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SECURITIES CLASS ACTIONS IN THE LIFE SCIENCES SECTOR

2021 ANNUAL SURVEY

TALENT. TEAMWORK. **RESULTS.**

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Introduction and Overview

Securities Class Actions in the Life Sciences Sector

2021 Annual Survey

INTRODUCTION AND OVERVIEW

This year-in-review survey addresses developments in securities class actions brought against life sciences companies in 2021. We begin with an overview and analysis of trends in decisions involving life sciences companies. We also briefly discuss the continuing impact of the COVID-19 pandemic on clinical trials and FDA approval and inspection activities. We then provide summaries of the 37 federal district court and appellate court decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2021.

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 THE APPROVAL PROCESS

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.

POST-APPROVAL: REGULATORY AND BUSINESS ISSUES

LAUNCH STAGE

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

Marketing — regulatory monitoring of marketing efforts, and the 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 Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007).

DECISIONS ISSUED IN 2021: TRENDS AND ANALYSIS

In this section, we discuss trends in the reported federal decisions issued in securities actions at the pleading stage (or in two 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 2021. Companies' success rate in 2021 was 58%, consistent with results over the previous three years.

2018: Companies won dismissal in 31 of the 48 decisions issued by the district courts, or 65%.

2019: Companies won dismissal in 23 of the 37 decisions issued by the district courts, or 62%.

2020: Companies won dismissal in 20 of the 35 decisions issued by the district courts, or 57%.

2021: Companies won dismissal in 19 of the 33 decisions issued by the district courts, or 58%.[3]

In past years, we have reported that companies with pre-approval drugs or devices did markedly better in the district courts than those with post-approval products. In 2021, by contrast, companies did as well in one category as in the other. They prevailed in 59% of the pre-approval cases (ten out of 17) and 56% of the post-approval cases (nine out of 16).

Companies fared well in the appellate courts in 2021, with affirmance of dismissal in three out of four cases and partial affirmance in the fourth. In contrast with 2020, in which we saw multiple significant published decisions from the Second and Ninth Circuits, only one published appellate decision was issued in 2021—the First Circuit's affirmance of dismissal in *Keryx*, a case involving supply chain problems. The *Keryx* plaintiffs, like many of the plaintiffs in the 2021 decisions, challenged the company's risk disclosures, arguing that events the company represented as contingencies were in reality certainties or had already come to pass. The First Circuit held that the district court had correctly rejected that claim because plaintiffs failed to allege the facts necessary to support it.

The remaining three appellate decisions—from the Second, Fifth and Ninth Circuits—are unpublished and contain relatively little substantive analysis, although the Second Circuit's *Alkermes* decision usefully consolidates scienter principles against the background of equivocal FDA statements about approval. The Fifth and Ninth Circuit decisions are quite terse.

As we discuss more fully below, the volume of new filings rose modestly in 2021.

2018–48 new complaints 2019–44 new complaints

2020–45 new complaints 2021–49 new complaints

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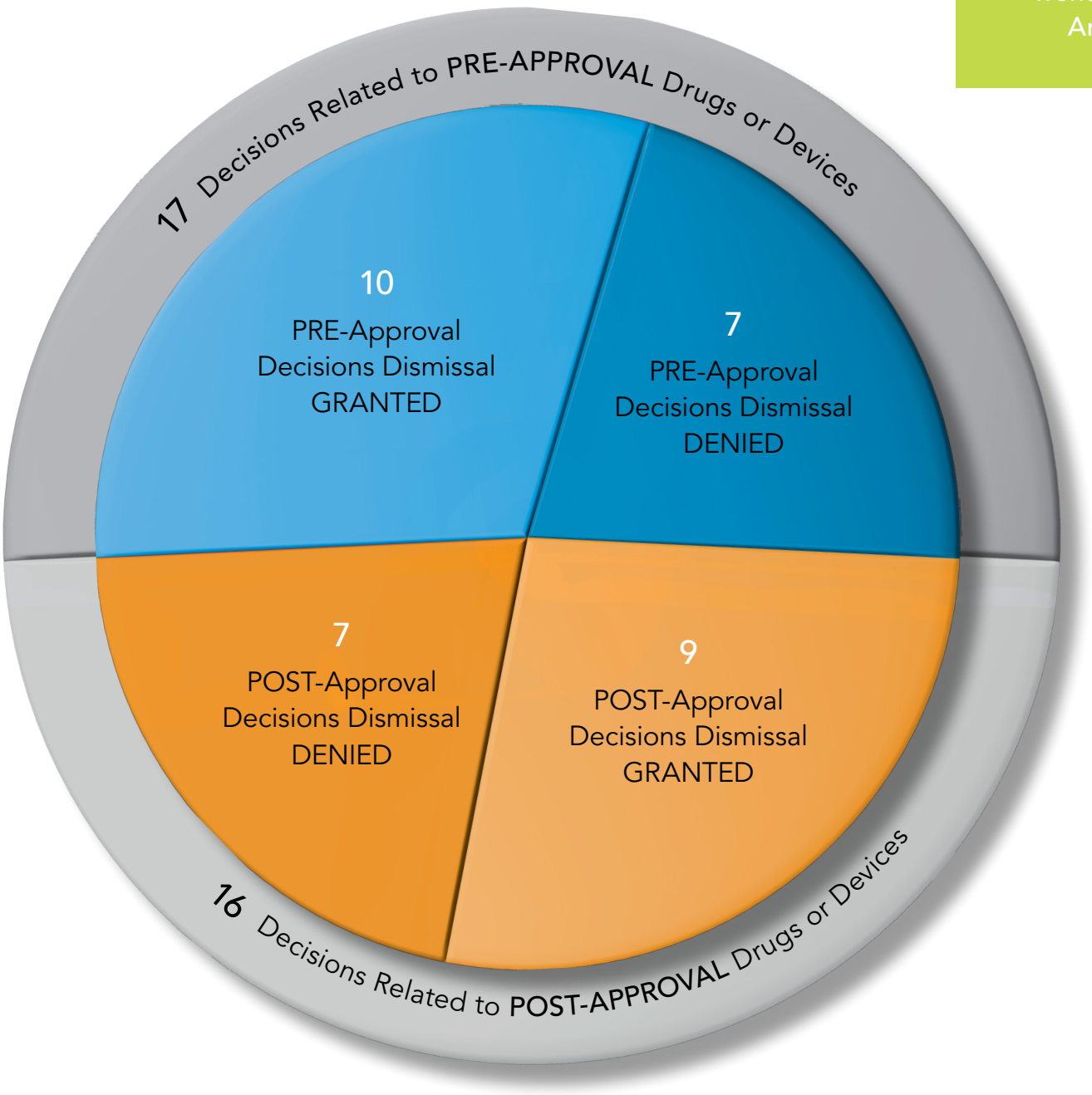
2 Under Section 10(b) (15 U.S.C. § 78j(b)), life sciences companies and their officers may be liable for consciously false or misleading statements they make in virtually any public context, including press releases, earnings calls, investor conferences and SEC filings. Defendants may also be liable for participating in a "scheme" to defraud, although successful scheme claims asserted by private plaintiffs are relatively 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

PRE-APPROVAL DECISIONS

As in past years, companies had the edge in the cases involving development-stage products. District courts granted motions to dismiss in ten cases and denied dismissal in whole or in part in seven. We discuss substantive developments in three areas.

First, we discuss the progress through the district courts of the first cases filed against companies developing COVID-19-related products. Courts ruled on motions to dismiss in four such cases in 2021, granting dismissal in two and denying dismissal in two. Companies won dismissal in cases involving development of a rapid antigen test and a monoclonal antibody treatment. In both cases, the courts placed the companies' highly optimistic statements in the context of the early months of the pandemic, when reasonable investors knew that many steps remained before the FDA could grant approval. Courts denied motions to dismiss in two cases involving the development of vaccines. The courts concluded there that plaintiffs had adequately alleged that the company's statements about manufacturing partnerships were misleading in light of undisclosed obstacles facing the manufacturers. The courts also examined, with split results, the companies' statements about selection for participation in Operation Warp Speed.

Next, we discuss developments in the analysis of scienter, focusing on the application of the Ninth Circuit's 2020 *Endologix* decision.[4] The analysis in that decision arose from circumstances unique to the pre-approval context and is perfectly tailored for broad application in pre-approval cases. The critical insight in *Endologix* and the 2021 decisions following it is that most alleged frauds in the pre-approval context are inherently unsustainable—which renders plaintiffs' theories of scienter in many of these cases implausible if not nonsensical.

We also discuss scienter developments apart from *Endologix*. Multiple 2021 decisions show that the comparative approach to scienter mandated by *Tellabs* generally benefits companies with development-stage products. When a company devotes massive resources to the development of a product, the most cogent inference will generally be that the company believed in its prospects—not that the company intended to deceive investors by discussing those prospects in optimistic terms.

Finally, we discuss three cases in which companies released clinical trial results in stages, reporting top-line, interim or selected results several months before publishing complete trial data. In two of the three cases, courts granted motions to dismiss, rejecting plaintiffs' contention that release of some results triggers a duty to report complete results. The third decision, in which the court denied the company's motion to dismiss in part, is significantly more equivocal on the subject.

Mixed Results in COVID-19 Cases

In our 2020 annual review, we noted that 15% of last year's new filings targeted companies developing COVID-19-related products. District courts have now issued decisions in four of those cases—three cases in California and one in the Eastern District of Pennsylvania. The results have been mixed. Companies won motions to dismiss in cases involving a COVID-19 rapid test (*Sona*, page 24) and a monoclonal antibody treatment (*Sorrento*, page 24). Courts denied motions to dismiss in two cases involving vaccines (*Inovio* and *Vaxart*, page 27).

Some common background features of cases are notable. The cases arise from statements companies made in the early months of the pandemic, and several involve very large stock swings—some in excess of 200%. During this early period, both life sciences companies and investors were in uncharted waters as they worked to understand the novel scientific, regulatory, financing and commercialization issues surrounding product development in this area. Several of the cases also have very short putative class periods. Purportedly "corrective" information often followed the allegedly false or misleading statements within a matter of weeks or even days during this chaotic time.

Legally, the decisions break no new ground. One through-line is the courts' close attention to context in an area in which they, along with the rest of the world, had recently gained first-hand experience.

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4 *Nguyen v. Endologix, Inc.*, 962 F.3d 405 (9th Cir. 2020).

In the two cases in which courts granted motions to dismiss, the companies had made sweepingly optimistic statements. Sona, which was developing a rapid antigen nasal swab test, told investors that it was "100% confident" in FDA approval. Sorrento, which worked to develop a monoclonal antibody treatment, announced early in the development process that "there is a cure" and "a solution that works 100%." Perhaps surprisingly, the courts in both cases held that the generality of the challenged statements foreclosed the plaintiffs' claims of falsity. The *Sorrento* court disposed of the company's reference to "a solution that works 100%" by explaining that "[i]t is well-established that generalized, vague and unspecific assertions of corporate optimism or statements of mere puffery cannot state actionable material misstatements of fact under federal securities law." The *Sona* court similarly characterized the company's "100% confident" statement as "just a hopeful optimistic statement … that did not come true," and cited law holding that "vague optimistic statements are not actionable."

The courts' somewhat surprising conclusion that the challenged statements amounted to non-actionable puffery may be explained in part by the close attention they paid to context. In evaluating another challenged statement in *Sona*—the company's July 2020 statement that it had brought its test "to fruition"—the court noted that the company was still in the midst of field trials when it said this, and that no investor could have been misled into believing that the product was ready for approval or commercialization. Likewise, Sorrento's statement, in May 2020, that "there is a cure" had to be understood in the context of preclinical testing. Investors knew that the company had not yet even begun Phase 1 trials, and could evaluate the reference to a cure accordingly.

The allegations in both *Sona* and *Sorrento* also fell short on scienter grounds. In *Sona*, the court applied the logic of the Ninth Circuit's 2020 *Endologix* decision (discussed more fully at page 24, below). The critical insight the Ninth Circuit offered there is that many claims of fraud in connection with FDA approval are facially implausible because the fraud is bound to fail. A company that misrepresents facts bearing on the prospects of approval can only delay the inevitable; the game will be up as soon as the FDA denies approval. *Sona* applies this reasoning to the COVID-19 context. In *Sorrento* too, the plaintiffs failed to advance a plausible theory of fraud. They alleged no facts suggesting that the company either intended to manipulate trial results or sought to deceive investors.

On the other side of the ledger, as to both falsity and scienter, are the two COVID-19 vaccine cases, *Inovio* and *Vaxart*. In *Vaxart*, context was again critical. The company made the challenged statements in that case in June 2020, a time at which media and investors were primed for news about which life sciences companies would be chosen for publicly-funded vaccine development under Operation Warp Speed. Vaxart's statement that it had been "selected" to participate in Operation Warp Speed was factually accurate: The company had been chosen for a program within Operation Warp Speed focused on primate studies, with no public funding. But the court concluded that plaintiffs had adequately pled that the statement was deliberately misleading when considered in context. Plaintiffs had "cogently allege[d] that Vaxart issued a series of statements with the intent to mislead the investing public into believing that the company was—like Pfizer and Moderna—on the precipice of mass-producing a successful coronavirus vaccine."

The same fact pattern was at issue in *Inovio*. There too, the company had been selected for the primate program, and plaintiffs alleged that the company's statement that it had been chosen to participate in Operation Warp Speed misleadingly suggested that it would receive public funding. But while the *Inovio* court denied the company's motion to dismiss as to certain categories of statements, it granted the motion as to the Operation Warp Speed statement. The court noted that the company had never claimed that it would receive public funding, and that any misleading impression its statements created was rendered immaterial by its disclosure that it had been selected for the primate study.

Beyond the statements about Operation Warp Speed, the courts in both *Vaxart* and *Inovio* denied the companies' motions to dismiss as to statements about their progress toward commercialization. Both companies spoke optimistically about their ability to produce large volumes of vaccines through manufacturing partnerships. But Vaxart failed to disclose that its manufacturing partner lacked approved capacity, while Inovio failed to disclose

serious obstacles with a technology transfer from one manufacturer to another. In both cases, plaintiffs had adequately alleged that the omissions rendered the optimistic statements about manufacturing misleading.

Inovio also stated in March 2020 that it had "fully constructed" a COVID-19 vaccine within three hours of accessing the genetic makeup of the virus. The court denied the company's motion to dismiss as to this statement as well, crediting the plaintiffs' theory that "construction"—as opposed to "design"—denotes an advanced stage of vaccine development the company had not yet reached.

Considered collectively, the COVID decisions break no new legal ground. They appear instead to illustrate a heightened sensitivity to context—for good or ill—in an area with which judges had become familiar through collective personal experience. One effect of the pandemic has been that narratives of drug development and FDA approval that courts otherwise encounter principally through allegations and briefing have become part of widely shared experience.

One of the four 2021 decisions, *Vaxart*, is additionally notable for its unusually candid analysis, as well as for a provocative observation about the relationship between falsity and scienter. The *Vaxart* decision begins with the statement "This is an unusual securities fraud case." The court goes on to explain that while the plaintiffs "easily satisfie[d] the 'scienter' requirement that plaintiffs often struggle with," the adequacy of plaintiffs' falsity allegations provided a much closer question. In the court's view, this reverses the normal situation, in which scienter is the higher hurdle. Whether that reversal is related to the COVID context is unclear. The court's summary of the relative strengths of the plaintiffs' falsity and scienter allegations appears to reflect its conclusion that the challenged statements—particularly those about Operation Warp Speed—were factually accurate but misleading in context. Once the court had resolved the nuanced question of whether the plaintiffs had adequately alleged that the company's true statements were misleading, it appears to have been a short step to conclude that they were deliberately so.

Endologix and The Holistic Analysis of Scienter

The power of Endologix in the pre-approval setting. In 2020, the Ninth Circuit affirmed dismissal solely on scienter grounds in *Endologix*, a case in which the FDA took adverse action, near the end of the approval process, on a company's pre-marketing application for a medical device treating aneurysms. In notably frank terms, the court stated that the plaintiffs' scienter theory "does not make a whole lot of sense." We predicted in last year's survey that the *Endologix* court's scienter analysis will be influential for years to come, particularly in pre-approval cases. Two decisions issued in 2021 have begun to bear this out.

The Ninth Circuit's critical insight in *Endologix*, as discussed in connection with *Sona*, above, was that many claims of fraud in connection with FDA approval are nonsensical—or at the very least implausible—because the alleged fraud cannot be sustained. A company that misrepresents facts bearing on the prospects of approval can only delay the day of reckoning. When the FDA denies approval, the fraud will be exposed. The Southern District of California, as discussed, relied on that insight in the COVID-19 context in *Sona*. The Northern District of California drew on it extensively in *Zosano* (page 21), a case in which, as in *Endologix* itself, the FDA denied approval in the final stages of the process.

In *Zosano*, the FDA issued a Discipline Review Letter while the company's NDA was pending, stating that approval was unlikely. The FDA later issued a Complete Response Letter denying approval based on the same issues it had identified in the Discipline Review Letter. Following *Endologix*, the *Zosano* court proceeded directly to the scienter inquiry, without ruling on falsity, and held that plaintiffs had failed to allege scienter because the fraud they accused the defendants of perpetrating did not make sense. By purportedly hiding the issues that caused the FDA to deny approval, the company at most delayed the inevitable.

Zosano also repeated an important caveat made in *Endologix*. Section 10(b) plaintiffs may be able to advance a plausible theory of scienter even in cases where misstatements about the prospects for approval only delay the inevitable *if* they can show that the company or its executives obtained a short-term financial benefit by selling stock at temporarily inflated prices. But the *Zosano*

plaintiffs failed to allege any such benefit with the required particularity. They pled only in general terms that the company was motivated to inflate its stock price to mitigate unease about its ability to continue as a going concern, and that it "engaged in regular securities offerings." The court held that routine corporate motives of this sort could not overcome plaintiffs' basic illogic in positing a scheme of fraud that would inevitably collapse.

Although the company in *Zosano* (like the company in *Endologix*) reached the final stages of the approval process—having submitted an NDA—the logic of *Endologix* should be a powerful tool for companies accused of fraud at virtually any stage of drug or device development up to approval. Just as a company can only delay the inevitable when it expresses confidence in approval that is not forthcoming, so too it can merely postpone the day of reckoning if it makes false or misleading claims about clinical or preclinical trials. Here too, the jig will be up when the FDA concludes that trial results are insufficient to support approval or to progress to the next phase of testing. Likewise, a company that reports only the favorable aspects of a trial with mixed results can keep the alleged fraud going only until it is obliged to publish full trial results. Under the logic of *Endologix*, fraud related to drug or device development at *any* stage before approval is ultimately unsustainable. Section 10(b) plaintiffs need to contend with this serious obstacle in pleading scienter in any pre-approval case (assuming, of course, that they are unable to identify short-term financial gains for defendants).

This differs from alleged fraud in other areas, including areas in which companies operate after their products have been approved. Financial statement fraud, for example, will not inevitably come to light. A company may issue inaccurate financial statements for one or even many quarters and never face exposure. The same is true of regulatory violations in the post-approval space. A company may stoke revenue by means of improper off-label marketing, may make public statements inconsistent with that conduct, and may never get caught. Companies accused of fraud in these areas will not be able to argue that a plaintiff's scienter theory is inherently implausible because the fraud will necessarily come to light. But under *Endologix* and its progeny, this should be an increasingly powerful argument in pre-approval cases.

Holistic analyses in the pre-approval setting. Other scienter rulings in pre-approval cases have also largely been positive in 2021. Outside the Ninth Circuit, where courts are not bound by *Endologix*, decisions in multiple cases bear out the continuing significance of the Supreme Court's comparative approach to scienter in *Tellabs*. Under that approach, courts must ultimately step back from individual scienter allegations and determine whether the alleged facts considered collectively support an inference of deliberate fraud as opposed to a more benign conclusion about intent. Considering facts holistically and comparatively is generally favorable for companies that have devoted enormous financial and personal resources to development of a drug or device candidate. Companies are unlikely to have done so without a good-faith belief in the product's prospects for approval.

This comparative and holistic review can be particularly favorable when courts consider the backdrop of regulatory give-and-take inherent in the approval process. In *Alkermes* (page 21), a case in which the FDA declined to approve the company's NDA, the district court dismissed on scienter grounds without considering falsity, explaining that "implicit in the ongoing dialogue between the FDA and Alkermes was a collective expectation that the process was an iterative one and that Alkermes would continue to respond to feedback in its continued effort to seek approval." The Second Circuit, affirming dismissal in an unpublished decision (page 18), similarly concluded that based on the record of communications between the company and the FDA, the stronger inference was "that the Defendants were optimistic about the FDA's review and were encouraged that the FDA was seriously considering [the] novel design" of the trial. The Second Circuit extended this "primary nonfraudulent inference" not only to the defendants' beliefs about approval but also to the defendants' state of mind in making the challenged statements. The strongest inferences arising from the facts alleged in the complaint, the court held, were "nonfraudulent—that the Defendants viewed [the drug's] chances of FDA approval with optimism, yet still made honest attempts to disclose the FDA's feedback where relevant and to caution the market as to the risks inherent in proposing new study designs."

A holistic review against the backdrop of complicated regulatory interactions led to a similar result in *Alnylam* (page 23), in which the FDA approved the company's drug for some but not all manifestations of a disease. The court rejected plaintiffs' claim that the company had deceived investors about the prospects of a broader label, noting that the FDA had not expressed disapproval of the broader indication before the company submitted its NDA. "[T]he more compelling inference," the court concluded, was "that the FDA merely disagreed with defendants' proposed scope for [the drug] and approved a more narrow label and indication than defendants anticipated and fairly believed was warranted."

A final favorable decision, *Amarin* (page 20), usefully confirms that the ultimate object of *Tellabs*' holistic analysis is not a defendant's *knowledge of particular facts* but instead the defendant's *beliefs about the challenged statement*. The *Amarin* plaintiffs alleged that the company had misleadingly reported favorable trial results without disclosing an issue that allegedly called those results into question—specifically, unusually poor performance on the placebo arm of a controlled trial. Addressing scienter, the defendants argued that the stronger inference was that they believed the placebo issue "did not alter the exceedingly positive results" they reported. Plaintiffs responded that defendants' focus on their beliefs was misguided, and that under the Supreme Court's *Omnicare* decision, plaintiffs are required simply to allege that defendants were aware of facts contradicting the challenged statements.[5] The *Amarin* court rejected that argument and endorsed the defendants' view that the appropriate focus under *Tellabs* was on their beliefs. *Omnicare* did not address scienter: Only Securities Act claims were at issue in *Omnicare*, and scienter was not an element of those claims. The Supreme Court's *Omnicare* analysis concerned the circumstances under which a challenged opinion statement may be actionably misleading under an omission theory. That is distinct from scienter, which relates to a defendant's intent (or lack of intent) to defraud investors by means of challenged statements.

Of course not every 2021 decision was a victory for defendants on scienter grounds. In both *Odonate* (page 26) and *Recro* (page 26), plaintiffs were able to support a strong inference of scienter based primarily on detailed confidential witness allegations. Plaintiffs also succeeded in pleading scienter in the two COVID-19 vaccine cases—*Inovio*, in which plaintiffs pointed to company and executive stock sales, and *Vaxart*, in which the court concluded that the company's announcement about Operation Warp Speed was accurate only at the level of fine print. A final decision, *Geron* (page 25), appears to reflect a somewhat freewheeling approach to scienter. The court there relied on (1) stock sales by two company insiders who were neither defendants nor even executives, and (2) its conclusion that the plaintiffs had adequately alleged that the company "should have corrected" the challenged statements. "Should have" is a negligence rather than a scienter standard.

Timing Issues—Reporting Trial Results in Stages

Three of the 2021 cases at the pre-NDA stage turn on a fact pattern we have discussed in previous surveys. A company reports only top-line or otherwise incomplete clinical trial results. The results are favorable and the stock price surges. The company also explains that it will provide complete results later, possibly at an important medical conference. When it does so, some commentators or market participants are disappointed, and the stock price falls. Investors sue, claiming that the company's initial announcement of favorable results was misleading in light of the omission of less positive details. In two of the three 2021 decisions with this fact pattern, *Amarin* and *Macrogenics*, (page 20), courts dismissed such claims. In a third (*Geron*, page 25), the court denied the company's motion to dismiss.

In *Amarin*, the company announced top-line results in a Phase 3 trial of its heart medication, and its stock rose 400%. The company also told investors that it would release complete results two months later, at the annual meeting of the American Heart Association. When it did so, some commentators expressed concern that the placebo used in the trial had worsened patients' condition, making results on the treatment arm appear better than they were. The stock price fell. Investors sued, claiming that the company had misled investors by waiting to release complete results (which included information about the placebo). The court dismissed the claim, stating as

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

a categorical matter that "dissemination of top-line results does not trigger a duty to disclose the full results of a study." The court also held that plaintiffs had failed to adequately allege scienter, reasoning (as discussed above) that the most cogent inference was not that defendants intended to deceive the market but instead that they believed the placebo issue did not materially diminish the strength of the top-line data. Although the court did not apply the logic of *Endologix* in analyzing scienter, the facts of the case appear to be an excellent fit for that analysis. The theory that defendants perpetrated a fraud that would necessarily unravel two months later is neither cogent nor plausible.

The facts and analysis in *Macrogenics* (page 20) are similar. The company there announced positive interim results from a trial of its breast cancer drug, reporting that the data showed a statistically significant benefit in progression-free survival (PFS) over the standard of care. Macrogenics did not report overall survival (OS) data, which it explained were still maturing and would be presented four months later, at the annual meeting of the American Society of Clinical Oncology. When the company reported those results, investors learned that the trial had failed to demonstrate a statistically significant benefit in OS. The company's stock price fell. Like the plaintiffs in *Amarin*, the plaintiffs in *Macrogenics* claimed that by releasing certain trial results, the company assumed a duty to disclose all such results. The court dismissed the claim, drawing in part on *Rigel*, an influential 2012 decision in which the Ninth Circuit rejected the concept that the securities laws impose a duty of completeness on companies reporting trial results.[6]

On the other side of the ledger is *Geron* (page 25). In March 2018, the company reported favorable results of a Phase 2 trial as to one metric, OS. The company did not disclose that Phase 2 data for two other metrics—remission and Total Symptom Score (TSS) reduction—were less favorable than data in a pilot study. Six months later, the company reported Phase 2 remission and TSS data. It also disclosed that its development partner was pulling out, and its stock price fell. The court denied the company's motion to dismiss in part, stating in broad terms that plaintiffs had adequately pled "that Geron should have disclosed the bad news when it touted the good and that its failure to do so was misleading." The court rejected the company's argument that *Rigel* controlled, noting factual differences between the two cases as to the information omitted.

Geron's analysis and broad statements about disclosing "the bad news" along with "the good" may appear inconsistent with *Amarin* and *Macrogenics*, or even with *Rigel* itself. But the facts of the case permit a narrower reading of *Geron*, and may harmonize the results in this group of cases. Geron's March 2018 report included the statement that TSS results "remain consistent with prior data reviews." Given the dropoff in TSS results between the pilot study and Phase 2—77% of patients versus 32% of patients with a TSS reduction of 50% or more—the statement "remain consistent" appears to be untrue. In that light, *Geron* might be understood to hold only that a company may not make an affirmatively false or misleading statement about trial results—and not that by reporting any "good" results, it assumes a duty to disclose all "bad" results as well.

POST-APPROVAL DECISIONS

Companies prevailed in nine of the 16 post-approval cases in which district courts issued decisions in 2021. The cases in which companies won dismissal arose from a variety of business setbacks. The most common fact pattern in these cases was poor sales performance largely unrelated to regulatory issues.

By contrast, all but one of the cases in which district courts denied dismissal involve allegations of off-label marketing or other purportedly improper sales and marketing activities. We discuss the themes emerging from the latter set of decisions first. We then consider the uneven application, in 2021, of the plaintiff-friendly "core operations" doctrine.

6 *E.g., In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012).

Unfavorable Outcomes in Cases Involving Alleged Improprieties in Sales and Marketing

District courts held in six cases that plaintiffs had adequately pled falsity and scienter in connection with allegedly improper activity related to sales and marketing. In several of these cases, plaintiffs piggybacked on government investigations or regulatory actions.

This piggybacking technique is common in Section 10(b) cases, and it illustrates the second-order nature of much securities litigation. After a company experiences a setback, securities plaintiffs' attorneys will claim that the company defrauded investors by failing to disclose the underlying facts earlier, and by making public statements that masked the risk that eventually materialized.

Where the setback involves potential or actual regulatory violations, courts have drawn on two general propositions in determining whether those improprieties can serve as the basis of a fraud claim—the foundation of which is a materially false or misleading statement. The two propositions, discussed immediately below, point in opposite directions.

Putting the source of revenue at issue. The first proposition is that when a company puts the source of its revenue "at issue" by discussing the reasons for its financial performance, it may be liable for fraud if it fails to disclose that its performance was driven by (purportedly) improper conduct. Courts applied this proposition to the detriment of defendants in *Galena* (page 34), *Aclaris* (page 39), and *Alexion* (page 42).

In *Galena*, the company attributed its successful opioid sales to legitimate practices. Plaintiffs claimed that the company's success was instead driven by illegal kickback agreements. After concluding that plaintiffs had adequately pled both the existence of a kickback scheme and the materiality of that scheme to the company's earnings, the court turned to the legal principle that "[a] company's accurate recitation of its past earnings can be materially misleading if it attributes such earnings to lawful activity when they are not in fact attributable to that activity." Based on that principle, the court concluded that plaintiffs had adequately pled falsity.

Much the same was true in *Aclaris*. The company there discussed the success of a new marketing campaign without disclosing that the FDA had raised questions about the campaign—questions that later culminated in the agency's conclusion that the company's advertising violated the Food, Drug and Cosmetic Act. The court concluded that plaintiffs had adequately pled falsity, citing case law holding that a company may be liable under Section 10(b) if it "puts the reasons for its success at issue but fails to disclose that a material source of its success is the use of improper or illegal business practices."

Alexion is similar. Plaintiffs in that case challenged statements attributing the company's sales growth to success in patient identification and strong uptake of its drug. Later, the company paid $13 million to settle DOJ charges related to kickbacks. The court concluded that plaintiffs had adequately pled falsity, citing the principle that "statements that put the source of … accurately reported … revenue at issue may be actionable if they fail to disclose the impropriety of the source."[7]

Considered in isolation, the "source at issue" rule may appear dangerously open-ended. A company cannot avoid putting the source of its revenue at issue. At a minimum, a company must do so once a year in the Management's Discussion and Analysis section of its Form 10-K. Under Item 303 of Regulation S-K, companies must "give the investor an opportunity to look at the company through the eyes of management by providing both a short and long-term analysis of the business of the company."[8] Consequently, if plaintiffs are able to establish for pleading purposes that a company has engaged in improper (and undisclosed) conduct that touches in any way on its financial performance, they will have little difficulty identifying a public statement rendered misleading by virtue of that conduct.

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7 The court in *Vanda* (page 40) applied a similar, although more generalized proposition. Plaintiffs there alleged off-label marketing and challenged the company's statements about its marketing practices. The court denied the company's motion to dismiss based on the concept that "once a company speaks on an issue or topic, there is a duty to tell the whole truth." The "whole truth" concept is not universally accepted. The Ninth Circuit in particular has repeatedly held that securities defendants do not owe investors a duty of completeness. *E.g.*, *Rigel*, 697 F.3d 869, 880 n.8.

8 Securities Act Release No. 6711 (April 17, 1987), 52 FR 13715.1987 (discussing 17 C.F.R. § 229.303).

In context, however, the facts of *Galena*, *Aclaris* and *Alexion* suggest that liability under the "source at issue" rule is not unchecked. The premise for applying the rule is that plaintiffs have adequately established improper conduct. In all three cases, plaintiffs were able to do so by reference to government activity—in *Aclaris*, the FDA's determination that the company was committing statutory violations; in *Galena* and *Alexion*, DOJ investigations or settlements. As long as courts remain rigorous in requiring that plaintiffs allege the purported regulatory violation with factual particularity, the ease with which plaintiffs can identify a misleading statement under the "source at issue" rule should not lead to an explosion in liability—particularly as companies may still pursue arguments related to scienter, materiality, timing and prior disclosures of risk.

No need to disclose uncharged misconduct. A second proposition courts often invoke in adjudicating securities claims arising from alleged regulatory violations is that companies have no obligation to characterize their actions in pejorative terms, and need not disclose uncharged or unadjudicated wrongdoing.[9] This proposition favors defendants.

The 2021 decisions, however, illustrate its limitation. Defendants invoked the proposition in *Alexion*, arguing that they "had no duty to paint their business in a negative light or to disclose uncharged conduct." The court rejected the argument, explaining that while defendants "were not required to describe their practices in a pejorative manner," they *were* required, under the "source at issue" rule, to provide a factual account of the allegedly improper conduct. In the court's view, the argument that a company need not condemn itself succeeds only if the company has disclosed enough factual detail about its conduct that investors can assess for themselves whether that conduct is improper, and whether it may lead to adverse scrutiny or actions by regulators.

In this way, *Alexion* may usefully be contrasted with *Ra* (page 41), in which the court dismissed plaintiffs' attack on the company's marketing-related statements (although it denied dismissal as to other, unrelated statements). The company in *Ra* did not accuse itself of off-label marketing, but it did disclose that a competitor had done so, and it stated in its risk disclosures that while it did not believe its marketing activity was improper, the FDA could view matters differently. By means of those statements, the court held, the company had adequately informed investors that it was encouraging physicians to use its product beyond the approved indications—and that it was risking regulatory scrutiny as a result.

Ra thus falls into a line of decisions we have discussed in past surveys, in which companies are able to defeat securities litigation even where regulators ultimately conclude that their sales, marketing or billing practices were improper. The key in these cases is that the companies had provided enough information about the violative conduct that investors could make their own risk assessments.[10] Particularly in areas in which the regulatory landscape is unclear, companies may do well to include such information in a carefully crafted risk disclosure.

Disputing the alleged impropriety. In cases where the government has accused a company of marketing or billing improprieties, the company will generally not argue in securities litigation that its actions were appropriate. Where the accusations come from private parties, however, that argument should be available. Disappointingly, the argument failed in the two 2021 decisions in which courts confronted it.

In *Vanda* (page 40), plaintiffs alleged off-label marketing based not on government action but on a short-seller report and a dismissed qui tam complaint. The company argued, much as the company did in *Alexion*, that it had no obligation to disclose uncharged conduct. The court rejected the argument with little analysis.

In *Corcept* (page 40), the off-label marketing allegations appear to have been generated solely by the securities plaintiffs themselves, who presented extensive and cross-corroborated

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9 *E.g.*, *Police & Fire Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228 (1st Cir. 2015) (no duty to adopt pejorative characterization of market activities); *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014) ("As we have explained, disclosure is not a rite of confession, and companies do not have a duty to disclose uncharged, unadjudicated wrongdoing") (cleaned up).

10 *E.g.*, *Abiomed*, 778 F.3d 228 (affirming dismissal of claims based on off-label marketing practices that ultimately led the company to recall its marketing materials); *Lovallo v. Pacira Pharms, Inc.*, 2015 WL 7300492 (D.N.J. Nov. 18, 2015) (dismissing claims based on off-label marketing practices that later drew FDA warning letter); *Singer v. Trans1, Inc.*, 2015 WL 2341907 (E.D.N.C. May 14, 2015) (dismissing claims based on what regulators ultimately viewed as billing fraud).

accounts from physicians and former members of the company's sales force. The company argued that the conduct alleged, assuming it had occurred, was permissible: The conduct did *not* amount to improper off-label marketing. The court declined to engage on the issue, stating that "whether these practices constitute off-label promotion of [the drug] is a factual dispute that is not appropriately resolved on a motion to dismiss." Particularly against the background of an otherwise thorough and balanced decision, this appears anomalous. At least arguably, whether the practices at issue violated FDA regulations is a *legal* question. In the absence of any suggestion that the government considered the company's actions improper, the burden should be on plaintiffs to demonstrate that it was—consistent with the PSLRA's requirement that plaintiffs specify the reasons a statement is allegedly false or misleading.

Confidential witness risks at smaller companies. The same two decisions, *Corcept* and *Vanda*, also highlight the securities liability risk faced by very small companies engaged in marketing conduct that may be open to question. The starting point of a Section 10(b) claim, of course, is the challenged statement, and the scienter inquiry is directed at the person who made it. Did the speaker intend to deceive investors by means of a deliberately false or misleading statement? In a large company, the speaker may be separated by multiple levels from sales representatives or other employees engaged in the purportedly improper conduct. In many contexts, courts will discount confidential witness allegations where the witness cannot speak from personal knowledge about a speaker's actions or beliefs. This is most obvious where the witness has never interacted with company executives. (Examples are *Becton, Dickinson* (page 33), and, from the pre-approval context, *Karyopharm* (page 22).)

But in a smaller company, the speakers themselves may have taken the actions at issue. This was the case in *Corcept*: Plaintiffs cited a confidential witness who claimed that she accompanied the CEO on physician visits and witnessed him personally promoting the drug off label. Another confidential witness claimed to have attended meetings in which the Vice President of Commercial, a defendant in the securities litigation, pushed sales representatives to find physicians willing to prescribe the drug off label. Similarly, plaintiffs in *Vanda* alleged that the CEO himself trained the company's sales force in off-label marketing. With accounts like these provided by former employees of smaller companies, securities plaintiffs are well ahead of the curve in pleading scienter.

Core Operations Analyses in the Post-Approval Context

In both the pre-approval and the post-approval setting, plaintiffs who are unable to plead particularized facts supporting a strong inference of scienter will fall back on generalized inferences. Most commonly, they will argue that a court can infer scienter when the alleged fraud occurred in an area at the "core" of a company's business.

As background, some courts—notably the Ninth Circuit—have accepted the core operations doctrine but have also carefully marked out its limitations. In the Ninth Circuit, the core operations inference is appropriate only (1) as part of a holistic scienter analysis, (2) where plaintiffs provide particularized facts showing defendants' access to disputed information, or (3) in rare cases where the facts at issue were of such prominence that it would be "absurd" to posit that management was unaware of them.[11] In the third circumstance, the core operations inference suffices in itself to establish that a company's executives knew of the facts purportedly contradicting their public statements. Outside of the Ninth Circuit, and in the Second Circuit in particular, the validity of the core operations inference remains an open question.[12]

Against that background, two courts—the Southern District of New York in *Abiomed* and the District of New Jersey in *Becton, Dickinson*—rejected plaintiffs' core operations arguments in 2021 decisions. In *Abiomed* (page 37), plaintiffs argued that the medical device at issue in a missed guidance case—a heart pump—accounted for 96% of the company's revenue. The court noted the uncertain status of the core operations doctrine in the Second Circuit, but at the same time summarized several rules adopted by the district courts within the circuit that

11 *South Ferry LP #2 v. Killinger*, 542 F.3d 776 (9th Cir. 2008).

12 *Frederick v. Mechel OAO*, 475 F. App'x 353, 356 (2d Cir. 2012) (the Second Circuit has "not yet expressly addressed whether, and in what form, the 'core operations' doctrine survives [enactment of the PSLRA] as a viable theory of scienter"); *City of Omaha Police & Fire Ret. Sys. v. Evoqua Water Techs. Corp.*, 450 F. Supp. 3d 379, 423-24 (S.D.N.Y. 2020) ("the future of the doctrine may be tenuous") (internal citation omitted).

had considered applying it: (1) while the core operations inference is not sufficient in itself to establish scienter, it may be incorporated into *Tellabs*' holistic analysis; and (2) "the operation at issue [should] make up nearly all of a company's business or be essential to its survival." Applying these rules, the *Abiomed* court concluded that plaintiffs' scienter allegations came up short. "[W]hile the importance of [the heart pump] should have strengthened Defendants' awareness of any specific contradictory fact or information, that import cannot substitute for specific allegations linking Defendants to the alleged fraud."

The analysis in *Becton, Dickinson*—another case involving a pump—was similar. The company there made multiple modifications to resolve issues with the device, and the FDA eventually halted sales pending the company's application of a comprehensive 510k application covering all modifications the company had made. Plaintiffs argued that they had adequately alleged scienter as to the company's statements about the pump and the risks of regulatory action based on the "outsized impact that [the pump] had on the Company's bottom line." The court rejected the argument, holding that neither the importance of the product nor the individual defendants' access to information by virtue of their positions was sufficient to support a strong inference of scienter.

On the other side of the ledger are two cases in which plaintiffs successfully alleged scienter by means of the core operations doctrine. Both decisions come from district courts in the Ninth Circuit—the Northern District of California in *Corcept* and the Southern District of California in *Ra*. Both courts concluded that plaintiffs' allegations fell within the third prong of the Ninth Circuit's *South Ferry* framework: Plaintiffs had shown that the facts at issue were so important that it would be "absurd" to conclude that management did not know about them.

Both courts relied on allegations about the economic significance of the drug or device at issue, together with allegations about the individual defendants' responsibilities. The drug at issue in *Corcept*, which was allegedly promoted off label, was the company's only product, and the individual defendants were "intimately involved in the operation of the company and the sale of [the drug]." The device at issue in *Ra*, which was the subject of a recall, was one of only two products sold by a 118-employee company; the court concluded that with five individual defendants responsible among themselves for technology and recall issues, "it would be absurd to suggest that any of those officers was ignorant of the situation."

Notwithstanding the analysis in *Corcept* and *Ra*, it would be a mistake to conclude that plaintiffs can successfully plead scienter under the core operations doctrine whenever (1) a company sells only one or a few products, and (2) the executives who made the challenged statements actively managed the company's business. In *Corcept*, the court's decision to grapple with the core operations inference in the first place is somewhat surprising. In an earlier decision in the same case, the court granted the company's motion to dismiss, explaining that while plaintiffs' many confidential witnesses spoke knowledgeably about the company's marketing practices, the witnesses were all physicians targeted by the company's sales representatives, and none could explain who if anyone within the company was directing the challenged practices. In their amended complaint, plaintiffs addressed this shortfall with four new confidential witnesses, all former Corcept sales employees. Among them, the four new witnesses traced the challenged practices directly to the individual defendants, alleging that the defendants participated in or directed off-label promotion. What changed between the original and the amended complaints was not that the basis for drawing a generalized inference of knowledge became stronger. What changed was that plaintiffs added new allegations *directly* implicating the individual defendants in the challenged conduct. No generalized inference based on the importance of a product or the individual defendants' management responsibilities was required.

Ra also appears somewhat anomalous. Based on the core operations doctrine, the court inferred that the individual defendants knew about issues with a recalled medical device. But the ultimate scienter inquiry is not whether defendants know particular facts. The question is whether they made the challenged *statements* with an intent to defraud investors (or with reckless disregard for the risk of deceit). The *Ra* court did not address the latter question, which would have focused on the sole set of statements as to which plaintiffs had adequately pled falsity: risk disclosures in which the company presented (allegedly) historical facts as mere

contingencies. Did plaintiffs' allegations support an inference that the individual defendants made these risk disclosure statements with an intent to deceive? Perhaps the answer would again have been yes—but it is notable that the court did not ask the question. Meanwhile, *Ra* involved unusual circumstances that may have raised suspicions of knowing misconduct in various areas. The CEO was terminated less than a year after the company's IPO, and an audit committee report issued two months later detailed a range of improprieties. Although the court did not discuss these facts in analyzing scienter, they may nevertheless have played a role. In *Ra*, as in *Corcept*, far more was in play than the importance of a product to the company's business.

CLINICAL TRIALS AND FDA APPROVALS IN THE ERA OF COVID-19

We reported last year on the multiple impacts of the COVID-19 pandemic on clinical trials and FDA approval processes. Commentators estimated that as many as 80% of clinical trials were affected in some way, from slowdowns in enrollment to outright suspension. The number of new trials initiated was also sharply down, particularly early-phase trials and those in which already vulnerable patients were at greatest risk of contracting COVID-19. These trends persisted to a degree in 2021, particularly when surges related to the delta and omicron variants consumed hospital and other resources. Some observers have worried that fear of infection may make patients reluctant for years to come to take the frequent trips to large medical facilities often required for participation in clinical trials.

On the other hand, there were already various indications of a return to normalcy in 2021. The FDA reported 50 approvals of novel drugs, a figure squarely in line with recent annual trends. After a significant pause in facility inspections in the first year of the pandemic—and then a renewed pause as the omicron wave hit—the FDA has announced a return to the customary level of domestic inspections, and has projected an imminent return to the ordinary cadence of foreign inspections. During the pandemic, the FDA worked to introduce "alternative inspectional tools"—including records requests and collaboration with foreign regulatory agencies—to make decisions in the absence of onsite inspections. The agency has indicated that while these alternative tools will continue to be part of its inspectional arsenal going forward, onsite inspections are considered an "irreplaceable standard."

We also reported last year on some apparent silver linings related to the clinical trial and approval processes. These too have extended into 2021. The FDA demonstrated extraordinary flexibility and speed in working with drug developers on COVID-related products, and many are optimistic that greater flexibility will characterize the agency's work going forward.

Outside the context of COVID-19-related products, the FDA issued guidance early in the pandemic that eased administrative burdens on companies seeking to amend protocols to protect patient safety in dramatically changed circumstances. Sponsors and others administering clinical trials turned to innovations including telemedicine, electronic informed consent, home delivery of drugs that can be self-administered, and decentralization of treatment and testing to community settings. Those innovations may well carry into the post-pandemic future, offsetting burdens on patients participating in trials and facilitating efficiencies in drug development.

Meanwhile, as to the COVID-19-related products themselves, the FDA has begun the transition from the Emergency Use Authorizations originally employed to bring the products to market quickly to conventional drug and device approval processes. Both the Pfizer and the Moderna vaccines have now received Biologics License Application approvals in addition to their original Emergency Use Authorizations.

Trends and Analysis

DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 18–29), 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 ten cases in the district courts. In another seven cases, district courts denied the companies' motions to dismiss.

Four of the 17 decisions involve the development of COVID-19-related products. The results there are mixed, with two victories and two defeats for defendants.

Other district court decisions reflect favorable application of the Ninth Circuit's 2020 *Endologix* opinion, which contains the key insight that many theories of scienter in pre-approval cases are inconsistent with common sense, as the alleged fraud is not sustainable.

Still other decisions show that life sciences companies with pre-approval products continue to benefit from the comparative approach to scienter adopted by the Supreme Court in *Tellabs*.

Companies did not, of course, win dismissal on scienter grounds in all of the 2021 cases. In those cases in which they failed to do so, plaintiffs were often able to clear the scienter bar by means of confidential witness allegations.

The two 2021 pre-approval appellate decisions, from the Second and Fifth Circuits, are unpublished.

APPELLATE DECISIONS

Callinan v. Lexicon Pharms., Inc., 858 F. App'x 162 (5th Cir. 2021), affirming dismissal. **NDA**

Lexicon developed sotagliflozin for the treatment of diabetes. Lexicon entered into a licensing and collaboration agreement with Sanofi and designed and carried out three Phase 3 trials. In the first two trials, Lexicon used a "composite" secondary endpoint that measured the number of patients who had achieved a defined efficacy benefit without an episode of diabetic ketoacidosis (DKA), a life-threatening condition. The same composite endpoint was used as the primary endpoint in the third Phase 3 trial. In March 2018, Lexicon reported that Sanofi had filed an NDA for sotagliflozin. In a briefing document published shortly before a January 2019 advisory committee meeting, FDA staff highlighted the increased risk of DKA and noted their concerns about the composite endpoint, which they suggested was not "a clinically meaningful way to frame both the benefits and the risks of sotagliflozin." The advisory committee voted 8-8 on approval, and the company's stock price fell 23%. In March 2019, Lexicon reported its receipt of the FDA's Complete Response Letter denying approval, and the stock fell 22%. In July 2019, Lexicon reported that Sanofi was exercising its right to terminate the collaboration agreement. The stock fell 70%.

Investors sued, alleging that the company had minimized the severity of DKA in trial subjects and wrongly omitted reference to the FDA's concerns about the composite endpoint. The district court granted the company's motion to dismiss in 2020 (reported in last year's review). The district court emphasized the company's thorough disclosure of trial results and concluded that plaintiffs were wrongly seeking to back-cast all negative responses in the FDA briefing document and advisory committee commentary onto the time of the company's earlier favorable statements—which was an impermissible theory of fraud by hindsight. The court also held that plaintiffs had failed to adequately allege scienter. Confidential witnesses were not tied to the individual defendants; the company did not depend for its existence on sotagliflozin; allegations about incentive compensation could be made about nearly any company. Finally, the court concluded that plaintiffs had failed to establish loss causation, as the FDA's comments and actions did not show that the company's statements were false or misleading.

The Fifth Circuit affirmed in a very brief unpublished decision, holding that for the reasons stated in the district court's lengthy ruling, plaintiffs had failed to plead in accordance with the PSLRA.

Midwest Op. Eng'rs Pension Tr. Fund v. Alkermes Public Ltd. Co., 2021 WL 5782079 (2d Cir. Dec. 7, 2021), affirming dismissal. **NDA**

Alkermes developed ALKS-5461 for the treatment of major depressive disorder. In its Phase 3 trials, Alkermes used a Sequential Parallel Comparison Design, in which placebo non-responders are re-randomized in a second stage of a clinical trial. The FDA told Alkermes that the design was novel and that whether the company could sufficiently establish efficacy with the design would be a review issue. In January 2016, the company reported that two of the three Phase 3 trials had been completed and had failed to reach their primary endpoint, but that a post hoc analysis could produce different results. The company's stock price fell 44%. In September 2016, Alkermes made various amendments to the Phase 3 trial protocol and Statistical Analysis Plan. One change was to use a six-factor rather than a ten-factor test to measure changes in a depressed patient's condition. Another was to measure efficacy in part by reference to a patient's improvement after three weeks of treatment rather than solely by reference to improvement at the end of the study. The FDA expressed concerns about these changes in February 2017. Alkermes submitted its NDA in January 2018. The FDA issued a Refuse to File Letter but ultimately agreed to review the application after the company submitted clarifying information. The FDA issued a briefing document on October 30, 2018; two days later, the advisory committee reviewing the application voted against approval. The company's stock fell 7.6%.

Investors sued, accusing the company of misleadingly omitting information about concerns the FDA had communicated since 2013. The district court granted the company's motion to dismiss solely on scienter grounds, and without discussing any challenged statement. (We discuss the district court's decision on page 21, below.)

The Second Circuit affirmed dismissal, also on scienter grounds. With respect to the company's use of the novel Sequential Parallel Comparison Design, the court noted both that Alkermes had disclosed the novelty of the design and that the FDA had at one point stated that use of the design appeared reasonable. Given those facts, the most compelling inference was that the company was optimistic about the FDA's review—particularly as the agency had never stated that use of the trial design was an insuperable obstacle to approval. With respect to the use of the six-factor rather than the ten-factor test, the court noted that Alkermes had disclosed the FDA's concerns, and that in any event the company had submitted both six-factor and ten-factor data in its NDA. The same was true of Alkermes' use of the three-week efficacy data: The data in the NDA enabled the FDA to calculate efficacy either with or without the three-week data point. Finally, while the use of post hoc analyses may be viewed with skepticism, Alkermes had disclosed that use, and "when it is clear that a post-hoc analysis is being used, it is understood that those results are less significant and should therefore have less impact on investors." Considered holistically, the facts supported an inference that the company "viewed [the drug's] chances of FDA approval with optimism, yet still made honest attempts to disclose the FDA's feedback where relevant and to caution the market as to the risks inherent in proposing new study designs."

DISTRICT COURT DECISIONS—MOTION TO DISMISS GRANTED

In re Anaptysbio, Inc. Sec. Litig., 2021 WL 4267413 (S.D. Cal. Sept. 20, 2021), granting motion to dismiss without prejudice. **Phase 2**

Anaptysbio developed etokimab to treat severe inflammatory disorders, including atopic dermatitis, peanut allergies and asthma. In October 2017, the company spoke favorably about a Phase 2a atopic dermatitis trial, stressing duration of effect and patient convenience. In March 2018, Anaptysbio reported positive interim trial data in a Phase 2a peanut allergy trial. But the market did not respond favorably to the peanut allergy data—apparently due to concerns about trial design—and the company's stock price fell 23%. In August 2018, the company reported that it had terminated the peanut allergy trial but that it was moving into Phase 2b trials for both atopic dermatitis and asthma. Bad news again followed: In November 2019, Anaptysbio reported that it had failed to reach the primary endpoint in the dermatitis trial and was postponing asthma studies. The stock fell 72%.

Investors sued, challenging the company's statements about both the atopic dermatitis and the peanut allergy trials. The court granted the company's motion to dismiss. Plaintiffs' theory as to the dermatitis trial was that the company had concealed the fact that a rescue therapy was used in the Phase 2a study, and that this had made results appear more favorable than they were. But the company had prominently disclosed the use of the rescue therapy on several occasions, and was not required to repeat that information every time it discussed the drug. Plaintiffs' theory as to the peanut allergy trial was that the company had (1) failed to disclose the cumulative peanut dose to which patients were exposed, and (2) excluded data from 20% of the patients—who were deemed to have an insufficiently severe form of the disease—which skewed the results favorably. The court rejected these theories too. The cumulative dose may have been of interest to investors, but omission of the information did not render any challenged statement misleading. As to the exclusion of patient data, the company had a defensible basis for doing this, and in any event had disclosed the exclusion in a way that enabled investors to tell that this had made results look more favorable. The court also held that plaintiffs' scienter allegations were inadequate. Insider sales were not unusual in amount once vested stock options were considered, and the CEO's sales were made under a trading plan. Plaintiffs' confidential witnesses failed to identify specific information known to the individual defendants that was inconsistent with the challenged statements; moreover, internal disagreement over the appropriate content of public statements does not establish deliberate fraud. Finally, executive resignations did not support a strong inference of scienter. The resignation

of a Chief Medical Officer in the wake of failed trials is neither atypical nor indicative of fraud, while the contention that the CFO resigned because he was nervous about the outcome of the trials was based on double hearsay and did not show an intent to deceive in any case.

In re Amarin Corp. PLC Sec. Litig., 2021 WL 1171669 (D.N.J. March 29, 2021), granting motion to dismiss without prejudice. **Phase 3**

Amarin develops Vascepa, a drug for the treatment of heart disease. After conducting two surrogate endpoint trials aimed at showing that Vascepa could lower triglycerides, Amarin conducted a trial designed to show that the drug could reduce major adverse cardiac events. The company reported positive top-line results in September 2018 and its stock price rose over 400%. Amarin also told investors that it would report detailed results in November 2018, at the American Heart Association's annual conference. When it did so, some commentators reacted unfavorably, noting that the mineral oil placebo used in the trial may have made the conditions of some patients on the control arm worse, thereby exaggerating the positive effect of Vascepa. Mineral oil potentially interferes with statins, which were administered to patients on both the placebo and the treatment arm. Amarin's stock price fell 25% after it reported detailed results in November 2018.

Investors sued, claiming that Amarin's report of top-line results was rendered misleading by the omission of (1) information about the effect of the placebo, and (2) the fact that the trial data could not explain how the drug worked. The court granted Amarin's motion to dismiss. With respect to the placebo, the company had repeatedly warned investors that mineral oil might not be biologically inert and could be viewed as artificially exaggerating Vascepa's clinical effect. More generally, the court held that "dissemination of top-line results does not trigger a duty to disclose the full results of a study." The court also rejected plaintiffs' claim that the company's statements were misleading insofar as the trial failed to illuminate Vascepa's mechanism of action: Amarin never purported to know that mechanism. Finally, the court held that plaintiffs had failed to allege scienter. The stock sales they identified were not unusual and were conducted under trading plans. The most cogent inference was that the company believed in the positive top-line results it reported, and further believed that potential issues with the placebo and mechanism of action did not compromise those results.

Emps.' Ret. Sys. of the City of Baton Rouge v. Macrogenics, Inc., 2021 WL 4459218 (D. Md. Sept. 29, 2021), granting motion to dismiss with prejudice. **Phase 3**

Macrogenics developed Margetuximab, a second-line treatment for metastatic breast cancer. In February 2019, the company announced favorable interim results from a Phase 3 trial, reporting that the data showed that the drug had a statistically significant benefit in progression-free survival (PFS) over the standard of care. Macrogenics did not report overall survival (OS) data, which it stated were still maturing and would be presented at the annual American Society of Clinical Oncology conference (ASCO) in June 2019. The company's stock price rose 130% following its February 2019 announcement, and Macrogenics conducted a secondary public offering shortly thereafter. In May 2019, the company reported initial interim OS data for the first time. The data showed a 1.7 month benefit for Margetuximab over the standard of care, and a 6.8 benefit for a pre-determined subset of patients who carried a particular allele. The company characterized this as a promising trend. At ASCO in June 2019, the company provided more complete interim data and specified that the OS results did not reach statistical significance. Macrogenics also presented Kaplan-Meier curves for the first time at ASCO; those curves can aid in assessing immature OS data. The company's stock price fell 21%.

Investors sued, challenging Macrogenics' statements about PFS results and OS data as well as its risk disclosures. The court granted the company's motion to dismiss. As to the PFS results, the court held that Macrogenics did not assume a duty to disclose OS results simply by discussing PFS results; nor did the company's discussion of PFS results falsely imply that OS results were on track for a positive outcome. Plaintiffs' attack on the company's characterization of the PFS results as positive and superior also failed, both because the challenged statements were too broad to be actionable and because they were true. On the subject of interim OS results—which the company had characterized as trending positive in May 2019—plaintiffs had again failed to allege

falsity. Nor were the statements misleading by virtue of Macrogenics' failure to present Kaplan-Meier curves at that time. Investors are not entitled to data in any particular format. Plaintiff also failed to establish falsity with respect to the company's risk disclosures, which were detailed and which did not, contrary to plaintiffs' claims, present historical facts as mere contingencies. On the element of scienter, plaintiffs had alleged little more than generic corporate incentives (the 130% increase in stock price; the secondary offering) and ubiquitous allegations about access to information. On balance, the more plausible inference was that the company failed to provide detailed OS data because the study was still ongoing—not in an effort to hide problems. Finally, the court dismissed plaintiffs' Securities Act claims, which arose from the secondary offering. Those claims were governed by Rule 9(b)'s particularity standard, as they were factually intertwined with the Exchange Act fraud claims. And plaintiffs failed to satisfy Rule 9(b) for the same reason they failed to satisfy the PSLRA's pleading standards.

In re Alkermes Public Ltd. Co. Sec. Litig., 523 F. Supp. 3d 283 (E.D.N.Y. 2021), granting motion to dismiss with prejudice. NDA

Alkermes developed ALKS-5461 for the treatment of major depressive disorder. The FDA granted the drug fast-track status in 2013, after the company had completed Phase 2 trials. In its Phase 3 trials, Alkermes used a Sequential Parallel Comparison Design, in which placebo non-responders are re-randomized in a second stage of a clinical trial. The FDA told Alkermes that the design was novel and that whether the company could sufficiently establish efficacy with the design would be a review issue. The primary endpoint of the trial was a patient's change from baseline on the Montgomery-Asberg Depression Rating Scale (MADRS), which measures depression by reference to ten general factors. In January 2016, the company reported that two of the three Phase 3 trials had been completed and had failed to reach their primary endpoint, although a post hoc analysis could produce different results. The company's stock price fell 44%. In September 2016, Alkermes made various amendments to the Phase 3 trial protocol and Statistical Analysis Plan. The effect of the changes was to use a six-factor rather than the ten-factor version of MADRS in certain instances, and to measure efficacy in part by reference to a patient's improvement after three weeks of treatment rather than solely by reference to improvement at the end of the study. The FDA expressed concerns about these changes in February 2017. Alkermes submitted its NDA in January 2018. The FDA issued a Refuse to File Letter but ultimately agreed to review the application after the company submitted clarifying information. The FDA issued a briefing document on October 30, 2018; two days later, the FDA Advisory Committee voted against approval. The company's stock fell 7.6%.

Investors sued, challenging Alkermes' statements about its Phase 3 trials and accusing the company of misleadingly omitting information about concerns the FDA had communicated since 2013. The court granted the company's motion to dismiss solely on scienter grounds, and without discussing any challenged statement. The court rejected plaintiffs' contention that the FDA briefing document was a "roadmap to Defendants' scienter." While the FDA had raised issues throughout the approval process, it had also permitted the drug to proceed through all stages of trial and review. "[I]mplicit in the ongoing dialogue between the FDA and Alkermes was a collective expectation that the process was an iterative one and that Alkermes would continue to respond to feedback in its continued effort to seek approval of ALKS-5461." In particular, the FDA never rejected or expressed disapproval of the novel trial design Alkermes used; the agency stated only that use of the design would present a review issue. (Later in 2021, the Second Circuit affirmed dismissal in an unpublished decision, reported above.)

Carr v. Zosano Pharma Corp., 2021 WL 3913509 (N.D. Cal. Sept. 1, 2021), granting motion to dismiss without prejudice. NDA

Zosano develops drugs administered through adhesive patches. Its lead candidate was Qtrypta, which delivered a previously-approved migraine drug through such a patch. In early 2017, the company reported favorable efficacy and safety results from a Phase 2/3 pivotal trial, and advised investors that the FDA had indicated that a single such positive trial, together with a positive outcome in a long-term safety study, would be sufficient for approval through a streamlined regulatory pathway. Zosano reported positive results from the safety study early in 2019, and continued to make favorable statements about the prospects for approval before and after it

submitted its NDA in December 2019. Trouble arose in September 2020: Zosano reported that the FDA had issued a Discipline Review Letter stating that approval was unlikely given (1) issues revealed through pharmacokinetic studies, and (2) differing exposure levels to the drug from one manufacturing lot to another. The company's stock price fell 57%. In October 2019, the FDA issued a Complete Response Letter identifying the same two items, among others.

Investors sued, challenging the company's reports of clinical trial results and statements about the prospects of FDA approval. After expressing its doubts that plaintiffs had adequately pled falsity, the court dismissed solely on scienter grounds. The court relied heavily on the Ninth Circuit's 2020 decision in *Endologix*, another case in which the FDA denied approval (there, of a medical device) at the final stage of the process. In *Endologix*, the Ninth Circuit explained that allegations of fraud in connection with FDA approval are often nonsensical, as a company can only postpone—not avoid—the bad news that the FDA will not approve a product. Only if Section 10(b) plaintiffs can identify a short-term financial benefit to the defendants—for example, through sales of stock while price is inflated—does a theory of fraud appear plausible. Like the plaintiffs in *Endologix*, the *Zosano* plaintiffs could identify no such financial benefit. They alleged that the company was short of cash, but the court held that raising necessary capital is a routine corporate objective insufficient to support a strong inference of deliberate fraud. The court also rejected as insufficiently detailed plaintiffs' allegations that the company had access to and awareness of undisclosed adverse information and that the core operations doctrine accordingly supported an inference of scienter.

In re Karyopharm Therapeutics Inc. Sec. Litig., – F. Supp. 3d – , 2021 WL 3079878 (D. Mass. July 21, 2021), granting motion to dismiss without prejudice. NDA

Karyopharm developed selinexor for the treatment of advanced cancers. In a Phase 1 trial, only one of 56 patients responded favorably, and several patients discontinued treatment prematurely because of the drug's toxicity. In an initial Phase 2 trial, SOPRA, overall survival was significantly worse on the treatment arm than on the control arm, and all patients on the treatment arm experienced adverse events. In March 2017, the company announced that it was terminating the SOPRA trial based on poor overall survival results. The company also conducted a single-arm Phase 2(b) trial, STORM. For this trial, the company reported good news, stating in March 2018 that the trial had succeeded in demonstrating efficacy, that selinexor had a manageable toxicity profile, and that the company would submit an NDA based on the STORM results. In June 2018, the company reported that it would also use real world data in the NDA—that is, data derived from outside the clinical trial setting—and that it was following FDA guidance on the use of such data. In February 2019, the FDA issued a briefing document in which it pointed to significant toxicity data, including data from STORM, and announced that it would delay review pending completion of an additional ongoing trial. Karyopharm's stock price fell 43%. The company thereafter amended its NDA to target a narrower indication: patients who had already gone through four rounds of treatment and had no other treatment options left. The FDA approved selinexor for that indication in July 2019.

Investors sued, challenging the company's statements about the SOPRA trial, the STORM trial, and the use of real world data. The court concluded that plaintiffs had failed to plead falsity as to the SOPRA trial and real world data, and that while they had adequately pled that the company's statements about STORM were materially misleading, they failed to plead scienter. As to SOPRA, while the company did not provide details about either safety or the failure to achieve efficacy, it did report that it had terminated the trial because it could not establish a statistically significant increase in overall survival. In light of that bottom-line information, omitted details would not have significantly altered the total mix of information. By contrast, the company described STORM as a success, and in this context, it was arguably misleading to omit unfavorable toxicity data. But the court also concluded that plaintiffs had failed to plead scienter as to the STORM data. Plaintiffs relied principally on accounts attributed to confidential witnesses, but most accounts referred to events outside the putative class period, and no witness claimed to have interacted with the individual defendants. The company's risk disclosures also weighed against scienter, and the company's argument that investors expect toxicity with drugs targeted at only the sickest cancer patients was plausible. As to real world data, the court concluded that the company's reference to

compliance with FDA guidance was too vague to be actionable, while the fact that the company interpreted those data more favorably than the FDA did reflected only a difference of opinion.

Smith v. Antares Pharma, Inc., 2021 WL 754091 (D.N.J. Feb. 26, 2021), granting motion to dismiss with prejudice. NDA

Antares developed a drug delivery product for use in testosterone replacement therapy and submitted an NDA after successful Phase 3 trials. The FDA initially accepted the NDA but later told Antares it was halting review as a result of unspecified deficiencies. The company's stock price fell 38%. In a subsequent Complete Response Letter, the FDA identified safety risks related to hypertension and suicidality. The FDA ultimately approved the product with a black box warning label.

Investors sued, challenging the company's statements about product safety. In a 2019 ruling (discussed in our 2019 review), the court dismissed the complaint, holding that plaintiff's confidential witness allegations lacked specificity and corroboration, and that plaintiff had failed to adequately specify which statements he was challenging. Plaintiff amended, and in a 2020 ruling (discussed in last year's review) the court again dismissed: The challenged statements consisted of nonactionable opinions and puffery, or were not materially misleading. The court also held that plaintiff failed to plead particularized facts supporting its theory of scienter.

Plaintiff again amended, adding new allegations related to falsity, materiality, and scienter. The court again dismissed, this time with prejudice. Plaintiff challenged the company's statements about pain data in the Phase 3 trials, but such interpretations of clinical trial data are opinions, and plaintiff had failed to meet the criteria for attacking opinion statements. Plaintiff also failed to plead materiality as to these statements, which related to pain rather than to the safety issues that led to the black box label. Plaintiff's new allegations of scienter were also insufficient; the confidential witness allegations in particular were generalized and ambiguous. The company's awareness that certain patients were excluded did not establish scienter either: The exclusions were made pursuant to the study design, which the FDA had approved.

Leavitt v. Alnylam Pharms., Inc., 525 F. Supp. 3d 259 (D. Mass. 2021), denying motion for leave to amend. NDA

Alnylam developed patisiran for the treatment of hereditary transthyretin-mediated (hATTR) amyloidosis, a gene mutation that causes a buildup of certain proteins in nerves and organs. The company conducted a Phase 3 trial studying the effect of patisiran on patients with polyneuropathy (damage affecting the nerves). Because hATTR amyloidosis causes both polyneuropathy and cardiomyopathy (damage affecting the heart), often in the same patients, the trial included a cardiac subpopulation and metrics to evaluate the drug's efficacy for cardiomyopathy. In September 2017, Alnylam announced that the study had met its primary and secondary endpoints. The company subsequently submitted an NDA in which it sought approval for use of the drug in all manifestations of hATTR amyloidosis. In August 2018, the FDA approved patisiran for treatment of polyneuropathy, but not cardiomyopathy. (By contrast, the European Medicines Agency approved the drug for all manifestations of hATTR amyloidosis.) Alnylam's stock price fell 6% and then rebounded. In September 2018, the FDA released a report discussing its review of patisiran. Analysts commented that the FDA report revealed more limited market opportunity for the drug than previously understood, that the FDA was concerned by cardiac deaths in patients treated with the drug, and that the company had not provided sufficient cardiac efficacy data to support approval for cardiac manifestations. Alnylam's stock price fell 5%.

Investors sued, challenging the company's statements about the prospects of FDA approval for all manifestations of hATTR amyloidosis, as well as statements about trial results. In a 2020 ruling (discussed in last year's review) the court granted the company's motion to dismiss on both falsity and scienter grounds. Plaintiffs moved for leave to amend, and the company opposed, arguing that the amendments still failed to establish a strong inference of scienter. The court denied leave to amend. Plaintiffs claimed that defendants knew or recklessly disregarded that the design of the Phase 3 trial rendered approval for all manifestations of hATTR amyloidosis implausible, but failed to plead facts supporting that inference. The court noted that plaintiffs did not allege that the FDA had expressed disapproval of the cardiac data prior to its final report; moreover, the

European Medicines Agency *did* approve the drug for cardiomyopathy. On these facts, the most plausible inference was that the company reasonably believed that a broad label was achievable. Because plaintiffs' new allegations could not support a strong inference of scienter, amendment would be futile.

In re Sona Nanotech, Inc. Sec. Litig., – F. Supp. 3d –, 2021 WL 5504758 (C.D. Cal. Oct. 28, 2021), granting motion to dismiss without prejudice. **Development of COVID test**

Sona Nanotech developed gold nanorod products for diagnostic tests and medical treatments. In early 2020, the company began developing a nasal swab to test for the COVID-19 virus. Sona announced its work on the product in February 2020 and updated the market frequently on its progress; it hoped for approval in the U.S., Canada and the EU. In July 2020, Sona reported that in only four months, it had brought a rapid, point-of-care antigen test "to fruition" and had laid the groundwork for regulatory approval and commercial distribution in the coming months. Sona announced a delay in early August, after which its stock fell 34%. By the end of the August 2020, however, the company had submitted an application for an Emergency Use Authorization with the FDA and a similar application in Canada. In October 2020, the CEO stated that he was "100% confident" in approval. But by the end of October 2020, the company reported that the FDA had not approved and had "deprioritized" its application. Sona's stock fell 48%. In November, Sona reported that it had withdrawn its application for approval in Canada, after which its stock fell 67%. Sona ultimately received authorization in the EU on December 31, 2020, but reported two months later that no firm orders for its product had emerged. The company's stock fell 13%.

Investors sued, challenging the company's reports of progress in developing the test. The court granted Sona's motion to dismiss. Each of the challenged statements, the court concluded, was objectively true. Plaintiffs claimed that the company's July 2020 statement that it had brought a test "to fruition" misleadingly suggested that the test was ready for approval, but the court rejected that claim as implausible. The appropriate interpretation of "fruition," the court held, was that Sona had a test that worked—not a test that was "FDA ready"—particularly in light of the company's statement one week earlier that it had only recently commenced field testing. The CEO's October 2020 expression of "100% confidence" was too vaguely optimistic to be actionable. And while plaintiffs faulted the company for stating later in October that the FDA had deprioritized its application rather than rejecting it outright, plaintiffs alleged no facts showing that the FDA had in fact done so. The court also held that plaintiffs had failed to adequately allege scienter. The court drew on *Endologix*, a 2020 decision in which the Ninth Circuit explained that allegations of fraud in connection with FDA approval are often nonsensical, as a company can only delay the inevitable. Unless a plaintiff can show that the company or its officers sought to profit from a temporarily inflated stock price, such a theory of fraud is not plausible—and plaintiffs had failed to adequately allege such economic motivation.

In re Sorrento Therapeutics, Inc. Sec. Litig., 2021 WL 6062943 (S.D. Cal. Nov. 18, 2021), granting motion dismiss without prejudice. **Development of COVID treatment**

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 price dropped 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. One of the short sellers responded, encouraging regulators to investigate. Sorrento's stock fell 13%. In September 2020, the company reported preclinical testing results and announced that it would begin a Phase 1 trial, but by January 2021 had withdrawn from the trial.

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 court granted the company's motion to

dismiss. The court held that statements that "there is a cure" and "a solution that works 100%" were too vague and generalized to be actionable. The remaining statements, in context, were likewise generalized expressions of corporate optimism and hence not actionable—particularly as Sorrento made clear that its optimistic statements were confined to data from preclinical testing. The court also dismissed on scienter grounds, as plaintiffs had failed to plead particularized facts suggesting that Sorrento manipulated trial results or intended to deceive investors. Plaintiffs claimed that the company had an incentive to inflate its stock price in order to raise capital and comply with repayment obligations, but such routine business objectives are insufficient to support a strong inference of scienter.

DISTRICT COURT DECISIONS—MOTION TO DISMISS DENIED

Junge v. Geron Corp., 2021 WL 1375960 (N.D. Cal. Apr. 12, 2021), denying in part motion to dismiss. Phase 2

Geron developed imetelstat for the treatment of myelofibrosis, a bone marrow cancer. In a pilot study, 23% of patients experienced remission and 77% had a Total Symptom Score (TSS) reduction of 50% or greater. Phase 2 results were significantly less favorable as to these two metrics (remission and TSS), but were favorable as to overall survival. In reporting Phase 2 results in March 2018, Geron included the favorable overall survival data but not the remission and TSS results. In September 2018, Geron reported complete Phase 2 results. Only one patient had experienced remission (as opposed to 23% in the pilot study). 32% of the patients reported a TSS reduction of 50% or more (as opposed to 77% of the patients in the pilot study). Although the drug progressed to Phase 3 trials, the company's development partner, Janssen, pulled out and Geron's stock price fell.

Investors sued, challenging multiple statements about Phase 2 results as well as the company's risk disclosures. The court denied the company's motion to dismiss in part, holding that in its March 2018 announcement, the company "did not sufficiently reveal the bad (TSS and remission) with the good (survival)." Indeed, the company stated in March 2018 that TSS results "remain consistent with prior data reviews." The court also concluded that plaintiffs had adequately pled scienter as to the March 2018 statements, based on defendants' close monitoring of trial data and two employees' stock sales. The court granted dismissal as to the company's favorable statements about survival, statements about another unfavorable metric (spleen volume reduction), and certain disclosures of risks that had not yet come to pass.

Kuhne v. Gossamer Bio, Inc., 2021 WL 1529934 (S.D. Cal. Apr. 19, 2021), denying in part motion to dismiss. Phase 2

Gossamer developed GB001, a treatment for asthma and allergic conditions. GB001 is an antagonist of DP2, a receptor involved in inflammatory processes that contribute to asthma. In October 2018, Gossamer began a Phase 2 trial for GB001. In February 2019, the company conducted its IPO at $16 per share. In the offering documents, Gossamer stated that DP2 antagonism had been validated by an earlier study conducted by its competitor Novartis. The company also stated that interim results of its own Phase 2 trial would be available in the first half of 2020, and that if those results supported further development, the company would initiate a Phase 3 trial. In October and December 2019, Novartis, Gossamer's competitor, reported that its Phase 3 trials had been unsuccessful, and that it was discontinuing development of its asthma drug. Gossamer did not release interim Phase 2 data. By April 2020, the company's stock price had fallen to just over $10.

Investors sued, asserting claims under the Securities Act based on statements in Gossamer's offering documents. The court denied the company's motion to dismiss in part, permitting plaintiffs to move forward with their challenge to the company's statement that interim Phase 2 results would be available in the first half of 2020. Because Gossamer did not make those results publicly available, plaintiffs had adequately pled falsity. (Plaintiffs were not required to plead scienter.) The court granted the company's motion as to Gossamer's description of Novartis' study of DP2. Plaintiffs alleged that Gossamer's description differed from Novartis' description,

but those differences did not make Gossamer's statements materially misleading. The court also rejected plaintiffs' challenge to Gossamer's statements about its plans to begin a Phase 3 trial for GB001. Plaintiffs argued that those statements signaled that Gossamer would commence Phase 3 without waiting for complete results from Phase 2, but the language in the offering materials was far more conditional: The company stated that it would initiate a Phase 3 trial *if* the Phase 2 data supported it.

Kendall v. Odonate Therapeutics, Inc., 2021 WL 3406271 (S.D. Cal. Aug. 4, 2021), denying motion to dismiss. **Phase 3**

Odonate developed tesetaxel, a chemotherapy drug for patients with locally advanced or metastatic breast cancer. In December 2017, the company announced that it was initiating CONTESSA, a Phase 3 study of tesetaxel in combination with an already-approved cancer drug, capecitabine. By the summer of 2018, CONTESSA trial sites reported that patients were experiencing a higher rate of neutropenia (low white blood cell count) than expected. As a result of both the neutropenia rates and other adverse events, patients began withdrawing from the trial. In August 2018, Odonate held a call with clinical site management regarding the neutropenia rates, and trained personnel at the trial sites how to identify early signs of neutropenia. Some trial sites implemented a revised trial protocol to address neutropenia; others dropped out. In June 2019, the company conducted a secondary offering. In August 2020, the company announced top-line results from CONTESSA. Although the trial met its primary endpoint, 71% of the patients on the treatment arm experienced neutropenia; this contrasted with only 8% on the control arm (treatment with capecitabine alone). Odonate's stock fell 45%. In September 2020, the company conducted another secondary offering. In March 2021, the company announced that the FDA had told it that approval of tesetaxel was unlikely on the existing clinical data. The company's stock fell 79%. Later in March 2021, Odonate reported that it was discontinuing tesetaxel development and winding down operations. The stock fell 14%.

Investors sued, challenging the company's statements about the CONTESSA trial, patient outcomes and likelihood of FDA approval. The court denied the company's motion to dismiss. The court concluded that plaintiffs had adequately pled falsity with respect to statements regarding enrollment in CONTESSA based on the company's failure to disclose that 10% of trial sites had dropped out and needed to be replaced. Plaintiffs' attack on statements related to tesetaxel's potential was also sufficient in light of the company's failure to disclose neutropenia rates and other adverse events. The same was true of Odonate's report of top-line trial results, given the company's failure to disclose the revised trial protocol and neutropenia training. Plaintiffs had also adequately pled scienter. Confidential witness allegations were particularized and cross-corroborated, and plaintiffs had alleged that Odonate's executives were told about the elevated neutropenia rates and were involved in the protocol change. The timing of the secondary offerings, combined with the company's failure to disclose the change in trial protocol, further supported a strong inference of scienter.

Alberici v. Recro Pharma, Inc., 2021 WL 798299 (E.D. Pa. Mar. 1, 2021), denying motion to dismiss. **NDA**

Recro developed IV meloxicam, a nonopioid pain medication for post-surgical use. The company conducted clinical trials on patients recovering from both soft-tissue and hard-tissue surgeries. The company publicly reported the trial results and submitted an NDA in July 2017. The FDA rejected the application in May 2018. In the Complete Response Letter, the FDA (1) raised issues related to manufacturing (which was done by an offshore contractor), and (2) concluded that the trials failed to demonstrate sufficient analgesic effect for approval. Later, however, the FDA approved meloxicam for use after both soft-tissue and hard-tissue surgeries.

Investors sued, alleging that Key Opinion Leaders (KOLs) had told the company that they were concerned about both the overseas manufacturing process and meloxicam's efficacy in soft-tissue procedures, and that the company had misleadingly omitted the KOLs' concerns when discussing these subjects. In a 2020 decision (discussed in last year's review), the court granted the company's motion to dismiss on scienter grounds. Plaintiff's scienter allegations were based largely on a confidential witness account, and that account was insufficiently detailed.

Plaintiff amended and the company again moved to dismiss. This time, the court denied the motion, holding that plaintiff had rectified the deficiencies in its confidential witness allegations. The new allegations showed when and how the witness informed (or saw others informing) the individual defendants of the KOLs' concerns. This was sufficient as a pleading matter to establish that the defendants were aware of those concerns and intentionally or recklessly concealed them from investors. The court also concluded that plaintiff's falsity allegations were sufficient, notwithstanding the FDA's eventual approval of meloxicam. Subsequent approval, the court held, did not show that the challenged statements were not false or misleading when made, and plaintiff had adequately pled that the omission of information about the KOLs' concerns made the company's statements about target opportunities in the soft-tissue surgery market misleading. As to manufacturing, the company had stated that multiple internal managers provided oversight; plaintiff adequately pled falsity by means of an allegation that only one internal manager had done so.

McDermid v. Inovio Pharms., Inc., 520 F. Supp. 3d 652 (E.D. Pa. 2021), denying in part motion to dismiss. **Development of COVID vaccine**

Inovio, which develops drugs to fight infectious diseases, ramped up efforts to develop a COVID vaccine in 2020. On March 2, 2020, Inovio's CEO stated during a televised meeting with President Trump that the company had "fully construct[ed] [its vaccine] within three hours" of accessing the genetic sequence of the novel coronavirus. The company's stock rose 70%. One week later, however, in response to a skeptical short-seller report, Inovio stated that it had "designed" (rather than "constructed") a vaccine. The stock fell 70%. Over the next several months, Inovio made statements about its relationships with three different manufacturing partners or potential manufacturing partners. Inovio announced in April 2020 that it planned to produce one million doses of the vaccine by the end of 2020 and in May 2020 that it was "on track" to do so. Also in May 2020, Inovio conducted an at-the-market offering, listing as a risk factor in its offering documents the potential failure to secure or maintain relationships with manufacturing partners. In June 2020, Inovio reported that it had been selected for participation in Operation Warp Speed.

Investors sued, challenging the company's statements about (1) its ability to "construct" a vaccine, (2) its manufacturing plans and capabilities, and (3) its selection for Operation Warp Speed. The court denied the company's motion to dismiss as to the first two categories of statements but granted it as to the third. With respect to Inovio's ability to "construct" a vaccine, the court credited plaintiffs' theory that vaccine "construction" is a far more advanced stage of development than "design," and that at the time of the challenged statement, Inovio had not "constructed" a vaccine. The court also concluded that plaintiffs had adequately alleged scienter as to the "construction" statement, based on the executives' experience and on motives furnished by individual stock sales (albeit according to trading plans) and the company's own offering. With respect to manufacturing capability, the court rejected the company's argument that the challenged statements were forward-looking: Inovio referred to capacity and to its progress in meeting projections ("on track") in the present tense. Plaintiffs had adequately pled falsity and scienter as to the challenged manufacturing statements by means of allegations that the company's original manufacturer had refused to make a technology transfer to a second manufacturer, and that a third manufacturer lacked the capacity Inovio attributed to it. The same allegations sufficed as to plaintiffs' attack on the challenged risk disclosure in Inovio's offering documents. The company stated there that its performance *could* suffer if it encountered difficulties in its manufacturing relationships; plaintiffs' allegations, however, indicated that this had already occurred. By contrast, the court granted the company's motion to dismiss as to the Operation Warp Speed statement. Plaintiffs claimed that Inovio had misleadingly suggested that it was receiving government funding under Operation Warp Speed, but the company did not say that.

In re Vaxart, Inc. Sec. Litig., 2021 WL 6061518 (N.D. Cal. Dec. 22, 2021), denying motion to dismiss. **Development of COVID vaccine**

Vaxart, a vaccine development company, underwent major changes when a hedge fund, Armistice, acquired a majority stake in late 2019. With the advent of the COVID-19 pandemic, Vaxart sought to position itself as a recipient of public funding for vaccine development through Operation Warp Speed. The government had announced that as many as eight companies might be chosen to receive funds. By early June 2020, five recipients had been announced—none of

which was Vaxart—and commentators speculated about who the others might be. On June 18, the company stated that it would commence Phase 1 trials in the summer of 2020, and compared its vaccine candidate to those of companies that had already been selected for Operation Warp Speed. On June 25, Vaxart announced that it had signed a memorandum of understanding with a contract manufacturer, Attwill, which could produce a billion or more COVID-19 vaccine doses per year. On June 26, the company reported that it had been "Selected for the U.S. Government's Operation Warp Speed." Smaller print in the same press release clarified that the company had been selected to participate in a primate study within Operation Warp Speed, which is different from being chosen to receive funds as a primary vaccine developer. The company's stock price rose 28%. On July 25, 2020, the New York Times published an article about the profits Armistice had made in selling Vaxart stock, and stated that some companies appeared to be exaggerating their role in Operation Warp Speed in an effort to inflate stock price. The same day, the Department of Health and Human services tweeted that while it had entered into funding agreements with certain vaccine manufacturers, Vaxart was not among them. Vaxart's stock fell 9%.

Investors sued, challenging the company's statements about its partnership with Attwill as well as its statement that it had been "selected" for Operation Warp Speed. The court denied the company's motion to dismiss. In the court's view, the case was unusual. Whether plaintiff had adequately pled falsity, the court explained, was a far closer call than whether it had adequately pled scienter—but ultimately plaintiff had done both. It had adequately pled falsity as to Vaxart's statements about the Attwill partnership based on the allegation that Attwill lacked the regulatory capacity to produce any dose, let alone one billion doses. As to scienter, the court credited plaintiff's allegation that Vaxart either knew about Attwill's limitations or was reckless in failing to perform due diligence before touting the partnership. With respect to Vaxart's statement that it had been "selected" for Operation Warp Speed, plaintiff had adequately pled that this was misleading. Although the company accurately reported that it had been chosen only for participation in the primate study—and not as a recipient of federal funds—the headline statement was misleading in context, given that the market was primed for the identification of companies that would receive funds. The court declined to follow Inovio (discussed immediately above), in which a challenge to similar statements about selection for Operation Warp Speed was dismissed. The Vaxart court explained that it could not tell whether the format of the announcement at issue in Inovio was similar to the headline/small print format before it, and could not tell whether the Inovio court had adequately considered such contextual issues. The same headline/small print format supported an inference that Vaxart intended to deceive the market. The court did dismiss one claim: plaintiff's scheme claim against Armistice, the hedge fund that had taken a majority position in Vaxart in 2019. The court noted that by the time Vaxart made the challenged statements, Armistice had sold the vast majority of its Vaxart stock.

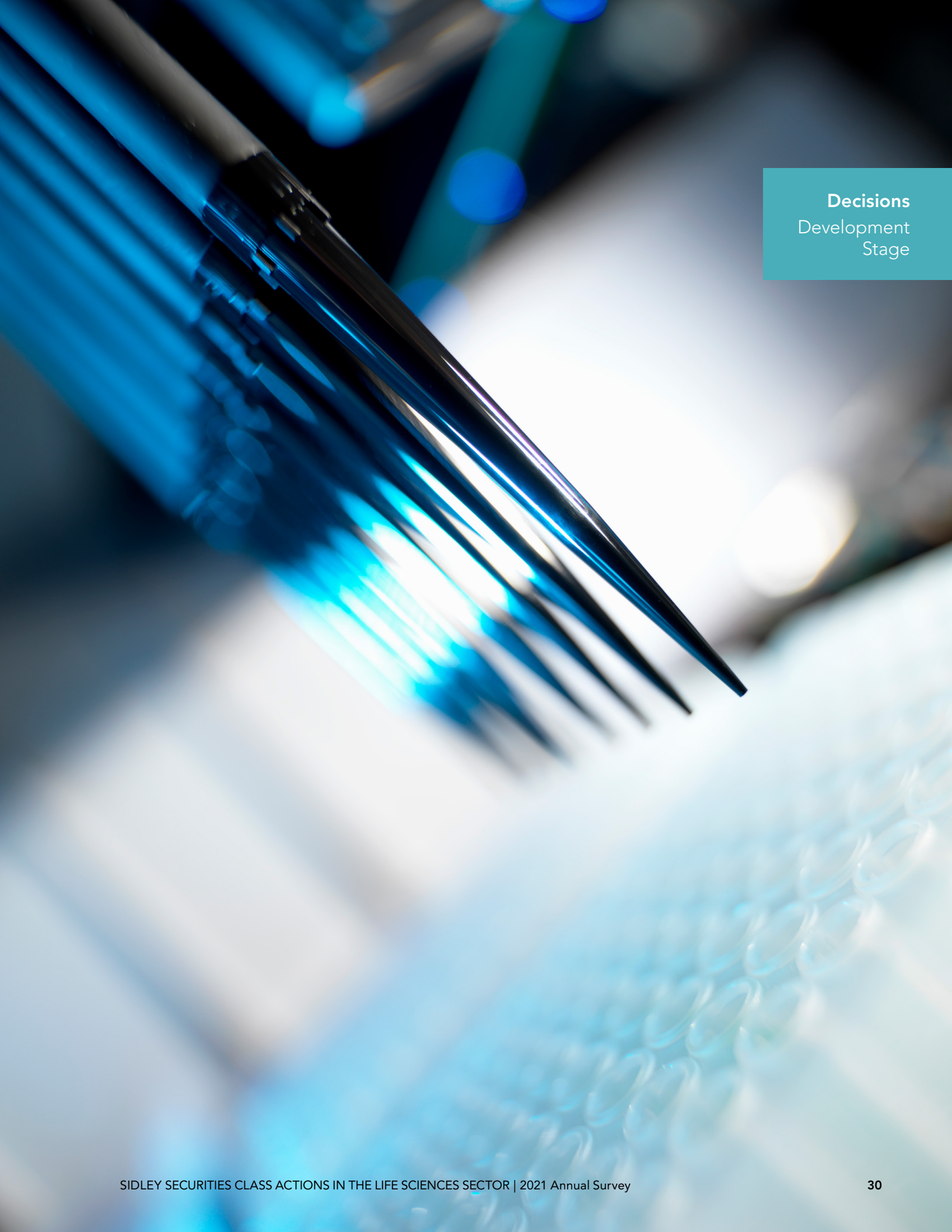
Dahhan v. OvaScience, Inc., 2021 WL 2186466 (D. Mass. May 28, 2021), denying motion to dismiss.
Liability of founders/financiers

Securities litigation against OvaScience, which develops fertility treatments, has been ongoing since 2017. Rather than pursuing clinical trials under FDA oversight, OvaScience offered its treatments in foreign IVF clinics, first free of charge and later for payment. Investors sued after the company failed to meet projections for paid treatments. The court denied the company's motion to dismiss in 2018 (reported in our review for that year) and litigation moved forward. In 2019, plaintiffs sought leave to amend in order to add three new defendants. Given other proceedings in the case, the court deferred ruling on the statute of limitations issues implicated by the amendment. In 2021, those issues became ripe when the newly-added defendants moved to dismiss.

The court denied the motion to dismiss. The three new defendants were a fund that had cofounded OvaScience, the general partner of the fund and one of the founders of the fund. Plaintiffs' theory was that the new defendants were controlling persons of OvaScience under Section 20(a) of the Exchange Act and hence liable for false or misleading statements the company made in violation of Section 10(b). The new defendants argued that the plaintiffs had discovered or should have discovered the relevant facts in 2015, and that the amendment was therefore untimely under the applicable two-year statute of limitations. The court rejected that argument. While OvaScience revealed in 2015 that it would miss its paid-treatment goal,

this did not trigger the two-year limitations period even for the underlying Section 10(b) claim. Under the Supreme Court's 2010 *Merck* decision, the limitations period begins to run not when plaintiffs should begin inquiring into fraud but only when they know or should know of the facts constituting the alleged fraud, including the element of scienter.[13] That did not occur until 2017. Even then, defendants had not shown that the plaintiffs had or should have discovered facts relevant to control, which, under First Circuit standards, requires active participation in decision-making processes.

13 *Merck & Co. v. Reynolds*, 559 U.S. 633 (2010).



Decisions
Development Stage

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 32–44), 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, defendants had a slight edge in the district court decisions. Defendants won motions to dismiss or for summary judgment in nine cases and lost their motions (at least in part) in seven. All but one of the cases in which companies were unsuccessful involve allegations of improper sales or marketing practices. The victories cover a wider variety of situations. A number of the cases in which companies prevailed arise simply from missed guidance, without any regulatory issues.

Decisions in the appellate courts are divided: one victory for defendants in a published decision from the First Circuit and one partial defeat in an unpublished decision from the Ninth Circuit.

APPELLATE DECISIONS

Karth v. Keryx Biopharms., Inc., 6 F.4th 123 (1st Cir. 2021), affirming dismissal. **Manufacturing; supply shortage**

Keryx sold Auryxia, a drug for kidney disease approved in 2014. Auryxia was manufactured in a two-step process. Keryx contracted with multiple companies to perform the first step, which was to manufacture the active pharmaceutical ingredient (API). For the second step, Keryx used a single manufacturer, Norwich. In its risk disclosures through the end of 2015, Keryx referred to manufacturing issues that might arise with "third parties"—using this plural form notwithstanding the existence of only a single second-step manufacturer. In the Form 10-K it filed in February 2016, Keryx amended the risk disclosure, now stating that the company had a "single supply source" for Auryxia. Keryx included a similar risk disclosure in its subsequent Form 10-Q, filed in April 2016. The day before Keryx filed the Form 10-Q, Norwich had informed the company of issues related to contaminated API. Norwich and Keryx were able to resolve the April 2016 issue and avoid supply shortages. But new issues arose in July 2016, and this time the companies were unable to resolve them. Keryx reported the risk of a supply shortage to the FDA that month, and told investors in August 2016 that a supply shortage was imminent. The company's stock price fell 36%.

Investors sued, alleging that Keryx had misled the market by failing to disclose the risks associated with a single manufacturer and the fragility of Auryxia's manufacturing process. After the completion of significant discovery, the company moved for judgment on the pleadings. The district court granted that motion on loss causation grounds in 2019 (reported in our 2019 survey). The court held that the company's references to a single supplier in February and April 2016 corrected any earlier misstatements about plural "third parties" manufacturing Auryxia. The court noted that plaintiff had purchased stock only after the February and April 2016 disclosures, and denied plaintiff's motion for leave to amend.

The First Circuit affirmed. Plaintiff's sole contention on appeal was that the district court had erred in denying leave to amend. The theory plaintiff sought to pursue in the amended complaint was that the February and April 2016 risk disclosures—which plaintiff now conceded had corrected any misimpression that Keryx was using multiple second-stage manufacturers—were themselves misleading given the magnitude of the risk associated with a single supplier. The First Circuit rejected that theory. The court recognized that risk disclosures may be misleading if they present a near-certainty or an already-materialized risk as a mere contingency. But plaintiff had not shown that this was the case, particularly as Keryx and Norwich were able to resolve the manufacturing issue that arose in April 2016.

New York Hotel Trades Council & Hotel Ass'n of N.Y.C., Inc. Pension Fund v. Impax Labs., Inc., 843 F. App'x 27 (9th Cir. 2021), reversing dismissal in part and affirming in part. **Antitrust**

Impax develops, manufactures, and markets generic drugs. In July 2014, the Connecticut Attorney General began a broad investigation into generic drug pricing, and Impax reported that it had received a subpoena requesting documents related to one of its drugs. In November 2014, Impax announced that one of its sales representatives had received a grand jury subpoena from the DOJ's antitrust division, also regarding the sale of generic drugs. In March 2015, Impax received a grand jury subpoena related to four of its generic drugs. In November 2016, Bloomberg reported that criminal charges in the DOJ's antitrust investigation were expected by year-end, and it identified Impax as a recipient of a DOJ subpoena. Impax's stock price fell 20%. The company's stock price had also fallen in May and August 2015, after it reported quarterly earnings misses.

Investors sued, alleging that Impax was part of a generic drug price-fixing conspiracy, and that its failure to disclose this rendered various statements about its business and finances misleading. The district court dismissed plaintiffs' claims without prejudice in 2018 and with prejudice in 2019 (reported in our reviews for those years). In its 2019 decision, the district court dismissed the price-fixing-related claims solely on loss causation grounds. With respect to the November 2016 Bloomberg article, the court cited case law holding that the announcement of an investigation cannot in itself establish loss causation. As to the May and August 2015

announcements, plaintiffs had tied the company's earnings misses only to the entrance of a new competitor, and not to the alleged fraud. The court also dismissed plaintiffs' attack on the company's statements about the drug diclofenac, whose price was declining; the court concluded that the statements were accurate representations of past performance, were not adequately alleged to have been misleading, or were non-actionable puffery or opinions. Finally, the court dismissed plaintiffs' attack on the company's positive statements about its acquisition of a second drug, budesonide, on scienter grounds. The stronger inference was that the company had honestly overvalued the acquisition, not that it sought to deceive investors about the value of the drug.

The Ninth Circuit reversed in part. The appellate court held that plaintiffs had adequately pled loss causation with respect to the May and August 2015 earnings misses. Plaintiffs alleged that these misses were the result of the company's actions in yielding market share to competitors as part of the purported conspiracy; plaintiffs had thereby traced the stock drop back to the subject of the alleged fraud (the conspiracy and its concealment). By contrast, the Ninth Circuit agreed with the district court that the November 2016 Bloomberg report could not establish loss causation: The stock drop following publication of the report reflected only market speculation about the accuracy of media speculation about criminal liability. The same was true of a stock drop that followed the DOJ's intervention in a civil suit against Impax. As to diclofenac, the court again reversed, holding that plaintiffs had adequately alleged that the company misstated the extent of past price erosion and adequately alleged actual knowledge of falsity with respect to projections of future performance. The court affirmed dismissal of the challenged statements about budesonide, reaching the same conclusion about scienter the district court had reached.

DISTRICT COURT DECISIONS—MOTION TO DISMISS GRANTED

Industriens Pensionsforsikring A/S v. Becton, Dickinson & Co., 2021 WL 4191467 (D.N.J. Sept. 15, 2021), granting motion to dismiss without prejudice. **510k clearance**

In 2015, Becton, Dickinson acquired the right to manufacture, market and distribute Alaris, an infusion pump system that delivers fluids (including medications) into a patient's body. The FDA classifies infusion pumps as Class II medical devices. Under the FDA's 510k program, these devices must receive clearance when first introduced (Alaris received clearance in 1995) and when modified in a way that significantly impacts their safety or efficacy. In the years before BD acquired Alaris, the product was subject to multiple recalls and to a government forfeiture action resulting in successive consent decrees. Recalls continued after BD acquired Alaris, including five recalls in 2016 and five in 2017. In November 2017, BD submitted a 510k application addressing changes made to the device. In April 2018, the company learned that the FDA would not accept the 510k application and withdrew it. Following an inspection in late 2018, the FDA issued a Form 483 identifying deficiencies in Alaris-related quality systems. In November 2019, the company imposed a shipping hold on Alaris. In February 2020, the company reported that the FDA had halted sales of Alaris and instructed it to submit a comprehensive 510k application covering all past recall remediation changes, software upgrades and other modifications made to the product. The company's stock fell 12%.

Investors sued, challenging the company's statements about software changes made to Alaris, risk disclosures addressing the effects of regulatory action, and financial statements and guidance. The court granted the company's motion to dismiss. The court observed generally that plaintiffs' case depended on the premise that BD knew or was required to predict that the FDA would require a comprehensive 510k application. The court rejected that theory, observing that companies have discretion in filing 510k applications after modifying products, and cannot be required to predict whether the FDA will conclude that a given modification crosses the threshold at which 510k approval is required. In the court's view, the FDA's inaction before February 2020 illustrated the impropriety of requiring companies to predict government conduct. Plaintiffs' claims also failed for reasons specific to each category of challenged statements. The court rejected as "mere pedantry" plaintiffs' contention that BD's reference to software "updates" masked the magnitude of software "remediations" required to protect patient safety. The company's risk disclosures were not false or misleading either. Plaintiffs argued that the disclosed

risk—that FDA action would affect sales—had already come to pass during the putative class period, but this was not true. Plaintiffs similarly failed to plead facts showing that BD's reports of financial results were inaccurate, while the company's revenue guidance came within the PSLRA's safe harbor for forward-looking statements. Plaintiffs also fell short on scienter grounds. Their confidential witnesses did not speak to the individual defendants' state of mind, let alone show that the defendants knew the FDA would halt sales in 2020. The stronger inference—particularly in light of the FDA's inaction after the company submitted and then withdrew a 510k application in 2017-18—was that the agency would *not* require comprehensive 510k approval. Plaintiffs' allegations about executive stock sales and invocation of the core operations doctrine did not put their scienter allegations over the bar.

In re Galena Biopharma, Inc. Sec. Litig., 2021 WL 50227 (D.N.J. Jan. 5, 2021), granting motion to dismiss without prejudice. **Opioid marketing**

Galena sold Abstral, an opioid used to manage breakthrough pain in cancer patients. The active ingredient in Abstral is fentanyl, the most powerful prescription opioid available. Most of Galena's Abstral sales were driven by a small number of clinics. On May 20, 2015, federal law enforcement officials raided clinics run by two physicians who were later convicted of opioid-related crimes; those clinics were important customers of Galena. Galena's stock price fell 7% after August 6, 2015, when the company hosted its first quarterly earnings call post-dating the raids. In November 2015, Galena announced that it was divesting its commercial business and had sold Abstral. The company's stock fell 11%. In December 2015, Galena announced that it had received a subpoena related to Abstral; its stock fell 3.6%. In May 2016, Galena reported that the government could be investigating its own Abstral sales practices, and its stock fell 7%. Finally, Galena announced the resignation of its CEO in January 2017 and its stock fell 22%.

Investors sued, claiming that Galena had misleadingly understated its exposure to criminal and civil liability for Abstral marketing and had failed to disclose that its sales growth was (purportedly) driven by illegal marketing and kickbacks. The court granted the company's motion to dismiss without prejudice in 2018 (reported in our review for that year) and again in 2019 (reported in our 2019 review). The court concluded in the latter decision that plaintiffs had potentially succeeded in alleging both falsity and scienter as to the company's positive statements about Abstral sales on August 6, 2015—after the government raids—but that plaintiffs' "shotgun approach" left the court "unable to effectively separate the wheat from the chaff."

Plaintiffs amended and the court again dismissed, concluding in its 2021 decision that plaintiffs had adequately pled both falsity and scienter but had come up short on loss causation. Plaintiffs adequately alleged falsity with respect to the company's statements about its financial performance before August 6, 2015. The court noted that as a legal matter, accurate statements of past earnings "can be materially misleading if [a company] attributes such earnings to lawful activity when they are not in fact attributable to such activity." Plaintiffs' factual allegations fit within that legal principle: Plaintiffs had adequately alleged that Galena was involved in illegal kickback arrangements with the raided clinics and that its income from the clinics was material to its financial performance. Plaintiffs had similarly pled falsity as to the company's statements on its August 6, 2015 earnings call, which post-dated the May 20, 2015 raids. The company continued to speak positively about Abstral sales notwithstanding the fact that important customers had been shut down by the government. As to scienter, plaintiffs had adequately pled that company executives knew about allegedly improper kickback arrangements.

Plaintiffs' loss causation allegations, however, were inadequate. Plaintiffs' theory was that when undisclosed risks related to falling Abstral sales and the criminal investigation materialized, the company's stock fell and they incurred investment losses. But the risk of falling sales became irrelevant when the company divested its Abstral business in November 2015. And the company's January 2017 announcement that its CEO had resigned—which was followed by a 22% stock drop, and which plaintiffs claimed reflected the materialization of the risk of criminal liability—did not relate to criminal wrongdoing. Confusingly, the court concluded that plaintiffs' loss causation allegations *were* adequate as to the November 2015 disclosure, which reflected the materialization of a risk allegedly concealed by the company's positive statements

about Abstral sales on August 6, 2015. The court did not explain why, given that conclusion, it did not deny the motion to dismiss in part. The court also gave plaintiffs leave to amend, which would result in a virtually unprecedented fourth successive complaint—or fifth counting the complaint filed before the lead plaintiff was appointed.

Turnofsky v. electroCore, Inc., 2021 WL 3579057 (D.N.J. Aug. 13, 2021), granting motion to dismiss. **Competition; reimbursement**

electroCore manufactures gammaCore, a device that treats cluster headaches and migraines by stimulating the vagus nerve. The FDA cleared gammaCore for commercial sale in April 2017. In June 2018, the company conducted its IPO, stating in the offering documents that gammaCore's advantages included "ease of use and suitability… without the frequency-of-use restrictions and contraindications associated with other treatments." The company also stated that it had entered into agreements with third party payers. In May 2019, the company announced that it had missed first-quarter revenue expectations; 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 coverage reimbursement. The stock fell 10%. In September 2019, the company disclosed that the FDA had requested an analysis of clinical data for its 510k submission. The stock fell 23%.

Investors sued under both the Securities Act and the Exchange Act, challenging electroCore's statements about its competitive strengths, the extent of its agreements with third-party payers, the extent of physician acceptance of gammaCore and the financial challenges the company faced. The court dismissed the Securities Act claims on falsity grounds. The company's opinions about gammaCore's competitive advantages did not mislead investors about other devices entering the market, particularly as the company had extensively disclosed the risk of competition. As to coverage and reimbursement, plaintiff did not dispute that electroCore had certain agreements in place with payers, and had not shown that investors would be misled by the company's projections about additional reimbursement agreements it was seeking; read in context, the company's statements did not imply that coverage would be provided without limitation. The company did not omit information about challenges in obtaining acceptance by physicians; it disclosed barriers to acceptance. As to plaintiffs' contention that electroCore omitted information about financial and product challenges, plaintiffs had identified no statement rendered misleading by the purported omissions.

The court dismissed plaintiff's Section 10(b) claim for similar reasons. Plaintiffs again challenged statements in the IPO documents, together with similar statements in subsequent SEC filings, and failed to plead falsity with the particularity required by the PSLRA. Plaintiffs also claimed that the company had misleadingly omitted from its Form 10-K the fact that gammaCore is generally used as a supplement to other treatments—but the company's description of its 510k clearance revealed that limitation. Plaintiff's Section 10(b) claim also failed on scienter grounds. Plaintiff relied on motive and opportunity allegations that are no longer sufficient in the Third Circuit, and on the boilerplate contention that the company's executives were part of a "highly experienced management team."

Plymouth Cnty. Ret. Ass'n v. ViewRay, Inc., – F. Supp. 3d –, 2021 WL 3773330 (N.D. Ohio Aug. 25, 2021), granting motion to dismiss with prejudice. **Sales performance; backlog**

ViewRay manufactures the Linac MRIdian, a $6 million medical device approved by the FDA in 2017 and used in radiation treatments for cancer patients. Because a customer needs time to prepare its facility for installation of the device, and ViewRay needs time to install it, the time between the placement of an order and ViewRay's receipt of revenue is 12-18 months. In public disclosures, ViewRay discussed the subjective and objective factors it considered in determining whether an order should be included in the backlog figures it reported. Those factors included the existence of an agreement and financing, a customer's expressions of intent over the 12-18 month period, changes in a customer's plans or financial condition, and regulatory requirements in the customer's jurisdiction. In early 2019, ViewRay valued its backlog in excess of $200 million. But in the summer of the same year, the company reported a $31 million loss, cut its revenue target and disclosed the removal of orders from the backlog. The stock price dropped 54%. In

late 2019, ViewRay told investors that backlog was stable and increasing, with a value of $231 million. In January 2020, the company again disclosed slow growth, and its stock fell 23%.

Investors sued, claiming that ViewRay failed to follow its own criteria for including orders in the backlog, and hence that its statements about those criteria were false. The court rejected that claim, noting that the company disclosed that some criteria were subjective and further warned that backlog was difficult to estimate. The court also rejected plaintiffs' allegations that the company had included sham orders in the backlog: Those allegations were based on insufficiently supported confidential witness accounts. Plaintiffs' attack on the numerical values of backlog the company reported also failed: Plaintiffs had not pled facts showing that the values were incorrect. (The court disagreed with the company, however, that the backlog values could be considered statements of opinion.) Meanwhile, the company's revenue forecasts came within the PSLRA's safe harbor for forward-looking statements, as they were accompanied by meaningful cautionary disclosures. Plaintiffs finally failed to plead a strong inference of scienter, given the defects in their allegations concerning sham transactions, as well as the strength of company's risk disclosures.

In re Synergy Pharms., Inc. Sec. Litig., 2021 WL 4480625 (E.D.N.Y. Sept. 30, 2021), granting motion to dismiss with prejudice. **Sales performance and formulary listing; financing**

Synergy's sole product was Trulance, a treatment for chronic idiopathic constipation (CIC). In November 2016, Synergy issued a press release stating that Trulance "was associated with low adverse events," and that the company was "encouraged about the positive impact that [the drug] will have in the market place as a differentiated therapeutic option for patients with CIC." The FDA approved Trulance in January 2017; at the time, the company had two competitors. In February 2017, a third party paid by the company published a "Guide to CIC," which stated: "Now there's a treatment that treats constipation without causing diarrhea." At investor conferences in March and May 2017, Synergy stated that Trulance, unlike other treatments, did not cause patients to cycle between constipation and diarrhea. In July 2017, pharmacy benefits management company Express Scripts released its National Preferred Formulary, which included Trulance's two competitors but not Trulance. The company's stock price fell 4%. In August 2017, the company published second-quarter results showing that revenue growth had slowed. The stock fell 13%. In November 2017, the company reported third-quarter results reflecting a further slowdown in prescriptions. The stock fell 8%. Synergy filed for bankruptcy in 2018.

On the financing side, Synergy entered into a $300 million term loan agreement in September 2017, with financing available in tranches. To obtain the second $100 million tranche, Synergy had to maintain cash or cash equivalents of $128 million. The company disclosed the loan in a September 5, 2017 Form 8-K, noting that it was required "to comply with a minimum market capitalization covenant" but not specifying the $128 million figure. During an analyst call on September 7, 2017, the company described the loan as non-dilutive and stated that it provided access to capital if and when needed. Two months later, on November 9, 2017, Synergy publicly filed the loan agreement for the first time, as an attachment to its Form 10-Q. On November 13, 2017, Synergy announced a secondary stock offering, and its stock fell 10%. The company filed its prospectus the next day, and the stock fell another 17%.

Investors sued, claiming that the company misleadingly suggested that Trulance's side effect profile was superior to that of its competitors and concealed the cash condition in the term loan agreement. The court granted defendants' motion to dismiss, rejecting both theories. With respect to Trulance's side effects, the court concluded that the company's statements, read in context, did not suggest that Trulance was superior to competitor drugs. Plaintiffs also failed to plead loss causation with respect to these statements: Plaintiffs did not allege that Express Scripts excluded Trulance from its formulary because of concerns about side effects, nor that slowing growth in the second and third quarters of 2017 was the result of side effects. With respect to the loan, plaintiffs adequately alleged that Synergy's omission of the $128 million condition rendered its statement that the loan was "non-dilutive" misleading. The court credited plaintiffs' theory that the company could meet the condition only by means of the secondary offering announced on November 13, 2017, which was dilutive. The court also concluded that plaintiff had adequately pled falsity with respect to the company's statement

that the loan provided it with access to capital if and when needed. But plaintiffs failed to plead scienter. Synergy publicly filed the loan agreement containing the cash condition with its November 9, 2017 Form 10-Q; critically, this was before the company announced the secondary offering on November 13. The timing of these events was inconsistent with an intent to deceive investors about financing arrangements.

Villare v. Abiomed, Inc., 2021 WL 4311749 (S.D.N.Y. Sept. 21, 2021), granting motion to dismiss without prejudice. **Sales performance**

Abiomed develops, manufactures, and markets heart pumps, Class III medical devices requiring premarket approval for sale to the public. In 2015, one of the company's models was granted a humanitarian exemption, which lifts effectiveness requirements. A period of substantial revenue growth followed. In February 2019, the FDA issued a letter to health care providers regarding clinical studies of the pump. Although a pre-market study had yielded a 30-day survival rate of 73%, a subsequent post-approval study reflected only a 17% survival rate. Inclusion and exclusion criteria were looser in the post-approval study, and the FDA identified various complicating heart disease events that affected patients in the later study, warning physicians that patients who experience such events may have lower survival rates. The company missed analysts' revenue expectations for the March 31, 2019 quarter. In May 2019, the FDA issued a second letter, noting that in the post-approval study, the 30-day survival rate of patients who would have qualified for the pre-market study was 64%, while the survival rate of those who would not have qualified was 11%. The FDA also stated that for patients who fit within the device's approved indication, benefits outweighed risks. The company again reported disappointing results for the June 30, 2019 quarter, and revised annual revenue guidance downward. The stock fell 26%.

Investors sued, challenging Abiomed's statements about revenue performance and growth, including the company's November 2018 statement that it was "positioned for sustainable growth." Plaintiffs' theory was that Abiomed's device had already achieved market penetration. The court granted the company's motion to dismiss. The court drew on Second Circuit law holding that a company cannot be liable under Section 10(b) simply for failing to disclose that its business is purportedly not sustainable in the long term. The court also noted that plaintiffs' unsustainability allegations were based on the subjective views of confidential witnesses, and that the company had provided detailed financial information about market penetration. In addition, many of the challenged statements were nonactionable puffery, forward-looking statements protected by the PSLRA safe harbor, or opinion statements as to which plaintiffs failed to comply with the applicable *Omnicare* framework. Plaintiffs' scienter allegations were also deficient. Stock sales pursuant to Rule 10b5-1 trading plans were not suspicious, the subjective views of confidential witnesses regarding limitations on growth did not necessarily reflect the company's views, and the core operations doctrine could not on its own support an inference of deliberate fraud.

In re Align Tech., Inc. Sec. Litig., 2021 WL 1176642 (N.D. Cal. Mar. 29, 2021), granting motion to dismiss without prejudice. **Sales performance**

Align is a medical device company that sells Invisalign, a set of plastic braces for the treatment of misaligned teeth. The company operates globally, with a focus in recent years on sales in China. In July 2019, the company announced its second-quarter financial results, reporting that sales growth in China had fallen to a range of 20-30%. Align's stock price dropped.

Investors sued, challenging the company's statements about sales growth earlier in 2019. The court granted the company's motion to dismiss. Many of the challenged statements were non-actionable expressions of generalized corporate optimism. This included both obviously "puffing" statements such as "dynamics in China are really good for us," and the statement that annual sales growth was 70%. The latter statement, which the company made on March 1, 2019, referred to growth in 2018, not growth in the second quarter of 2019. Plaintiffs' attack on the company's more concrete statements about sales growth also failed on falsity grounds. This category included statements about competition, list pricing, and demographic and economic features of the Chinese market. Plaintiffs failed to allege facts showing that any of these statements was false when made. The court separately addressed plaintiffs' claim that Align omitted negative information about sales growth necessary to make its positive statements not

misleading. That negative information, according to plaintiffs, was that sales were down in the first two months of the quarter, April and May. But plaintiffs failed to plead facts supporting that assertion. Their claim was based on the company's statement in July 2019 that it became aware of issues with sales growth in June 2019. Plaintiffs saw this as an implicit admission that sales had been weak in April and May, and that a strong performance in June was needed to compensate. The court rejected that interpretation of Align's July 2019 statement, which it held could *not* fairly be characterized as an admission that "I knew it all along."

In re Aceto Corp. Sec. Litig., 2021 WL 4350501 (E.D.N.Y. Mar. 16, 2021), denying motions to amend judgment of dismissal. **Supply chain**

Aceto developed and distributed pharmaceutical products. In November 2016, Aceto acquired approximately 80 generic drug products from two companies, Citron and Lucid. Those companies had used an Indian company called Aurobindo to manufacture the drugs, and when Aceto acquired the drugs, it entered into its own supply agreement with Aurobindo. In November 2017, Aceto disclosed that it was experiencing supply challenges "on the manufacturing side." In May 2018, Aceto reported that it was making progress on supply chain challenges but had incurred over $10 million in failure-to-supply penalties owed to its customers. In September 2018, the company announced that those penalties had grown to $27.8 million. Aceto filed for bankruptcy in February 2019 and thereafter sued Aurobindo for fraud and breach of contract.

Investors sued, alleging that Aceto's executives had failed to adequately disclose the company's supply problems with Aurobindo. As we reported in last year's survey, the court dismissed those claims with prejudice. After dismissal, plaintiff (1) moved to amend the judgment based on a purported change in controlling law, and (2) moved for relief from the judgment based on new evidence. The court denied both motions. The purported change in law was a 2020 decision from the Second Circuit that the *Aceto* court concluded "stands for the unremarkable proposition that defendants in a securities fraud case act with scienter when they make a conscious decision to conceal a fact, the omission of which renders a previously made affirmative statement materially misleading."[14] The Aceto plaintiff had not alleged any such "conscious decision" to conceal information. The allegedly omitted information was that Aurobindo was *intentionally* breaching the supply agreement—but plaintiff failed to plead facts showing that Aceto's executives knew this to be the case. The executives knew that Aurobindo was *causing* supply problems, but they disclosed that to investors. As to the purportedly new evidence, this consisted of government insider trading charges against Aceto's former CFO, who was also a defendant in the private securities action. But the non-public information on which the insider selling charges were based did not relate to Aurobindo; it concerned the risk that the company would breach financial covenants in the loan agreement by means of which it had purchased Citron's and Lucid's assets. In any event, the CFO's stock sales occurred only after plaintiff had purchased Aceto stock, which meant plaintiff lacked standing to assert claims based on those sales.

Evanston Police Pension Fund v. McKesson Corp., 2021 WL 4902420 (N.D. Cal. Oct. 21, 2021), granting motion for partial summary judgment. **Antitrust**

McKesson is a wholesaler of generic and branded drugs. In 2013 and 2014, a number of drug manufacturers steeply increased the list prices of certain generic drugs. Between 2013 and 2016, McKesson regularly updated the market on the impact of the manufacturers' drug price increases—and subsequent curtailment of those increases—on its own business. In January 2016, McKesson announced that it expected only nominal price increases in generic drugs in the year to come. The company's stock price fell 10%. On November 3, 2016, Bloomberg and other media reported that the DOJ had been investigating a possible price-fixing conspiracy among generic drug manufacturers and was expected by year-end to bring criminal charges against manufacturers (but not McKesson, a wholesaler). McKesson's stock fell less than 5%.

Investors sued, challenging statements related to increased generic drug prices and the impact of price increases on McKesson's business and financial performance. In a 2019

14 *Setzer v. Omega Healthcare Inv'rs. Inc.*, 968 F.3d 204 (2d Cir. 2020).

decision (reported in our review for that year), the court dismissed plaintiff's primary theory—that McKesson was a participant in the alleged manufacturer conspiracy. But the court permitted plaintiff to go forward, as to a narrowed set of challenged statements, on the alternative theory that McKesson knew about the alleged conspiracy and misleadingly failed, when communicating with investors, to accuse the manufacturers of antitrust violations. On a motion for reconsideration, the court clarified that plaintiff had adequately alleged loss causation only as to alleged corrective disclosures in January and November 2016.

In a 2021 ruling, the court granted defendants' motion for partial summary judgment as to the alleged November 2016 corrective disclosure. The court concluded that plaintiff had failed to establish a proximate causal relationship between McKesson's alleged fraud and the modest November 3, 2016 stock decline (also at issue in the Ninth Circuit's *Impax* decision discussed at page 32). The Bloomberg article did not provide new information to the market, which had already been informed about decreasing generic drug price inflation. In addition, the November 3 stock decline was only tangentially related to McKesson's alleged fraud, which related to its own business. As a matter of law, "it d[id] not follow that everything the manufacturers' fraud proximately caused was also proximately caused by McKesson."

DISTRICT COURT DECISIONS—MOTION TO DISMISS DENIED

Rosi v. Aclaris Therapeutics, Inc., 2021 WL 1177505 (S.D.N.Y. Mar. 29, 2021), denying in part motion to dismiss. **FDA regulation of marketing and advertising**

Aclaris developed Eskata to treat seborrheic keratosis (age spots). The FDA approved Eskata in December 2017. Eskata's side effects included eye disorders and local skin reactions, which were listed on the drug's FDA label. Aclaris marketed Eskata in two stages. In the spring of 2018, Aclaris sent sales representatives to promote the drug to dermatologists. Beginning in September 2018, the company began to market directly to consumers, with before-and-after pictures on its website, social media accounts, and print and TV ads. The TV program "The View" also aired a segment on Eskata. Both stages of the company's marketing campaign drew regulatory scrutiny. In March 2018, the FDA's Office of Prescription Drug Promotion recommended that the company revise its presentation to physicians so as not to misrepresent risks or overstate the drug's efficacy. In June 2019, the FDA told Aclaris that the segment on "The View" contained false and misleading statements regarding safety and efficacy in violation of the Food, Drug and Cosmetic Act. Specifically, the FDA stated that the segment failed to disclose serious risks, including permanent eye injury, blindness, severe skin reactions, and scarring. The FDA referred to its earlier March 2018 recommendations and ordered Aclaris to immediately cease the violations or explain how its conduct was legally compliant. The company's stock price fell 11%. In August 2019, Aclaris announced that it was abandoning the commercialization of Eskata, and the stock fell 14% to close at under $1 per share.

Investors sued, challenging the company's statements about (1) the success of its consumer marketing campaign, (2) patients' experiences with Eskata, (3) the number of treatments patients needed, and (4) the risk that the FDA would withdraw or limit approval. The court held that plaintiffs had adequately pled falsity and scienter as to the first category only. Plaintiffs' theory was that the company's favorable statements about its marketing campaign were rendered misleading by its failure to disclose that the campaign violated FDA regulations. The court agreed, drawing on case law holding that a duty to disclose "can arise when a corporation puts the reasons for its success at issue but fails to disclose that a material source of its success is the use of improper or illegal business practices." The FDA's March 2018 letter, although couched as a recommendation, signaled to the company that the same advertising statements it later used on "The View" misrepresented Eskata's safety and efficacy. The letter was sufficient for pleading purposes as to both falsity and scienter.

Plaintiffs failed to establish falsity with respect to the other three categories. Plaintiffs challenged the company's statements that patients' responses to the drug were "encouraging," claiming that this was inconsistent with the accounts of sales representatives/confidential witnesses who

said that patients experienced pain. But the challenged statements were puffery, and plaintiffs had pled no facts showing that the executives who made the statements were familiar with the sales representatives' accounts. Plaintiffs challenged the company's statement that patients needed fewer treatments than originally anticipated, arguing that this falsely suggested that poor sales performance could be explained by this fact rather than by issues with safety or efficacy. But the company did not offer any such explanation, and plaintiffs themselves had not shown what caused the poor sales performance. Finally, plaintiffs argued that the risk of FDA withdrawal or post-marketing restrictions, which the company disclosed, had already come to pass—and that this rendered the risk disclosure misleading. But that risk had *not* come to pass. The FDA faulted the company for aspects of its marketing campaign; it did not withdraw approval of the drug.

Gordon v. Vanda Pharms. Inc., 2021 WL 911755 (E.D.N.Y. Mar. 10, 2021), denying in part motion to dismiss. **Off-label marketing**

Vanda Pharmaceuticals markets and sells two drugs, Fanapt and Hetlioz. The FDA approved Fanapt to treat schizophrenia in adults and Hetlioz to treat Non-24, a rare circadian rhythm disorder that occurs almost exclusively in blind patients. In February 2019, a short seller wrote that the company had improperly marketed Fanapt to treat schizophrenia in children and Hetlioz for conditions other than Non-24, including mundane sleep issues in patients who were not blind. Vanda's stock fell 5%.

Investors sued, challenging the company's statements about its marketing practices, including the statement that it marketed Fanapt for adult use. The court denied the company's motion to dismiss. The court held that plaintiffs had adequately pled that the challenged statements were misleading by omission, given the alleged marketing of Fanapt to treat children. The court also concluded that the plaintiffs had adequately pled scienter on the part of the CEO and the company, based on allegations that the CEO attended sessions in which sales representatives were trained to market the two drugs off label. (The court dismissed claims against other officer defendants on scienter grounds.) As to loss causation, the company argued that the short seller report could not constitute a corrective disclosure because the information it contained had already been revealed to the market by means of a qui tam complaint. The court rejected that argument as premature, holding that it raised factual issues that could be resolved only with evidence.

Ferraro Family Found., Inc. v. Corcept Therapeutics Inc., 2021 WL 3748325 (N.D. Cal. Aug. 24, 2021), denying in part motion to dismiss. **Off-label marketing**

Corcept's sole product is the orphan drug Korlym, which treats endogenous Cushing Syndrome (a condition in which a patient's adrenal glands produce too much cortisol). Korlym was approved only for use in patients who have failed or are ineligible for surgery as a treatment for Cushing Syndrome. The FDA's orphan drug designation provided Corcept with market exclusivity through February 2019. In January 2019, an investigative journalist, SIRF, published a report claiming that Corcept was reimbursing physicians through honoraria payments in exchange for agreements to prescribe Korlym for off-label uses. The company's stock fell 11%. Later in January 2019, the company announced preliminary results for fourth-quarter and full-year 2018. This included revenue below analysts' projections and a further slowdown projected to follow. The company's stock fell 10%.

Investors sued, challenging statements about marketing and physician education, FDA compliance, and rates of on-label prescription. Plaintiffs' attack on all statements depended on the premise that the company was engaged in an off-label marketing scheme. According to plaintiffs, the company targeted physicians less likely to be familiar with Cushing Syndrome and encouraged them to use Korlym in a large population of patients, including those who had not had surgery or even received a Cushing Syndrome diagnosis. In a 2020 ruling (reported in last year's survey), the court granted the company's motion to dismiss, holding that plaintiffs had failed to adequately allege that Corcept engaged in an off-label marketing scheme. While plaintiffs had provided the accounts of multiple confidential witness physicians stating that Corcept employees had encouraged them to prescribe Korlym off label, this did not show

that company leadership was directing a scheme of off-label promotion. Plaintiffs notably did not provide any accounts of Corcept employees or former employees. The court also held that plaintiffs had failed to plead scienter: Plaintiffs did not connect their allegations to the individual defendants, and the core operations theory failed in the absence of an adequately alleged off-label marketing scheme. Plaintiffs finally came up short on loss causation. They had failed to show that the SIRF report contained any analysis not previously performed by other market participants, and did not tie the company's reported financial performance to any alleged misstatements.

Plaintiffs amended their complaint, the company again moved to dismiss and the court denied the motion in part. Plaintiffs' most significant amendment was the addition of accounts from four former Corcept sales representatives (all confidential witnesses). By means of these new witness accounts, the court held, plaintiffs had adequately pled the existence of a company-wide scheme of off-label marketing. One former employee reported attending training sessions in off-label marketing led by one of the individual defendants. Another former employee stated that she had accompanied the CEO on visits to physicians, that the CEO had himself encouraged physicians to prescribe the drug off label, and that when questioned about this, the CEO had stated "I can say what I want." The same former employee stated that sales representatives had been fired for refusing to engage in off-label promotion. All of these accounts, the court concluded, along with other allegations, supported the existence of a company-wide scheme. The court rejected the company's argument that the conduct the confidential witnesses described did not constitute improper off-label promotion, holding that this was a factual issue. The court then analyzed five categories of challenged statements and denied the company's motion to dismiss as to three—statements that the company marketed the Korlym for on-label uses, that the company believed its marketing practices did not constitute off-label promotion, and that 99% of Korlym prescriptions were on label. The court granted dismissal as to statements describing revenue growth and the company's physician education program; those statements were not inconsistent with the alleged misconduct.

The court also concluded that plaintiffs had adequately alleged scienter. Somewhat oddly, the court relied on the core operations doctrine, under which scienter can be inferred from an executive's access to particularly important company information. Given the confidential witness accounts directly tying the individual defendants to the alleged misconduct, a generalized inference of knowledge would seem unnecessary. Finally, the court held that plaintiffs had adequately alleged loss causation as to the SIRF report, which was based in part on information obtained through FOIA requests. Defendants had not shown that other market participants had previously compiled or analyzed that information. But the court granted dismissal as to the second alleged corrective disclosure—the report of slowing sales—holding that plaintiffs had failed to tie that slowdown to the alleged off-label marketing scheme or its consequences.

Derr v. Ra Med. Sys., Inc., 2021 WL 1117309 (S.D. Cal. Mar. 24, 2021), denying in part motions to dismiss. **Product recall; off-label marketing**

Ra manufactures and sells the DABRA laser system and catheter. The FDA approved the device for use in some—but not all—atherectomy procedures, in which accumulated plaque is cut away from a patient's arteries. Beginning in February 2018, Ra learned that the device was failing to calibrate properly during set-up, and this became an ongoing issue. Ra conducted its IPO in September 2018. In August 2019, the company terminated its CEO and founder, announced an Audit Committee investigation of an anonymous complaint, and reported inconsistencies in manufacturing and an increase in the number of systems that failed to calibrate. A month later, in September 2019, the company initiated a voluntary recall of catheters used in the DABRA system. The recall was necessary to relabel the devices with a two-month rather than a 12-month expiration period. The company's stock fell following its August 2019 and September 2019 announcements. In October 2019, the Audit Committee issued a report identifying a range of improprieties.

Investors sued, challenging statements in the company's IPO registration statement and subsequent disclosures. The company and its former officers filed separate motions to dismiss, which the court denied in part. The court held that plaintiffs had adequately pled falsity as to risk factors in the registration statement related to recalls and manufacturing issues. Ra had reported a risk of recalls and "unforeseen" manufacturing problems at a time when these risks had already

materialized in the form of calibration problems. Plaintiffs also adequately pled scienter as to the risk disclosures under the core operations doctrine. Given the size of the company (118 employees) and the fact that it sold only two products, the court concluded that it would be "absurd" to conclude that the individual defendants were unaware of the calibration issues.

The court granted the motions to dismiss as to the remaining categories of challenged statements. Plaintiffs failed to plead facts showing that statements about the strength of Ra's sales force were false or misleading. As to plaintiffs' contention that Ra was engaged in undisclosed off-label marketing, the court concluded that the company's risk disclosure on the subject, together with a disclosure that a competitor had accused it of off-label promotion, adequately informed investors that Ra was encouraging physicians to use its product beyond the approved indications—and that the company was risking regulatory scrutiny as a result.

Boston Ret. Sys. v. Alexion Pharms., Inc., – F. Supp. 3d –, 2021 WL 3675180 (D. Conn. Aug. 19, 2021), denying in part motions to dismiss. **Kickbacks**

Alexion develops and manufactures orphan drugs. Between 2014 and 2017, Alexion had only one commercial drug, Soliris. The two diseases for which the drug is prescribed are exceedingly rare; the worldwide patient population is only 11,000. Soliris costs $500,000–$700,000 per patient per year. Given the size of the market, Alexion sought to increase awareness of the drug through outreach by nurses directly to patients and through partnerships with labs performing tests to diagnose potential sufferers of the two diseases. Alexion also made donations to patient assistance organizations, which help patients with the costs of expensive drugs. In November 2016, Alexion pulled out of an analyst conference and announced that it would delay filing its Form 10-Q pending a board investigation into allegations related to sales practices. The company's stock fell 11%. Alexion's CEO and CFO resigned the following month, and the stock fell 17%. In January 2017, the company reported the findings from the board investigation: a material weakness in internal controls, attributed to the "tone at the top." In May 2017, the company's offices in Brazil were raided as part of a government investigation into healthcare fraud. The stock fell 3%. Later in May 2017, four more executives resigned, including the new CFO, and the stock fell 9%. The next day, *Bloomberg* published an article related to Alexion's sales practices, and the stock fell 7%. In July 2017, reports emerged that Alexion was the subject of a DOJ investigation. In 2019, Alexion announced a $13 million settlement with the DOJ. The settlement agreement revealed that the government had been pursuing claims for violation of the Anti-Kickback Statute, related to Alexion's payment to patient assistance organizations.

Investors sued, challenging (1) statements attributing sales growth to success in patient identification and strong uptake of Soliris, (2) Sarbanes-Oxley certifications, and (3) statements that the company was in compliance with a code of ethics. The court denied the company's motion to dismiss as to the first two categories. With respect to the first, the court credited plaintiffs' theory that the company had misleadingly omitted the purported fact that its financial success was the result of allegedly improper conduct. The court drew on authorities holding that "statements that put the source of the accurately reported revenue at issue may be actionable if they fail to disclose the impropriety of the source." The court rejected the company's argument that it had no duty to accuse itself of uncharged conduct; in the court's view, that argument succeeds only where a company has publicly disclosed enough factual detail about its conduct that investors can assess for themselves whether the conduct is improper and will lead to regulatory action. Plaintiffs had also adequately pled falsity as to the company's Sarbanes-Oxley certifications, given the board's finding of an internal control weakness. On the other hand, plaintiffs' claim failed as to the challenged statements about ethics code compliance; such statements are too broad to be actionable. The court concluded that plaintiffs had sufficiently pled scienter based largely on detailed confidential witness allegations tying certain individual defendants to the challenged sales practices. Finally, the court held that plaintiffs had adequately alleged scheme liability against the company and the same individual defendants as to which they had successfully pled scienter.

In re Myriad Genetics, Inc., Sec. Litig., 2021 WL 977770 (D. Utah Mar. 16, 2021), denying motion to dismiss. **Regulation of genetic test products; CMS reimbursement and revenue recognition**

Myriad Genetics sold genetic testing products, including tests for hereditary cancer and a pharmacogenetic test called GeneSight. Pharmacogenetic tests are aimed at predicting which among competing drugs will work best with a patient's genetic makeup. GeneSight had received regulatory certification under the Clinical Laboratory Improvement Amendments. The product included three separate panels, related to drugs for the treatment of depression, pain and ADHD. Myriad told investors that GeneSight had been clinically proven to enhance medication selection for all three groups of drugs. In particular, the company referred to a clinical trial called GUIDED, which consisted of a treatment arm on which patients took drugs for depression with the guidance of GeneSight, and a control arm on which patients took drugs for depression without using GeneSight. The company reported statistically significant differences between the two arms on remission and response, and a difference approaching statistical significance on symptom reduction.

In October 2018, the FDA issued a Safety Communication warning against the use of pharmacogenetic tests with unapproved claims about patient response. The FDA did not identify any manufacturer or product. Myriad responded by reminding investors of the results produced by the GUIDED study. On August 1, 2019, the company announced that a major insurer had decided to cover GeneSight. The company's stock price rose 55% and the CEO and CFO made significant stock sales under their trading plans. Less than two weeks later, Myriad reported that it had discontinued GeneSight's analgesic and ADHD drug panels in May 2019—as those panels were not supported by sufficient clinical evidence of efficacy—which had led to a 23% reduction in GeneSight revenue. The company's stock price fell 42%. In November 2019, Myriad announced that it had overstated revenue for a different product—a hereditary cancer test—by failing to incorporate changes in CMS billing codes and reimbursement. The stock price fell 40%. In February 2020, Myriad announced that its CEO was resigning effective immediately, and that it was experiencing challenges obtaining reimbursement from the same payer who had earlier decided to cover GeneSight. The company's stock fell 28%.

Investors sued, challenging statements about (1) the efficacy of GeneSight's analgesic and ADHD panels, (2) the GUIDED trial, (3) the FDA's concerns about GeneSight, and (4) revenue for the hereditary cancer drug. The court denied the company's motion to dismiss with respect to all but the third category. As to the analgesic and ADHD panels, the court credited the accounts of confidential witnesses that executives had been told that no clinical data supported the company's efficacy claim—and had then declined to conduct tests for fear they would fail to yield positive results. As to the GUIDED trial, the court accepted plaintiffs' theory that the company misleadingly omitted the fact that the trial had failed to meet its primary endpoint and cherry-picked three among 65 secondary endpoints without making a multiplicity adjustment. The court rejected plaintiffs' claim that Myriad had wrongly omitted an imminent FDA warning letter targeting GeneSight: Plaintiffs failed to identify any affirmative statement rendered misleading by that omission. On the other hand, on the subject of revenue recognition for the hereditary cancer test (as distinct from GeneSight), the court held that plaintiffs had adequately pled falsity in light of the company's restatement.

The court also concluded that plaintiffs had adequately alleged scienter, based on, among other things, (1) confidential witness accounts that the individual defendants knew they lacked clinical support for efficacy claims related to GeneSight's analgesic and ADHD panels, (2) as to the GUIDED study, FDA guidance on the permissibility of presenting positive results on secondary endpoints when a trial has failed to meet its primary endpoint, and on the need for multiplicity adjustments when numerous tests are conducted, (3) as to revenue recognition, the denial of claims under new CMS codes months before the company announced the restatement, (4) insider selling, notwithstanding the existence of trading plans, within a very tight 12-day window between a 55% stock increase and a 42% decline, and (5) the announcement of the CEO's immediate departure, without designation of a successor. The court explained that certain of these factors might be insufficient in isolation, but that considered collectively, they supported an inference of fraud at least as compelling as an innocent alternative.

In re Perrigo Co. PLC Sec. Litig., 2021 WL 3005657 (S.D.N.Y. July 15, 2021), denying motion for summary judgment. **Financial statements/tax liability**

Perrigo manufactures private-label over-the-counter medications. In 2013, Perrigo's predecessor purchased the Ireland-based company Elan, allowing Perrigo to establish its tax domicile in Ireland. Before the acquisition, Elan had sold its stake in Tysabri, a multiple sclerosis drug, to another pharmaceutical company. In its tax returns, Perrigo treated proceeds from the Tysabri sale as trading income—subject to a 12.5% tax rate—rather than capital gains—subject to a 33% tax rate. In November 2017, the Irish Office of the Revenue Commissioners began to audit Perrigo's 2012 and 2013 taxes. Perrigo disclosed the tax audit in its March 2018 Form 10-K. In October 2018, Irish Revenue sent an Audit Findings Letter to Perrigo, including the finding that the company should have applied capital gains treatment to the sale of Tysabri. Irish Revenue concluded in the letter that Perrigo had a tax liability of approximately €1.6 billion—although the company was invited to respond if it disagreed. In its November 2018 Form 10-Q, the company disclosed the Audit Findings Letter but not the amount of the tax liability. Later in November 2018, Irish Revenue sent Perrigo a Notice of Amended Assessment, which included a balance payable of €1.6 billion. After Perrigo disclosed this liability in a Form 8-K, its stock fell 29%.

Investors sued, alleging that Perrigo's financial statements violated GAAP and were therefore false or misleading. In a 2020 ruling on the company's motion to dismiss (reported in last year's survey), the court permitted plaintiffs to go forward with claims based on statements in Perrigo's November 2018 Form 10-Q and granted dismissal as to statements made before November 2018. After a class was certified and discovery completed, both parties moved for summary judgment. The court denied Perrigo's motion—which was directed at scienter—holding that scienter was a fact issue a jury would need to resolve. The court granted plaintiffs' motion for partial summary judgment on falsity and materiality. Having previously concluded that ASC 450 (regarding recognition of loss contingencies) governed the company's disclosure obligations, the court held that the exclusion of the €1.6 billion figure from the November 2018 Form 10-Q was presumptively misleading. Once Perrigo had received the Audit Findings Letter, the court held, it was required to disclose the loss contingency, which was "more than remote." The company also had a duty to quantify the exposure, even if it disagreed with Irish Revenue's assessment. With respect to materiality, the court stated that "[r]easonable minds cannot differ that the omission of such a large number in relation to Perrigo's revenues and available cash would be material." Materiality was a therefore not a fact question, and could be determined as a matter of law on summary judgment.

TABLE OF NEW FILINGS IN 2021

In 2021, 49 new securities fraud class actions were filed against life sciences companies.[15] This is consistent with the number of new filings we've seen over the past five years.

2017 54 new complaints
2018 48 new complaints
2019 44 new complaints
2020 45 new complaints
2021 49 new complaints

Of the new actions filed in 2021, 39 were filed against companies with development-stage drugs or devices. Nearly half of these new actions (18 of the 39) arise from setbacks at the final stages of the approval process, after a company has submitted an NDA, BLA or premarket clearance application.

Another six cases involve COVID-19 vaccines, tests or treatments. This is consistent with the COVID-19-related filings in 2020 (seven new filings).

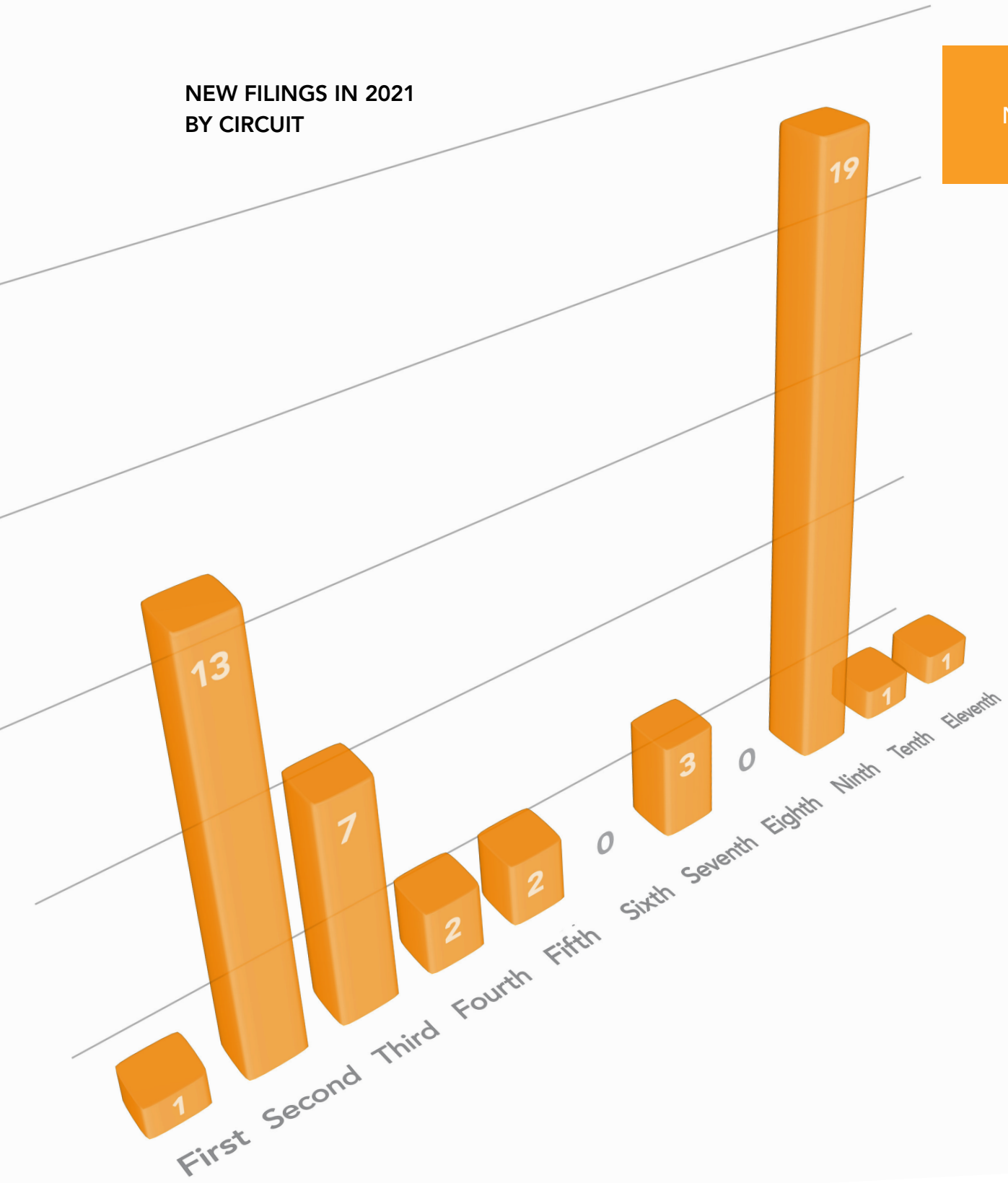
Ten actions were filed against companies with mature products. These complaints arise from a range of regulatory and non-regulatory setbacks, clustered around product defects/recalls and alleged improprieties in marketing and billing. These ten new filings reflect a drop-off in this space. In both 2019 and 2020, we saw 17 new actions against companies with approved products.

In past years we've also observed that companies with pre-approval products tend to win dismissal at a higher rate than those with mature products. With the mix of new 2021 filings tilted sharply toward pre-approval products, a year or two of high success rates in the district courts may lie ahead, as the new cases move through the pleading stage.

As in previous years, the new filings are clustered in district courts in the Second, Third and Ninth Circuits. We show all of these breakdowns in the following three pages.

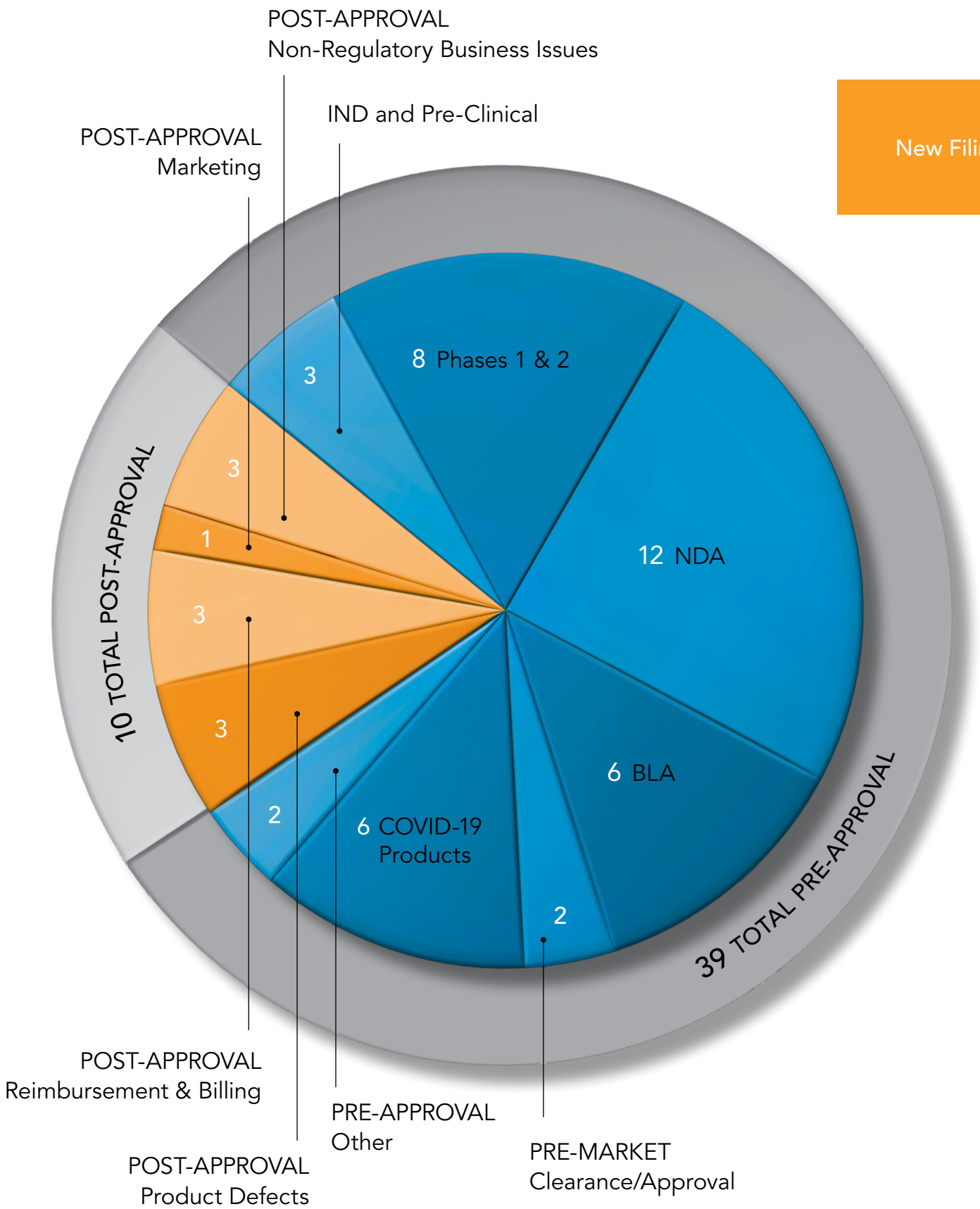
15 We take this figure and list of actions from the Stanford Securities Class Action Clearinghouse. The list includes those cases categorized by Cornerstone Research as within the "healthcare sector" but excludes deal litigation and cases involving hospital management issues unrelated to any drug or 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 2021 BY CIRCUIT



PRODUCT LIFECYCLE		SECURITIES FRAUD CLASS ACTIONS FILED IN 2021
PRE-APPROVAL	IND and Preclinical	3
	Phases 1 and 2	8
	NDA	12
	BLA	6
	Premarket Clearance/Approval	2
	COVID-19 products	6
	Other Pre-approval	2
	TOTAL PRE-APPROVAL	39
POST-APPROVAL	Post-Approval: Product Defects	3
	Post-Approval: Reimbursement and Billing	3
	Post-Approval: Marketing	1
	Post-Approval: Non-Regulatory Business Issues	3
	TOTAL POST-APPROVAL	10

New Filings


POST-APPROVAL
Non-Regulatory Business Issues
IND and Pre-Clinical
POST-APPROVAL
Marketing
8 Phases 1 & 2
12 NDA
6 BLA
2
39 TOTAL PRE-APPROVAL
6 COVID-19
Products
2
3
3
1
3
3
10 TOTAL POST-APPROVAL
POST-APPROVAL
Reimbursement & Billing
POST-APPROVAL
Product Defects
PRE-APPROVAL
Other
PRE-MARKET
Clearance/Approval

VOYAGER THERAPEUTICS, INC. **1/22/2021** **E.D.N.Y.**

IND Voyager Therapeutics develops treatments for severe neurological diseases, including VY-HTT01 for the treatment of Huntington's Disease. Plaintiffs allege that the company overstated the likelihood of FDA approval based on its Investigational New Drug submission and failed to disclose that the submission was deficient. Stock prices fell after the FDA placed Voyager's IND on hold.

POLARITYTE, INC. **9/24/2021** **D. Utah**

IND PolarityTE develops SkinTE, a tissue product used to treat wounds, burns and other skin injuries. Plaintiffs allege that the company failed to disclose chemistry, manufacturing, and control deficiencies. Stock prices fell after the company announced that the FDA would issue a clinical hold letter based on those deficiencies.

EXICURE, INC. **12/13/2021** **N.D. Illinois**

PRECLINICAL Exicure develops XCUR-FXN for the treatment of Friedreich's ataxia. Plaintiffs allege that the company failed to disclose improprieties in its preclinical program. Stock prices fell after the company reported that it was investigating possible improprieties in the program, and fell again after it announced that it was suspending the program indefinitely.

SILVERBACK THERAPEUTICS, INC. **11/5/2021** **W.D. Wash.**

PHASE 1/1B Silverback develops SBT6050, a cancer treatment. Plaintiffs allege that the company overstated the drug's efficacy. Stock prices fell after the company released disappointing Phase 1/1b trial results.

BIOMARIN PHARMACEUTICAL INC. **10/22/2021** **N.D. Cal.**

PHASE 1/2 BioMarin develops BMN 307 for the treatment of phenylketonuria. Plaintiffs allege that the company misrepresented the safety of the drug. Stock prices fell after the company reported that the FDA had placed a hold on clinical trials based on interim safety findings.

IMMUNOVANT, INC. **2/19/2021** **E.D.N.Y.**

PHASE 2 Immunovant develops IMVT-1401, a monoclonal antibody, for the treatment of myasthenia gravis, thyroid eye disease and warm autoimmune hemolytic anemia. Immunovant merged with a special purpose acquisition company in 2019 and conducted an offering in 2020. Plaintiffs allege that in the offering documents (and elsewhere), the company falsely represented that the drug was well tolerated and generally overstated the drug's prospects for approval and commercialization. Stock prices fell after the company announced a pause in dosing in ongoing Phase 2 trials.

BELLUS HEALTH INC. 3/16/2021 S.D.N.Y.

PHASE 2 BELLUS Health's lead drug candidate is BLU-5937, for the treatment of chronic cough. Plaintiffs allege that the company falsely stated that its Phase 2 trial mirrored the successful trials of a competitor drug while eliminating the risks of adverse effects related to taste. Stock prices fell after the company announced the possibility of a Phase 2b trial, and fell again after the company revealed that BLU-5937 was not significantly better than placebo at reducing the frequency of coughs.

FREQUENCY THERAPEUTICS, INC. 6/3/2021 D. Mass.

PHASE 2 Frequency develops a hearing loss treatment called FX-322. Plaintiffs allege that the company knew while its Phase 2a trial of FX-322 was ongoing that the trial would be a failure. Stock prices fell after the trial ended and the company reported disappointing results.

ANNOVIS BIO, INC. 8/17/2021 E.D. Pa.

PHASE 2 Annovis develops ANVS401, a drug designed to inhibit neurodegeneration. Plaintiffs allege that in announcing Phase 2 trial results, the company misleadingly omitted negative information. Stock prices fell after Annovis reported more complete information at a medical conference.

LONGEVERON INC. 9/13/2021 S.D. Fla.

PHASE 2 Longeveron develops Lomecel-B for the treatment of aging frailty. Plaintiffs allege that the company overstated the product's clinical and commercial prospects. Stock prices fell when the company disclosed that its Phase 2 trial did not generate statistically significant efficacy results.

CASSAVA SCIENCES, INC. 8/27/2021 W.D. Tex.

PHASE 2B Cassava develops simufilam, a small molecule drug designed to treat Alzheimer's disease. Plaintiffs allege that Cassava's report of preliminary Phase 2b trial results was false and misleading. Stock prices fell after the company disclosed that the FDA had received a Citizen Petition alleging issues with data integrity and seeking to halt two ongoing trials of simufilam.

TRICIDA, INC. 1/6/2021 N.D. Cal.

NDA Tricida develops veverimer for the treatment of chronic kidney disease. Plaintiff alleges that the company failed to disclose the locations of its Phase 3 trial sites, misrepresented the nature of the FDA's Accelerated Drug Application program, misrepresented interactions between the company and FDA staff at a late-cycle meeting, and made misleading statements about the design of its confirmatory trial. Stock prices fell after the company disclosed a deficiency notification from the FDA regarding its NDA, and fell again after the company reported its receipt of a Complete Response Letter denying approval.

AQUESTIVE THERAPEUTICS, INC. **3/1/2021** **D.N.J.**

NDA Aquestive developed Libervant for the treatment of recurrent epileptic seizures. Aquestive sought FDA approval through Section 505(b)(2) of the Food, Drug, and Cosmetic Act (requiring equivalence to an approved drug). Plaintiffs allege that the company failed to disclose unfavorable results of a trial comparing Libervant to Diastat, an approved drug. Stock prices fell after the company announced receipt of a Complete Response Letter denying approval in light of the results of the comparison trial.

ATHENEX, INC. **3/3/2021** **W.D.N.Y.**

NDA Athenex develops cancer drugs, including Oraxol for the treatment of metastatic breast cancer. Plaintiffs allege that the company failed to disclose significant flaws in a Phase 3 trial. Stock prices fell after Athenex announced receipt of a Complete Response Letter denying approval. Prices fell again after Athenex announced that it would not perform another Phase 3 trial.

KADMON HOLDINGS, INC. **4/2/2021** **E.D.N.Y.**

NDA Kadmon develops belumosudil, a treatment for chronic graft-versus-host disease. Plaintiffs allege that Kadmon misrepresented the strength of its NDA for the drug. Stock prices fell after Kadmon announced that the FDA had extended the NDA review period because it needed time to consider additional information the company had submitted.

FIBROGEN, INC. **4/12/2021** **N.D. Cal.**

NDA FibroGen develops Roxadustat for the treatment of anemia in patients with chronic kidney disease. Plaintiffs allege that the company falsely stated that Phase 3 trials showed that the drug had efficacy "superior" to the standard of care and was safer than the placebo; plaintiffs also allege data manipulation. Stock prices fell multiple times: after the release of top-line results; after the FDA unexpectedly announced that it would convene an advisory committee to review the NDA; after the company disclosed that its prior analyses had incorporated post-hoc changes to stratification factors; and after the advisory committee voted against approval.

CHEMOCENTRYX, INC. **5/5/2021** **N.D. Cal.**

NDA ChemoCentryx develops avacopan for the treatment of anti-neutrophilic cytoplasmic autoantibody-associated vasculitis. Plaintiffs allege that the company failed to disclose that Phase 3 data raised serious safety concerns and that the complex trial design used in Phase 3 created a risk that the FDA would conclude that trial data could not be interpreted to define a clinically meaningful benefit of avacopan. Stock prices fell in May 2021, after FDA staff published a briefing document that appeared to some to bode ill for avacopan's chances of approval.

ORPHAZYME A/S — 7/9/2021 — N.D. Ill.

NDA Orphazyme develops arimoclomol for the treatment of neurodegenerative orphan diseases. Plaintiffs allege that Orphazyme overstated the drug's efficacy and failed to disclose that its NDA for arimoclomol was incomplete. Stock prices fell after Orphazyme announced that its clinical trial did not meet its primary and secondary endpoints, and fell again after the FDA issued a Complete Response Letter rejecting the NDA.

CORMEDIX INC. — 7/22/2021 — D.N.J.

NDA CorMedix develops DefenCath, a drug designed to prevent catheter-related bloodstream infections. Plaintiffs allege that the company downplayed deficiencies with DefenCath's manufacturing process and the facility manufacturing DefenCath. Stock prices fell after the company announced receipt of a Complete Response Letter denying approval based on manufacturing issues.

ARDELYX INC. — 7/30/2021 — N.D. Cal.

NDA Ardelyx develops tenapanor to control serum phosphorus in chronic kidney disease patients on dialysis. Plaintiffs allege that the data submitted in the tenapanor NDA showed that the drug's treatment effect lacked clinical relevance and hence could not support approval. Stock prices fell after the FDA issued a deficiency letter.

ITERUM THERAPEUTICS PLC — 8/5/2021 — N.D. Ill.

NDA Iterum is developing sulopenem to treat urinary tract infections. Plaintiffs allege that Iterum failed to disclose that its NDA lacked sufficient data to support approval. Stock prices fell after the FDA denied approval.

REATA PHARMACEUTICALS, INC. — 12/20/2021 — E.D. Tex.

NDA Reata develops bardoxolone for the treatment of chronic kidney disease caused by Alport syndrome. Plaintiffs allege that the company failed to disclose the FDA's concerns about the validity of its Phase 3 trial design. Stock prices fell after the FDA released a briefing document referring to issues with the trial design, and fell again after the FDA denied the NDA.

ACADIA PHARMACEUTICALS, INC. — 4/19/2021 — S.D. Cal.

sNDA Acadia develops pimavanserin as a treatment for dementia-related psychosis, schizophrenia and major depressive disorder. Plaintiffs allege that the company failed to disclose that materials submitted in support of the pimavanserin sNDA contained statistical and design deficiencies. Stock prices fell after the company reported that the FDA had identified deficiencies in the pimavanserin sNDA, and fell again after the FDA issued a Complete Response Letter denying approval of the sNDA.

BLUEBIRD BIO, INC. **2/12/2021** **E.D.N.Y.**

BLA bluebird bio develops gene therapies for severe genetic diseases, including LentiGlobin for the treatment of sickle cell disease. Plaintiffs allege that the company failed to disclose that the data in its LentiGlobin BLA was insufficient to support approval. Stock prices fell after bluebird disclosed that the FDA had directed it to provide additional data.

PROVENTION BIO, INC. **5/21/2021** **D.N.J.**

BLA Provention develops teplizumab for the treatment of immune-mediated diseases. Plaintiff alleges that the company failed to disclose that its teplizumab BLA was deficient, and that the FDA would not grant approval without additional data. Stock prices fell after Provention announced that the FDA had identified deficiencies in the BLA.

SESEN BIO, INC. **8/19/2021** **S.D.N.Y.**

BLA Sesen Bio develops Vicineum for the treatment of bladder cancer. Plaintiffs allege that the company failed to disclose that more than 2,000 protocol violations occurred during the clinical trials of the drug; that several clinical investigators were found guilty of protocol violations; that the clinical trials revealed potentially dangerous side effects; and that tainted data were submitted with the BLA. Stock prices fell after the FDA denied the BLA and again after the publication of media reports related to scientific misconduct in the trials and toxic side effects of the drug.

SPECTRUM PHARMACEUTICALS, INC. **8/31/2021** **D. Nev.**

BLA Spectrum develops oncology and hematology drugs, including ROLONTIS. Plaintiffs allege that Spectrum failed to disclose that its manufacturing facility maintained deficient controls and procedures, decreasing the likelihood of FDA approval. Stock prices fell after Spectrum reported its receipt of a Complete Response Letter citing deficiencies in the manufacturing process.

BRISTOL-MYERS SQUIBB COMPANY **10/6/2021** **S.D.N.Y.**

BLA Bristol Myers develops Liso-cel, a cancer therapy. Plaintiffs hold contingent value rights, which entitle them to a payout if the company meets specified milestones—in this case, approval of Liso-Cel by December 31, 2020. Plaintiffs allege that the company deliberately slow-rolled the approval process by submitting a deficient BLA, and that its statement in offering documents that it would make diligent efforts was accordingly false. Liso-Cel was approved 36 days after the milestone date, and the CVR holders received no payout.

REVANCE THERAPEUTICS, INC. **12/10/2021** **N.D. Cal.**

BLA Revance develops DAXI for the treatment of various facial conditions. Plaintiffs allege that Revance failed to disclose quality control deficiencies at the company's manufacturing facility. Stock prices fell after the FDA issued a Form 483 identifying deficiencies, and fell again when Revance reported its receipt of a Complete Response Letter denying its BLA on the basis of manufacturing deficiencies.

OWLET, INC. 11/17/2021 C.D. Cal.

PREMARKET CLEARANCE/APPROVAL Owlet developed Smart Sock, a monitor used to track infants' oxygen levels, heart rate, and sleep trends. Plaintiffs allege that the company failed to disclose that it could not distribute the device until it obtained premarket clearance or approval. Stock prices fell after the FDA issued a warning letter stating that the company had not received premarket clearance or approval.

NANO-X IMAGING LTD. 10/5/2021 E.D.N.Y

510k Nano-X develops a medical imaging system. Plaintiffs allege that the company's 510k application was deficient and unlikely to be approved. Stock prices fell after the company reported that the FDA had requested additional information and put the 510k submission on hold.

DECISION DIAGNOSTICS CORP. 1/15/2021 C.D. Cal.

COVID-19 PRODUCTS Decision Diagnostics, which manufactures and sells diagnostics and home testing products, worked to develop a COVID-19 test. Plaintiffs allege that the company misrepresented the viability of the test, its progress with the FDA in obtaining an Emergency Use Authorization for the test and the timeline on which it could bring the test to market. Stock prices fell after the SEC filed a complaint alleging that the company had misrepresented the viability of the test.

ASTRAZENECA PLC 1/26/2021 S.D.N.Y.

COVID-19 PRODUCTS AstraZeneca partnered with Oxford University to develop a COVID-19 vaccine. Plaintiffs allege that the company concealed problems that arose during clinical trials. Stock prices fell after the company released interim results revealing that a manufacturing error had led to two different dosing regimens, that the vaccine's full-dosing regimen was less effective than its half-dosing regimen, and that the half-dosing regimen had not been tested in people over the age of 55.

EMERGENT BIOSOLUTIONS INC. 4/19/2021 D. Md.

COVID-19 PRODUCTS During the early months of the COVID-19 pandemic, Emergent entered into agreements with both Johnson & Johnson and AstraZeneca to manufacture COVID-19 vaccines. Plaintiff alleges that the company failed to disclose that issues in its manufacturing facility would compromise its ability to manufacture the vaccines. Stock prices fell after media reports revealed that contamination and other manufacturing issues had led to the forced destruction of millions of doses of both Johnson & Johnson and AstraZeneca vaccines.

OCUGEN, INC. 6/17/2021 E.D. Pa.

COVID-19 Products Ocugen worked to develop a COVID-19 vaccine, for which it originally intended to obtain an Emergency Use Authorization. Plaintiffs allege that the company failed to disclose that it would be unable to secure an EUA. Stock prices fell after the company announced that it would pursue a BLA instead of an EUA.

NOVAVAX, INC. 11/12/2021 D. Md.

COVID-19 PRODUCTS Novavax develops NVX-CoV2373, a COVID-19 vaccine. Plaintiffs allege that the company overstated its manufacturing capabilities and downplayed manufacturing issues. Stock prices fell after The Washington Post and Politico reported that the company's EUA filing was delayed by manufacturing and other regulatory issues.

CYTODYN INC. 3/17/2021 W.D. Wash.

COVID-19 PRODUCTS CytoDyn developed leronlimab as a treatment for HIV and submitted a BLA in April 2020. Also in 2020, the company conducted Phase 2 and Phase 2b/3 trials testing the drug as a treatment for COVID-19. Plaintiff alleges that the company made false and misleading statements about the drug's prospects of approval for both HIV and COVID-19 indications, and engaged in an improper stock promotion scheme as to the COVID-19 indication. Stock prices fell on multiple occasions, including when the FDA issued a Refuse to File letter as to the HIV BLA, and when both the company and the FDA reported on the failure of the COVID-19 trials.

ATHIRA PHARMA, INC. 6/25/2021 W.D. Wash.

OTHER: ALLEGED SCIENTIFIC MISCONDUCT Athira is developing drugs for the treatment of neurological diseases. Plaintiffs allege that Athira failed to disclose that its research was tainted by scientific misconduct. Stock prices fell after Athira announced that its President and CEO had been placed on temporary leave pending a review of issues stemming from her doctoral research amid allegations of scientific misconduct.

RENOVACARE, INC. 7/16/2021 D.N.J.

STOCK PROMOTION RenovaCare is developing a product to regenerate skin cells. Plaintiffs allege that RenovaCare engaged in an illegal stock promotion scheme. Stock prices fell after the SEC charged the company with securities fraud.

PENUMBRA, INC. 1/15/2021 N.D. Cal.

POST-APPROVAL: PRODUCT RECALL Penumbra manufactures and sells medical devices for patients suffering from strokes and other vascular diseases. Plaintiff alleges that one such device, the Jet 7 Xtra Flex catheter, had design defects that made it unsafe for normal use, and that the company misleadingly failed to disclose the risk that the device could cause serious injury or death and the likelihood that it would be recalled. Stock prices fell after media reports raised questions about the safety of the catheter, and fell again after the company recalled the device.

KONINKLIJKE PHILIPS N.V. 8/16/2021 E.D.N.Y.

POST-APPROVAL: PRODUCT RECALL Koninklijke Philips sells Bi-Level PAP and CPAP devices and mechanical ventilators to treat patients with obstructive sleep apnea. Plaintiffs allege that the company misrepresented the quality of its manufacturing controls and procedures, and that as a result of the control deficiencies, the company's products were manufactured using hazardous materials. Stock prices fell after the company issued a voluntary recall of some of its devices.

BERKELEY LIGHTS, INC. 12/8/2021 N.D. Cal.

POST-APPROVAL: PRODUCT DEFECTS Berkeley Lights operates a platform used to analyze and process cell data in the development of biotherapeutics. Plaintiffs allege that the company failed to disclose that consumers had complained about design and manufacturing defects in its automation system, and that the market for its products and services was a fraction of the $23 billion represented to investors. Stock prices fell after a research analyst firm released an investigative report criticizing the company's technology and products and questioning its business relationships and growth plan.

ACELRX PHARMACEUTICALS, INC. 6/8/2021 N.D. Cal.

POST-APPROVAL: MARKETING AcelRx sells DSUVIA for the treatment of moderate to severe acute pain. Plaintiffs allege that the company failed to disclose that it had deficient disclosure controls and procedures with respect to marketing. Stock prices fell after the company disclosed receipt of an FDA warning letter identifying inappropriate promotional communications.

iRHYTHM TECHNOLOGIES, INC. 2/1/2021 N.D. Cal.

POST-APPROVAL: CMS REIMBURSEMENT iRhythm, a digital healthcare company, sells long-term ambulatory electrocardiogram devices to diagnose cardiac arrhythmias. In 2021, CMS issued a final rule on physician reimbursement. Plaintiffs allege that the company misrepresented the information it had provided to CMS in support of favorable reimbursement rates during the rulemaking process, and failed to disclose that the final rule would harm its business. Stock prices fell several times: after CMS published its final rule; after a Medicare administrative contractor published reimbursement rates under the CMS 2021 fee schedule that were significantly lower than prior rates; and after iRhythm's CEO abruptly resigned.

EARGO, INC. 10/6/2021 N.D. Cal.

POST-APPROVAL: INSURANCE REIMBURSEMENT Eargo develops hearing aids, which are medical devices. Plaintiffs allege improprieties in the company's reimbursement practices for customers covered by federal employee health plans. Stock prices fell after the company reported that it was the target of a DOJ criminal investigation into those practices.

ORGANOGENESIS HOLDINGS INC. 12/10/2021 E.D.N.Y.

POST-APPROVAL: BILLING Organogensis develops Affinity and PuraPlyXT, both used to treat wounds. Plaintiffs allege that the company improperly billed the federal government for its products by setting prices higher than those for similar products, and induced doctors to use its products through lucrative reimbursements. Stock prices fell after a short seller claimed that the company improperly billed the federal government for $250 million per year and offered doctors improper rebates.

REPRO MED SYSTEMS, INC. 3/26/2021 S.D.N.Y.

POST-APPROVAL: SALES PERFORMANCE Repro Med designs, manufactures and markets portable medical devices for the ambulatory infusion market. Plaintiff alleges that beginning in January 2020, the company failed to disclose that it had ramped up the use of allowances to retain key customers and promote growth, which would hurt net sales figures. Stock prices fell after the company reported its third quarter 2020 results, including a decline in net sales attributed in part to "higher allowances for gross rebates for certain customers." Stock prices fell again after the company reported financial results for fiscal 2020 and announced the resignation of its CEO.

AMARIN CORPORATION PLC 10/21/2021 D.N.J.

POST-APPROVAL: PATENT ISSUES Amarin sells Vascepa, a drug used to treat heart disease. Plaintiffs allege that Amarin failed to disclose the risk that certain patents would be invalidated in ongoing litigation. Stock prices fell after the court presiding over the patent litigation ruled against the company, and fell again after the company announced the departure of its President and CEO.

GINKGO BIOWORKS HOLDINGS, INC. 11/18/2021 N.D. Cal.

POST-APPROVAL: FINANCIAL REPORTING Ginkgo operates a horizontal platform for cell programing. Plaintiffs allege that the company misclassified and underreported related-party revenue. Stock prices fell after a market research report alleged that the company's revenue was highly dependent on related-party transactions.

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.

For more information about our securities litigation capabilities and work for life sciences companies, please contact:

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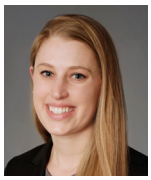

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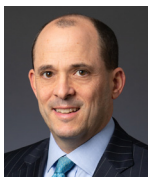

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