

The authors of this report are Sara Brody, Norm Blears, Robin Wechkin and Sarah Hemmendinger. Sara and Norm are partners, Robin is a counsel and Sarah an associate in the firm's Securities and Shareholder Litigation practice area. All four represent life sciences companies and related individuals in securities and shareholder litigation, investigations and regulatory enforcement proceedings. The authors thank Sidley associates Alison Dame-Boyle and Tom Magaña for their valuable assistance in writing the report. This Securities Class Actions in the Life Sciences Sector has been prepared by Sidley Austin LLP for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, an attorney-client relationship. Readers should not act upon this without seeking professional counsel. © 2019 Sidley Austin LLP and Affiliated Partnerships (the "firm"). All rights reserved. The firm claims a copyright in all proprietary and copyrightable text in this report.

# SECURITIES CLASS ACTIONS IN THE LIFE SCIENCES SECTOR

### 2018 Annual Survey

INTRODUCTION AND OVERVIEW	1
DECISIONS ISSUED IN 2018—TRENDS AND ANALYSIS	3
TABLE AND SHORT SUMMARIES OF 2018 DECISIONS	19
DETAILED SUMMARIES OF 2018 DECISIONS  Decisions Related to Development-Stage Drugs or Devices	29
Appellate Decisions	30
District Court Decisions: Motion to Dismiss Granted	34
District Court Decisions: Motion to Dismiss or for Summary Judgment Denied	45
DETAILED SUMMARIES OF 2018 DECISIONS	
Decisions Related to Post-Approval Drugs or Devices	49
Appellate Decision	83
District Court Decisions: Motion to Dismiss Granted	50
District Court Decisions: Motion to Dismiss or for Summary Judgment Denied	57
TABLE OF NEW FILINGS IN 2018	65
ABOUT THE PRACTICE	83

#### INTRODUCTION AND OVERVIEW

This year-in-review addresses developments in securities class actions brought against life sciences companies in 2018. 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 then provide summaries of the 55 federal district court and appellate court decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2018.

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, this year-in-review is structured with reference to the following stages:

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

#### PRE-APPROVAL: CLINICAL TRIALS AND PRECLINICAL STUDIES

#### PRECLINICAL DEVELOPMENT

#### **CONDUCT OF PHASES 1-3**

of clinical trials and analysis and report of trial results.

#### SUBMISSION OF APPLICATION FOR REGULATORY APPROVAL OF PRODUCT

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

#### COMMERCIALIZATION AND LAUNCH OF THE NEW DRUG OR DEVICE

#### POST-APPROVAL: MATURE PRODUCT

#### LAUNCH STAGE

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

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

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

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

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

#### NON-REGULATORY 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.

Introduction

<sup>1</sup> Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 310 (2007).

#### **DECISIONS ISSUED IN 2018: TRENDS AND ANALYSIS**

In this section, we discuss trends in the reported federal decisions issued in securities actions at the pleading stage.<sup>1</sup> Unless otherwise noted, these decisions concern class actions brought under Section 10(b) of the Securities Exchange Act of 1934.<sup>2</sup>

In the district courts, companies prevailed more often than not in 2018. Companies' success rate in 2018 was well above the recent low in 2017 but below the recent high in 2016. The volume of district court decisions in 2018 was markedly larger than in prior years.

- 2016: Companies won dismissal in 25 of the 33 decisions issued by the district courts, or 76 percent
- 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<sup>3</sup>

As in past years, companies with pre-approval products or devices fared better than those in the post-approval cases, although the discrepancy was far less marked in 2018 than it has been previously. Companies prevailed in 73 percent of the pre-approval cases and 58 percent of the post-approval cases. By contrast, companies last year prevailed in 63 percent of the pre-approval cases but only 30 percent of the post-approval cases.

Companies fared less well in the appellate courts in 2018. While defendants won affirmance of district court dismissals in four of the seven appellate decisions, defendants' defeats were substantively more significant than their victories. Three of the four pro-defendant rulings in 2018 took the form of unpublished, non-precedential decisions. Each of the three pro-plaintiff rulings were published and each reversed a significant district court victory below. One of the three, *Orexigen*, represents a serious course-correction on important procedural issues affecting all securities defendants, as well as a significant adverse development on substantive issues of particular interest to life sciences companies involved in clinical trials.

As we discuss more fully below, the volume of new filings was down slightly in 2018, after sharp rises in 2016 and 2017:

2015: 39 new complaints

2016: 50 new complaints

2017: 54 new complaints

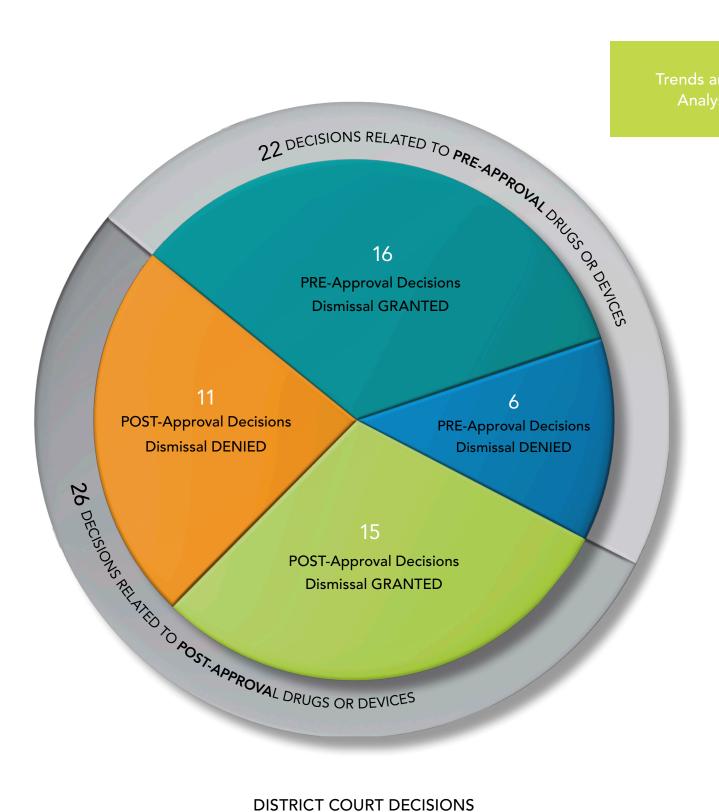
2018: 48 new complaints

The increased volume in new filings in 2016–2017 is reflected in the increased district court output in 2018—48 new decisions, as opposed to the 25–35 decisions we have seen between 2014 and 2017. We discuss the possible relationship between the volume of new filings and parties' relative success rates below.

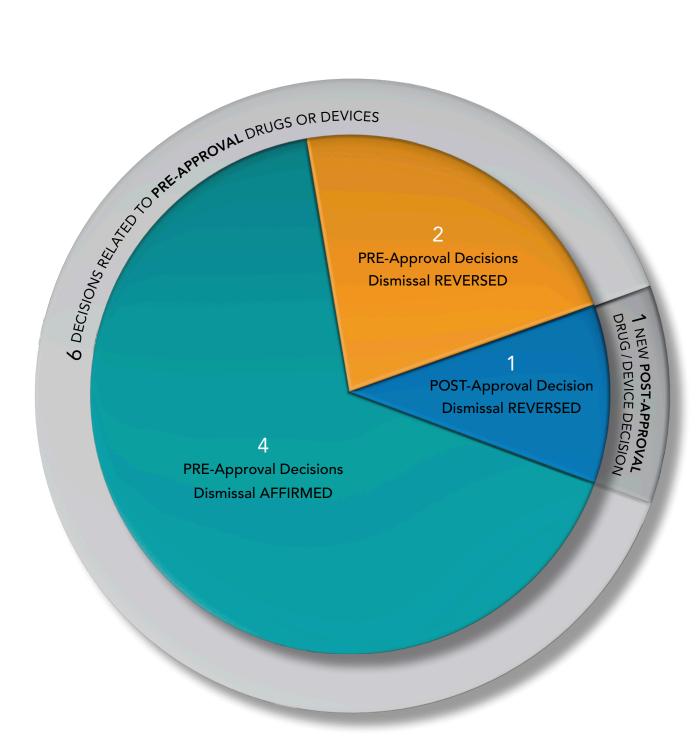
<sup>1</sup> This includes a handful of summary judgment decisions. Only a small fraction of securities class actions reach the summary judgment stage.

<sup>2</sup> Under Section 10(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. 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.

<sup>3</sup> 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**



APPELLATE COURT DECISIONS

Trends and Analysis

Before turning to the decisions reflected in these charts, we take note of one United States Supreme Court decision from 2018 affecting securities litigation generally. In Cyan, the Supreme Court settled a dispute among federal district courts that had been growing in intensity over the previous decade.4 Under the Securities Litigation Uniform Standards Act of 1998, federal courts were given exclusive jurisdiction over certain categories of securities class actions, including securities class actions arising under state law. The issue that divided the district courts was whether state courts retained jurisdiction over class actions arising under the Securities Act of 1933—that is, class actions based on allegedly false or misleading statements in stock offering documents. In general, federal courts in California had concluded that state courts retained such jurisdiction, and therefore rejected securities defendants' attempts to remove Securities Act class actions to federal court. In contrast, many courts in the East held that the 1998 statute had stripped state courts of jurisdiction over Securities Act class actions, and accordingly rejected plaintiffs' attempts to remand the cases to state court. The Supreme Court sided with the plaintiffs in Cyan. The effect of the decision is that in cases filed solely under the Securities Act—cases confined to claims arising from alleged misstatements in stock offering documents—plaintiffs will be permitted to litigate in state court if they so choose. Federal court remains the exclusive forum for claims under the Exchange Act. Many plaintiffs' firms believe that state courts provide a more hospitable forum for their claims than federal courts. State court filings of Securities Act actions can therefore be expected to increase in certain parts of the country. The new filings may encompass two kinds of cases both Securities Act cases that were previously filed in federal court and Securities Act cases that were deemed by plaintiffs' attorneys to be too weak to withstand testing in federal court but may now be seen as plausible ventures in state courts operating under more permissive pleading regimes.

#### PRE-APPROVAL DECISIONS

In 2018, as in the past several years, district court decisions involving pre-approval products broke decisively in favor of defendants. Defendants were successful in 73 percent of the district court decisions: The district courts granted defendants' motions to dismiss in 16 cases and denied motions to dismiss (or for summary judgment) in whole or in part in only six.

The appellate picture is less favorable, with four wins for defendants and two losses in the pre-approval setting. The raw numbers understate the appellate setback in 2018. Three of the four favorable decisions were unpublished and each of the two unfavorable decisions is significant. *Orexigen*, from the Ninth Circuit, is among the most important of all securities decisions of 2018, not restricted to those affecting life sciences companies. The decision deals with a procedural issue—the question of which facts and materials a court may consider on a motion to dismiss—in a markedly pro-plaintiff way. The court was hostile to what it perceived as attempts by defendants—both in *Orexigen* itself and more broadly—to mount factual attacks at the pleading stage. Substantively too, the decision is significant on a subject of particular interest to life sciences companies in the pre-approval space. *Orexigen* adopts the principle that companies that choose to report favorable interim trial results as they become available assume a duty to report unfavorable interim results as well. In a second appellate defeat for defendants, the Sixth Circuit in *Esperion* adopted a notably harsh approach to a company's account of interim agency communications where that account was undercut by later regulatory developments.

We discuss developments in four areas below. The decisions involving *interim trial results* reflect the initial principle that companies have wide latitude in deciding whether to disclose such results at all. Companies prevailed on motions to dismiss where they remained silent on the subject of interim trial results, or where they could point to a record of periodic rather than current reporting of such results. When companies disclose favorable results on a current basis, however, they may face liability both for insufficiently cautioning investors about the reliability of those results and for failing to report subsequent unfavorable results.

On the subject of *interim regulatory developments*, courts have continued to consolidate prodefendant law holding that companies generally have no duty to report on the details of their

<sup>4</sup> Cyan, Inc. v. Beaver Cnty. Emps. Trust Fund, 138 S.Ct. 1061 (2018).

interactions with the FDA at various interim stages of the approval process. On the other side of the ledger, *Esperion* illustrates the risk of characterizing FDA communications in a way that the FDA itself may later undercut. And a district court decision, *Chiasma*, suggests that at least in Securities Act cases, a duty to disclose interim agency communications may be imposed by Regulation S-K, which governs the content of offering documents.

Also, as in past years, the courts have granted motions to dismiss where defendants were successful in framing plaintiffs' claims as disputes over trial design, data interpretation or other scientific matters. Indeed, defendants prevailed in all the cases of this type in 2018.

Finally, three of the 2018 district court decisions involve situations in which a *company releases* information about trial results over a series of announcements. In each of these cases, a company reported favorable top-line information first and provided details that caused investors to regard the top-line results more skeptically only later. A company may have various reasons for staggering the release of information in this way, including the need to comply with the requirements of publishers that prohibit the pre-publication of complete trial results. In two of the cases in this area, companies prevailed on motions to dismiss: The courts found nothing amiss in the staggered release of complete trial results. In the third case, *Puma*, defendants were defeated at summary judgment, but partially exonerated when the case proceeded to trial in early 2019.

#### Public Statements About Interim Results in Ongoing Trials

2018 saw significant developments in an area on which we began reporting in our 2017 review—claims based on a company's communications about interim results in the context of ongoing trials. The 2018 decisions, even more than the 2017 decisions, reflect the perils of communicating favorable interim results. Companies that choose to do so face two distinct risks. First, companies may be liable for failing to sufficiently caution investors that interim results may not be reliable. And second, companies may assume a duty to report future interim negative results and may face liability when they fail to do so. On the other side of the ledger, companies that do not comment on interim results, or that adopt a plan of periodic rather than current reporting of such information, are far less likely to face liability for omitting negative interim results.

The most significant development in this area is the Ninth Circuit's *Orexigen* decision (page 32), which has attracted attention for its pro-plaintiff analysis of a procedural issue—whether a court may consider facts outside the complaint when ruling on a motion to dismiss. The court's substantive holdings are equally significant for life sciences companies conducting clinical trials. Orexigen, which was conducting a post-approval cardiovascular safety study for its weight-loss drug, received unexpectedly good results in a scheduled 25 percent interim review. The results suggested that far from posing cardiovascular safety risks, the drug might actually improve cardiovascular health.<sup>5</sup> Orexigen publicly disclosed those results in March 2015 by describing a new patent it had been granted to cover potential cardiovascular benefits of the drug. That announcement was problematic for a reason separate from the securities laws: The FDA considered the disclosure to be a breach of a data access agreement between the company and the agency.

Orexigen's situation worsened after the disclosure. In May 2015, the company received 50 percent interim results, and those results were not favorable. Orexigen did not immediately disclose the 50 percent data. Meanwhile, the steering committee overseeing the trial determined that the trial should be halted as a sanction for the earlier breach of the data access plan. Orexigen did not disclose that development either; on the contrary, it characterized the trial as "ongoing."

Plaintiffs challenged both the March 2015 and the May 2015 statements. The district court granted Orexigen's motion to dismiss but the Ninth Circuit reversed, holding the company potentially liable for both sets of statements. As to the March 2015 disclosure of the 25 percent interim data, the court rejected Orexigen's argument that it had cautioned investors that the interim results were preliminary. The Ninth Circuit held that the company was obliged to go further and characterize the results as *unreliable*.<sup>6</sup> With respect to the May 2015 omission of

<sup>5</sup> Although most of the events in *Orexigen* occurred after approval, we discuss it here because the issues in the case arose from the company's statements about clinical trials, a classic topic in cases involving pre-approval products.

<sup>6</sup> The Ninth Circuit's holding on this point was based on the fact that the FDA had allegedly told the company that the 25 percent interim results had "a high degree of uncertainty." Possibly in a different factual setting, a lesser caution than "unreliable" would suffice. In Arrowhead (page 30), an unpublished decision from earlier in 2018, the Ninth Circuit affirmed dismissal of a claim challenging the reporting of interim results on the basis, among others, that the challenged statements were "cabined by cautionary language." The exact nature of that cautionary language, however, is

the unfavorable 50 percent data, the court held that by making the 25 percent results public, Orexigen had assumed a duty to report the 50 percent results too. The court rejected Orexigen's argument that publicizing the results would have constituted a further breach of the data access agreement, viewing this as a problem of the company's own creation. The court also held that plaintiffs had identified an actionable statement in the company's characterization of the trial as "ongoing" following the steering committee's determination that it should be halted.

Orexigen shows how a report on favorable interim results can create a duty to disclose future unfavorable results, as well as creating potential liability for the statement of favorable results itself. In Puma (page 45), liability of the latter sort was in play. The company in Puma had completed Phase 3 trials but had not yet finished validating Phase 3 data. In response to questions about safety, side effects and dropout rates, Puma's CEO noted that the company had not yet seen complete, validated results but anticipated that the results would be in line with those in earlier trials. Plaintiffs challenged that statement, claiming that the company had already compiled top-line information that showed safety results less favorable than those in the earlier trials. The company argued in response that its comments about safety and dropout rates were not false or misleading in light of its qualification that it did not yet have validated data on these points. The court rejected the argument in a ruling denying the company's summary judgment motion: "[The CEO] had information, even if not-yet-totally-final, showing that [the] safety results were worse than previous studies...Even assuming [the CEO] had no duty to disclose the information pending validation, he chose to make statements directly inconsistent with the information he did have." Thus in Puma, as in Orexigen, a company's caution that results are still preliminary or unvalidated may not be sufficient protection if the factual accuracy of the data is questioned.7

On the other side of the ledger, companies have prevailed where plaintiffs are unable to identify an affirmative duty to disclose unfavorable interim results. Stemline (page 34) provides a clear example and suggests ways in which companies can minimize risk in this area. The plaintiffs in Stemline claimed that the company had wrongly failed to disclose that a patient in a Phase 2 trial had died two days before the company filed its secondary offering prospectus. Plaintiffs claimed that this was a material omission and that it rendered misleading the company's affirmative statements disclosing two earlier patient deaths. Having identified the earlier deaths, plaintiffs claimed the company was obliged to disclose the "whole truth" about patient deaths at the time of the secondary offering. The court disagreed, holding that reasonable investors would not expect an up-to-date tally of patient deaths given the company's history of reporting deaths on a periodic rather than a current basis. In this way, Stemline underscores the benefit, when companies expect to have access to interim data, of adopting a consistent disclosure plan at the outset and adhering to it for both good and bad news.

More generally, companies may in many cases avoid liability for omitting adverse interim results simply by remaining silent on the subject of all interim results. This was the case in *ProNAi* (page 30), where the court rejected plaintiffs' claim that the company failed to release interim results from two Phase 2 trials. The court observed that in the absence of any affirmative statements about developments in those trials, the company had no duty to release unfavorable interim results.

In other situations, however, defendants will not have the option of remaining wholly silent on the subject of interim results. Certain interim developments may trigger regulatory filing obligations—for example, the amendment of a trial protocol, which must be publicly reported to the FDA. In such cases, companies will need to carefully consider what and how much to say about the interim development. This is illustrated in *Cempra* (page 41), where the company made a protocol amendment during Phase 2 trials and was then questioned by analysts about the reason for the amendment. The company responded by identifying adverse events of one type but not of a second arguably different type. The court held that this omission could plausibly have misled a reasonable investor (but then dismissed the claim on scienter grounds). *Cempra*'s falsity ruling provides a good reminder that where a company is required by sources

Trends and Analysis

not specified in the decision, and as an unpublished decision, Arrowhead lacks precedential value.

<sup>7</sup> The Puma case was tried to a jury in early 2019, with mixed results. Defendants were exonerated as to the safety-related statement but not as to a statement concerning differences between results on the treatment and control arms.

outside the securities laws to disclose unfavorable interim developments, it needs to take great care to ensure that its disclosures do not appear so selective that they run afoul of the securities laws.

#### **Interim Regulatory Communications**

In 2018, as in past years, courts have largely continued to embrace the pro-defendant principle that companies have no duty to report on regulatory communications at interim stages of the approval process. A notable outlier, discussed in detail below, is the Sixth Circuit's *Esperion* decision.

Taking the pro-defendant cases first, the First Circuit in *Sarepta* (page 30) affirmed dismissal where the company discussed various interactions with the FDA during the closely watched trial of a muscular dystrophy drug. The company did not, however, disclose that the FDA at one point expressed concerns with the accuracy of tissue biopsies and requested that further tests be conducted by independent researchers. The appellate court held that the omission of this information did not render earlier statements false or misleading, particularly given that the omitted FDA comments were short of definitive: The agency had not made independent analysis a *mandatory* basis for approval. The court then synthesized previous authorities on the subject of interim regulatory communications, touching on both falsity and scienter:

[A]s we have previously held, when defendants do not divulge the details of interim regulatory back-and-forth with the FDA, that alone cannot support an inference of scienter under the PSLRA when the defendants *do* provide warnings in broader terms. There must be some room for give and take between a regulated entity and its regulators. Defendants [have] no legal obligation to loop the public into each detail of every communication with the FDA.<sup>8</sup>

A similar synthesis comes from *Dynavax* (page 83), a decision from the Northern District of California:

The FDA approval process necessarily involves a dialogue between the company and the agency...Simply failing to divulge the details of interim regulatory back-and-forth with the FDA...alone cannot support an inference of scienter. Reasonable investors would expect that the company and the FDA would be engaged in a dialogue about the sufficiency of the clinical trials and that such dialogue would include presentation of contrary views.<sup>9</sup>

The *Dynavax* court also suggested a limitation to the general rule that a company need not disclose interim communications: Where feedback from the FDA is "highly unusual, outside the normal process, or so contradictory to [a company's statements about a drug's] approval prospects," then a duty to disclose may arise.

In these and other cases involving interim communications, the issue is generally not whether a company has reported on its interactions with regulators but rather how much information the company has provided. Plaintiffs' position in such cases is invariably that the company has not provided enough information, and in particular not enough negative information. Novan (page 40) provides a good example of the failure of such a claim. The company there told investors that in a pre-Phase 3 meeting with the FDA, it had discussed the possibility of conducting Phase 3 trials under a Special Protocol Assessment (SPA) but had ultimately decided to forego a formal SPA, believing it had already sufficiently incorporated the FDA's input on trial design. When the company later disclosed additional details of the FDA's input after the failure of a Phase 3 trial, plaintiffs claimed that the company should have reported those details at the outset. The court rejected that claim, drawing on the statement from a 2015 Southern District of New York decision that "in a series of cases, courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review."

In *Insmed* (page 44), similarly, the company reported generally on its interactions with regulators, speaking positively about feedback it received from the European Medicines Agency (EMA) at the conclusion of Phase 2 trials. The EMA later advised the company that its Marketing Authorization Application did not support approval. Investors sued, challenging the company's

<sup>8</sup> Quotation marks and other internal notations omitted; citing previous First Circuit decisions in Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228 (1st Cir. 2015), and Corban v. Sarepta, Inc., 868 F.3d 31 (1st Cir. 2017).

<sup>9</sup> Quotation marks and other internal notations omitted; citing Kader v. Sarepta, Corban v. Sarepta and Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016).

<sup>10</sup> Citing In re Sanofi Sec. Litig., 87 F. Supp. 3d 510 (S.D.N.Y. 2015).

Trends and Analysis

positive statements about agency interactions. The court rejected the challenge, noting that the company had described the agency's feedback in highly generalized opinion statements: "I think Europe finds this to be an exciting drug"; "we feel like we're doing exactly what [the EMA] asked." Plaintiffs had pled no facts showing that these generalized statements were inaccurate, and the company's conduct in submitting its application earlier than planned showed its belief in its positive characterization of the regulators' position. The court also emphasized, consistent with *Sarepta* and earlier authorities, that interim communications are by definition less than conclusive, and that "a biopharmaceutical corporation is not required to disclose a regulatory agency's inconclusive findings, even if they undercut that corporation's position." A company has no standalone duty to air all of a regulator's stated concerns. Nor does a company take on such a duty by continuing to speak favorably about its drug; the regulator's views may evolve up until the point at which it adopts a conclusive position.

The Sixth Circuit's pro-plaintiff ruling in Esperion (page 32) stands in stark contrast to decisions like these. Esperion, which was developing a cholesterol medication, met with the FDA between Phase 2 and Phase 3 trials to discuss the potential need and timing for a cardiovascular outcomes trial (or CVOT). Such safety studies are typically not required for cholesterol drugs, which are presumed to improve cardiovascular health rather than putting it at risk. After the meeting, Esperion reported that it believed the FDA would approve the drug without a CVOT for one indication, but that the company intended to conduct a CVOT in any event to support a different, broader indication. On an analyst call, Esperion's CEO cautioned that the company's statements about the FDA's position were provisional and that Esperion could not speak definitively on the subject until seeing the FDA's formal meeting minutes after which the company might need to change its Phase 3 trial design. The CEO declined to answer certain questions on the basis that the FDA's minutes were not yet available: "we have [zero] interest in front running the FDA on this. The FDA's minutes are the only minutes that matter, so we're going to wait for those minutes." After the FDA released its minutes a month later, Esperion published an update: "FDA has encouraged the Company to initiate a cardiovascular outcomes trial promptly, which would be well underway at the time of the New Drug Application submission and review, since any concern regarding the benefit/risk assessment of [the drug] could necessitate a completed cardiovascular outcomes trial before approval." Esperion's stock price fell 48 percent and investors sued.

The Sixth Circuit reversed the district court's dismissal of the complaint. The Sixth Circuit proceeded directly to an analysis of scienter, without considering falsity. After describing the company's extensive cautionary statements in a background section of the decision, the court did not further analyze those statements in ruling on scienter. Significantly, the court rejected Esperion's argument that the difference between its initial positive characterization of the meeting and its post-minutes disclosure could reflect a change of position by the FDA, or the company's own imperfect understanding of the agency's position at the meeting. Although both explanations would seem to fall easily within the concept of "regulatory give-and-take" frequently recognized in this context, the Sixth Circuit took a starkly dualistic approach: Because Esperion's pre-minutes and post-minutes statements were different, one of them must have been not only false but deliberately or recklessly so.

If widely followed, *Esperion* would seem to put companies in a difficult position when characterizing agency communications. Perhaps Esperion could have cautioned investors even more strongly that the FDA's position could differ from the company's current understanding—although it is difficult to imagine how. Or the company could have described the meeting in vaguer terms, declining to comment on whether a pre-approval cardiovascular trial would be required. Perhaps the safest course would have been simply to refuse to comment on substantive details of the meeting until the minutes became available—although doing so might have sent an unduly negative message to investors.

In various situations, moreover, companies will not have the option to remain silent about interim communications. *Dynavax* suggests that when communications deviate sharply enough from what a company has previously said about prospects for approval, the company may have a duty to update, depending on the content of its earlier statements on the subject. A final 2018 decision, *Chiasma* (page 46), reflects another limitation on silence, at least in the context of Securities Act cases. The FDA told Chiasma in pre-NDA meetings that it would

have preferred that the company's Phase 3 trials, which were conducted overseas, had taken place in the U.S. instead. The agency also said that the trials would have been more informative if structured differently. Investors did not learn of either of these comments until after the agency had denied the NDA. The court agreed with plaintiffs that these omissions were potentially actionable. The court located the company's duty to disclose in Item 503 of Regulation S-K, which requires that issuers of stock disclose certain risk factors in offering documents. While this holding may have limited application in Section 10(b) cases, it represents another potential limitation on a company's ability to remain silent about unfavorable details in interim regulatory communications.

#### Releasing Data in Stages

The previous two topics share a theme. Both in the course of clinical trials and in the course of interacting with regulators, a company is likely to receive various pieces of information, both good and bad, that are short of definitive with respect to the ultimate question of regulatory approval. With each piece of information, the company faces disclosure decisions concerning how much, if any, detail about interim developments to provide to the market against the background of a process that is still unfolding. At the most general level, the 2018 decisions show that companies have a great deal of choice in this area, and that a decision to remain silent about interim matters is most often protected by the securities laws—although non-legal factors may create a different kind of pressure to disclose. When companies choose to disclose interim matters, more difficult questions arise about the accuracy of the disclosures and the creation of new disclosure duties.

In a subset of situations, a company will have complete information about a particular development but will choose for some reason to disclose that information over the course of several announcements rather than all at once. This fact pattern arose in three of the 2018 decisions. Defendants prevailed in two of the cases and plaintiffs prevailed in one. In this area too, courts respect companies' decision to disclose information at their own pace—so long as that information is accurate.

In the first decision, *Neurotrope* (page 36), the company initially reported favorable results from a nine-patient Phase 2b trial. In subsequent announcements, the company provided additional information about trial design. The company's stock price fell following those announcements, suggesting that investors believed the newly revealed aspects of trial design rendered the positive trial results less meaningful than previously understood. In granting the company's motion to dismiss, the court in no way suggested that the company acted improperly in staging disclosures over a series of announcements. In the court's view, plaintiffs' claims that the company was obligated to disclose all features of trial design at the outset depended on the premise that those features were so unusual that investors would be misled about trial results unless they were disclosed. And in order to evaluate that premise, the court would need to opine on the appropriateness of the trial design. This the court declined to do, drawing on a line of authorities (discussed below) holding that courts should not adjudicate disputes over scientific issues. The court also concluded that reasonable investors would not have been misled about the definitiveness of a trial involving only nine patients.

In a second decision, *Roche* (page 39), the company similarly staggered information about trial results over multiple announcements. The company initially reported that a Phase 3 trial had met its primary endpoint, had shown a statistically significant improvement in disease-free survival and had demonstrated a safety profile consistent with that seen in earlier trials. The company promised to provide complete results at ASCO in June 2017. When it did so, investors learned that the improvement in disease-free survival was 19 percent, that the improvement was attributable to one subgroup and that the drug substantially increased safety risks. The court granted the company's motion to dismiss, concluding that while the later-disclosed information may have been disappointing to investors, it did not contradict anything the company had said in its earlier announcement. Investors may have believed that the threshold for disease-free survival was 20 percent, but the company was not responsible for creating that belief. The safety risks, though high, were in line with those in previous trials, just as the company had said. And while the company might have chosen to provide information about the role of the subgroup in its initial statements, it was not required to do so. As in *Neurotrope*, the court did not suggest that the

company acted improperly in staggering its release of information about trial results over the course of multiple announcements.

The third case, *Puma* (page 45), also involved an initial report of high-level results followed by additional disclosures at ASCO. But unlike in *Roche*, the information provided at ASCO contradicted statements made in the initial announcement. For example, the company made statements in the initial announcement suggesting that the spread between disease-free survival rates on the treatment and control arms was 4–5 percent; the data released at ASCO, however, showed that the spread was only 2.3 percent. On these facts, the court denied the company's motion for summary judgment, holding that plaintiffs had created a factual issue as to falsity. On scienter, the company argued that in failing to disclose full trial results in the initial announcement, it was operating not with the motive of defrauding investors but instead in accordance with ASCO rules prohibiting the publication of trial results before the conference. The court rejected that argument too, suggesting that the ASCO rules may have provided the company with an appropriate motivation to stay silent about trial results—but that no such rules could justify making false or misleading statements. The unsurprising lesson of *Puma* is thus that while a company may choose to stagger its reporting on trial results over a series of announcements, it may not misstate those results at any point along the way.

#### Scientific Disputes

In 2018, as in previous years, courts have sided with defendants where plaintiffs' claims can be characterized as disputes over scientific matters. These defense victories are consistent with a line of earlier decisions, anchored by the Second Circuit's 2013 ruling in *Kleinman*, holding that courts lack the institutional expertise to adjudicate such disputes about science.<sup>11</sup>

In the first of the 2018 decisions in this category, *Neurotrope* (page 36), the Southern District of New York drew on *Kleinman* explicitly. As noted above, the company there disclosed information about its Phase 2b trial in stages, first announcing positive results and only later revealing certain features of trial design—that the trial was one-tailed rather than two-tailed, and that results would be measured under a p-value of < 0.10, rather than the more typical (and demanding) p-value of < 0.05. When these features were reported, the stock price fell. Plaintiffs sued, claiming that the company should have disclosed these features in the first instance. The court rejected the claim, explaining that in order to determine whether the omissions were actionable, it would need to opine that the undisclosed features of the trial design were so anomalous that the reported results were misleading in the absence of the omitted information. This the court declined to do, citing *Kleinman* and stating that "[i]t is not the Court's job to determine an appropriate p-value for pharmaceutical studies."

The court in *Insmed* (page 44), rejected a similar theory on similar reasoning. The company there sought approval in the EU for a drug treating lung infections. The Phase 2 trial on which the company's application for approval was based included results for patients who already tested negative for infection on the first day of trial. Plaintiffs claimed that the inclusion of data from these patients artificially inflated the apparent benefit of the drug. The court rejected that challenge. The court noted that plaintiffs had *not* alleged that the company had misreported trial data. Their theory instead was that an otherwise accurate account of trial results "transforms into a statement that is materially false and misleading when accounting for the flawed methodology" under which the results were analyzed. This, however, was simply "an attack on the methodology of the Phase 2 trial," and "courts throughout the country have consistently rejected this approach." The court in *Novan* (page 40) articulated the same principle, concluding that "plaintiffs' real contention appears to be that the design of the trials did not appropriately judge the efficacy of the drug" and holding that "Plaintiffs may not utilize securities litigation to second guess the decisions made by scientists and company officials in how they approached the clinical trials."

In a fourth decision, NewLink, the court rejected a claim it characterized as a critique of trial design while at the same time expressing considerable sympathy for plaintiffs' position. The company in NewLink made comments throughout the course of a Phase 3 trial based on the stated expectation that patients on the control arm would have a survival rate of 18 months.

Trends and Analysis

<sup>11</sup> Kleinman v. Elan Corp., 706 F.3d 145 (2d Cir. 2013).

During a scheduled interim data analysis, the company learned that the average survival rate on the control arm was 30 months and the average survival rate on the treatment arm was 27 months. The trial had thus proven to be a failure; it was halted and the company's stock price fell. The court characterized the revelation of the 30-month survival rate as "shocking" and stated that "it is easy to understand why Plaintiffs seek to characterize Defendants' statements as false and misleading." In the same vein, the court stated that "[u]nderstandably, one investment analyst remarked that 'NewLink deserves to be investigated for this disastrous pancreatic trial result.'" Nevertheless, the court concluded that plaintiffs' attack on statements reflecting the 18-month expected survival rate was "essentially a criticism of trial methodology," and that under *Kleinman*, such critiques cannot support claims under the securities laws.

This baseline principle—that courts will not adjudicate disputes over scientific matters—extends beyond the issue of trial design. It applies equally to the interpretation of trial or other data. *Intellipharmaceutics* (page 47) provides a good example. The court in that case denied the company's motion to dismiss as to challenged statements characterizing the contents of the company's NDA. In those statements, the company implied that it had complied with FDA guidance for developers of abuse-resistant opioids. In reality, the company had not complied with that guidance. But the court granted the motion to dismiss as to the company's opinion statements that its drug was bioequivalent to an approved opioid. The court rejected plaintiffs' claim that the company lacked a reasonable basis for that opinion. The company was able to point to studies underlying its opinion and, in light of those studies, plaintiffs' claim "involved little more than a dispute about the proper interpretation of data, a dispute the Second Circuit has rejected as a basis for liability."

#### POST-APPROVAL DECISIONS

Defendants' success rate in post-approval decisions improved significantly between 2017 and 2018. In 2017, defendants prevailed in only three out of 10 district court decisions involving approved products or devices. In 2018, defendants prevailed in 15 out of 26 such decisions.

The larger denominator may account in part for the improved success rate. 2016 and 2017, as noted above and reported previously, saw a large uptick in the number of new filings. The failure of a majority of those cases to survive motions to dismiss as they move through the district courts may reflect a drop-off in the quality of new filings over the past several years. The rise in the number of new filings, that is, may have been tied to a less selective approach by certain firms on the plaintiffs' side, and that in turn may be partially responsible for plaintiffs' diminishing success in the post-approval cases.

The 2018 decisions reflect several themes. At least seven of the cases involved allegations that drug manufacturers interacted improperly with third parties—including physicians, pharmacy benefit managers and others—who occupy various positions in the chain between the manufacturers and the patients who are the ultimate consumers of the drugs. The single appellate decision, *Singer*, is adverse to defendants: The Fourth Circuit there took a broad view of a company's disclosure obligations when it interacts with physicians on matters at the heart of the regulatory and reimbursement environment. Companies fared better in the district courts, winning dismissal in four of the six cases turning on interactions with regulated intermediaries.

Another five cases arise from a factual development we noted in our 2016 review—a series of investigations by the Connecticut Attorney General and DOJ into price fixing in the generic drug industry. As the investigations became public, the securities plaintiffs' bar filed multiple actions against the named manufacturers. Meanwhile, numerous private antitrust plaintiffs filed actions that have now been consolidated into multidistrict antitrust litigation in the Eastern District of Pennsylvania. Of the five 2018 decisions in the securities cases arising from the alleged antitrust activity, defendants have prevailed in two and plaintiffs in three. The courts are notably split in their analyses of scienter and their conclusions on loss causation.

#### Interactions with Intermediaries Between the Manufacturer and Patients

Several of the decisions from 2018 relate to allegations that manufacturers improperly induced intermediaries to provide favorable treatment for their products—whether the manufacturers' aim was to include those products on formulary lists, to increase prescriptions, or to obtain reimbursement. Plaintiffs' task in these cases is two-fold. Plaintiffs must establish that improper conduct occurred in the first place and must then identify public statements rendered false or misleading against the background of undisclosed misconduct (or alternatively, show that the misconduct amounted to a "scheme" prohibited by the securities laws).

In two of the 2018 decisions, courts sided with defendants where allegations concerned misconduct attributable only to lower-level employees. In the first, *Endo* (page 53), plaintiffs alleged that the company offered improper discounts and rebates to pharmacy benefit managers (PBMs) to induce them to include one of Endo's migraine drugs on their formularies, and that sales representatives were improperly instructed to provide pre-filled reimbursement forms to physicians. The court rejected plaintiffs' "scheme" theory on scienter grounds: The purported scheme regarding pre-filled reimbursement forms originated with a former low-level employee and was not connected to any executive. As to the rebates paid to PBMs, plaintiffs stopped short of "actually alleging that the tactics at issue were fraudulent."

Plaintiffs' inability to tie allegedly improper conduct to company executives was also dispositive in *Cardiovascular Systems* (page 52), where the court rejected plaintiffs' allegation that the company paid illegal kickbacks to physicians who prescribed its devices. In the court's view, plaintiffs had pled only a "patchwork of alleged misconduct"; plaintiffs had not shown that the alleged wrongdoing was sufficiently widespread that the executives who made the challenged statements could be inferred to have known about or recklessly disregarded it.

Plaintiffs' attacks on a company's interactions with intermediaries will also fail where plaintiffs cannot show that the interactions were improper in the first place. This was the case in *Horizon Pharma* (page 83), where the company created a program to provide doctors with the means to transmit prescriptions directly to designated specialty pharmacies. While the program was initially successful, the company's stock price fell after a PBM removed one of Horizon's specialty pharmacies from its network. Plaintiffs alleged that Horizon made false statements about its relationship with the pharmacies participating in its program and failed to disclose that the pharmacies were "captive" to Horizon. The court rejected the allegations, reasoning that the alleged "financial dependence" of the pharmacies on Horizon did not amount to "financial control" and noting that "many suppliers have leverage over their vendors."

Plaintiffs may also fail to state a securities claim in even the most lurid of cases involving improper interactions with intermediaries where they do not satisfy baseline pleading requirements. Plaintiffs in *Galena* (page 52) alleged that two physicians who accounted for 30 percent of the company's opioid prescriptions were also investors in the company; meanwhile, the company paid \$7.55 million to resolve a government investigation into kickbacks paid to opioid prescribers. Nevertheless, the court granted dismissal, holding that plaintiffs had failed to conduct the statement-by-statement analysis of challenged representations required by the PSLRA.

On the other side of the ledger is the Fourth Circuit's decision in *Singer* (page 50). In 2009, the American Medical Association re-categorized the company's surgical device from a Category I (non-experimental) reimbursement code to a Category III (experimental) code, making reimbursement less likely. In response, the company conducted a series of trainings, established a hotline and distributed reimbursement guides to physicians. Plaintiffs alleged that the company had encouraged surgeons to code incorrectly, that the company's revenue depended on the use of improper billing codes, and that the company did not disclose any of this. The district court dismissed in a 2015 decision, noting that the company had not concealed but instead openly discussed its physician training programs with investors, and holding that the company was not required to "accuse itself of wrongdoing." The Fourth Circuit took a very different view, holding that "by choosing to inform the market that it was training surgeons on how to obtain reimbursements for the system in the wake of the AMA's Category III coding requirement, the Company was obligated to further disclose its fraudulent reimbursement scheme."

Frends and Analysis Plaintiffs also prevailed in *Novo Nordisk* (page 61), an intermediary-related case at the district court level. Plaintiffs in *Novo Nordisk* alleged that the company misleadingly attributed its success to the strength of its products, only later disclosing that "PBM rebates were key." Defendants argued that the company had acknowledged PBMs in earlier public statements—and that the market was well aware of the role of PBMs in any event—but the court concluded that plaintiffs had adequately pled misstatements regarding the role of PBM rebates.

Finally, 2018 saw another chapter in the long-running litigation against Medtronic (page 60), which was accused in media pieces and congressional investigations in 2008 of improperly influencing physician authors to promote its products in scientific articles. The district court granted the summary judgment motions of certain individual executives but denied others in a case that has tested the scope of the securities laws in situations where purportedly untrue statements are made by third parties rather than by securities defendants.

#### Alleged Price Fixing in the Generic Drug Industry

In late 2016, media outlets began reporting on state and federal investigations into price fixing in the generic drug industry. A November 3, 2016 *Bloomberg* article predicted that criminal charges would be filed by year-end and named several companies being investigated. Stock prices fell at several of those companies. In December 2016, multiple state attorneys general filed a complaint alleging a broad conspiracy to fix generic drug prices; six companies were named as defendants. In 2017, executives at one company, Heritage, pled guilty to federal price fixing charges.

Securities plaintiffs filed complaints based on the allegations in the state attorney general complaints, supplemented with allegations based on statements plaintiffs' counsel had purportedly obtained from confidential witnesses. Five of the cases led to written decisions on motions to dismiss in 2018. Defendants prevailed in two cases, *Impax* (page 53) and *Lannett* (page 53). Plaintiffs prevailed in three, *Mylan*, *Taro* and *Perrigo* (pages 61, 62 and 62). The courts' analyses can be harmonized on some issues but are notably divergent on others. Collectively, the courts addressed four issues.

#### What is required to sufficiently allege an underlying antitrust violation?

This issue is addressed in all the decisions save *Lannett*. The four analyses are largely consistent, and each led to an adverse result for defendants on the issue. Each court analyzed the price fixing allegations as if it were testing the sufficiency of an *antitrust* complaint. The courts, that is, noted that under the Supreme Court's *Twombly* decision and related circuit-court precedent, allegations of parallel price movement among competitors are not sufficient to a state a price fixing claim. Where plaintiffs can also identify so-called "plus factors," however—features of the market or the conduct at issue—they may be able to survive a motion to dismiss. In all four cases, plaintiffs successfully pled such plus factors. In *Perrigo*, for instance, plaintiffs pled motive, actions contrary to the company's economic interests and evidence implying a "traditional conspiracy." In *Impax*, plaintiffs pled market concentration, inelastic demand, a commoditized product, barriers to entry and the ease of information-sharing. Somewhat oddly, the two Southern District of New York decisions (*Mylan* and *Taro*) include the analysis of plus factors under a scienter rather than a falsity analysis.

# What categories of statements are actionable where a company does not disclose that it engaged in price fixing?

This question too was at issue in all decisions except *Lannett*. The courts have thus far addressed it consistently and in a largely pro-plaintiff way, with the most explicit discussions appearing in the two Southern District decisions, *Mylan* and *Taro*. Collectively, the decisions hold that a company's financial statements or other factual reports of financial results are *not* actionable simply by virtue of a company's omission of the (alleged) fact that it achieved those results by means of price fixing. On the other hand, the courts have held that statements in which a company attributes its results to factors other than price fixing are actionable. In the words of *Mylan*, "where a company puts at issue the cause of its financial success, it may mislead investors if the company fails to disclose that a material source of its success is the use of improper or illegal business practices."

<sup>12</sup> Bell Atl. Corp. v. Twombly, 552 U.S. 662 (2009).

Similarly, according to *Mylan*, a company's "statement disclosing some sources of past income create[s] a duty to tell the whole truth about past sources of income."

This analysis is by no means foreordained. In past years, courts have carefully monitored the line between alleged regulatory violations and false or misleading statements actionable under the securities laws, holding, among other things, that companies are not required to accuse themselves of uncharged or unproven conduct. *Mylan*'s approach risks blurring that line, as it is difficult to conceive of a situation in which a company will not make some sort of substantive comment on its financial results—but will obviously stop short of attributing those results to allegedly illegal activities that have yet to be charged or proven. *Mylan*'s reference to "the whole truth" also arguably runs counter to a series of appellate authorities that have explicitly rejected the concept of a "duty of completeness." 13

The courts have also permitted plaintiffs to proceed with other categories of statements alleged to be false or misleading in light of alleged and undisclosed price fixing activities. This includes statements that the generic drug marketplace is "competitive" (*Mylan*) and certain statements about a company's pricing strategy (*Perrigo*).

#### What is required to plead scienter in a securities claim based on price fixing?

In analyzing scienter, each of the five 2018 antitrust decisions focuses primarily on the individual defendants, and in particular on those defendants' proximity to the corporate defendant's pricing decisions. The most straightforward situation was presented in *Impax*, where plaintiffs were unable to plead facts showing that the individual defendants had control over or even access to pricing decisions—and hence were unable to establish scienter.

The situation in *Lannett, Taro* and *Mylan* was more nuanced. Plaintiffs in those cases, relying on confidential witnesses, were able to show that the individual defendants knew about or controlled the company's pricing decisions; plaintiffs were not, however able to show that the defendants knew about price fixing. In *Lannett*, this distinction was dispositive. The court rejected plaintiffs' attempt to show scienter on the basis of allegations that the company's CEO, Arthur Bedrosian, was involved in the company's pricing decisions.

The confidential witness' claim that Bedrosian could set drug prices is...unavailing in showing scienter. Alleging that Bedrosian had authority to raise prices is not the equivalent of alleging that Bedrosian illegally price-fixed with peer companies...Indeed, Bedrosian's ability to set prices for drugs crucial to the company's survival would be expected of a CEO in conducting legitimate business.<sup>14</sup>

The Lannett court also rejected allegations that the company had coordinated price fixing at various industry events, noting that plaintiffs had pled no facts tying the individual defendants to those events. Allegations about government investigations and complaints were similarly insufficient, as they did not include specific facts tying the individual defendants to the activities being investigated or charged.

The Southern District of New York took a very different approach in *Taro* and *Mylan*. The *Taro* court largely rejected the distinction between an individual defendant's knowledge of pricing decisions and knowledge of alleged price fixing, specifically finding *Lannett* "minimally persuasive" and declining to follow it. In *Mylan* too, the court concluded that confidential witness statements linking individual defendants with pricing decisions were sufficient, notwithstanding the absence of direct allegations that the defendants agreed to fix prices or knew about price fixing.

In *Perrigo*, finally, the court appeared to accept an inference of scienter based largely on the fact that the individual defendants spoke frequently about drug pricing in response to analysts' questions. That result appears curious. A defendant's statements on a given subject Trends and

<sup>13</sup> E.g., Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002) ("Rule 10b-5 prohibits only misleading and untrue statements, not statements that are incomplete") (emphasis in original); Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., 759 F.3d 1051, 1061 (9th Cir. 2014) ("We have expressly declined to require a rule of completeness"); In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 880 n.8 (9th Cir. 2012); Indiana Elec. Workers' Pension Tr. Fund v. Shaw Gr., 537 F.3d 527, 541 (5th Cir. 2008) (allegedly "incomplete" statements are actionable only if misleading) (citing Brody); Winer Family Trust v. Queen, 503 F.3d 319, 330 (3d Cir. 2007) (same). We collected and discussed the line of cases rejecting the "duty of completeness" and related disclosure concepts in our 2015 and 2016 annual reports.

<sup>14</sup> Internal quotation marks omitted.

are generally viewed as the baseline precondition for liability rather than as an indication of deliberate fraud.

#### What is required to plead loss causation in a securities claim based on price fixing?

The difficulty in reconciling the 2018 antitrust decisions with one another is clearest on the issue of loss causation, where the same allegedly corrective announcement supported plaintiffs' allegations of loss causation in one case but failed to support such allegations in another. That announcement was a November 3, 2016 Bloomberg article naming various companies involved in government price fixing investigations and stating that criminal charges could be expected by year-end. The announcement was sufficient to establish loss causation for pleading purposes in *Taro*. In its abbreviated discussion of the issue, the court rejected defendants' argument that the market was aware of potential price fixing issues in the industry even before the November 3 article appeared. The same announcement was *insufficient* in *Impax*, where the court cited and followed Ninth Circuit law holding that the announcement of a government investigation is not in itself sufficient to constitute a corrective disclosure for pleading purposes.



#### **TABLE AND SHORT SUMMARIES OF 2018 DECISIONS**

In this section (pages 19–28), we provide very brief summaries of each of the decisions issued in 2018, organized by stage of a product's or company's life cycle. We have grouped the 55 decisions according to outcome, with those in which companies prevailed listed first. As noted above, life sciences companies were successful more often than not in both the pre-approval and post-approval settings in 2018. Companies won dismissal in 16 of the 22 pre-approval decisions in the district courts (73 percent) and won affirmance in four of the six appeals.

In the post-approval setting, companies won dismissal in 15 of the 26 cases in the district courts (58 percent). The single appellate decision in the post-approval setting was the reversal of a motion to dismiss.

The page numbers in this section refer to more detailed summaries of the same decisions included in the following section (pages 29–63).

#### **DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES**

#### APPELLATE DECISIONS

In re Arrowhead Research Corp. Sec. Litig., 711 Fed. Appx. 434, 2018 WL 896416 (9th Cir. Feb. 15, 2018)30
Company reports favorable interim results from Phase 2a trial of hepatitis B drug but final results are disappointing; court affirms dismissal, holding that plaintiffs have failed to plead either falsity or scienter, particularly in light of cautionary statements about interim results.
Gregory v. ProNAi Therapeutics, Inc.,—Fed. Appx.—, 2018 WL 6288008 (2d Cir. Dec. 3, 2018)30
Company reports disappointing interim and final results from multiple Phase 2 trials of oncology drug; court affirms dismissal of claims that company wrongly failed to disclose earlier interim results as well as claims based on opinion statements about the feasibility of the drug, concluding that plaintiffs failed to plead facts showing that the company believed that internal studies undermined its positive statements about the drug.
Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48 (1st Cir. 2018)30
FDA expresses concerns to company about the reliability of tissue biopsy results and requests review by independent labs; investors later learn of these concerns when the FDA airs them publicly; court affirms dismissal, holding that company had no duty to disclose agency communications that were simply part of an "interim regulatory back and forth."
Jasin v. Vivus, Inc., 721 Fed. Appx. 665, 2018 WL 416106 (9th Cir. Jan. 18, 2018)31
One member of European committee reviewing weight loss drug tells company that drug will not be approved without a prior CVOT; investors later learn about this when committee votes not to recommend approval; court affirms dismissal, holding that company accurately characterized its interactions with regulators.
Dougherty v. Esperion Therapeutics, Inc., 905 F.3d 971 (6th Cir. 2018)32
After pre-Phase 3 meeting with the FDA, company tells investors that regulators will not require a pre-approval CVOT, but minutes later the FDA calls the company's characterization of the meeting into question; court reverses dismissal, holding that the most plausible explanation of the discrepancy between the company's statements and the FDA minutes is that the company did not tell the truth about the meeting.
Khoja v. Orexigen Therapeutics, Inc., 899 F.3d 988 (9th Cir. 2018)32
Company reports that interim trial results in post-approval CVOT were more favorable than expected (and that it has filed a patent application based on those results), but when later interim results prove to be disappointing, company does not immediately disclose this; court reverses dismissal, holding that plaintiffs may proceed both with allegations that the company insufficiently cautioned investors about the unreliability of favorable interim results and that the company wrongly failed to disclose later

Summaries of Decisions

unfavorable interim results.

#### DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

In re Stemline Therapeutics, Inc. Sec. Litig., 313 F. Supp. 3d 543 (S.D.N.Y. 2018)				
Company conducting Phase 2 trials of blood cancer drug discloses two patient deaths in Form 10-Q but does not disclose recent death of a third patient in secondary offering prospectus; court dismisses claims, holding that reasonable investors would not expect up-to-date tally of patient deaths in light of company's previous practice of reporting such data only periodically.				
Erste-Sparinvest Kapitalanlagegesellschaft MBH v. Seres Therapeutics, Inc., 2018 WL 1567614 (D. Mass. March 30, 2018)34				
Phase 1b/2 trial is successful but Phase 2 trial is not; court dismisses claim that company knew during the course of the trial that it would fail, finding that plaintiffs pled no facts showing that trial blind was broken.				
Gregory v. ProNAi Therapeutics, Inc., 297 F. Supp. 3d 372 (S.D.N.Y. 2018)35				
Phase 1 trial of oncology drug is successful but Phase 2 trial is not; court dismisses claim that company wrongly failed to disclose interim data, holding that company had no duty to disclose; court also dismisses challenge to optimistic opinion statements, finding that plaintiffs failed to plead facts showing when the company came to understand that the therapeutic concept underlying its drug was not feasible.				
In re Neurotrope, Inc. Sec. Litig., 315 F. Supp. 3d 721 (S.D.N.Y. 2018)36				
Company announces favorable results from Phase 2b trial of Alzheimer's Disease drug but stock price falls when company later discloses aspects of trial design, including p-value of $< 0.10$ ; court dismisses claims, holding that plaintiffs are indirectly (and impermissibly) asking it to opine on what the p-value of a clinical trial should be.				
Emerson v. Genocea Biosciences, Inc., 353 F. Supp. 3d 28 (D. Mass. 2018)36				
Phase 2b trial of genital herpes drug includes endpoints related to improvement of two different aspects of the disease; company discloses positive results as they become available but results at the completion of the trial cause company to abandon the drug; court dismisses claims, rejecting as impermissibly speculative allegation that company knew of negative results while trial was ongoing.				
Whitehead v. Inotek Pharm. Corp., 2018 WL 4732774 (D. Mass. June 27, 2018)37				
Several Phase 2 trials of glaucoma drug are successful but Phase 3 trial and remaining Phase 2 trial are not; court dismisses claim that company wrongly omitted negative trial data from its announcements, as claim is contradicted by record on this issue; court further dismisses challenge to optimistic statements about the drug's potential under the PSLRA's safe harbor for forward-looking statements.				
Nguyen v. NewLink Genetics Corp., 297 F. Supp. 3d 472 (S.D.N.Y. 2018)38				
Company comments favorably on patient enrollment for Phase 3 trial of pancreatic cancer drug and states while trial is ongoing that it has confidence in drug and trial design, including assumption that patients on control arm will live for 18 months; when trial concludes, company announces that patients on control arm lived 30 months, as opposed to 27 months on the treatment arm; court holds that plaintiffs have successfully pled knowingly false statements about enrollment but dismisses on causation grounds; court dismisses as to other statements on falsity and scienter grounds, given that trial was blinded.				
Patel v. Seattle Genetics, Inc., 2018 WL 2359137 (W.D. Wash. May 24, 2018)39				
Company conducting Phase 3 trial of leukemia drug with known hepatotoxicity risks announces FDA holds resulting from patient deaths; court dismisses claims on scienter grounds, holding that plaintiffs' confidential witnesses have failed to show that executives knew of patient deaths at the time of the challenged statements.				

Biondolillo v. Roche Holding Ag, 2018 WL 4562464 (D.N.J. Sept. 24, 2018)39
Company performing Phase 3 trials to support combination therapy involving two approved cancer drugs announces that trial has met its primary endpoint, but stock price falls when additional details about trial results are reported at ASCO; court dismisses claims, holding that earlier statements are not contradicted by details in later announcement and that company had no duty to disclose those details earlier.
In re Novan, Inc., 2018 WL 6732990 (M.D.N.C. Nov. 30, 2018)40
After failure of Phase 3 trials for acne medication, company explains that patients taking birth control drugs with an acne indication were included in the trials and that patients with severe condition were unequally assigned to the treatment arm, both of which may have skewed results; magistrate recommends dismissal, holding that company had no duty to disclose earlier FDA comments on the birth control issue and that plaintiffs were impermissibly attacking trial design.
In re Innocoll Holdings Pub. Ltd. Co. Sec. Litig., 2018 WL 4252537 (E.D. Pa. Sept. 5, 2018)40
Company submits NDA for implanted collagen-based pain medication but FDA issues refuse-to-file letter, explaining that product needs to be approved both as a drug and as a device; court dismisses claims on scienter grounds, holding that plaintiffs have failed to plead facts showing that the company knew what the FDA's position would be.
Hirtenstein v. Cempra, Inc., 348 F. Supp. 3d 530 (M.D.N.C. 2018)41
Company submits NDA for pneumonia drug based on successful Phase 3 trial but FDA rejects application based in part on briefing document identifying liver injuries in patients both in the Phase 3 trial and in a later Phase 2 trial for a different indication; court dismisses claims, finding that most plausible inference is that company did not believe that adverse events were related to its drug and did not know that the FDA would view matters differently.
In re Aratana Therapeutics, Inc. Sec. Litig., 315 F. Supp. 3d 737 (S.D.N.Y. 2018)42
Company developing appetite stimulant for dogs is required to push back launch date because FDA has not yet approved commercial manufacturing facilities; court dismisses claims, holding that company's forward-looking statements come within the PSLRA safe harbor, company's present-tense statements about launch preparation have not been shown to be false, and company's activities in preparing for launch on the projected date undercut any inference of scienter.
In re Dynavax Sec. Litig., 2018 WL 2554472 (N.D. Cal. June 4, 2018)42
After company submits Biologics License Application for hepatitis vaccine, it announces that the FDA has expressed concern about the rate of adverse cardiac events; court dismisses claims, rejecting plaintiffs' theory that company had a duty to report adverse events as they occurred and distinguishing the Supreme Court's <i>Matrixx</i> decision on the ground that plaintiffs there had pled a causal link between the defendant's product and adverse events; court further holds that plaintiffs had no duty

Summaries of Decisions

to report the details of its interim communications with the FDA.

	Nguyen v. Endologix, Inc., Case No. 17-0017-AB (C.D. Cal. Sept. 6, 2018)43
	Company with EU-approved device for treating aneurysms seeks U.S. approval but later reveals that the FDA will not consider application until the company has collected two years' worth of additional data; court dismisses claims on scienter grounds, holding that plaintiffs have failed to plead facts connecting anecdotal information about the functioning of the device in the EU with defendants' knowledge about its chances for approval in the U.S.
	Hoey v. Insmed, Inc., 2018 WL 902266 (D.N.J. Feb. 15, 2018)44
	Company developing antibiotic for patients with lung infections reports that the European Medicines Agency has rejected its application for approval based on concerns with Phase 2 trial design; court dismisses claims, holding that plaintiffs have failed to plead facts showing that European regulators told the company at the time of the challenged statements that they would not approve the drug and that the company had no duty to report all details of its interim communications with regulators.
••••	
	STRICT COURT DECISIONS: MOTION TO DISMISS R FOR SUMMARY JUDGMENT DENIED
	Cohen v. Kitov Pharm. Holdings, 2018 WL 1406619 (S.D.N.Y. March 30, 2018)45
	Israeli company conducting Phase 3 trials of combination therapy reports favorable results but later acknowledges that Israeli securities authorities are investigating CEO for falsifying trial results; court denies motion to dismiss as to challenged statements directly pertaining to trial results and grants motion as to other challenged statements.
	Hsu v. Puma Biotechnology, Inc., 2018 WL 4945703 (C.D. Cal. Oct. 5, 2018)45
	Company developing breast cancer drug reports favorable pre-validated results from Phase 3 trial, but complete validated results later reported at ASCO are less favorable; court denies motion for summary judgment, holding that once company chose to report pre-validated results it had an obligation to do so accurately, and that cautioning investors that the results were not yet final was insufficient.
	Gerneth v. Chiasma, Inc., 2018 WL 935418 (D. Mass. Feb. 15, 2018)46
	FDA raises concerns about certain aspects of company's Phase 3 trial of drug for the treatment of acromegaly and later denies NDA; court denies company's motion to dismiss in significant part, crediting plaintiffs' theory that company had a duty under Item 503 of Regulation S-K to disclose risks related to the FDA's stated concerns in stock offering documents.
	Shanawaz v. Intellipharmaceutics Int'l, Inc., 2018 WL 6605426 (S.D.N.Y. Dec. 17, 2018)47
	Company tells investors that the trials supporting its NDA for an abuse-resistant opioid were designed with reference to the FDA's guidance for approval of such drugs, but the FDA later denies application based on company's failure to follow that guidance; court denies motion to dismiss with respect to statements about conformity with guidance and grants motion with respect to statements about bioequivalence to approved drug.
	Dahhan v. OvaScience, Inc., 321 F. Supp. 3d 247 (D. Mass. July 31, 2018)47
	Having failed to obtain exemption from IND requirement for fertility drug, company instead provides drug to patients in overseas clinics but is unable to attract the number of patients it projected; court denies motion to dismiss, holding that plaintiffs have pled sufficient facts to

show that company knew it lacked a reasonable basis for the challenged projection.

#### DECISION RELATED TO STOCK PROMOTION ACTIVITIES

Rabkin v. Lion Biotechnologies, Inc., 2018 WL 905862 (N.D. Cal. Feb. 15, 2018) .......48

Company developing immunotherapy for melanoma receives SEC subpoena related to stock promotion activities and CEO resigns six months later; several years after that, SEC issues cease-and-desist order related to improper stock promotion; court denies motions to dismiss, holding that plaintiffs have sufficiently alleged stock promotion scheme and adequately identified statements rendered misleading by virtue of omission of information related to the alleged scheme.

Summaries of Decisions

#### **DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES**

#### APPELLATE DECISION

Singer v. Reali, 883 F.3d 425, 436 (4th Cir. 2018)......50

After company's medical device is re-categorized by the American Medical Association under an experimental code not widely accepted for reimbursement, company discloses a subpoena from the Department of Health and Human Services and analyst reports states that more than half of company's revenue from the device stems from physicians improperly coding to obtain reimbursement; appellate court reverses dismissal, holding that plaintiffs have sufficiently pled that company downplayed the impact of the reimbursement code change on expected revenue and knew about improper coding practices adopted to secure reimbursement after the change was made.

#### DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

In re Rockwell Med., Inc. Sec. Litig., 2018 WL 1725553 (S.D.N.Y. March 30, 2018)......50

Company makes positive statements about the launch of its liquid-form drug for the treatment of kidney disease but sales are disappointing and the company announces that it has been pursuing an NDA for a more versatile powder form of the drug; court dismisses claims, holding that company's projections were supported by data and company had no duty to disclose its NDA for the powder-form drug any earlier than it did.

In re Egalet Corp. Sec. Litig., 340 F. Supp. 3d 479 (E.D. Pa. 2018)......51

Company seeks abuse-deterrent labeling for opioid, but another drug is granted a period of market exclusivity for one aspect of that label; court dismisses claims, holding that challenged statements are protected under the PSLRA's safe harbor provisions and that company did not know of the adverse development concerning the competitor drug's label exclusivity until after company had made the challenged statements.

Schaffer v. Horizon Pharma PLC, 2018 WL 481883 (S.D.N.Y. Jan. 18, 2018) ......51

Company creates program to provide doctors with means to transmit prescriptions to designated specialty pharmacies but pharmacy benefit manager removes one of the specialty pharmacies from its network, and company later discloses DOJ investigation; court dismisses claims, rejecting plaintiffs' allegation that the company secretly and improperly "controlled" the specialty pharmacies.

In re Galena Biopharma, Inc. Sec. Litig., 2018 WL 3993453 (D.N.J. Aug. 21, 2018)52			
Two doctors prescribe company's opioid pain medication off-label, meanwhile buying the company's stock; DOJ separately investigates allegations that company paid kickbacks to doctors to induce them to prescribe opioid; court dismisses, holding that plaintiffs' complaint did not conform to the statement-by-statement analysis required by the PSLRA.			
Shoemaker v. Cardiovascular Systems, Inc., 300 F. Supp. 3d 1046 (D. Minn. 2018)52			
Former sales manager of company files <i>qui tam</i> action alleging off-label marketing, improper discounts and kickbacks; company settles action for \$8 million; court dismisses securities claims on scienter grounds, holding that plaintiffs failed to plead facts showing that executives knew about patchwork of allegedly improper practices.			
Friedman v. Endo Int'l Plc, 2018 WL 446189 (S.D.N.Y. Jan. 16, 2018)53			
Company acquires two generic drug manufacturers and receives civil investigative demand related to interactions with pharmacy benefit managers; court grants motion to dismiss, holding that statements were inactionable under <i>Omnicare</i> or the PSLRA safe harbors and that the underlying practices were not sufficiently alleged to have been improper in any event.			
Utesch v. Lannett Co., 316 F. Supp. 3d 895 (E.D. Pa. 2018)53			
Manufacturer of generic drugs receives inquiry and subpoena from state and federal regulators investigating possible price fixing in the generic drug industry; stock price falls following media coverage of the investigations; court grants motion to dismiss, holding that plaintiffs failed to plead facts establishing that individual defendants knew of the alleged anticompetitive activity.			
Fleming v. Impax Labs., Inc., 2018 WL 4616291 (N.D. Cal. Sept. 7, 2018)53			
Manufacturer of generic drugs receives inquiry and subpoena from state and federal regulators investigating possible price fixing in the generic drug industry; stock price falls following media coverage of the investigations; court grants motion to dismiss, holding that plaintiffs failed to plead facts establishing that individual defendants knew of the alleged anticompetitive activity and that announcement of government investigation does not constitute a corrective disclosure sufficient for loss causation purposes.			
Jackson v. Halyard Health, Inc., 2018 WL 1621539 (S.D.N.Y. March 30, 2018)54			
After companies allegedly advertise surgical gowns as providing "AAMI Level 4" liquid barrier protection, media outlets report that the gowns failed quality assurance tests; court grants motion to dismiss on scienter grounds, holding that confidential witness allegations related to defendants' purported knowledge were insufficiently particularized and that insider stock sales did not support inference of scienter either.			
Yan v. ReWalk Robotics, Ltd., 2018 WL 4039357 (D. Mass. Aug. 23, 2018)54			
Company is required by the FDA to perform post-market surveillance on medical device; after back-and-forth with the FDA, agency issues a warning letter regarding the company's substantial failure to comply with the post-market surveillance requirement; court dismisses Securities Act claims, holding that plaintiffs misread the FDA correspondence and that various statements were inactionable puffery or protected by the PSLRA safe harbor provisions.			
Costabile v. Natus Med., Inc., 293 F. Supp. 3d 994 (N.D. Cal. 2018)55			
Company enters into contract to provide medical equipment to Venezuelan government but experiences delays in receiving payments under the contract; court grants motion to dismiss on scienter grounds but notes that if plaintiffs can amend to substantiate their allegation that the contract was never executed, that may change the calculus.			

Ellis v. Spectranetics Corp., 2018 WL 1583837 (D. Colo., April 2, 2018)55
Company announces disappointing results in vascular intervention business segment; plaintiffs challenge statements related to quarter-end discounting and risks posed by competing product; court grants motion to dismiss on scienter grounds, holding that at best plaintiffs' allegations show that the company misjudged the strength of competition in the market.
Paciga v. Invuity, Inc., 2018 WL 7286503 (N.D. Cal. Sept. 26, 2018)
Manufacturer of surgical device issues annual revenue guidance and subsequently states that it is on track but lowers guidance after the third quarter, citing lack of repeat purchasing by customers; court grants motion to dismiss on both falsity and scienter grounds, holding that plaintiffs failed to establish that declining sales volumes within individual customer accounts showed that overall sales growth had plateaued, and further failed to establish that discounts offered to customers undermined the company's projections.
Metzler Asset Mgmt. GmbH v. Kingsley, 305 F. Supp. 3d 181 (D. Mass. 2018)56
Following change to the label for one of its drugs to reflect the danger of an infection, company reports weaker-than-expected earnings; court grants motion to dismiss on scienter grounds, holding that the allegations do not show that defendants knew the challenged revenue projections were false or misleading.
Mahoney v. Found. Med., Inc., 342 F. Supp. 3d 206 (D. Mass. 2018)57
Diagnostic test company faces competitive pressure from less expensive tests with better insurance coverage; draft coverage determination from a Medicare administrative contractor is expected to improve matters but does not; court grants motion to dismiss on scienter grounds, holding that plaintiffs have failed to show that defendants were aware of certain changes to Medicare standards governing coverage eligibility.
STRICT COURT DECISIONS: MOTION TO DISMISS  FOR SUMMARY JUDGMENT DENIED
SEB Inv. Mgmt. AB v. Endo Int'l, PLC, 351 F. Supp. 3d 874 (E.D. Pa. 2018)57
Company seeks abuse-deterrent labeling for reformulated opioid; FDA not only rejects petition for abuse-deterrent labeling but also asks company to withdraw reformulated drug altogether; plaintiffs challenge company's statements about viability of its abuse-deterrent labeling efforts and court denies motion to dismiss, holding that plaintiffs adequately alleged that statements about a decrease in intranasal abuse were misleading in light of data showing shift from intranasal to intravenous abuse.
Karth v. Keryx Biopharmaceuticals, Inc., 2018 WL 3518497 (D. Mass. July 19, 2018)58
Company uses single contract manufacturer for active ingredient conversion and halts distribution because of production issue with contract manufacturer; court denies motion to dismiss in part, holding that plaintiffs adequately alleged falsity with respect to company's references to plural "manufacturers."
Shah v. Zimmer Biomet Holdings, Inc., 348 F. Supp. 3d 821 (N.D. Ind. 2018) 58
After internal facilities audit exposes instances of regulatory noncompliance, company lowers annual revenue guidance but attributes this to supply constraints rather than to issues exposed in the audit; subsequent disclosures, including a Form 483 warning letter, ultimately reveal the issues first exposed in the audit; court denies motion to

# Summaries of Decisions

them through its audit.

dismiss, holding that company had duty to disclose facilities issues when it discovered

#### In re Insys Therapeutics, Inc. Sec. Litig., 2018 WL 2943746 (S.D.N.Y. June 12, 2018) ........59

Following CEO's guilty plea to charges involving kickbacks to physicians prescribing opioids off-label, company restates six quarters of financial entries related to estimating sales allowances; in the aggregate, restatements are quantitatively immaterial; court denies motion to dismiss, holding that plaintiffs have sufficiently pled qualitative materiality, given their allegation that the company made inaccurate entries to conceal business decline caused by termination of the kickback scheme.

# West Va. Pipe Trades Health & Welfare Fund v. Medtronic, Inc., 299 F. Supp. 3d 1055 (D. Minn. 2018)......60

Company is accused in media and congressional investigations of improperly paying doctors to write medical journal articles favoring its bone-growth product; after reversal of an earlier summary judgment dismissal and remand by the Eighth Circuit, court denies in part and grants in part second round of summary judgment motions filed by six executives, holding that two are potentially liable as participants in the publication scheme, two are potentially liable as control persons and two are entitled to dismissal.

#### 

Company announces that it is being investigated by government regulators in connection with possible Medicare and Medicaid fraud, and ultimately settles with government for \$13.8 million; company moves for summary judgment on loss causation grounds and court denies motion, holding that the Ninth Circuit "does not require that fraud be affirmatively revealed to the market to prove loss causation."

#### In re Novo Nordisk Sec. Litig., 2018 WL 3913912 (D.N.J. Aug. 16, 2018).....61

Company issues a series of disappointing earnings announcements, after which its ADS price falls; court denies motion to dismiss, holding (among other things) that plaintiffs adequately pled falsity with respect to statements attributing the company's success to the efficacy of its products rather than to allegedly improper rebate practices.

#### In re Mylan N.V. Sec. Litig., 2018 WL 1595985 (S.D.N.Y. March 28, 2018) ......61

Manufacturer is required to reclassify its EpiPen product into a higher rebate classification and to pay \$465 million to DOJ; manufacturer is also the subject of government investigations into price fixing in the generic drug industry; court denies motion to dismiss, holding that plaintiffs sufficiently alleged that the company's statements that the government "may" change its position on the EpiPen were misleading; court also denies motion as to price fixing, holding that plaintiffs sufficiently pled anticompetitive conduct and sufficiently pled that the company's statements attributing income to sources other than price fixing were misleading.

#### Roofer's Pension Fund v. Papa ("Perrigo"), 2018 WL 3601229 (D.N.J. July 27, 2018) ........62

Manufacturer of branded and generic drugs successfully wards off tender offer but later takes actions arguably inconsistent with valuations it provided in blocking the takeover; company also becomes involved in federal probe into price fixing in the generic drug industry; court denies motion to dismiss both as to statements about certain aspects of the company's business during the tender offer period and as to statements allegedly rendered misleading in light of the purported price fixing scheme.

#### Speakes v. Taro Pharm. Indus. Ltd., 2018 WL 4572987 (S.D.N.Y. Sept. 24, 2018)......62

Manufacturer of generic drugs receives inquiry and subpoena from state and federal regulators investigating price fixing in the generic drug industry; stock price falls following media coverage of the investigations; court denies motion to dismiss, holding that plaintiffs have plausibly alleged antitrust violations, have linked individual defendants with price fixing activity by means of confidential witnesses placing them at pricing meetings, and have alleged loss causation by reference to media coverage of the investigations.

Company introduces new product, which is favored in the market over its original product, and later attributes missed revenue forecast to lower-than-expected sales of original product; court denies motion to dismiss in part, holding that cautionary language about new products was insufficiently specific: The new product had already been introduced and had already led to an erosion in sales, meaning that the risk the company identified had already come to fruition.

Summaries of Decisions

# DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 29–48), 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 nearly 75 percent of the district court decisions. The district courts issued uniformly positive rulings where plaintiffs' claims could be characterized as matters of scientific dispute. The district courts also largely continued to reject claims based on the purported duty to disclose unfavorable interim regulatory developments.

The appellate picture was less favorable in 2018, with reversals of dismissal by the Ninth Circuit in *Orexigen* and the Sixth Circuit in *Esperion*. Both appellate and district court decisions also illustrate the special risks following from the disclosure of interim trial results. Companies that disclose such results must take care to warn investors about the extent to which they may or may not rely on the results. Companies may also inadvertently take on an obligation to disclose all later interim trial results, whether or not they are favorable.

#### **APPELLATE DECISIONS**

In re Arrowhead Research Corp. Sec. Litig., 711 Fed. Appx. 434, 2018 WL 896416 (9th Cir. Feb. 15, 2018), affirming dismissal. Phase 2a

Arrowhead developed ARC 520, a hepatitis B drug candidate that works through RNA interference—halting the production of hepatitis B genes. The presence of hepatitis B in a patient's body is measured by examining the number of hepatitis surface antigens, and a 90 percent reduction in antigens is considered the benchmark for approval of hepatitis B drugs. After a study involving an infected chimpanzee treated with ARC 520 showed an 80 percent reduction, Arrowhead began a human Phase 2a trial. On August 12, 2014, the company announced favorable interim results from the Phase 2a trial: The reduction in surface antigens was "surprisingly large" and compared favorably to data in the chimp study. The company also stated that its goal was to achieve a 90 percent reduction with a single dose. At the same time, Arrowhead cautioned that the Phase 2a interim data was incomplete and remained blinded to the company. In October 2014, Arrowhead announced complete Phase 2a trial results, including an antigen reduction of only 50 percent. The company's stock price fell 44 percent.

Investors sued, challenging oral and written statements made on August 12, 2014. The district court granted the company's motion to dismiss. The court held that plaintiffs had failed to plead facts showing that the interim reduction in antigens in the Phase 2a trial was not surprisingly large, and that the company's statements about its "goal" were forward-looking and protected by the PSLRA safe harbor. The challenged comparative statements were not false or misleading either, given the company's disclosure of differences between the chimp and human studies. The court also held that plaintiffs had failed to plead scienter, as they relied on conclusory allegations of knowledge, on stock sales not shown to have been unusual in timing or amount, and on financial motives shared by nearly all public companies. In denying a motion for reconsideration, the court rejected plaintiffs' use of the core operations theory, finding no reason to believe that the challenged statements were so "obviously" false that scienter could be inferred.

The Ninth Circuit affirmed in a very brief unpublished decision. On the element of falsity, the court held that "Arrowhead's statements regarding the preliminary results of its human testing were cabined by cautionary language, included accurate comparisons to past studies, were qualified, and often were made as forward-looking statements about future knockdown goals." As to scienter, "Arrowhead made factually true statements, and Plaintiffs allege no additional facts, such as a stock selloff or resignation, supporting an inference of scienter."

*Gregory v. ProNAi Therapeutics, Inc.,*—Fed. Appx.—, 2018 WL 6288008 (2d Cir. Dec. 3, 2018), affirming dismissal. Phase 2

In this unpublished decision, the Second Circuit affirmed a district court dismissal issued earlier in 2018. The district court and Second Circuit decisions are discussed on page 35, below.

Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48 (1st Cir. 2018), affirming dismissal. Phase 2b/NDA

Sarepta developed eteplirsen for the treatment of Duchenne muscular dystrophy. Sarepta told investors that if it was able to produce sufficiently robust results in its Phase 2b trial showing that the drug enables cells to produce dystrophin (a protein necessary for muscle function), the FDA would be receptive to an NDA under its Accelerated Approval program. The production of dystrophin was a surrogate endpoint in the Phase 2b trial and was measured through tissue biopsies. In April 2014, Sarepta announced that with the data it currently had, it believed an NDA was "fileable," but that because the FDA had expressed skepticism about the biopsy data, the company planned to gather additional data before filing. In July 2014, after visiting the sole trial site, the FDA requested that independent pathologists at independent labs review the biopsy results. Sarepta did not publicly report that request, and in August 2014 made statements in which it repeated that existing data could support accelerated review. In October 2014, Sarepta announced that the FDA had provided updated guidance requiring additional and reassessed data, and that in light of this, the company was delaying its projected NDA. The company's stock price dropped 32 percent. Three days later, the

**Decisions** Development Stage FDA issued a public statement highlighting its concerns about the methods used in the tissue biopsies—but also noting in response to questions from the patient community that it had found no fraud at the trial site. The company then filed an NDA in June 2015. In a January 2016 briefing document, the FDA again expressed concern about the biopsy data and indicated that it had strongly encouraged the company to obtain independent lab verification of the data. In September 2016, the FDA approved the drug.

Investors sued after the October 2014 stock drop, challenging Sarepta's April 2014 statement that an NDA was "fileable" and its repetition of that message even after the FDA's July 2014 request for independent lab analyses. In a 2016 decision, the district court dismissed plaintiffs' claims on falsity and scienter grounds. Plaintiffs thereafter sought to amend the complaint to include allegations taken from the FDA's January 2016 briefing document. In a 2017 decision, the district court denied the motion to amend.

Plaintiffs appealed from both the 2016 and the 2017 decisions and the First Circuit affirmed. The court held that plaintiffs had failed to plead facts showing that the company's April 2014 "fileable" statement was false or misleading. The FDA's October 2014 announcement did not indicate otherwise: While the agency emphasized its concerns with the methodology underlying Sarepta's dystrophin analysis, it did not say that it had ever told the company that those concerns rendered the data categorically inadequate. The court affirmed dismissal as to the August 2014 statement on scienter grounds, given the many disclaimers Sarepta made and the fact that the FDA had not told the company in July 2014 that compliance with its request for independent lab analysis was mandatory. In light of the latter factor, the court characterized the July 2014 communication as part of an "interim regulatory back-and-forth" that companies are not required to disclose. Finally, the First Circuit affirmed the district court's denial of plaintiffs' motion to amend. Plaintiffs had waited to make that request until after the district court had expended resources in ruling on the adequacy of the previous complaint, a practice that hampers judicial efficiency.

# *Jasin v. Vivus, Inc.,* 721 Fed. Appx. 665, 2018 WL 416106 (9th Cir. Jan. 18, 2018), affirming dismissal. EU approval

Vivus developed and sells Qsymia, a weight-loss drug approved by the FDA in 2012. Vivus also sought approval from the European Medicines Agency, which approves medicines for sale in the EU. After Vivus submitted its application in the EU, it received a series of communications from the committee reviewing the application, the Committee for Medicinal Products for Human Use (CHMP). Several of the CHMP's communications were in the form of reports from the committee as a whole; other communications, by contrast, were reports in the name of one or the other of the two leaders of the committee (called rapporteurs). In early reports, the two rapporteurs took different positions. One rapporteur stated that the drug could not be approved before Vivus conducted a cardiovascular outcome trial (or CVOT), while the other rapporteur left open the possibility that, as in the U.S., a CVOT could be conducted post-approval. Vivus told investors that the questions raised in the FDA and CHMP processes were similar but that the outcomes could differ. The company also noted that the FDA had never raised the possibility of a pre-approval outcome trial, but elsewhere cautioned that the risk remained that the CHMP could require a pre-approval CVOT. In October 2012, Vivus announced that the CHMP had voted 19-10 against approval, citing concerns with cardiovascular safety (among others). The company's stock price dropped modestly.

Individual investors sued, challenging multiple statements related to EU approval. The district court granted the company's motion to dismiss on both falsity and scienter grounds and the Ninth Circuit affirmed in an unpublished decision. The court held that plaintiffs had failed to allege falsity with respect to the company's statement that the *issues* raised in the two regulatory processes were similar. Plaintiffs had shown only that the *outcomes* were different, and Vivus had warned investors that this could occur. Similarly, plaintiffs failed to plead falsity with respect to Vivus' statement that the FDA had never raised the possibility of a pre-approval cardiovascular outcome trial. This statement was factually true, and could not have misled investors about outcomes given Vivus' repeated warnings that outcomes could differ. The court also rejected plaintiffs' theory that Vivus had misled investors by disclosing the risk that the CHMP "may" require a pre-approval study. While plaintiffs correctly noted that one of the two rapporteurs had stated that he "would" require such a study, that rapporteur did not speak for the committee as a

whole—and the other rapporteur's comments pointed in the opposite direction. Finally, Vivus' statement that the drug was "looking good for approval," was a mild expression of generic corporate optimism and hence inactionable. The court also affirmed the dismissal of plaintiffs' state-law claims, which plaintiffs had voluntarily dismissed with prejudice in an earlier state court proceeding.

Dougherty v. Esperion Therapeutics, Inc., 905 F.3d 971 (6th Cir. 2018), reversing dismissal. Phase 2/3

Esperion developed ETC-1002, a cholesterol medication designed as an alternative to statins. After an August 2015 meeting with the FDA to discuss completed Phase 2 trials, Esperion publicly discussed upcoming Phase 3 trials and its anticipated NDA. The company stated that the FDA had confirmed that a lowered cholesterol rate was an acceptable surrogate endpoint for improved cardiovascular health and, relatedly, that the FDA would not require a completed cardiovascular outcome trial (CVOT) before approval. Esperion also announced that it planned to have a CVOT underway when it filed its NDA, in part as an effort to seek support for a broader label. Esperion cautioned that it had not yet received the FDA's minutes from the meeting and that it was possible that the company would need to alter its strategy after reviewing the minutes. The CEO emphasized the point, stating "we have [zero] interest in front running the FDA on this. The FDA's minutes are the only minutes that matter, and so we're going to wait for those minutes." When the FDA released the minutes a month later, Esperion issued an update explaining that the agency had encouraged it to initiate a CVOT promptly, "since any concern regarding the benefit/risk assessment of [the drug] could necessitate a [CVOT] before approval." Esperion's stock price declined nearly 50 percent.

Investors sued, challenging the company's August 2015 statements about its meeting with the FDA. The district court granted the company's motion to dismiss on scienter grounds. The Sixth Circuit reversed, addressing scienter and the availability of the PSLRA safe harbor but not directly reaching the element of falsity. Applying a nine-factor scienter analysis not commonly used in securities litigation, the appellate court held that the most plausible explanation for the discrepancy between Esperion's August 2015 statements about the FDA meeting and the September update the company issued after seeing the FDA minutes was that defendants made the August statements knowing that they were false. Esperion pointed to two competing explanations: The FDA had changed course while preparing its final minutes, or the company had not fully understood the FDA's position during the meeting. The court rejected both theories, concluding that they were less plausible than an inference of knowing or reckless fraud. With respect to Esperion's argument that the FDA had changed course between August and September in particular, the court faulted the company for failing to use a procedure available to applicants to challenge and correct FDA meeting minutes. The court also rejected Esperion's argument that the challenged statements came within the PSLRA's safe harbors, holding that statements that characterize a regulator's communications—even when made in connection with the regulator's anticipated future actions—are not forward-looking.

# *Khoja v. Orexigen, Therapeutics, Inc.*, 899 F.3d 988 (9th Cir. 2018), reversing dismissal. Post-approval cardiovascular outcome trial

Orexigen developed Contrave, an obesity drug. The FDA agreed to approve the drug while a cardiovascular outcome trial was ongoing, provided that a 25 percent interim review of the CVOT showed that the drug increased the risk of major adverse cardiovascular events by less than 50 percent. The results of the interim review were far better than required: Patients taking the drug experienced *fewer* cardiovascular events than patients on the placebo. The FDA accordingly approved Contrave in September 2014 and the company began to market the drug. As Orexigen discussed and explored the ramifications of the favorable 25 percent interim results, however, issues arose. Orexigen had entered into a data access agreement with the FDA limiting the number of people who had access to the interim results. Even before approval, the FDA found that Orexigen had violated the terms of the agreement and required the company to enter into a new agreement further limiting

**Decisions** Development Stage

<sup>15</sup> Although most of the events in *Orexigen* occurred after approval, we classify it with the pre-approval decisions because the issues arose from the company's statements about clinical trials, a classic topic in cases involving pre-approval products.

disclosure of interim results. Orexigen subsequently applied for a patent covering Contrave for a new indication—cardiovascular benefit. In March 2015, the company made a series of public statements announcing that the patent had been awarded and discussing the 25 percent interim data on which its patent application was based. Orexigen also cautioned that the 25 percent interim results were preliminary and subject to change. Analysts responded to news about the patent favorably. The FDA, however, expressed serious concerns about what it viewed as a new breach of the data access plan, and more generally about the public dissemination of inherently unreliable interim data.

Subsequently, 50 percent interim data became available, and that data showed no cardiovascular benefit from Contrave. In addition, the steering committee overseeing the trial voted to halt the trial as a sanction for Orexigen's breaches of the data access agreement. Six weeks after these developments, Orexigen stated in its May 8, 2015 earnings release that the trial was ongoing. Four days after that, on May 12, 2015, the company reported that the trial had been terminated but did not discuss the unfavorable 50 percent interim data. On the same day, the chair of the steering committee issued a press release containing the 50 percent data and criticizing Orexigen's disclosures. In a media piece, the steering committee chair accused the company of misleading both patients and investors. The company's stock price fell 26 percent.

Investors sued, challenging both the March 2015 statements related to the patent and the May 2015 statements characterizing the trial as ongoing and omitting reference to the 50 percent results. The district court granted defendants' motion to dismiss but the Ninth Circuit reversed in one of the leading securities decisions of 2018. With respect to the March 2015 statements, the Ninth Circuit held that the company had an obligation to disclose not only that the 25 percent interim results were preliminary but also that they were unreliable. The court also agreed with plaintiffs that the company had misleadingly failed to disclose its own role in making the 25 percent data available as part of the patent application process. The district court had concluded that the company was required to present those data to the Patent Office, but the Ninth Circuit found a factual dispute on the issue. With respect to the May 2015 statements, the Ninth Circuit held that having chosen to publicize the 25 percent data, Orexigen assumed a duty to reveal the 50 percent data as well. Although doing so would have again breached the data access plan, the Ninth Circuit held that Orexigen had brought that problem on itself with its earlier breaches, and that in any event the securities laws trumped the company's contractual obligations under the plan. The appellate court also concluded that Orexigen's references to a "continuing" or "ongoing" trial were misleading given the steering committee's vote six weeks earlier to terminate the trial. The district court had believed that the steering committee's power was limited to recommending termination, but the Ninth Circuit identified allegations in the complaint indicating that the committee had the authority to halt the trial, and further concluded that even a recommendation should have been disclosed. The appellate court sided with defendants only on narrow issues, holding that Orexigen had no obligation to disclose that it had breached the data access plan and that plaintiffs had failed to plead a Section 10(b) "scheme" claim distinct from their false statement claim.

In addition to its substantive holdings, the Ninth Circuit made significant and plaintiff-friendly rulings on the procedural question of which documents a court may consider on a motion to dismiss. On the issue of judicial notice, the court held that if the contents of a document such as a transcript or government report are not susceptible to a single clear interpretation, a court should not take notice of them. On the subject of incorporation by reference, the court held that only documents that plaintiffs use "extensively" in the complaint or on which they base their claims are properly before the court. More broadly, the court identified a "concerning pattern" in securities litigation in which defendants seek to "improperly exploit" the doctrines of judicial notice and incorporation by reference "to defeat what would otherwise constitute adequately stated claims at the pleading stage." The court held that extrinsic documents should not be used to "resolve competing theories against the complaint," and reasoned that if defendants were "permitted to present their own version of the facts at the pleading stage," plaintiffs would find it "near impossible" to state a plausible claim for relief. Curiously, the Ninth Circuit did not attempt to square this analysis with the PSLRA or Tellabs, which require courts to weigh competing inferences in assessing scienter allegations. Indeed, the Ninth Circuit conducted no separate analysis of scienter at all.

### **DISTRICT COURT DECISIONS**

#### Motion to Dismiss Granted

*In re Stemline Therapeutics, Inc. Sec. Litig.*, 313 F. Supp. 3d 543 (S.D.N.Y. 2018), motion to dismiss granted with prejudice. **Phase 2** 

Stemline Therapeutics develops treatments for fatal blood cancers. Its drug SL-401 targets one such disease, blastic plasmacytoid dendritic cell neoplasm. In December 2015, the company disclosed that two patients had died in the expansion stage of a Phase 2 trial of SL-401. Those two patients, as well as a third who required emergency care, had contracted severe capillary leak syndrome, which was later determined to be a side effect of SL-401. Notwithstanding the deaths, the FDA granted SL-401 a Breakthrough Therapy designation. Meanwhile, the company adopted a new safety and dosage protocol to minimize the risk of capillary leak syndrome. On January 18, 2017 a third patient in the Phase 2 trial died from capillary leak syndrome. Two days later, on January 20, 2017, the company filed a prospectus for a secondary stock offering. The prospectus did not refer to the third patient death. On February 2, 2017, following the publication of an article in *The Street* containing several inaccurate assertions about the death, Stemline issued a press release discussing the development. Its stock price fell 43 percent but rebounded shortly thereafter.

Investors sued under both the Securities Act (on behalf of those who bought stock in or traceable to the January 20, 2017 secondary offering) and Section 10(b) (with a 13-day class period running from January 20, 2017 through February 1, 2017). With respect to all claims, plaintiffs challenged statements in the 2015 Form 10-K (incorporated into the offering documents) in which Stemline described the new safety and dosage protocol developed after the first two patient deaths. The court dismissed plaintiffs' claims in their entirety on falsity grounds. Plaintiffs' theory, the court concluded, was based in large part on a mischaracterization of Stemline's statements. Plaintiffs alleged that Stemline had claimed that its new protocol eliminated the risk of capillary leak syndrome; in reality, the company had stated only that the protocol was designed to minimize the risk of the syndrome. "Plaintiffs cannot make up statements and then attribute them to defendants in order to support a Section 10(b) claim." The court also rejected plaintiffs' contention that because the company had revealed two 2015 patient deaths, it was required to disclose the "whole truth," which included the third patient death in 2017. Reasonable investors, the court held, would not have expected an up-to-date tally of patient deaths, particularly in light of statements in the offering documents cautioning investors that the incorporated Forms 10-Q and 10-K were accurate only as of the date they were originally filed, and not as of the date the prospectus itself was filed. The court finally rejected plaintiffs' challenge to affirmative opinion statements characterizing the drug's safety profile as "stable." Under Omnicare, the question was whether a reasonable investor would have expected the third death to have been disclosed in connection with defendants' opinions. The court held that investors would not have expected this, given that capillary leak syndrome was a known side effect of the drug and that Stemline had historically reported deaths on a periodic basis rather than contemporaneously. The court granted plaintiffs leave to amend but plaintiffs chose instead to appeal to the Second Circuit immediately.

Erste-Sparinvest Kapitalanlagegesellschaft MBH v. Seres Therapeutics, Inc., 2018 WL 1567614 (D. Mass. March 30, 2018), motion to dismiss granted. Phase 2

Seres develops SER-109, a drug intended to treat colon infections by improving the function of a patient's microbiome. In June 2015, after conducting a successful Phase 1b/2 trial, Seres announced plans for a Phase 2 trial that would be methodologically similar to the Phase 1b/2 trial—and that the company expected would again be successful. Seres also explained that the Phase 2 trial would differ from the Phase 1b/2 trial in certain ways: The FDA had required Seres to move manufacturing in-house for Phase 2, and the company would be using a different manufacturing formulation involving a purer form of the drug. The Phase 2 trial was double-blinded. In July 2016, when partial results of the trial were available, Seres announced that while patients taking the drug had a lower disease recurrence rate than those in the control group, the trial had fallen short of its primary endpoint. The stock price fell 72 percent. In early 2017,

Seres reported full trial results. Seres explained that it believed the unfavorable outcome could be attributed to dosing choices and to a testing mechanism that may have led to overestimation of disease recurrence. Seres thereafter announced a new Phase 2 trial.

Investors sued on the basis of the 72 percent drop, challenging Seres' statements between June 2015 and July 2016 that it expected success in the Phase 2 trial and that the two trials were similar. The court granted the company's motion to dismiss. On the question of whether the trial would succeed, plaintiffs sought in various ways to show that Seres knew the trial was failing—but could not overcome the fact that the trial remained blinded at the time the challenged statements were made. The court rejected plaintiffs' attempts to establish that the blind had been broken, finding that plaintiffs' arguments on this point were based on faulty chronology. Plaintiffs' contention that the blind was broken when the company was given access to interim safety data additionally failed in light of the fact that drug sponsors are generally not told whether adverse events have occurred on the treatment or the control arm. On the question of whether the company had suppressed the differences between the Phase 1b/2 and the Phase 2 trials, plaintiffs' claim failed because the company had in fact disclosed those differences.

*Gregory v. ProNAi Therapeutics, Inc.,* 297 F. Supp. 3d 372 (S.D.N.Y. 2018), motion to dismiss granted with prejudice. **Phase 2** 

ProNAi developed PNT 2258, an oncology drug based on the concept of genetic interference with cancer cells. No drug based on that concept had previously been approved. In its July 2015 IPO prospectus, the company described a successful Phase 1 safety study, a pilot Phase 2 efficacy trial that had yielded promising results but was not "statistically powered for a formal efficacy analysis," and two ongoing Phase 2 trials called Wolverine and Brighton. The company also disclosed risks in its IPO prospectus, including the novelty of the concept behind its drug. Over the next several months, ProNAi made multiple amendments to both the Wolverine and the Brighton trial protocols. In June 2016, the company announced disappointing interim data from Wolverine and final data from Brighton and explained that on the basis of those results, it was discontinuing development of PNT 2258. The company's stock price fell 68 percent.

Plaintiffs sued, challenging 70 statements in the IPO prospectus and subsequent quarterly and annual filings. (Plaintiffs did not assert Securities Act claims.) The court granted the company's motion to dismiss as to all statements. Plaintiffs relied in part on an omission theory, claiming that the company had wrongly omitted efficacy data in discussing the Phase 1 trial and wrongly failed to disclose interim results from the ongoing Wolverine and Brighton trials. The court rejected both theories. Phase 1 was a safety study, not an efficacy study, and in the absence of any affirmative statements about the progress of Wolverine and Brighton, the company had no duty to disclose interim results. The court also rejected plaintiffs' challenge to a series of favorable statements about the medical and commercial potential of the genetic principles on which PNT 2258 was based. Many of those statements were forward-looking and protected by cautionary disclosures about the novelty of the company's technology and the risks inherent in the FDA approval process. Other statements were opinions and were not undermined by undisclosed interim data or final data. With respect to the challenged opinions, the court acknowledged the potential strength of one of plaintiffs' theories—that the company had wrongly failed to disclose that the novel concept underlying its drug had never been conceptually validated—but held that plaintiffs had fallen short of pleading the facts necessary to support that theory. Among other things, plaintiffs failed to plead facts showing when the underlying therapeutic concept became "inescapably dubious." The court also rejected plaintiffs' claim that the company had misleadingly failed to disclose the protocol amendments: There was no obligation to do so under the securities laws and in any event the information was available on a government website. Finally, the court held that plaintiffs had failed to plead scienter. Executive departures did not establish recklessness, and the purported omission in the IPO prospectus of complete data from the completed Phase 2 study did not show that defendants had lost faith in the potential of the drug.

As noted on page 30, above, the Second Circuit affirmed the district court's ruling in an unpublished decision issued in December 2018. On the question of whether the company had mislead investors by failing to disclose amendments to trial protocols, the appellate court held that the company's publication of the amendments on a government website was inconsistent with scienter, even assuming plaintiffs had adequately pled falsity. The Second Circuit also

rejected plaintiffs' claim that the company wrongfully failed to disclose that patients who discontinued treatment and had been given PNT2258 had experienced faster disease progression than patients on other therapies. In the absence of affirmative statements on this subject, the company had no duty to disclose. Finally, the court rejected plaintiffs' claim that the company's positive statements were undermined by internal studies that failed to validate the mechanism of action on which the drug was based. Plaintiffs pled no facts showing that the company believed those studies were dispositive at the time the statements were made. And at the same time, results from the pilot had suggested that patients were responding to the drug, while patients in the Phase 2 trials were still receiving treatment.

*In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721 (S.D.N.Y. 2018), motion to dismiss granted. Phase 2b

Neurotrope developed Bryostatin, a drug for the treatment of Alzheimer's Disease. In early 2017, the company announced favorable results from a nine-patient Phase 2b trial. Combined with compassionate use data, the Phase 2b trial data led the company "to believe that our mechanism of action can be very effective in reversing Alzheimer's Disease." When Neurotrope released additional details about the Phase 2b trial, however, its stock price fell. First, in May 2017, Neurotrope revealed that the Phase 2b trial design required a p-value of only < 0.10, rather than < 0.05, and that the design was one-tailed rather than two-tailed. The stock fell 63 percent. Then, in July 2017, the company reported that the successful results it had reported earlier related only to the lower of two doses used in the trial, and that patients given the higher dose had not experienced statistically significant improvement even at a p-value of < 0.10. The stock fell 24 percent.

Investors sued, alleging that the company had defrauded the market by failing to disclose these additional unfavorable facts when it began discussing the Phase 2b trial. The court granted the company's motion to dismiss. Although the court recognized that a p-value of < 0.05 is standard in clinical trials, and that a two-tailed design is preferable to a single tail, it rejected plaintiffs' theory that defendants had an obligation to disclose these features in the first instance. Drawing heavily on the Second Circuit's 2013 Kleinman decision, the court concluded that plaintiffs were "indirectly asking" it to opine that the Phase 2b trial design was "so anomalous that the resulting statistical modeling is fraudulent if the p-value is not disclosed." The court declined to do so: Issues related to the validity of trial design fell outside its jurisdiction. The court also concluded that a reasonable investor, having learned that the Phase 2b trial involved only 9 patients, would have understood that favorable results were not dispositive. As to the company's omission of data related to treatment at the higher dose, the court concluded that such data may simply have indicated that the lower dose was more effective. The court also held that representations about Bryostatin's "potential" and defendants' "excitement" about the trial results were inactionable statements of corporate optimism. Finally, the court held that plaintiffs had failed to establish scienter. They had shown no motive to commit fraud, and articles by Seeking Alpha bloggers speculating about stock promotion activities were neither reliable nor tied to the individual defendants.

*Emerson v. Genocea Biosciences, Inc.,* 353 F. Supp. 3d 28 (D. Mass. 2018), motion to dismiss granted. Phase 2(b)

Genocea's primary product candidate was a genital herpes immunotherapy called GEN-003. The company's Phase 2b trial tested a version of the drug manufactured in a way that would be scalable for commercial production. The trial tested two symptoms—"viral shedding" and genital lesions—at three times: immediately after dosing, six months after dosing and 12 months after dosing. The primary endpoint was a reduction in viral shedding rates immediately after dosing. Secondary endpoints included a reduction in viral shedding at six and 12 months, as well as the reduction of genital lesions at six and 12 months. In September 2016, Genocea reported positive results for the first testing point, immediately after dosing. In November 2016, the company announced that the six-month results for viral shedding would be released on a different schedule than the six-month results for genital lesions. In January 2017, Genocea reported positive six-month results for genital lesions but did not report six-month results for viral shedding. In July 2017, Genocea reported positive 12-month results for genital lesions but

negative 12-month results for viral shedding. The company attributed the negative viral shedding results to the sporadic nature of this symptom and the small sample size, which it did not expect would be a factor in Phase 3 trials. The company's stock price rose on this announcement. In September 2017, however, Genocea announced that it would not be moving forward with planned Phase 3 trials, was ceasing development of GEN-003 and was laying off 40 percent of its workforce. Genocea's stock price fell 77 percent. The company never released six-month viral shedding results.

Investors sued, claiming that Genocea was in possession of the six-month viral shedding results as early as January 2017 but did not release them because they were negative. The court granted the company's motion to dismiss. Plaintiffs relied on confidential witnesses who claimed that company executives had stated in January 2017 that funding partners had no intent in sponsoring Phase 3 trials; plaintiffs claimed that this showed that the executives knew at that time that the six-month results were negative. The court rejected that inference, holding that it was entirely speculative. Plaintiffs also argued that knowledge of viral shedding results in January 2017 could be inferred from the company's release of the genital lesion results in January 2017, given that the company had reported results regarding the two types of symptoms at the same time in previous trials. The court rejected that argument too: Genocea had explained that this would not be done in the Phase 2b trial. The court further agreed with the company that the six-month viral shedding results were immaterial in light of the market's reaction to the 12-month viral shedding results in July 2017. Although those results were negative, the company's stock price rose. Finally, the court concluded that plaintiffs had failed to plead scienter. The company's disclosure of the negative 12-month viral shedding results undercut the inference that it was deliberately hiding negative six-month results. Insider selling allegations did not show scienter either: Only one of the three individuals had sold stock and did so under a Rule 10b5-1 plan adopted before plaintiffs plausibly alleged the company was in possession of the six-month results.

# Whitehead v. Inotek Pharm. Corp., 2018 WL 4732774 (D. Mass. June 27, 2018), motion to dismiss granted. Phases 2 and 3

Inotek's leading product candidate, trabodenoson (or trabo) was intended to reduce intraocular pressure in glaucoma patients. The company conducted multiple Phase 2 trials testing trabo both as a monotherapy and as a combination therapy with approved drugs. Inotek described the Phase 2 trials as showing trabo's "potential" for use in convenient once-daily dosing. The Phase 3 trial was less successful: Inotek announced in January 2017 that the trial had failed to meet its primary endpoint. The stock fell 70 percent. Over the next several months, the company continued to express optimism in trabo. During this time, a final Phase 2 trial studying once-daily dosing of trabo in combination with a drug called latan was still under way. In July 2017, the company announced that this final trial failed to show that the trabo/latan combination offered any clinically meaningful benefit over latan alone. The stock fell 48 percent. The next month, the company announced that it was discontinuing its development efforts for trabo.

Investors sued and the court granted the company's motion to dismiss. The court rejected plaintiffs' theory that Inotek had omitted negative information in reporting on Phase 2 results. The company had in fact included that information in its Form 10-Ks, where it presented charts comparing trabo to all available treatment options and showing both positive and negative results from the Phase 2 trials. The company did not need to repeat that information with every positive statement it made. The inclusion of the allegedly omitted information was also fatal to plaintiffs' scienter allegations: "The relevant question is not whether Inotek knew the results of the Phase [2] trials but whether Inotek chose to conceal or misstate the results knowing their statement posed a risk of misleading investors." Meanwhile, the company's statements of continuing optimism were forward-looking and protected under both PSLRA safe harbors. The statements were accompanied by meaningful cautionary language and the company's continuing investment in its trials showed that defendants did not have actual knowledge that the trials would fail. As to trabo's possible use in once-daily dosing, the court divided the challenged statements into those relating to the drug's "potential" and those relating to its "ability." Statements about "potential" were not actionable because they contained no affirmative misrepresentation. Statements about "ability" were plausibly misleading but not materially so, given the company's disclosure of Phase 2 results and methods in the Form 10-Ks.

**Nguyen v. NewLink Genetics Corp.,** 297 F. Supp. 3d 472 (S.D.N.Y. 2018), motion to dismiss granted without prejudice. **Phase 3** 

NewLink Genetics developed HyperAcute Pancreas, an immunotherapy for treating pancreatic cancer. After a successful Phase 2 trial, the company moved to Phase 3 under multiple favorable regulatory treatments: a Special Protocol Assessment, fast track designation and orphan drug designation. In Phase 3, HyperAcute Pancreas was tested against the standard of care—chemotherapy—on which patients were expected to live 18-19 months. The trial design included four major milestones: patient enrollment and three interim data analyses. With respect to the first two data analyses, the design provided that if the drug achieved a pre-specified improvement in overall survival rate over the control, the company could stop the trial and move directly to the approval stage. With respect to the third and final interim analysis, if the drug did *not* achieve a specified improvement over the control, the trial would be stopped. Each of the three interim analyses was performed by the data safety monitoring committee, such that only the ultimate result—and not the underlying data—was accessible to the company.

NewLink reported on each of the milestones as it reached them, first commenting favorably when it had completed patient enrollment. The trial fared less well at the first two interim analyses: The drug failed to show improvement over chemotherapy at the pre-specified levels. NewLink nevertheless reported that it was confident in the trial and trial design, including the expectation that patients receiving chemotherapy would live for only 18-19 months. The company also reported that it was preparing for commercialization. NewLink's two co-founders made substantial stock sales during this period, amounting to 81 percent and 252 percent of their holdings respectively. The trial then failed under the third and final interim analysis. It turned out that patients on the control arm had an overall survival rate of 30 months—far in excess of what had been expected—and patients on the treatment arm had an overall survival rate of 27 months. The trial was halted and the company's stock fell 30 percent.

Investors sued, challenging statements related to four subjects: (1) patient enrollment; (2) chemotherapy survival rates; (3) Phase 2 efficacy; and (4) commercialization efforts. The court granted the company's motion to dismiss with respect to all four categories. As to the first, however—patient enrollment—the court concluded that plaintiffs had adequately pled both falsity and scienter. The court dismissed this claim only because plaintiffs had failed to adequately plead a causal link between the challenged statements (patient enrollment was complete) and the disclosure triggering the stock price drop (the trial had failed). On the issue of falsity, more specifically, the court concluded that confidential witness allegations sufficiently established that NewLink had pushed sites to enroll patients who did not satisfy the criteria of the Special Protocol Assessment. Plaintiffs had also established scienter based largely on the co-founders' stock sales, which greatly exceeded those made before and after the class period. While the co-founders made those sales under Rule 10b5-1 trading plans, they had entered into the plans during the class period, changed the plans frequently, and sold irregular amounts under them at irregular intervals. In addition, NewLink's compensation system incentivized executives to enroll patients quickly in order to secure bonuses of 50-60 percent.

With respect to the other three groups of challenged statements, however, plaintiffs failed to establish falsity. Plaintiffs' attack on the chemotherapy survival rate estimate incorporated into the Phase 3 trial design was an impermissible challenge to the scientific underpinnings of the trial. The expected survival rate also permissibly reflected NewLink's opinions: It was an estimate based on defendants' interpretation of survival rate data from previous trials. As to statements NewLink made about the chemotherapy survival rate while the trial was in progress, the data at this point were blinded to the company, which meant defendants could not have known that the 18-19 month expectation was far off base. The court also rejected plaintiffs' attack on the company's statements about Phase 2 efficacy: Reasonable investors understand the limitations of data from a Phase 2 trial in predicting Phase 3 results. Finally, the company's statements about commercialization activities were either factually true or forward-looking and protected by the PSLRA safe harbors.

*Patel v. Seattle Genetics, Inc.,* 2018 WL 2359137 (W.D. Wash. May 24, 2018), granting motion to dismiss with prejudice. **Phase 3** 

Seattle Genetics' drug candidate 33A was an antibody-drug conjugate (ADC) designed to fight acute myeloid leukemia. Previous ADCs had met with limited success. Although two such drugs had been approved, Seattle Genetics itself had abandoned the trial of a predecessor drug, SGN-33, and Pfizer, which had gained approval for Mylotarg, withdrew it from the market when it became linked with fatal treatment-related hepatotoxicity. Seattle Genetics told investors that 33A was a more sophisticated drug than these precursors, with a better safety profile, and the company commenced multiple Phase 3 trials. In December 2016, the company reported six instances of hepatotoxicity in the Phase 3 trials—including four patient deaths—as a result of which the FDA placed holds on all 33A trials. The company's stock fell 15 percent. In March 2017, the FDA lifted the holds and permitted Seattle Genetics to resume the trials with additional risk mediation measures in place. In June 2017, however, the company announced that it was abandoning several of the 33A trials and the FDA again placed a hold on the others.

Investors sued, challenging the company's favorable statements about safety and the progress of the Phase 3 trials. The court granted the company's motion on scienter grounds, without addressing the element of falsity. Plaintiffs relied heavily on allegations from two confidential witnesses and the court rejected those allegations. The first witness was knowledgeable only about workplace-related risks affecting employees handling the drugs, not about the risk of hepatotoxicity to patients in the Phase 3 trials. Plaintiffs also failed to show that the individual defendants knew about the witness's safety concerns. A second witness, who emphasized the connection between 33A and Mylotarg, similarly failed to provide details about what the individual defendants knew about hepatotoxicity risks and when they knew it. Significantly, the fact that the company knew about toxicity risks generally did not show scienter: All constituents in the market were aware of toxicity risks associated with ADCs. The court also rejected plaintiffs' theory that defendants must have known about patient deaths at some point before publicly disclosing them, given that the trials had been ongoing for years and that it was unlikely that all deaths would have been clustered in the last several weeks of the class period. Without allegations showing when the individual defendants learned of the deaths, and which of the multiple trials the deaths occurred in, plaintiffs' allegations were impermissibly speculative. In general, plaintiffs had failed to "offer details that would bridge the gap between the existence of material facts and actual knowledge on the part of the defendants."

*Biondolillo v. Roche Holding Ag*, 2018 WL 4562464 (D.N.J. Sept. 24, 2018), motion to dismiss granted without prejudice. **Phase 3** 

Roche's breast cancer drug, Herceptin, entered the market in 1998. With the emergence of biosimilars and a patent expiring in 2019, Herceptin's market dominance was threatened. The company therefore developed a combination treatment pairing Herceptin with a newer Roche drug, Perjeta. With the combination therapy, Roche hoped to compete effectively against new market entrants. Roche won approval of the combination therapy for pre-surgical use and moved into a Phase 3 trial testing the combination in the post-surgical setting. In March 2017, Roche issued a press release announcing that the latter study had met its primary endpoint, had shown a statistically significant improvement in invasive disease-free survival and had demonstrated a safety profile consistent with that seen in earlier trials. The company's stock price rose six percent, its largest single-day increase in eight years. In April 2017, the company repeated these favorable points in an analyst call, expressing confidence that the Herceptin franchise could survive the introduction of biosimilars and promising complete results of the Phase 3 trial at ASCO in June 2017. The company reported those results at ASCO as promised, including the facts that the improvement in disease-free survival was 19 percent, that the improvement was attributable solely to a single subgroup, and that the drug substantially increased safety risks in three areas. Analysts and oncologists reacted negatively, having expected an improvement in disease-free survival of at least 20 percent. The stock price fell five percent.

Investors sued, challenging the March 2017 and April 2017 statements. The district court dismissed all claims. Plaintiffs failed to show that any of the statements in the March 2017 press release was false. The safety risks disclosed at ASCO, though high, were in line with data in previous studies, just as the company had stated, and while the 19 percent improvement rate was

inconsistent with the market's belief that the endpoint required a 20 percent improvement, Roche had not created and was not responsible for that belief. Roche might have disclosed that the improvement was attributable to a single subgroup, the court held, but it had no obligation to do so. As to the April 2017 analyst call, the court concluded that the challenged statements were opinions inactionable under pre-Omnicare law and were puffery in any event. Finally, although the court disposed of all claims on falsity grounds, it also ruled on scienter. Oddly, the court held that plaintiffs had adequately pled scienter as to the company and one individual defendant but had failed to do so with respect to the remaining three individuals. Because a ruling on scienter generally presupposes falsity, this pro-plaintiff aspect of the court's analysis is unusual.

*In re Novan, Inc.*, 2018 WL 6732990 (M.D.N.C. Nov. 30, 2018), report and recommendation to grant motion to dismiss. **Phase 3** 

Novan developed an acne medication called SB204. Phase 2b trials were successful and Novan met with the FDA to discuss conducting two Phase 3 trials under a Special Protocol Assessment. After receiving and incorporating feedback on its Phase 3 trial design, Novan decided not to pursue a formal SPA. In January 2017, Novan announced that one of the two Phase 3 trials, the 302 Trial, had met all three of its co-primary endpoints but that the other, the 301 Trial, had met only one of the three. Novan's stock price fell 76% on the news. In an analyst call five weeks later, Novan discussed its post-trial data review, emphasizing two points. First, while trial participants had generally been prohibited from using other acne treatments, they had been allowed to use birth control pills approved as acne treatments. The FDA had suggested when discussing trial design that Novan separately analyze the results from this group of patients, which the company did. When Novan excluded these patients, it was able to show statistically significant improvement in the otherwise unsuccessful 301 Trial. Second, while the 301 and 302 Trials were identical in design, the population on the treatment arm in the (unsuccessful) 301 Trial after randomization included a higher percentage of patients with "severe" disease than the population on the control arm. This was not true of the (successful) 302 Trial. Patients with severe disease posed a special challenge under the trial design: For their treatment to be considered successful, they needed not only to improve as a comparative matter but also to achieve an absolute condition of "clear" or "almost clear."

Investors sued under both Section 10(b) and the Securities Act; the latter claims were based on statements in Novan's IPO registration statement and prospectus. Plaintiffs challenged (1) the omission from the offering documents and other public statements of the FDA's suggestion that Novan separately analyzed results from women taking birth control pills (a suggestion Novan implemented) and (2) statements that the 301 and 302 Trials were identically designed. The magistrate recommended dismissal of all claims and the district judge adopted the magistrate's recommendation in early 2019. Novan had no obligation to report the FDA's suggestion that it separately analyze results from women on oral contraceptives; that suggestion did not indicate that the agency was critical of trial design or dubious about the efficacy of the drug. Nor did the FDA's suggestion bear on the truth or falsity of Novan's statements about proceeding without a formal SPA. As to Novan's statement that the 301 and 302 Trials were identically designed, plaintiffs had alleged no facts showing that this was untrue. At most, plaintiffs had shown that the trials were not identically administered. With respect to both of the factors Novan identified in its post-review analysis—the inclusion of women taking oral contraceptives and the uneven distribution of patients with severe symptoms—the court noted that plaintiffs had conceivably articulated a legitimate critique of trial design. But without more, such a critique is not a sufficient basis for a claim under the securities laws.

*In re Innocoll Holdings Pub. Ltd. Co. Sec. Litig.*, 2018 WL 4252537 (E.D. Pa. Sept. 5, 2018), motion to dismiss granted without prejudice. **NDA** 

Innocoll, which is based in Ireland, 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 there. Innocoll met with the FDA twice in connection

with Phase 2 and Phase 3 trials and reported that the agency had approved the Phase 3 trial protocol. Innocoll also told investors that it expected the FDA to approve XaraColl. After Innocoll submitted its NDA, however, the FDA issued a refusal-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. The court granted defendants' motion solely on scienter grounds; the court did not analyze the adequacy of plaintiffs' falsity allegations. In support of scienter, plaintiffs claimed (1) that a confidential witness had stated that executives other than the individual defendants believed that XaraColl would be considered a device, (2) that Innocoll had sought approval for other collagen products as devices, and (3) that Innocoll had described XaraColl as a device on a patent application. The court gave some weight to these factors but also discounted each of them. The confidential witness's allegations were uncorroborated and did not bear on the individual defendants' state of mind; plaintiffs had not shown that previous products the company had treated as devices were similar to XaraColl; and the patent application had been written six years before the individual defendants joined the company. Added to this, plaintiffs did not explain why, if the company in fact understood that device testing was required, it would not have conducted that testing at the same time as it tested the drug component. The facts pled thus fell short of creating a strong inference of scienter.

*Hirtenstein v. Cempra, Inc.*, 348 F. Supp. 3d 530 (M.D.N.C. 2018), motion to dismiss granted without prejudice. **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, following 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, stating that they had met both primary and secondary endpoints. 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 spoke favorably of its analysis differentiating the two by reference to a part of the Ketek molecule not present in solithromycin. 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 and the company in response 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, eight from the Phase 3 trials. The advisory committee nevertheless voted 7-6 in favor of approval. The FDA thereafter declined to approve the drug and suggested that Cempra conduct an additional Phase 3 trial enrolling 10 times more patients than it had in previous trials before submitting any further NDA. On this series of announcements, the company's stock price fell in three stages, for a cumulative loss of 86 percent. The company's CEO also resigned during the course of these announcements.

Investors sued, alleging that the company had concealed evidence of adverse events. Defendants characterized the matter differently, arguing that they had made all significant trial data public and that the case involved not fraud but instead a situation in which the FDA interpreted publicly disclosed data differently than the company had—which is not actionable under the securities laws. The court largely sided with the company and dismissed plaintiffs' claims in their entirety. Several of the challenged statements were opinions, and the court applied *Omnicare* to conclude that the company had no obligation to disclose data from the ongoing pulmonary disease/hepatitis Phase 2 trials that arguably undermined its positive opinions. With respect to the eight Phase 3 patients the FDA identified as experiencing liver injury, the court suggested that plaintiffs had may have pled falsity adequately but had not established scienter. The most compelling inference was that the company had adequately reported the relevant ALT elevations but had not anticipated that the FDA would view those data as evidence of potential drug-induced liver

injuries. The court also rejected plaintiffs' challenge to statements differentiating solithromycin from Ketek, pointing to the company's risk disclosures warning investors that the FDA might not be persuaded by its scientific analysis on this issue. The court was most troubled by the company's affirmative statements about developments in the Phase 2 trial: Cempra had acknowledged the changes to the trial protocol but had not provided a complete explanation of the adverse events underlying those changes. In isolation, the court found Cempra's statements plausibly misleading. In context, however, and in light of conflicting interpretations of the adverse event data, the court held that the challenged statement did not support a strong inference of scienter.

*In re Aratana Therapeutics, Inc. Sec. Litig.*, 315 F. Supp. 3d 737 (S.D.N.Y. 2018), motion to dismiss granted with prejudice. NADA

Aratana develops pharmaceuticals for animals, including Entyce, an appetite stimulant for sick dogs. The FDA evaluates such drug candidates through the New Animal Drug Application (or NADA) process. In 2015-17, Aratana was on three occasions required to push back the anticipated launch date for Entyce, in each case because FDA approval of commercial manufacturing facilities—a part of the NADA process—was proceeding more slowly than anticipated. In connection with the third pushback of the expected launch date, Aratana explained that the FDA had required additional information because the company was transferring manufacturing to a new vendor. The stock price fell 18 percent on the announcement. Aratana thereafter announced two inventory adjustments, explaining that inventory intended for an earlier launch date had to be written off. The stock price fell an additional 24 percent.

Investors sued, challenging a series of statements in which Aratana had announced launch dates that were ultimately superseded. Plaintiffs claimed that the statements were misleading insofar as the company omitted the fact that it had not yet secured an FDA-approved commercial manufacturer. The court dismissed plaintiffs' claims in their entirety. The bulk of the statements were forward-looking and protected by the PSLRA safe harbors, were opinion statements protected under Omnicare, or were inactionable puffery. The company's detailed risk disclosures shielded the forward-looking statements: Aratana had repeatedly warned that it depended on third-party manufacturing, that such manufacturing would need to be scaled up for commercial production, that FDA approval of manufacturing was required, and that delays in obtaining approval could impact product launch timelines. As to the company's present-tense factual statements about steps it was taking to prepare for commercialization, the court found that plaintiffs had failed to plead facts showing that the company was not taking such steps. The court also dismissed on scienter grounds. Plaintiffs' financial motive allegations were generic and the alleged insider trading activity was insignificant or conducted under Rule 10b5-1 plans. Meanwhile, the actions the company took to prepare for a launch on the publicly-announced timelines—building inventory, hiring a sales force—supported defendants' good-faith belief in the accuracy of their predictions.

*In re Dynavax Sec. Litig.*, 2018 WL 2554472 (N.D. Cal. June 4, 2018), motion to dismiss granted with prejudice. BLA

Dynavax's lead product candidate was a hepatitis vaccine, HBV-23. The FDA rejected a Biologics License Application Dynavax had submitted in 2012, explaining that the company needed to perform a larger safety study to assess the possibility of rare autoimmune side effects. In response, Dynavax designed and performed additional Phase 3 trials. Dynavax and the FDA agreed on a defined list of Adverse Events of Special Interest, or AESIs for this trial; those events were related solely to potential autoimmune and inflammatory disorders. In connection with a new BLA submitted in March 2016, Dynavax reported that the Phase 3 trials had met their co-primary endpoints, had shown a safety profile for HBV-23 comparable to that of the drug on the control arm and had demonstrated a low rate of AESIs. In September 2016, the FDA canceled a scheduled advisory committee meeting, and the company's stock price dropped 30 percent. Dynavax then reported to investors that it was working with the FDA to address its concerns and was continuing to target a PDUFA date in December 2016. On November 14, 2016, Dynavax announced that it had received a Complete Response Letter

evaluating its BLA and that the FDA had expressed concerns about issues including the rate of adverse *cardiac* events. The company's chief medical officer explained that Dynavax had consulted with highly regarded external experts and believed there was no relationship between the cardiac events and HBV-23. Nevertheless, the stock price dropped 64 percent.

Investors sued, alleging that Dynavax had misleadingly omitted events about adverse cardiac events and had falsely stated that the safety profile on the treatment and control arms was generally comparable. Plaintiffs also challenged statements in which the company acknowledged "some numerical imbalances" in safety events between the treatment and control arms but did not identify cardiac events in particular. The court granted the defendants' motion to dismiss. The court both drew on and distinguished the Supreme Court's Matrixx decision, emphasizing that the company there had evidence of a causal link between its product and adverse events, while Dynavax did not. The court also rejected plaintiffs' theory that the company must have known that the FDA's concerns about cardiac events put approval in jeopardy: Plaintiffs pled no facts showing that this was the case. Nor did Dynavax have an obligation to disclose the details of its interactions with the FDA between the September 2016 cancellation of the advisory committee meeting and the November 2016 issuance of the Complete Response Letter: "In the absence of any factual allegations to suggest that the dialogue with the FDA was highly unusual," the company had no such duty. Finally, the court held that plaintiffs had failed to plead scienter. Again, the fact that Dynavax was in dialogue with the FDA about trial results did not support an inference that the company knew at the time it made the challenged statements that the agency's concern with cardiac events would derail approval. And while plaintiffs cited a medical journal article referring to cardiac events as a "known concern" in the approval setting, plaintiffs did not establish either that defendants knew about the article or that the generalized concern referred to there applied to the HBV-23 trials in particular.

**Nguyen v. Endologix, Inc.,** Case No. 17-0017-AB (C.D. Cal. Sept. 6, 2018), motion to dismiss granted with prejudice. **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 submitted its PMA application in May 2016. For the next several months, Endologix predicted FDA approval in the fourth quarter of 2016 or the first quarter of 2017. The company also stated that no safety issues had emerged in the U.S. trials. Early in November 2016, the company reported that instances of "migration"—movement of the device within a patient's body—had been found in patients in the trial who had been followed for two years. The company also said that the migration problem would be "very easy to address." 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 and the court granted defendants' motion to dismiss, ruling solely on scienter grounds. The court rejected plaintiffs' principal theory that Endologix knew, based on information about problems with the approved product in Europe, that Nellix would not be approved in the U.S. Plaintiffs had failed to allege sufficient facts connecting anecdotal information about migration issues in Europe with the prospects of FDA approval. For example, European standards defined migration as a movement of four millimeters, whereas the migration standard in the U.S. was 10 millimeters. Because the challenged statements were limited to the U.S. trials, defendants had not made those statements with knowledge of their purported falsity. Nor did defendants make knowingly false statements by opining that the migration issues could be "addressed." "Addressed" is not the same as "fixed," and the migration problem could have been "addressed" by excluding from the trial patients prone to experience it. Finally, the company did not make a knowingly false statement when characterizing Nellix's European performance as "fantastic." That ambiguous term did not bear on the likelihood of approval in the U.S.

*Hoey v. Insmed, Inc.,* 2018 WL 902266 (D.N.J. Feb. 15, 2018), motion to dismiss granted without prejudice. **EU approval** 

Insmed developed Arikayce, an inhaled drug that delivers an antibiotic for patients suffering from the lung infection NTM (for nontuberculous mycobacterial lung disease). A Phase 2 trial failed to meet its primary endpoint but met the secondary endpoint of culture conversion, i.e., cultures tested negative for mycobacteria on the final day of the initial phase of the trial. After discussion with the European Medicines Agency, Insmed decided to seek approval in the EU based on the Phase 2 trial results. Insmed accordingly filed a Marketing Authorization Application (MMA) with the European agency. The company simultaneously initiated a Phase 3 trial to support FDA approval in the U.S. In public statements, Insmed opined that its drug could provide improved efficacy and a better safety profile than intravenouslyadministered antibiotics. While Insmed's MMA was under review, the company conducted a secondary offering. In 2015, Insmed received the EMA's "120 Day Questions" — a regulatory communication outlining the agency's concerns at an interim stage of review. Insmed reported that the 120 Day Questions contained no surprises and that the company was well positioned to answer them. Insmed then made certain amendments to its MMA in response to the questions. Ultimately, however, the EMA advised Insmed that its MMA did not support approval. Among other things, the EMA criticized the Phase 2 trial design, which tested culture conversion with respect to a single day rather than over a longer period of time. Insmed withdrew the MMA and announced that it would resubmit after completing its ongoing Phase 3 trial. The company's stock fell eight percent.

Investors sued, challenging Insmed's statements about efficacy and about its interactions with the EMA. Plaintiffs asserted claims both under Section 10(b) and, for those who bought shares in or traceable to the secondary offering, under the Securities Act. The court granted Insmed's motion to dismiss with respect to all claims. Plaintiffs' challenge to the company's statements about efficacy, the court concluded, was in reality a critique of trial design. Plaintiffs challenged the efficacy statements based on the fact that patients whose condition had already improved on the first day of the trial were still included. Such a critique of trial methodology cannot support a claim under the securities laws. The court also rejected plaintiffs' challenge to Insmed's statements about its ability to respond to the 120 Day Questions. In seeking to show falsity, plaintiffs relied on an erroneous chronology, citing regulatory communications that post-dated the challenged statements. Critically, plaintiffs did not show that the EMA had told Insmed at the time of the challenged statements that it would not accept a culture conversion measure keyed to a single date. Beyond that, Insmed had no duty to disclose the entire contents of the interim 120 Day Questions, or to refrain from expressing its own optimism about the drug simply because the EMA was not yet convinced. As to the company's optimistic statements about the Phase 2 results and prospects for approval, these were opinions that were not undercut by the EMA's critique of various features of the trial design. Indeed, the opinions were "substantiated" by various circumstances, including the company's decision to devote resources to an expensive Phase 3 trial. Other statements were inactionable puffery or protected under the PSLRA's safe harbors. Insmed's investment in Phase 3 also cut against the required strong inference of scienter, as did the absence of insider stock sales and plaintiffs' inability to provide details about when company executives purportedly learned that the EMA would reject the single-day culture conversion measure used in the trial. Because each of the challenged statements failed on falsity or safe harbor grounds as well as scienter grounds, the court also dismissed plaintiffs' Securities Act claims—which do not require scienter—arising from the secondary offering.

#### **DISTRICT COURT DECISIONS**

### Motion to Dismiss or for Summary Judgment Denied

Cohen v. Kitov Pharm. Holdings, 2018 WL 1406619 (S.D.N.Y. March 30, 2018), motion to dismiss denied in part. Phase 3

Kitov, an Israeli company, developed KIT-302, a combination therapy consisting of two generic drugs previously approved to treat pain and hypertension. After conducting Phase 3 trials under a Special Protocol Assessment, the company enlisted a data monitoring committee to evaluate whether trial results were sufficient to support an NDA. The DMC concluded that the trial had met its primary endpoint and Kitov announced this favorable outcome to the market. Israeli media subsequently reported that Kitov's CEO had been arrested and questioned by Israeli securities authorities. The price of the company's American Depository Shares fell 11 percent. The next day, the company acknowledged the Israeli investigation but stated that it stood behind the validity of its clinical trial results and intended to move forward with an NDA. The ADS price fell an additional 14 percent.

Investors sued, claiming that the trial data submitted to the DMC had been falsified and challenging a wide variety of statements in the company's press releases, annual report and other publicly filed documents. The court denied defendants' motion to dismiss with respect to statements in which the company directly characterized trial results—for example, the statement that the trial had met its primary efficacy endpoint. The court held that plaintiffs had sufficiently pled that these statements were misleading by way of omission, given Kitov's failure to disclose the purported fact that trial results had been falsified. The court rejected Kitov's argument that because the trial was conducted by independent research organizations, defendants had no access to and could not have tampered with the data. Although Kitov's public filings supported that proposition, the court declined to rely on them: Plaintiffs, after all, were contesting the company's public statements. The court granted the motion to dismiss with respect to all challenged statements not directly related to trial results, concluding that the omitted information about purported data falsification was not sufficiently related to those statements to render them misleading by way of omission. The court then rejected the company's loss causation argument, citing precedent holding that the disclosure of a government investigation can constitute the required corrective disclosure. Finally, the court held that plaintiffs had established scienter on the part of the company and the CEO but had failed to do so with respect to the CFO: The most plausible inference was that the CEO had hidden the alleged data falsification from the CFO.

*Hsu v. Puma Biotechnology, Inc.*, 2018 WL 4945703 (C.D. Cal. Oct. 5, 2018), motion for summary judgment denied in part. **Phase 3** 

Puma developed neratinib, a breast cancer drug. The company announced the results of a Phase 3 trial in a July 2014 press release, stating that the drug demonstrated a 33 percent improvement over the placebo in disease-free survival. In a conference call the same day, an analyst asked whether the disease-free survival rate was approximately 86 percent on the placebo arm and approximately 90-91 percent on the treatment arm (a spread of 4-5 percent). The CEO agreed with those figures. In reality, the correct figures were 91.6 percent for the placebo and 93.9 percent for neratinib (a spread of 2.3 percent). The CEO also stated that Kaplan-Meier curves continued to separate over time—a favorable result. Finally, the CEO said that Puma did not yet have validated results on safety and dropout rates but anticipated they would be similar to results in earlier trials. Nearly a year later, in May 2015, additional trial data became available through an ASCO abstract, and then, in June 2015, through a presentation at ASCO itself. These data revealed the accurate 2.3 percent spread in disease-free survival rates, as well as adverse side effects and dropout rates higher than in previous trials. The stock price dropped roughly 20 percent after the abstract was released in May 2015 and an additional 20 percent over the two days following the June 2015 ASCO presentation.

Investors sued and the case proceeded to discovery after the court twice denied in part or in whole the company's motions to dismiss. The court also largely denied the company's summary judgment motion, dismissing only as to one individual defendant (who was not shown to have been knowledgeable about the technical matters at issue) and as to the statement about

neratinib's 33 percent improvement over the placebo (whose accuracy plaintiffs eventually conceded). The court rejected defendants' argument that the difference between a 2.3 percent spread and a 4-5 percent spread on disease-free survival rates was not materially misleading in light of the company's accurate statement that neratinib showed a 33 percent improvement over the placebo. In the court's view, a factual dispute remained on the issue. The court also rejected the defendants' argument that the challenged statement about safety and dropout rates was not false or misleading in light of Puma's qualification that it did not yet have validated data on these points. "[The CEO] had information, even if not-yet-totally-final, showing that [the] safety results were worse than previous studies... Even assuming [the CEO] had no duty to disclose the information pending validation, he chose to make statements directly inconsistent with the information he did have." On scienter, the court rejected the company's argument that its decision not to disclose complete results before ASCO could be explained by ASCO's own rules requiring that results be kept confidential: "Puma's desire to keep information secret doesn't erase [its] duty not to make false or misleading statements about the data it's purportedly keeping secret." Finally, the court rejected the company's loss causation argument, holding that plaintiffs' economic expert had provided sufficient information linking the disclosures made at ASCO with the stock price drop that followed.

**Note:** The *Puma* case was tried to a jury in January-February 2019, only the 15th securities class action to reach this stage since the PSLRA was enacted in 1995. The jury found for plaintiffs on challenged statements about disease-free survival rates and found for defendants on the remaining statements.

Gerneth v. Chiasma, Inc., 2018 WL 935418 (D. Mass. Feb. 15, 2018), motion to dismiss denied. NDA

Chiasma developed Mycapsaa, an oral capsule form of a drug previously approved in injectable form for the treatment of acromegaly (a hormonal growth disorder). Chiasma decided to seek approval through the FDA's 505(b)(2) hybrid NDA pathway, which enabled it to rely on some data from trials of the injectable drug. The company thus conducted its own Phase 1 and Phase 3 trials but relied on previous Phase 2 trials. The Phase 3 trial was performed overseas because Chiasma had not provided sufficient animal safety data for the FDA to approve a U.S. trial site. During an initial pre-NDA meeting in May 2014, the FDA raised questions about the applicability of the 505(b)(2) pathway, the duration of the Phase 3 trial and the durability of Mycapsaa's treatment effect. At a second meeting in December 2014, the FDA told the company that its Phase 3 trial had been structured in a way that made it less informative than certain alternatives, although this did not preclude filing an NDA. At one of the two meetings, the FDA also said that it would have preferred that the trial had been conducted in the U.S. The company held its IPO in April 2015. One year later, in April 2016, the FDA issued a Complete Response Letter denying the NDA. The agency explained that Chiasma had not provided sufficient evidence of efficacy, and that to gain approval, the company would need to perform an additional Phase 3 trial, ideally in the U.S. and with a longer duration. The company's stock price fell 63 percent.

Purchasers of IPO shares sued under Section 11, alleging primarily omissions in the IPO registration statement. The court denied the company's motion to dismiss in significant part. For pleading purposes, the court credited plaintiffs' premise that Chiasma should have disclosed the issues raised by the FDA in the two pre-NDA meetings. The court located the company's obligation to do so in Item 503 of Regulation S-K, which requires the disclosure of certain risks in stock offering documents. The court rejected the company's argument that it had in fact identified the relevant risks by warning investors that the FDA might disagree with its Phase 3 trial design and deny approval. This, to the court, was the misleading characterization of a known fact as a mere possibility. The court also suggested more broadly that companies have a duty to disclose the FDA's "subjective scientific disagreements." On the other side of the ledger, the court granted defendants' motion in part, dismissing plaintiffs' challenges where allegedly omitted information was in fact disclosed or was as a chronological matter not available to the company at the time of the challenged statements. The court also rejected plaintiffs' claim that Chiasma had misleadingly failed to disclose aspects of the Phase 3 trial design that plaintiffs—but apparently not the FDA—viewed as problematic. The court viewed this as an improper invitation to "evaluate the prudence of the Phase 3 trial."

Shanawaz v. Intellipharmaceutics Int'l, Inc., 2018 WL 6605426 (S.D.N.Y. Dec. 17, 2018), motion to dismiss denied in part. NDA

Intellipharmaceutics developed Rexista, an opioid tablet designed to be abuse-resistant. In 2015, the FDA published nonbinding guidance for developers seeking approval of abuse-resistant opioids. In the guidance, the FDA recommended that developers conduct trials in three categories (laboratory, pharmacokinetic and clinical abuse) and study three separate pathways of abuse (oral, nasal and intravenous). The company submitted an NDA in November 2016, and in describing the NDA, stated that it had conducted a "comprehensive array of abuse-deterrent studies...having reference to" the FDA's 2015 guidance. In July 2017, the FDA released a briefing document in advance of advisory committee review of the NDA and revealed that the company had conducted studies in only one of the three recommended categories (laboratory) and with respect to only one of the three abuse pathways (intravenous). The advisory committee voted overwhelmingly against approval, based largely on the company's noncompliance with the 2015 guidance. The FDA followed the committee's recommendation and denied the NDA.

Investors sued, challenging the company's description of the contents of its NDA. The court denied the company's motion to dismiss, holding that "Defendants chose to publicly represent that their NDA in fact included other types of studies that it did not in fact contain." The company argued that the FDA could have approved Rexista notwithstanding its deviation from the guidance, and pointed out that at one point, the agency considered approving the drug with a narrower label—for IV abuse-resistance rather than for general abuse-resistance. The court rejected the argument, holding that it did not change the fact that the company had mischaracterized the contents of the NDA and underlying studies. The court also held that plaintiffs had adequately pled scienter: Company executives could be presumed to have known the contents of the NDA. On the other side of the ledger, the court granted the company's motion with respect to two other sets of statements. Plaintiffs challenged the company's opinion statements that Rexista was bioequivalent to Oxycontin; the court held that the challenge was an inactionable dispute about data interpretation. Plaintiffs also challenged statements that Rexista had certain feature that deterred oral and nasal abuse; the court held that plaintiffs had not shown that the drug lacked those features, only that the advisory committee questioned the company's failure to evaluate those features according to the criteria in the 2015 guidance.

# *Dahhan v. OvaScience, Inc.*, 321 F. Supp. 3d 247 (D. Mass. July 31, 2018), motion to dismiss denied. Foreign trials and commercialization

OvaScience is the developer of Augment, a treatment used in IVF procedures. The company initially believed it could conduct trials without first filing an Investigational New Drug application under an exemption for certain cellular and tissue-based products. When the FDA informed OvaScience that it was not entitled to the exemption, the company adopted a strategy of testing and commercializing the product outside the U.S. The company offered Augment free of charge at certain foreign IVF clinics with the plan of soon converting to paid treatments. OvaScience told investors in late 2014 that it expected 1000 paying patients in 2015. In March 2015, the company presented data from 34 patients. The data were substantively disappointing, as was the fact that so few patients had accepted even free treatment. The company's stock price fell approximately 20 percent. At various points between March and August 2015, the company stated that it was on track to achieve its 1000 paying-patients projection. In September 2015, the company disclosed that only 35 commercial patients had been treated to date, and the stock fell an additional 40 percent.

Investors sued, challenging both the paying-patients projection and company's statements about efficacy. The court denied the company's motion to dismiss, concluding that plaintiffs had pled sufficient facts to show that the company knew it lacked a reliable basis for the commercial projection, and that it was not in fact on track to achieve the projection when it claimed that it was. The challenged projections thus fell outside the PSLRA safe harbors for forward-looking statements. The court also concluded that plaintiffs had sufficiently alleged both falsity and scienter with respect to statements about efficacy, given the company's assurances that it was closely monitoring the data at the IVF clinics where Augment was being used and tested.

### **DECISION RELATED TO STOCK PROMOTION ACTIVITIES**

Rabkin v. Lion Biotechnologies, Inc., 2018 WL 905862 (N.D. Cal. Feb. 15, 2018), motion to dismiss denied.

Lion worked to develop an immunotherapy for melanoma using tumor-infiltrating lymphocytes. Between September 2013 and March 2014, fourteen favorable posts about Lion and its prospects appeared on the investment website Seeking Alpha. In its Forms 10-Q and 10-K filed during this period, Lion identified stock price volatility as a risk factor and noted that events related to its own and competitors' drug development successes and failures could drive prices up or down. Lion also conducted a secondary public offering during this period. In early 2014, two bloggers identified what they believed were improper stock promotion activities at a number of development-stage biopharmaceutical companies. In May 2014, Lion reported that it had received a subpoena in connection with the SEC's investigation of one of those companies, Galena Biopharma. Under the subpoena, the SEC sought documents related to Lion's own use of investor relations firms. Lion's stock price fell 11 percent. In November 2014, Lion announced the resignation of its CEO; the next day, one of the original two bloggers speculated that this departure could be linked with stock promotion activities. The company's stock again fell 11 percent. Two and a half years later, in April 2017, the SEC published ceaseand-desist orders resolving proceedings with Lion and its CEO in which the SEC alleged that the CEO had engaged in improper stock promotion by indirectly paying for favorable coverage and then concealing that fact. The company's stock price fell three percent.

Investors sued Lion and its former CEO as well as the principal of the investor relations firm the company had hired in 2013. Plaintiffs asserted both false statement and "scheme" claims under Section 10(b), as well as Securities Act claims in connection with the secondary offering. The court largely denied defendants' motions to dismiss. All defendants argued that they were not the "makers" of the statements in the challenged promotional articles; the court concluded, however, that the defendants had sufficient authority over the contents of the articles to establish maker status under the Supreme Court's Janus decision. The court also held that plaintiffs had sufficiently pled falsity with respect to two of the company's own statements in its periodic filings. Plaintiffs had adequately pled that Lion's risk disclosures concerning stock volatility were misleading insofar as Lion failed to include stock promotion as a factor that could affect volatility. And plaintiffs had sufficiently pled that Lion's Sarbanes-Oxley certifications were misleading because those statements failed to provide sufficient information about the company's "financial standing." Plaintiffs also sufficiently pled scienter by including specific facts related to the CEO's and investor relations firm's involvement in soliciting and editing the promotional articles. The court further rejected defendants' loss causation argument, concluding that a series of three disclosures—concerning the subpoena, the CEO's departure, and the cease-and-desist orders—sufficiently tied investment losses to the challenged statements. The court also concluded that plaintiffs had sufficiently alleged an actionable scheme by reference to activities beyond the challenged statements—cooperation between the CEO and the investor relations firm in soliciting, paying for and concealing the origins of the promotional articles. Defendants' sole victory related to the Securities Act claims, which the court dismissed on the ground that plaintiffs had not traced their purchases to the secondary offering.

#### **DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES**

In this section (pages 49–63), we provide detailed summaries of 52 decisions in cases arising from developments at the post-approval stage. As discussed in the "Trends and Analysis" section above, companies fared far better in the post-approval cases in 2018 than they did in 2017. While companies prevailed in only 30 percent of the post-approval cases in the district courts in 2017, they were successful in 15 out of 26 cases, or 58 percent, in 2018.

Many of the 2018 decisions involved allegations of regulatory misconduct as a basis for the securities claims—plaintiffs' theory being that a company's descriptions of its business or its sales practices are misleading if the company does not disclose that it conducts its business in part through practices that violate applicable regulations. In many of the cases in which defendants prevailed, the courts focused on scienter, concluding that plaintiffs had not identified a connection between the allegedly improper conduct and the company executives who made the challenged statements. Courts also rejected several missed revenue guidance cases on scienter grounds.

The post-approval cases in which plaintiffs prevailed in 2018 cover a variety of situations, including challenged sales practices or anticompetitive activity, issues with manufacturing and forecasting for new products.

#### APPELLATE DECISION

*Singer v. Reali*, 883 F.3d 425, 436 (4th Cir. 2018), reversing dismissal of motion to dismiss. Insurance coding

TranS1 is a medical device company that sells the AxiaLIF system (the System), a mechanism designed to perform minimally invasive surgery on the lower lumbar spine. The System was TranS1's principal revenue generator, and the company's financial success depended on reimbursements paid to surgeons by government-funded healthcare programs. On January 1, 2009, the American Medical Association re-categorized the System under an experimental reimbursement code not widely accepted for reimbursement. Between 2009 and 2011, the company conducted a series of on-site training sessions, established a hotline to assist surgeons with coding the surgery, and distributed a reimbursement guide to physicians. On October 17, 2011, the company filed a Form 8-K stating that it had received a subpoena from the Department of Health and Human Services. The following day, an analyst report revealed that approximately half of TranS1's revenues originated from physicians improperly coding to obtain reimbursement. The company's stock fell over 40 percent.

Investors sued, alleging that TranS1 had failed to disclose that it had encouraged doctors to continue to use the non-experimental code despite the AMA's code assignment, and that the company's revenues were generated from the physicians' improper coding practices. The district court granted the company's motion to dismiss, but the Fourth Circuit reversed. The Fourth Circuit held that plaintiffs had sufficiently pled falsity both with respect to the company's statements about the training it was providing to surgeons and with respect to statements in which the company downplayed the impact of the experimental reimbursement code on expected revenue. The Fourth Circuit also held that plaintiffs had adequately pled scienter through their allegation that the illegality of the challenged coding practices was both obvious and known to TranS1 and its officers. The court finally rejected TranS1's loss causation argument, holding that the facts revealed in the Form 8-K and the analyst's report collectively constituted a corrective disclosure.

### **DISTRICT COURT DECISIONS**

#### Motion to Dismiss Granted

*In re Rockwell Med., Inc. Sec. Litig.,* 2018 WL 1725553 (S.D.N.Y. March 30, 2018), motion to dismiss granted with prejudice. **Product launch** 

Rockwell develops drugs for patients suffering from kidney diseases. In January 2015, the company announced that the FDA had approved liquid Triferic, a drug used to treat iron deficiency experienced by dialysis patients. The standard of care prior to approval was treatment by erythropoiesis stimulating agents (ESA), which is expensive and accompanied by serious safety risks. Rockwell made optimistic statements about commercialization and launched the product in September 2015. Some commentators expressed doubts. An analyst noted that label limitations hampered the company's ability to promote Triferic's cost savings as compared to ESA. A professor of medicine was skeptical that Triferic was better or safer than existing treatments. In February 2016, Rockwell reported that the 2015 sales of Triferic were immaterial and below expectations. The company also announced the same day that in April 2015, it had submitted a second NDA for a powder form of Triferic that could be produced more cheaply and stored more easily by customers. If the FDA approved the powder form of the drug, Rockwell explained, it would phase out the liquid form. Rockwell's stock price fell 34 percent.

Investors sued, challenging Rockwell's positive statements about the launch of liquid Triferic and the omission of the fact that the company had submitted an NDA for powder Triferic. The court granted the company's motion to dismiss. Many of the challenged statements were inactionable expressions of optimism; with respect to others, plaintiffs failed to establish falsity. Plaintiffs challenged statements about the superiority of Triferic over alternative treatments, but pointed to no internal documents or other facts showing that the company's

statements were false. On the contrary, those statements were supported by a study based on the administration of 100,000 doses of Triferic. Plaintiffs also argued that Rockwell's references to a "supply contract" were in fact based on a customer's pilot program, but failed to show that the two concepts were inconsistent. Most significantly, plaintiffs failed to establish that Rockwell had a duty to disclose its pending NDA for powder Triferic. The court drew on authorities holding that securities defendants have no obligation to disclose all facts that investors would find "interesting," even if defendants have made other statements on the subject. The court was particularly critical of plaintiffs' theory insofar as companies routinely seek to develop new products even while continuing to invest in the existing products they will replace. The court also held that plaintiffs had failed to plead scienter. Plaintiffs did not show that defendants even knew about the positions adopted by the two skeptics, much less that defendants were required to discount their own positive beliefs about the drug—particularly as those beliefs were supported by the 100,000-dose study. As for plaintiffs' assertion that the company's purportedly fraudulent intent could be seen in its failure to disclose the NDA for powder Triferic, the court found this "wholly conclusory and circular in its logic" as well as "pernicious and contrary to law." Indeed, plaintiffs only narrowly avoided sanctions.

# *In re Egalet Corp. Sec. Litig.*, 340 F. Supp. 3d 479 (E.D. Pa. 2018), motion to dismiss granted with prejudice. **New indication/licensing exclusivity**

Egalet developed the extended-release morphine tablet ARYMO ER for the management of severe long-term pain. In November 2014, a competing company submitted a 505(b)(2) NDA for a product called MorphaBond, also intended for severe long-term pain management. 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, Egalet announced that it had filed a 505(b)(2) NDA for ARYMO ER, and that its submission included studies intended to support abuse-deterrent label claims for injection, oral, and nasal abuse. In August 2016, an FDA joint advisory committee voted in favor of abuse-deterrent labeling for ARYMO ER in all three areas—injection, oral and nasal. In January 2017, however, Egalet announced that while the FDA had approved the ARYMO's NDA, ARYMO would not receive nasal abuse-resistant labeling because MorphaBond had been granted a period of market exclusivity for that label. Egalet's stock fell approximately 22 percent.

Investors sued, claiming that Egalet had failed to disclose adverse facts related to ARYMO's ability to obtain abuse-resistant labeling. The court dismissed the complaint with prejudice. The court ruled that a number of Egalet's allegedly misleading assertions were protected under the PSLRA's safe harbor provision, as they were forward-looking statements accompanied by cautionary language addressing the possibility that the FDA could fail to approve certain types of abuse-deterrent labeling. The court also ruled that plaintiffs had failed to identify false or misleading statements about ARYMO's prospects for obtaining the label it sought. The scope of MorphaBond's market exclusivity period was not publicly announced until November 29, 2016, which was after the company had made all of the statements challenged by plaintiffs.

### *Schaffer v. Horizon Pharma PLC*, 2018 WL 481883 (S.D.N.Y. Jan. 18, 2018), motion to dismiss granted with prejudice. Sales and marketing practices

Horizon Pharmaceuticals manufactures two drugs used to treat the symptoms of rheumatoid arthritis, Duexis and Vimovo. In July 2014, two major pharmacy benefit managers announced that they would begin recommending that healthcare providers exclude Duexis and Vimovo from their plans, citing the availability of cheaper over-the-counter alternatives. In response, Horizon announced that it would accelerate its use of a program called Prescriptions Made Easy (PME), through which Horizon sales representatives would provide doctors with the means to transmit prescriptions directly to specialty pharmacies designated by Horizon. Horizon also stated that if a patient's health plan rejected a drug prescribed through the PME program, the company would arrange payment through a third-party vendor. The PME program was initially successful. In November 2015, however, one of the pharmacy benefit managers removed one of the specialty pharmacies from its network. The company's stock price fell almost 20 percent. In February 2016, the company disclosed a DOJ investigation, after which the stock price fell 13 percent. In April

2016, Horizon announced lower-than-expected revenue for the first half of 2016 and the stock price fell more than 25 percent.

Investors sued, challenging statements and alleged omissions related to the viability of the PME business model, Horizon's control over various pharmacies involved in the program and Horizon's sales and marketing techniques. Plaintiffs asserted claims under Section 10(b) as well as Securities Act claims based on a public stock offering in April 2015. The court dismissed all claims. The court held that neither the pharmacies' financial reliance on Horizon nor their synergistic working relationship implied that Horizon had secretly "controlled" them, and that the allegations of improper sales practices therefore failed to meet applicable pleading standards. The court further held that Horizon's alleged misstatements regarding the overall viability of the PME program were either inactionable opinion statements or inactionable puffery.

*In re Galena Biopharma, Inc. Sec. Litig.,* 2018 WL 3993453 (D.N.J. Aug. 21, 2018), motion to dismiss granted without prejudice. Sales and marketing practices

Galena sold an opioid medication, Abstral, which had been approved for pain management in cancer patients. Beginning in 2014, two doctors accounted for 30 percent of Galena's Abstral revenue and prescribed Abstral off-label for neck, back and joint pain. These doctors purchased \$1.6 million worth of Galena stock and sought to manipulate the stock price by inflating sales of Abstral. The DOJ subsequently commenced an investigation into allegations that Galena paid kickbacks to doctors to induce them to prescribe Abstral. Galena paid \$7.55 million to resolve the matter. The company made a series of disclosures announcing government investigations, executive resignations and its decision to divest its commercial business, including Abstral. The company's stock price fell following these announcements.

Investors sued, challenging statements regarding Galena's financial results (among others) and claiming that Galena had failed to disclose information required by Item 303 of Regulation S-K (which requires companies to provide information about ongoing trends in certain circumstances). Plaintiffs alleged that Galena had pushed salespeople to promote Abstral offlabel, that the company knew that the two off-label prescribing doctors were trading in Galena stock while trying to inflate Abstral sales, and that because Abstral sales were boosted by the offlabel prescribing, the company's revenue performance was not sustainable. The court granted defendants' motion to dismiss, holding that plaintiffs had failed to conduct the statement-by-statement analysis required under the PSLRA, and rejecting plaintiffs' Item 303 theory.

Shoemaker v. Cardiovascular Syss., Inc., 300 F. Supp. 3d 1046 (D. Minn. 2018), motion to dismiss granted with prejudice. Sales and marketing practices

CSI develops and manufactures devices used to treat arterial disease. A former sales manager filed a sealed qui tam action, *i.e.*, an action purportedly on behalf of the government. The sales manager alleged that the company had engaged in off-label marketing and had issued improper discounts and kickbacks in the form of free travel to desirable locations. When the company settled the qui tam action for \$8 million and the matter was unsealed, the company's stock price dropped. Separately, an employee in a California whistleblower action alleged that a sales director had improperly provided marketing services to physicians who promoted the company's devices.

Investors sued, alleging that the company had misled them by attributing its sales growth to legitimate practices, by certifying its financial reporting as required by Sarbanes-Oxley, and by stating that it was in compliance with legal and regulatory obligations. Plaintiffs relied on the allegations made in the qui tam action and subsequent settlement, on the claims made in the California whistleblower action, and on information purportedly provided by two confidential witnesses. The court dismissed plaintiffs' claims on scienter grounds. In order to adequately plead scienter, the court held, plaintiffs were required to show that the patchwork of improper marketing practices they alleged had coalesced into a pattern sufficiently widespread that the company's executives could be inferred to have known about or recklessly disregarded them. Plaintiffs failed to do this: The various sources on which they relied established only isolated instances of purported misconduct.

*Friedman v. Endo Int'l Plc*, 2018 WL 446189 (S.D.N.Y. Jan. 16, 2018), motion to dismiss granted with prejudice. **Acquisition/integration issues**; sales practice issues

Endo develops, manufactures and distributes branded and generic pharmaceuticals. In 2010, Endo acquired a generics manufacturer, Qualitest Pharmaceuticals, and in 2015 Endo acquired another generics manufacturer, Par Pharmaceuticals. After the Par acquisition, Endo made optimistic statements about integrating Par into its business. Subsequently, the company announced revenue and earnings shortfalls due to sales issues at the legacy Qualitest company. In February 2016, Endo announced losses for the fourth quarter of 2015, after which its stock price fell 21 percent. Endo then twice softened or revised downward its 2016 earnings expectations, following which the stock fell another 11 percent and 39 percent respectively. Separately, in May 2016, Endo announced that it had received a civil investigative demand from the U.S. Attorney's office for the Southern District of New York seeking information related to the company's interactions with pharmaceutical benefit managers in connection with two of the company's migraine drugs.

Investors sued, challenging statements related to the integration of Par. Drawing on the civil investigative demand, plaintiffs also claimed that the company had engaged in improper discounting and rebate practices in order to inflate sales of its migraine drugs. On the basis of those alleged practices, plaintiffs alleged both that the company had engaged in an unlawful "scheme" under Section 10(b) and that it had misleadingly failed to disclose the purported misconduct in describing its sales practices. The court granted the company's motion to dismiss with respect to both the false statement claims and the scheme claim. The court held that the challenged statements about the Par integration were inactionable opinion statements under *Omnicare*, while the challenged descriptions of sales practices were forward-looking, general statements of corporate optimism—in addition to which plaintiffs had not sufficiently alleged that the company's sales practices were in fact improper. Finally, the scheme claim failed because plaintiffs did not adequately plead scienter.

*Utesch v. Lannett Co.,* 316 F. Supp. 3d 895 (E.D. Pa. 2018), motion to dismiss granted without prejudice. **Antitrust** 

Lannett manufactures generic drugs. In July 2014, Lannett announced that it had received an inquiry from the Connecticut Attorney General regarding pricing of its generic drug, Digoxin. Lannett's stock price fell 21 percent. In December 2014, the company disclosed that it had been served with a grand jury subpoena related to the DOJ's investigation of the generic pharmaceutical industry. Lannett's share price fell 12 percent. In November 2016, *Bloomberg* and other media reported that criminal charges were expected in connection with the DOJ's investigation into generic drug pricing; Lannett was mentioned in the article. Lannett's stock price fell 27 percent.

Investors sued, challenging statements and purported omissions related to the competitiveness of drug pricing as well as statements about the company's internal controls. The court granted defendants' motion to dismiss, finding that plaintiffs' allegations of scienter were deficient. The court noted that none of plaintiffs' allegations raised the inference that the two individual defendants (the company's CEO and CFO) knew about or directed the alleged anticompetitive agreements, and held that because the scienter allegations were insufficient as to the executives, plaintiffs had failed to plead scienter as to the company as well.

*Fleming v. Impax Labs., Inc.* 2018 WL 4616291 (N.D. Cal. Sept. 7, 2018), motion to dismiss granted without prejudice. **Antitrust** 

Impax develops, manufactures and markets generic pharmaceutical products and develops products used to treat central nervous system disorders. In July 2014, the State of Connecticut began an investigation into generic drug pricing. Also that month, Impax filed a Form 8-K disclosing that it had received a subpoena from the Connecticut Attorney General requesting documents about one of its generic drugs. In November 2014, Impax announced that one of its sales representatives had received a grand jury subpoena from the DOJ's antitrust division regarding the sale of generic drugs. In March 2015, Impax received a grand jury subpoena related to four of its generic medications. In November 2016, *Bloomberg* reported that charges

in the DOJ's antitrust investigation were expected by year-end, and named Impax among the manufacturers who had received subpoenas from the DOJ. Impax's share price fell 20 percent following this announcement.

Investors sued, challenging statements and purported omissions related to price increases for two of Impax's generic drugs. Plaintiffs alleged that beginning in 2013, Impax entered into agreements with its competitors to fix the prices for its generic drugs digoxin and pyridostigmine. According to plaintiffs, Impax and a competitor, Lannett, both suddenly increased the price of generic digoxin by more than 700 percent in November 2013. Impax and another competitor, Valeant both suddenly raised the price of pyridostigmine by 116 percent beginning in December 2014. Plaintiffs alleged that natural market behavior does not explain such correlated price increases, and that market factors such as high levels of concentration, inelastic demand, and substantial barriers to entry make the markets for these drugs susceptible to collusion. The court granted the company's motion to dismiss. The court concluded that plaintiffs had adequately alleged that statements attributing price increases to natural market factors were false in light of Impax's purported price fixing activities. On scienter, however, the court held that plaintiffs had not sufficiently tied those purported activities to the individual defendants. The court also rejected plaintiffs' attempt to establish scienter through a core operations theory. Plaintiffs' claims also failed on loss causation grounds. The announcement of a government investigation, in the court's view, does not constitute a corrective disclosure and hence did not serve to link the challenged statements to the stock price decline. Finally, the court rejected plaintiffs' claims that Impax concealed negative trends related to two other products, holding that the challenged representations were forward-looking projections or verifiably accurate statements about drug pricing.

*Jackson v. Halyard Health, Inc.,* 2018 WL 1621539 (S.D.N.Y. March 30, 2018), motion to dismiss granted with prejudice. **Product defect** 

Halyard, an entity spun off another defendant in the same action, manufactures medical supplies, including the MicroCool Breathable High Performance Surgery Gown (MicroCool), a product intended to protect healthcare providers from highly infectious diseases such as Ebola. The MicroCool 501(k) summary submitted to the FDA in 2010 stated that the MicroCool met the Level 4 Liquid Barrier requirements of the Association for the Advancement of Medical Instrumentation (AAMI), the highest liquid barrier protection defined by the AAMI system. Halyard allegedly advertised the MicroCool as providing AAMI Level 4 protection on its website as well as in published letters to customers. On May 1, 2016, 60 Minutes reported that the MicroCool had failed numerous quality assurance tests and laboratory reports in 2012 and 2013 and that defendants had knowingly provided defective surgical gowns to U.S. workers at the height of the Ebola crisis. The following day, Halyard's stock price fell 14 percent.

Investors sued, claiming that defendants had knowingly misrepresented the MicroCool as capable of providing AAMI Level 4 protection. Plaintiffs relied in part on statements from two confidential witnesses who claimed that the MicroCool had seam sealing issues. The court granted defendants' motion to dismiss on scienter grounds. The court held that plaintiffs had failed to allege that defendants had personally received the reports identified by the confidential witnesses with a level of particularity that would satisfy the heightened pleading requirements of the PSLRA. The court also rejected plaintiffs' allegations of insider stock sales, holding that plaintiffs had failed to allege that the sales were unusual in timing or amount.

Yan v. ReWalk Robotics, Ltd., 2018 WL 4039357 (D. Mass. Aug. 23, 2018), motion to dismiss granted. Post-market surveillance

ReWalk is a medical device company that designs and develops exoskeleton devices for people with spinal cord injuries. One of ReWalk's devices is the ReWalk Personal, which is designed for "everyday use" —as distinguished from use in a clinical rehabilitation setting. In 2014, the FDA approved the ReWalk Personal as a Class II device and ordered the company to conduct post-market surveillance to determine the product's risks. ReWalk conducted its IPO in September 2014. Two weeks after the IPO, the FDA advised ReWalk that its proposed post-market surveillance study was deficient. ReWalk continued to correspond with the FDA about post-market surveillance periodically over the next year. In September 2015, the FDA cautioned

ReWalk that it still had not submitted a revised study plan addressing the deficiencies identified by the agency the previous year. Later that month, the FDA issued a warning letter regarding ReWalk's substantial failure to comply with the post-market surveillance requirement. After the FDA disclosed the warning letter publicly on March 1, 2016, the company's stock price fell 13 percent.

Investors sued under the Securities Act, challenging statements and purported omissions in the company's September 2014 registration statement related to the ReWalk Personal's safety profile and the nature of the post-market surveillance requirement. The court granted the company's motion to dismiss. The court rejected plaintiffs' claim that the company had improperly failed to disclose that the ReWalk Personal was dangerous. That claim, the court held, was based on a misreading of the FDA correspondence. The FDA warning letter did not actually state that the device was dangerous; rather the agency explained that the purpose of the post-market surveillance requirement was to determine the product's safety in certain environments. The court also held that challenged statements referring to "compelling" clinical data and to a "breakthrough product" were inactionable puffery, and that statements regarding the company's intent to conduct further clinical studies were protected under the PSLRA safe harbor for forward-looking statements.

**Note:** Plaintiffs in *ReWalk* also asserted Section 10(b) claims. The company moved to dismiss those claims on the ground that plaintiffs, who purchased shares only after the challenged statements were made, lacked standing. The court denied the company's standing motion without prejudice, inviting further briefing by the parties and/or the substitution of a new plaintiff.

*Costabile v. Natus Med., Inc.,* 293 F. Supp. 3d 994 (N.D. Cal. 2018), motion to dismiss granted without prejudice. **Revenue projections** 

Natus Medical designs and manufactures newborn care and neurology healthcare products. In October 2015, Natus announced that it had entered into a three-year, \$235 million supply contract to provide medical equipment, supplies and services to the Venezuelan Ministry of Health (the Supply Contract). In a press conference the next day, Natus announced that it had increased its revenue guidance for the fourth quarter of 2015, citing the Supply Contract, and that it expected to receive three payments totaling \$69 million by the first quarter of 2016. From October through December 2015, the company's CEO stated in a variety of settings that Natus expected to begin receiving payments on the Supply Contract before the end of 2015. In January 2016, Natus filed a Form 8-K announcing that it had failed to meet its revenue guidance for the fourth quarter of 2015, citing delays in receipt of payments under the Supply Contract. In February 2016, Natus filed an unsigned copy of the Supply Contract with its 2015 Form 10-K. In April 2016, Natus issued a press release describing lower-than-anticipated preliminary revenue results for the first quarter of 2016. The company also revealed that it had still received no revenue related to the Supply Contract. The company's stock price fell approximately 20 percent.

Investors sued, challenging statements regarding the nature and execution of the Supply Contract, the relevant currency risk, and the company's prior dealings with the Venezuelan government. The court granted the company's motion to dismiss. The court held that plaintiffs had successfully pled false or misleading statements about contractual terms governing the timing of the \$69 million in prepayments, but had failed to allege facts sufficient to support a strong inference of scienter. The court noted that the challenged statements concerned the company's "expectations," and hence did not constitute falsehoods in direct conflict with the Supply Contract. Plaintiffs' insider selling allegations did not support an inference of scienter either, as the executives' stock sales in late 2015 were not abnormal in light of their trading history. But the court also stated that if plaintiffs could amend their complaint to substantiate the allegation that the Supply Contract was never actually executed—a claim based largely on confidential witnesses recounting secondhand information—this would likely substantiate several of plaintiffs' other claims as well.

*Ellis v. Spectranetics Corp.*, 2018 WL 1583837 (D. Colo., April 2, 2018), motion to dismiss granted with prejudice. Revenue projections

Spectranetics manufactures and sells medical devices to treat arterial blockages in the legs and heart, and to remove pacemaker and defibrillator cardiac leads. In April 2015, the company

announced disappointing results for the first quarter of 2015, citing weakness in its vascular intervention business segment and revising 2015 revenue guidance downward. The company's stock price fell 23 percent. In July 2015, the company disclosed that its vascular intervention business segment had not met targets and further revised 2015 guidance downward. The stock price fell further.

Investors sued, challenging statements and purported omissions related to quarter-end discounting and the risks posed by a competing product. Plaintiffs alleged that the company engaged in quarter-end bulk sales of product on heavy discount and that the company knew of, but ignored risks to its vascular intervention unit sales posed by the introduction of a competing product that made use of drug-coated balloons. The court granted defendants' motion to dismiss on scienter grounds. After walking through a number of confidential witness allegations, the court held that at best, plaintiffs' allegations showed that defendants encouraged bulk sales and misjudged the strength of competition in the market, which was not sufficient to support an inference that the company knew the challenged statements were false or misleading.

*Paciga v. Invuity, Inc.,* 2018 WL 7286503 (N.D. Cal. Sept. 26, 2018), motion to dismiss granted without prejudice. Revenue projections

Invuity develops, markets and sells medical devices used to provide illumination and improve visibility during surgery. In February 2016, the company issued annual revenue guidance for 2016 and thereafter stated that its sales growth was on track and had not plateaued. The company also made broadly optimistic statements about its success in executing against its growth model and about its opportunities generally. In July 2016, the company announced a secondary public offering. In November 2016, Invuity reported lower-than-expected revenue growth for the third quarter, citing sales below expectations from active accounts. The company accordingly reduced its 2016 revenue guidance and projected slower revenue growth in 2017. The company's stock price fell 45 percent.

Investors sued, challenging the company's revenue projections, generalized statements of optimism and statement of its cash position. The district court dismissed the complaint on both falsity and scienter grounds. The court rejected plaintiffs' claim that allegedly undisclosed discounts offered to customers undermined the company's revenue projections; plaintiffs failed to allege facts demonstrating that the purported discounts had a material impact on the company's sales figures. The court also rejected plaintiffs' challenge to the company's statement that its sales had not plateaued; plaintiffs' confidential witnesses established at most that some customers made a single large order followed by smaller subsequent orders, and this did not show that the company was incapable of further growth. Plaintiffs' challenge to generalized statements of optimism failed under law holding that such statements constitute inactionable puffery. And the company's announcement of a secondary offering did not show that its earlier statement of cash position was false or misleading. As to scienter, plaintiffs' allegations that the company's executives had "access" to negative internal information meant nothing in the absence of specific facts detailing what that information was. Plaintiffs' allegations about insider stock sales were also defective: Plaintiffs did not show that the sales were unusual in timing or amount, and the sales were made under trading plans in any event.

Metzler Asset Mgmt. GmbH v. Kingsley, 305 F. Supp. 3d 181 (D. Mass. 2018), motion to dismiss granted with prejudice. Adverse events; revenue projections

Biogen developed and sold the oral multiple sclerosis medication Tecfidera. During an October 2014 earnings call, Biogen announced that a patient taking Tecfidera had died from an infection related to a weakened immune system caused by a low level of lymphocytes (lymphopenia). In November 2014, the FDA issued a public warning in which it advised physicians to monitor Tecfidera patients for side effects. In December 2014, Biogen updated Tecfidera's U.S. label—which already included a lymphopenia warning—to reflect the danger of the relevant infection. In April 2015, Biogen reported weaker-than-expected quarterly earnings. In July 2015, Biogen revised its annual revenue guidance, stating that it expected revenue growth to be approximately six to eight percent, which was down from the company's January estimate of 14 to 16 percent. The company attributed the change to greater caution on the part of physicians and patients after the 2014 safety event. Biogen's stock price fell over 20 percent.

Investors sued, alleging that Biogen had known both that Tecfidera potentially weakened patients' immune systems and that the patient death had materially affected Tecfidera sales, but that the company had misrepresented or concealed those facts in its public statements. The court granted defendants' motion to dismiss, holding that while plaintiffs had adequately alleged falsity with respect to six challenged statements, they had failed to plead facts creating a strong inference of scienter. The court rejected plaintiffs' confidential witness allegations, which consisted of purported reports from Biogen area business managers stating that sales of Tecfidera had fallen substantially in late 2014 and early 2015. The court held that without some measurement of the decline or a particularized description of how it occurred, the allegations did not show that defendants knew that the challenged revenue projections were false or misleading. Plaintiffs also relied on the statements of physicians who purportedly said that they had notified Biogen that patients taking Tecfidera had a higher risk of developing lower lymphocyte counts. But this too was insufficient to establish scienter: The lymphopenia risk had been disclosed nearly 18 months before the challenged statements, and was included on the pre-incident warning label.

# *Mahoney v. Foun. Med., Inc.*, 342 F. Supp. 3d 206 (D. Mass. 2018), motion to dismiss granted. Insurance coverage; revenue projections

Foundation Medicine develops, manufactures and sells diagnostic tests that identify genomic mutations associated with cancer. When Foundation launched the product, private insurance covered the tests only to a limited extent, and government insurance programs did not cover the tests at all. In 2014, Foundation reported increasing revenue and test volumes, driven by initial adoption by major academic medical centers and key opinion leaders. Throughout 2014, Foundation faced competitive pressure from less expensive tests with better insurance coverage. Despite these pressures, Foundation in February 2015 reported test volumes at the high end of its forecast range, citing the "broad adoption of our comprehensive genomic profiling approach." Beginning in May 2015, Foundation began reporting lower test volumes. Foundation had by this time received a draft coverage determination from a Medicare administrative contractor in South Carolina, and the company expected that determination to have a broad impact. Ultimately, however, the effect of the positive draft determination in the field was less than anticipated, and in July 2015, Foundation revised its annual revenue guidance downward and the company's stock price fell 24 percent. In November 2015, Foundation reported disappointing third-quarter revenue and test volumes and its stock price fell 28 percent.

Investors sued, challenging Foundation's positive statements about its tests, its competitive advantages and growth prospects, and the favorable Medicare coverage and reimbursement decisions it was anticipating. Plaintiffs also claimed that the company had failed to disclose information related to competitive pressures and the clinical utility of the tests. The court granted the company's motion to dismiss on scienter grounds (although much of the court's analysis appears to turn on falsity). The court held that plaintiffs had failed to identify facts showing that defendants were aware of new standards for determining Medicare eligibility at the time of the challenged statements and that the individual defendants' stock sales did not support an inference of scienter either.

#### DISTRICT COURT DECISIONS

### Motion to Dismiss or for Summary Judgment Denied

SEB Inv. Mgmt. AB v. Endo Int'l, PLC, 351 F. Supp. 3d 874 (E.D. Pa. 2018), motion to dismiss denied. Reformulation and relabeling

Endo developed and manufactured the opioid pain medication Opana ER. In July 2010, Endo submitted an NDA for an abuse-resistant, reformulated version of Opana ER. In December 2011, the FDA approved the reformulated Opana ER but denied Endo's request to label the drug as abuse-deterrent. In August 2012, Endo submitted a Citizen Petition to the FDA, asking the FDA to determine that the *original* Opana ER was discontinued for safety reasons, and to reject pending ANDAs for generic versions of the drug. Endo supplemented its Citizens Petition with

post-marketing surveillance data that it said indicated that the reformulation of Opana ER was having the desired effect on the rates of abuse. In February 2013, the company submitted an SNDA seeking FDA approval to place abuse-deterrent language on the reformulated Opana ER's label, relying on the same studies submitted with the Citizens Petition.

In May 2013, the FDA denied Endo's petition for abuse-deterrent labeling, and in September 2014 the FDA concluded that following Endo's reformulation of Opana ER, abuse of the drug had shifted from the nasal to the intravenous pathway. In June 2015, Endo filed a Registration Statement announcing a \$1.75 billion common stock offering. In August 2015, the company announced plans to submit a supplemental request for abuse-deterrent labeling for Opana ER. In November 2015, Endo released a report stressing the crush resistance of reformulated Opana ER; the company did not, however, discuss the increase in intravenous abuse. In January 2017, the FDA convened an advisory committee to discuss marketing data regarding abuse of the reformulated Opana ER and the risk-benefit profile of the product. Endo's stock price fell 6.7 percent on the day the FDA announced that it would convene the advisory committee and 8.5 percent the following day. In June 2017, the FDA announced that it had asked Endo to voluntarily withdraw reformulated Opana ER from the market. The company's stock price dropped 16 percent.

Investors sued, alleging misstatements and opinions about Opana ER's abuse deterrent properties and the viability of the company's abuse-deterrent labeling efforts. The court denied Endo's motion to dismiss, finding that plaintiffs had adequately alleged that the company's statements about a decrease in intranasal abuse were misleading in light of the data showing a shift from intranasal to intravenous abuse. The court also held that plaintiffs had adequately alleged falsity with respect to Endo's statements that its situation with Opana ER was similar to that of a different drug, reformulated OxyContin. Unlike Opana ER, reformulated OxyContin was difficult to inject.

*Karth v. Keryx Biopharmaceuticals, Inc.,* 2018 WL 3518497 (D. Mass. July 19, 2018), motion to dismiss denied in part. *Manufacturing issues* 

Keryx sells Auryxia, a drug approved for the treatment of elevated phosphorus levels in patients with chronic kidney disease. To convert the active pharmaceutical ingredient (API) of Auryxia into tablets, Keryx used a contract manufacturer, Norwich Pharmaceuticals. Keryx did not have another contract manufacturer approved by the FDA to perform that role. In earnings calls and in its financial reporting, Keryx referred to the third parties and "manufacturers" it relied on to produce Auryxia. Keryx also issued generally positive forward-looking guidance about its performance in February and April 2016. In August 2016, Keryx announced that it was halting the distribution of Auryxia until at least October 2016, due to a production issue with its contract manufacturer, and withdrew its 2016 financial guidance. On a conference call, Keryx stated that it had only one contract manufacturer for API conversion and that it had been "experiencing difficulties" in the manufacturing process. Keryx's stock price fell 36 percent.

Investors sued, challenging statements referring to "manufacturers" in the plural, statements related to obtaining FDA approval for a second contract manufacturer, and statements containing favorable revenue guidance. The court denied in part and granted in part defendants' motion to dismiss. The court held that plaintiffs had stated a claim based on statements referring to contract manufacturers in the plural. Keryx had disclosed that it had a single contract manufacturer in an earlier Form 10-K, but had failed to repeat that disclosure in the challenged filings, instead using ambiguous language that a reasonable investor could interpret to mean that the company had engaged additional manufacturers. The court also held that plaintiffs had plausibly alleged falsity with respect to the statement that management had achieved the goal, tied to incentive compensation, of obtaining regulatory approval for an "additional contract manufacturer." A reasonable investor could understand that statement as a reference to a contract manufacturer retained for the API conversion. The court granted defendants' motion to dismiss with respect to forward-looking statements regarding the strength of Auryxia.

# *Shah v. Zimmer Biomet Holdings, Inc.,* 348 F. Supp. 3d 821 (N.D. Ind. 2018), motion to dismiss denied. *Facility issues*

Zimmer Biomet Holdings (ZBH) manufactures medical orthopedic and joint-replacement medical devices. In the spring of 2016, a series of internal audits at ZBH's North Campus manufacturing facility revealed quality systems failures that rendered the facility potentially FDA non-compliant, but ZBH elected to postpone an overhaul of the factory until November 2016. In September 2016, the FDA commenced an inspection of ZBH's North Campus and identified sterilization issues so severe that ZBH issued a complete hold on all products leaving the North Campus facility. In October 2016, ZBH announced its third quarter financial results and lowered its full-year 2016 projections to reflect an absence of growth. The company attributed the revised projection not to the hold but instead to unanticipated supply constraints. ZBH's stock dropped 14 percent, and several analysts publicly questioned the truth of the company's supply chain explanation. On November 8, 2016, ZBH acknowledged in a Form 10-Q and associated press release that the supply shortages it had previously identified related to an FDA inspection at North Campus. The company further stated that it had been unable to meet demand for products during a postinspection remediation period, which was still ongoing. ZBH's stock price fell further. Later in November 2016, the FDA issued a Form 483 warning letter identifying 14 procedure deficiencies at North Campus. ZBH acknowledged in a December 2016 response letter that corporate management had been aware of systemic issues at North Campus as a result of internal audits.

Investors sued, challenging the company's statement in October 2016 that the third-quarter revenue miss was the result of supply constraints. Plaintiffs alleged that the company had misleadingly masked the real reason for the miss—the ongoing issues at North Campus. Plaintiffs also challenged numerous statements between the time of the audit and the start of the FDA's inspection; in those statements, the company projected accelerating revenue growth and failed to acknowledge the risks revealed during the internal audits. The court denied defendants' motion to dismiss, holding that plaintiffs had adequately pled that the company had a duty to disclose the facility issues it had discovered through its internal audits. The court rejected defendants' argument that the PSLRA safe harbor provisions protected the statements, holding that the company's generic statements about risk were insufficiently cautionary as a pleading matter in light of plaintiffs' specific factual allegations about the quality system issues at North Campus.

# *In re Insys Therapeutics, Inc. Sec. Litig.*, 2018 WL 2943746 (S.D.N.Y. June 12, 2018), motion to dismiss denied in part. Kickbacks; financial statement misstatements

Insys sold Subsys, a fentanyl spray designed and approved to treat breakthrough cancer pain. In 2016, prosecutors indicted multiple Insys executives on federal racketeering charges, alleging a kickback scheme in which physicians were rewarded for prescribing the drug off label. The company's former CEO later pled guilty to certain charges. On March 15, 2017, the company announced that an audit committee investigation had revealed errors in the company's processes related to estimating sales allowances. The company's stock price fell 4.64 percent. On March 31, 2017, the company announced that it would restate its financial statements for the first three quarters of 2015 and 2016, explaining that it had miscalculated rebate obligations. On April 7, 2017, the company issued restated financial statements. For three of the six quarters at issue, the restatement resulted in *upward* revisions to both net revenue and net income. In the aggregate over the six quarters, net revenue decreased by 0.05 percent and net income increased.

Investors sued, alleging that the company had engaged in financial statement fraud to cover up adverse financial impacts it experienced when the purported kickback scheme was exposed and terminated. Investors challenged the company's financial statements, statements of accounting policies and certification of internal controls. The court denied motions to dismiss filed by the company and three of its executives and granted only the motion of a fourth executive, who had served as Chief Medical Officer at the time of the challenged statements. The court held that plaintiffs had adequately pled falsity with respect to all categories of challenged statements; indeed, as in any restatement case, the company had admitted falsity as to its financial statements. The court also held that plaintiffs had adequately pled materiality, notwithstanding the quantitative *immateriality* of the aggregate financial statement errors. The court concluded that qualitative factors were dispositive, including defendants' alleged purpose of concealing the business decline purportedly caused by the termination of the kickback scheme. Plaintiffs had

also adequately pled scienter, given the company's alleged motivation to conceal the impact of the kickback scheme. The court finally rejected defendants' loss causation argument, holding that in context, the company's March 15, 2017 announcement of the audit committee's findings was a sufficient corrective disclosure notwithstanding the absence of information in that announcement about whether a restatement would be required.

West Va. Pipe Trades Health & Welfare Fund v. Medtronic, Inc., 299 F. Supp. 3d 1055 (D. Minn. 2018), motion for summary judgment denied in part. Payment to physician authors

This long-running litigation arose from 2008 media coverage and a congressional investigation in which Medtronic was accused of paying doctors to write medical journals articles minimizing the side effects of the bone-growth product Infuse and exaggerating the disadvantages of alternative treatments. The company's stock price fell following these accusations.

Plaintiffs originally sued Medtronic, its executives, and the physician authors, alleging that all had participated in an unlawful scheme. The district court dismissed the claims against the physician authors but permitted plaintiffs to proceed against the company and executives. The court then granted summary judgment in favor of all remaining defendants on statute of limitations grounds. The Eighth Circuit reversed in a 2016 decision, rejecting both defendants' statute of limitations argument and their alternative argument that they had not participated in an unlawful scheme. The Eighth Circuit agreed with defendants that a scheme requires more than simply false statements—but held that plaintiffs had established something "more" in the act of paying physician authors to write favorable articles. The appellate court also rejected defendants' argument that in a scheme premised on allegedly false statements, only the "maker" of those statements is liable. (The United States Supreme Court recently rejected a related argument in *Lorenzo v. SEC*, No. 17-1077, (March 27, 2019). The Court held there that defendants who knowingly disseminate false statements to investors may be liable as participants in a scheme whether or not they made those statements themselves.)

After the Eighth Circuit remanded the case, the six individual executive defendants again moved for summary judgment, this time on the basis that they had not participated in the alleged scheme within the applicable chronological period (Section 10(b)'s statute of repose bars claims asserted more than five years after the conduct at issue). The district court rejected plaintiffs' attempt to reach beyond that period with a theory of continuing wrong and further rejected plaintiffs' argument that any deceptive act, whether or not connected to the purported scheme, was sufficient to establish liability. The court defined its task as determining whether plaintiffs had shown that each defendant committed a deceptive act in furtherance of the scheme within the five-year period. The court then reached different results for the six individual defendants. Two of them—one who had retired before the relevant period and worked only as a consultant, and another who was identified only by job title—were entitled to summary judgment on all claims. Two others—executives linked to publication of the articles or design of the underlying trials—were not entitled to summary judgment on the scheme claim but were entitled to judgment on control person claims. The last two—the CEO and CFO—were entitled to summary judgment on the scheme claim but remained in the case as control persons.

*Mauss v. NuVasive*, 2018 WL 656036 (S.D. Cal., Feb. 1, 2018), motion for summary judgment denied. Sales and marketing practices

NuVasive designs, develops and markets products for the surgical treatment of spine disorders. In 2011, the company's board of directors requested a "look-back" audit into expenses and concluded that half the expenses under review were inappropriate. The problems revealed included expense reports that did not comply with statutory requirements or internal policies. Among other things, the audit exposed misstatements of expenses for entertaining physicians. In July 2013, the company reported that it was being investigated by the Office of the Inspector General in connection with possible false or improper Medicare and Medicaid claims. On an investor call the same day, the company stated that the OIG subpoena was a broad request specific to NuVasive, and not part of a request to similarly situated companies. Analysts then reported that the likely outcome of the subpoena was a settlement, along with associated monitoring costs. The company's stock price fell 12 percent.

Investors sued, challenging statements related to NuVasive's legal compliance and the risk of regulatory scrutiny. After the company filed motions to dismiss successive versions of the complaint, the court permitted plaintiffs to proceed with a fifth amended complaint. Plaintiffs then filed a further sixth amended complaint, which became the operative complaint. The company moved for summary judgment on the issue of loss causation, arguing that plaintiffs had identified no evidence that the market "ever learned of the practices that Plaintiffs allege underlies their claim of securities fraud." The court rejected this argument, stating that the Ninth Circuit "does not require that fraud be affirmatively revealed to the market to prove loss causation."

# *In re Novo Nordisk Sec. Litig.*, 2018 WL 3913912 (D.N.J. Aug. 16, 2018), motion to dismiss denied. Rebates and pricing

Novo Nordisk makes diabetes products and derives approximately 80 percent of its revenue from insulin-based medications. In November 2016, a company executive stated that the company had raised prices to compensate for increased rebates paid to pharmacy benefit managers. Later that month, the company stated on its website that it calculates profits after deducting rebates, fees and other price concessions it provides to payers. In August 2016, Novo Nordisk announced disappointing earnings for the first half of 2016 due to a "challenging pricing environment especially in the basal insulin" segment, and adjusted forecasts downward. The company made similar announcements over the next six months, and the price of its ADRs fell 20 percent cumulatively.

Investors sued, challenging statements and purported omissions related to the PBM rebates and to pricing pressures in the market for the company's long-acting insulin drug, Tresiba. Specifically, plaintiffs alleged that (1) Novo Nordisk inflated the list prices for its drugs and then paid rebates to PBMs in exchange for inclusion or preferential treatment on formulary lists, (2) Novo Nordisk failed to disclose details of its relationship with PBMs, including alleged kickbacks, and (3) Novo Nordisk falsely stated that Tresiba would protect the company from pricing pressures when it knew that the drug was not an improvement over existing products. The court denied defendants' motion to dismiss, holding that plaintiffs had adequately pled falsity with respect to statements attributing Novo's success to the efficacy of its products; later disclosures showed that the PBM rebates were in fact critical to the company's success. The court also held that plaintiffs had adequately pled falsity with respect to the company's assurances that its growth would continue and that Tresiba would contribute to that growth. The court rejected defendants' arguments that statements about Tresiba's expected performance and the company's pricing targets were protected under the PSLRA safe harbors, holding that the statements were not forward looking. The court also rejected defendants' scienter arguments, concluding that confidential witness allegations, combined with facts related to compensation and executive departures, supported a strong inference of scienter.

# *In re Mylan N.V. Sec. Litig.*, 2018 WL 1595985 (S.D.N.Y March 28, 2018), motion to dismiss denied in part. Rebates; antitrust

Mylan develops and manufactures both brand-name and generic pharmaceuticals, including the EpiPen Auto-Injector (EpiPen). Mylan classified the EpiPen as a noninnovator multiple source drug (N Drug) for purposes of the Medicaid Drug Rebate Program, which requires pharmaceutical companies to give rebates to the Centers for Medicare and Medicaid Services. In 2009, CMS informed Mylan that it had misclassified the EpiPen and would likely need to begin paying a higher rebate rate under the appropriate categorization. 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 in the generic drug market.

Investors sued, alleging that Mylan had misled shareholders with regard to both its misclassification of the EpiPen and its alleged anticompetitive activity, which they claimed included price fixing agreements for generic drugs, a "pay for delay" clause in a patent infringement suit and exclusive dealing arrangements with schools. Plaintiffs challenged statements related to Mylan's sources of income, its explanations of market conditions, rebate rates and regulatory risk, and its claimed adherence to its codes of conduct and business

ethics. The court denied Mylan's motion to dismiss in part. The court held that plaintiffs had adequately pled falsity as to Mylan's statements about the sources of its income, given the omission of information about the miscalculated Medicaid rebates and the allegedly anticompetitive activities. The court explained that while quantitative statements of earnings are not actionable, the statements in which Mylan put the sources of its income at issue were.

The court also held that plaintiffs had adequately alleged falsity as to Mylan's statements about the EpiPen rebate rates, its statement that the government *may* take a contrary regulatory position with regard to the EpiPen, and its statement that the market for its products was "very competitive." The court granted the company's motion to dismiss, however, as to Mylan's opinion statements about the general complexity and subjectivity of the regulatory environment and statements in Mylan's code of business ethics, which the court characterized as inactionable puffery.

Roofer's Pension Fund v. Papa ("Perrigo"), 2018 WL 3601229 (D.N.J. July 27, 2018), motion to dismiss denied in part. M&A; antitrust

Perrigo is a worldwide manufacturer of both branded and generic pharmaceuticals. In April 2015, the pharmaceutical company Mylan announced an unsolicited offer to purchase Perrigo for cash and stock. Perrigo rejected the offer and Mylan proceeded with a tender offer in September 2015. While Mylan's tender offer was pending, Perrigo made representations about the health of the company and strength of its revenue streams. In November 2015, Mylan's tender offer expired; fewer than 50 percent of the Perrigo's shares had been tendered. In February 2016, Perrigo reported fourth quarter 2015 revenues below the projections it had made during the takeover bid and revised its 2016 earnings guidance downward. Over the following several months, Perrigo announced impairment charges related to problems with its integration of Omega, a recently acquired company. The impairment charges ultimately totaled over \$600 million. In February 2017, Perrigo announced that it would sell its royalty stream for the drug Tysabri—one of its major revenue generators—for \$2.2 billion dollars, substantially less than the value Perrigo had assigned to the asset while Mylan's offer was pending. Perrigo also announced on the same day that it would not timely file its 2016 Form 10-K because it needed to review historical revenue recognition practices for the Tysabri royalty stream (among other issues). In March 2017, Bloomberg reported that Perrigo's generic drug pricing was under investigation by the DOJ, and in May 2017, the company's offices were raided by federal law enforcement.

Investors sued, claiming that Perrigo had made material misrepresentations in four areas in order to discourage shareholders from accepting Mylan's tender offer. Specifically, plaintiffs alleged that Perrigo had (1) inflated its revenues by engaging in a generic drug price fixing scheme with other manufacturers, (2) misrepresented the success of the Omega integration, (3) misled investors about the value of the Tysabri revenue stream, and (4) misrepresented its organic growth rate. The court denied the company's motion to dismiss with regard to the first two theories. The challenged statements about Perrigo's generic drug business, the court held, were actionable in light of the plausibly-pled underlying antitrust allegations. As to the Omega integration, while certain forward-looking statements on the subject came within the PSLRA safe harbor, Perrigo's statements that it had met integration milestones did not. On the other side of the ledger, the court granted the company's motion to dismiss with respect to plaintiffs' third and fourth theories. Plaintiffs' challenge to statements about the Tysabri revenue stream failed on scienter grounds in light of the fact that Perrigo's auditors had not identified any issue as to the company's accounting classification of the asset. And while plaintiffs had alleged falsity as to statements about organic growth rates, they failed to allege scienter with the necessary specificity.

*Speakes v. Taro Pharm Indus. Ltd.,* 2018 WL 4572987 (S.D.N.Y., Sept. 24, 2018), motion to dismiss denied in part. **Antitrust** 

Taro produces and markets generic dermatological drugs. In July 2014, the State of Connecticut commenced an investigation into generic drug pricing, which was followed by an investigation and litigation by the DOJ. On September 8, 2016, Taro and two senior officers received grand jury subpoenas from the DOJ seeking information about generic drug products and pricing. On September 9, 2016, Taro disclosed the subpoenas, and company's stock price

fell three percent. In November 2016, *Bloomberg* reported that criminal antitrust charges would likely be filed by year-end; the article mentioned Taro. The company's stock price fell seven percent following publication of the article.

Investors sued, challenging statements related to the competitiveness of the pharmaceutical industry, the attribution of Taro's revenue growth to pricing adjustments, and Taro's sales and revenue figures. The court held that the company's statements about the competitiveness of the industry—when the industry was, according to plaintiffs, collusive—were sufficiently alleged to be misleading. The court explained that to the extent that Taro was engaged in a price fixing conspiracy with its competitors, statements that the industry was "intensely competitive" were misleading in the absence of a disclosure of the alleged anticompetitive conduct. The court further held that while Taro's sales and revenue figures standing alone were not actionable misstatements, statements attributing Taro's growth to pricing adjustments were actionable because plaintiffs alleged that a good portion of the growth was attributable to the price fixing conspiracy, and not to price adjustments and other factors disclosed by Taro. The court also held that plaintiffs had adequately pled scienter based on allegations that the company's CEO and CFO attended pricing meetings. Finally the court rejected the company's argument that because investors were aware of alleged price fixing activities in the generics industry before the revelations of September 2016 and November 2016, plaintiffs could not establish loss causation on the basis of the stock price declines following those revelations. Information about the generics industry generally, the court held, was not the same as the information revealed in September and November 2016, which tied Taro in particular to the alleged price fixing conspiracy.

*In re Illumina, Inc. Sec. Litig.*, 2018 WL 500990 (S.D. Cal. Jan. 22, 2018), motion to dismiss denied in part. Revenue projections

Illumina produces three genetic sequencing products: the older HiSeq product, and the newer HiSeq X and Next Seq products. When HiSeq X and Next Seq were introduced in January 2014, customers began to favor them over the original HiSeq product. During an investor call in July 2016, Illumina executives forecast an increase in HiSeq sales during the second half of 2016. In the fall of 2016, Illumina announced that it had missed its third-quarter 2016 revenue forecast and attributed the miss to lower-than-expected sales of the HiSeq systems. Illumina's stock price fell 26 percent following these announcements.

Investors sued, challenging statements related to Illumina's financial forecasting. The court denied the company's motion to dismiss in part, holding that while the company's revenue projections and underlying factual assumptions were forward-looking statements, they were not accompanied by meaningful cautionary language, and therefore did not fall within the PSLRA safe harbor. The court rejected the company's argument that it had provided sufficient cautionary language by warning investors of forecasting risks related to the introduction of "new or enhanced products." At the time the company provided that caution, the court explained, it had already introduced the "new or enhanced" products that led to lower levels of sales of the HiSeq product. The court also held that plaintiffs had plausibly alleged that defendants knew that HiSeq sales were declining when they projected increased sales. The court granted the company's motion, however, with respect to challenged statements relating to the adequacy of internal controls.



### **TABLE OF NEW FILINGS IN 2018**

In 2018, 48 new securities fraud class actions were filed against life sciences companies. This is a slight dropoff from the numbers of new complaints in 2016 and 2017 but still well above what we saw in earlier years:

2014 42 new complaints2015 39 new complaints2016 50 new complaints2017 54 new complaints

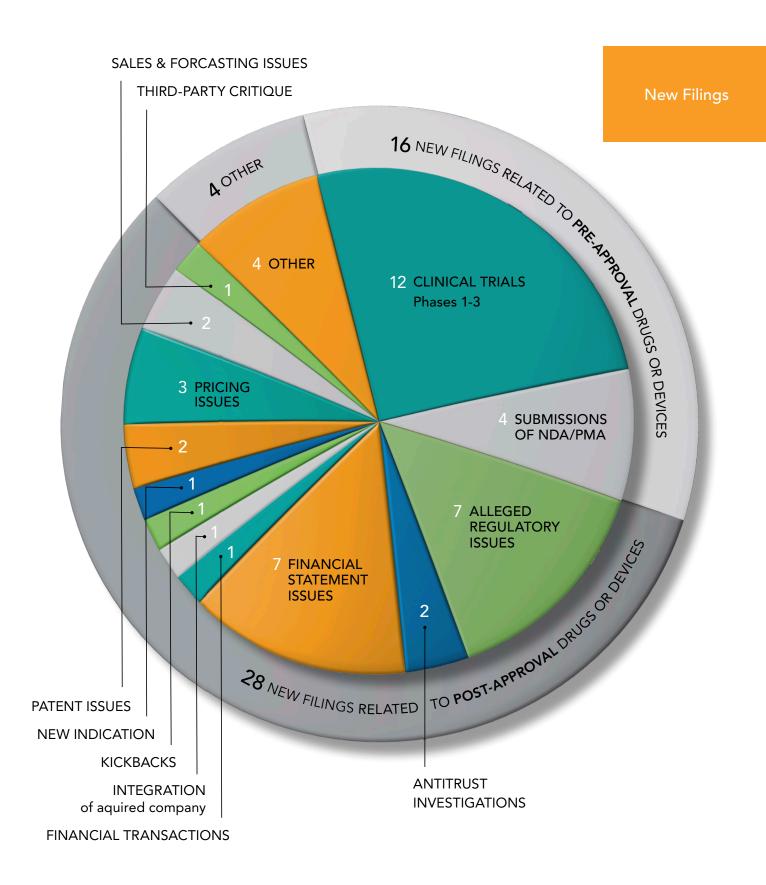
Of the 48 new actions filed in 2018, 16 were filed against companies with development stage drugs or devices. The remaining 32 actions involve a broad spectrum of regulatory and non-regulatory issues with mature products, ranging from alleged regulatory violations in the areas of data integrity, to alleged financial statement fraud, to issues concerning revenue forecasting and performance.

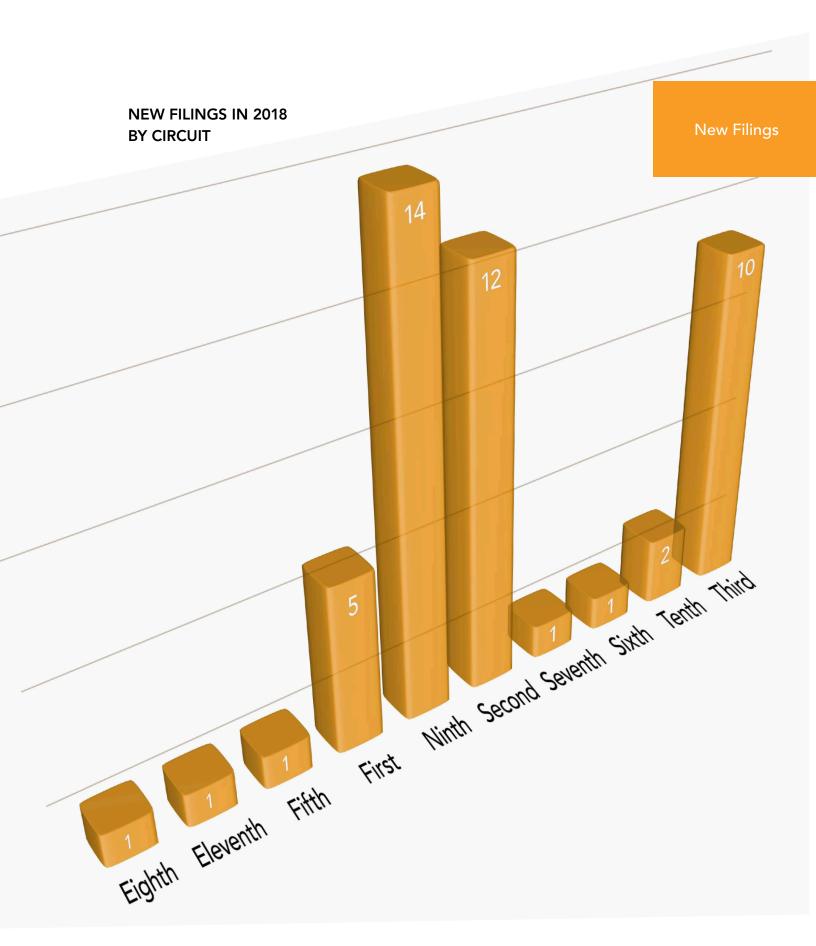
Several trends emerge from the new filings. The most significant change from 2017 to 2018 came in the number of actions in the pre-approval area, which dropped from 34 to 16. Meanwhile, actions in the post-approval area have increased—most notably, actions involving alleged financial statement irregularities.

As in previous years, the new filings are clustered in district courts in the Second, Third, and Ninth Circuits. We show the breakdown graphically on page 68.

New filings in 2018 by stage of drug or product development:

PRODUCT LIFECYCLE	SECURITIES FRAUD CLASS ACTIONS FILED IN 2018		
PRE-APPROVAL	Clinical Trials: Phases 1-3	12	
	Submission of NDA/PMA	4	
	Total Pre-Approval	16	
POST-APPROVAL	Alleged Regulatory Issues	7	
	Antitrust Investigation	2	
	Financial Statement Issues	7	
	Financial Transactions	1	
	Integration of Acquired Company	1	
	Kickbacks	1	
	New Indication	1	
	Patent Issues	2	
	Pricing Issues	3	
	Sales Forecast and Demand Issues	2	
	Third-party Critique	1	
	Total Post-Approval	28	
OTHER		4	





COMPANY	DATE	COURT	
BELLICUM PHARMACEUTICALS, INC.	2/6/2018	S.D. Texas	
BLUEBIRD BIO, INC.	12/12/2018		
SOLID BIOSCIENCES, INC.	3/27/2018		
NEKTAR THERAPEUTICS		S.D. California	
FLEX PHARMA, INC.		S.D. New York	
PROTHENA CORPORATION PLC	5/15/2018	N.D. California	
AMPIO PHARMACEUTICALS, INC.	8/25/2018	C.D. California	

**PHASE 1/2** Bellicum developed BPX-501, a T-cell therapy. Plaintiffs allege that the company's disclosures implied that the drug was proceeding through the approval process, but failed to disclose a high risk of potential brain damage. Stock prices fell after the company announced that BPX-501 studies had been placed on hold following cases of encephalopathy potentially related to the drug.

**PHASE 1/2** bluebird develops a drug to treat sickle cell disease. Plaintiffs claim that bluebird failed to disclose that the drug was less efficacious than reported. Stock prices fell following the release of Phase 1/2 trial results and the publication of an article stating that the results were worse than previously reported data.

**PHASE 1/2** Solid Bioscience's leading product candidate is a gene transfer treatment for Duchenne muscular dystrophy. Plaintiffs allege that the company failed to disclose the likelihood of adverse events related to the drug. Stock prices fell after the company reported that the FDA had placed a clinical hold on its Phase 1/2 trial in connection with a patient's unexpected adverse reaction to the drug.

**PHASE 1/2; THIRD-PARTY CRITIQUE** Nektar develops new drugs in areas of high medical need. One of the company's leading candidates is NKTR-214, an immuno-oncology drug. Plaintiffs claim that Nektar failed to disclose negative information about both the efficacy and the safety of the drug. Stock prices fell after *Seeking Alpha* published the report of a short seller claiming that the drug was not efficacious alone or in the combination the company was exploring.

**PHASE 2** Flex develops drugs to treat muscle cramps and spasms, including FLX-787, which the company was evaluating for the treatment of two diseases. Plaintiffs claim that Flex overstated the likelihood of viability and approval for the drug as a treatment for both diseases. Stock prices fell after the company announced it was halting Phase 2 trials for both indications.

**PHASE 2B** Prothena developed NEOD001, a drug intended to treat amyloid light chain amyloidosis. Plaintiffs claim that the company cited positive results from the Phase 1/2 trials while withholding negative data. Stock prices fell after the company announced that it was terminating development after the Phase 2b trial data indicated the drug was less effective than a placebo.

**PHASE 3** Ampio is in the process of developing Ampion, a treatment for inflammation caused by osteoarthritis in the knee. Plaintiffs allege that the company failed to disclose that the FDA would find its trials inadequate to support approval. The company's stock price fell after it announced that the FDA had advised the company to perform an additional Phase 3 trial before submitting a Biologics License Application.

COMPANY	DATE	COURT
EDGE THERAPEUTICS, INC.	4/23/2018	D. New Jersey
ESPERION THERAPEUTICS, INC.	5/7/2018	E.D. Michigan
OHR PHARMACEUTICAL, INC.	2/14/2018	S.D. New York
TETRAPHASE PHARMACEUTICALS, INC.	7/27/2018	S.D. New York
TG THERAPEUTICS, INC.	10/4/2018	S.D. New York
ALKERMES PUBLIC LIMITED CO.	12/27/2018	E.D. New York
ARADIGM CORPORATION	1/11/2018	N.D. California
RECRO PHARMA, INC.	5/31/2018	E.D. Penn.

**PHASE 3** Edge is a clinical-stage biotechnology company that developed a drug called EG-1962. The company discontinued its Phase 3 trial of the drug on the recommendation of the Data Monitoring Committee overseeing the study after a pre-specified interim review demonstrated a low probability of success. Plaintiffs allege that the company wrongly failed to disclose the likely failure of the trial at an earlier point. Stock prices fell after the company announced that it was discontinuing the Phase 3 trial.

**PHASE 3** Esperion produces a cholesterol-lowering medication. Plaintiffs claim that the company touted the medication's positive effects during trials but failed to warn of serious safety risks. Stock prices fell after the company reported adverse events in Phase 3 trials.

**PHASE 3** Ohr's lead drug candidate is Squalamine, a treatment for vision deterioration. Plaintiffs allege that the company made misleading statements about its Phase 2 trial and knew that its Phase 3 trial would fail. Stock prices fell after the company announced negative results in the Phase 3 trial.

**PHASE 3** Tetraphase develops an antibiotic called eravacycline. Plaintiffs claim that the company failed to disclose during a Phase 3 trial that it was increasing patient enrollment, allegedly demonstrating that the existing patient population was inadequate to meet the trial's endpoints. The trial ultimately failed to meet its primary endpoints and stock prices fell following the company's announcement of those results.

**PHASE 3** TG develops treatments for hematologic malignancies and autoimmune disorders. Plaintiffs allege that the company continued to paint itself as poised for success despite early access to data showing negative results in a Phase 3 study evaluating two of its therapies in tandem. Stock prices fell after the company failed to meet its target date for releasing the data. Prices fell again after the company announced the study had failed to meet its endpoint.

**NDA** Alkermes manufactures ALKS 5461, designed to treat depression. Plaintiffs claim that Alkermes made positive statements about its NDA process for the drug while failing to disclose that the FDA had advised the company to use different trial methodologies. Stock prices fell after the company reported that the FDA had issued a Refuse to File Letter. After the company later successfully filed an NDA and the advisory committee voted against approval, stock prices fell again.

**NDA** Aradigm develops inhalable drugs, including Linhaliq, an inhalable version of an antibiotic to treat infections associated with respiratory disorders. Plaintiffs claim that the methodologies and endpoint for the Phase 3 trials were faulty. Stock prices dropped after FDA staff released an advisory committee briefing document raising concerns about certain elements of the trial design.

**NDA** Recro develops non-opioid pain treatments. Plaintiffs claim that the company failed to disclose that its leading drug product lacked the clinical data necessary for FDA approval. The company's stock price fell after the FDA rejected the company's NDA.

COMPANY	DATE	COURT
TREVENA, INC.	10/10/2018	
ACADIA PHARMACEUTICALS INC.	7/19/2018	
IMMUNOMEDICS, INC.	12/27/2018	D. New Jersey
MYRIAD GENETICS	4/20/2018	
ALLERGAN PLC	12/21/2018	
ROCKWELL MEDICAL, INC.	7/27/2018	E.D. New York
AKORN, INC.	3/8/2018	N.D. Illinois

**NDA** Trevena is the developer of oliceridine, a pain medication. Plaintiffs allege that the company misleadingly reported that in its End-of-Phase 2 meeting with the FDA, the parties had reached agreement on key issues related to Phase 3 trials. Stock prices fell after FDA staff released an advisory committee briefing document in connection with review of the company's NDA. According to plaintiffs, the briefing materials showed areas of fundamental disagreement between the company and the agency. The FDA later denied the company's NDA.

**POST-APPROVAL; ALLEGED REGULATORY ISSUES** Acadia produces Nuplazid, a treatment for psychosis induced by Parkinson's Disease. Plaintiffs claim that the company downplayed information about adverse events and engaged in other practices likely to attract regulatory scrutiny. Stock prices fell after the company announced disappointing Nuplazid sales in Q4 2017 and fell again in April 2018 and July 2018 following negative media and other third-party coverage related to the safety of the drug and the propriety of the company's interactions with prescribing physicians.

**POST-APPROVAL; ALLEGED REGULATORY ISSUES** Immunomedics develops targeted antibody-based treatments for cancer. Plaintiffs allege that Immunomedics failed to disclose that the FDA had cited the company for issues related to data integrity. Stock prices fell after the FDA citations and a report on the data integrity breach were publicized.

**POST-APPROVAL; ALLEGED REGULATORY ISSUES** Myriad provides molecular diagnostic products. Plaintiffs allege that the company engaged in improper Medicare and Medicaid billing practices. Share prices fell after the company announced a Department of Health and Human Services investigation into its billing practices.

**POST-APPROVAL; ALLEGED REGULATORY ISSUES** Allergan develops and manufactures products including breast implants and tissue expanders. Plaintiffs claim that the company misled investors by hiding the fact that the CE Mark, a certification of compliance with European health and safety standards, for these products was expiring. Stocks dropped after the Mark expired and the company withdrew the products from European markets.

**POST-APPROVAL; ALLEGED REGULATORY ISSUES** Rockwell sells products to treat kidney disease. Plaintiffs allege that the company repeatedly touted the likelihood that its leading drug would gain approval for separate – as opposed to bundled – Medicare and Medicaid reimbursement, even after it knew that this would not be the case. Stock prices fell after the company's auditor resigned over disclosure issues related to reimbursement.

**POST-APPROVAL; ALLEGED REGULATORY ISSUES** Akorn is a pharmaceutical company that was to be acquired by a larger healthcare company, Fresnius. Plaintiffs allege that Akorn suffered from significant data integrity problems, including the submission of false data to the FDA, and that it covered up those problems in order to facilitate the acquisition. Stock prices fell after Fresnius announced that it was terminating the proposed acquisition based on its investigation into the data integrity issue.

COMPANY	DATE	COURT
TESARO, INC.	1/17/2018	D. Mass
HENRY SCHEIN, INC.	3/7/2018	E.D. New York
PATTERSON COMPANIES, INC.	3/28/2018	D. Minnesota
AKERS BIOSCIENCES, INC.	6/13/2018	D. New Jersey
MABVAX THERAPEUTICS HOLDINGS	6/4/2018	S.D. California
MIMEDX GROUP, INC.	2/23/2018	N.D. Georgia
OBALON THERAPEUTICS, INC.	2/14/2018	S.D. California

POST-APPROVAL; ALLEGED REGULATORY ISSUES Tesaro develops cancer therapeutics and related care products. Its principal drug is Varubi, for the prevention of chemotherapy-induced nausea and vomiting. Varubi was approved for intravenous use in 2017. Plaintiffs allege that the company failed to disclose health risks associated with intravenous Varubi. Stock prices fell after Tesaro announced that it was issuing new labeling and "Dear Healthcare Provider" letters following instances of anaphylaxis, anaphylactic shock and other serious hypersensitivity disorders in some patients receiving intravenous Varubi.

**POST-APPROVAL; ANTITRUST INVESTIGATION** Henry Schein is a provider of healthcare products and services across several industries. Plaintiffs allege that the company failed to disclose that it colluded with other dental products companies to maintain profitability. The company's stock price fell when it reported weaknesses in the dental business and fell further when the FTC filed a lawsuit against the company.

**POST-APPROVAL; ANTITRUST INVESTIGATION** Patterson is a distributor of dental supplies. Plaintiffs allege that the company failed to disclose that it colluded with other major dental products companies to maintain profitability. Stock prices dropped after the FTC filed a complaint against the company following a three-year investigation.

**POST-APPROVAL; FINANCIAL STATEMENT ISSUES** Akers develops and supplies rapid screening products. Plaintiffs allege that the company improperly recognized revenue and downplayed reports of weaknesses in its internal controls. Stock prices fell after the company submitted a series of Forms 8-K to the SEC detailing potential financial statement issues and a dispute between a former director and the company.

**POST-APPROVAL; FINANCIAL STATEMENT ISSUES** MabVax develops antibody-based products. Plaintiffs allege that the company lacked required internal controls over financial reporting and allowed improper influence over the company by certain stockholders. The company's share price fell after it announced an SEC investigation into these issues.

**POST-APPROVAL; FINANCIAL STATEMENT ISSUES** MiMedx is a medical device and supply company. Former employees filed a whistleblower action against the company, alleging that they had reported channel stuffing and had been terminated in retaliation. The company initially denied the employees' charges but later announced that it was undertaking an investigation into their claims and that its next Form 10-Q would not be timely filed. The company's stock price fell following the latter announcement.

**POST-APPROVAL; FINANCIAL STATEMENT ISSUES** Obalon produces an FDA-approved gas-filled balloon that patients swallow in an effort to achieve weight loss. Plaintiffs allege that the company oversold the balloon's usability despite negative trial results and then improperly recognized revenue to cover up lagging sales. They also allege the company hired an undisclosed stock promoter. Stock prices fell after a whistleblower disclosed the accounting practices to the company's auditor and the company later conceded inflated revenues.

COMPANY	DATE	COURT
TESARO, INC.	11/9/2018	D. Mass.
SYNERGY PHARMACEUTICALS INC.	2/8/2018	E.D. New York
CANCER GENETICS, INC.	4/5/2018	D. New Jersey
ABBVIE, INC.		C.D. California
BRISTOL-MYERS SQUIBB COMPANY		S.D. New York
NEVRO CORPORATION	8/23/2018	N.D. California
CELGENE CORPORATION	3/29/2018	D. New Jersey

**POST-APPROVAL; FINANCIAL STATEMENT ISSUES** Tesaro develops cancer therapeutics and related care products. The FDA approved its principal drug, Varubi, for oral use in 2015. In a Form 10-Q filed November 4, 2016, the company stated that its cash and expected cash from sales of Varubi were expected to be sufficient to fund operations for 12 months. Plaintiffs allege that this was not the case. Stock prices fell after the company announced a secondary offering on November 14, 2016.

**POST-APPROVAL; FINANCIAL TRANSACTIONS** Synergy's only commercial product is Trulance, a treatment for chronic idiopathic constipation. Plaintiffs allege that the company misled the public about the drug's side effects and about the terms of a major loan. Stock prices fell after Trulance was excluded as a covered drug for a major pharmacy benefits manager, and fell again after disclosure of the loan's terms.

**POST-APPROVAL; INTEGRATION OF ACQUIRED COMPANY** Cancer Genetics, a DNA-based diagnostics company acquired Response Genetics, also a diagnostics company. Plaintiffs allege that Cancer Genetics touted the acquisition as a success but failed to integrate the two companies' billing and invoice systems for several years. Stock prices dropped after Cancer Genetics announced that integration issues had led to financial losses.

**POST-APPROVAL; KICKBACKS** AbbVie is the developer of HUMIRA, a leading arthritis drug. Plaintiffs claim that the company implied that expanding sales of HUMIRA were key to its success while hiding kickbacks to healthcare providers to inflate sales. Stock prices dropped after California sued AbbVie for engaging in a kickback scheme.

**POST-APPROVAL; NEW INDICATION** Bristol-Myers is a global biopharmaceutical company that produces Opdivo, a drug used to treat certain cancers. Plaintiffs allege that the company was overly optimistic in predicting the results of a trial to support a new indication. Stock prices fell after the company announced the trial had failed.

**POST-APPROVAL; PATENT ISSUES** Nevro manufactures FDA-approved medical devices for the treatment of chronic pain. Plaintiffs claim that the company knowingly used confidential and proprietary information belonging to another company to develop the devices. The other company sued Nevro for patent infringement and theft of trade secrets. Stock prices fell after Nevro revealed significant litigation expenses, the judge overseeing the trade secrets litigation issued an unfavorable tentative ruling and analysts downgraded the stock.

**POST-APPROVAL; PATENT ISSUES** Celgene is a biotechnology company with a successful drug, Revlimid, that will lose patent exclusivity in the next few years. Plaintiffs allege that Celgene made misleading statements about the prospects of three drugs it hoped would replace Revlimid revenues. According to plaintiffs, the company failed to disclose negative Phase 1/2 trial results for one drug, overstated the likelihood of approval for another, and failed to disclose waning sales for the third. Stock prices dropped after these issues emerged.

COMPANY	DATE	COURT
ALIGN TECHNOLOGY, INC.	11/5/2018	N.D. California
DENTSPLY SIRONA, INC.	12/19/2018	
MCKESSON CORPORATION	10/25/2018	N.D. California
ACETO CORPORATION	4/24/2018	E.D. New York
RESTORATION ROBOTICS, INC.	6/21/2018	N.D. California
LANNETT CO.	8/24/2018	E.D. Penn.
ALNYLAM PHARMACEUTICALS, INC.	9/26/2018	D. Mass.

**POST-APPROVAL; PRICING ISSUES** Align Technology sells Invisalign, a clear device for treating misaligned teeth. Plaintiffs allege that Align misled the public as to the extent of discounts offered for Invisalign. Stock prices dropped after the company announced that the average retail price for the product had fallen and dropped again after the company announced that its Chief Marketing Officer would be working only part-time.

**POST-APPROVAL; PRICING ISSUES** Dentsply Sirona is a manufacturer of dental products. Plaintiffs claim the company knowingly misled the public about product demand and also knew that an anticompetitive conspiracy among dental supply distributors was driving up prices. Stock prices fell after a series of announcements related to an SEC investigation and the departure of high-ranking officers.

**POST-APPROVAL; PRICING ISSUES** McKesson is a supplier of pharmaceuticals, medical supplies and healthcare technology. Following the filing of a private antitrust action against McKesson, securities plaintiffs filed a complaint alleging that the company knew about but failed to disclose anticompetitive practices among generic drug manufacturers. Stock prices dropped after McKesson announced disappointing financial results purportedly triggered by the ending of the alleged price fixing conspiracy.

**POST-APPROVAL; FINANCIAL STATEMENT ISSUES** Aceto develops, markets, and distributes drugs and pharmaceutical products. Plaintiffs allege that the company misstated its financial results and failed to disclose a lack of effective internal controls. Stock prices fell after the company, citing persistent adverse conditions in the generic drug market, recorded a large goodwill impairment charge, withdrew previously issued financial guidance, and announced that it was exploring strategic alternatives while negotiating a waiver of debt service covenants with its lenders.

**POST-APPROVAL; SALES AND FORECASTING ISSUES** Restoration Robotics manufactures an FDA-approved device to assist in hair transplants. Plaintiffs claim that, in the run-up to an IPO, the company misled the public about its ability to expand the hair transplant market, the reliability of its devices, and the numbers of devices actually sold.

**POST-APPROVAL; SALES AND FORECASTING ISSUES** Lannett develops and distributes primarily generic drugs. Plaintiffs allege that the company failed to disclose that there was a high risk of losing an exclusive distribution agreement on which revenue depended. Stock prices fell after the company announced that the distribution agreement would not be renewed.

**POST-APPROVAL; THIRD-PARTY CRITIQUE** Alnylam develops ONPATTRO, an RNAi therapeutic for the treatment of hereditary ATTR amyloidosis. Plaintiffs allege that the company overstated the safety and efficacy of ONPATTRO. Stock prices fell after an analyst issued a report claiming that a review document issued by the FDA's Center for Drug Evaluation and Research highlighted safety issues and limited market opportunities.

COMPANY	DATE	COURT
EKSO BIONICS HOLDINGS, INC.	1/2/2018	N.D. California
POLARITYTE	6/26/2018	D. Utah
JOHNSON & JOHNSON	2/8/2018	D. New Jersey
CV SCIENCES	8/24/2018	D. Nevada
COCRYSTAL PHARMA, INC.	9/20/2018	D. New Jersey

**POST-APPROVAL; FINANCIAL STATEMENT ISSUES** Ekso produces wearable exoskeletons. Plaintiffs allege that the company failed to disclose a material weakness in the company's internal controls. After the company disclosed the weakness, its stock price fell.

**OTHER; PATENT ISSUES** As a result of a merger, PolarityTE owned a patent application for a skin regeneration and treatment technology. This application was listed as the company's key asset in SEC filings. Plaintiffs allege that the company failed to disclose that, a week before the merger, the original owner of the patent application received a non-final rejection notice. Stock prices fell after the patent was finally rejected.

**OTHER; PRODUCT ISSUES** Plaintiffs claim that Johnson & Johnson knowingly concealed that products containing talc and talcum-powder were contaminated with asbestos and could cause cancer. Stock prices dropped after consumers filed product-liability actions that attracted widespread public attention.

**OTHER; THIRD-PARTY CRITIQUE** CV Sciences makes a chewing gum that combines cannabidiol and nicotine to treat tobacco addiction. Plaintiffs allege that the company repeatedly advertised the product as proprietary and patent-pending, despite knowing the patent application had already been rejected. Stock prices dropped after a writer for Citron Research sent a tweet claiming that the patent application had previously been rejected.

**OTHER; STOCK PROMOTION; MANIPULATIVE TRADING** Cocrystal, formerly BioZone, is a clinical stage biotechnology company. Plaintiffs allege that the company's principal shareholders fraudulently created the appearance of an active market for the stocks and failed to disclose that the company had hired a stock promoter to laud the stocks. The company's stock price fell after the SEC announced charges against the company's principal shareholders related to stock manipulation and stock promotion.

#### **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 on the Securities and Shareholder Litigation practice, please contact:



**SARA B. BRODY** +1 415 772 1279 sbrody@sidley.com



NORM BLEARS +1 650 565 7103 nblears@sidley.com



WALTER C. CARLSON +1 312 853 7734 wcarlson@sidley.com



JAMES W. DUCAYET +1 312 853 7621 jducayet@sidley.com



YOLANDA C. GARCIA +1 214 981 3414 ygarcia@sidley.com



DAVID F. GRAHAM +1 312 853 7596 dgraham@sidley.com



**YVETTE OSTOLAZA** +1 214 981 3401 yvette.ostolaza@sidley.com



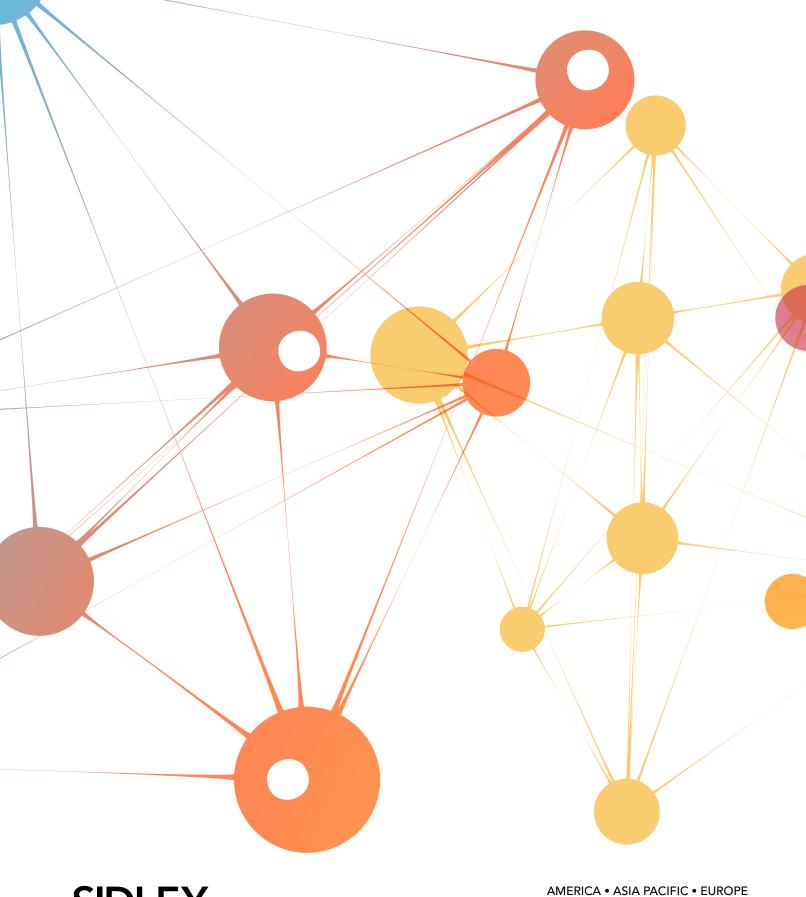
JACK W. PIROZZOLO +1 617 223 0304 jpirozzolo@sidley.com



HILLE R. SHEPPARD +1 312 853 7850 hsheppard@sidley.com



ANDREW W. STERN +1 212 839 5397 astern@sidley.com



**SIDLEY** 

sidley.com

Attorney Advertising - Sidley Austin LLP, One South Dearborn, Chicago, IL 60603. + 1 312 853 7000. Sidley and Sidley Austin refer to Sidley Austin LLP and affiliated partnerships as explained at www.sidley.com/disclaimer. Prior results do not guarantee a similar outcome. Photos may include Sidley alumni or other individuals who are not Sidley lawyers. Photos may be stock photographs.