SIDLEY

SECURITIES CLASS ACTIONS IN THE LIFE SCIENCES SECTOR

2020
ANNUAL SURVEY

TALENT. TEAMWORK. **RESULTS.**

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IN MEMORIAM

The authors also recognize in memoriam the contributions of Norm Blears, one of the founding authors of the report and a career-long mentor to many attorneys in Sidley's securities and shareholder litigation practice, as well as to countless attorneys at other firms, companies and on the bench. Norm passed away in November 2020 and is sorely missed by his colleagues.

Securities Class Actions in the Life Sciences Sector

2020 Annual Survey

INTRODUCTION AND OVERVIEW

This year-in-review survey addresses 2020 developments in securities class actions brought against life sciences companies. We begin with an overview and analysis of trends in decisions involving life sciences companies with products at two distinct stages of development — pre- and post-FDA approval. We also briefly discuss the impact of the extraordinary events of 2020 related to the COVID-19 pandemic on clinical trials, FDA approval, and securities litigation. We then provide summaries of the 43 federal district court and appellate court decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2020.

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 a few 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 Preclinical Studies

Post-Approval: Launch and Marketing of the Product

PRE-APPROVAL: CLINICAL TRIALS AND PRECLINICAL STUDIES

PRECLINICAL DEVELOPMENT

CONDUCT OF PHASES 1-3

of clinical trials and analysis and report of trial results.

SUBMISSION OF APPLICATION FOR REGULATORY APPROVAL OF PRODUCT

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

COMMERCIALIZATION AND LAUNCH OF THE NEW DRUG OR DEVICE

POST-APPROVAL: MATURE PRODUCT

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

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

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

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

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

NONREGULATORY ISSUES

Sales Forecasting

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 "cogent" and "compelling" inference that the company made deliberately false statements.[1]

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

DECISIONS ISSUED IN 2020: TRENDS AND ANALYSIS

In this section, we discuss trends in the reported federal decisions issued in securities actions at the pleading stage. 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 2020. Companies' success rate in 2020 was 57 percent, a slight decrease from the past two years but still above the recent low in 2017.

- 2017: Companies won dismissal in 13 of the 26 decisions issued by the district courts, or 50 percent
- 2018: Companies won dismissal in 31 of the 48 decisions issued by the district courts, or 65 percent
- 2019: Companies won dismissal in 23 of the 37 decisions issued by the district courts, or 62 percent
- 2020: Companies won dismissal in 20 of the 35 decisions issued by the district courts, or 57 percent.[3]

As in past years, companies with pre-approval products or devices fared better than those in the post-approval cases. This difference was marked in 2020. Companies prevailed in 67 percent of the pre-approval cases but only 43 percent of the post-approval cases.

Companies fared well in the appellate courts in 2020: they won affirmance in seven of the eight appeals. In contrast with the appellate decisions in 2019, which were few in number and limited in impact, several of the 2020 decisions will likely be influential. In the pre-approval context, the Ninth Circuit in *Endologix* adopted a markedly skeptical approach to plaintiffs' theories of scienter. The court emphasized the commonsense notion that companies are unlikely to invest resources in products they know will not be approved, and equally unlikely to engage in frauds that will inevitably be discovered. On the other hand, the Second Circuit's reversal of a defense victory in *NewLink Genetics* injects uncertainty into that court's previously defense-friendly approach to opinion statements and to disputes over trial design. In the post-approval context, the Second Circuit's decision in *Jackson* is a solid defense victory on the recurrent issue of corporate scienter.

As we discuss more fully below, the volume of new filings has remained constant since last year, and well below its peak in 2016-2017.

- 2016: 50 new complaints
- 2017: 54 new complaints
- 2018: 48 new complaints
- 2019: 44 new complaints
- 2020: 45 new complaints

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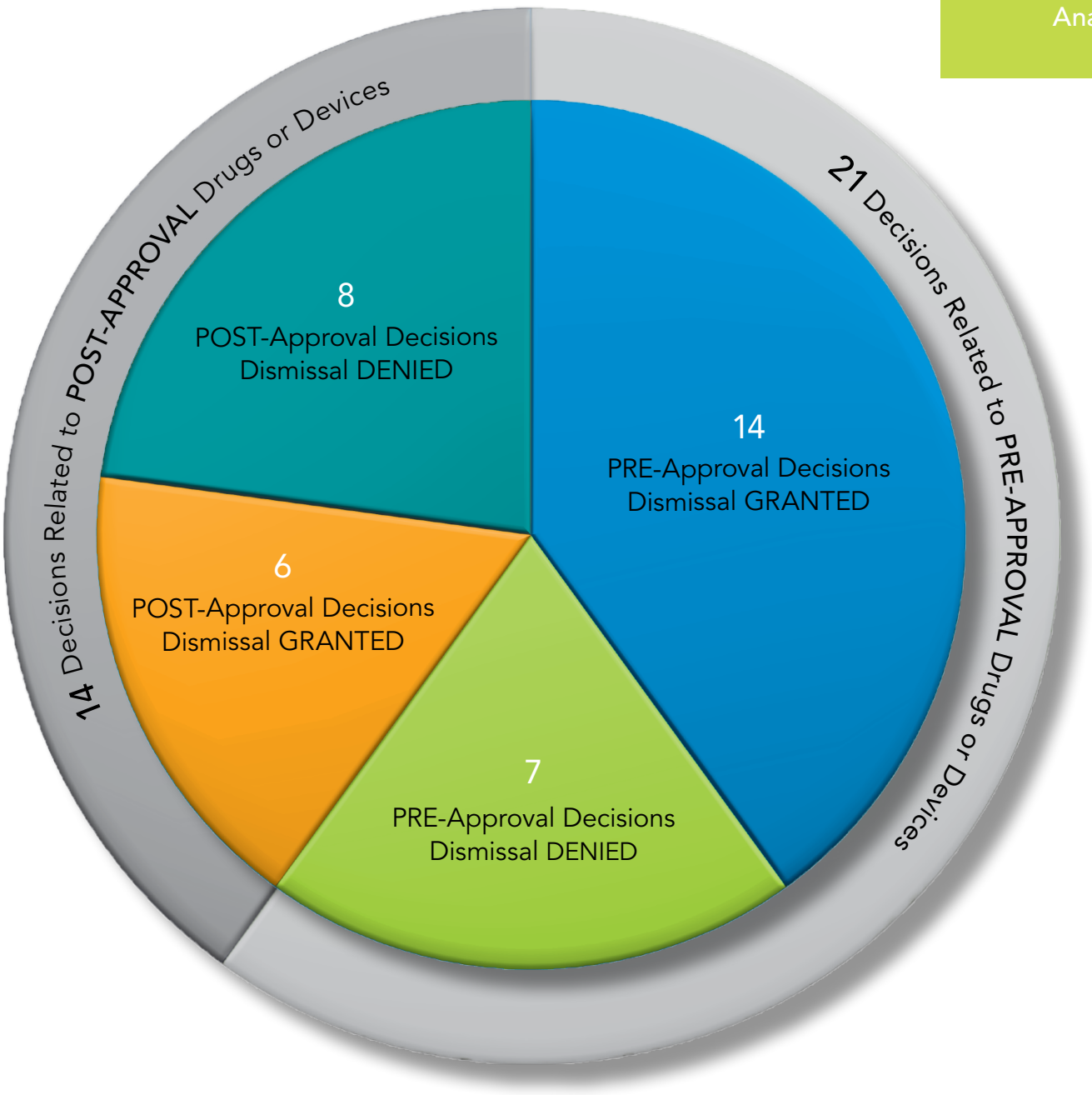
2 Under Section 10(b) (15 U.S.C. § 78j(b)), life sciences companies and their officers may be liable for consciously false or misleading statements they make in virtually any public context, including press releases, earning calls, investor conferences and SEC filings. Defendants may also be liable for 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

In 2020, as in the past several years, district court decisions in cases involving development-stage companies or products broke decisively in favor of defendants. Defendants were successful in 67 percent of the district court pre-approval decisions. The district courts granted defendants' motions to dismiss in 14 cases and denied motions to dismiss in whole or in part in seven.

We discuss developments in four areas below. First, we compare two very different approaches to financial motivation during the approval process, and at the NDA stage in particular. Both plaintiffs and defendants frequently point to financial motivation in arguing for and against an inference of scienter. On the one hand, defendants will argue that it makes little sense to posit that a company would expend resources on a trial it believes will fail, or on an NDA that it knows will not be approved. The Ninth Circuit embraced this principle in strong terms in *Endologix,* and several district courts have applied it in 2020 decisions as well. On the other hand, plaintiffs will argue that a cash-strapped company may "gamble" on approval when it has few other options, particularly if the company or individual executives may realize short-term gains from doing so. Several district courts have embraced that theory in 2020 where plaintiffs were able to plead facts that, taken as true, supported it.

We next discuss the 2020 decisions reflecting continued application and analysis of the Supreme Court's 2015 ruling in *Omnicare*, which governs challenges to opinion statements. The most important decision in this area is *NewLink Genetics,* in which the Second Circuit took the unexpected position that the distinction between statements of fact and statements of opinion is relatively unimportant. This marks a notable departure from earlier post-*Omnicare* law in the Second Circuit. In an earlier ruling, the Second Circuit had held, under *Omnicare*'s framework, that companies are not required to disclose during the approval process all facts investors might like to know that cut against the prospects of success. Reconciling *NewLink Genetics* with earlier Second Circuit law may complicate the analysis of *Omnicare*.

NewLink Genetics may also be a setback for life sciences companies in another way, at least in the Second Circuit. That court has held since its 2013 decision in *Kleinman* that disputes over trial design — and matters of science and medicine in the pre-approval space generally — lie outside the scope of the securities laws. In *NewLink Genetics,* however, the court entered directly into a debate about what the scientific literature showed on an issue related to overall survival rates. The Second Circuit made no reference in *NewLink Genetics* to its own precedent in *Kleinman,* indeed, the court showed no awareness of that earlier (and influential) decision.

Finally, we discuss five decisions in which courts considered companies' disclosure obligations when they receive Forms 483. Three decisions favored defendants; two favored plaintiffs. When a company chooses to disclose receipt of a Form 483, this will go a long way toward dispelling any inference that the company sought to deceive investors about manufacturing issues. That was the First Circuit's holding in *Ocular,* which affirmed the district court's dismissal on scienter grounds. When a company is silent about a Form 483 it has received, more nuanced questions arise about materiality and the duty to disclose. The outcome may depend on the substance of the FDA's inspectional observations, as well as on the statements plaintiffs claim were rendered misleading by the omission of information about the Form 483. Challenged statements in the 2020 decisions have included those made as a matter of course in annual filings — in particular, statements about compliance with Current Good Manufacturing Practices regulations and risk disclosures related to inspections, warning letters and other interactions with regulators. A company that has received a Form 483 would do well to review and where appropriate to revise such statements in periodic filings.

Scienter: Two Contrasting Approaches to Economic Motivation

In a surprising number of 2020 decisions, courts ruling on motions to dismiss proceeded directly to an analysis of scienter, without first determining whether plaintiffs had adequately alleged materially false or misleading statements. This was the case in each of the four appellate decisions in which courts affirmed dismissal — *Ohr, Cempra, Ocular* and *Endologix* (pages 18-20). It was also the case in three district court decisions —

Ampio, Bellicum and *Bristol-Myers Squibb* (pages 23-24). By contrast, in the one unfavorable appellate decision, *NewLink Genetics* (which we discuss in detail below), the Second Circuit did not reach scienter at all. The court held that plaintiffs had sufficiently pled falsity and loss causation, but did not so much as mention scienter.

The 2020 decisions illustrate two very different approaches to scienter in cases where companies run into trouble at the end of the drug development process. By the time a company submits an NDA or premarket approval application, it has devoted very substantial resources to the effort — often many years and hundreds of millions of dollars. That economic reality can be central to a court's assessment of scienter in cases at the NDA stage. But this cuts both ways. In one group of cases, courts have recognized that these expenditures weigh heavily against scienter: rational actors do not knowingly invest resources in losing propositions. In a second group of cases, by contrast, plaintiffs have succeeded in persuading courts that when a company has invested heavily in a drug and is in reduced circumstances, it may recklessly gamble on approval if it sees no better option.

In the first category of cases, and in keeping with a long line of securities decisions both inside and outside the life sciences context, courts have rejected scienter allegations on practical grounds. It is counterintuitive to posit that a company would devote resources to expensive clinical trials and other preparations for approval if the company believes that approval is out of reach. It is similarly counterintuitive to posit that a company would engage in a fraud that will inevitably be exposed when approval is denied.

In 2020, the Ninth Circuit embraced this approach in *Endologix* (page 20), which is likely to be an influential decision. The company in that case was already marketing its medical device in Europe and was in the midst of U.S. trials. Issues arose with "migration" of the device — that is, movement within a patient's body. The company expressed optimism about its ability to address the issue, but the FDA thereafter halted the review process and directed the company to gather an additional two years' worth of patient follow-up data. The company ultimately abandoned the product in favor of a newer-generation variant. The district court dismissed plaintiffs' fraud claims on scienter grounds, and the Ninth Circuit affirmed. Plaintiffs had argued in stark terms that the migration issue was "intractable" and "unresolvable." That theory, the Ninth Circuit concluded, "does not make a whole lot of sense." Why would a company artificially inflate its stock price if it knew that the day of reckoning was unavoidable? A defendant might do so if the inflation led to some short-term economic advantage — which would be the case if the company or its executives sold stock — but no such economic motive had been alleged in *Endologix*. Drawing on the plausibility standard of Rule 12(b)(6), the court rejected plaintiffs' scienter theory in broad terms, holding that it did not "resonate in common experience."

The district court in *Ampio* (page 24) employed similar reasoning. Plaintiffs there alleged that the company knowingly proceeded with a Phase 3 trial that could not support approval: "The crux of Plaintiffs' Complaint is that Defendants knew or were deliberately reckless [ ] to the fact the [trial] was poorly designed and would not be approved by the FDA." The court squarely rejected this premise. "[T]he idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly [carry] on a defective trial — so that any defects were not remedied — virtually defies reason." Plaintiffs sought to explain why the company would pursue an economically implausible course of action by pointing to an SEC subpoena directed at insider stock sales and by speculating that the company was in search of a merger partner. But the court rejected that theory as well, largely because plaintiffs had provided few supporting details. The court concluded that any inference of scienter based on short-term economic gain was "significantly less compelling than the opposing inference — that Defendants designed an inexpensive trial (because companies always have a desire to keep costs low), tried [their] best to ensure that the trial was well-controlled and adequate, but despite their best efforts, the FDA did not accept this trial."

On the other side of the ledger are decisions in which courts have accepted plaintiffs' depiction of an economic motivation that weighs in favor of scienter. The scienter theory in these cases is that once a company has expended resources on approval, and particularly if it is short of funds, the company may "gamble" on approval even if it has become very unlikely.

The court credited this theory in *Acer* (page 32). The company in that case sought approval of a drug by means of the Section 505(b)(2) regulatory pathway, in which the sponsor may rely on prior clinical trials performed by third parties. Acer told investors that the FDA had agreed to permit it to submit a Section 505(b)(2) NDA based on a clinical trial performed in 2004. The FDA ultimately issued a Complete Response Letter stating that the company needed to conduct a new trial demonstrating efficacy. In holding that plaintiffs had adequately alleged scienter, the court relied heavily on allegations of economic motivation. The court noted that the company had included a going concern qualification in a recent Form 10-Q and concluded that defendants "had an incentive to gamble that the FDA" would approve the drug:

> If Acer did not raise funding, its SEC filings represented that it would run out of money and Defendants would have had no chance to bring [the drug] to market. Better to say what was necessary to raise the money and hope that the FDA would eventually approve [the drug].

The court in *Trevena* (page 33) applied similar reasoning, crediting plaintiffs' theory that the company took a "calculated gamble" that the FDA would approve its drug despite purportedly having raised concerns about trial design at an End-of-Phase-2 meeting.

A third decision in this category, *Innocoll* (page 34), is particularly striking because the court's treatment of economic motivation differed sharply between its ruling on the company's first motion to dismiss — which the court granted — and its ruling on the company's second motion to dismiss — which the court denied. Innocoll developed a product containing both a drug and a device component. The company submitted an NDA seeking approval of the product as a drug only. The FDA responded with a refuse-to-file letter, stating that the application was incomplete because the company had failed to include necessary information about the device component. In ruling on the company's first motion to dismiss, the court asked why, assuming rational economic behavior, it made any sense for plaintiffs to posit that the company would choose not to test the device component along with the drug component if it knew this was necessary for approval. Because the plaintiffs had no satisfactory answer to that question, the court dismissed their complaint on scienter grounds.

In their amended complaint, however, plaintiffs provided an answer the court deemed satisfactory. Plaintiffs alleged that the company had no money to study the device component, that the company's economic situation overall was dire, and that the executives, whose careers were on the line, were negotiating an acquisition of the company and needed to keep its valuation high. As the court characterized plaintiffs' allegations, "Defendants, strapped for cash and eager to cut corners, decided to forgo spending the necessary $10 million for device trials" — and then "refrained from disclosing their calculated risk for financial and personal reasons." The court accepted these allegations for pleading purposes, concluding that they supported an inference of fraud at least as compelling as defendants' position that "they simply made a very expensive and unintended mistake." The court also credited plaintiffs' allegation that FDA guidance showed that the company "should have known" that approval of the device component was necessary — although "should have known" is generally considered to be a negligence rather than a scienter standard.

In contrast to *Acer, Trevena* and *Innocoll,* the courts in *Antares* and *Zogenix* rejected allegations that drug developers were motivated to gamble on approval. In *Zogenix* (page 26), the FDA faulted the company for failing to include in its NDA certain information about prior toxicity studies related to one of the ingredients of its drug. As in the cases described above, plaintiffs characterized the company's actions as "a deliberate and reckless gamble." Here, however the court was sharply critical of that theory. Central to the court's reasoning was plaintiffs' inability to refute the "benign explanation" offered by the company: "namely, that [the company] had every incentive to get it right the first time, and to put [the drug] on the path to approval." In the absence of particularized allegations showing that the company knew how the FDA would respond to its application, or showing that the company or its executives were driven by short-term economic gain, plaintiffs' "reckless gamble" theory collapsed in favor of the more plausible inference that the company did everything it could to increase the likelihood of approval.

The district court in *Antares* (page 28) reached a similar conclusion. Plaintiffs in that case alleged that financial motivations — the risk of NASDAQ delisting and one executive's stock sales — drove the company to "gamble heavily" on a product that it knew faced significant obstacles to approval. The court rejected that theory, distinguishing decisions in which plaintiffs had alleged particularized facts showing that a company's survival was in jeopardy, or that the FDA had clearly signaled that a drug would not be approved. Taken together, *Zogenix* and *Antares* — along with *Endologix* and *Ampio* — seem to mark the limits of the "reckless gamble" theory of scienter. Unless plaintiffs can identify particular short-term economic motivations, or can plead particularized facts showing that defendants knew of the FDA's likely course of action, that theory will be eclipsed by the more obvious inference that companies do not squander resources on lost or even highly risky causes.

Opinion Statements: The Second Circuit's New Take on Omnicare

The courts in 2020 have continued to develop the law on opinion statements, which underwent a significant transformation with the Supreme Court's 2015 decision in Omnicare.[4] To briefly recap the *Omnicare* decision itself: the Supreme Court there considered a challenge under Section 11 to legal compliance opinions in the defendant company's registration statement. Under prior Second and Third Circuit case law, plaintiffs were required to show that opinion statements were both subjectively and objectively false. The Supreme Court reshaped this law under Section 11. The Court analyzed challenges to opinion statements separately under Section 11's false statement clause and Section 11's omission clause. The Court held that an opinion statement may be actionable under the false statement clause only if the speaker did not subjectively hold the belief expressed. But an opinion statement may be actionable under the omission clause if plaintiffs can show that defendants omitted facts about the basis of the opinion that are contrary to what a reasonable investor would expect. Most courts have subsequently applied *Omnicare* to Section 10(b) as well as to Section 11 claims.

Although *Omnicare* was in one sense a setback for securities defendants — plaintiffs no longer need to establish subjective falsity in every case — life sciences companies have generally fared well under the new framework. The courts have classified many statements about medicine, science, and clinical trial results as matters of opinion, and plaintiffs have often been unable to state a claim under either of *Omnicare*'s two prongs in challenging such statements.

The Second Circuit's opinion in the early post-*Omnicare* decision *Tongue v. Sanofi*, decided in 2016, illustrates the power of *Omnicare*'s analysis for life sciences defendants.[5] The plaintiffs in that case challenged the company's statements about the prospects for FDA approval, claiming that the statements were misleading insofar as the company had omitted to disclose FDA concerns about the Phase 3 trial design. In notably strong language, the Second Circuit affirmed dismissal:

> Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections — Plaintiffs were not entitled to so much information as might have been desired to make their own determination about the likelihood of FDA approval by a particular date. Certainly, Plaintiffs would have been interested in knowing about the FDA feedback, and perhaps would have acted otherwise had the feedback been disclosed, but *Omnicare* does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed in the registration statement.

In 2020, however, the Second Circuit took a markedly different approach to opinion statements. The company in *NewLink Genetics* (page 20) tested a pancreatic cancer drug against a control and announced throughout a Phase 3 trial that patients on the control arm were expected to have an overall survival rate of 18-19 months. The trial was a failure: patients on the control arm had an overall survival rate of 30 months, while patients on the treatment arm had an overall survival rate of 27 months. Plaintiffs challenged, among other things, the company's statement that according to all "major" U.S. studies, the overall survival rate

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

5 *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

for patients similar to those on the control arm was 15-20 months. In rulings in 2018 and 2019 (discussed in our previous reviews), the district court held that this was a statement of opinion and that plaintiffs had failed to adequately plead falsity. In its 2019 ruling, the district court drew on *Sanofi* and rejected plaintiffs' contention that the statement was actionably misleading simply because certain *other* studies showed a longer overall survival rate for pancreatic cancer patients.

The Second Circuit in 2020 reversed the district court's dismissal as to the statement about overall survival rate in previous studies. Significantly, the appellate court declined to determine whether the challenged statement was one of fact or opinion — a question that, in the district court's analysis, turned on the company's reference to "major" studies. In the Second Circuit's view, *Omnicare* has "reduced the significance of district courts' classification of statements as those of fact or opinion." The Second Circuit determined that it did not need to make a distinction between fact and opinion statements — which many courts have seen as a critical threshold issue — because whether the challenged statement was materially false or misleading "would not differ based on whether [it] was a statement of fact or one of opinion."

With that conclusion in place, the Second Circuit went on to reason that however the statement about "major" studies was characterized, investors would understand it to mean that no significant study had shown that the overall survival rate for patients similar to those on the control arm exceeded 20 months. The court then turned to plaintiffs' allegation that several studies had shown survival rates between 25 and 43 months. The Second Circuit concluded that this allegation was sufficient for plaintiffs to avoid dismissal, explaining that "a jury" could decide that the company's "confident statement" about a 15-20 month overall survival rate was "a bridge too far" given the omission of information about the studies purportedly showing longer survival rates. The reference to a jury here — rather than to the PSLRA's heightened pleading standards — is notably odd, as is the fact that the Second Circuit did not once in the decision refer to scienter. Those anomalies aside, however, the *NewLink* decision may complicate the *Omnicare* analysis going forward, at least in the Second Circuit.

Disputes Over Science and Medicine

Since 2014, we have reported nearly every year on cases in which companies characterize plaintiffs' challenges as disagreements over scientific matters. Where courts agree with such a characterization, they grant dismissal on this ground, holding that disputes over science and medicine must be settled within the research community — including the FDA — and not by judges and lawyers under the securities laws. Courts that embrace this analysis often draw on the Second Circuit's 2013 *Kleinman* decision or the Ninth Circuit's 2012 *Rigel* decision, both of which provide substantial, appellate-level support for it.[6] Over the years, the courts have employed this analysis to dismiss or affirm dismissal of claims relating to a broad range of subjects — for example, the selection of trial endpoints and p-values, the criteria for including or excluding patients, and the conclusion that one drug is the bioequivalent of another. In the Second Circuit in particular, defendants have succeeded where they could characterize plaintiffs' fraud claims as attacks on trial design.

Two 2020 decisions illustrate courts' response to a technique plaintiffs' firms occasionally employ in an effort to persuade courts that a particular dispute over scientific matters is in fact justiciable. In both *Nektar* (page 21) and *Bristol-Myers* (page 23), plaintiffs included expert opinions in their allegations. In both cases, the companies had won initial motions to dismiss, and plaintiffs introduced expert allegations in their amended complaints in an effort to cure the previously identified pleading defects. In neither case did the plaintiffs succeed: the courts dismissed the amended complaints incorporating expert opinions just as they had dismissed the earlier complaints.

In *Nektar,* the plaintiffs alleged that the company's statements about the mean increase in a favorable biomarker in Phase 1 trials — a 30-fold increase in the number of certain cancer-fighting cells — was misleading because the company had purportedly included an "outlier" patient in computing the mean. In two successive orders, both issued in 2020, the district court concluded that plaintiffs had failed to plead that the challenged statements were false or misleading.

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6 *Kleinman v. Elan Corp.*, 706 F.3d 145 (2d Cir. 2013); *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869 (9th Cir. 2012).

"Instead," the court held in the later of the two rulings, "Plaintiffs' allegations amount to a disagreement with Nektar's statistical methodology, and such a disagreement is insufficient to allege falsity." The expert's opinion did not change the analysis. Although the expert claimed that the purported inclusion of the outlier violated "industry and scientific standards," neither the expert nor the plaintiffs ever specified what those standards were. "The Court rejects Plaintiffs' attempt to distinguish Rigel based on unspecified standards …. It is insufficient to allege that the challenged statements regarding the 30-fold increase chart were false or misleading because the Defendants did not use Plaintiffs' preferred statistical methodology."

In *Bristol-Myers*, the court rejected expert allegations on similar grounds, although here the court's focus was on scienter rather than falsity. The question in *Bristol-Myers* was whether the company had misled investors in stating that it had restricted the patient population in the trial of an immuno-oncology drug to "strong" expressers of a particular protein. After reporting disappointing trial results, the company disclosed for the first time that "strong" expression in the context of the trial meant that 5 percent of a patient's cancer cells expressed the protein. In their second-round consolidated complaint, plaintiffs included the statement of a medical oncologist who claimed that industry consensus was that 5 percent expression was "low" or "minimal," and that "strong" expression meant 50 percent. The court held that the expert's opinion was insufficient to establish scienter. First, neither the expert nor the plaintiffs had identified any industry publication or guidance that supported the expert's assertion about what "strong" expression meant. And second, the expert had "do[ne] nothing to bring his claim of an industry standard home to BMS." The expert, that is, had only stated his own opinion; he had not shown that the company would have shared that opinion.

The Second Circuit's *NewLink Genetics* decision, discussed above, treats the subject of disputes over scientific matters very differently. Plaintiffs there, as noted, attacked the company's statement that previous major studies had shown an overall survival rate of 18-19 months for pancreatic cancer patients; plaintiffs asserted that other studies showed far longer survival rates. The district court dismissed plaintiffs' attack on the statement about what previous studies had shown, concluding that plaintiffs' claim was "essentially a criticism of trial methodology" — and that under *Kleinman,* such critiques cannot support claims under the securities laws. The Second Circuit reversed dismissal and made no reference to *Kleinman* or the principle it embodies. The appellate court simply dove into the dispute in *NewLink Genetics*, analyzed the dispute according to what a jury might conclude, and then concluded that plaintiffs had pled enough to proceed to discovery and trial. As with its treatment of opinion statements, the Second Circuit's treatment of disputes over scientific matters in *NewLink Genetics* may complicate the analysis going forward, at least within the Second Circuit.

Forms 483: Disclosure Issues and Affirmative Statements

In five of the 2020 pre-approval decisions, courts have considered statements or omissions related to Forms 483. In three of the decisions — *Ocular, PolarityTE,* and *Nabriva* (pages 19, 25, and 29) — the courts dismissed or affirmed dismissal of Form 483-related claims. In the other two decisions — *Odeh v. Immunomedics* and *Teligent* (page 35) — the courts denied the motions to dismiss.

The clearest issues in these cases arise when a company affirmatively discusses Forms 483. This was the case in *Ocular*, where the company received two rounds of Forms 483 during two successive NDA review cycles. The company disclosed the Forms 483 and spoke optimistically about rectifying the issues the FDA had identified. The FDA ultimately denied both NDAs, citing manufacturing issues. The First Circuit nevertheless affirmed dismissal, holding that the company's disclosure of the Forms 483 undermined any inference that the company intended to deceive investors about problems with its manufacturing processes.

On the other end of the spectrum is *Teligent,* in which the company received a Form 483 but affirmatively reported to investors that it had received no Forms 483 over the previous several review cycles. The company argued that its statement was not false or misleading: properly understood, the company argued, its statements referred to Forms 483 the FDA issues during cGMP audits (which the company had not in fact received), as opposed to Forms 483 the

FDA issues as part of its Bioresearch Monitoring program (which the company had received). The court rejected the company's argument, concluding that the challenged statements had not made this distinction clear, and that plaintiffs had adequately pled both falsity and scienter.

Different issues arise when a company receives a Form 483 and says nothing about Forms 483 at all. This was the case in *Nabriva, PolarityTE,* and *Odeh v. Immunomedics*. Here, the issue is whether the company has a duty to disclose the Form 483. The court in *Nabriva* considered whether that issue could be resolved on a wholesale level, by a determination that all Forms 483 are *per se* immaterial (and hence need not be disclosed) because they are not final agency actions. The court found some support for that position in prior case law, but noted that other courts had held that Forms 483 are *per se* material in the pre-approval setting, as they can slow the approval process. The *Nabriva* court concluded that the issue could not be resolved in the abstract, and that whether a Form 483 is material — and whether it must be disclosed — depends on the circumstances of a particular case.

Those circumstances can include, most obviously, the nature and number of the FDA's observations in a Form 483. An equally critical factor is the nature of the company's challenged statement. Disclosure duties under Section 10(b) do not arise in the abstract. An omission is actionable only if it renders an affirmative statement misleading, and a plaintiff claiming that a company misled investors by failing to disclose a Form 483 must accordingly identify a statement rendered misleading by that omission. The 2020 decisions show two principal kinds of statements targeted by the plaintiffs' bar: (1) those related to a company's compliance with Current Good Manufacturing Practices regulations (cGMP), and (2) risk disclosures cautioning investors that a company may receive Forms 483 or other adverse regulatory communications.

Here, too, the details can be significant. In *Ocular*, the company stated that it "used" cGMP, and the First Circuit relied in part on the generality of that statement in holding that plaintiffs had failed to plead that the company knowingly or recklessly misled investors. In *Teligent*, by contrast, the company stated that it was "cGMP-compliant" — a statement the court concluded plaintiffs had adequately alleged was misleading in light of an undisclosed Form 483. Given these rulings, a company that has received a Form 483 would be wise to review — and if necessary revise — statements in subsequent Forms 10-K about cGMP.

The same is true of risk disclosures related to manufacturing issues or to regulatory action more generally. In both *Nabriva* and *Teligent*, the courts held that plaintiffs had adequately pled falsity as to risk disclosures related to the *possibility* of receiving a Form 483. In light of an actual receipt of a Form 483, the courts reasoned, a reference to mere possibility could be misleading. (In *Nabriva,* the court nevertheless dismissed, concluding that plaintiffs had failed to establish a strong inference of scienter with respect to the challenged risk disclosure.) A similar approach appears in *Odeh v. Immunomedics,* where the company suffered a data breach followed by a Form 483. The court concluded that a risk disclosure cautioning investors of the possibility of a data breach could be misleading after an actual data breach occurred. Given these decisions, a company that has received a Form 483 would be well advised to review and update its risk disclosures, as well as its statements about cGMP.

POST-APPROVAL DECISIONS

In the post-approval cases, companies lost on motions to dismiss in the district courts more often than they prevailed. Courts granted motions to dismiss in six cases and denied motions to dismiss in part or in whole in eight. No common feature appears to unite the cases in which companies were unsuccessful. The cases involve a range of regulatory issues (alleged kickbacks, Medicare rebates), commercial issues (product discounts), and the continuation of the plaintiffs' bar's effort to capitalize on antitrust investigations and litigation in the generic drug industry.

We discuss two subjects below. First, we examine the courts' treatment of expansive scienter theories to which plaintiffs turn in the absence of facts establishing knowledge and intent to deceive. Second, we consider the complexities that have arisen in cases built on alleged antitrust violations that are being litigated in the first instance elsewhere.

Scienter Theories in the Post-Approval Context

As discussed above, pre-approval decisions in 2020 frequently included substantial analyses of economic motivation in the assessment of scienter allegations. In the post-approval context, by contrast, courts more often turned to theories on which plaintiffs rely where they have a very limited factual basis — or no factual basis at all — for asserting that the executives who made the challenged statements knew that those statements were false or misleading, and deliberately deceived investors. Two such plaintiff-friendly theories are corporate scienter and the core operations doctrine. Companies obtained victories on the corporate scienter theory in 2020, while results on the core operations doctrine were mixed.

To be clear, plaintiffs frequently draw on these scienter theories in the pre-approval context too. We focus on the post-approval decisions from 2020 because they include some notable developments and illustrate significant contrasts in the law in this area.

Collective Corporate Scienter. Plaintiffs who invoke the concept of corporate scienter argue that they need not show that executives who made challenged statements knew of their falsity. Plaintiffs argue under this theory that it suffices to establish that *some* person within a company knew of facts showing that the challenged statements were false — even if this is not the person who made the challenged statements.

That theory received a chilly reception from the Second Circuit in *Jackson* (page 39), where the court held that plaintiffs must establish a connection between the challenged statement and the employee whose knowledge they seek to impute to the company. The background of the securities action in *Jackson* was a consumer class action in which customers alleged that the company's surgical gowns had failed quality control tests. In the district court, plaintiff sought unsuccessfully to show that the company's senior executives knew of the problems with the gowns. On appeal, plaintiff abandoned not only this theory of scienter, but also all claims against the individual executives: plaintiff appealed dismissal only as to the company defendants. Plaintiff's appellate theory was that testimony in the consumer class action showed that three testifying witnesses knew of purported problems with the gowns — and that the knowledge of those employees could be imputed to the company. The Second Circuit rejected the theory that the witness testimony established scienter at the corporate level: the witnesses took steps to raise, not hide, their concerns, and no senior executive ignored their warnings. Although plaintiff had "set[] forth allegations that three employees knew of problems" with the gowns, the complaint provided "no connective tissue between those employees and the alleged misstatements."

Jackson was presaged by the Southern District of New York's decision in *Intercept* (page 39). In that case, both the company and the FDA issued warnings to physicians about mis-dosing the company's drug, which had been connected to patient deaths when prescribed in amounts exceeding the labeled dose. Plaintiffs sought to create the required inference of scienter by reference to employees other than the executives who had made the challenged statements. The court rejected that effort, holding that "a plaintiff must allege some connection at the corporation between a misstatement and the requisite quantum of knowledge of its falsity," and that plaintiffs had been unable to "bridge this gap." Plaintiffs were required — but had failed — to identify management-level employees who both "knew … of the adverse event reports and approved or were aware of the allegedly misleading statements."

Core Operations Doctrine. In contrast to the company victories in *Jackson* and *Intercept*, the courts delivered a mixed set of rulings on the core operations doctrine. 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, a court may infer scienter from the premise that a challenged statement related to the company's core operations 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.[7]

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

In the Second Circuit, by contrast, the validity of the core operations inference remains an open question.[8]

With that as background, two district courts — *AbbVie* in the Seventh Circuit and *Align* in the Ninth — denied motions to dismiss where core operations allegations supported other scienter allegations. Notably, plaintiffs in both cases claimed that the company was engaged in undisclosed conduct related to its key product. In *AbbVie* (page 44), plaintiffs alleged that the company had provided illegal kickbacks to physicians who prescribed Humira, a drug that accounted for more than half the company's annual revenue. The court held that plaintiffs had adequately alleged scienter "especially … because sales of Humira constituted a majority or even supermajority of AbbVie's yearly net revenues." In *Align* (page 46), plaintiffs alleged that the company had provided undisclosed discounts on a product that represented 86 percent of its revenue. The court agreed with plaintiffs that the company "must have known" about the discounting program because a discount on the "main revenue source qualifies as facts critical to a business's core operations."

The *Corcept* court (page 41), also in the Ninth Circuit, granted the company's motion to dismiss but nevertheless noted that the case might exhibit the "rare circumstances" in which the Ninth Circuit has held that the core operations inference could be sufficient *in itself* to support an inference of scienter. Plaintiffs in *Corcept* accused the company of off-label marketing in connection with a drug that accounted for 100 percent of its revenue. The court held that plaintiffs had failed to plead a companywide off-label marketing scheme, and therefore dismissed without prejudice on falsity grounds. But the court also remarked that given the significance of the product at issue, an inference of scienter might be warranted on the basis of the core operations doctrine alone — provided plaintiffs were able to establish falsity.

In contrast, several courts in 2020 declined to infer scienter on the basis of the core operations doctrine, even with respect to products that made up a substantial portion of a company's portfolio. In *Higgins* (page 41), plaintiffs alleged misstatements related to off-label marketing of an opioid that accounted for 62 percent of the company's revenue. The court dismissed on scienter grounds (among others), holding that the core operations doctrine could not replace allegations that the individual defendants knew their statements were false or misleading. Likewise, in *Intercept* (page 39), the Southern District of New York rejected plaintiff's core operations allegations — which were based on serious adverse events related to the company's "lead product" — noting that the doctrine "is used to bolster other substantial grounds for scienter rather than constitute independent means to plead the requisite mental state." And in *Jackson*, discussed above, the Second Circuit rejected the core operations inference in connection with the plaintiff's corporate scienter theory. The court held that the "naked assertion" that a product was "of such core importance" that "senior officers must have known that the [statements about that product] were false" was "plainly insufficient to raise a strong inference of collective corporate scienter."

Duty to Disclose. In several of the 2020 decisions, courts approached scienter in *omission* cases from the perspective of a duty to disclose. The reasoning in these decisions is that where a plaintiff can show that the company plainly had an obligation to disclose an omitted fact, the same allegations that establish that duty can support an inference of scienter. The reverse is true too: where a disclosure duty is less than clear, a court cannot infer knowing or reckless fraud on the basis of an omission.

A focus on disclosure duties led to a defeat for the defendants in *Perrigo* (page 47). The company in that case was subject to a tax audit and ultimately received an Audit Findings Letter from Irish taxing authorities including the finding that the company had a tax liability of €1.6 billion. The company disclosed its receipt of the letter but not the amount at issue. In moving to dismiss, the company argued that the taxing authorities had invited it to respond to the letter, that the amount of liability was accordingly in flux at the time of the challenged statements, and that the company therefore had no duty to disclose the amount. The court rejected that theory,

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8 *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).

concluding that the company had an obvious duty to disclose the amount at issue — and that this supported a strong inference of recklessness.

The First Circuit's decision in *ReWalk* (page 38) stands in contrast. There too, plaintiffs alleged that the company wrongfully failed to disclose the substance of its communications with regulators. The communications at issue in *ReWalk* related to the company's post-market studies, which the FDA had told the company were inadequate. The First Circuit rejected the premise that the company had a duty to disclose those communications, which the court characterized as "run-of-the mill regulatory back-and-forths." And in the absence of a duty to disclose, plaintiffs failed to establish a strong inference that defendants believed their statements were fraudulent.

The court in *Aceto* (page 40) was even more critical of plaintiffs' effort to infer scienter from a purported duty to disclose. The company there disclosed that a supplier was failing to meet its needs, that the company was in turn unable to meet its customers' needs, and that this had led to financial penalties. Plaintiffs claimed that the company was required to go further and to disclose that the supplier had breached the parties' contract. The court rejected the premise that the company had a duty to make this additional disclosure and rejected plaintiffs' scienter allegations on the same basis: "[T]he caselaw does not suggest Defendants owed investors a duty to make additional disclosures about the [supply] problem that was clear enough to imply scienter."

The Complexities of Securities Litigation Derived From Ongoing Antitrust Proceedings

2020 saw further developments in an area on which we reported in our 2018 and 2019 reviews — claims based on alleged price fixing in the generic drug industry. Beginning in 2014 and continuing throughout 2015 and 2016, companies and media outlets reported on state and federal investigations into alleged price fixing by generic drug manufacturers. On November 3, 2016, a *Bloomberg* article named several companies being investigated, and predicted that the federal government would file criminal charges by year-end. In December 2016, the DOJ filed charges against former executives of one company, while multiple state attorneys general filed a complaint alleging a broad price-fixing conspiracy among many manufacturers. State attorneys general filed additional complaints over the next several years, naming additional manufacturers and drugs.

Securities plaintiffs filed complaints premised on the various government investigations and allegations beginning in late 2016 and continuing over the next several years. Companies have fared poorly in moving to dismiss these cases. Results on motions to dismiss were mixed in 2018, with three victories for plaintiffs and two for defendants. By the end of 2019, however, seven companies had lost motions to dismiss and only one company, Impax, had succeeded in obtaining dismissal with prejudice. That victory was reversed in relevant part by the Ninth Circuit in early 2021.[9]

In 2020, district courts denied two additional motions to dismiss in this set of cases, bringing the total number of actions proceeding beyond the pleading stage to nine. Together with the earlier decisions, the 2020 decisions highlight the continued complexities these cases present. As we noted in our 2019 review, the underlying allegations in these cases are being litigated in a multidistrict proceeding in the Eastern District of Pennsylvania at the same time as the securities actions. Given the pace at which the various lawsuits are moving, the possibility has arisen that the securities actions — which *derive* from the antitrust investigations and litigation — could become the vehicle in which the underlying antitrust issues are decided in the first instance.

The district court in *Endo* (page 45), seeing this possibility, stated that it would not countenance an "antitrust trial within a securities trial." But it is unclear how the court will avoid this. The court dismissed plaintiffs' claims in *Endo* to the extent plaintiffs alleged that Endo was itself a conspirator. The court applied antitrust pleading standards and held that plaintiffs had shown only that the company was involved in parallel pricing, which is legal; plaintiffs had failed

9 *N.Y. Hotel Trades Council Pension Fund of N.Y., Inc. v. Impax Labs., Inc.*, 2021 WL 81719 (9th Cir. Jan. 11, 2021).

to allege the "plus factors" necessary to support a conspiracy claim. But the court denied the motion to dismiss as to plaintiffs' alternative theory — that in light of the company's purported knowledge of a conspiracy among third parties, plaintiffs had adequately pled that the company's statements about the competitive environment and sources of its generic drug revenue were misleading. The *Endo* court followed a decision from 2019, *Lannett II*, in which plaintiffs had similarly avoided dismissal by shifting from the theory that the company was itself a conspirator to the theory that the company knew about a conspiracy among third parties operating in the same market. Neither *Endo* nor *Lannett* makes clear how claims like these can avoid devolving into an antitrust trial within a securities trial. The substitution of third parties for the securities defendant as the purported conspirators does not appear to solve the problem. Indeed, that substitution only raises new difficulties related to the scope of discovery and the rights of the third parties — accused of criminal violations — in litigation in which they are not defendants.

The second 2020 decision, *Mylan* (page 45), is a ruling on an amended complaint in which plaintiffs, having survived earlier motions to dismiss, added allegations related to multiple drugs they had not previously claimed were subject to price-fixing agreements. The court granted the company's motion to dismiss as to 18 of the 19 drugs at issue in its motion, holding that plaintiffs had failed to allege a conspiracy under antitrust pleading standards. The case is nevertheless moving forward with respect to conspiracy allegations related to different drugs.

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

Before turning to detailed case summaries, we offer a few observations on the impact of the COVID-19 pandemic on securities litigation, and more importantly, on the clinical trial and FDA approval processes that are frequently in the foreground of securities litigation against life sciences companies. An exhaustive treatment of these issues is outside the scope of this review.

A notable fraction of new securities filings against life sciences companies in 2020 relate to the pandemic: in seven of the 45 new cases, plaintiffs have challenged statements made by companies developing COVID-19-related products. The reported decisions, of course, lag behind. No securities decision from 2020 addresses the development of COVID-19-related products or other impacts of the pandemic on life sciences companies. But federal district courts have begun in the first few months of 2021 to issue decisions in this area. In one case, *Inovio,* investors challenged the company's statements about a prospective COVID-19 vaccine.[10] The court denied in part and granted in part the company's motion to dismiss in a straightforward application of the securities laws. In a second case — not involving a life sciences company — investors alleged that a financial institution that conducted its IPO in January 2020 should have disclosed uncertainty facing the real estate market as a result of the pandemic.[11] The court granted the company's motion to dismiss. As the new filings make their way through the courts in 2021, it remains to be seen whether the treatment of COVID-19-related litigation will differ in any thematic way from the treatment of litigation involving other products regulated by the FDA.

More generally on the litigation front, the pandemic does not appear to have slowed either the pace of new filings or the progress of securities litigation through the courts. The 2020 figures for new filings and court decisions are very close to the 2019 figures. (See pages 3 and 4, above.)

The more profound effects of the pandemic have been — and will likely continue to be — on clinical trials and the FDA approval process rather than directly on securities litigation. Throughout 2020, the FDA published guidance related to the development of COVID-19-related products such as diagnostic tools and PPE, and cleared the way to make many such products available through Emergency Use Authorizations. As to COVID-19 vaccines, the FDA issued guidance on safety and efficacy criteria and again turned to Emergency Use Authorizations rather than standard approval processes. Vaccine development was also supported through the White House's Operation Warp Speed program.

10 *McDermid v. Inovio Pharm. Inc.*, 2021 WL 601159 (E.D. Pa. Feb. 16, 2021).
11 *Berg v. Velocity Fin. Inc.*, 2021 WL 268250 (C.D. Cal. Jan. 25, 2021).

Of even broader interest to the industry, the FDA began in March 2020 to publish guidance for companies that are developing products unrelated to COVID-19, but are conducting clinical trials in the new circumstances ushered in by the pandemic. Not surprisingly, the FDA stated in March 2020 that the paramount concern is protecting the safety of trial participants. The agency updated and expanded this guidance frequently in 2020 and has continued to do so in 2021.

The FDA has also shown considerable flexibility in ensuring that drug sponsors are able to achieve the goal of patient safety. In the same March 2020 guidance, the FDA stated that sponsors may make changes to protocols to protect patient safety without waiting for approval from independent review boards or ethics committees, and before filing amendments to critical regulatory documents. At the same time, the FDA has encouraged sponsors to engage with the relevant independent review boards and ethics committees as early as possible. And the agency has stated that sponsors *must* report any such protocol changes consistent with existing regulations, and must describe such changes in detail in clinical trial reports.

With that guidance in place, accounts of COVID-19's impact on clinical trials have varied, with some commentators estimating that as many as 80 percent of non-COVID-19-related trials were stopped or interrupted in 2020.[12] The impact appears to have been greatest on early-phase trials, and for treatments in which patient populations are at greatest risk of COVID-19 complications (autoimmune diseases, cancer).[13] The silver lining may be that some of the innovations used to protect patient safety while keeping trials running — for example, telemedicine, electronic informed consent, home delivery of drugs that can be self-administered, decentralization of treatment and testing to community settings — could carry into the post-pandemic future and facilitate efficiencies in drug development.

The same may be true of regulatory functions. On the one hand, some drug sponsors in 2020 at times experienced diminished responsiveness from the FDA, as the agency devoted resources to COVID-19-related products. While the FDA has largely continued to meet user-fee timelines for review and approval of products, sponsors have in some cases reported more difficulty than usual in setting meetings, and a greater incidence of Complete Response Letters as opposed to continued discussion and negotiation on the path to approval. Other aspects of the approval process — such as facility inspections — have largely stopped as a result of the logistical challenges in COVID-19 life and travel. On the other hand, the FDA's extraordinary flexibility and speed in working with drug developers on COVID-19-related products may carry over to other products going forward. A variety of innovations in the approval process — from "master protocols" to the use of real-world data in addition to clinical trial data — may be on the table as a result of the pandemic experience.

12 *Covid-19 and Readjusting Clinical Trials,* Aaron van Dorn, *The Lancet* vol. 396 Issue 10250 (Aug. 22, 2020).

13 *The Impact of COVID-19 on Clinical Trials,* Dustin Phan, *In Vivo Pharma Intelligence/Informa* (June 8, 2020).

DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 17-36), 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 have fared well in the district courts, winning dismissal in two-thirds of the cases surveyed.

Companies have fared even better in the appellate courts, which affirmed dismissal in four of the five decisions. *Endologix,* a favorable decision from the Ninth Circuit, is notable. The appellate court focused on economic motivations at the approval stage and concluded that plaintiffs' theory of scienter was inconsistent with common sense. On the other side of the ledger is the Second Circuit's surprising decision in *NewLink Genetics*. In reversing dismissal, that court adopted pro-plaintiff positions on opinion statements and disputes over scientific matters without accounting for previous Second Circuit law pointing in the opposite direction.

APPELLATE DECISIONS

Lehmann v. Ohr Pharm., Inc., 830 F. App'x 349 (2d Cir. 2020), affirming dismissal. **Phase 3**

Ohr developed eye drops to treat wet age-related macular degeneration, a degenerative eye disease. The company reported successful interim results in Phase 2 trials. In the Phase 3 trials, however, patients on the control arm outperformed patients on the treatment arm. When Ohr reported these results, its stock price fell 81 percent.

Investors sued, claiming that the only reason the Phase 2 results had appeared successful was that patients on the control arm had performed worse than anticipated, and that the company had misled investors by omitting that fact. The district court granted the company's motion to dismiss. The court analyzed the company's statements reporting trial results as statements of opinion, and held that the Supreme Court's *Omnicare* decision and related Second Circuit law do not require Section 10(b) defendants to disclose all purported facts that might undermine their projections or opinions. The court held that plaintiffs had failed to establish scienter for similar reasons, and because no allegations suggested that the company had a motive to defraud investors.

The Second Circuit affirmed on scienter grounds, without addressing falsity. The Second Circuit concluded that the motives plaintiffs ascribed to the company — maintaining its stock price, continuing as a business — were universal and hence insufficient. Plaintiffs also claimed that stock offerings within the putative class period furnished a motive to defraud, but the Second Circuit held that this was inconsistent with common sense and chronology: the stock offerings were not made when the stock was trading at class-period highs. Plaintiffs similarly failed to establish a strong inference of recklessness, as they had pled no nonconclusory facts that would have supported such an inference. The Second Circuit accordingly affirmed dismissal but remanded because the district court had not explained why it had denied plaintiffs leave to amend. On remand, plaintiffs moved for leave to amend and the district court denied their motion, concluding that the amendments plaintiffs had identified would have been futile, as they had already been considered and rejected either by the district court or by the Second Circuit. 2020 WL 6729116 (S.D.N.Y. Nov. 16, 2020).

Janies v. Cempra, Inc., 816 F. App'x 747 (4th Cir. 2020), affirming dismissal. **NDA**

Cempra developed solithromycin, a treatment for community-acquired bacterial pneumonia. A prior drug in the same class, Ketek, had been linked with severe liver injury after FDA approval, after which the FDA withdrew approval for all but one indication and required a black box warning label even for that use. Cempra reported favorably on Phase 3 trials of solithromycin. The company acknowledged that some patients had experienced elevations of a liver enzyme called ALT, but stressed that the elevations were generally asymptomatic and reversible. Cempra also acknowledged that the similarity between solithromycin and Ketek posed regulatory risks, but stated that across its trials, no patient had experienced the kinds of issues that arose with Ketek. After the Phase 3 trials were completed, but before it submitted its NDA, Cempra conducted Phase 2 trials testing solithromycin as a treatment for different illnesses — pulmonary disease and hepatitis, as opposed to pneumonia. Patients in the Phase 2 trials experienced more serious ALT elevations, in response to which the company modified the trial protocol to lower the dose. Two days before the advisory committee meeting on Cempra's NDA for the treatment of pneumonia, the FDA released its briefing document and a memo by an FDA doctor. The doctor identified 13 potential instances of drug-related liver injury. The advisory committee nevertheless recommended in favor of approval by a 7-6 vote. The FDA thereafter declined to approve the drug and suggested that Cempra conduct an additional Phase 3 trial enrolling 10 times as many patients as it had enrolled in previous trials. On this series of announcements, the company's stock price fell in three stages, for a cumulative loss of 86 percent.

Investors sued, and the district court dismissed their complaint. On appeal, plaintiffs focused on three categories of challenged statements and one omission: (1) statements that elevated levels of ALT were asymptomatic and reversible, (2) statements that ALT elevations were not indicative of liver toxicity, (3) statements that patients in the clinical had not experienced issues similar to those that arose with Ketek, and (4) omission of the fact that the Phase 2 protocol modification was triggered by a liver injury. The Fourth Circuit affirmed on scienter grounds. The court rejected plaintiffs' argument that the company was motivated to keep its stock price high — that argument could be made in virtually any case — and held that the company's detailed disclosures of regulatory risk undercut any inference of scienter. Along the way, the appellate court favorably reviewed the district court's falsity rulings on the four categories of statements/omissions listed above. Statements that ALT elevations were asymptomatic were based on objective clinical data. Statements that ALT elevations did not show liver toxicity were neither false nor misleading based on the definition of toxicity the company explained it was using. The facts related to the Ketek comparison showed that the company believed that the adverse results one solithromycin patient suffered were distinguishable from reactions to Ketek. As to the protocol modification, while the company's Chief Medical Officer purportedly stated that the change was made for reasons related to efficacy, the CEO later qualified the statement to make clear that safety as well as efficacy concerns had motivated the protocol change.

Mehta v. Ocular Therapeutix, Inc., 955 F.3d 194 (1st Cir. 2020), affirming dismissal. **NDA/Forms 483**

Ocular developed Dextenza, a drug designed to treat post-surgical eye pain and inflammation. In connection with its consideration of Ocular's NDA, the FDA inspected the company's manufacturing facility and issued a Form 483 containing inspectional observations. The company disclosed those observations in its March 2016 Form 10-K. The FDA subsequently issued a Complete Response Letter denying the NDA and citing manufacturing deficiencies. The company's stock price fell 15 percent. In a subsequent earnings call, the company announced that it would resubmit its NDA and was optimistic about resolving manufacturing issues. After Ocular resubmitted the NDA, the FDA again inspected the company's facilities and again issued a Form 483. The company disclosed this second Form 483 in a May 2017 earnings call but expressed optimism about resolving the manufacturing issues. In July 2017, media reports put the Forms 483 in the public domain and the company's stock fell 30 percent. The FDA thereafter issued a Complete Response Letter rejecting the resubmitted NDA based on manufacturing deficiencies. The company's stock price fell an additional 12 percent.

Investors sued, challenging (1) statements in the company's 2016 and 2017 Forms 10-K that it used current Good Manufacturing Practices (cGMP), and (2) optimistic statements on earnings calls about resolving the manufacturing issues. The district court dismissed plaintiffs' claims on both falsity and scienter grounds. The First Circuit affirmed dismissal, ruling on scienter grounds only. Taking the cGMP statements first, the court held that the company's disclosure of the Forms 483 in its Forms 10-K undercut any inference that the company deliberately or recklessly misled investors with statements about cGMP. The court also stressed the generality of the challenged statement that the company "used" cGMP, and noted that Forms 483 are not final agency determinations. With respect to the company's May 2017 earnings call, plaintiffs focused on the company's statement that its manufacturing process was "fully developed"; plaintiffs argued that the receipt of the Forms 483 showed that this statement was false. The court again focused on the disclosures the company made; in discussing the most recent Form 483 on the earnings call, the company made clear that the FDA considered its manufacturing processes deficient. The court also adopted the company's argument that "fully developed" is a term of art in describing manufacturing processes: it means that the process has advanced beyond the pilot stage but does not suggest that the process has been validated. That too undercut any inference of scienter.

Nguyen v. Endologix, Inc., 962 F.3d 405 (9th Cir. 2020), affirming dismissal. **Medical device premarket approval application**

Endologix developed the medical device Nellix, which treats aneurysms by sealing them. Nellix had already been approved and was being sold in Europe. Endologix conducted clinical trials in the U.S. and reported favorable results from the first year of trials in May 2016. The company submitted its PMA application in June 2016 and predicted approval in late 2016 or early 2017. Endologix also reported at the same time on an unfavorable development in Europe: A study of European patients' experiences with Nellix showed that 17 percent of the devices "migrated" — that is, they moved within the patients' bodies. But Endologix further explained that the standards for migration were stricter in Europe than in the U.S. (4 millimeters v. 10 millimeters of movement). Early in November 2016, Endologix reported that data from the second year of the U.S. trials showed an increased migration rate for a subpopulation of patients, and that the company was responding by narrowing the indication for which approval was sought. Endologix characterized this as "a very easy situation to address," although it also acknowledged that approval was likely to be pushed out until the third quarter of 2017. Two weeks later, in mid-November 2016, Endologix revealed that because of the migration issue, the FDA would not consider a PMA application until the company had gathered an additional two years' worth of patient follow-up data. The stock fell 21 percent. In May 2017, the company announced that it was abandoning approval for the original Nellix device and would instead seek approval for a second-generation device. The stock fell 36 percent.

Investors sued, alleging that the company knew, based on the European experience, that the FDA would not approve Nellix, or at the very least, that approval would be delayed. The district court granted defendants' motion to dismiss on scienter grounds and the Ninth Circuit affirmed on the same basis. Plaintiffs had argued in stark terms that the migration issue was "intractable" and "unresolvable." That theory, the court concluded, "does not make a whole lot of sense." Why would a company artificially inflate its stock price if it knew that the day of reckoning was unavoidable? A defendant might do so if the inflation led to some short-term economic advantage — as would be the case if the company or its executives sold stock — but no such economic motive was alleged in the case. Drawing on "common experience" and the Rule 12(b)(6) plausibility standard, the court rejected plaintiffs' scienter theory in broad terms. The court also rejected the account of a confidential witness who claimed that serious migration problems surfaced in 2015 and were urgent and insoluble. The witness's account lacked details about the degree of migration and any associated medical problems. The account was also inconsistent with an inference of fraud, as the witness stated that company officials met openly with third parties at a March 2016 European conference to discuss migration issues.

Abramson v. NewLink Genetics Corp., 965 F.3d 165 (2d Cir. 2020), reversing dismissal. **Phase 2/ Phase 3**

NewLink Genetics developed HyperAcute Pancreas, an immunotherapy for pancreatic cancer. After a successful Phase 2 trial, the company moved to Phase 3 trials, in which HyperAcute Pancreas was tested against the standard of care, chemotherapy. The company stated that it expected patients on the control arm to have a survival rate of 18-19 months. The trial design included four major milestones: patient enrollment and three interim data analyses. The data analyses were performed by the trial's data safety monitoring committee, such that only the ultimate results of the interim reviews — and not the underlying data — were accessible to the company.

The company made favorable statements about its Phase 2 trial results and its success in completing Phase 3 enrollment. In September 2013, a company executive stated during an earnings call that according to all "major" U.S. studies, the survival rate for post-surgery pancreatic cancer patients was 15-20 months. In March 2014, the results from the first interim data analysis were released and were unfavorable. In response to a question about whether patients on the control arm might be living as long as 24 or 25 months, the company stated that it continued to expect those patients to have a survival rate of 18-19 months. The results from the

second and third interim data analyses were also unfavorable. When the results were unblinded, it turned out that the overall survival rate for patients on the control was 30 months — far in excess of what NewLink had projected — while the overall survival rate for patients on the treatment arm was only 27 months. The trial was halted and the company's stock fell 30 percent.

Investors sued, and the district court dismissed the complaint over the course of two rulings, one in 2018 and one in 2019 (both reported in our previous reviews). The district court held that the plaintiffs had failed to plead falsity as to the company's favorable statements about the Phase 2 trials. Plaintiffs had also failed to plead falsity with respect to challenged statements about chemotherapy survival rates: because the company had framed its statements about expected survival rates by referring to what "major" studies showed, these were statements of opinion as to which plaintiffs had failed to satisfy the requirements of *Omnicare*. The district court held that plaintiffs had succeeded in pleading both falsity and scienter as to challenged statements about enrollment but had failed to establish loss causation.

The Second Circuit affirmed the district court's dismissal as to statements about Phase 2 trials, holding that references to "encouraging" results constituted inactionable puffery. But the appellate court reversed the district court's dismissal as to statements about survival rate, holding that plaintiffs had adequately pled falsity. The Second Circuit's analysis of these statements — which the district court had analyzed as opinions — is surprising but may be influential. The Second Circuit declined to determine whether or not the company's use of the word "major" made the statements opinions. In Second Circuit's view, *Omnicare* has made the distinction between statements of fact and statements of opinion relatively unimportant; the court explained that the outcome of its analysis "would not differ based on whether the [challenged statement] was a statement of fact or one of opinion." The Second Circuit reasoned that however the statement about "major" studies was characterized, reasonable investors would understand it to mean that no significant study had shown that the survival rate exceeded 20 months. The court went on to credit plaintiffs' allegations that several studies had shown survival rates between 25 and 43 months. This too may be influential: The Second Circuit was willing to enter into a dispute about what the scientific literature showed that many courts would likely have held fell outside the securities laws. The Second Circuit's approach is notable in other ways as well: the court referred repeatedly to what a jury might reasonably find, which is distinct from the PSLRA's heightened pleading standard analysis. The Second Circuit did not address or even mention scienter.

As to challenged statements about enrollment, the Second Circuit, like the district court, concluded that plaintiffs had adequately pled falsity by reference to a confidential witness who claimed to have witnessed the enrollment of ineligible patients. The Second Circuit parted ways with the district court on loss causation, concluding that the enrollment of those patients "may have affected the trial results," and that "at this early pleading stage, we do not require 'conclusive proof' of the causal link between the fraud and Plaintiffs' losses."

DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

In re Nektar Therapeutics, 2020 WL 3962004 (N.D. Cal. July 13, 2020), granting motion to dismiss without prejudice. **Phase 1/Phase 2**

Nektar developed NKTR-214, an immuno-oncology drug. In 2017 and 2018, Nektar reported interim results from Phase 1 trials showing that patients experienced increases in CD8 cells (which help fight cancer) without corresponding increases in T-regulatory cells (which can inhibit the immune response when present in large numbers). Nektar also reported favorable interim results on tumor shrinkage from Phase 2 trials, in which patients were given a combination therapy of NKTR-214 and Opdivo, an approved drug made by Bristol Myers Squibb. In June 2018, Nektar reported somewhat less favorable interim Phase 2 tumor shrinkage data and the company's stock price fell 41 percent. In October 2018, a short seller posted a blog positing that NKTR-214 was ineffective. The company's stock price fell 7 percent.

Investors sued, challenging statements about the CD8 biomarker in the Phase 1 trial, and, in particular, the statement that interim trial results showed an average 30-fold increase in patients'

CD8 cells. Plaintiffs did not challenge any statements about the Phase 2 trial but alleged that Nektar's executives had engaged in a scheme to manipulate Phase 2 data by means of improper contacts with trial investigators and improper selection of favorable data. The court dismissed plaintiffs' claims in all respects. Plaintiffs' theory about the Phase 1 statement, which was based on the short-seller blog, was that the 30-fold increase was by driven the improper inclusion of a single "outlier" patient. The court rejected that theory, holding that plaintiffs had not shown that the "outlier" had been included in the first place — and that even if plaintiffs could have shown this, they had not shown that such inclusion would have been improper. The court also rejected plaintiffs' scheme claim, holding that plaintiffs had failed to show that any of the actions attributed to Nektar's executives was improper. For similar reasons, the court concluded that plaintiffs had failed to demonstrate scienter. Plaintiffs had not shown that either the purported inclusion of the Phase 1 "outlier" patient or Nektar's purported involvement in selecting Phase 2 data was improper, let alone that the defendants made knowingly false statements or committed knowingly wrongful acts. Finally, the court dismissed the complaint on loss causation grounds. Plaintiffs had failed to show that the disappointing interim Phase 2 trial results reported in June 2018 disclosed any previously concealed truth. As to the October 2018 short-seller blog, this consisted solely of the authors' opinions on publicly available information, and could not establish loss causation as a matter of law.

Mulquin v. Nektar Therapeutics, – F. Supp. 3d –, 2020 WL 7773580 (N.D. Cal. Dec. 30, 2020), granting motion to dismiss with prejudice. **Phase 1**

After the court dismissed the claims in the case just discussed (*In re Nektar*), plaintiffs filed a second amended complaint. The court granted the company's motion to dismiss this complaint with prejudice. In this complaint, plaintiffs dropped their scheme claim (related to Phase 2 trial data) but sought to buttress their false statement claim (related to Phase 1 data) with additional confidential witness and expert allegations. The court held that these allegations were insufficient. As in the previous complaint, plaintiffs had failed to show that Nektar included the "outlier" patient in its interim Phase 1 results in the first place. As significantly, under the Ninth Circuit's controlling *Rigel* decision, disputes over appropriate statistical methodology — which was the most plaintiffs had alleged — cannot support a Section 10(b) claim.[14] Plaintiffs' expert allegations could not salvage their claim. Plaintiffs had not shown that Nektar concealed or misrepresented its methodology; they had shown at most that Nektar had not followed plaintiffs' preferred methodology, and this was insufficient under *Rigel*. The court also once again concluded that plaintiffs had failed to adequately allege scienter. Plaintiffs recycled their abandoned Phase 2 scheme allegations as purported indicia of scienter for their Phase 1 false statement claim but failed to connect the two sets of allegations with one another and additionally failed to tie the repurposed scheme allegations to the individual defendants. Finally, the court once again held that plaintiffs had failed to establish loss causation. The disappointing interim Phase 2 results reported in June 2018 did not "correct" the challenged statements about Phase 1 biomarkers. As to the short seller's October 2018 blog, the law had changed to some extent after the court had issued its first ruling. Under a recent Ninth Circuit decision, *Bofl,* a short-seller or other third-party report may constitute new information — and hence a corrective disclosure — even if it is based on previously disclosed information.[15] In this case, however, the anonymous short seller had disclaimed any representation of factual accuracy in its post and had revealed its interest in driving Nektar's stock price down. Under the same *Bofl* decision, publications of this sort do not plausibly constitute new information and hence cannot establish loss causation.

14 *In re Rigel Pharm, Inc. Sec. Litig.*, 697 F.3d 869 (9th Cir. 2012).
15 *In re Bofl Holding, Inc. Sec. Litig.*, 977 F.3d 781 (9th Cir. 2020).

Kakkar v. Bellicum Pharm., Inc., 2020 WL 2845279 (S.D. Tex. May 29, 2020), granting motion to dismiss with prejudice. **Phase 1/2**

Bellicum developed BPX-501, a therapy given alongside primary treatment to improve outcomes for patients who receive stem cell transplants derived from peripheral blood. The company began a Phase 1/2 trial involving children with leukemia, lymphoma, or other blood disorders. After three adverse events, one of which resulted in a patient death, the FDA issued a clinical hold. Bellicum's stock fell 25 percent.

Investors sued, challenging a range of statements regarding Bellicum's BPX-501 program, including statements about trial data and about clinical procedures. The court granted defendants' motion to dismiss, ruling solely on scienter grounds. The court rejected plaintiffs' attempt to support an inference of scienter by relying on defendants' "collective knowledge" of safety and clinical procedure issues: the court held that plaintiffs were required, but failed, to identify specific facts demonstrating scienter for each statement made by each individual defendant. The court also concluded that plaintiffs had not adequately pled that defendants knew about the adverse events at issue or were severely reckless in failing to disclose them.

Tung v. Bristol-Myers Squibb Co., 2020 WL 5849220 (S.D.N.Y. Sept. 30, 2020), granting motion to dismiss with prejudice. **Phase 3**

BMS conducted a Phase 3 trial of its approved immuno-oncology drug Opdivo, testing whether the drug would outperform chemotherapy as a treatment for non-small cell lung cancer. The drug was believed to be most effective for patients who were "expressers" of PD-L1, a protein that can interfere with the immune system's response to cancer but that can be neutralized by immuno-oncology drugs called checkpoint inhibitors. In designing the trial, the company needed to set a cutoff for PD-L1 expression. The company set the cutoff at 5 percent — that is, if 5 percent of a patient's cells expressed PD-L1, that patient would be included in the trial. The company did not disclose the 5 percent figure to the market, stating only that the trial was limited to patients who "strongly" expressed PD-L1. The trial failed to meet its primary endpoint and, when the company reported both that failure and the 5 percent cutoff figure, its stock fell 16 percent. Two months later, BMS explained that, because of the way trial data had been collected, the company could not use those data to determine results for any patient population that expressed PD-L1 at a rate *greater* than 5 percent. The company's stock fell an additional 10 percent.

Investors sued, claiming that the company misled the market by using the term "strongly" to characterize the degree of PD-L1 expression of patients who made the cutoff. In a 2019 decision (reported in our 2019 review), the court dismissed the complaint on scienter grounds. Plaintiffs cited no authority suggesting that the company knew that the term "strong" as applied to PD-L1 expression was inconsistent with a 5 percent cutoff. And while the company's competitor, Merck, had used a 50 percent cutoff in the trial of a comparable drug, that did not establish that "strong" can refer only to a 50 percent cutoff in industry usage.

After plaintiffs amended their complaint, the district court again dismissed, this time with prejudice. Plaintiffs tried to strengthen their claim by adding allegations that an expert had stated that 5 percent expression of PD-L1 is not "strong" according to industry standards. The court rejected that allegation: the expert stated his own opinion, but cited no industry standards and provided no facts suggesting that the company knew that 5 percent expression is not "strong." The court also rejected new allegations that slides presented by a different company, Nektar, showed that five percent expression is not "strong." Those slides actually showed that the meaning of "strong" is susceptible to multiple interpretations. The court therefore held that plaintiffs had again failed to plead scienter.

Hackel v. AVEO Pharm., Inc., 474 F. Supp. 3d 468 (D. Mass. 2020), granting motion to dismiss with prejudice. **Phase 3**

AVEO developed tivozanib, a medication for the treatment of renal cell carcinoma. In May 2016, the company announced that it would conduct a Phase 3 trial comparing tivozanib to a competitor's drug. The primary endpoint was progression-free survival, with overall survival as a secondary endpoint. AVEO announced that it expected a topline analysis to

be available in the first quarter of 2018. The events necessary to measure progression-free survival, however, occurred more slowly than expected, and the company made three successive announcements in 2018 that results would be delayed. In October 2018, the company also reported that it would analyze only 242 events in connection with the topline reporting, rather than the 255 events previously reported. The company's stock price fell 10 percent. AVEO finally reported topline results in November 2018, announcing that the trial had met its primary endpoint. But the company also announced that overall survival rates were not yet mature — only 46 percent of results had been reported — and that to date, there was no statistically significant difference between tivozanib and the control as to overall survival. In January 2019, the company announced it had accepted a recommendation from the FDA to delay filing its NDA until it had more mature data on overall survival. The company's stock price fell 35 percent.

Investors sued, challenging (1) statements about when topline results would be presented, and (2) the November 2018 statement about overall survival data. The court dismissed plaintiffs' claims in their entirety. The first group of statements were forward-looking and protected under the PSLRA's cautionary statement safe harbor. The court rejected plaintiffs' argument that the company's cautionary statements were boilerplate; to the contrary, the disclosures could scarcely have been more specific, as the company had cautioned investors that its projections about when it would report Phase 3 trial data were subject to risk. As to the November 2018 statement, plaintiffs argued that defendants' disclosure of overall survival data was misleading because the company did not specify the number of subjects who were lost to follow-up as distinct from the number who had withdrawn from the study — and data from the former group of patients could make the results worse. The court rejected this claim on materiality grounds: "Plaintiff has failed demonstrate that knowing the exact number of additional results that might be provided through previously-lost-to-follow-up subjects versus withdrawn subjects or active subjects would be relevant in the 'total mix' of information provided to investors."

Jun Shi v. Ampio Pharm., Inc., 2020 WL 5092910 (C.D. Cal. June 19, 2020), granting motion to dismiss with prejudice. **Phase 3/BLA**

Ampio developed Ampion, a drug designed to treat pain due to osteoarthritis of the knee and other inflammatory conditions. In order to submit a Biologics License Application (BLA) for Ampion, the company needed to complete two Phase 3 trials. In 2013, Ampion completed one successful Phase 3 trial. The company, thereafter, made two unsuccessful attempts to complete a second Phase 3 trial. In one attempt, a breakdown in temperature management during the drug distribution process made the results unusable; in the other, the trial failed to demonstrate efficacy. In May 2017, Ampio reported the initiation of a new Phase 3 trial. The new trial, unlike one of the earlier trials, was not governed by a Special Protocol Assessment. The new trial also involved fewer patients than previous trials and lacked a concurrent control group — meaning that the results of the treatment group would be compared to historical control group data rather than to data gathered contemporaneously. In December 2017, Ampio announced that the new trial was successful, and that it planned to move forward with a BLA. The FDA subsequently informed the company that the new trial was inadequate based on the small number of participants and the lack of a concurrent control group. Ampio's stock price fell.

Investors sued, alleging that the company knew or should have known that the FDA would not approve of the design of the second Phase 3 trial. The court granted defendants' motion to dismiss on scienter grounds. The court explained that the "idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly [carry] on a defective trial ... virtually defies reason." Plaintiffs also alleged that the SEC was investigating insider stock sales at the company, but the court rejected these allegations as well: plaintiffs had failed to plead facts showing that the sales were inconsistent with the insiders' prior trading history. The court also rejected plaintiffs' theory that the company made misleading statements in an attempt to obtain financing or attract merger partners, holding that the financing theory was implausible, and the merger theory lacked necessary detail. The court similarly rejected plaintiffs' invocation of the core operations doctrine and held that plaintiffs' confidential witness allegations lacked particularity.

In re PolarityTE, Inc. Sec. Litig., – F. Supp. 3d –, 2020 WL 6873798 (D. Utah Nov. 22, 2020), granting motion to dismiss with prejudice. **Section 361/BLA**

PolarityTE created SkinTE, which uses a patient's own skin to heal damaged or lost skin tissue. In October 2017, the company announced that it had registered SkinTE as an HCT/P — that is, a human cell or tissue-based product. Under Section 361 of the Public Health Service Act, such products need not be FDA-approved if they meet various requirements, including only minimal manipulation of the cells or tissue. In July 2018, Seeking Alpha published an article arguing that SkinTE did not meet Section 361's requirements, and another media outlet published a similar article. The company's stock price fell 12 percent after these articles appeared. Two years later, in August 2020, the company announced that it had concluded after discussions with the FDA that SkinTE did not satisfy the requirements of Section 361, and that the company had accordingly initiated the approval process by filing an IND application. During roughly the same period, the company also faced setbacks in the area of intellectual property: the Patent Office issued first a nonfinal rejection and then a final rejection of the patent application for SkinTE. Both Seeking Alpha and a short seller published articles about this development too, and the company responded to those articles in a press release. The company's stock price fell 4 percent after the Seeking Alpha article appeared, 32 percent after the short seller report appeared, and another 13 percent after the company's own press release. A short seller and another media outlet also published articles about a third development: the company's receipt of a Form 483, which the company had not itself disclosed. Finally, PolarityTE announced in October 2018 that it had informed government authorities of suspected illegal trading in its stock, which appeared to be coordinated with the publication of media pieces.

Investors sued, challenging statements related to (1) registration under Section 361, (2) patent protection for SkinTE, (3) the company's manufacturing facilities, and (4) government proceedings. The district court dismissed with prejudice as to all claims. As to Section 361, the court concluded that the company's factual statements — that the product was registered under Section 361 — were demonstrably true. Plaintiffs also challenged opinion statements — that the Section 361 registration was appropriate — but had "likely" failed to meet *Omnicare*'s requirements. Beyond that, the court held, plaintiffs had failed to establish loss causation: the articles and reports that preceded the stock drop were based on publicly available information about the formulation of SkinTE, and the authors did not claim to have any special expertise in analyzing that information. Plaintiffs' attack on the company's statements about patent protection failed for a slightly different set of reasons. While the company had at times falsely referred to SkinTE as a "patented" product, it had also reported on many other occasions that the patent application was still pending. The challenged statements were thus immaterial in light of the total mix of information. Here too, moreover, plaintiffs had failed to establish loss causation: the articles that preceded the stock drops were based on information that was already publicly available. The court also rejected plaintiffs' attack on statements about manufacturing, which plaintiffs had claimed were false or misleading in light of the Form 483 the company had received. The challenged statements were either factually true or immaterial puffing, and the company could reasonably have believed that its responses to the nonfinal Form 483 had sufficiently rectified the issues the FDA had identified. Finally, plaintiffs failed to sufficiently plead falsity as to the company's statements that it was not involved in any government or regulatory proceeding. While the SEC had requested documents following the company's report of potentially illegal trading, that request fell short of a government proceeding.

Lake v. Zogenix, Inc., 2020 WL 3820424 (N.D. Cal. Jan. 27, 2020), granting motion to dismiss without prejudice. NDA

Zogenix developed Fintelpa to treat seizures. One of the components of Fintelpa was fenfluramine, which the FDA had previously approved as part of the diet drug fen-phen (fenfluramine combined with phentermine). Fenfluramine came to be associated with heart valve problems, and fen-phen was withdrawn from the market. Zogenix reported to investors that the FDA was permitting the company to file an NDA under the Section 505(b)(2) regulatory pathway (in which drug sponsors may rely on prior studies). Zogenix also conducted its own Phase 3 trials, which yielded positive results on both efficacy and safety. Zogenix filed its NDA in February 2019. In April 2019, the FDA issued a refuse-to-file letter. Zogenix reported to investors that one of the bases for the FDA's decision was the company's failure to submit certain historical nonclinical toxicity studies. The company's stock price fell 20 percent.

Investors sued, challenging statements that (1) Zogenix had filed its NDA, (2) the NDA was based on data from the company's Phase 3 trials, (3) the FDA had permitted the company to use the Section 505(b)(2) pathway, and (4) the FDA could require additional studies. The court noted that all of these statements were undisputedly true, and that plaintiffs' case thus depended on the theory that the statements were misleading by omission. According to plaintiffs, Zogenix had omitted certain information from the NDA and had failed to inform investors of that fact. A principal problem with that claim, the court explained, was that plaintiffs had left unclear *what* exactly was omitted from the NDA — whether *any* reference to prior studies or only references to a particular toxicity study. The court assumed that plaintiffs' theory depended on the purported omission of the single toxicity study and held that plaintiffs had failed to sufficiently plead both falsity and scienter. Plaintiffs had pled no facts showing that the company knew that the FDA would require references to the toxicity study — and inferring that the company knew this simply because the FDA identified the issue in its Complete Response Letter would amount to fraud by hindsight. The court also rejected plaintiffs' argument that by omitting the toxicity study, the company had taken "a deliberate and reckless gamble." Nothing supported that theory, and the benign inference — "that Zogenix had every incentive to get it right the first time" — was far stronger. The court noted that plaintiffs had neither pled insider stock sales nor identified any motive for fraud; indeed, the stock price drop hurt the defendants as much as it hurt any other stockholder. While motive is not a separate element of a Section 10(b) case, the court noted, plaintiffs' failure to identify a plausible motive, coupled with a strong inference of benign intent, was fatal to their scienter case.

Callinan v. Lexicon Pharms., Inc., 479 F. Supp. 3d 378 (S.D. Tex. 2020), granting motion to dismiss with prejudice. 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 a defined efficacy benefit (the lowering of A1c levels to a specified degree) 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 as a treatment for Type 1 diabetes. An advisory committee meeting was scheduled for January 2019. In a briefing document published shortly before the meeting, FDA staff highlighted the increased risk of DKA and stated 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 percent. In March 2019, Lexicon reported its receipt of the FDA's Complete Response Letter denying approval, and the stock fell 22 percent. In July 2019, Lexicon reported that Sanofi was exercising its right to terminate the collaboration agreement, and the company's stock fell 70 percent.

Investors sued, challenging statements about the composite endpoint, the extent and severity of DKA experienced by trial participants, and the benefits of sotagliflozin. The

court granted the company's motion to dismiss, holding that plaintiffs had failed to establish that any of the challenged statements was false or misleading. Plaintiffs claimed, based on the transcript of the advisory committee meeting, that the FDA had earlier told the company that it had concerns about the composite endpoint. Plaintiffs did not, however, specify when or how those concerns were relayed. With respect to DKA, plaintiffs argued that the company had falsely characterized increased incidence as "slight" or "low" when in reality the incidence had increased eight-fold; the court concluded, however, that the challenged statements were not false in light of the company's thorough disclosure of trial results. As to statements about the benefits of sotagliflozin, the court again relied on the company's disclosure of trial results, as well as citing precedent holding that Section 10(b) defendants are not required to denigrate their businesses. The court also rejected plaintiffs' omission theory. Plaintiffs claimed that the company had failed to disclose that several metrics on which it reported favorable results were not "validated" for use in regulatory decision-making. The advisory committee transcript, however, showed that those metrics were significant to decision-makers. With respect to falsity writ large, the court concluded that plaintiffs were wrongly seeking to back-cast all negative responses in briefing documents or by advisory committee members to show that the company's earlier favorable statements were false — and that this was impermissible 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; and allegations about incentive compensation could be made about nearly any company. Finally, the court concluded that plaintiffs had failed to establish loss causation: the stated views of FDA staff and advisory committee members did not show that the company's statements were false or misleading and hence were not corrective disclosures.

Alberici v. Recro Pharma, Inc., 2020 WL 806719 (E.D. Pa. Feb. 14, 2020), granting motion to dismiss without prejudice. NDA

Recro developed IV Meloxicam, a nonopioid pain medication intended for post-surgical use. Recro contracted with an offshore manufacturer to produce Meloxicam. The company conducted clinical trials on patients recovering from both soft-tissue surgeries (abdominoplasties) and hard-tissue surgeries (bunionectomies). The company publicly reported the trial results and submitted an NDA in July 2017. The company reported in May 2018 that the FDA had rejected the application and that in the Complete Response Letter, the FDA had (1) raised issues related to manufacturing, and (2) concluded that the trials failed to demonstrate sufficient analgesic effect for approval.

Investors sued, alleging that Recro had been in contact with 200 to 300 Key Opinion Leaders (KOLs) during the approval process, that the KOLs had raised concerns about both offshore manufacturing and the drug's efficacy in soft-tissue procedures, and that the company's statements about manufacturing oversight and the suitability of the drug for soft-tissue procedures were accordingly false or misleading. The court granted the company's motion to dismiss on scienter grounds, after first rejecting the company's argument that plaintiffs had failed to establish materiality and loss causation. On materiality, the company argued that the KOL opinions were immaterial in light of its disclosure of the underlying clinical trial data to which those opinions related. The court disagreed, explaining that lay investors were not likely to be able to analyze the data by themselves, which made the KOL opinions significant. The company's loss causation argument was based on the fact that the FDA rejected the NDA as to both soft and hard tissue procedures, which suggested that neither the FDA's rejection nor the stock price decline was linked to any misleading statement about soft-tissue efficacy. The court again disagreed, focusing principally on plaintiffs' allegation that omission of the KOL opinions had artificially inflated Recro's stock price. (Oddly, the court did not cite the Supreme Court's 2005 *Dura* decision, which requires not only artificial inflation, but also the removal of that inflation by means of a corrective disclosure to establish loss causation.[16]) On scienter, however, the court sided with the company. Plaintiffs' scienter allegations were based primarily on the account of a confidential witness who claimed to have relayed the KOL concerns to three of the five individual defendants. The court deemed these allegations deficient because plaintiffs did not specify precisely what the witness conveyed to the defendants, nor when, nor how often. The confidential

16 *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336 (2005).

witness allegations also failed to tie the KOL concerns to the prospect of FDA approval. Finally, the company's disclosure of the underlying trial results undercut an inference that defendants had tried to deceive investors.

Leavitt v. Alnylam Pharm., Inc., 451 F. Supp. 3d 176 (D. Mass. 2020), granting motion to dismiss without prejudice. NDA

Alnylam developed patisiran, a drug 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, the company announced that the study had met its primary and secondary endpoints. Alnylam 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. Alnylam's stock price fell six percent and then rebounded. (By contrast, the European Medicines Agency approved the drugs for all manifestations of hATTR amyloidosis.) In September 2018, the FDA released a report discussing its review of patisiran and the approval process. 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. The company's stock price fell five percent.

Investors sued, challenging statements regarding the prospects of FDA approval for all manifestations of hATTR amyloidosis, as well as statements about trial results. The court granted the company's motion to dismiss as to all challenged statements. Plaintiffs claimed that the company's statements were false because the company had never intended to evaluate efficacy for cardiomyopathy in the Phase 3 trials. That theory, the court explained, was contradicted by the study design and statistical analysis plan, which included secondary endpoints designed to test the efficacy of patisiran in the cardiac subpopulation. The court also emphasized the EMA's approval of the drug to treat cardiomyopathy, which undermined plaintiffs' claims that such approval was impossible. The court similarly rejected plaintiffs' theory that the company had failed to submit cardiac efficacy data to the FDA; both the FDA's report and the European approval contradicted that theory. In the same vein, the court rejected plaintiffs' claim that statements regarding cardiac safety data were false or misleading in light of higher levels of cardiac-related deaths in the Phase 3 treatment group than in the control group. This too was contradicted by the FDA's report, in which the agency concluded that there was no imbalance in deaths between treatment and control groups. The court also held that challenged statements about the prospects of approval were forward-looking and came within the PSLRA's safe harbor, while statements about trial results were inactionable opinions. Finally, plaintiffs failed to establish a strong inference of scienter: while plaintiffs pointed to insider sales, the alleged trading patterns were not unusual, and all trades were made pursuant to Rule 10b5-1 trading plans.

Smith v. Antares Pharma, Inc., 2020 WL 2041752 (D.N.J. Apr. 28, 2020), granting motion to dismiss without 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 that it was halting review as a result of unspecified deficiencies. The company's stock price fell 38 percent. 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 statements related to 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. After plaintiff amended the

complaint, the company moved to dismiss and the court again granted the motion. The court held that interpretations of clinical trial data — including statements that the trials had generated "positive safety data" or that the product was "found to be safe" — were opinion statements as to which plaintiff had failed to meet *Omnicare*'s requirements. The court also rejected plaintiff's challenge to statements regarding adverse reactions, as well as to statements about the prospect of approval. On the other hand, the court sided with plaintiff as to the statement that "anyone" who was diagnosed with testosterone deficiency is the "perfect candidate" for the product: plaintiff had adequately pled that this statement could be misleading given issues with hypertension. The court nevertheless dismissed the complaint as to this statement too, which it concluded was immaterial puffery. Certain statements related to safety were also immaterial, given the company's disclosure of adverse events. As to scienter, the court rejected plaintiffs' contention that Antares had "gambled heavily" on the product and that any acknowledgement of safety risks would have "doomed" the company: plaintiff had failed to plead particularized facts supporting that theory. The court also held that plaintiff had failed to plead economic loss and loss causation.

Schaeffer v. Nabriva Therapeutics plc, 2020 WL 7701463 (S.D.N.Y. April 28, 2020), granting motion to dismiss without prejudice. **NDA/Forms 483**

Nabriva developed fosfomycin, a drug designed to treat complicated urinary tract infections. Nabriva contracted the manufacturing of the drug to Ercros, which was obligated to inform Nabriva of any communications it received from the FDA as well as any information suggesting that Ercros' manufacturing facility was not in compliance with cGMP. Nabriva filed its NDA for fosfomycin in October 2018. In December 2018, the FDA inspected Ercros' facility and issued a Form 483 to Ercros, listing 10 observations suggesting noncompliance with cGMP. In January 2019, Nabriva stated publicly that the FDA had identified no potential review issue in connection with its NDA. The company also spoke optimistically about FDA approval. Nabriva filed its Form 10-K in March 2019, identifying as risk factors, among other things, its reliance on a third-party manufacturer and the possibility of regulatory action if manufacturing problems arose. In April 2019, Nabriva announced that the FDA had denied its NDA based on manufacturing deficiencies. The company's stock price fell 27 percent.

Investors sued, challenging the company's statements about its NDA and FDA approval, as well as the risk disclosures in the Form 10-K. The court granted the company's motion to dismiss. After concluding that a number of the challenged statements were inactionable puffery or fell within the PSLRA safe harbor, the court surveyed the law on the materiality of Forms 483. Some courts had held that Forms 483 are *per se* material; others had held that they are *per se* immaterial, as they are not final agency determinations. The court concluded that it could not decide the motion on materiality grounds and therefore proceeded to analyze falsity and scienter. The key issue, the court stated, was "whether the Form 483's observations regarding potential cGMP violations substantially indicated [Ercros' facility] could not comply with FDA regulations by [the PDUFA date]." Given the broad scope of the Form 483, the court concluded that plaintiffs had sufficiently pled that two statements were false or misleading: the statement that the FDA had identified "no potential review issue" and the risk disclosure about the possibility of receiving warning letters in connection with manufacturing deficiencies. But the court also concluded that plaintiffs had failed to adequately allege scienter for those statements. Plaintiffs had not shown that defendants believed that receipt of the Form 483 rendered their statements false or misleading. "Plaintiff needs to plead something more to indicate why Defendants' failure to mention the Form 483 was 'highly unreasonable.' That could be additional information indicating the Form 483 substantially contradicted Defendants' public statements, or it could be another kind of information otherwise bearing on Defendants' state of mind."

Khoja v. Orexigen Therapeutics, Inc., 2020 WL 6395629 (S.D. Cal. Nov. 2, 2020), granting partial motion to dismiss without prejudice. **Post-approval cardiovascular outcome trial**

Orexigen developed Contrave, an obesity drug. After the FDA granted approval, the company performed a cardiovascular outcome trial to confirm safety. Results from a scheduled 25 percent interim assessment suggested that the drug might actually improve cardiovascular health. A data access plan prohibited the company from disclosing the interim results, but in a March 3, 2015

Form 8-K, the company publicized those results in the course of describing a patent it had just been granted. The company characterized the results as preliminary but did not say that they were unreliable. The trial's lead investigator then directed that the trial be halted. A second scheduled interim assessment, at 50 percent completion, reversed the positive trend shown in the 25 percent interim data. On May 8, 2015, the company stated that the trial was still ongoing. On May 12, 2015, the company announced that the study was being discontinued but did not release the 50 percent data. Minutes later, the chair of the trial's steering committee, Dr. Nissen, issued a press release disclosing the 50 percent data and accusing the company of misleading both patients and investors. The company's stock price fell 26 percent.

Investors sued, challenging the company's March 2015 and May 2015 statements. The district court dismissed the complaint, and plaintiffs appealed. The Ninth Circuit largely reversed the dismissal in one of the leading securities decisions of 2018 (discussed in our 2018 review). The Ninth Circuit's decision imposed duties on companies disclosing interim trial results and tightened the rules governing a court's ability to consider documents outside the complaint on a motion to dismiss. After the case was remanded, three individual defendants moved to dismiss on scienter and loss causation grounds, as no court had previously ruled on those elements. In a 2019 ruling (discussed in our 2019 review), the court largely denied the motion to dismiss, but held that Dr. Nissen's May 12, 2015 press release was not a corrective disclosure as to the company's March 3, 2015 Form 8-K. Later in 2019, plaintiffs amended their complaint and defendants moved to dismiss in part, primarily on loss causation grounds.

The court granted defendants' motion. In an effort to connect the May 2015 stock price decline to Orexigen's March 3, 2015 statement about its new patent, plaintiffs now relied not on Dr. Nissen's May 12, 2015 press release, but instead on an article published by *Bloomberg* on the same day, reporting that Orexigen's commercialization partner, Takeda, had begun dispute resolution proceedings accusing Orexigen of breaching the parties' collaboration agreement. Plaintiffs' new theory was that the company's March 3, 2015 Form 8-K was misleading, among other reasons, because Orexigen had failed to disclose that it was breaching the data access plan *without providing notice to Takeda* that it would do so. The court rejected this new theory on both falsity and loss causation grounds. On falsity, plaintiffs had failed to show that Orexigen had a duty to disclose any interactions or lack of interactions with Takeda related to its March 3, 2015 public statements: Orexigen had not commented and was not required to comment one way or the other about the matter. On loss causation, plaintiffs had failed to show that Takeda's May 2015 initiation of dispute resolution proceedings was a response to Orexigen's March 2015 action in failing to give notice to Takeda that it was breaching the data access plan. No facts showed that the two events were connected, and the timing weighed against the purported connection: Takeda did not begin proceedings until more than two months after Orexigen's March 3, 2015 breach.

DISTRICT COURT DECISIONS: MOTION TO DISMISS DENIED IN PART OR IN WHOLE

Fergus v. Immunomedics, Inc., 2020 WL 2832565 (D.N.J. June 1, 2020), denying motion to dismiss. Phase 2

Immunomedics, a developer of immuno-oncology drugs, announced that ASCO had accepted two of its abstracts and one poster for presentation at the June 2016 conference. (ASCO — the American Society of Clinical Oncology — holds meetings in June of every year, and these are major industry and investor events.) On June 3, 2016, the company reported that ASCO had cancelled the presentation of one of the two abstracts, which dealt with a Phase 2 breast cancer trial. ASCO presenters are prohibited from publicizing results prior to the meeting, and ASCO had determined that the company had violated this "embargo" by discussing results at a presentation in April 2016. The company also told investors that it disagreed with ASCO's decision and would seek to reverse it: in the company's view, the information presented in April 2016 pertained to a different patient population and different trial results than those at issue in the cancelled abstract. ASCO did not reverse its decision. Later, in June 2016, the company announced the resignation of its CFO. The company's stock price fell 62 percent during the weeks in which these events unfolded.

Investors sued, challenging the company's statements about its ASCO presentations. In an order issued in 2019 (discussed in our 2019 review), the court granted defendants' motion to dismiss on both falsity and scienter grounds, with leave to amend. Plaintiff amended and the company again moved to dismiss. This time, however, the court denied the company's motion. In the amended complaint, plaintiff subtly shifted his theory. The previous theory was that the company had misled investors by saying it would make a presentation at ASCO. The new theory was that the company had misled investors by signaling that it had *new* data to report — which was a condition of making an ASCO presentation. The original theory had failed because the challenged statements were demonstrably true when made. But under the new theory, plaintiff had adequately pled falsity by alleging with particularity that the company had no new data on the breast cancer trial. The court also held that plaintiff had adequately pled scienter, citing allegations that the company knew about ASCO's confidentiality requirements, allegations that the company knew that the data to be presented at ASCO had already been presented elsewhere, and stock sales alleged to have occurred after the presentation was cancelled but before ASCO closed without the company's participation.

Voulgaris v. Array Biopharma, Inc., 2020 WL 8367829 (D. Colo. Nov. 24, 2020), denying motion to dismiss. NDA

Array developed binimetinib, an oncology drug. Array began a Phase 3 trial in 2013 and reported favorable results in 2015. The trial had met its primary endpoint: patients on the treatment arm experienced progression-free survival of 2.8 months, as opposed to 1.5 months on the control/chemotherapy arm. Array also reported that a prespecified subgroup — patients who had taken an immuno-oncology drug as a first-line treatment — had a progression-free survival of 5.5 months, as opposed to 1.6 months on the control arm. But Array cautioned investors that any interpretation of the subgroup results should be made with care. Array submitted its NDA for binimetinib in June 2016. In March 2017, ten days before a scheduled advisory committee meeting, the company reported that it was withdrawing the NDA based on discussions with the FDA. The company's stock price fell 14 percent. Several days after Array announced the withdrawal of its NDA, the advisory committee issued a notice that it would no longer be considering binimetinib. The notice revealed that Array had been seeking approval of the drug for patients who had previously received immuno-oncology treatment, which was a narrower indication than Array had previously reported. In November 2017, the European Medicines Agency denied a marketing application for binimetinib filed by one of Array's European collaborators. The EMA concluded that negative data on toxicity and on patients' rate of deterioration and functionality was so detrimental that it eliminated the modest clinical benefit of the drug (that is, the improvement in progression-free survival from 1.5 months to 2.8 months).

Investors sued, challenging the company's statements (1) that the Phase 3 study had met its primary endpoint, and (2) that the subgroup results, while of interest, had to be interpreted with care. The court denied the company's motion to dismiss. Plaintiffs' first theory of falsity was that the company's statements about trial results were misleading in that the company had reported only the positive primary endpoint data and had omitted the unfavorable secondary results that later led the EMA to deny approval. The court rejected the company's argument that the secondary results were immaterial. Although FDA guidance documents cast some doubt on the utility of certain of the secondary measures in making approval decisions, those documents were not definitive, and in any event did not address secondary outcomes such as toxicity and patients' ability to function — on which the drug had fared poorly — which the company failed to disclose. The court also rejected the company's argument that the EMA had disclaimed reliance on the secondary endpoint; here, too, the documents on which the company relied were at best inconclusive. Finally as to this first theory, the court rejected the company's argument that it had no duty to discuss the secondary results because they were not "in play." Among other things, the company's statement that the drug was "generally well tolerated" put the secondary results in play.

Plaintiffs' second theory was that in cautioning investors about the significance of the subgroup analysis, the company had concealed the fact that it had modified its NDA and was at the time of the challenged statements seeking approval *only* for an indication corresponding to the subgroup — that is, only for patients who had already received immuno-oncology treatments. The court concluded that plaintiffs had sufficiently pled that the company had made this change to its NDA, based both on the company's own statements and on the advisory committee's post-withdrawal notice. The court rejected the company's argument that it had sufficiently alerted investors to the change in its NDA by stating publicly that it believed that physicians would in practice prescribe binimetinib only as a second-line treatment after immuno-oncology.

Finally, the court rejected the company's scienter arguments as to both theories, concluding that the company and its executives were aware of the negative secondary data and similarly aware that their statements — including that the drug was "generally well tolerated" — were false or misleading. Plaintiffs' motive allegations, the court held, also supported an inference of scienter. The company undertook a stock offering while the NDA was pending and was incentivized to raise enough money to keep itself afloat while it completed clinical trials and filed an NDA for another drug candidate. Those circumstances differed from the kinds of general corporate motivations that could be ascribed to any company.

Skiadas v. Acer Therapeutics Inc., 2020 WL 3268495 (S.D.N.Y. June 6, 2020), denying in part and granting in part motion to dismiss. NDA

Acer developed celiprolol, a treatment for a rare genetic connective tissue disorder called Vascular Ehlers-Danlos Syndrome (vEDS). Celiprolol, a beta-blocker, had been approved in Europe to treat hypertension. Some U.S. physicians prescribed the drug off-label to treat vEDS. Acer met with the FDA to discuss approval of celiprolol for the treatment of vEDS based on a trial that had taken place in 2004. The trial had included only 53 patients, and questions had arisen as to whether patients had been properly randomized between the treatment and the control arms. In connection with a December 2017 stock offering, Acer reported that "the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA." In a subsequent Form 10-K, Acer made a related — but not identical — statement: "the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA." Acer submitted the NDA in October 2018. The FDA denied the application in June 2019. In reporting that outcome, the company noted that the FDA's Complete Response Letter stated that the company needed to conduct a trial demonstrating efficacy. Acer's stock price fell 79 percent.

Investors sued, challenging the two statements about FDA "agreement," and alleging that because the FDA denied approval, it must have disagreed with the company's position that it could submit an NDA without performing its own trials. The court largely denied the company's motion to dismiss. The company argued that its statements referred only to

FDA agreement on *submission*, not agreement on *approval*, but the court concluded that the statements were ambiguous and had to be construed in plaintiffs' favor. Construed in that way, the statements were plausibly false in light of the Complete Response Letter. (By contrast, the court concluded that plaintiffs had failed to adequately allege falsity in connection with the company's statement that it had received "guidance" from the FDA on the presentation of clinical data.) The court also concluded that plaintiffs had adequately pled scienter. The court noted that the second statement about "agreement" was more qualified than the first statement, and concluded that this suggested that the company knew that the first statement was inaccurate. The court focused primarily on economic motivation, accepting plaintiffs' argument that a going concern qualification gave the company an "incentive to gamble" on FDA approval. The court rejected the company's argument that plaintiffs' theory of fraud was "fundamentally illogical," since the alleged fraud would have inevitably been exposed when the FDA denied approval. The court concluded that plaintiffs had adequately alleged that the company's statements and course of conduct in submitting the NDA without performing its own study reflected a reckless gamble.

Tomaszekski v. Trevena, Inc., – F. Supp. 3d – , 2020 WL 5095865 (E.D. Pa. Aug. 28, 2020), denying in part and granting in part motions to dismiss. **NDA**

Trevena developed oliceridine, an IV pain medication designed to be a safer and better-tolerated alternative to morphine. In March 2016, after successful Phase 2 trials, Trevena and the FDA participated in an End-of-Phase 2 meeting. Trevena reported in May 2016 that the meeting had been a success and that the company and the FDA had reached general agreement on specified key elements of the upcoming Phase 3 trials. In February 2017, after the Phase 3 trials were largely complete, the company reported that the trials had demonstrated oliceridine's efficacy but had not shown that oliceridine had a statistically significant safety advantage over morphine. Trevena submitted its NDA in November 2017. Two days before the scheduled advisory committee meeting in October 2018, FDA staff released a briefing document. In that October 2018 document, the FDA stated that during the March 2016 End-of-Phase 2 meeting, it had expressed disagreement with several features of Trevena's planned Phase 3 trials. The company's stock price fell 64 percent. The advisory committee then recommended against approving Trevena's NDA by a vote of 8-7. In November 2018, Trevena reported that the FDA had rejected its NDA, and that in its Complete Response Letter, the FDA had cited a lack of sufficient ECG data and stated that Trevena's proposed dose was not adequately supported by the safety database provided. Trevena later addressed these issues in a resubmitted NDA, and the FDA approved oliceridine in August 2020.

Investors sued, challenging the company's May 2016 statements about the End-of-Phase 2 meeting as well as other statements about events in the clinical trial and NDA submission process. The court largely denied the defendants' two motions to dismiss (the first filed by the company and one of the individual defendants and the second filed by the remaining individual defendant, who had been served late). Trevena argued that the FDA's staff briefing document did not accurately reflect the comments the FDA had made at the March 2016 End-of-Phase 2 meeting. Those comments were set forth in the FDA's near-contemporaneous minutes of the meeting, which showed that Trevena and the FDA had in fact reached agreement on both the key elements and subsidiary elements of the Phase 3 trial. The court declined to consider the meeting minutes: although plaintiffs had cited the minutes in their complaint, the minutes were not publicly available and plaintiffs did not have access to them until the company filed its motion to dismiss. Because the court concluded that the company's substantive falsity and scienter arguments were intertwined with the contents of the minutes, the court did not reach those arguments. (The court also declined to consider the August 2020 approval of oliceridine.) The court did reach the merits of arguments made by the late-served individual defendant. The court held that plaintiffs had adequately pled falsity as to that defendant's statements about trial design, reasoning that any description of trial design created a duty to disclose the FDA's purported disagreements. On the other hand, the court rejected plaintiffs' challenge to the defendant's statement that he did not expect the FDA to impose labeling restrictions: the facts purportedly showing falsity did not arise until after the defendant had made the statement (and, indeed, had left the company). The court finally concluded that plaintiffs had adequately pled scienter. The court accepted the theory that Trevena had begun designing its Phase 3 trials before the FDA had relayed its views at the End-of-

Phase 2 meeting, and that after the FDA purportedly expressed disagreement at that meeting, Trevena took a "calculated gamble" that the FDA would nevertheless approve the drug.

In re Innocoll Holdings Public Ltd. Co. Sec Litig., 2020 WL 1479128 (E.D. Pa. Mar. 25, 2020), denying motion to dismiss. **NDA**

Innocoll develops medical products based on collagen technologies. Collagen is the principal structural protein in skin and connective tissue. One of Innocoll's product candidates was Xaracoll, a collagen matrix that is implanted at a surgical site and that gradually releases pain medication. Innocoll met with the FDA twice in connection with Phase 2 and Phase 3 trials and reported that the agency had "agreed to Innocoll's approach for Xaracoll's Phase [3] trials." Innocoll also told investors that it expected the FDA to approve Xaracoll. One month after Innocoll submitted its NDA, however, the FDA issued a refuse-to-file letter, explaining that Xaracoll was a combination drug and device treatment, and that the NDA was incomplete because it dealt only with the drug component of the product (the pain medication) and not the device component (the collagen matrix). The company's stock price fell 61 percent.

Investors sued, claiming that the company knew but failed to disclose that Xaracoll could not be approved without trial data related to the device component. In a 2018 ruling (discussed in our 2018 review), the court granted defendants' motion solely on scienter grounds. Plaintiffs had alleged that the company knew it was required to obtain device approval based on past approvals of other collagen products; plaintiffs had also noted that the company had described Xaracoll as a device on a patent application. The court held that these factors were ultimately inadequate, as was plaintiffs' scienter theory generally: plaintiffs had failed to explain why, if the company understood that device testing was required, it would not have conducted that testing at the same time it tested the drug component.

In its 2020 ruling on the company's motion to dismiss the plaintiffs' amended complaint, the court changed course. The court noted that plaintiffs had added substantial new allegations and held that they had cured their previous scienter shortfall. Plaintiffs' new scienter allegations included (1) facts tying the CEO to the patent allegations describing Xaracoll as a device, (2) detailed allegations about the company's financial peril at the time of the Phase 3 trials, including allegations that the company could not afford the $10 million needed to test the device and was negotiating with a potential acquirer, and (3) allegations about FDA guidance documents and website information indicating that products similar to Xaracoll are considered drug/device combinations. The court relied heavily on the last category of allegations, agreeing with plaintiffs that defendants "should have known" that their statements were misleading (which appears to substitute a negligence standard for the scienter requirement). The court also credited plaintiffs' allegations about the company's financial motivation, rejecting the company's argument that such motivations are ubiquitous. The court was no longer troubled by the issue it had identified in its previous order — the lack of an explanation for the company's alleged choice to ignore the device approval requirements. The explanation, the court stated, was that the company could not afford to perform device testing and thus took a "calculated risk" that the FDA would approve the product without that testing — and that the individual defendants then chose to conceal the risk from investors for "financial and personal reasons."

Because the court rejected the company's scienter arguments, it reached falsity issues for the first time in its second decision. The court was not persuaded by the company's argument that investors, like the company itself, could evaluate the risk that the FDA would require device testing. Although the company framed this as a materiality argument, the court concluded that it was a premature attempt to pursue a "truth on the market" defense. The court was also unpersuaded by the company's argument that its statements should be evaluated in the context of the "continuous dialogue between the FDA and the proponent of a new drug." According to the court, "sophisticated investors would reasonably expect Defendants to have *utilized* this continuous dialogue as an opportunity to inquire into their rudimentary hurdles to success." Finally, the court rejected the company's argument that its statements about the prospects for approval were forward looking and protected by the cautionary statement safe

harbor. The company's risk disclosures were insufficiently specific, as they could apply to any drug developer seeking FDA approval.

Odeh v. Immunomedics, Inc., 2020 WL 4381924 (D.N.J. July 31, 2020), denying motion to dismiss. BLA/Form 483

Immunomedics developed IMMU-132, a biologic for the treatment of metastatic triple-negative breast cancer. In January 2018, the company discovered a data integrity breach at its manufacturing plant: employees were manipulating batch records and bioburden samples (a measure of the number of microbes living on a surface). Immunomedics reported the breach to the FDA but did not disclose it publicly. In May 2018, the company submitted a Biologics License Application for IMMU-132. In August 2018, while the BLA was pending, the FDA inspected the company's manufacturing facility. The FDA then issued a Form 483 listing 13 issues, two of which related to the earlier data integrity breach. In a subsequent Establishment Inspection Report, the FDA stated that the scope of the data integrity breach was far broader than the company had reported in early 2018. In December 2018, the website *FDANews* published an article revealing that the FDA had cited Immunomedics for violations related to the data integrity breach. The company's stock price fell 5 percent. Several days later, an analyst disclosed details of the Form 483, after which the company's stock price fell 26 percent. In January 2019, the company announced that the FDA has issued a Complete Response Letter declining to approve IMMU-132. The company's stock price again fell 26 percent.

Investors sued, challenging statements about the BLA approval process and alleging that the company had misleadingly failed to disclose both the data integrity breach and the Form 483. The court denied the company's motion to dismiss. The court concluded that plaintiffs had adequately pled falsity as to the company's statements that the FDA approval process would be a "check-the-box" exercise, and that "all critical work streams [for FDA approval], including … manufacturing validation runs, [were] yielding positive results." Likewise, the court held that plaintiffs had adequately pled falsity as to risk disclosures in the company's SEC filings: there, the company spoke of data breaches as a risk rather than an actual occurrence. The court also held that plaintiffs had adequately alleged scienter. Plaintiffs had pled facts showing that the individual defendants knew of the data breach, failed to disclose it to investors, and failed to disclose its broad scope to the FDA. Plaintiffs had also pled facts showing that Immunomedics had a motive for misleading the market: The company had conducted a secondary stock offering in June 2018, while the BLA was pending but before the data breach was publicly disclosed.

Okla. Police Pension Fund & Ret. Sys. v. Teligent, Inc., 2020 WL 3268531 (S.D.N.Y. June 17, 2020), denying in part and granting in part motion to dismiss. ANDA/Forms 483

Teligent historically worked as a contract manufacturer, producing drugs for third parties. In 2014, Teligent announced that it was shifting its focus to manufacturing generic drugs of its own, for which it intended to seek approval through ANDA (Abbreviated NDA) submissions. In September 2016, the company received a Form 483 identifying five issues, including the failure to reserve drugs for randomized testing and the insufficiency of drug accountability records. The FDA followed the Form 483 with an Establishment Inspection Report further discussing the issues in the Form 483 and asserting that the company's procedures were "not adequate and current to ensure quality in analytical observations." Teligent responded to the FDA by acknowledging and committing to rectify these issues. The company did not publicly disclose these interactions with the FDA. The FDA issued additional Forms 483 in October 2017 and May 2019. Teligent told investors that it had received no Forms 483 over the last several inspection cycles. The company also stated that it was on track to meet its goal of submitting numerous ANDAs per year. In November 2017, Teligent reported disappointing quarterly results and downgraded its annual guidance. Teligent also acknowledged delays in preparing its manufacturing facilities for the production of generic drugs in its pipeline. The company's stock fell 44 percent.

Investors sued, challenging a range of statements related to manufacturing and inspections. The court granted the motion in part, holding that (1) the company's statements that it was required to comply with cGMP were factually true, (2) statements that the company was committed to its regulatory responsibilities were inactionable puffery, (3) projections as to when the company

would be ready to begin producing injectable drugs were forward-looking, and plaintiffs had failed to sufficiently allege actual knowledge of falsity, and (4) statements that the company's *suppliers* had received Forms 483 were factually accurate. The court denied the motion to dismiss as to the company's statements that it was cGMP-compliant. While noting that Forms 483 are not conclusive agency determinations, the court held that the Forms 483 issued in the case raised questions about cGMP compliance. The court also ruled against the company with respect to risk disclosures referring to the possibility of receiving FDA warning letters: plaintiffs had adequately pled that these disclosures were misleading in light of the company's actual receipt of a Form 483. Perhaps most significantly, the court held that plaintiffs had sufficiently pled falsity as to the company's statements that it had not received Forms 483. The company argued that plaintiffs had taken these statements out of context, and that properly understood, the statements referred to Forms 483 related to the FDA's cGMP audits — which the company had not in fact received — as opposed to Forms 483 issued as part of the FDA's Bioresearch Monitoring program. The court rejected that argument, concluding that the challenged statements had not made that distinction clear. The court also ruled that plaintiffs had adequately alleged scienter, given that the September 2016 Form 483 was addressed to the company's CEO, who made the challenged statements. As to loss causation, the court agreed with plaintiffs that the losses and delays the company reported in November 2017 were foreseeable materializations of undisclosed risks posed by the company's alleged regulatory compliance failures.

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 37-48), 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, the district court decisions are almost evenly split, with companies prevailing on motions to dismiss in six cases and courts denying motions to dismiss at least in part in eight cases. Defendants fared better in the appellate courts, which affirmed dismissal in each of the three 2020 decisions, two of which are published opinions.

APPELLATE DECISIONS

Yan v. ReWalk Robotics Ltd., 973 F.3d 22 (1st Cir. 2020), affirming dismissal. **Post-market safety study**

ReWalk designs and manufactures robotic exoskeletons for individuals with spinal cord injuries. The FDA granted ReWalk permission to label its product a class II medical device, which means that "its use carries a medium risk requiring some 'special controls.'" The FDA also ordered ReWalk to conduct a post-market surveillance study. Before obtaining FDA approval on its study, ReWalk conducted its IPO. In the IPO registration statement, the company described its device as a "breakthrough product" with "compelling clinical data," but also disclosed that the FDA had ordered a post-market study. Following the IPO, ReWalk failed to meet the FDA's submission deadlines, and the FDA ultimately deemed ReWalk's study plan inadequate. The FDA issued a warning letter stating that the device was misbranded and threatening sanctions. ReWalk did not disclose the FDA's sanctions threat on quarterly earnings calls. When ReWalk did disclose the threat, its stock price dropped 13 percent.

Investors sued, alleging that ReWalk and certain officers violated the Securities Act by omitting material information about the post-market study from the Registration Statement, and that they violated the Exchange Act by failing to disclose the difficulties the company was encountering in obtaining FDA approval following the IPO. The district court dismissed the complaint. The Securities Act claims failed because plaintiff had not identified actionable omissions or misstatements. The Exchange Act claims failed because the alleged omissions occurred after plaintiff made his last stock purchase. The district court also held that plaintiff lacked standing to pursue the Exchange Act claims and was barred from amending the complaint to add a purchaser who did have standing.

The First Circuit affirmed, albeit on slightly different grounds. With respect to the Securities Act claims, the court held that the company's disclosures, when read in context, adequately advised investors of the relevant risks related to its products and the post-market study. The court also concluded that the company's references to its "breakthrough product" and to "compelling clinical data" were inactionable puffery; moreover, the FDA's classification of the device as "de novo" supported the company's characterization of the product's novelty. Other challenged statements in the IPO registration statement were forward-looking and came within the PSLRA's safe harbor.

On the Exchange Act claims, however, the First Circuit rejected the district court's approach to standing — that is, the district court's conclusion that the timing of plaintiff's stock purchases barred the claims. The appellate court proceeded to the merits of the Exchange Act claims and affirmed on the basis that plaintiff had failed to allege scienter. While confidential witnesses had alleged that executives knew about the company's back-and-forth with the FDA, the company was under no obligation to disclose the details of those regulatory communications — and thus nothing in the complaint supported a strong inference that the defendants believed that the challenged omissions were fraudulent.

Spizzirri v. Zyla Life Scis., 802 F. App'x 738 (3d Cir. 2020), affirming dismissal. **Product labeling**

Zyla (formerly Egalet) developed an extended-release morphine tablet called ARYMO ER for the management of severe long-term pain. In November 2014, a competitor submitted a 505(b)(2) NDA for a similar product called MorphaBond. In October 2015, the FDA approved MorphaBond as the "first single-entity ER morphine product with labeling describing intranasal abuse-deterrent properties." In December 2015, Zyla announced that it too had filed a 505(b)(2) NDA for ARYMO ER, the purpose of which was to obtain authorization to make abuse-deterrent label claims for oral, nasal and injection abuse. In August 2016, an FDA advisory committee voted in favor of abuse-deterrent labeling for ARYMO ER in all three areas. In January 2017, however, Zyla announced that although the FDA had approved the ARYMO NDA, ARYMO would not receive nasal abuse-resistant labeling because MorphaBond had been granted a three-year period of market exclusivity for that label. The company's stock fell 22 percent.

Investors sued, challenging the company's positive statements about the abuse-resistant qualities of the drug and the prospects of obtaining favorable labeling. The district court dismissed the complaint, relying in part on a memo from the FDA's Center for Drug Evaluation and Research. The company had argued that this memo showed that at the time of the relevant challenged statements, the FDA had not yet decided to grant market exclusivity to MorphaBond for nasal abuse-deterrent labeling. On appeal, plaintiffs argued that the district court had erred in considering the FDA memo. The Third Circuit affirmed dismissal, holding that the district court did not abuse its discretion in considering the memo. The memo was a matter of public record available on the FDA's website and was quoted in and integral to the complaint.

Jackson v. Abernathy, 960 F.3d 94 (2d Cir. 2020), affirming denial of motion to set aside judgment and amend pleading. **Manufacturing/advertising**

Halyard (which was spun off from Kimberly-Clark and which later changed its name to Avanos) manufactured medical supplies, including the MicroCool surgical gown, which is intended to protect healthcare providers from highly infectious diseases such as Ebola. The MicroCool 510(k) summary submitted to the FDA stated that MicroCool gowns met the Level 4 Liquid Barrier requirements of the Association for the Advancement of Medical Instrumentation. In a consumer class action filed in California, customers alleged that the gowns had failed quality control tests.

Following amplification of the consumer allegations in a 60 Minutes report, Halyard's stock price fell and investors sued, alleging that defendants misled the market about the protective capability of the gowns. The district court dismissed the complaint, and plaintiffs moved to set aside the judgment and to file an amended complaint including testimony and the jury verdict from the California consumer action. The district court denied plaintiff's motion as futile, as plaintiffs failed to adequately plead scienter even in the proposed amended complaint.

On appeal to the Second Circuit, plaintiff abandoned any claims against the executives and argued that the proposed amended complaint adequately demonstrated collective corporate scienter. The Second Circuit disagreed and affirmed the dismissal. The court held that plaintiff had failed to identify individual employees or executives whose scienter could be imputed to the entity defendants, rejecting plaintiffs' argument that testimony from three employees in the California consumer action reflected anything other than a good faith effort to uncover problems with the gowns. Testimony from the consumer action in fact belied any inference of fraudulent intent: nothing showed that the executives failed to heed the employees' warnings. The Second Circuit therefore rejected Plaintiff's collective scienter theory: plaintiffs' "proposed amended complaint sets forth allegations that employees know of problems with the MicroCool gowns, but it provides no connective tissue between those employees and the alleged misstatements." The court also rejected plaintiffs' argument that the gowns were a "key product" such that senior officers must have known that statements about them were false. This "naked assertion" was "plainly insufficient" to create a strong inference of scienter.

DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

Hou Liu v. Intercept Pharm., Inc., 2020 WL 1489831 (S.D.N.Y. Mar. 26, 2020); ***Hou Liu v. Intercept Pharm., Inc.,*** 2020 WL 5441345 (S.D.N.Y. Sept. 9, 2020), granting motion to dismiss and denying motion to alter judgment. **Adverse events**

Intercept manufactures and markets Ocaliva for the treatment of primary biliary cholangitis, a rare liver disease. The company's Phase 3 trial included 1,325 participants, two of whom died during the trial. In May 2016, the FDA approved Intercept's drug under the Accelerated Approval Program. Part of the approval was a recommendation that lower dosages be prescribed for late-stage patients, and the company's FDA label reflected this. The FDA also instructed the company to continue to monitor safety in late-stage patients and to conduct a Phase 4 clinical trial (which is required under the Accelerated Approval Program). Between June 2016 and June 2017, Intercept received and submitted to the FDA 30 serious adverse event (SAE) reports for 27 patients — 19 deaths and 11 serious injuries. Twelve of the 27 patients had received an incorrect dosage of Ocaliva. In July 2017, Intercept announced that a patient from its Phase 2 trial had died. In September 2017, the company issued a Dear Healthcare Provider Letter warning against providing

higher-than-recommended doses to late-stage patients and explaining that patients had been injured or had died after receiving incorrect dosing. The company's stock price fell 20 percent. Later in September 2017, the FDA issued a drug safety communication in which it warned about dosing and referred to the SAEs. The company's stock price fell 37 percent.

Investors sued, challenging statements about Ocaliva's safety and tolerability, dosing, and the severity of the SAEs. The court dismissed plaintiffs' attack on statements related to safety on materiality grounds: plaintiffs could not establish materiality simply by referring to the 30 SAEs, which represented less than 1 percent of Ocaliva patients. The court rejected plaintiffs' argument that they had pled "something more" than the mere number of events by alleging that deaths increased from the Phase 3 to the post-trial period, and that the FDA was particularly concerned about liver injury. With respect to statements about dosing, plaintiffs relied on an omission theory, claiming that the company's failure to disclose information about dosage compliance rendered certain statements misleading. The court rejected this theory too, explaining that it rested on the "flawed premise" that pharmaceutical companies, as opposed to physicians, make prescribing decisions for patients. As to the severity of the SAEs, plaintiffs had identified no false or misleading statements. The court also concluded that plaintiffs had failed to adequately plead scienter. The individual defendants' stock sales were not suspiciously timed, as plaintiffs had failed to link the sales to the executives' receipt of material nonpublic information about dosing errors or adverse events. Plaintiffs also failed to establish the company's scienter, as they had not connected those within the company who made the challenged statements with those who purportedly believed the statements were false. After the court dismissed the complaint with prejudice, plaintiffs moved to amend the judgment or to set it aside so that they could replead. The court denied plaintiffs' motion, having reviewed the proposed amended complaint and concluded that it remained inadequate.

Police & Fire Ret. Sys. of the City of Detroit v. Axogen, Inc., Case No. 8:19-cv-69 (M.D. Fla. April 21, 2020), granting motion to dismiss without prejudice. **Market estimates**

Axogen develops and markets surgical products including Avance, which is used in treating peripheral nerve injuries. In 2017, Axogen estimated that, based on the number of annual nerve repair surgeries, the addressable market opportunity for all of its products was approximately $2 billion, and the market opportunity for Avance in particular was $976 million. In December 2018, a short seller released a report challenging the company's estimates and asserting that the Avance market was only $52 million. Axogen's stock price dropped 38 percent.

Investors sued, challenging, among other things, the company's statements about the size of the market for its products. The complaint included the opinions of an unidentified expert who purported to calculate the true market for Axogen's products at a fraction of Axogen's estimates. The court granted the motion to dismiss without prejudice, concluding that the challenged statements fell within the PSLRA safe harbor for forward-looking statements because they were estimates of market size, market opportunity, and maximum revenue that the company might achieve. Notably, the court stated that "the notion of a 'market' in the context presented here is inherently a future-oriented abstraction of where and to whom goods might be sold, rather than a present, observable fact." The court also dismissed claims based on a number of other statements, concluding that these statements were inextricably interwoven with the forward-looking statements, were immaterial, or, in context, were not false. The court finally rejected plaintiffs' scienter allegations: the allegation from a confidential witness that people within the company knew the "truth" about limited market opportunity supported at most an inference of negligence, given the absence of any allegation that senior executives knew this purported information.

In re Aceto Corp. Sec. Litig., 2020 WL 4452059 (E.D.N.Y. Aug. 3, 2020), granting motion to dismiss with prejudice. **Supply chain**

Aceto developed, marketed, sold, and distributed pharmaceutical products. The company disclosed to investors that it was dependent on suppliers and that it could be harmed by any interruption in supply. Before November 2016, the company received certain generic drugs from two suppliers, Citron and Lucid, who in turn acquired products from Aurobindo, an

Indian company. In November 2016, Aceto reported that it had acquired Citron and Lucid and had entered into its own supply agreement with Aurobindo, which would supply nearly all of the products Aceto had previously bought from Citron and Lucid. In November 2017, Aceto reported that it was experiencing supply challenges "on the manufacturing side." In May 2018, Aceto disclosed that it was making progress on its supply chain challenges but that it had incurred over $10 million in failure-to-supply penalties it was obligated to pay to its customers. In September 2018, the company disclosed 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. (Plaintiffs dropped earlier claims they had asserted against the bankrupt company.) The court dismissed the claims against the executives. The court concluded that Aceto had sufficiently disclosed that Aurobindo was failing to meet Aceto's supply needs, that this was preventing Aceto from filling its customers' orders, and that this in turn was leading to financial penalties. The court rejected the plaintiffs' argument that Aceto was clearly obligated to report that Aurobindo had breached the supply agreement and was competing with Aceto for customers. Because plaintiffs had not shown that Aceto had a clear obligation to disclose this additional information, they had also failed to create a strong inference of scienter.

Inchen Huang v. Higgins, 443 F. Supp. 3d 1031 (N.D. Cal. 2020), granting motion to dismiss with prejudice. **Off-label marketing**

Assertio Therapeutics (formerly Depomed) acquired the rights to tapentadol, an opioid-based pain medication, in 2015. Tapentadol sales grew substantially under Assertio's ownership and eventually accounted for 62 percent of the company's revenue. In November 2016, Assertio announced decreased revenue guidance for 2016. In March 2017, a Senate investigation into the sales and marketing practices of several opioid manufacturers, including Assertio, became public. In August 2017, Assertio announced that it had received subpoenas from federal and state authorities investigating off-label marketing. Over the course of these announcements, the company's stock price declined 73 percent.

Investors sued, claiming that the company had misrepresented the basis for its sales growth and had failed to disclose the purported off-label marketing campaign. The court dismissed the complaint. It noted that while confidential witness allegations supported an inference that sales representatives were told to recommend off-label dosing, the allegations did not support the inference that such recommendations were made on a widespread basis. This defeated plaintiffs' falsity allegations. For much the same reason, the court held that plaintiffs failed to plead scienter. The core operations doctrine was also insufficient to support an inference of scienter, as were plaintiffs' allegations about pressure from activist investors to increase revenues. The court finally concluded that plaintiffs had failed to establish loss causation: they had not pled an adequate connection between Assertio's alleged off-label marketing and the announcements of government investigations, which were directed at the opioid industry as a whole.

Ferraro Family Found., Inc. v. Corcept Therapeutics Inc., – F. Supp. 3d –, 2020 WL 6822916 (N.D. Cal. Nov. 20, 2020), granting motion to dismiss without prejudice. **Off-label marketing**

Corcept develops and commercializes drugs to treat metabolic, oncologic, and psychiatric disorders by modulating the effects of the hormone cortisol. In July 2007, the FDA granted Corcept orphan drug designation for its drug Korlym, which treats endogenous Cushing Syndrome (a condition in which adrenal glands produce too much cortisol). The orphan drug designation gave Corcept market exclusivity for the drug through February 2019. In April 2011, the company submitted an NDA for Korlym, and the FDA approved the drug for the treatment of endogenous Cushing Syndrome in certain patients. In January 2019, an investigative journalist 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 price fell 11 percent. Later in January 2019, the company announced preliminary results for fourth-quarter and full-year 2018. This included a projected slowdown in Korlym sales and revenue below analysts' projections. The company's stock price fell 10 percent.

Investors sued, challenging a wide array of statements about the company's physician education programs, marketing, compliance with FDA regulations, screening and diagnosis rates for

Cushing Syndrome, revenue growth, and insurance reimbursements. Plaintiffs claimed that all of these statements were false or misleading in light of the alleged off-label marketing scheme. According to plaintiffs, the company had targeted nonspecialist endocrinologists and primary care physicians and had encouraged them to use Korlym as an off-label diagnostic tool. The court granted the company's motion to dismiss on falsity, scienter, and loss causation grounds. Most broadly, the court held that plaintiffs had failed to adequately allege that Corcept engaged in an off-label marketing scheme in the first place. While plaintiffs pointed to statements from multiple confidential witnesses, none of the statements attributed to CWs (all of whom were doctors, not Corcept employees) showed that Corcept sales representatives were directed to market Korlym off-label, or connected company leadership to any off-label marketing. Plaintiffs' allegations of increased spending on physician education programs were not sufficiently linked to increased off-label prescriptions, and allegations related to increased diagnosis rates by particular doctors were likewise not linked to off-label marketing. The court also rejected plaintiffs' claim that modified insurance reimbursement practices by particular insurers evidenced an off-label marketing scheme. In the absence of an adequately pled off-label marketing scheme, the court held that plaintiffs had failed to plead falsity as to each category of challenged statements. 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. On loss causation, defendants argued that the investigative journalist's report was not a corrective disclosure because it contained only publicly available material. The court held that while this was not dispositive, plaintiffs had failed to show that the journalist's report contained any analysis that had not also been performed by other market participants, and thus failed to establish loss causation with respect to the report. Plaintiffs' remaining alleged corrective disclosure was not sufficiently connected to any alleged misstatements.

Yaron v. Intersect ENT, Inc., 2020 WL 6750568 (N.D. Cal. June 19, 2020), granting motion to dismiss without prejudice. **Sales and sales discounting**

Intersect sold two lines of products, PROPEL and SINUVA. When it launched SINUVA in March 2018, the company warned investors that the launch could detract from PROPEL sales, as the sales force would be focused on the new product line. Intersect repeated this warning over the next six quarters but also reported that PROPEL sales were growing. The company twice reduced revenue guidance during this period, and its stock price dropped on each of those announcements. In June 2019, Intersect brought in new management. In August 2019, the new interim CEO announced the results of an investigation into market demand and customer ordering dynamics. Through the investigation, the CEO said, the company had learned that while it had been preoccupied with the SINUVA launch, the sales force had altered its approach to PROPEL and had switched from educating physicians about the products to offering discounts on high-volume orders. The CEO further explained that bulk discounting had increased over the past six quarters, although it still accounted for only 2-3 percent of annual revenue. Intersect announced that it had decided to stop offering bulk discounts and to return to the basics of physician education. The company projected reduced revenue for the remainder of the year as customers worked through their inventory. Intersect's stock price fell 18 percent.

Investors sued, challenging three categories of statements: (1) financial reports and guidance, (2) statements that PROPEL sales were "strong," and (3) statements that decreases in PROPEL sales were the result of the SINUVA launch. The court granted the company's motion to dismiss as to all statements. The court began by discussing whether alleged channel stuffing generally is an appropriate basis for a Section 10(b) claim. On this point, the court rejected the company's argument that channel stuffing claims are "disfavored," holding that "channel stuffing may support a Section 10(b) claim when plaintiff alleges that defendants knew that business was weak, falsely represented to investors that business was strong, and used channel stuffing to bolster their misrepresentations in the short term." The court also rejected the company's argument that plaintiffs had failed to identify the particular customers, transactions or amounts involved in channel stuffing. Intersect's August 2019 admissions about bulk discounts sufficiently established the challenged conduct. As to challenged *statements,* however, the court sided with the company. Intersect's financial reports and guidance were

neither false nor misleading, given that the company did not ascribe any cause to its positive results. The matter would have been different if Intersect had said, for example, that financial results were produced by "organic" or "sustainable" growth. Plaintiffs similarly failed to plead falsity as to the company's statements that PROPEL growth was "strong." Sales grew over the class period, and the company met guidance more often than not. As to the third category of challenged statements — the company's attribution of changes in PROPEL sales to the SINUVA launch — plaintiffs again failed to show falsity: plaintiffs' own allegations showed that the sales force turned from educating physicians to offering discounts because it was preoccupied with SINUVA. The court also ruled for the company on scienter. Confidential witnesses did not claim to have interacted with the individual defendants, and the core operations inference failed in the absence of facts showing that management was closely monitoring the relevant issues. Finally, the court ruled for the company on loss causation. Plaintiffs failed to plead facts showing that any purportedly hidden risk of channel stuffing — as opposed to the disclosed risk that the SINUVA launch would be a distraction — materialized or caused the stock price decline for which plaintiffs sought to recover.

DISTRICT COURT DECISIONS: MOTION TO DISMISS DENIED IN PART OR IN WHOLE

Pritchard v. Apyx Med. Corp., 2020 WL 1180731 (M.D. Fla. Mar. 11, 2020), denying motion to dismiss. **New indication for medical device**

Apyx developed, manufactured, and sold a device called J-Plasma, which the FDA had approved for certain surgical uses. Physicians also used J-Plasma off-label for dermal resurfacing — that is, wrinkle reduction. In December 2018, the company announced that based on a recently completed clinical study, it had submitted a Premarket Notification 510(k) application for use of J-Plasma in dermal resurfacing. The company stated that it was "very pleased with the clinical results" and "optimistic [about] receiving regulatory clearance." In February 2019, an analyst published a report noting that the company had never revealed the results of the clinical study underlying the 510(k) application. Based on this, the analyst surmised that the study had failed to meet its endpoint. The company's stock price fell 25 percent. In a March 2019 analyst call, the company stated that the February 2019 analyst report was "unsubstantiated" and a "blatant mischaracterization" of trial results; the company also reminded investors that the purpose of its clinical study had been to demonstrate the safety and efficacy of the product for the new indication. In April 2019, Apyx reported that it had withdrawn its 510(k) application because of concerns expressed by the FDA. The company also revealed that the study had missed its primary efficacy endpoint by 13 percent. The company's stock price fell 36 percent.

Investors sued, challenging, among other things, the company's March 2019 statement that the February 2019 analyst report was unsubstantiated. The court denied the company's motion to dismiss, holding that plaintiffs had adequately pled that the March 2019 statement was misleading by way of omission. The court reasoned that when the company criticized the analyst report and referred to the clinical study as a method of demonstrating safety and efficacy, the company assumed a duty to disclose that the study had in fact failed to demonstrate efficacy. The court declined to analyze any other challenged statement: "One actionable omission is sufficient to defeat Defendants' Motion to Dismiss." The court also held that plaintiff had adequately pled scienter by means of the allegation that company's CEO had access to reports showing that the study had failed. Finally, the court rejected the company's argument that plaintiff had failed to plead loss causation with respect to the stock price decline following the publication of the February 2019 analyst report. In the court's view, the analyst report did not merely recycle previously publicized information; instead, the report revealed information about the clinical study that had previously been concealed.

In re Acadia Pharm. Inc. Sec. Litig., 2020 WL 2838686 (S.D. Cal. June 1, 2020), denying in part and granting in part motion to dismiss. **Clinical trial deaths, kickbacks**

Acadia manufactured Nuplazid, a drug to treat psychosis symptoms associated with Parkinson's disease. Acadia conducted four controlled trials for safety and efficacy. Three of the trials did not generate statistically significant results, but the fourth one did, and the company submitted an NDA. In September 2015, an FDA reviewer recommended against approval because of the high rate of deaths in the trial. After a favorable advisory committee vote, the FDA approved the drug in April 2016, albeit with a black box label warning of the risk of death in certain patient populations. In April 2018, CNN reported concerns about deaths and Acadia's stock price fell 23 percent. Later that month, CNN reported that the FDA was reexamining Nuplazid, and the stock dropped 22 percent. In July 2019, another media outlet alleged that Acadia had provided cash incentives to doctors to prescribe Nuplazid, after which the stock dropped seven percent.

Investors sued, challenging statements about trial results and post-marketing events and alleging that the company misleadingly failed to disclose kickbacks to physicians. Before addressing the merits of the company's motion to dismiss, the court denied the company's request that it take judicial notice of 56 documents, including press releases and transcripts of earnings calls. The court then granted in part and denied in part the motion to dismiss. The court concluded that some opinion statements and some forward-looking statements were inactionable, but declined to "parse through" each such statement. With respect to plaintiffs' allegation that the company misleadingly failed to disclose deaths in its Phase 3 trial, the court rejected the company's argument that those deaths had been disclosed to the public in a medical journal; the court characterized this as a premature "truth on the market" defense. The court also concluded that because the company "discussed [its] commercialization strategy," it had a duty to disclose that it was allegedly paying kickbacks. The court held that plaintiffs had adequately alleged scienter based on defendants' duty to report to regulators any transfers of value to physicians, on the importance to the company of Nuplazid (its only product), and on the fact that three directors had resigned four days after the FDA approved Nuplazid. The court also rejected the company's loss causation arguments, concluding that the media reports that preceded the three stock drops did more than simply rehash information that was already public.

Holwill v. AbbVie Inc., 2020 WL 5235005 (N.D. Ill. Sept. 1, 2020), denying motion to dismiss. **Kickbacks**

AbbVie's flagship drug is Humira, which is used to treat a range of inflammatory conditions including Crohn's disease. In public statements between 2013 and 2018, the company attributed the growth of Humira sales to its sales and marketing practices and programs. The company also said that its programs complied with applicable law. In 2018, two *qui tam* complaints were filed; in both, the plaintiffs claimed that AbbVie was providing illegal kickbacks to physicians in an effort to induce them to prescribe Humira. The first *qui tam* complaint was unsealed in March 2018. The second was unsealed in September 2018, when the California Department of Insurance intervened in the action. The company's stock price fell three percent on the day that development became public and five percent the following day.

Investors sued, challenging both the company's legal compliance statements and its statements attributing the success of Humira to legitimate sales and marketing practices. The court denied the company's motion to dismiss. The court acknowledged that pharmaceutical companies may lawfully offer product support services, but concluded that plaintiffs had adequately alleged that AbbVie provided classic kickbacks — meals, drinks, gifts — that were not integrally related to the product it was selling. The court also concluded that plaintiffs had adequately pled that the company's Nurse Ambassador program offered value to physicians independent of Humira itself, and hence that the program was potentially unlawful. The court further reasoned that while the company had no independent obligation to disclose the challenged practices, its attribution of success to legitimate conduct made that omission actionable. The court also agreed with plaintiffs that statements in the company's code of conduct — such as "[w]e never offer or provide anything of value to healthcare professionals … to inappropriately influence the[m]" — were actionable. As to scienter,

the court concluded that plaintiffs had adequately alleged facts showing that defendants knew about the purportedly unlawful practices, given the volume of their statements on the issue and the importance of Humira sales and marketing practices to the company. The court acknowledged the company's argument for a competing innocent inference — that it would not have publicly advertised the Nurse Ambassador program if it had believed it was unlawful. But the court rejected that inference, reasoning that plaintiffs had also alleged "classic" kickbacks. Finally, the court rejected the company's argument that plaintiffs had failed to allege loss causation. The company argued that all relevant information about the alleged kickbacks was incorporated into its stock price when the first *qui tam* complaint was unsealed in March 2018, and that plaintiffs therefore could not recover for the stock price declines in September 2018. The court ruled that this argument would have to await summary judgment.

Pelletier v. Endo Int'l PLC, 439 F. Supp. 3d 450 (E.D. Pa. 2020), denying in part and granting in part motion to dismiss. **Antitrust**

Endo manufactures branded and generic drugs. In 2010, the company acquired Qualitest, which became Endo's generic manufacturing division. In 2013, a new CEO joined Endo and oversaw the acquisition of a number of smaller companies. In 2015, Endo acquired Par, another manufacturer of generic drugs. In the summer of 2014, the Connecticut Attorney General issued subpoenas to generic drug manufacturers — not including Endo — concerning generic drug pricing. Later in 2014, the DOJ issued subpoenas to generic manufacturers — this time including Par. In December 2015, the Connecticut AG subpoenaed Endo. On November 3, 2016, Bloomberg published an article about the DOJ and Connecticut AG probes, noting that Par was being investigated. Endo's stock price fell 20 percent. In February 2017, the company released disappointing financial results, and its stock price fell further.

Investors sued, claiming that statements related to the competitiveness of generic drugs markets, the sources of Endo's income, and the reasons for Endo's pricing decisions were false or misleading in light of an alleged conspiracy among generic drug manufacturers. The court dismissed plaintiffs' claims to the extent that they were premised on Endo's purported participation in the conspiracy. Plaintiffs had alleged only that Endo was engaged in parallel pricing; they had failed to allege "plus factors" sufficient to support their price-fixing allegations. Notably, the court stated that plaintiffs had failed to plead facts sufficient to warrant what would amount to an unprecedented "antitrust trial within a securities trial." In addition, the court held that companies do not have a duty to disclose uncharged wrongdoing, and noted that defendants could not plausibly be expected to admit price fixing in public filings. Nevertheless, the court allowed plaintiffs to proceed on the theory that defendants' statements about market conditions and sources of revenue were misleading — even in the absence of a price-fixing conspiracy. The court held that plaintiffs had sufficiently alleged that defendants had obscured or omitted material information about these issues. The court acknowledged that certain of plaintiffs' allegations appeared to be in tension with one another but concluded that this was permissible at the pleading stage. The court also held that plaintiffs had adequately alleged scienter, pointing to senior executives' direct control of pricing decisions.

In re Mylan N.V. Sec. Litig., 2020 WL 1673811 (S.D.N.Y. Apr. 6, 2020), denying in part and granting in part motion to dismiss. **Antitrust; Medicaid rebates**

Mylan develops and manufactures both brand-name and generic pharmaceuticals, including the EpiPen Auto-Injector. Mylan classified the EpiPen as a noninnovator multiple source drug; this is a favorable classification for companies under the Medicaid Drug Rebate Program, which requires drug companies to give certain rebates to the Centers for Medicare and Medicaid Services. In 2009, CMS told Mylan that it had misclassified the EpiPen and that Mylan would likely need to begin paying a higher rebate rate under the appropriate classification. In 2014, Mylan received a subpoena from the DOJ regarding an investigation into whether the EpiPen was properly classified. In October 2016, Mylan announced that it had entered into a $465 million dollar settlement with the DOJ that required it to reclassify the EpiPen. Mylan was also subject to several DOJ, congressional, and state investigations into potentially anticompetitive practices related to generic drugs.

Investors sued, alleging that Mylan had misled shareholders as to both its misclassification of the EpiPen and its alleged anticompetitive activity. In a 2018 decision (reported in our 2018 review), the district court granted defendants' motion to dismiss as to opinion statements about the general complexity and subjectivity of the regulatory environment and statements in the company's code of business ethics, but otherwise denied the motion. Investors then filed an amended complaint, in which they alleged that Mylan was engaged in price fixing with respect to three additional generic drugs and had also engaged in anticompetitive conduct to protect the EpiPen from competition. In a 2019 decision (reported in our 2019 review), the court denied defendants' motion as to the new EpiPen allegations, but granted the motion to dismiss as to the three new generic drugs.

Investors amended again, now alleging that Mylan was engaged in price fixing with respect to 32 generic drugs and illegal market allocation with respect to seven generic drugs. The court granted in part and denied in part the company's partial motion to dismiss. With respect to statements about Medicaid rebate calculations, Mylan argued that intervening statutory changes showed ambiguity in the previous law governing rebates and thus undermined any inference of scienter. The court rejected this argument: the statutory change on which Mylan relied was expressly intended to close a loophole and to prevent Mylan's misclassification, and CMS had specifically told Mylan that it was misclassifying the EpiPen. The court also rejected the company's argument that plaintiffs had failed to plead scienter or loss causation as to claims premised on purportedly anticompetitive payments made to Pharmacy Benefit Managers. On scienter, the court held it sufficient for plaintiffs to allege that the company consciously engaged in an anticompetitive scheme and that top executives were personally involved in pricing — and therefore would have been aware of the rebate payments to PBMs. On loss causation, the court held that commentary reflecting "public outcry" due to the high price of the EpiPen, as well as the FTC's announcement of an investigation of Mylan were adequately alleged to be corrective disclosures with respect to the company's payments made to PBMs. With respect to plaintiffs' claims premised on alleged antitrust violations related to generic drugs, however, the court largely sided with the company: plaintiff had failed to meet the pleading standards required by Section 1 of the Sherman Act for 18 out of the 19 drugs at issue in the company's motion. The court rejected plaintiffs' allegations that price-fixing activity was so rampant that it would have affected all of Mylan's generic drugs, and held that plaintiffs were required to plead anticompetitive activity on the level of individual drugs. The court permitted plaintiffs to move forward with their antitrust-based claim related to the single remaining drug, and held that plaintiffs had adequately pled loss causation based on an analyst report providing details on antitrust suits brought by state AGs.

SEB Inv. Mgmt. AB v. Align Tech., Inc., 485 F. Supp. 3d 113 (N.D. Cal. 2020), denying in part and granting in part motion to dismiss. **Product discounts**

Align Technologies is a medical device company that designs, manufactures, and markets orthodontic products, including Invisalign. In public statements from May to September 2018, Align expressed optimism about its quarterly earnings, advising investors that competitive pressure was in line with its expectations. The company responded to a question about competition by stating that "there's not a momentum piece or anything that we're adjusting the business around right now." In October 2018, the company disclosed that in the third quarter, it had implemented a $200-per unit discount plan in response to competitive pressures, which resulted in a $100 decline in its average sales price compared to the previous quarter. Align's stock price fell 20 percent.

Investors sued, claiming that six statements were false or misleading in light of the undisclosed discount plan. The court dismissed plaintiff's claims as to five of the six statements but concluded that plaintiff had adequately stated a claim with respect to the sixth. The first statement — conveying the company's expectations about the effect sales prices would have on quarterly earnings — was forward-looking, was accompanied by meaningful cautionary language, and hence was protected by the PSLRA safe harbor. Plaintiff failed to adequately allege falsity as to the next four statements, which it claimed downplayed or omitted the company's concerns about competition. The court held that plaintiff's interpretation of those statements was implausible and depended on omitting necessary context, and that when that

context was considered, the claims were neither false nor misleading. As to the sixth statement, however, the court held that plaintiff had adequately pled both falsity and scienter. This was the CEO's assertion, in response to the question about competition, that the company was not "adjusting" anything "right now." The court held that the discount program itself could be considered an "adjustment" — which meant that plaintiff had adequately pled falsity — and that plaintiff had adequately alleged scienter insofar as the product and discounting programs were "core operations" of the company. The court finally dismissed an insider trading claim against the CEO, holding that plaintiff had failed in multiple ways to satisfy the requirement that he traded contemporaneously with the defendant.

In re Perrigo Co. PLC Sec. Litig., 435 F. Supp. 3d 571 (S.D.N.Y. 2020), denying in part and granting in part motion to dismiss. **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 percent tax rate — rather than capital gains — subject to a 33 percent tax rate. In November 2017, the Irish Office of the Revenue Commissioners commenced an audit of Perrigo's 2012 and 2013 taxes. In November 2017, Irish Revenue sent the company a list of areas it wanted to review, including the sale of Tysabri and the tax treatment of the proceeds from the sale. In January 2018, the company attended an initial audit meeting with Irish Revenue. 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 Perrigo 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 the company a Notice of Amended Assessment, which included a balance payable of €1.6 billion. After the company disclosed this liability in a Form 8-K, its stock price fell 29 percent.

Investors sued, alleging that Perrigo's financial statements violated GAAP and were therefore false or misleading. The court granted in part and denied in part the company's motion to dismiss, drawing a distinction between financial statements issued before the receipt of the October 2018 Audit Findings Letter and financial statements issued thereafter. The court granted the company's motion with respect to its pre-October 2018 financial statements. The court held that plaintiffs had adequately pled falsity as to these financial statements: the company was required under ASC 450 to disclose a loss contingency reflecting the Irish Revenue Audit. On scienter, however, the court sided with the company on the pre-October 2018 financial statements. Plaintiffs relied principally on the magnitude of the potential liability, and that was insufficient. As to the post-October 2018 financial statements, the court denied the company's motion to dismiss. The company had a duty to quantify its exposure, even if it disagreed with Irish Revenue's position and intended to contest it. Nor was this a matter of opinion governed by the *Omnicare* framework: the €1.6 billion liability figure in the Audit Findings Letter was a matter of fact rather than opinion. Plaintiffs had also adequately alleged scienter as to the post-October 2018 financial statements: the company had an "obvious" duty to disclose the loss contingency under ASC 450, and plaintiffs had sufficiently pled that the company acted recklessly in failing to recognize that duty.

Alpha Capital Anstalt v. Intellipharmaceutics Int'l Inc., 2020 WL 3318029 (S.D.N.Y. June 18, 2020), denying in part and granting in part motion to dismiss. **CFO resignation**

Intellipharmaceutics develops and manufactures controlled-release and targeted-release oral solid dosage drugs. In September 2018, the company filed a registration statement in preparation for an offering of stock and warrants. In the registration statement, the company stated that the CFO's employment agreement provided for automatic annual renewal. In the risk factor discussion in the registration statement, the company stated that its success depended in part on the ability to retain highly qualified management. Three weeks after the offering, the company announced its CFO's imminent resignation.

Investors sued, alleging that the failure to disclose the CFO's impending resignation was a material omission that violated the Securities Act. The court denied the company's motion to dismiss. The court credited plaintiffs' allegation that the company's CEO had admitted that he knew of the CFO's upcoming departure at the time of the registration statement; the company's disagreement with that allegation created a factual issue that could not be resolved at the pleading stage. The court then concluded that the company had a duty to disclose the upcoming departure in light of statements in the registration statement that, taken as a whole, suggested that the CFO would continue as a member of senior management. The court issued a divided ruling on the question of whether the defendants were statutory "sellers" who could be sued under Section 12(a)(2) of the Securities Act: The court concluded that the CFO and the company were sellers, but that the CEO was not.

TABLE OF NEW FILINGS IN 2020

In 2020, 45 new securities fraud class actions were filed against life sciences companies.[17] This is consistent with what we saw in 2019, but a dropoff from highs in 2016 and 2017:

2016: 50 new complaints

2017: 54 new complaints

2018: 48 new complaints

2019: 44 new complaints

2020: 45 new complaints

Of the new actions in 2020, 29 were filed against companies with development-stage drugs or devices. The remaining 16 actions involve a broad spectrum of regulatory and nonregulatory issues with mature products, ranging from alleged regulatory violations in sales and marketing, to financial statement issues, to issues concerning revenue forecasting and performance. The balance between pre-approval and post-approval filings is similar to what we saw in 2019:

2019: 24 pre-approval filings, 20 post-approval filings

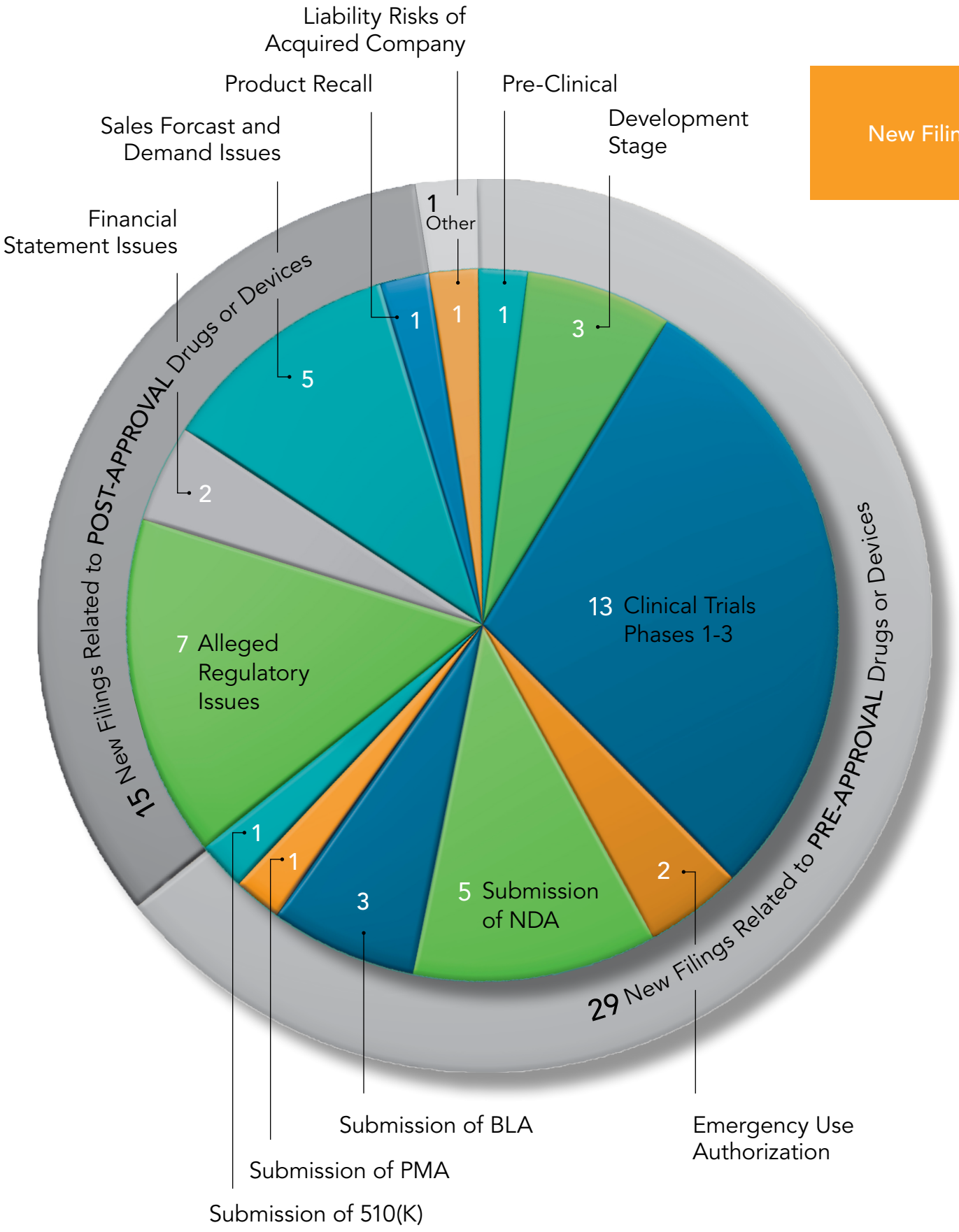
2020: 29 pre-approval filings, 16 post-approval filings

The most significant development in new filings in 2020 relates to the pandemic. Seven of the 45 new filings relate to the development of COVID-19 products, including both tests and vaccines.

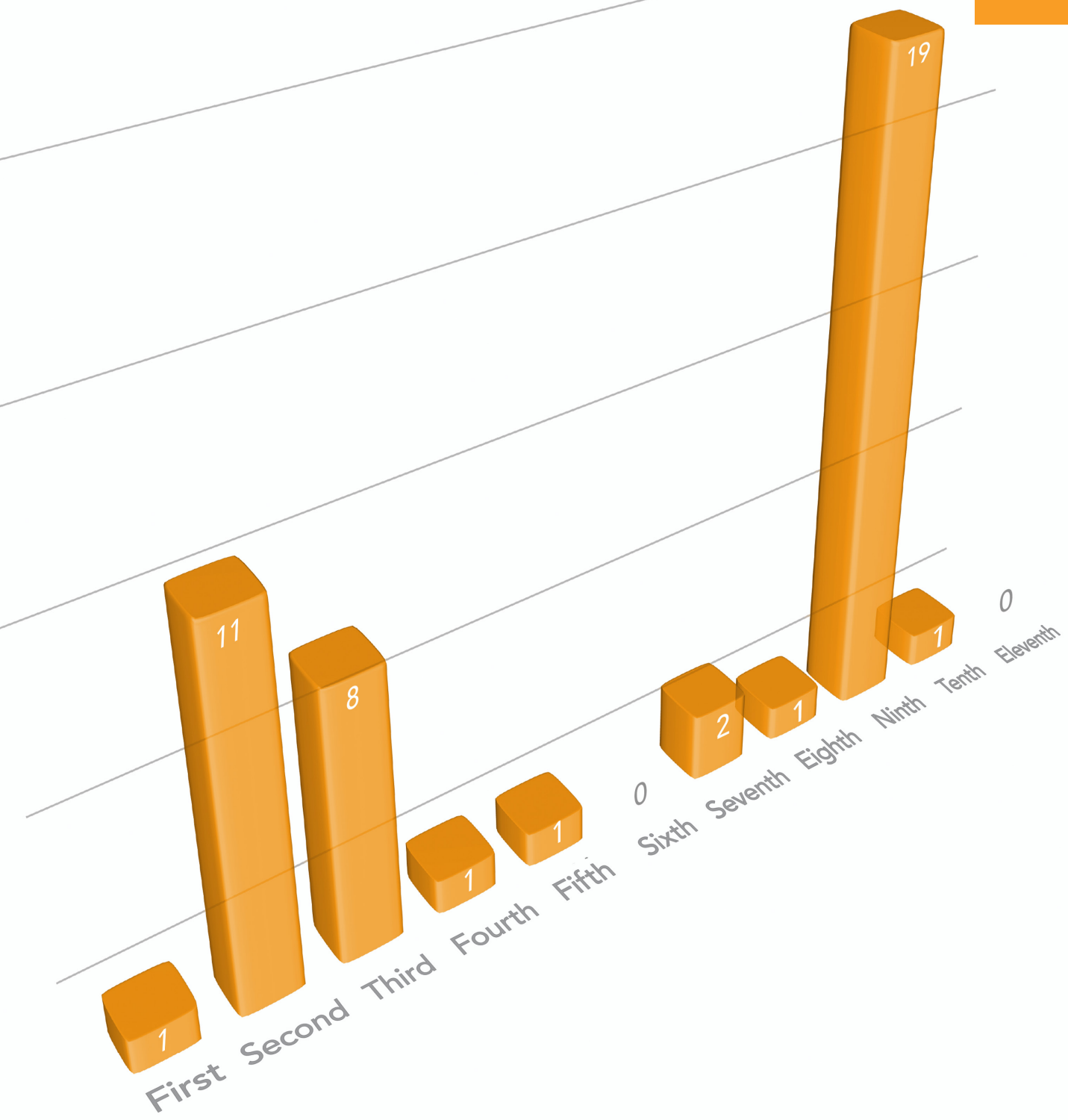
As in previous years, the new filings are clustered in district courts in the Second, Third, and Ninth Circuits. Among those circuits, activity has shifted in 2020 from the East to the West Coast. In 2019, 21 new cases were filed in the Second and Third Circuits combined, as opposed to only nine in the Ninth Circuit. In 2020, 19 new cases have been filed in the Ninth Circuit — the same number as in the Second and Third Circuits combined. We show the breakdown graphically on page 52.

PRODUCT LIFECYCLE		SECURITIES FRAUD CLASS ACTIONS FILED IN 2020
PRE-APPROVAL	Preclinical	1
	Development Stage	3
	Clinical Trials: Phases 1–3	13
	Emergency Use Authorization	2
	Submission of NDA	5
	Submission of BLA	3
	Submission of PMA	1
	Submission of 510(k)	1
	Total Pre-Approval	29
POST-APPROVAL	Alleged Regulatory Issues	7
	Financial Statement Issues	2
	Sales Forecast and Demand Issues	5
	Product Recall	1
	Total Post-Approval	15
OTHER	Liability Risks of Acquired Company	1

17 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.


Liability Risks of Acquired Company
Product Recall
Pre-Clinical
Sales Forcast and Demand Issues
Development Stage
Financial Statement Issues
1 Other
1
1
1
3
5
2
13 Clinical Trials Phases 1-3
7 Alleged Regulatory Issues
1
1
3
5 Submission of NDA
2
15 New Filings Related to POST-APPROVAL Drugs or Devices
29 New Filings Related to PRE-APPROVAL Drugs or Devices
Submission of BLA
Emergency Use Authorization
Submission of PMA
Submission of 510(K)

NEW FILINGS IN 2020 BY CIRCUIT



COMPANY	DATE	COURT
LOGICBIO THERAPEUTICS, INC.	3/18/2020	D.N.J.
SORRENTO THERAPEUTICS, INC.	5/26/2020	S.D. Cal.
VAXART, INC.	8/24/2020	N.D. Cal.
SONA NANOTECH INC.	12/17/2020	C.D. Cal.
INOVIO PHARMACEUTICALS, INC.	3/12/2020	E.D. Pa.
NEXTCURE, INC.	9/21/2020	S.D.N.Y.
CYTOMX THERAPEUTICS, INC.	5/21/2020	N.D. Cal.
GERON CORPORATION	1/23/2020	N.D. Cal.

SUMMARY OF ALLEGATIONS

PRECLINICAL LogicBio is a genome editing company developing LB-001 for the treatment of Methylmalonic Acidemia. Plaintiffs allege that the company failed to disclose that it was behind schedule in submitting its IND to the FDA. Stock prices fell after the company announced that the FDA had put a clinical hold on its submission.

DEVELOPMENT STAGE Sorrento researches human therapeutic antibodies for the treatment of cancer and other diseases, and worked to develop a treatment for COVID-19. Plaintiffs allege that the company failed to disclose that in vitro testing results would not necessarily translate to the same results in human patients. Stock prices fell when a third party published a report casting doubt on the validity of the company's claims.

DEVELOPMENT STAGE Vaxart worked to develop an oral COVID-19 vaccine. Plaintiffs allege that the company misleadingly claimed that its vaccine was selected to participate in Operation Warp Speed. Stock prices fell after *The New York Times* published an article stating that the company was not selected to receive significant funding from Warp Speed.

DEVELOPMENT STAGE Sona Nanotech is developing gold nanorod products for diagnostic test applications, including a COVID-19 antigen test. Plaintiffs allege that the company misleadingly claimed that it would receive results from field studies of its COVID-19 antigen tests within a month, and that the data would be sufficient for authorization by the FDA or Health Canada. Stock prices fell after Sona reported a delay in results from the field studies; prices fell further after the FDA deprioritized its Emergency Use Authorization for the company's test and the company withdrew its application for authorization by Health Canada.

PHASE 1 Inovio developed a COVID-19 vaccine called INO-4800. Plaintiffs allege that Inovio misstated its development prospects and production capabilities. Stock prices fell following a series of public reports expressing doubt about Inovio's ability to produce a vaccine.

PHASE 1/PHASE 2 NextCure develops NC318, an immunomedicine for patients with metastatic solid tumors. Plaintiffs allege that the company overstated the efficacy of the drug. Stock prices fell when Eli Lilly ended its deal with NextCure and fell again when NextCure issued a press release announcing it was discontinuing several cohorts of patients in the second stage of Phase 1/Phase 2 trials.

PHASE 1/PHASE 2 CytomX is developing a novel class of investigational antibody therapeutics for the treatment of cancer. Plaintiffs allege that the company misleadingly downplayed drug safety and efficacy issues. Stock prices fell when CytomX released clinical trial results.

PHASE 2 Geron, together with Janssen, developed imetelstat, a drug intended to reduce spleen size and other debilitating symptoms in myelofibrosis patients. Plaintiffs allege that the company failed to timely disclose that imetelstat did not meet the primary endpoints of Phase 2 trials. Stock prices fell after the company disclosed trial results and reported that Janssen would terminate the companies' partnership.

COMPANY	DATE	COURT
ALLAKOS INC.	3/10/2020	N.D. Cal.
ANAPTYSBIO, INC.	3/25/2020	S.D. Cal.
GOSSAMER BIO, INC.	4/3/2020	S.D. Cal.
REATA PHARMACEUTICALS, INC.	10/12/2020	E.D. Tex.
MEI PHARMA, INC.	8/10/2020	S.D. Cal.
ODONATE THERAPEUTICS, INC.	9/16/2020	S.D. Cal.
INNATE PHARMA S.A.: AMERICAN DEPOSITARY SHARES	10/23/2020	C.D. Cal.
CELSION CORPORATION	10/29/2020	D.N.J.

SUMMARY OF ALLEGATIONS

PHASE 2 Allakos developed AK002, a drug designed to treat inflammatory diseases of the stomach and small intestine. Plaintiffs allege that the company omitted facts about its Phase 2 trial and trial design. Stock prices fell after a third party published a report claiming that the trial had been compromised.

PHASE 2 AnaptysBio develops etokimab, a drug for the treatment of inflammatory conditions. Plaintiff allege that the company misrepresented the efficacy of the drug following a Phase 2a trial testing the drug's effect on peanut allergies and dermatitis. Stock prices fell following the publication of analyst reports questioning the veracity of the company's trial data for various patient groups.

PHASE 2 Gossamer develops immunology, inflammation, and oncology drugs. Plaintiffs allege that Gossamer misrepresented the results of its Phase 2 trial for a drug treating asthma and rhinosinusitis, and failed to disclose that a competitor had completed a successful Phase 2 trial. Stock prices fell when Gossamer announced that it was terminating development of an asthma medication in the same class.

PHASE 2 Reata developed omaveloxolone for the treatment of Friedrich's ataxia. Plaintiffs allege that the company failed to disclose that a Phase 2 trial was insufficient to support single-study marketing approval. Stock prices fell after the company reported that the FDA had advised it to conduct a second pivotal trial.

PHASE 3 MEI develops Pracinostat, a drug for the treatment of acute myeloid leukemia in patients unable to receive intensive chemotherapy. Plaintiffs allege that the company overstated Pracinostat's potential efficacy and failed to disclose that a Phase 3 trial was unlikely to meet its primary endpoint. Stock prices fell when the company reported that it was discontinuing the Phase 3 trial following an interim futility analysis showing that the trial was unlikely to meet its primary endpoint.

PHASE 3 Odonate develops tesetaxel, an orally administered chemotherapy agent. Plaintiffs allege that the company misleadingly touted the drug as generally well tolerated and omitted safety issues. Stock prices fell after the company announced topline results from its Phase 3 trial, which revealed a high number of adverse events.

PHASE 3 Innate and AstraZeneca had a collaboration agreement under which Innate was to receive an incentive payment at the start of the first Phase 3 clinical trial for monalizumab. Plaintiffs allege that Innate concealed an amendment of the agreement under which it would receive payments in two parts during the Phase 3 trial. Stock prices fell after the company reported amended payment terms.

PHASE 3 Celsion develops ThermoDox, a drug candidate for the treatment of liver cancer. Plaintiffs alleged that the company overstated the drug's efficacy, approval prospects and commercialization potential. Stock prices fell after the company reported that the data monitoring committee for its Phase 3 trial recommended stopping the trial.

COMPANY	DATE	COURT
MINERVA NEUROSCIENCES, INC.	12/8/2020	D. Mass.
CHEMBIO DIAGNOSTICS, INC.	6/18/2020	E.D.N.Y.
CHEMBIO DIAGNOSTICS, INC.	8/17/2020	E.D.N.Y.
VERRICA PHARMACEUTICALS INC.	7/14/2020	E.D. Pa.
FENNEC PHARMACEUTICALS INC.	9/3/2020	M.D.N.C.
ZOSANO PHARMA CORPORATION	10/29/2020	N.D. Cal.
INTERCEPT PHARMACEUTICALS, INC.	11/5/2020	E.D.N.Y.

SUMMARY OF ALLEGATIONS

PHASE 3 Minerva develops roluperidone, a drug for the treatment of schizophrenia. Plaintiffs allege that the company failed to disclose FDA feedback from an End-of-Phase 2 meeting suggesting that the company's planned combination of studies would be unlikely to support an NDA. Stock prices fell after Minerva announced that its Phase 3 trial did not meet its primary or secondary endpoints, and fell further when Minerva reported that the FDA had advised against submitting an NDA based on data from its Phase 2b and Phase 3 studies.

EMERGENCY USE AUTHORIZATION Chembio developed a rapid serological and antibody test for COVID-19. Plaintiffs allege that Chembio falsely represented its COVID-19 test as 100 percent accurate in determining current and past exposure. Stock prices fell after the FDA announced that it had revoked the test's Emergency Use Authorization due to higher than expected false results.

EMERGENCY USE AUTHORIZATION Chembio developed a rapid serological and antibody test for COVID-19. Plaintiffs allege that the company overstated the accuracy of its test. Stock prices fell after the company reported that the FDA had revoked the company's Emergency Use Authorization due to concerns about the test's accuracy.

NDA Verrica developed VP-102 for the treatment of warts and molluscum, a pediatric skin disease. Plaintiffs allege Verrica failed to disclose known safety risks related to its proprietary applicator for VP-102. Stock prices dropped after the company disclosed a letter from the FDA discussing a potential safety issue with the applicator.

NDA Fennec developed PEDMARK, an injection for the prevention of ototoxicity in pediatric cancer patients. Plaintiffs allege that the company failed to disclose that the third-party manufacturing facilities it used did not comply with current Good Manufacturing Practices. Stock prices fell after the company disclosed that the FDA had issued a Complete Response Letter denying its NDA and citing manufacturing deficiencies.

NDA Zosano develops Qtrypta, an intracuteanous drug delivery path coated with the drug zolmitriptan. Plaintiffs allege that the company failed to disclose that clinical results were affected by different levels of drug exposure among subjects receiving different lots of Qtrypta. Stock prices fell after the company disclosed a discipline review letter from the FDA regarding its NDA for Qtrypta, and fell further after the company disclosed a Complete Response Letter in which the FDA recommended that the company repeat a bioequivalence study with three lots used in development.

NDA Intercept develops Ocaliva for the treatment of PBC, a rare and chronic liver disease, and nonalcoholic steatohepatitis (NASH). Plaintiffs allege that the company downplayed the severity of safety concerns associated with Ocaliva's use in treating PBC and NASH. Stock prices dropped after Intercept announced that it had received a Complete Response Letter rejecting the NDA for Ocaliva as a treatment for NASH-related liver fibrosis, and fell further when news outlets reported that Intercept was facing an FDA investigation over the potential risks of taking Ocaliva as a treatment for PBC.

COMPANY	DATE	COURT
FORTRESS BIOTECH, INC.	11/27/2020	E.D.N.Y.
BIOMARIN PHARMACEUTICAL INC.	9/25/2020	N.D. Cal.
MESOBLAST LIMITED: AMERICAN DEPOSITARY SHARES	10/8/2020	S.D.N.Y.
BIOGEN INC.	11/13/2020	C.D. Cal.
NEOVASC INC.	11/5/2020	S.D.N.Y.
NANO-X IMAGING LTD.	9/16/2020	E.D.N.Y.
BECTON, DICKINSON AND COMPANY	2/27/2020	D.N.J.

SUMMARY OF ALLEGATIONS

New Filings

NDA Fortress develops intravenous Tramadol for pain management in adults. Plaintiffs allege that the company failed to disclose that IV Tramadol was not safe for the intended patient population and accordingly would not be approved. Stock prices fell after the company disclosed a Complete Response Letter citing safety issues for the intended patient population.

BLA BioMarin develops valoctocogene roxaparvovec for the treatment of hemophilia A. Plaintiffs allege that the company failed to disclose that differences between the Phase 1/Phase 2 and Phase 3 studies of the drug limited the reliability of the Phase 1/Phase 2 study to support the durability of the drug's effect. Stock prices fell after the company disclosed a Complete Response Letter recommending two additional years of Phase 3 safety and efficacy data.

BLA Mesoblast develops Ryoncil, a stem cell treatment for children with steroid refractory acute graft versus host disease. Plaintiffs allege that the company failed to disclose that comparative analyses in its NDA between its Phase 3 trial and three historical studies could not establish efficacy given differences in trial design, and that as a result the FDA would require further studies for approval. Stock prices fell after the FDA's advisory committee briefing materials revealed the design differences among the studies; prices fell further when the company reported a Complete Response Letter recommending an additional study.

BLA Biogen develops therapies for neurological diseases, including aducanumab for the treatment of early Alzheimer's disease. Plaintiffs allege that the company failed to disclose that its studies did not establish efficacy. Stock prices fell when *Reuters* published an article and Biogen issued a press release reporting that an FDA advisory panel had recommended against approval on efficacy grounds.

PMA Neovasc developed the Reducer, which treats refractory angina by altering blood flow in the heart's circulatory system. Plaintiffs allege that the company failed to disclose issues with trial blinding that revealed treatment assignment to patients on the trial's control arm. Stock prices fell after the company reported that an FDA advisory panel had recommended against approval.

SUBMISSION OF 510(K) Nano-X develops x-ray source technology for the medical imaging industry. Plaintiffs allege that the company's Registration Statement reflected fabricated commercial agreements, failed to provide data comparing the company's images with images from competitors' machines, and failed to disclose that the company's technology was not original. Stock prices fell after a short seller released a report claiming that the company's technology was not unique, as evidenced by the company's 510(k) filing.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Becton, Dickinson and Company sells Alaris, a software-based medical device that delivers medication and other fluids to patients intravenously. Plaintiffs allege that defendants downplayed compliance issues and their effect on Alaris revenue. Stock prices fell when the company reported that it was halting Alaris sales because of compliance deficiencies and reduced guidance.

COMPANY	DATE	COURT
CO-DIAGNOSTICS, INC.	6/15/2020	D. Utah
ENDO INTERNATIONAL PLC	6/19/2020	D.N.J.
MYLAN N.V.	6/26/2020	W.D. Pa.
TEVA PHARMACEUTICAL INDUSTRIES LIMITED: AMERICAN DEPOSITARY SHARES	9/23/2020	E.D. Pa.
TACTILE SYSTEMS TECHNOLOGY, INC.	9/29/2020	D. Minn.
EVOLUS, INC.	10/16/2020	S.D.N.Y.
RTI SURGICAL HOLDINGS, INC.	3/23/2020	N.D. Ill.
PROGENITY, INC.	8/28/2020	S.D. Cal.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Co-Diagnostics owns proprietary technology that can perform diagnostic DNA testing. Plaintiffs allege that the company misstated the accuracy of its COVID-19 diagnostic test. Stock prices fell when news outlets reported that company refused to participate in testing to verify the accuracy of its tests.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Endo manufactures and sells generic and branded drugs, including opioids. Plaintiffs allege that Endo downplayed its potential liability in connection with selling and marketing opioids. Stock prices fell when the New York Department of Financial Services announced administrative charges against the company.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Mylan is a generic drug manufacturer. Plaintiffs allege that the company failed to disclose FDA investigations at its plants, and that the company's statements about profits and its dedication to quality were misleading. Share prices fell after the FDA issued a warning letter concerning violations of Good Manufacturing Practices at one of the company's plants and fell again after the company decreased revenue guidance.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Teva sells Copaxone, a multiple sclerosis drug. Plaintiffs allege that the company failed to disclose that it had made kickback payments to charitable foundations to cover patients' Medicare copayment obligations, and that its Copaxone revenue was consequently unsustainable. Stock prices fell after the DOJ announced that it had filed a complaint against Teva under the False Claims Act.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Tactile Systems develops compression devices for home use. Plaintiffs allege that the company overstated its market opportunity and failed to disclose that it was involved in marketing practices that purportedly violated anti-kickback laws. Stock prices dropped after the unsealing of a *qui tam* complaint containing allegations of illegal sales.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Evolus developed Jeuveau, a Botox competitor for treatment of frown lines. Plaintiffs allege that the company misrepresented the formula for Jeuveau as proprietary and concealed the fact that the product was based on trade secrets misappropriated from the distributor of Botox. Stock prices fell after the International Trade Commission issued a determination that the company had misappropriated the Jeuveau formula and manufacturing processes and recommended a 10-year ban on the company's ability to import and sell the product in the U.S.

POST-APPROVAL: FINANCIAL STATEMENT ISSUES RTI is a surgical implant company. Plaintiffs allege the company improperly recognized revenue on certain contracts. Stock prices fell following the company's announcement that its audit committee was investigating the company's revenue recognition practices.

POST-APPROVAL: FINANCIAL STATEMENT ISSUES; SALES FORECAST AND DEMAND ISSUES Progenity sells molecular testing products, including products for prenatal testing. Plaintiffs allege that the company's IPO Registration Statement did not disclose that it had overbilled for certain tests, that its revenues were accordingly overstated, and that testing volume and selling price trends were down. Stock prices fell after the company disclosed a $10 million accrual related to overbilling, and fell further after the company announced preliminary third quarter 2020 revenue and test volumes.

COMPANY	DATE	COURT
PORTOLA PHARMACEUTICALS, INC.	1/16/2020	N.D. Cal.
ALIGN TECHNOLOGY, INC.	3/2/2020	S.D.N.Y.
ELANCO ANIMAL HEALTH INCORPORATED	5/20/2020	S.D. Ind.
STAAR SURGICAL COMPANY	8/19/2020	C.D Cal.
FLUIDIGM CORPORATION	9/21/2020	N.D. Cal.
BOSTON SCIENTIFIC CORPORATION	12/4/2020	E.D.N.Y.
BAYER AKTIENGESELLSCHAFT: AMERICAN DEPOSITARY SHARES	7/15/2020	N.D. Cal.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Portola makes Andexxa, a drug intended to reverse anticoagulant drug-based bleeding events. Plaintiffs allege that the company's statements about demand for Andexxa and its use in hospitals were false and misleading insofar as the company had failed to disclose the existence of cheaper alternatives. Stock prices fell when the company announced fourth quarter 2019 results and reduced revenue guidance by 27 percent.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Align manufactures Invisalign braces, clear aligners used in orthodontics. Plaintiffs allege that Align misrepresented sales growth for Invisalign in China. Stock prices fell when Align disclosed a decline in quarterly year-over-year growth.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Elanco develops medicines for animals, including vaccines, parasiticides and pain treatments. Plaintiffs allege that the company failed to disclose that after consolidating its distributorship, its distributors had excess inventory that they were unable to sell through. Stock prices fell when Elanco announced disappointing first quarter 2020 financial results and reported a $60 million reduction of channel inventory.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES STAAR sells implantable eye lenses. Plaintiffs allege the company overstated its sales and growth in China and mischaracterized its marketing spend and research and development expenses. Stock prices fell after a short seller claimed that STAAR had overstated its sales in China.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Fluidigm sells products used to study health and disease, identify biomarkers, and accelerate the development of therapies. Plaintiffs allege that the company failed to disclose that it was experiencing longer sales cycles and that its revenue would likely decline. Stock prices fell after the company announced weaker than expected second quarter 2019 results, and fell further after the company reported that third quarter 2019 revenue was down 8.5 percent year over year.

POST-APPROVAL: PRODUCT RECALL Boston Scientific sells the LOTUS Edge Aortic Valve System. Plaintiffs allege that the company failed to disclose that the device's product delivery system was dysfunctional and misrepresented the commercial viability and profitability of the product. Stock prices fell after Boston Scientific announced a global recall of unused LOTUS inventory.

OTHER: LIABILITY RISKS OF ACQUIRED COMPANY Bayer, a pharmaceutical company, acquired Monsanto, an agricultural chemical company. Plaintiffs allege that Bayer downplayed liability risks related to Monsanto's Roundup weed killer, which was the subject of litigation in which consumers alleged that it caused cancer. Stock prices fell after a jury in one Roundup case found that the product was a "substantial factor" in causing the plaintiff to develop non-Hodgkin's lymphoma, and fell further after the court upheld the jury's verdict. Stock prices again fell after a jury in another Roundup case issued an adverse verdict on causation.

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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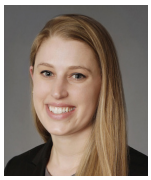

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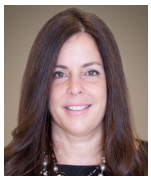

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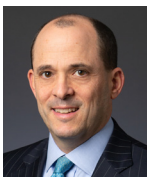

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