected under the PSLRA's safe harbors. Others were opinions as to which plaintiffs pled no contradictory facts. The balance reflected interpretations of data that were reasonable notwithstanding the FDA's ultimate disagreement with them.

Christiansen v. Spectrum Pharms., Inc., 2024 WL 246020 (S.D.N.Y. Jan. 23, 2024), denying in part motion to dismiss. NDA

Spectrum conducted clinical trials of a lung cancer drug between 2017 and 2020. The company applied for accelerated approval in November 2021. At that time, the FDA had expressed concerns that data were inadequate to justify the dosage used in one trial, but it had also "agreed" to the submission. The company announced that it intended to launch a confirmatory clinical trial—the Pinnacle Study—which is a necessary step in the accelerated approval pathway. FDA guidance states that a confirmatory trial should already be under way when a drug sponsor applies for accelerated approval. In December 2021 and throughout 2022, the FDA raised concerns about the Pinnacle Study related to safety, to delay in starting the trial, and to dosage and the lack of dosage optimization data. Between May and August 2022, Spectrum announced that the FDA was "aligned" on Spectrum's intended dosage regimen. The company also reported that patients were being randomized, that testing sites were being opened, and that the FDA would act on the NDA in the next five months. In September 2022, the FDA released a briefing document disclosing its concerns that no patients had yet been enrolled in the Pinnacle Study, and that the initial results from that study were not anticipated for several years. Spectrum's stock fell 37%. Later that month, an FDA advisory committee recommended against approval. The stock fell 31%.

Investors sued, challenging the company's statements that the FDA was "aligned" on the Pinnacle Study's dosage regimen, that patients were enrolled in the study, that the company had optimized dosage, and that the FDA would likely approve the drug. The court denied Spectrum's motion to dismiss in part. Plaintiffs adequately pled that the "aligned" statement was false because it was contrary to FDA feedback. They also adequately alleged that the statements about enrollment were misleading in context. Plaintiffs established the required inference of scienter as to statements about both the dosage regimen and patient enrollment, based on facts showing that company officials were aware of the FDA's contrary positions on these issues. But the court granted the company's motion on falsity grounds as to other challenged statements. Statements about FDA approval were protected projections, while statements about dosage optimization were opinions as to which plaintiffs had failed to satisfy applicable pleading requirements. The court also rejected plaintiffs' attack on the company's warnings that regulatory approval could be delayed. Plaintiffs alleged that this risk had already materialized, but they identified facts showing only that the Pinnacle Study had been delayed—not that accelerated approval would be.

Pardi v. Tricida, Inc., 2024 WL 1056013 (N.D. Cal. Mar. 11, 2024), denying in part motion to dismiss. NDA

Tricida developed veverimer for the treatment of metabolic acidosis associated with chronic kidney disease. Tricida sought approval under the FDA's accelerated approval program, in which a drug is conditionally approved based on a successful surrogate endpoint trial. The sponsor then conducts a post-approval Phase 4 trial to confirm efficacy by showing clinical benefit. Tricida conducted a Phase 3 trial in which the surrogate endpoint was an increase in patients' serum bicarbonate levels. The company reported favorable results from the trial in 2018. In November 2019, the FDA accepted Tricida's NDA for review, and in the first six months of 2020 it held mid-cycle and late-cycle review meetings with the company. In July 2020, the FDA told Tricida that it had identified deficiencies that precluded further review. Tricida's stock fell 40%. In August 2020, the FDA issued a CRL identifying two deficiencies, one related to the applicability of data from

foreign trial sites to U.S. patients and the other related to the magnitude and durability of the serum bicarbonate treatment effect. The company's stock fell 23%. The stock continued to fall as Tricida reported further setbacks in the approval process.

Investors sued, challenging Tricida's statements about (1) the requirements of the accelerated approval program, (2) enrollment in the Phase 4 trial, (3) the location of the Phase 3 trial sites, (4) the "multicenter" nature of the Phase 3 trial, and (5) the FDA's comments at the May 2020 late-cycle meeting. In July 2022, the court granted the company's motion to dismiss as to all statements save the last. In January 2023, the company filed for bankruptcy, and the case proceeded solely against the former CEO.

After receiving documents from the FDA in discovery, plaintiff amended his complaint, challenging statements about (1) the location of the Phase 3 trial sites, (2) the "multicenter" nature of the Phase 3 trial, (3) the FDA's comments at the May 2020 late-cycle meeting, and (4) the Phase 3 trial design and endpoints. The court granted defendant's motion to dismiss as to all challenged statements, except one additional statement about the May 2020 late-cycle meeting. The court held that a statement that an Advisory Committee meeting was not scheduled "due in part to the logistical challenges posed by COVID-19" was sufficiently alleged to be false or misleading in light of allegations that an AdCom was not scheduled because of alleged issues with the NDA and not because of COVID-19. However, the other challenged statements were opinions—expressing optimism about the submission, review, and approval of the NDA, for example—as to which plaintiffs did not meet the pleading standards set forth by the Supreme Court in *Omnicare*. The court emphasized that "there is no general requirement under the securities laws for a company to engage in a rolling, communication-by-communication disclosure of every detail arising from the back-and-forth dialogue with the FDA throughout its complex review and approval process, or to adopt the FDA's position as correct and share it with the public when discussing its product."

In re Celgene Corp., Inc. Sec. Litig., 2024 WL 3503486 (D.N.J. July 23, 2024), 2024 WL 4047674 (D.N.J. Sept. 4, 2024), denying in part motions for summary judgment. **NDA**

Celgene develops a treatment for multiple sclerosis. Throughout 2017, Celgene told investors that Phase 3 trials were showing positive results and that it was on track to submit an NDA by year-end. While the Phase 3 trials were underway, Celgene was also testing whether use of the treatment might generate metabolites—chemical byproducts formed when the body breaks down a drug. The FDA considers the production of metabolites in evaluating NDAs. In the summer of 2017, Celgene's testing confirmed a major metabolite. Celgene asked the FDA if it could submit its NDA on the planned schedule and results from the metabolite study later. The FDA denied the request in November 2017. Celgene proceeded to file its NDA the following month, publicly stating that the application was based on the Phase 3 results. The FDA rejected the application as incomplete because it did not provide enough information about the results of metabolite testing. The stock fell 9%.

Investors sued, challenging the company's statements about the efficacy of the drug and potential regulatory approval. The company separately moved for summary judgment. The court granted the COO's motion. The COO was not the maker of any challenged statement, and his role on the company's disclosure committee was not enough to confer maker status under *Janus*. The court noted that plaintiffs had appeared to abandon their claims as to certain remaining individual defendants and statements but gave them leave to submit supplemental arguments.

The court denied the company's summary judgment motion in part in a separate ruling. Plaintiffs adequately marshaled facts showing that two other executives knew by the fall of 2017 that an end-of-year NDA filing deadline was out of reach as a result of the metabolite findings. The facts also showed that the executives knew the FDA had rejected the company's request to submit an NDA without the metabolite results. A reasonable jury could find scienter on the part of these executives for the company's statements in early 2018, and the executives' scienter could be imputed to the company. On the defendants' side, the court granted summary judgment as to several statements predating the NDA filing under the law of the case

doctrine, but it held the motion in abeyance as to other statements pending further briefing on one executive's scienter.

Butala v. Owlet, Inc., 2024 WL 3648141 (C.D. Cal. Aug. 5, 2024), 2024 WL 4560173 (C.D. Cal. Sept. 26, 2024), denying motion to dismiss and granting motion for reconsideration in part. **Premarket clearance for medical devices**

Owlet sells the Smart Sock, a device that monitors an infant's heart rate and oxygen levels. In 2013, Owlet debuted a prototype of the device that sends a notification or alarm if the baby's heart rate or oxygen levels become problematic. The company stated that the alarm and other features made the prototype a Class II medical device requiring FDA clearance. A few months later, Owlet launched a version of the Smart Sock that did not contain alarm or notification features and stated in a press release that this version too needed FDA clearance. In early 2015, the FDA issued guidance explaining that it did not intend to regulate "low-risk general wellness products" as medical devices. Later that year, Owlet launched a version of the Smart Sock with alarm and notification features; the company did not seek or obtain FDA clearance for the product. In 2016, the FDA told Owlet that the Smart Sock was a medical device and not a general wellness product. Owlet did not disclose the correspondence and continued to sell the Smart Sock. In connection with a February 2021 SPAC merger to take the company public, Owlet stated that the Smart Sock was not a medical device and did not require FDA clearance, and that the company was in compliance with applicable law. Owlet also stated that the FDA *could* require that it obtain authorization for the Smart Sock. In October 2021, the FDA issued a public warning letter stating that the Smart Sock was a medical device and that it had been corresponding with the company about the matter since 2016. The stock fell 23%.

Investors sued, challenging the company's statements that it had been in compliance with FDA regulations since 2018 and had all necessary clearances, that it had received no notices of noncompliance, and that no agency was considering changing the Smart Sock's marketing classification. The court denied the company's motion to dismiss. Given the 2016 communications from the FDA, plaintiffs had adequately pled that the company knew the FDA required premarketing approval. The court rejected the company's argument that the FDA had not issued a factual finding in that correspondence; plaintiffs satisfactorily alleged that the FDA had consistently maintained through 2021 that the Smart Sock was a medical device. The company's disclosure that the FDA could require authorization did save the statements as a pleading matter. As to scienter, the court considered it significant that the company had previously admitted that a device with an alarm would likely qualify as a Class II medical device. Plaintiffs also adequately alleged a motive for the company to deceptively market its flagship product as a wellness product: The company lacked the funding necessary to obtain FDA clearance. Plaintiffs also adequately alleged a Section 14(a) claim.

Subsequently, the court granted the company's motion for reconsideration as to certain statements. Citing recent Ninth Circuit law, the company targeted the statements it made before it merged with the SPAC. Because plaintiffs acquired stock only in the post-merger, public entity, they lacked standing to challenge the earlier statements, which were made by and about the pre-merger entity.

Decisions
Development Stage

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 35–46), we provide detailed summaries of decisions in cases arising from developments at the post-approval stage. As discussed in the "Trends and Analysis" section above, companies won dismissal in 11 out of 18 post-approval cases in the district courts.

Defendants also prevailed in all four appellate decisions; only one of these decisions was published in the Federal Reporter.

APPELLATE DECISIONS

Zhou v. Desktop Metal, Inc., 120 F.4th 278 (1st Cir. 2024), affirming dismissal.
Manufacturing issues

Desktop Metal, which specializes in 3D printing, acquired a company that made medical and dental devices and then created a subsidiary to handle that business. In manufacturing the dental products, Desktop used photopolymer printing, a 3D printing process that uses light to cure (*i.e.,* harden) resin into objects such as dentures. In May 2021 Desktop received 501(k) clearance from the FDA for its Flexcera denture products. In early November, Desktop disclosed that, in response to employee concerns, it was investigating manufacturing and compliance practices in its photopolymer printing process. Desktop also announced that the CEO of the new subsidiary had resigned. The stock dropped 10%. A week later, Desktop disclosed that it would notify the FDA about compliance issues with the resin used in the Flexcera products and with one of the types of curing units used to harden the resin, known as the PCA 4000 curing box. The stock dropped 15%.

Investors sued, alleging that (1) the company's statements about compliance with FDA regulations were misleading because the company did not disclose that it produced Flexcera in facilities not registered with the FDA, and (2) the company's statements about the PCA 4000 curing box were misleading because PCA 4000 was not strong enough to properly cure Flexcera products. The district court dismissed on falsity grounds and also dismissed plaintiffs' scheme liability claim.

The First Circuit affirmed. Plaintiffs conceded that Flexcera had received 501(k) clearance, and they failed to allege that noncompliance with the FDA's facility-registration requirement affected clearance. In its risk disclosures, moreover, the company did not promise full compliance but disclaimed it. Meanwhile, in discussing robust demand for the product, the company made no mention of regulatory compliance. The court acknowledged that plaintiffs had plausibly alleged corporate mismanagement, but that this was distinct from a securities fraud claim. The court also held that plaintiffs had failed to preserve their scheme liability claim.

Tibbs v. electroCore, Inc., 2024 WL 4987243 (3d Cir. Dec. 5, 2024), affirming dismissal.
Competition; reimbursement

electroCore manufactures gammaCore, a device that treats various types of headaches. The FDA cleared gammaCore for commercial sale in April 2017. In June 2018, the company conducted its IPO, stating that it had entered into agreements with third-party payers. In May 2019, the company announced that it had missed first-quarter revenue expectations, and its stock fell 30%. Later that month, the company announced a restructuring and cost reduction plan, and its stock dropped again. In August 2019, electroCore reported a restructuring charge and restrictions on reimbursement. The stock fell 10%. In September 2019, the company disclosed that the FDA had requested an analysis of clinical data for its 510(k) submission. The stock fell 23%.

Investors brought Section 11 and Section 10(b) claims, challenging electroCore's statements about its agreements with third-party payers and the voucher program it had implemented to increase demand for gammaCore, as well as statements in which the company allegedly omitted information about the difficulty of qualifying gammaCore for industry-standard diagnostic codes. As we reported in last year's review, the district court dismissed the Section 11 claim on falsity grounds and the Section 10(b) claim on falsity and scienter grounds.

The Third Circuit affirmed. The company's statements about third-party payers were not misleading in context. Plaintiffs argued that the term "commercial payor" was misleading because the company had entered into contracts only with pharmacy benefit managers (PBMs), and not with insurance companies. But the term "commercial payor" encompasses both PBMs and insurance companies. The court also rejected plaintiffs' attack on the company's statement that its agreement with CVS would give it access to 30 million patients. This was an opinion, and while one of plaintiffs' confidential witnesses offered a different opinion (7 million "commercial lives"), that did not establish falsity. Plaintiffs' challenges to statements about the

vouchers were similarly premised on confidential witness allegations showing only a difference of opinion about business strategy. As to statements about diagnostic codes, the company disclosed the difficulty and risks of obtaining insurance coverage. Plaintiffs' failure to allege falsity was also fatal to scienter; "circumstantial pleadings fail to make up the difference."

Menorah Mivtachim Ins. Ltd. v. Sheehan, 2024 WL 1613907 (2d Cir. Apr. 15, 2024), affirming grant of summary judgment. **Medicaid rebates; antitrust**

Mylan develops and manufactures both generic and brand-name pharmaceuticals, including the EpiPen. Mylan classified the EpiPen as a non-innovator multiple source drug; manufacturers of such drugs receive the most favorable rebate treatment. In 2014, Mylan received a DOJ subpoena in an investigation into the classification of the EpiPen. In 2016, Mylan announced that it had entered into a $465 million settlement with the DOJ over the matter.

Investors sued, alleging that Mylan had made false statements about the classification of the EpiPen. Plaintiffs also alleged that Mylan's EpiPen contracts with pharmacy benefits managers were anticompetitive. Apart from the EpiPen, plaintiffs alleged that Mylan had engaged in a price-fixing conspiracy for generic drugs. As we reported in last year's review, the company prevailed on summary judgment on all three categories of claims. Plaintiffs appealed the district court's ruling on the Epi-Pen classification and generic drug claims.

The Second Circuit affirmed. On Epi-Pen classification, plaintiffs argued that the district court's scienter analysis did not apply to the challenged statements. The Second Circuit rejected that scope argument and further held that plaintiffs had waived any challenge to the merits of the district court's scienter ruling on the classification issue. As to alleged generic drug price-fixing, the court affirmed dismissal on loss causation grounds. Plaintiffs failed to disaggregate the losses caused by the purported price-fixing scheme from losses triggered by the announcement of other negative developments. In addition, the alleged corrective disclosures about price fixing revealed little if any new information about Mylan. Even if one news article may have added new details about the DOJ's investigation into price-fixing, the article was largely confined to a negative characterization of already-public information.

DeKalb Cty. Pension Fund v. Allergan PLC, 2024 WL 677081 (2d Cir. Feb. 20, 2024), affirming grant of summary judgment. **Product recall**

Allergan manufactures breast implants, which are regulated by the FDA as Class III medical devices. Breast implants have been associated with a cancer of the immune system called breast implant-associated anaplastic large-cell lymphoma. Reports associated this cancer primarily with "textured" breast implants, including Allergan's Biocell product. Allergan noted the possible link between breast implants and cancer in its risk disclosures, stating that negative publicity could hurt its implant business and that product liability claims or investigations could lead to restrictions on sale. In December 2018, French regulatory authorities asked Allergan to recall its textured implants, which it did. The stock fell 7%.

Investors sued, challenging the company's references to cancer in connection with other manufacturers' products. Plaintiffs claimed that these references were misleading because Allergan's textured implants were associated with higher rates of cancer than its competitors' products. The district court granted summary judgment for the company in a decision we reported in our 2022 review. The court reasoned that the challenged statements were not comparative and that Allergan had no duty to disclose information about relative rates of the cancer.

The Third Circuit affirmed. Two of the challenged statements were true and in any event did not refer to textured breast implants; no reasonable investor would have interpreted the statements to represent anything about the comparative rates of the cancer. The third statement, which concerned FDA reports of the cancer in patients with textured implants from all manufacturers, was also true and contained no reference to the relative cancer risks among manufacturers. In addition, the context of the third statement (a news article) revealed uncertainty in the scientific community about the linkage of specific manufacturers' textured implants to cancer. The court added that the company did not assume a duty to disclose information about comparative safety by disclosing the FDA reports.

DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

Ortmann v. Aurinia Pharms., Inc., 2024 WL 3784566 (D. Md. Aug. 13, 2024), granting motion to dismiss with prejudice. **Product launch**

Aurinia develops a treatment for active lupus nephritis. The FDA approved the drug in 2021, after which Aurinia worked to provide the drug—its flagship product—to as many patients as possible. Aurinia made positive statements about the success and prospects of the treatment. In February 2022, Aurinia issued revenue guidance short of expectations. The stock dropped 24%.

Investors sued, challenging the company's positive statements as misleading by omission. Specifically, plaintiffs alleged that the company failed to disclose that (1) it had engaged primarily with rheumatologists although lupus nephritis is typically treated by nephrologists, (2) lupus nephritis patients were hard to reach as a result of their social and economic backgrounds, (3) target patients were often noncompliant with drug regimens, (4) doctors found the prescription paperwork tedious and thought the drug was too expensive, and (5) insurance coverage limitations further deterred doctors from prescribing the drug. The court dismissed on falsity grounds. The company repeatedly disclosed the purportedly omitted information. While the company did not explicitly state that patients were hard to reach and often noncompliant, it did repeatedly inform investors that patients came from underserved and under-resourced communities, with difficulty accessing ongoing care. The court noted that the company was not required to state every obstacle in the most specific language possible. Investors were capable of taking the "minor critical thinking step" required to deduce the potential difficulties with the patient population based on the information the company disclosed.

Brill v. Invivyd, Inc., 2024 WL 4228832 (D. Mass. Sept. 18, 2024), granting motion to dismiss with prejudice. **Product efficacy; COVID-19**

Invivyd developed a monoclonal antibody therapy to prevent and treat COVID-19. The therapy had been successful in combatting the original strain of the disease and its early variants. After the Omicron variant emerged in November 2021, Invivyd publicly predicted that the therapy would continue to be effective. But by mid-December, Invivyd announced that in vitro testing demonstrated a significant reduction in effectiveness against Omicron. The stock fell 88%.

Investors sued, challenging the company's statements about projected efficacy against Omicron. The court dismissed on falsity and scienter grounds. The challenged statements were all opinions, and because the company conveyed uncertainty, reasonable investors would not have interpreted them as guarantees of efficacy. Plaintiffs failed to allege that the company disbelieved its own opinions or omitted critical facts about their bases. The court declined to credit plaintiffs' claim that published research about the shortcomings of a similar antibody should have alerted the company that its product would be ineffective against Omicron even before it received the in vitro testing results. The company had no duty to conduct exhaustive research before making efficacy predictions; more broadly, there is no duty to conduct "good science" under the securities laws. Plaintiffs' scienter allegations failed in the absence of conclusive evidence, from the time of the challenged statements, that the antibody therapy was ineffective against Omicron—let alone evidence that anyone at the company knew this at the relevant time. Plaintiffs' attempt to cast the later adverse test results back to the time of the challenged statements was impermissible fraud by hindsight.

Meyer v. Organogenesis Holdings Inc., 2024 WL 1346432 (E.D.N.Y. Mar. 29, 2024), granting motion to dismiss with prejudice. **Medicare reimbursement**

Organogenesis manufactures and sells products for advanced wound care. For a time, two of the company's products, Affinity and PuraPly XT, had not been assigned an average sales price (ASP) under the Centers for Medicaid and Medicare Services' pricing formula. In accordance with government guidance, regional Medicare Administrative Contractors (MACs) instead reimbursed physicians selling the product. In August 2022, Affinity received an average sales price, which reduced the reimbursement rate for the products. The company's stock dropped 20%.

Investors sued, challenging the company's statements about compliance and sales performance. Plaintiffs claimed that the company had marketed the products by reference to a "spread" physicians could earn between MAC reimbursement and their own costs. According to plaintiffs, the challenged statements were misleading because the company did not reveal that the source of its growth was a purportedly unsustainable marketing scheme. The court dismissed with prejudice on both falsity and scienter grounds. Plaintiffs failed to allege that any statement was objectively false or misleading by omission. The court ruled that the alleged statements about growth, sales performance, and compliance were general, and did not trigger a duty to disclose. Plaintiffs' claims also failed as to the company's statements about the financial performance of Affinity and PuraPly XT in particular. The court concluded those statements were not misleading because the company did not (1) refer to specific marketing strategies, (2) suggest that the alleged scheme was not occurring, or (3) suggest that reimbursement status was not important or would not affect financial success. The company also warned investors about reimbursement risk. The court ruled that the Plaintiffs' scienter allegations were inadequate in the absence of references to specific reports or statements contradicting the challenged statements, or confidential witness allegations identifying any discussion or meeting with the individual defendants.

Sneed v. AcelRx Pharms., Inc., 2024 WL 2059121 (N.D. Cal. May 7, 2024), granting motion to dismiss with prejudice. **Misbranding**

AcelRx develops DSUVIA, an opioid painkiller administered sublingually. The FDA approved the drug in November 2018, as well as AcelRx's Risk Evaluation and Mitigation Strategy. In 2021, the FDA issued a warning letter asserting that two of its promotional materials—a banner advertisement and a tabletop display—contained false or misleading representations about risk and efficacy, which amounted to misbranding. The promotional materials used the term "Tongue and Done," which the FDA concluded "dangerously undercut" the conditions of use under which it had granted approval. After the company disclosed the warning letter, its stock price fell 8%.

Investors sued. The court granted the company's motions to dismiss two earlier versions of the complaint, in decisions we reported on in our 2022 and 2023 reviews. Plaintiffs amended their complaint, narrowing their claims to the company's statements about the administration of DSUVIA. The court dismissed on scienter grounds, this time with prejudice. The court again concluded that one statement presented a "close call" on falsity: a statement about administration that left out restrictions on use and dosage information. The court acknowledged that the company had presented the omitted information elsewhere, but concluded that while this undercut plaintiffs' falsity allegations, it did not altogether dispose of them. The company's "Tongue and Done" materials similarly presented a "close call"; here again, the company left out known information about administration and restrictions on use. But once again, plaintiffs fell short on scienter. Plaintiffs relied primarily on confidential witness allegations. While the witnesses were credible, the allegations showed only that the defendants were aware of the promotional materials and of general regulatory risk—not that they intended to deceive investors or knew the slogan "Tongue and Done" would produce a warning letter.

Trustees of Welfare & Pension Funds of Local 464A – Pension Fund v. Medtronic PLC, 726 F. Supp. 3d 938 (D. Minn. 2024), granting motion to dismiss with prejudice. **Product recall; manufacturing issues**

Medtronic sells insulin pumps for diabetes patients. In November 2019, the company issued a voluntary field safety notification regarding a potential defect in two pump models. Medtronic did not describe the event as a recall and expressed optimism about its pipeline to launch a new pump. But in February 2020, the FDA determined that the notice was a Class I recall and identified additional models at risk for the same defect. Medtronic announced that it expected sustained demand for the pumps notwithstanding the recall and spoke positively about the FDA's review of its latest pump application. In July 2021, the FDA completed an inspection of a Medtronic facility and issued a Form 483 raising various concerns extending beyond the defect at issue in the recall. In subsequent statements about the new pump, Medtronic did not disclose the inspection, the Form 483, or how either event might affect approval. In December 2021, the FDA concluded that Medtronic had not resolved the deficiencies identified in the inspection and issued a formal warning letter. Medtronic announced that it had received a warning letter, but that it expected

only a modest financial impact on its diabetes business. In May 2022, Medtronic stated that it no longer expected to receive timely FDA approval of the new pump and acknowledged a significant revenue decline given the absence of new product approvals. The stock fell 6%.

Investors sued, alleging that the company engaged in a scheme to hide product issues and their financial impact, and misrepresented the degree to which timely FDA approval for the company's latest insulin pump was in jeopardy. The court granted the company's motion to dismiss on falsity and scienter grounds. Plaintiffs failed to allege falsity as to the company's statements about the financial success of its pumps. Plaintiffs did not allege that financial data were manipulated or that sales growth was attributable to an illegal or unsustainable source. Quality issues did not render the statements misleading. Statements that advancements by competitors hurt the company's business similarly were not rendered misleading simply because product quality issues also caused pressure on the business. Plaintiffs also failed to allege falsity as to statements of optimism and opinion about progress toward FDA approval of the new pump and business growth. Medtronic never assured investors that the FDA would approve the pump or do so on a specific timeline. Other statements were forward looking and accompanied by warnings about the risks in seeking approval for new medical devices. Significantly, the company had no duty to disclose the Form 483 in the absence of affirmative representation about regulatory compliance. Plaintiffs' scienter allegations also failed. Plaintiffs alleged no contemporaneous facts showing that the company knew the FDA would deny approval of the new pump—based on the inspection or otherwise—and other facts showed that the company had a reasonable expectation of approval. Plaintiffs' remaining scienter allegations were also insufficient—allegations about confidential witnesses, a hands-on management style, executive departures, insider stock stales, and SOX certifications. Plaintiffs scheme liability claim failed in the absence of adequate scienter allegations.

Dang v. Amarin Corp. plc, 2024 WL 4285900 (D.N.J. Sept. 25, 2024), granting motion to dismiss without prejudice. **Patent issues**

Amarin developed Vascepa, a product made up of an omega-3 fatty acid that lowers triglycerides and lipoproteins without increasing cholesterol. Amarin applied for U.S. patents for Vascepa in 2010. At that time, a Japanese manufacturer had already launched a drug pharmacologically equivalent to Vascepa. Amarin's patent application thus turned on demonstrating that Vascepa's reduction of lipoproteins was unexpected and not supported by prior art. Amarin obtained the patents in 2012. The FDA designated Vascepa a New Chemical Entity the same year. Four years later, Amarin brought an infringement action against various competitors who had filed abbreviated NDAs for generic versions of Vascepa. That litigation put the prior art at issue. In 2018, while the patent litigation was pending, Amarin announced positive results from one of its clinical trials, which demonstrated that Vascepa reduced the likelihood of cardiovascular events in patients with elevated triglycerides who were already on cholesterol medication. But in 2020, the district court presiding over the patent litigation invalidated the Vascepa patents. The court found that the Japanese study had already demonstrated that the omega-3 fatty acid in Vascepa lowered lipoproteins, and thus that prior art rendered the patent claims obvious. The court added that Amarin's patent examiner did not consider this study. The company's stock fell 70%. The Federal Circuit affirmed the decision later that year, and the stock fell 40%. Amarin's CEO announced his retirement in April 2021. The stock fell 13%.

Investors sued, challenging the company's statements about the patent litigation, Vascepa's "unique" characteristics, and Vascepa's financial prospects following the positive results from the clinical trial. Plaintiffs alleged that all statement were misleading because the company failed to disclose that Vascepa was not actually entitled to patent protection in the first place. Plaintiff further alleged that Amarin concealed from the patent examiner the Japanese study that rendered the patent claims obvious. The court dismissed on falsity and scienter grounds. First, the company *did* disclose the study to the examiner. Second, the challenged statements were opinions as to which plaintiffs failed to meet applicable pleading requirements, non-actionable puffery, or forward-looking statements protected by the PSLRA's safe harbors. No facts indicated that the company knew that the patents were invalid or that it would not prevail in the patent litigation. Moreover, the company disclosed the risks of litigation and the potential that its patents would be invalidated. As to scienter, the court deemed implausible

plaintiffs' theory that the company would spend a decade to obtain and defend patents it purportedly knew could be undone by the consideration of a single study.

In re Evolus Inc. Sec. Litig., 2024 WL 4306786 (S.D.N.Y. Sept. 26, 2024), granting motion to dismiss without prejudice. **Trade secrets**

Evolus had an exclusive license to market Jeuveau, a competitor of Botox developed by a South Korean company. In 2019, Allergan, which partners with a different South Korean company to manufacture Botox, filed a complaint with the International Trade Commission. Allergan alleged that a former employee of its South Korean partner misappropriated propriety materials related to the manufacture of Botox and provided them to Evolus's South Korean partner, which then used the materials to develop Jeuveau. In 2020, the ITC determined that, based on the genetic similarity between the products, Evolus's South Korean partner had misappropriated trade secrets from Allergan's partner to develop Jeuveau. The ITC recommended an order prohibiting Evolus from importing and marketing Jeuveau in the U.S. for ten years. Evolus's stock fell 37%.

Investors sued, challenging the company's statements expressing confidence in its legal position in the ITC litigation, describing Jeuveau as its proprietary product, and discussing Jeuveau's competitive strengths. Plaintiffs also challenged one statement that Evolus's founder had "developed" Jeuveau. The court dismissed on falsity and scienter grounds. The expressions of confidence were opinions, and plaintiffs did not adequately allege that the company disbelieved its opinions or omitted critical facts about their bases. Significantly, under the ITC's protective order, Evolus had no access to the confidential business information of other entities, including its South Korean partner. This restriction undercut plaintiffs' argument that, according to a former employee, the company failed to investigate the misappropriation claims: Plaintiffs did not explain what such an investigation would have uncovered. The company's statement that Jeuveau was "proprietary" were accurate—Evolus had an exclusive license to market the product in the U.S. Statements about Jeuveau's competitive strengths were not misleading in light of disclosures of the risks of an unfavorable outcome in the ITC proceeding. The single statement that the company's founder had developed Jeuveau was not misleading when viewed alongside the company's numerous disclosures that the product was developed by its South Korean partner. Plaintiffs' speculative scienter allegations were also insufficient.

In re Viatris Inc. Sec. Litig., 2024 WL 4252060 (W.D. Pa. Sept. 20, 2024), granting motion to dismiss with prejudice. **Business strategy**

In November 2020, Pfizer's generics division merged with Mylan to form Viatris, whose portfolio spanned brand, generic, and biosimilar products. Throughout 2021, Viatris provided updates about its strategic planning and review process. In February 2022, Viatris announced a partnership with Biocon. Under the partnership agreement, Viatris divested its biosimilars portfolio in exchange for equity in Biocon. Viatris' stock fell 24%.

Investors sued, challenging the company's financial guidance and statements about its commitment to biosimilars and its strategy to leverage its broad portfolio. The court dismissed the complaint on falsity grounds. Most of the challenged statements were forward looking and came within the PSLRA's safe harbors: The statements consisted of revenue projections or otherwise related to the company's future economic performance. The court rejected plaintiffs' theory that the company's projections were inherently unreasonable in light of its ongoing strategic review. The company disclosed the review and expressly cautioned investors that it was considering divestitures. The court also declined to credit plaintiffs' conclusory and speculative allegations that the company must have known that it would eventually divest business to Biocon. The remaining challenged statements about the company's business model and pipeline were puffery or non-actionable opinions.

Helo v. Sema4 Holdings Corp., 2024 WL 3593677 (D. Conn. July 31, 2024), granting motion to dismiss. **Sales performance; insurance**

Sema4 uses AI in connection with personalized medicine. In early 2022, Sema4 announced that it would acquire a company that provided rare disease diagnostic and exome sequencing services. The acquisition closed in May 2022. Sema4 stated that the transaction would significantly

enhance the power of its clinical data platform, Centrellis. Sema4 also spoke favorably about its progress in obtaining reimbursement from health plans, its increasing test volumes, and its financial prospects. But in August 2022, the company announced that it was reversing over $30 million in revenue from prior periods. The reversal related to negotiations with one of the company's larger commercial payors, which sought to recoup payments it had made for Sema4's screening services. The company also reported that it had established a $39 million reserve to cover other potential recoupments. The stock fell 33%.

Investors sued, challenging the company's statements about (1) Centrellis, and (2) financial performance, including both reimbursement from third-party payors and the volume and prices of tests sold. The court granted the company's motion to dismiss. On the subject of financial performance, plaintiffs claimed that the company's August 2022 disclosures showed that its business practices were unsustainable and unprofitable, and that the company had misleadingly failed to reveal this in its earlier statements. But the company *had* disclosed the considerable risks to its business model, including challenges related to payor reimbursements and the fact that payors often attempt to renegotiate their fee. Several of the challenged statements also concerned future opportunities and came within the PSLRA's safe harbors. Others were non-actionable corporate optimism. As to Centrellis, plaintiffs adequately alleged falsity: Confidential witness allegations suggested that the technology simply did not exist. But on this subject, plaintiffs failed to establish a strong inference of scienter. They pled no particularized facts about the individual defendants. The confidential witness did not purport to have interacted with them, and plaintiffs did not otherwise show that they were aware of issues with Centrellis. Meanwhile, the motives plaintiffs ascribed to the executives—that they wanted to maintain high stock prices and protect their compensation—were entirely generic.

Ng v. Berkeley Lights, Inc., 2024 WL 695699 (N.D. Cal. Feb. 20, 2024), granting motion to dismiss without prejudice. **Sales performance**

Berkeley Lights develops a lab instrument called the Beacon, which analyzes and processes cell data used in biotherapeutics and other cell-based products. In its July 2020 IPO registration statement and prospectus, the company highlighted the capabilities of the Beacon compared to existing technology. The company conducted a second public offering a few months later. In May 2021, Berkeley Lights released first-quarter results, which reflected fewer sales of the Beacon than in the prior quarter. The company also missed subsequent quarterly projections. In September 2021, short-seller Scorpion Capital released a report discussing customer complaints and stating that only a small number of biotech companies could afford the Beacon. The company's stock fell 19%. In January 2022, Berkeley Lights announced that its 2021 revenue was expected to fall far short of projections and that it was replacing its CEO. The stock fell 39%.

Investors sued under Sections 11 and 10(b), challenging statements about the Beacon's capabilities and the company's revenue prospects. The court dismissed the Section 11 claim for failure to allege falsity, and the Section 10(b) claim on falsity, scienter, and loss causation grounds. The company's characterizations of its technology were classic puffery, and plaintiffs failed to plead that any of these statements was contradicted by information known to the company at the time. The company had no duty to disclose all product defects or customer complaints when it referred to the Beacon, and plaintiffs failed in any event to connect those references to the alleged defects and complaints. The Scorpion Capital report, which the court assessed "with caution," was not reliable, as it lacked particularized details about confidential sources. The company's statements about its finances and growth prospects were also puffery or were protected forward-looking statements. Plaintiffs' scienter allegations failed for lack of specific facts about the individual defendants' contemporaneous knowledge of the Beacon's defects or customer complaints. Plaintiffs alleged that executives resigned after adverse developments, but did not dispel the assumption that the resignations were triggered by those developments rather than by purported fraud. On loss causation, the Scorpion Capital report, put out by a self-interested short-seller who made standard disavowals, did not constitute a corrective disclosure. Nor did the company's disappointing earnings releases or announcement that the CEO would be replaced. Neither revealed any past misconduct or facts contrary to the challenged statements.

Lowe v. Tandem Diabetes Care Inc., 2024 WL 1898473 (S.D. Cal. Apr. 30, 2024), granting motion to dismiss without prejudice. **Sales performance**

Tandem manufacturers and sells insulin pumps for diabetes patients. In August 2022, Tandem lowered its 2022 revenue guidance but noted that competition from other insulin pump manufacturers was in line with expectations. At two healthcare conferences the following month, Tandem discussed three market headwinds affecting its sales: competition, pandemic-related conditions (including staffing shortages in physician offices), and macroeconomic factors (inflation and unemployment). Tandem also reaffirmed its existing guidance at the conferences. In November 2022, Tandem reported revenue below guidance and further decreased guidance for subsequent periods. The stock fell 28%.

Investors sued, arguing that the company's statements concealed and materially downplayed adverse market conditions. The court dismissed on falsity and scienter grounds. The company repeatedly warned investors about precisely the factors plaintiffs claimed it concealed, and no contemporaneous facts showed that any statement was false when made. Plaintiffs' confidential witness allegations were not persuasive. The allegations were vague and conclusory, and failed to establish that the purported witnesses were reliable or had personal knowledge of facts sufficient to establish falsity or scienter. Plaintiffs also failed to allege a plausible motive for fraud.

DISTRICT COURT DECISIONS: MOTION TO DISMISS DENIED

Okla. Firefighters Pension & Ret. Sys. v. Biogen Inc., 2024 WL 3178638 (D. Mass. Mar. 19, 2024), granting in part motion to amend judgment dismissing action. **Product launch**

The FDA approved Biogen's Alzheimer's disease drug Aduhelm in June 2021. On the day it announced approval, Biogen reported that 900 sites were ready to begin treatment and that Medicare coverage was "automatically presumed" following approval. The company also said it was engaging with stakeholders to determine the price for Aduhelm. The launch was not a success. Among other things, six weeks after approval, only 325 of the 900 sites had completed pharmacy and therapeutics committee reviews, Medicare instituted a National Coverage Determination and decided to cover Aduhelm only in the clinical trial setting, and private insurers denied coverage. In December 2021, Biogen cut the annual price for Aduhelm from $56,000 to $28,000. Biogen's stock price rose $100 on the announcement of approval but fell by that amount and more over the next seven months. Following the announcement that Medicare would not cover the drug, Biogen largely abandoned commercialization.

Investors sued, challenging, among other things, the company's statements that (1) it believed 900 sites were ready to treat, (2) Medicare coverage was presumed, and (3) it had received stakeholder input in setting the drug price. As we reported last year, the district court dismissed as to all statements on both falsity and scienter grounds. Plaintiffs moved to amend or alter the judgment, offering additional confidential witness allegations as well as a report by a House of Representatives oversight committee titled "The High Price of Aduhelm's Approval." The court noted at the outset that plaintiffs had access to the House report before the court entered its judgment, and that plaintiffs could have made the confidential witness allegations "earlier with due diligence." The court then declined to alter its holding as to the 900-sites statement. Plaintiffs' new confidential witness allegations suggested that some sites were improperly coded as ready, but this did not show that fewer than 900 sites were ready, nor that the company knew this. The court also declined to alter its holding as to the company's statement about stakeholder input into pricing. Although the House report showed that the company knew that 55% of payers found the price to be excessive, this did not contradict the company's statement that it had obtained input; indeed, it confirmed the statement.

But the court granted plaintiffs' motion as to the company's statement that Medicare coverage was presumed. The court concluded that the House report supported a cogent inference of scienter. The report showed that before Biogen made the challenged statements, the company was internally discussing the high likelihood that Medicare coverage would be narrower than desired. On this statement, the litigation has accordingly moved forward.

Patel v. Koninklijke Philips N.V., 2024 WL 4265758 (E.D.N.Y. Sept. 23, 2024), denying in part motion to dismiss. **Product recall**

KPNV is a health technology corporation whose subsidiary, Philips Respironics, manufacturers devices for sleep, breathing, and respiratory conditions. In 2015, Philips began receiving customer complaints that a foam component of its devices could degrade into particles that users ingested or inhaled, with ill effects on their health. Philips conducted an investigation and reported internally that the foam in certain devices was degrading. Neither Philips nor KPNV spoke about the issue publicly until April 2021. At that point, KPNV disclosed that user complaints and testing had revealed a quality issue in certain devices, and that the company had taken a reserve to cover the cost of repairing the devices. The stock dropped 4%. In June 2021, KPNV issued a recall of several devices; the FDA later classified the recall as a Class I, which is the most serious recall category. The stock dropped another 4%. In July 2021, KPNV announced another significant loss provision to cover the cost of the recall. The stock again dropped 4%.

Investors sued, challenging the parent company's statements about (1) its commitment to compliance, quality, and safety; (2) its business and products; (3) its financial performance; and (4) the reserve for repair costs and the scope of the foam issue. Plaintiffs also challenged optimistic statements by the subsidiary's CEO. The court denied the motion to dismiss. Plaintiffs adequately alleged both falsity and scienter based on statements by the parent company's CEO that he had learned of foam issues from market surveillance; plaintiffs alleged that the CEO attended meetings between 2018 and 2021 at which the company discussed surveillance issues. Plaintiffs adequately alleged that the subsidiary's CEO had learned of the foam issues even earlier, in connection with a 2015 Form 483, although the court declined to impute the scienter of the subsidiary's CEO to the parent company. Similar allegations were sufficient—on both falsity and scienter grounds—with respect to challenged statements about compliance and customer response to the products. Other statements, by contrast, were either demonstrably true or non-actionable puffery.

Stadium Capital LLC v. Co-Diagnostics, Inc., 2024 WL 456745 (S.D.N.Y. Feb. 5, 2024), denying in part motion to dismiss. **Sales performance; COVID-19**

Co-Diagnostics makes tests to diagnose diseases, including COVID-19. When the pandemic hit in 2020, the company's revenues increased substantially. The company posted revenue in excess of $20 million for eight straight quarters. In May 2022, Co-Diagnostics reported fluctuating orders for tests and declined to provide guidance. The company told investors that it was not seeing a decline in demand but was unsure about the timing of orders. In August 2022, the company reported second-quarter revenue of $5 million, attributing the decrease to lower demand for its COVID-19 tests. The stock dropped 31%.

Investors sued, challenging the company's statements about its prospects and financial results. The court largely denied the company's motion to dismiss. The court reasoned that because the company made the challenged May statement in the middle of the second quarter (May 12), it would by then have known that revenue was tracking well below previous quarters, given that the second-quarter total was only $5 million. The company put current demand and risks to future demand at issue and thereby assumed a duty to speak about these subjects truthfully and fully, which meant disclosing negative trends. The challenged statements were neither opinions nor puffery. And even if they were forward looking, the court held, the company's cautionary language was boilerplate and described risks that had already materialized. As to scienter, plaintiffs had established a cogent and compelling inference by reference to the company's decision not to provide quarterly guidance. In the court's view, plaintiffs had satisfactorily alleged that this showed that the company knew demand had dropped and hoped to mask that fact until demand rebounded.

San Antonio Fire & Police Pension Fund v. Dentsply Sirona Inc., 732 F. Supp. 3d 300 (S.D.N.Y. 2024), denying in part motion to dismiss. **Financial reporting**

Dentsply manufactures dental technology and equipment, including high-tech imaging and orthodontics, as well as dental instruments. Starting in June 2021, Dentsply faced a sharp drop

in demand and supply-chain issues resulting from the pandemic. At the same time, the company experienced problems with a popular product that milled crowns. This further exacerbated the supply-chain issues by adding to the backlog. Customers complained. In February 2022, Dentsply reported disappointing financial results, and the stock dropped 8%. In April, the company reported more disappointing results and announced that its CEO had been terminated. The stock fell 13%. In May 2022, Dentsply disclosed that it had begun an internal investigation into financial reporting matters, including the possibility that the company had used incentives to induce distributors to buy product. In November 2022, Dentsply announced the results of the investigation: (1) Incentives to distributors had contributed to the company's ability to meet third- and fourth-quarter 2021 guidance, but the company's public disclosures "potential[ly] omi[tted]" information about the use and future impact of the incentives; (2) the company would restate its financial statements; and (3) senior leadership was at fault, but the investigation had uncovered no intentional wrongdoing. The stock fell 13%. Later in November, Dentsply again announced disappointing financial results, and the stock fell 5%.

Investors sued, challenging the company's statements about inventory, supply chain, product quality, and the overall health of its business. The company moved to dismiss and the court denied the motion in part. Several statements were immaterial puffery or opinions as to which plaintiffs failed to meet *Omnicare*'s requirements. But other statements were definite and verifiable, including statements discussing the strength and sustainability of the company's earnings, the demand for its products, and the adequacy of its supply. Plaintiffs plausibly pled that these statements were misleading based on allegations about channel stuffing as well as product defects and difficulties in obtaining supplies. Among other things, plaintiffs alleged that in the second half of 2021, the company's sales team was holding weekly inventory calls and had become concerned about the supply chain. Plaintiffs also adequately alleged scienter. They drew a direct link between millions of dollars in performance-based pay for the individual defendants and the purported fraud. The company's own statements about inventory tracking and in-depth knowledge of the supply chain further supported an inference that the individual defendants knew facts contradicting the challenged statements. Plaintiffs' allegations about an improper tone at the top, poor internal controls, and executive departures also contributed to a strong inference of scienter. As to loss causation, plaintiffs plausibly linked each disappointing earnings report to the risks concealed by the alleged fraud.

City of Warwick Ret. Sys. v. Catalent, Inc., 2024 WL 3219616 (D.N.J. June 28, 2024), denying in part motion to dismiss. **Manufacturing issues; financial reporting**

Catalent manufacturers drugs for pharmaceutical and biotech companies, including COVID-19 vaccines. By mid-2021, as demand for vaccines decreased, Catalent was left with excess production capacity and employees, as well as increased quality control issues costly to remediate. In October 2021, Catalent received a Form 483 for its Brussels facility, which it shut down for several months in 2022. In August 2022, Catalent received another Form 483 regarding the Brussels facility; at the same time, the FDA raised concerns following an inspection of the company's Bloomington facility. Throughout this period, Catalent spoke positively to investors about its quality control procedures, its compliance with GAAP, and the demand for non-vaccine products. In September 2022, the media reported that the FDA had delayed the release of millions of vaccine booster shots as a result of problems at the Bloomington facility. The stock fell 9%. In April 2023, Catalent reported operational challenges across all of its major facilities. The stock fell 27%. In May 2023, the company reported that it had identified accounting issues that would delay the release of its next quarterly financial report. The stock fell 26%.

Investors sued, challenging the company's statements about quality control, GAAP compliance, and demand for non-vaccine products. The court denied the company's motion to dismiss as to multiple statements. Plaintiffs adequately alleged that the company's positive statements about commercial activity at the Brussels facility in February 2022 were misleading; the company had shut down the facility in January after receiving the Form 483. Plaintiffs also adequately alleged falsity as to statements about GAAP compliance given the subsequent identification of accounting issues. Plaintiffs adequately established a strong inference of scienter based on confidential witness allegations suggesting that the individual defendants were aware of information contradicting their statements, as well as the company's own professions that high-

level executives were involved with quality standards, inventory, and disclosure procedures. Plaintiffs also adequately pled that purported corrective disclosures presented new information about the alleged fraud to the public.

Cont'l Gen. Ins. Co. v. Olafsson, 2024 WL 4263211 (D.N.J. Sept. 23, 2024), denying motion to dismiss. **Bankruptcy**

In 2020, Mallinckrodt filed for Chapter 11 bankruptcy. Under the bankruptcy plan, the company agreed to disburse into a trust installment payments it owed under a settlement agreement arising from previous opioid litigation. After emerging from the bankruptcy restructuring, Mallinckrodt made positive statements about its financial strength and ability to comply with the bankruptcy plan. But in June 2023, a *Wall Street Journal* article revealed that Mallinckrodt was exploring a second bankruptcy as an upcoming opioid payment became due. The stock fell 40%. Later that month, Mallinckrodt disclosed that it could be required to file for bankruptcy, and the stock dropped 30%. In August 2023, Mallinckrodt announced it had signed a restructuring support agreement and an agreement to file for bankruptcy. The stock fell 19%.

Investors sued, challenging statements about the company's financial health on its emergence from bankruptcy protection and its ability to make payments to the opioid settlement trust. (Plaintiffs terminated their claims against the company in light of its second bankruptcy filing, electing to proceed against the individual defendants only.) The court denied defendants' motion to dismiss in a brief opinion. The court credited plaintiffs' allegations that the challenged statements were false because the company lacked the financial resources to make required payments to the trust and had generally overstated its financial strength. Plaintiffs also sufficiently established a strong inference of scienter, based on allegations about the individual defendants' high-level positions, their close examination of the company's financial condition with an investment banker, their engagement in a top-to-bottom strategic review, and their SOX certifications. The court further credited plaintiffs' motive allegations. The executives generally wanted to avoid revocation of the bankruptcy plan, and were incentivized by stock options, which would be extinguished if the company filed for bankruptcy again too quickly.

Roofers Local No. 149 Pension Fund v. Amgen Inc., 2024 WL 4354809 (S.D.N.Y. Sept. 30, 2024), denying in part motion to dismiss. **Tax liability**

Amgen used an accounting technique known as transfer pricing—allowing it to lower its overall tax liability. In its July 2020 Form 10-Q, Amgen disclosed that it had received a Revenue Agent Report (RAR) from the IRS for its 2013–2015 tax years. An RAR shows the changes the IRS has made to a taxpayer's returns, as well as tax, penalties, and interest due. In the same Form 10-Q, Amgen repeated earlier disclosures it had made about Notices of Proposed Adjustments (NOPAs) it had received for both the 2013–2015 and the 2010–2012 tax periods and disclosed that it was disputing the merits of the IRS's position. In August 2021, Amgen reported that it had received a Notice of Deficiency through which the IRS sought $3.6 billion in back taxes for Amgen's 2010–2012 tax years. The stock dropped 6.5%. In April 2022, Amgen announced that it had received a Notice of Deficiency for the 2013–2015 tax years, resulting in additional tax liability of $5.1 billion, plus $2 billion in penalties. The stock dropped 8.6%.

Investors sued, claiming that Amgen had misled investors by (1) failing to disclose the $10.7 billion figure potentially at issue, and (2) suggesting that the IRS had not quantified the tax amounts at issue. The court denied the company's motion to dismiss as to the first theory, ruling that plaintiffs had adequately alleged that the company's statements were unclear and incomplete. The court noted that the company's statements could have misled investors about the size of the tax risk. The court rejected plaintiffs' second theory, however: Amgen's references to the status of the IRS dispute in legal contingencies discussions did not suggest that the IRS had not quantified the tax liability.

TABLE OF NEW FILINGS IN 2024

In 2024, 44 new securities fraud class actions were filed against life sciences companies, reflecting an increase from last year and a return to the levels we saw during the height of the COVID-19 pandemic.[11]

2020: 45 new complaints
2021: 49 new complaints
2022: 37 new complaints
2023: 34 new complaints
2024: 44 new complaints

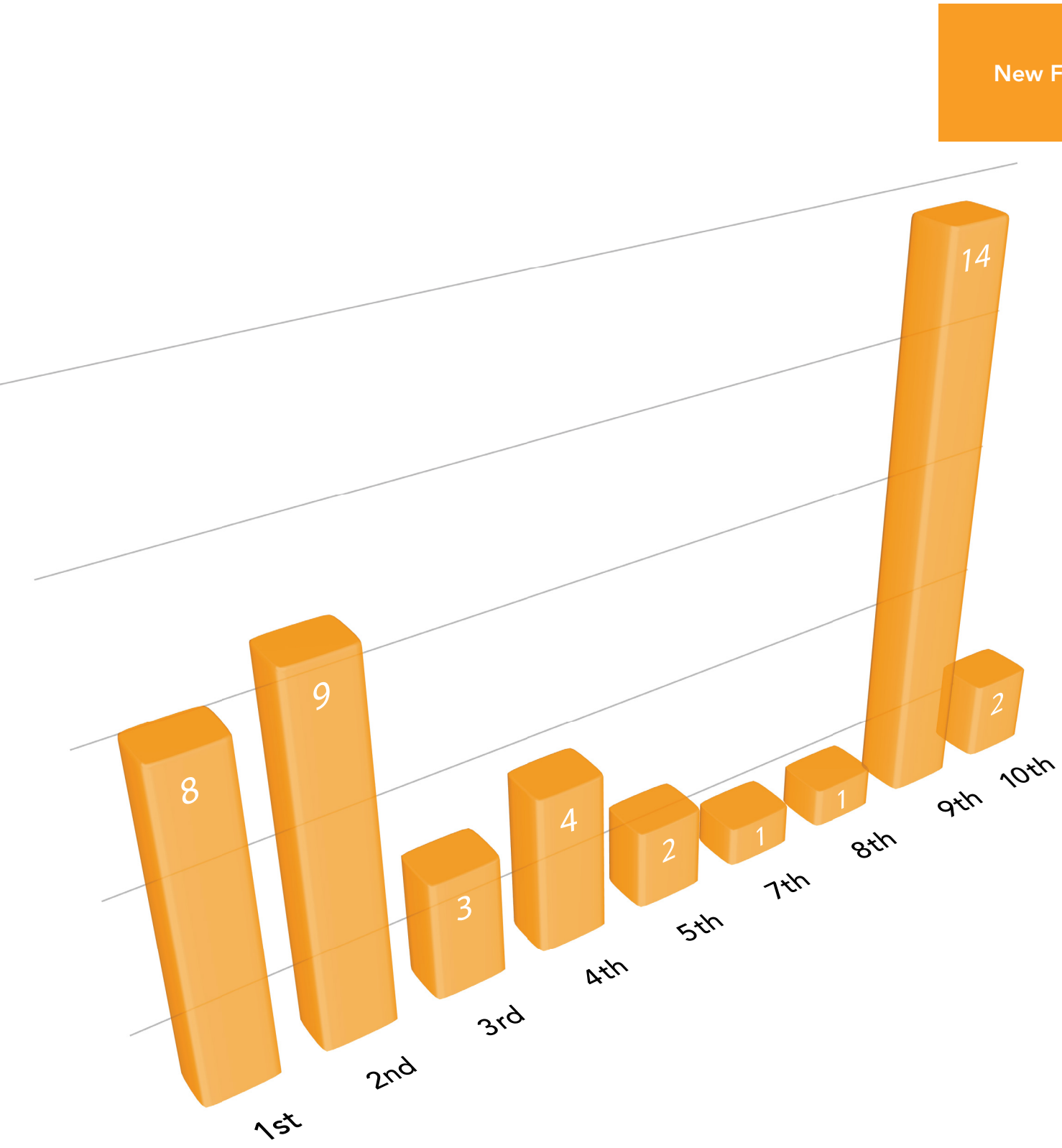
Of the new actions filed in 2024, 25 were filed against companies with development-stage drugs or devices—over half the total number of filings for the year, which is in line with what we have seen in prior years. The exception was last year, when less than half of the new filings were in the pre-approval space. The majority of this year's new cases arise from setbacks at the final stages of the approval process, after a company has submitted an NDA or BLA.

Nineteen actions were filed against companies with mature products. The majority of these new filings arise from setbacks not unique to life sciences companies, such as disappointing sales performance. In previous years, we had seen a greater concentration of cases arising from regulatory issues.

The Ninth Circuit saw the most filings overall, followed by the Second Circuit. A notable number of new filings were clustered in the First Circuit this year, as well as a relatively large number in the Fourth Circuit. We saw far fewer filings in the Third Circuit compared to 2023. We show these geographic and subject-matter breakdowns on the following three pages

11 We take this figure and list of actions from the Stanford Securities Class Action Clearinghouse. The list includes those cases categorized by Cornerstone Research as within the "healthcare sector" but excludes deal litigation and cases involving hospital management issues unrelated to any drug or medical device. The list also excludes cannabis-related litigation involving issues unrelated to FDA approval of a drug or product. Those cases are outside the scope of our analysis.

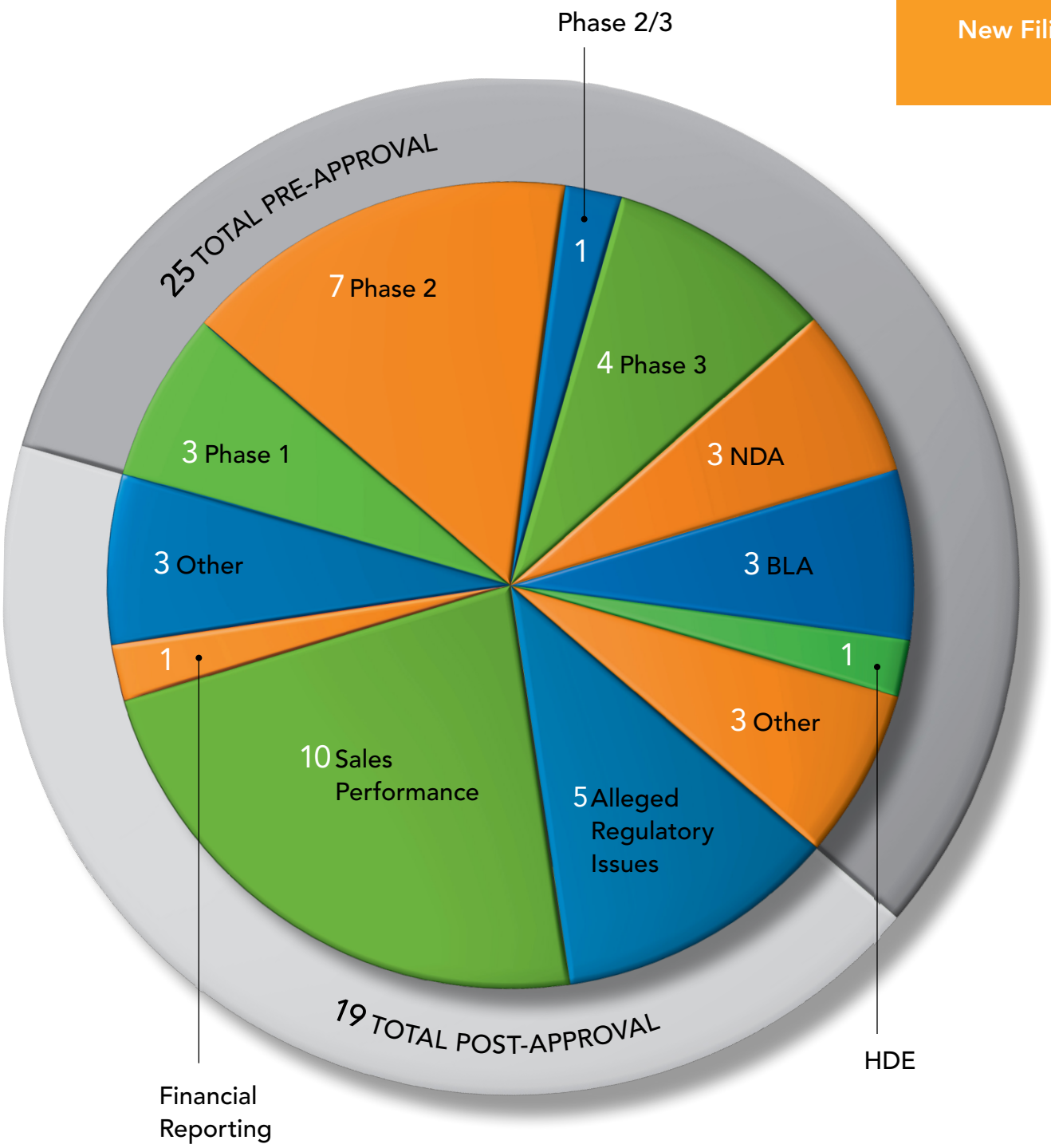
NEW FILINGS IN 2024 BY CIRCUIT



PRODUCT LIFECYCLE		SECURITIES FRAUD CLASS ACTIONS FILED IN 2024
PRE-APPROVAL	Phase 1	3
	Phase 2	7
	Phase 2/3	1
	Phase 3	4
	NDA	3
	BLA	3
	HDE	1
	Other	3
	TOTAL PRE-APPROVAL	25
POST-APPROVAL	Alleged Regulatory Issues	5
	Sales Performance	10
	Financial Reporting	1
	Other	3
	TOTAL POST-APPROVAL	19

NEW FILINGS IN 2024

New Filings



VERVE THERAPEUTICS, INC. 08/26/2024 D. MASS.

PRE-APPROVAL: PHASE 1 Verve develops VERVE-101, a gene editing treatment for patients with high cholesterol and cardiovascular disease. Stock prices fell after the company announced it had paused enrollment in its Phase 1b clinical trial. Plaintiffs challenge the company's statements about the potential benefits of the treatment and the risk a single adverse event posed to the trial.

KYVERNA THERAPEUTICS, INC. 12/09/2024 N.D. CAL.

PRE-APPROVAL: PHASE 1 Kyverna develops KYV-101, a cell therapy drug to treat lupus nephritis. Stock prices fell after the company disclosed adverse clinical trial data in an investor presentation. Plaintiffs challenge statements in the company's stock offering documents about the clinical trial data and the drug's commercial prospects.

CARIBOU BIOSCIENCES, INC. 12/24/2024 N.D. CAL.

PRE-APPROVAL: PHASE 1 Caribou's lead product candidate is CB-010, a therapy the company is evaluating in patients with certain types of non-Hodgkin lymphoma. Stock prices fell after an analyst questioned whether the company's therapy would be competitive based on data from the Phase 1 trial, and fell again after the company disclosed a workforce reduction. Plaintiffs challenge the company's statements about its cash position and the commercial prospects of CB-010.

VENTYX BIOSCIENCES, INC. 03/01/2024 S.D. CAL.

PRE-APPROVAL: PHASE 2 Ventyx develops oral medicines to treat inflammatory and autoimmune diseases. Stock prices fell after the company reported that its drug candidate, VTX958, did not meet the company's internal target for magnitude of efficacy in its Phase 2 trial, and that the company would terminate the ongoing trial immediately. Plaintiffs allege Ventyx overstated VTX958's efficacy and commercial prospects in its IPO filings and subsequent communications.

AKERO THERAPEUTICS, INC. 04/26/2024 N.D. CAL.

PRE-APPROVAL: PHASE 2 Akero develops efruxifermin to treat nonalcoholic steatohepatitis (NASH). Stock prices fell after the company revealed that its Phase 2 trial included patients with cryptogenic cirrhosis, a distinct medical condition from NASH-induced cirrhosis. Plaintiffs challenge the company's statements about the design and patient population of the Phase 2 trial.

ALTIMMUNE, INC. 05/06/2024 D. MD.

PRE-APPROVAL: PHASE 2 Altimmune develops pemvidutide to treat obesity and liver diseases. Stock prices fell after two news articles questioned whether pemvidutide could compete with other weight loss drugs, and whether the company could secure a strategic funding partner. Plaintiffs allege the company overstated the drug's efficacy and commercial prospects as well as the likelihood of securing a strategic partnership.

GRITSTONE BIO, INC. 06/07/2024 N.D. CAL.

PRE-APPROVAL: PHASE 2 Gritstone develops vaccine-based immunotherapies, and contracted with the Biomedical Advanced Research and Development Authority to fund a Phase 2 trial of the company's COVID-19 vaccine candidate. Stock prices fell after the company announced the delay of the proposed Phase 2 trial and resulting loss of external funding. Plaintiffs allege the company overstated its ability to launch the Phase 2 trial within the required time and consequently its ability to receive external funding and to commercialize the vaccine.

BOLT BIOTHERAPEUTICS, INC. 07/02/2024 N.D. CAL.

PRE-APPROVAL: PHASE 2 Bolt develops immunotherapies including the drug BDC-1001 to treat cancer. Stock prices fell after the company announced that it would cease development of BDC-1001 in response to disappointing Phase 2 trial results, that its CEO and CMO would move to advisory roles, and that it would reduce its workforce by 50%. Plaintiffs challenge the company's statements about the drug's efficacy.

MACROGENICS, INC. 07/26/2024 D. MD.

PRE-APPROVAL: PHASE 2 MacroGenics develops vobra duo to treat prostate cancer. Stock prices fell after the company reported disappointing interim safety results. Plaintiffs challenge the company's statements about safety data from the Phase 2 study, alleging that the company underreported adverse events and fatalities.

AGENUS INC. 09/06/2024 D. MASS.

PRE-APPROVAL: PHASE 2 Agenus develops a combination immuno-oncology therapy to treat metastatic colorectal cancer. Stock prices fell after the company announced that the FDA had advised against submitting the therapy's Phase 2 results in support of Accelerated Approval. Plaintiffs challenge the company's statements about the therapy's efficacy and clinical and commercial prospects.

ANAVEX LIFE SCIENCES CORPORATION 03/13/2024 S.D.N.Y.

PRE-APPROVAL: PHASE 2/3 Anavex develops ANAVEX 2-73 to treat Rett Syndrome, a rare neurological disorder. Stock prices fell after the company reported that the drug did not meet a primary endpoint in the Phase 2/3 trial. Plaintiffs challenge the company's statements about primary endpoint data and the drug's prospects for approval.

BIOVIE, INC. **01/19/2024** **D. NEV.**

PRE-APPROVAL: PHASE 3 BioVie develops NE3107, a drug candidate for the reduction of neuroinflammation in patients with Alzheimer's disease and Parkinson's disease. Stock prices fell after the company disclosed potential scientific misconduct and Good Clinical Practice violations at trial sites in its Phase 3 study and further disclosed that the trial did not achieve statistical significance due to the number of patients excluded because of suspected misconduct. Plaintiffs challenge the company's statements about the number of enrolled patients and status of patient enrollment in the study, risk disclosures about potential GCP violations, and statements that the "totality" of the data supported a favorable outcome.

ALLOVIR, INC. **01/19/2024** **D. MASS.**

PRE-APPROVAL: PHASE 3 AlloVir's lead product candidate is posoleucel, a therapy intended to target six viral diseases. Stock prices fell after the company announced that it was terminating three Phase 3 trials for futility after an interim review suggested the studies were unlikely to meet their primary endpoints. Plaintiffs challenge the company's statements about positive Phase 2 results as well as statements that the company was on track to complete the Phase 3 trials.

MARINUS PHARMACEUTICALS, INC. **06/05/2024** **E.D. PA.**

PRE-APPROVAL: PHASE 3 Marinus developed IV ganaxolone to treat seizure disorders. Stock prices fell after the company announced disappointing interim results for its Phase 3 trial, and fell again after the company announced it would not invest more money in IV ganaxolone development. Plaintiffs challenge the company's statements about its commitment to completing the Phase 3 trial and the financial resources it had to do so.

CASSAVA SCIENCES, INC. **12/12/2024** **W.D. TEX.**

PRE-APPROVAL: PHASE 3 Cassava develops simufilam as a treatment for Alzheimer's disease. Stock prices fell after the company announced the drug failed to meet primary and secondary endpoints in its Phase 3 clinical trial. Plaintiffs challenge the company's statements about simufilam's efficacy.

CHECKPOINT THERAPEUTICS **04/05/2024** **S.D.N.Y.**

PRE-APPROVAL: BLA Checkpoint develops cosibelimab to treat cutaneous squamous cell carcinoma. Stock prices fell after the company announced the FDA had rejected its BLA for cosibelimab. Plaintiffs challenge the company's statements about the drug's prospects for approval, alleging that the company failed to disclose known data integrity problems at its third-party manufacturer.

MODERNA, INC. 08/09/2024 D. MASS.

PRE-APPROVAL: BLA Moderna developed the vaccine mRNA-1345 to treat RSV. Stock prices fell after the company reported a lower-than-expected efficacy rate and fell again after the company disclosed an 18-month efficacy rate that was lower than that of competitors. Plaintiffs challenge the company's statements about mRNA-1345's efficacy and commercial prospects.

HUMACYTE, INC. 11/18/2024 M.D.N.C.

PRE-APPROVAL: BLA Humacyte manufactures Acellular Tissue Engineered Vessel, a lab-grown blood vessel implant that can act as a replacement for an injured or damaged blood vessel. Stock prices fell after the company announced that the FDA would require additional time to review its BLA following inspections of the company's manufacturing facilities and clinical sites, and again after the FDA released a Form 483 listing violations at one facility. Plaintiffs allege the company overstated the likelihood of approval by misleadingly omitting unfavorable information about its manufacturing processes.

ALLARITY THERAPEUTICS, INC. 09/13/2024 S.D.N.Y.

PRE-APPROVAL: NDA Allarity develops Dovitinib, an oncology drug to treat renal cell carcinoma, and Dovitinib-DRP, a companion diagnostic technology. Stock prices fell after the company announced it had received a Refusal to File letter in response to the Dovitinib NDA and Dovitinib-DRP PMA. Plaintiffs allege the company overstated the regulatory prospects of the Dovitinib NDA and failed to disclose alleged misconduct from former officers related to the Dovitinib NDA and Dovitinib-DRP PMA.

SAGE THERAPEUTICS, INC. 08/28/2024 S.D.N.Y.

PRE-APPROVAL: NDA; PHASE 2 Sage develops and commercializes brain health medicines, including those for to treat postpartum depression (PPD) and major depressive disorder (MDD). Stock prices fell after the company announced that the FDA had approved one drug for PPD but not MDD, and that it would stop development of two other drugs because neither had met Phase 2 primary endpoints. Plaintiffs challenge the company's statements about the drugs' clinical and commercial prospects.

APPLIED THERAPEUTICS, INC. 12/17/2024 S.D.N.Y.

PRE-APPROVAL: NDA Applied Therapeutics develops govorestat for the treatment of Galactosemia, a genetic metabolic disease that affects the body's ability to process the sugar galactose. Stock prices fell after the company announced receipt of a CRL for the NDA for govorestat, and fell again after the company disclosed receipt of a warning letter related to related to one of its clinical studies. Plaintiffs challenge the company's statements about its Phase 3 trial and NDA.

SEASTAR MEDICAL HOLDING CORPORATION — 07/05/2024 — D. COLO.

PRE-APPROVAL: HDE SeaStar develops a device for the treatment of hyperinflammation. Stock prices fell after the company announced it had received a letter from the FDA rejecting its Humanitarian Device Exemption application, and fell again after the company announced it would restate financial statements from fiscal years 2022 and 2023. Plaintiffs challenge the company's statements about the device's regulatory and commercial prospects as well as its financial reporting.

OCUGEN, INC. — 04/11/2024 — E.D. PA.

PRE-APPROVAL: OTHER Ocugen develops gene therapies to address retinal diseases. Stock prices fell after the company disclosed the departure of the CFO and disclosed that its Q1 2020 through Q3 2023 financial statements were materially misstated. Plaintiffs allege that the company's statements about its disclosure controls and accounting for a co-development and commercialization agreement were false and misleading.

EXSCIENTIA P.L.C. — 04/26/2024 — D.N.J.

PRE-APPROVAL: OTHER Exscientia is an AI-driven drug design and development company. Stock prices fell after the company announced the departure of its CEO, who the company found had engaged in inappropriate relationships with two employees. Plaintiffs challenge the company's statements about its adherence to its code of conduct and about its corporate culture.

METAGENOMI INC. — 09/26/2024 — N.D. CAL.

PRE-APPROVAL: OTHER Metagenomi is a genetics medicines company that had a longstanding collaboration agreement with Moderna to develop next-generation therapies for genetic diseases. Stock prices fell after the company announced the termination of its collaboration with Moderna. Plaintiffs challenge statements in Metagenomi's IPO documents about the stability and future of the collaboration agreement.

iRHYTHM — 02/06/2024 — N.D. CAL.

POST-APPROVAL: ALLEGED REGULATORY ISSUES iRhythm sells a wearable heart monitoring device, the Zio AT. Stock prices fell after the FDA issued a Warning Letter that the device was mislabeled and not designed to transmit real-time telemetry data to patient providers. Plaintiffs challenge the company's statements about "timely transmission" of arrythmia data, use of the device for a high-risk patient population, and the status of the device as a mobile cardiac telemetry.

bluebird bio — 03/28/2024 — D. MASS.

POST-APPROVAL: ALLEGED REGULATORY ISSUES bluebird develops lovo-cel, a gene therapy for treating sickle cell disease. Stock prices fell after the FDA approved lovo-cel with a black box warning for cancer risk and denied the company's request for a priority review voucher. Plaintiffs allege the company overstated lovo-cel's clinical and commercial prospects, including the likelihood of FDA approval without box warnings and the likelihood the FDA would grant the voucher.

ARDELYX, INC. — 08/16/2024 — D. MASS.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Ardelyx developed XPHOZAH to treat patients with chronic kidney disease on dialysis. Stock prices fell after the company announced it would not apply to include the drug in a Medicare payment program. Plaintiffs challenge the company's statements that it would apply for the payment program, alleging that the company misrepresented the drug's commercial prospects.

OUTSET MEDICAL, INC. — 08/29/2024 — N.D. CAL.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Outset develops the Tablo series of medical devices for dialysis care. Stock prices fell after the company announced it had received a warning letter from the FDA stating the company was selling an uncleared device accessory and marketing Tablo products for an unapproved use; stock prices fell again after the company announced financial results and updated revenue guidance following its receipt of the warning letter. Plaintiffs challenge the company's statements about its products' FDA-approved uses and commercial prospects.

DENTSPLY SIRONA INC. — 11/26/2024 — S.D.N.Y.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Dentsply manufactures Byte, a clear dental aligner. Stock prices fell after the company announced the voluntary suspension of Byte sales and marketing while it conducted a review of its onboarding workflow and regulatory requirements, and fell again after the company announced third quarter 2024 financial results. Plaintiffs challenged the company's statements about growth and demand, alleging that many patients signing up for Byte were ineligible for treatment.

INMODE LTD. — 02/14/2024 — C.D. CAL.

POST-APPROVAL: SALES PERFORMANCE; ALLEGED REGULATORY ISSUES InMode produces medical equipment for rejuvenation technologies like body sculpting. Stock prices fell after an investigative publication stated that the company purportedly threatened customers with legal action after they filed complaints about its devices and sales practices, and fell again after a report claimed that InMode significantly discounted its products and the company announced revised 2023 revenue guidance. Plaintiffs challenge the company's statements about regulatory compliance and about the pricing of and demand for its products.

QUIDELORTHO CORPORATION 04/12/2024 S.D.N.Y.

POST-APPROVAL: SALES PERFORMANCE QuidelOrtho develops tests for the detection and diagnosis of respiratory diseases. Stock prices fell after the company announced disappointing financial results for Q4 2023, and again after the company announced it had withdrawn its 510(k) submission for its next product, the Savanna RP4 Test, when data fell short of expectations. Plaintiffs challenge statements about the company's revenue and the commercial launch of the Savanna RP4 Test, alleging that the company misleadingly omitted problems with excess inventory and issues delaying the test's approval.

BIOGEN, INC. 05/22/2024 D. MASS.

POST-APPROVAL: SALES PERFORMANCE; ALLEGED REGULATORY ISSUES Biogen develops biologics for the treatment of conditions including multiple sclerosis and Alzheimer's disease. Stock prices fell on multiple occasions: after the FTC announced an inquiry into PBM business practices (which included a reference to one of Biogen's products); after the company discussed challenges with the launch of Leqembi, an Alzheimer's disease product; after further developments in the government's PBM inquiry; after the EMA refused marketing authorization for Leqembi; after Australian regulators denied marketing authorization for Leqembi; and after the EMA approved Leqembi with a restricted label. Plaintiffs challenge the company's statements about the competitive environment for its MS products, the function of managed care rebates, the reasons for the company's operating results, and Leqembi's safety profile and commercial prospects.

ASSERTIO HOLDINGS, INC. 1/05/2024 N.D. ILL.

POST-APPROVAL: SALES PERFORMANCE Assertio sells Indocin, a drug used to treat rheumatoid arthritis and inflammation. Stock prices fell after the company announced that a generic manufacturer had received approval to market a product that would compete with Indocin. Plaintiffs challenge the company's statements about the risk of generic competition and about an acquisition intended to offset the decline in revenue from increased competition.

BIONTECH SE 01/12/2024 S.D.N.Y.

POST-APPROVAL: SALES PERFORMANCE BioNTech, in collaboration with Pfizer, developed the Comirnaty COVID-19 vaccine. Stock prices fell after the company announced its Q2 2022 financial results, which missed estimates; after it announced guidance for 2023 vaccine revenue; and after it announced inventory write-offs and other charges. Plaintiffs challenged the company's statements about orders of vaccine doses and backlog.

AMYLYX 02/09/2024 D. MASS.

POST-APPROVAL: SALES PERFORMANCE Amylyx sold Relyvrio for the treatment of ALS. Stock prices fell after the company announced its Q3 2023 financial results, which missed consensus estimates. Plaintiffs allege that the company made false or misleading statements about the launch, demand for the treatment, and the potential for further growth.

INDIVIOR PLC — 08/02/2024 — E.D. VA.

POST-APPROVAL: SALES PERFORMANCE Indivior developed Perseris to treat schizophrenia and other drugs designed to treat opioid use disorder. Stock prices fell after the company announced that it would cease all sales and marketing of Perseris and reduced its 2024 revenue guidance. Plaintiffs allege the company overstated its forecasting capabilities and the commercial prospects of its products.

DEXCOM, INC. — 08/21/2024 — S.D. CAL.

POST-APPROVAL: SALES PERFORMANCE DexCom manufactures continuous glucose monitoring systems for diabetes management. Stock prices fell after the company reported Q2 2024 financial results and a reduced revenue guidance for 2025. Plaintiffs challenge the company's financial reporting as well as its statements about growth prospects, alleging that the company failed to disclose problems with its salesforce and the challenges of moving customers to its newest platform.

EDWARDS LIFESCIENCES CORPORATION — 10/14/2024 — C.D. CAL.

POST-APPROVAL: SALES PERFORMANCE Edwards develops the Transcatheter Aortic Valve Replacement platform to treat aortic stenosis. Stock prices fell after the company announced financial results for Q2 2024 and reduced revenue guidance for the fiscal 2024. Plaintiffs challenge the company's statements about demand and growth, claiming that the company overestimated patient engagement and hospital adoption rates.

INARI MEDICAL, INC. — 05/13/2024 — S.D.N.Y.

POST-APPROVAL: SALES PERFORMANCE; FINANCIAL REPORTING Inari manufactures catheter-based devices used to treat venous thromboembolism. Stock prices fell after the company disclosed it had received a civil investigative demand from the Department of Justice regarding potentially illegal payments to healthcare providers. Plaintiffs challenge the company's statements about its financial performance, alleging that the company failed to disclose that its performance depended on illegal conduct.

PARAGON 28, INC. — 09/30/2024 — D. COLO.

POST-APPROVAL: FINANCIAL REPORTING Paragon 28 develops and sells orthopedic implants for foot and ankle use. Stock prices fell after the company announced a restatement related to inventory accounting. Plaintiffs challenge the company's financial reporting and statements about disclosure controls and procedures.

LIFECORE BIOMEDICAL, INC. 07/29/2024 D. MINN.

POST-APPROVAL: OTHER Lifecore is a contract development and manufacturing company. Stock prices fell after the company reported that its disclosure controls and procedures were not effective for the quarter ended August 28, 2022, and fell again after the company disclosed that it was not in compliance with NASDAQ listing requirements. Plaintiffs challenge the company's statements about its internal controls over financial reporting.

ORTHOFIX MEDICAL INC. 08/21/2024 E.D. TEX.

POST-APPROVAL: OTHER Orthofix sells biologics, spinal hardware, bone growth therapies and specialized orthopedic solutions; the company merged with SeaSpine, which offers surgical solutions for spinal disorders. Stock prices fell after the company announced the departure of the CEO, CFO, and CLO of the combined company and the appointment of interim leadership. Plaintiffs challenged the company's statements about its senior leadership and its compliance and ethics program.

ASTRAZENECA PLC 12/23/2024 C.D. CAL.

POST-APPROVAL: OTHER AstraZeneca is a biopharmaceutical company. Stock prices fell after the company announced an investigation into senior executives of its Chinese subsidiary. Plaintiffs challenge the company's statements about legal and regulatory compliance.

New Filings

ABOUT THE PRACTICE

Securities and Shareholder Litigation

Publicly traded companies can face securities and other shareholder suits following disappointing announcements or stock declines. Life sciences companies have industry-specific events and disclosure issues, including those relating to drug development, regulatory approval, and continued regulatory oversight of manufacturing, marketing and sales activities that can trigger litigation or investigations. Our lawyers understand the securities laws and the intersection of industry-specific issues relevant to life sciences companies.

Sidley is a leader in defending securities class action litigation and has successfully represented many life sciences clients in securities and shareholder cases. Sidley's securities litigation practice team includes true first chair trial lawyers and experienced appellate lawyers in many offices, and some of our partners have the unusual experience of having tried securities class actions. We are able to work collaboratively, through a coordinated team of professionals in a variety of practices, in order to provide clients with comprehensive representation.

Life Sciences

On four continents, Sidley's Global Life Sciences team offers coordinated cross-border and national advice on Food, Drug and Medical Device Regulatory, Life Sciences Enforcement, Litigation and Compliance, Healthcare Regulatory, Products Liability, Intellectual Property, Corporate and Technology Transactions, Securities and Corporate Finance, International Trade and Arbitration, FCPA/Anti-Corruption, Antitrust/Competition and Environmental/Nanotechnology. Globally rated as one of the top life sciences practices, our team includes former senior government officials, medical doctors and leaders in various life sciences fields.

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