SECURITIES CLASS ACTIONS IN THE LIFE SCIENCES SECTOR
2016 Annual Survey
SIDLEY
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 litigation, investigations and regulatory enforcement proceedings. The authors thank Sidley associates Stephen Chang and Naomi Igra and Sidley summer associate Zhize Wang for their research assistance.

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INTRODUCTION AND OVERVIEW

This year-in-review addresses developments in securities class actions brought against life sciences companies in 2016. 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. Next, we provide summaries of the 41 federal district court and appellate court decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2016.

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 IN THE FOLLOWING AREAS:

- **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.
- **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 or other statutory or regulatory violations.
- **Other Regulatory Issues** — Changes in label or product design that may trigger regulatory obligations.

NON-REGULATORY ISSUES

- **Sales and Sales Forecasting**
- **Other Issues Not Specific to Life Sciences Companies**

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

In this section, we discuss the reported federal decisions issued in securities actions at the pleading stage. Unless otherwise noted, these decisions concern class actions brought under Section 10(b) of the Securities Exchange Act of 1934. In 25 of the 33 cases at the district court level, courts granted defendants’ motions to dismiss; in the remaining eight cases, the motions were denied at least in part. The appellate decisions stem from plaintiffs’ appeals of orders granting defendants’ motions to dismiss (or, in a few cases, motions for summary judgment). The appellate courts affirmed dismissal in five of the eight cases discussed below and reversed in three. This activity can also be represented graphically by reference to stage of drug or device development, as shown on the page opposite.

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2 Under Section 10(b), life sciences companies and their officers may be liable for consciously false or misleading statements made in virtually any public context, including press releases, earnings calls, investors conferences and SEC filings. Defendants may also be liable for participating in a “scheme” to defraud; successful scheme claims, however, are rare. (We discuss only one in the 41 cases surveyed.) Several cases discussed in this review include claims under Sections 11 and 12 of the Securities Act of 1933 as well as 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.
Decisions related to the APPROVAL process

- 26 decisions

Decisions related to LAUNCH-STAGE issues

- 12 decisions

Decisions related to OTHER MATURE PRODUCT issues

- 7 decisions

Decisions related to MANUFACTURING defects

- 2 decisions

Decisions related to STOCK PROMOTION activities

- 3 decisions
PRE-APPROVAL CASES

In 2016, as in 2015, the district court decisions in securities fraud cases involving pre-approval products broke decisively in favor of defendants. The district courts granted defendants’ motions to dismiss in 17 cases and denied defense motions in only four. Appellate decisions, again as in 2015, were more evenly split, with three victories for defendants, one victory for plaintiffs, and one decision affirming dismissal in large part but also reinstating plaintiffs’ claims in part.3

As a substantive matter, the courts have continued to consolidate the law around several principles generally helpful to life sciences companies. As in 2015, decisions have continued to mount up in support of the proposition that companies with drugs in development are not required to report every interim communication with regulators. The courts are sensitive to the give-and-take nature of the approval process, and recognize that regulators often take positions that are subject to change.

Courts in 2016 have also often applied a distinctly practical approach to questions of intent. They have rejected theories of fraud that depend on the premise that a company knew from an early stage that a drug would not be approved but nevertheless continued to pour resources into the approval process. Similarly, courts have rejected the premise that the failure of a Phase 2 or Phase 3 trial could have been predicted from some aspect of an earlier trial; the courts recognize that the FDA would not continue to support clinical testing under such circumstances, and that companies would not continue to make expenditures they knew would lead nowhere.

The 2016 decisions also show that courts continue to recognize institutional limitations in adjudicating issues that turn on disputes over science or medicine. In several cases, courts have rejected claims that depend on the contention that a drug candidate or trial methodology was based on faulty science. These courts have held that they neither can nor should resolve such disputes. There are limits in this area, however. Courts will draw the line when companies affirmatively characterize trial results as uniformly positive in a case where an opposing viewpoint is manifest. A leading decision in 2016 for companies with development-stage drugs—the Ninth Circuit’s ruling in Arena Pharmaceuticals (page 26)—illustrates this point. The Ninth Circuit explained pointedly there that even if a company believes it has the better of the FDA on an issue of scientific disagreement, it is misleading to describe the evidence in a way that suggests that no controversy exists.4

We discuss the issue of scientific disagreement in more depth below, and then turn to salient developments in three other areas: (1) the largely pro-defendant law on interim communications with regulators; (2) the largely pro-defendant commonsense approach to scienter; and (3) the continuing development of the law regarding statements of opinion following the Supreme Court’s 2015 Omnicare decision.

Scientific Disagreement

For several years, the courts have rejected securities fraud claims in which plaintiffs challenge on scientific grounds some aspect of a company’s clinical trials or case for approval. In its leading Kleinman decision, the Second Circuit in 2013 distinguished between a critique of trial methodology—which courts are not equipped to evaluate—and a challenge to a company’s public statements on their own terms—which courts handle routinely.5

In 2016, courts have continued to apply Kleinman’s basic holding. A good example is Cellceutix (page 27), from the Southern District of New York, in which plaintiffs questioned the company’s choice of a particular efficacy biomarker in Phase 1 trials. The district court rejected plaintiffs’ challenge in strong terms:

> [S]ecurities law is not a tool to second guess how clinical trials are designed and managed…
> [T]he idea that [a particular biomarker] could serve as a meaningful indicator of [the drug’s] effects is a non-actionable medical opinion…[The complaint] alleges at most that there are

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3 This excludes the decisions dealing with stock promotion activity, which we discuss separately below.
4 In this discussion 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.
5 Kleinman v. Elan Corp., 706 F.3d 145 (2d Cir. 2013). Citation information for other cases discussed in this section is provided in the summaries immediately following.
research scientists who believe that [the biomarker] does not correlate with improved prognoses...Securities law is simply not a vehicle through which courts will police disagreements in the cancer research community or the parameters of clinical trials...
The Court is certainly not in the position to evaluate the scientific validity of [a party’s] explanation...

While these principles are not new, they are forcefully stated in Cellceutix. The concept of a “non-actionable medical opinion” in particular may provide a useful sound bite for securities defendants with development-stage products.

Given the clarity of Kleinman’s essential holding, securities plaintiffs do not often directly challenge a company’s public statements on scientific grounds. A more nuanced plaintiffs’ technique—and one that appeared often in 2016 decisions—is to argue that facts relating to earlier trials provided sufficient information for a company to conclude that later trials would fail. This was the plaintiffs’ theory, for example, in Celladon (page 28), where plaintiffs claimed that flaws in randomizing patients between placebo and treatment arms in Phase 2a trials put the company on notice that its Phase 2b trials would fail. Likewise, in both Aerie Pharmaceuticals (page 31) and Sapir v. Averback (page 32), plaintiffs argued that critical differences between earlier and later studies showed that the later trials would fail where the earlier trials had succeeded. For varying reasons, the courts rejected plaintiffs’ theories in all of these cases: The theories were not supported by factual allegations, or the company had sufficiently described the differences between earlier and later trials. But at least implicitly informing these decisions was the courts’ institutional reluctance to delve deeply into areas in which they lack expertise. In each case, plaintiffs were in essence second-guessing the company’s scientific judgment that a trial could succeed. And in each case, the court declined to endorse that effort.

Courts’ deference to development-stage companies in this area can be of service to defendants even in cases where scientific disagreement is manifest in a company’s interactions with regulators. In Endocyte (page 32), plaintiffs claimed not only that alleged flaws in Phase 2 trials put the company on notice that its Phase 3 trials would fail, but also that the FDA had brought those flaws to the company’s attention. The court rejected plaintiffs’ argument that the company had an obligation to disclose the alleged flaws. Citing Kleinman and other cases, the court concluded that plaintiff had “not pled any facts to distinguish [their situation] from the long line of cases wherein interim FDA criticism regarding study design was considered part of an ongoing dialogue.”

Nevertheless, it would be a mistake to conclude that companies have complete freedom to describe trial results in a positive way whenever they believe that scientific evidence supports their favorable views. In the pre-approval space, the overarching question is whether the product will be approved. And this depends not only on whether the company is right about the science but also on whether regulators agree that the company is right about the science. In cases where a company’s positive statements affirmatively mask the fact that regulators have expressed a negative view of some aspect of the company’s efforts, courts will permit plaintiffs to move forward with fraud claims.

This was the case in Arena Pharmaceuticals (page 26), where the developer of a weight-loss drug told investors that all of the trials it had conducted, both human and animal, had yielded positive results. The company did not disclose that rats given a high dose of the drug had developed tumors, and that the FDA had expressed concerns about carcinogenicity on that basis. In defending its statements, the company argued that it believed at all times that the results in the rat study could be explained in a way that would rule out safety concerns for humans. The Ninth Circuit rejected the argument, reversing the district court’s dismissal and holding that the case involved more than simply “a good-faith scientific disagreement between the FDA and [the company].” According to the Ninth Circuit, the simple fact that [the company] had an explanation for its view of the data does not mean investors would not want to know that [the company] and the FDA were at odds...It is the failure to disclose “issues” and “concerns” with the Rat Study and the FDA’s interest in the outcome of those studies—not who was ultimately right about the underlying science—that matters.
The court also qualified its holding in an important way, explaining that the company “could have remained silent about [its] dispute” with the FDA. The duty to disclose arose only because the company’s positive statements amounted to a representation “that there was no controversy here because all the data was favorable.”

The same limitation on a company’s freedom to make certain kinds of positive statements in the face of scientific disagreement emerges from Ariad Pharmaceuticals (page 25). In Ariad, as in Arena, the appellate court reversed a defense victory on a motion to dismiss. The reversal was only a partial one in Ariad. The First Circuit reinstated plaintiffs’ claims with respect to a single statement made in the course of a two-year-long class period. This was a statement of optimism that the FDA would approve the company’s leukemia drug with a favorable safety label. At the time the statement was made, the FDA had rejected the company’s proposed label based on an 8 percent rate of serious cardiovascular events. The First Circuit held that in light of that rejection, plaintiffs had sufficiently pled that the company’s optimistic statement was misleading: “While management may have held out hope of achieving [the desired label], the expression of that hope without disclosure of recent troubling developments created an impermissible risk of misleading investors.” Thus in Ariad, as in Arena, the company’s unequivocally positive description triggered a duty to disclose the FDA’s dimmer view of what the data showed.

A district court decision, Aeterna Zentaris (page 36), shows that a company may assume a duty to disclose potential weaknesses in its position on scientific matters even in the absence of a disagreement with regulators. In Aeterna, the company’s NDA included an analysis based on a modified intent-to-treat population rather than the original intent-to-treat population in a Phase 3 trial. The company’s rationale for making the modification was that two subjects in the trial should not have been included because they did not have the condition the drug was intended to treat. The court held that because this modification (allegedly) breached the trial protocol, the company could not make positive statements about the trial results without also disclosing the modification, which put approval into question:

Even if [the company] had not believed this modification in the study would have adversely affected its application, the modification warranted some disclosure to investors, especially in light of the prior ongoing positive statements during the approval process.

A final district court decision, STAAR Surgical (page 37), illustrates similar principles at work on a slightly different fact pattern. There, the company told investors that it was in compliance with applicable regulations but did not disclose that it had been unable to produce required documentation during a facilities inspection. After the inspection, the FDA issued a warning letter stating that no new products would be approved until manufacturing issues were resolved. The court rejected the company’s argument that the FDA may have been incorrect in finding at the time of the inspection that the company’s documentation was inadequate. “Far more important is Defendants’ alleged failure to disclose to its investors that the FDA did come to that conclusion, which could postpone approval of the much-anticipated [product].”

The 2016 decisions, in sum, continue to build on the distinction set out in Kleinman in 2013. Where a plaintiff’s claim is based on a challenge to the science underlying a company’s trial design or analysis, the courts will generally dismiss that claim. But where plaintiffs can point to a statement that affirmatively conceals an existing or anticipated dispute over science, plaintiffs will generally be permitted to move beyond the pleading stage into discovery.

Interim Communications With Regulators

In 2016, as in 2015, courts confronted a significant number of cases in which plaintiffs claimed that companies committed fraud by failing to disclose negative comments made by regulators at an interim stage in the process. In most cases, investors become aware of the full range of communications with regulators only at the end of the approval process, when FDA staff publish briefing documents setting forth earlier developments. As we discussed in our 2015 review, courts have begun to consolidate the law holding that securities defendants have no duty in the first instance to disclose interim communications. Courts in 2016 have continued to build on the point. Indeed, several of the decisions discussed in the previous section illustrate both the pro-defendant principle—the absence of a general duty to disclose interim communications
with regulators—and its limitation—that such a duty will arise if a company makes affirmative statements rendered misleading by virtue of the omitted information.

*Arena Pharmaceuticals* (page 26) is again a leading case. The Ninth Circuit explained there that the developer of a weight-control drug had no duty in the first instance to disclose the FDA's concerns about trials in which rats given high doses of the drug had developed tumors. But the company took on such a duty when it represented that all studies, including the animal studies, supported approval. Much the same was true in *Ariad* (page 25), where the company expressed optimism about a favorable safety label without disclosing the fact that the FDA had already indicated that it would not approve the company’s proposed label. Likewise in *STAAR Surgical* (page 37), the court rejected the company’s argument that it had no duty to disclose the FDA's non-final observation that it had failed to comply with documentation requirements. Because the company had affirmatively stated that it was in substantial compliance with FDA regulations, it had a duty to disclose facts that contradicted that statement.

On the other side of the ledger are decisions in which courts have agreed that defendants had no obligation to disclose interim communications. In addition to articulating that rule in helpful ways, these courts have applied it to a variety of types of interim communications. Their holdings may therefore serve as useful precedents in future cases in which similar kinds of regulatory communications are at issue.

- In *Endocyte* (page 32), the court referred to the “long line of cases wherein FDA criticism …was considered part of an ongoing dialogue and was, therefore, determined to be immaterial.” The court applied that line of cases in rejecting plaintiffs’ claim that the company had wrongfully failed to disclose, in connection with Phase 3 trials, the FDA’s alleged criticism during a face-to-face meeting of aspects of the company’s successful Phase 2 trials.
- In *Vivus* (page 35), the district court drew on precedent holding that Section 10(b) “do[es] not create an affirmative duty to disclose any and all material information,” and that companies are not required to disclose regulatory communications that “do not represent a final agency determination.” Applying these principles, the court rejected plaintiffs’ claim that the company had wrongfully failed to disclose comments in interim reports issued by the Committee for Medicinal Products for Human Use, which reviews drugs for approval in the European Union.
- In *QRX* (page 34), the court stated that it is “well established that there is no affirmative duty to disclose the substance of interim feedback received from the FDA during the pendency of a drug application.” The court applied this law in rejecting plaintiffs’ claim that the company had a duty to disclose a series of FDA No Agreement Letters, which the company received in response to its attempt to obtain a Special Protocol Assessment for its Phase 3 trials.
- In *Sarepta* (page 29), the court held that the company had no duty to disclose where “there was no final decision to communicate—merely interim feedback in the context of an ongoing dialogue on [the company’s] planned NDA submission, which had yet to be filed.” The court rejected plaintiffs’ claim that the company wrongly failed to disclose the FDA’s request for a reassessment of data from trials the company intended to use to support its NDA. The court also rejected a fairly novel argument by plaintiffs—that the company’s failure to release the full text of FDA guidance documents was indicative of fraud.
- In *Amarin* (page 33), the court held, as it had in a 2015 order in the same case, that the company had no obligation to report FDA comments from a face-to-face meeting relating to the significance of other parties' trials for the company's own NDA. The company had made no statements inconsistent with the FDA’s comments at the meeting.
- Finally, in *Tongue v. Sanofi* (page 24), the Second Circuit affirmed a 2015 decision in which the district court held that “[t]he law [does] not impose an affirmative duty to disclose the FDA’s interim feedback just because it would be of interest to investors.”

In sum, while there are limitations to the interim communication rule, the 2016 decisions have continued to build pro-defendant law in this area.
A Commonsense Approach to Scienter

In assessing allegations of scienter, multiple courts in 2016 have applied a practical approach. The courts have focused on the motivations and actions of companies both in developing drugs for approval and in communicating with the market about the approval process.

Several courts have observed that the claim by plaintiffs that a company knew it would fail to obtain approval is undercut by the company’s continued investment of resources in the approval process. This line of analysis is well illustrated by QRX (page 34):

>[As pled, the scheme that the [complaint] imagines lacks a coherent rational objective. The [complaint] alleges that QRX, with [its CEO] at the helm, knew for years…that [its drug] would face a heightened proof hurdle…that it could not clear. Nevertheless, it alleges, QRX continued to invest substantial time and resources in clinical studies and NDA submissions that it knew were doomed to fail, all the while misrepresenting to the public that approval was likely. That QRX’s principals harbored this state of mind is implausible.

Similarly, in Endocyte (page 32), the court noted that the company continued to fund Phase 3 studies for years after the event that, in plaintiffs’ view, signaled that approval would not occur. The court found that the company’s continued funding undermined any inference that defendants knew that the Phase 3 study would fail to establish efficacy. The court also noted that the FDA’s continued support for the trial undercut an inference that the company knew the FDA would ultimately deny approval.

This line of reasoning is ideally suited to aid companies with drugs at the pre-approval stage in defeating scienter allegations. The logic of these cases grows directly out of the pre-approval context itself, in which companies expend very significant resources by continuing to pursue approval.

A different line of scienter analysis takes off from a company’s risk disclosures or other cautionary statements. Under the PSLRA, risk disclosures can be effective in taking certain forward-looking statements entirely outside of the zone of liability. If forward-looking statements are identified as such and are accompanied by meaningful cautionary language, then they are protected under statutory safe harbor provisions. But even outside of those provisions, risk disclosures may defeat plaintiffs’ claims. Courts have found that transparency about risk generally undercuts the inference that a company is seeking to defraud investors. And this can lead to dismissal of all claims, not just claims in which forward-looking statements are challenged.

This was the case in Vivus (page 35), where the court found that the thoroughness of the company’s risk disclosures—which specifically included the risk that European regulators might require an additional expensive trial—negated the inference that the company sought to conceal that possibility from investors. In XBiotech (page 31), similarly, the court found that specific enrollment figures in the company’s stock offering documents undercut plaintiffs’ claim that the company was trying to hide difficulties in enrolling patients. In Zafgen (page 30) too, the court found that the company’s offering documents disclosed risks of the type plaintiffs complained had been concealed. There, the company’s disclosure of serious adverse events in a Phase 2 trial undercut the inference that the company sought to defraud investors by failing to disclose superficial adverse events. Finally, in Sarepta (page 29), the court found that a series of 8-Ks disclosing the company’s interactions with the FDA negated the inference that defendants were fraudulently concealing other regulatory communications.

Taken together, these decisions show that courts are willing to look at the totality of a company’s disclosures in assessing scienter, and that robust disclosures and transparency generally may go a long way toward defeating fraud claims.

A final positive decision illustrates the courts’ willingness to examine scienter in a practical way even where a company has made a concededly false statement. In Vertex (page 24), the developer of a cystic fibrosis drug misstated Phase 2 trial results, erroneously reporting that patients had experienced an absolute increase in lung function. The company’s stock price soared on the announcement. Three weeks later, the company corrected the error, explaining that patients had experienced only a relative increase in lung function—still a positive outcome, but not the breakthrough the earlier announcement had suggested. In affirming the district court’s dismissal, the First Circuit pointed to the irrationality of plaintiffs’ claim that the company had knowingly made an error it would need to correct later. “Announcing good results on [the Phase
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2] study would have been clearly better for Vertex than announcing great results only to reduce them to good results by shortly thereafter confessing error, thereby harming the company’s credibility and its reputation for competence.” In Vertex, as in the cases discussed above, the scienter analysis ultimately turned on a very human view of motivation and behavior, rather than on more technical factors.

There is a potential downside to such commonsense approaches to scienter, although it was manifest in only one pre-approval case this year. This is the “core operations” theory, in which scienter is inferred in cases where the subject matter of the alleged fraud is of such central importance to a company that it would be irrational to posit that defendants did not know fraud was occurring. This theory and its limitations are set out in a series of Ninth Circuit decisions culminating with South Ferry v. Killinger in 2008. In 2016, the theory was applied in Acadia, one of only four district court decisions involving pre-approval products in which a motion to dismiss was denied. The company in Acadia (page 37) stated that it was “on track” to submit its NDA by a specified date, but twice needed to adjust that date, having discovered that its manufacturing facilities were not yet ready for FDA inspection. Given the small size of the company, the importance of the drug candidate and the significance of manufacturing and quality assurance issues in the NDA process, the court concluded that “it would be incredible to conclude” that company executives “were not aware of the information at issue that made their ‘on track’ representations misleading.” (We discuss the core operations theory further below, in connection with post-approval cases involving manufacturing issues.)

Opinion Statements After Omnicare

In at least five of the pre-approval decisions this year, courts turned to the Supreme Court’s Omnicare decision to evaluate challenged statements of opinion. Defendants fared well in the three cases in which the challenged opinion statements related to clinical trials and what they augured for approval. Defendants fared poorly in two cases involving manufacturing issues in the pre-approval setting.

To briefly recap the Omnicare decision itself: The Supreme Court there considered a challenge under Section 11 to legal compliance opinions in the defendant company’s registration statement—that is, opinions that certain aspects of the company’s business were in compliance with applicable law. The Supreme Court analyzed the challenge separately under Section 11’s false statement clause and Section 11’s omission clause. The Court held that an opinion statement may be actionable under the false statement clause if the speaker did not subjectively hold the belief expressed. An opinion statement may be actionable under the omission clause if a reasonable investor would be misled by virtue of the omitted information. In practice, plaintiffs generally choose to proceed under the omission clause, given the difficulty of pleading subjective falsity. While Omnicare itself was confined to claims under Section 11—a strict liability statute for issuers—courts often apply it to Section 10(b) claims without substantial analysis. Whether this is legally correct or not is another matter, and one to which we return in discussing the post-approval decisions.

As to the pre-approval cases, the most common fact pattern is one in which plaintiffs allege that an opinion statement was misleading by way of omission because the company left out the fact that the FDA had expressed concerns or raised questions about an underlying study. The leading decision here is Tongue v. Sanofi (page 24), in which the Second Circuit stressed that securities defendants are not required under Omnicare to disclose every “fact cutting the other way” whenever they state an opinion. Rather, Omnicare requires only that an opinion statement “fairly align with the information in the issuer’s possession at the time.” The Sanofi court concluded that defendants had met that standard because there was no “serious conflict” between the company’s statements of optimism about approval and the FDA’s statements of concern about the single-blind design of a trial. In notably strong language, the court explained further:

Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections—Plaintiffs were not entitled to so much information as might

6 South Ferry LP #2 v. Killinger, 542 F.3d 776 (9th Cir. 2008).
have been desired to make their own determination about the likelihood of FDA approval by a particular date. Certainly, Plaintiffs would have been interested in knowing about the FDA feedback, and perhaps would have acted otherwise had the feedback been disclosed, but Omnicare does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed in the registration statement.

In addition to this pro-defendant gloss on Omnicare, the Sanofi decision sheds light on the intersection between the Omnicare analysis and the interim communication issues discussed above. That is, in challenging an opinion statement under Omnicare’s omission clause, plaintiffs will often argue that the omitted information consists of interim regulatory feedback. In such cases, the substance of the omitted information—and even more importantly, the degree of disconnect between that information and the challenged statements—will be critical to the Omnicare analysis. This was the case in Endocyte (page 32), where plaintiffs claimed that the FDA had criticized aspects of the company’s Phase 2 study design and had required modifications for Phase 3. In plaintiffs’ view, this showed that the Phase 2 trial was fatally flawed and that Phase 3 would fail. Before addressing Omnicare, the Endocyte court concluded that the FDA communications on which plaintiffs relied did not “so severely” undercut the adequacy of the Phase 2 trial design as to suggest that any of the company’s statements were false—much as the Sanofi court found no “serious conflict” between the FDA’s statements and the company’s opinions. The Endocyte court then held that the company had no duty to disclose criticism of its Phase 2 study design; that criticism was merely part of an ongoing dialogue with the FDA. And for precisely the same reason, the court concluded that the company’s positive opinion statements were not misleading under Omnicare.

While defendants prevailed in cases challenging opinions that implicated scientific issues—Sanofi, Endocyte, QRX—defendants lost in two cases in which plaintiffs’ claims were rooted in manufacturing issues. In Acadia (page 37), the court found that plaintiffs had sufficiently pled that the company’s opinion statement that it was “on track” to submit an NDA by its target date was misleading; the company had not meaningfully assessed its manufacturing systems until shortly before the anticipated submission date. Although the court did not explicitly analyze the company’s statements under Omnicare, it cited Omnicare for the proposition that whether an opinion is misleading depends on context. The relevant context, the court explained, was that the company knew that it needed to be prepared for a manufacturing inspection as part of the NDA approval process. Given that context, plaintiffs had sufficiently pled that the company’s failure even to assess its manufacturing systems until shortly before the planned NDA submission date rendered the “on track” statement misleading. In STAAR Surgical, (page 37) the court found that plaintiffs had adequately pled that the company’s legal compliance opinion statement was misleading by way of omission. The company had failed to disclose its receipt of FDA letters citing manufacturing violations. (The STAAR Surgical court was also one of the few that explicitly considered whether Omnicare applies to Section 10(b) claims; the court concluded that Omnicare applies to the analysis of falsity but not to scienter.)

In both Acadia and STAAR Surgical, the challenged statements were in conflict with what the defendants were alleged to have known about the FDA’s manufacturing requirements. Acadia and STAAR Surgical stand in contrast to Sanofi, Endocyte and QRX, in which the allegedly omitted information consisted of more fluid dialogue with FDA about what its scientific requirements would be. Although the sample size is small, this may indicate that courts look more favorably on claims relating to manufacturing setbacks than on claims that more plainly implicate scientific issues. In the post-approval cases too, plaintiffs succeeded more often than not where manufacturing issues were involved (as discussed further below).
STOCK PROMOTION CASES

In our 2015 review, we reported on a new sub-category of cases—those in which relatively small and thinly capitalized companies with development-stage products are accused of concealing stock promotion activities. In these cases, companies are alleged to have paid authors, through investor relations firms acting as intermediaries, to write favorable articles and boost stock prices shortly before public offerings.

In 2016, three new decisions were issued in this area, all favorable to defendants. In Galectin, the Eleventh Circuit affirmed dismissal. Plaintiffs in that case had challenged both statements made in third-party articles paid for by the company and statements made by the company itself. The court held that the company could not be liable for statements in the third-party articles, as the company did not make those statements. As to the company’s own statements describing its securities offerings, these were not rendered misleading by omission of information about the company’s use of stock promoters. The Eleventh Circuit, like the district court whose decision it affirmed, distinguished the facts of Galectin (page 38) from the facts in cases where companies played an active role in drafting or editing articles by stock promoters.

A similar analysis led to dismissal in Anavex (page 38), from the Southern District of New York. There, the court rejected the claim that the company had participated in an illegal scheme with stock promoters; the facts plaintiffs alleged did not link the company to the content of the promoters’ articles. Meanwhile, the company’s own statements about its offerings were neither false nor misleadingly incomplete; the duty to disclose that an article is paid for by the issuer of stock rests on the author of the article, not the issuer.

Finally, Cellular Biomedicine (page 39) illustrates the significant point that the use of paid stock promoters is not itself improper or illegal. In that case, it was undisputed that the company used paid promoters and that the authors of the articles appropriately included the statement that the company was compensating them for their work. During the time the paid articles appeared, the company’s stock price more than tripled. A blogger thereafter published an article compiling all instances in which the company had paid for favorable coverage, and the company’s stock price fell. The court dismissed plaintiffs’ claims, holding that the blogger had not revealed any previously concealed “truth.” The aggregation of information already in the public realm cannot serve as the necessary corrective disclosure linking investment losses with allegedly false or misleading statements.

We note that no new complaints filed in 2016 include challenges to stock promotion activities.
POST-APPROVAL CASES

Decisions involving post-approval products were split evenly between victories for plaintiffs and victories for defendants in 2016. Defendants prevailed in six of the 10 district court decisions. Plaintiffs prevailed in the other four and in the two appellate decisions. Several themes emerge.

Appellate Decisions on Liability for Third-Party Statements

The two appellate decisions, Pfizer (page 43) and Medtronic (page 44), turn on somewhat technical matters of securities law rather than on issues specific to life sciences companies. Both decisions involved the question of whether a securities defendant can be held liable for allegedly false or misleading statements made by somebody else. (As discussed above, the same issue arises in the stock promotion cases.) In Pfizer (page 43), from the Second Circuit, plaintiffs sought to hold the acquirer of the anti-inflammatory drugs Celebrex and Bextra responsible for statements made by the companies that had previously owned the drugs and had sold them to Pfizer. Under the Supreme Court’s Janus decision, liability for a third party’s statements depends on whether a defendant exercises ultimate control over the content of those statements. The Second Circuit reversed the district court’s grant of summary judgment, holding that plaintiffs had presented sufficient evidence of control to go to a jury.

In Medtronic (page 44), from the Eighth Circuit, plaintiffs’ claims were based on favorable physician reviews of the company’s medical device; the company was alleged to have paid the doctors for their reviews. Here, the court concluded that there was no requirement that the company have controlled the content of the reviews. This was so because plaintiffs in Medtronic were proceeding under a theory of scheme liability, in which the actionable conduct by the company was not making false statements but rather paying physician authors for favorable reviews. Under this theory of liability, the court held, plaintiffs were not required to show that the company controlled the substance of the statements at issue.

The result in Medtronic differs to some degree from that in Galectin, discussed above. In Galectin, the company was not liable for buying favorable coverage from stock promoters. In Medtronic, the company was potentially liable for buying favorable coverage from physicians. The factual difference between stock promoters in the one case and physicians in the other may explain the difference in outcomes more than any legal principle. As an ethical and political matter, the idea that physicians are paid for favorably reviewing a medical product or treatment may simply be more troubling than the idea that a blogger is paid for a favorable review of stock in the company that makes the product. Notably, Medtronic’s payment of physicians was the subject of extensive media coverage and a Senate investigation. The use of stock promoters has not attracted public attention of this sort—although it has been the subject of numerous SEC investigations.

Regulatory Setbacks Do Not Equate to Securities Fraud

Turning to the district courts, several post-approval decisions in 2016 show the significant hurdles plaintiffs may face when they seek to convert certain types of regulatory setbacks into claims of securities fraud.

In Orexigen (page 42), from the Southern District of California, the court took a highly disciplined approach in distinguishing between conduct that may be improper in its own right and securities fraud. At the time Orexigen began commercializing its obesity drug, the drug was also being evaluated in a post-approval cardiovascular outcome trial. Orexigen had access to interim safety data at certain predetermined points in the trial, but under a data access agreement with the FDA, was prohibited from discussing the data publicly. Cardiovascular safety data sampled when the trial was 25 percent complete greatly exceeded expectations, and the company publicly disclosed the data notwithstanding the data access agreement. The company made the disclosure by means of a press release describing a successful patent application based on the interim data. That disclosure drew fire from the FDA. It also led to criticism from the chair of the steering committee for the trial, who accused the company in strong terms of misleading both patients and investors. Later interim data erased the positive effect seen in the first interim data review. Against this background, the district court nevertheless dismissed investors’

securities fraud claims, carefully distinguishing between acts that may have been in violation of the company’s agreement with the FDA and the company’s actual statements to the public, none of which had been shown to be false or misleading.

In Biogen (page 44) too, the court rejected plaintiffs’ attempt to find fraud in a regulatory setback—there, a patient death linked to the company’s drug and a corresponding safety label change required by the FDA. After reporting the death and the label change, the company predicted that sales of its drug would be unaffected, and this proved to be wrong. The district court dismissed investors’ fraud claims, although it agreed that plaintiffs had sufficiently alleged that at least some of the company’s optimistic statements about sales were false or misleading. The court concluded that dismissal was nevertheless warranted because plaintiffs failed to show knowing misconduct. As in several of the pre-approval cases, the company’s detailed risk disclosures and overall transparency weighed heavily in the court’s determination that no conscious wrongdoing was involved. Pointing to the company’s prompt disclosure of the patient death and subsequent label change, the court remarked that “these are not the actions of a company bent on deceiving investors as to their future earnings prospects.”

Divided Outcomes on Manufacturing Problems

Three post-approval decisions in 2016 dealt with contamination in the manufacturing process. Plaintiffs prevailed in two cases and defendants prevailed in one. The difference appears to turn principally on matters of timing. In Albany Molecular (page 46), plaintiffs were able to show that an undisclosed power outage at one of the company’s plants led to contamination; plaintiffs were also able to plead sufficient facts to support the inference that company executives knew of the outage when it occurred. In Sientra, contamination occurred not in the company’s plant but in that of the third-party foreign manufacturer of the company’s products. At the same time the company was conducting a public offering, foreign regulators were revoking permission for products made by the manufacturer to be sold within their jurisdictions. And while shipments of the product to the U.S. were not stopped until after the stock offering was completed, the court concluded that plaintiffs had pled sufficient facts to support an inference that the company knew of the manufacturing issues at the time of the offering.

In both Albany Molecular and Sientra, the court relied in part on the “core operations” theory, discussed on page 10, above, in which the importance of an issue to a company’s business is used to support an inference that company executives knew the allegedly concealed “true” facts about that issue. While this theory can be injurious to securities defendants, courts generally apply it with some care. This was true to some extent in Sientra itself. The court was willing to infer knowledge on the part of executives at the time of the securities offering, which coincided with several adverse regulatory developments affecting the manufacturer. But the court was not willing to stretch the inference to statements made in the company’s two previous 10-Qs, which were filed well before the adverse regulatory events occurred.

Similar issues with timing led to a defense victory in a third contamination case, Conformis (page 46). There, plaintiffs were unable to plead facts suggesting that the manufacturing problems were already apparent to the company at the time of the challenged statements—rather than months later, when the company disclosed those problems. Among other things, the Conformis decision reflects a practical approach to manufacturing problems and risk. The court rejected a challenge to the company’s risk disclosures, in which plaintiffs argued—as they do in a great many cases—that the company misleadingly described as risks that may occur events that had already occurred. The challenged risk disclosure, in the court’s view, was not a misleading statement but instead “essentially a truism. Investors be warned: Stuff happens.” The court went on to observe that “all manufacturing processes entail risk,” and that “[l]ack of clairvoyance is not actionable.”

Pro-Plaintiff Ruling on Scientific Disagreement and Omnicare

A final post-approval decision, IsoRay (page 47), reflects a pro-plaintiff approach to both science-based challenges and the application of Omnicare. Plaintiffs in IsoRay challenged a press release in which the company reported that its product had performed favorably in a trial comparing that product with two other treatments. The day after the press release was issued,
a writer posting on TheStreet.com website accused the company of misleadingly omitting the fact that the two other treatments had also performed well. The company’s stock price fell after the latter post appeared.

It was undisputed in IsoRay that the challenged statements in the company’s press release were literally true. It was also undisputed that the complete text of the scientific article summarized in the press release was available through a link in the press release itself. The court nevertheless accepted plaintiffs’ theory that the press release misleadingly suggested that the company’s product had performed better than alternative treatments. Among other things, the court rejected the company’s argument that the underlying scientific article in fact did conclude that the company’s product was superior to others for certain procedures.

In all of its analysis, the IsoRay court was willing to enter into a dispute about science in a way that differs markedly from the more hands-off approach characteristic in the pre-approval setting. Perhaps this reflects the fact that in the post-approval setting, the FDA no longer serves the same adjudicatory function over a company’s scientific claims. Or perhaps IsoRay is simply an outlier—a decision by a court that does not preside over a heavy volume of securities litigation (the Eastern District of Washington).

IsoRay also reflects a potentially troubling application of Omnicare to Section 10(b) cases. Omnicare’s omissions analysis provides plaintiffs in 1933 Act cases with a possible roadmap for challenging statements of opinion. Plaintiffs may be able to state a claim if they can show that the reader of an opinion statement would expect the speaker to have conducted certain inquiries or formed certain reasonable bases for its opinion—and if plaintiffs can also show that the speaker neither did those things nor disclosed that it had failed to do them. This formulation is rooted in the independent omission clause of Section 11; it is also rooted in the status of Section 11 as a strict liability statute as to securities issuers. But Section 10(b) contains no omission clause; Section 10(b) also requires scienter. The “reasonable basis” standard of Omnicare is at the very least arguably inconsistent with Section 10(b)’s scienter requirement. The IsoRay court nevertheless applied Omnicare’s reasonable basis standard to Section 10(b) claims without analysis. Indeed, the court went further than this, faulting the company for not communicating the basis of its opinion statements to investors. In this way, the decision again may be an outlier, issued by a court not as experienced as others with the standards applicable to pleading motions under the PSLRA.
Trends and Analysis
In this section (pages 17-22), we provide very brief summaries of each of the decisions issued in 2016, organized by stage of a product’s or company’s life cycle. We have grouped the 41 decisions according to outcome, with those in which companies prevailed on dispositive motions listed first. As noted, above, life sciences companies largely fared well in securities litigation in 2016. At the pre-approval stage (including stock promotion cases), companies succeeded in winning dismissal or affirmance of dismissal in 24 of the 29 cases summarized below. Results were more evenly divided in cases arising from post-approval developments. In this area, companies prevailed in six of the 12 cases.

The page numbers in this section refer to more detailed summaries of the same decisions included in the following section (pages 23-48).
APPELLATE DECISIONS

Local No. 8 IBEW Ret. Plan & Trust v. Vertex Pharm., Inc., 878 F.3d 76 (1st Cir. 2016) ..... 24
Company erroneously reports that Phase 2 trial showed an absolute as opposed to a relative increase in patients’ lung function; appellate court affirms dismissal based on plaintiffs’ inability to show that company knew of the error when it made the challenged statements.

Anderson v. Peregrine Pharmaceuticals, Inc., 654 F. App’x 281 (9th Cir. 2016) (unpublished)................................................................. 24
After reporting favorable results from Phase 2 trial, company discovers that contract research organization administering the trial mixed up patient vials and that trial results are accordingly unreliable; appellate court affirms dismissal based on plaintiffs’ inability to show that company knew of error or breached a duty to verify that results were correct.

Tongue v. Sanofi, 816 F.3d 199 (2nd Cir. 2016)............................................................................................. 24
FDA rejects NDA based in part on single-blind trial design; appellate court affirms dismissal on the basis that company honestly believed and had a reasonable basis for making challenged opinion statements about approval.

In re Ariad Pharms. Sec. Litig., 842 F.3d 744 (1st Cir. 2016) ................................................................. 25
FDA requires black-box warning label for leukemia drug and later halts trials and suspends commercial distribution of drug; appellate court affirms dismissal with respect to all but one challenged statement, in which the company expressed optimism about obtaining a favorable label after the FDA had already rejected its proposed label.

Schueneman v. Arena Pharms., Inc, 840 F.3d 698 (9th Cir. 2016) ............................................................. 26
In company’s animal study, rats develop tumors, leading to FDA concerns about carcinogenicity and rejection of NDA; appellate court reverses dismissal, holding that plaintiffs had sufficiently pled that company’s statement that all trials yielded favorable results was false and made with scienter.

DISTRICT COURT DECISIONS

Motion to Dismiss Granted

Short seller publishes article challenging company’s statement that its diagnostic system is “culture free”; court dismisses, holding that reasonable consumers would not have been misled by company’s description.

Short seller publishes article challenging poster statements relating to one drug and Phase 1 trial design for another drug; court dismisses, holding that statements relating to the first drug were not false and statements relating to the second were “non-actionable medical opinions.”

Interim safety data from Phase 2a trial suggest that drug is well-tolerated, but final data do not show efficacy; court dismisses, rejecting plaintiffs’ claim that lack of efficacy could be discerned from interim safety data and that the company had a duty to disclose those data.
**In re Arrowhead Research Corp. Sec. Litig., 2016 WL 6562066**
(C.D. Cal. Mar. 29, 2016) ............................................................................................................. 28

After interim review of Phase 2a trial data, company reports results comparable at certain doses to results in favorable animal study, but final data from human trial do not match the most favorable results in the animal study; court dismisses, concluding that challenged statements of comparison were neither false nor misleading in context and that plaintiffs failed to establish the required strong inference of scienter.


Phase 2b trial fails to meet endpoint; court dismisses, rejecting plaintiffs’ claim that company knew in advance that Phase 2b trial would fail based on flaws in Phase 2a trial design.


Several months after FDA asks for reassessment of Phase 2 trial data, company delays projected NDA date; court dismisses, holding that FDA’s request for reassessment was an interim communication the company was not required to disclose.

**Dougherty v. Esperion Therapeutics, Inc., 2016 WL 7439196**

After FDA first tells company that completion of a cardiovascular outcome trial is not a precondition for approval, FDA says that company should have that trial well under way when submitting its NDA; court dismisses, holding that company’s statements related to approval were forward-looking and the company disclosed exactly the risk that came to pass.

aff’d, __ F.3d __, 2017 WL 1291194 (Apr. 7, 2017) ........................................................................... 30

Company discloses serious but not superficial adverse events from Phase 2 trial; after patient dies in Phase 3 trial, FDA imposes clinical hold; court dismisses, holding that company’s truthful disclosure of the serious events undermines any inference that it knowingly misled investors by omitting information about superficial events.

**Kelley v. Aerie Pharms., Inc., 2016 WL 3437603** (D.N.J. June 20, 2016) ......................... 31

Company predicts Phase 3 trial will establish efficacy, based on Scandinavian trial conducted 20 years earlier; Phase 3 trial does not succeed; court dismisses, finding that company adequately disclosed differences between the earlier trial and its own Phase 3 trial.


Company hires inexperienced clinical research organization, which mishandles data and causes study to have reduced statistical power; court dismisses, holding that plaintiffs have alleged mismanagement, rather than fraud in connection with CRO hiring, and that company’s repeated updates on enrollment data cut against inference of scienter.


Data safety monitoring board conducts interim safety review and recommends that Phase 3 trial be stopped due to lack of efficacy; court dismisses, rejecting plaintiffs’ claim that company knew on the basis of alleged flaws in Phase 2 that Phase 3 trial would fail.


Phase 3 trial fails to show efficacy as a result of better-than-expected response to placebo; court dismisses, finding no factual support for plaintiffs’ contention that company knew all along that this would be the result.
Phase 3 trial fails, and company says in post-hoc analysis that efficacy could be shown if results from certain patients were excluded, including patients who should not have participated in the trial; court dismisses, holding that challenged statements of optimism were inactionable corporate puffery or were not false to begin with.

Phase 3 trial using surrogate endpoint (lower triglycerides) succeeds, but competitors’ trials testing clinical endpoint (increased cardiovascular health) do not succeed, leading to denial of NDA; court dismisses, concluding that company made no false or misleading statements about the relevance of the competitors’ trials to its own NDA.

Phase 3 trial of combination drug fails to meet FDA’s “superiority requirement,” under which combination drugs must be shown to be safer or more effective than their constituent parts; court dismisses, holding that company initially did not know that FDA would impose a superiority requirement, and that when the company did know, it disclosed that fact.

FDA-approved drug fails to get approval in the European Union as a result of advisory committee’s concerns about cardiovascular safety; court dismisses, holding that company could not have predicted that outcome based on interim communications, and that it had no duty to disclose those communications.

Company describes claims in ongoing intellectual property litigation as “without merit” but is ultimately defeated at trial; court grants motion to dismiss in securities litigation, holding that the challenged “without merit” statements were forward-looking, and that the company specifically warned of potential loss in the intellectual property litigation.

After Phase 3 trial, company makes allegedly misleading statement about disease-free survival rate on placebo arm; court denies motion to dismiss, holding that disputes over falsity and scienter are better resolved at a later stage in litigation.

Phase 3 trial results establish efficacy when data from two patients are omitted but not when the data are included, and FDA denies NDA; court denies motion to dismiss, holding that plaintiffs sufficiently pled that company misleadingly omitted from its public statements the fact that efficacy was shown only when certain patient data were excluded.

Company twice delays NDA filing date, having discovered that manufacturing facilities are not yet ready for FDA inspection; court denies motion to dismiss, holding that plaintiffs sufficiently pled that company’s statements that it was “on track” for timely submission of NDA were misleading.

Company receives Form 483 and later receives warning letter stating that no new medical devices will be approved until manufacturing issues are resolved; court denies motion to dismiss, holding that plaintiffs sufficiently pled that company’s statements about approval and legal compliance opinion statements were rendered misleading by virtue of the omitted information concerning FDA inspections and subsequent Form 483 and warning letter.
DECISIONS RELATED TO STOCK PROMOTION ACTIVITIES

*In re Galectin Therapeutics, Inc. Sec. Litig.*, 843 F.3d 1257 (11th Cir. 2016)..........................38
Company hires stock promoters in advance of securities offering and two promoters wrongly state that they are not being paid for their work; appellate court affirms dismissal, holding that company cannot be liable for statements made by third parties, and distinguishing cases in which companies edit and control the content of paid promoters’ articles.

*Cortina v. Anavex Life Sciences Corp.*, 2016 WL 7480415 (S.D.N.Y. Dec. 29, 2016)..........38
Company hires stock promoters after its stock is uplisted from the over-the-counter market to NASDAQ; court dismisses, holding that plaintiffs did not sufficiently tie company executives to the purchased articles, and that duty to disclose payment arrangements belongs to authors of the articles, not the company.

Court hires stock promoters to create positive spin about its business; court dismisses, holding that article accusing company of stock promotion activity did not disclose any facts that were not already in the public realm.

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

LAUNCH ISSUES

Patients using inhaled form of insulin must repeatedly have their lung function tested, a cumbersome process that slows adoption; company also receives unfavorable treatment from formularies, and its distribution partner terminates relationship; court dismisses, concluding that company adequately disclosed issues in earnings calls and could not have predicted the actions of its distribution partner.

*Khoja v. Orexigen Therapeutics, Inc.*, 189 F. Supp. 3d 998 (S.D. Cal. May. 19, 2016)......42
In post-approval cardiovascular trial, court enters into data access agreement with FDA but discloses favorable interim safety data in an 8-K relating to patent application, drawing criticism from FDA and steering committee; court dismisses, holding that while company may have breached data access agreement, none of the challenged statements indicated otherwise.

MATURE PRODUCT ISSUES

Appellate Decisions

*In re Pfizer Inc. Sec. Litig.*, 819 F.3d 642 (2nd Cir. 2016)..................................................43
Company acquires two anti-inflammatory drugs from third parties that have made reassuring statements about the safety of the drugs; district court grants summary judgment, holding that acquiring company cannot be liable for statements made by third parties; appellate court reverses, holding that plaintiffs made sufficient showing that acquiring company controlled the content of the challenged statements.

*W. Virginia Pipe Trades Health & Welfare Fund v. Medtronic, Inc.*, 845 F.3d 384 (8th Cir. Dec. 28, 2016)........................................................................................................44
Company pays physician authors for favorable reviews of its products; district court grants summary judgment on statute of limitations grounds; appellate court reverses, holding that claims are timely and that company may be liable even if it did not control the content of the authors’ articles, given that actionable conduct alleged by plaintiffs was paying for articles rather than making false or misleading statements.
District Court Decisions: Motion to Dismiss Granted

Patient death and revised warning label halt sales growth and company revises revenue guidance; court dismisses, holding that most challenged statements were forward-looking or inactionable puffery; with respect to a few statements adequately alleged to have been false or misleading, plaintiffs fail to establish scienter in light of company’s overall transparency about the issues.

**In re Sanofi Sec. Litig., 155 F. Supp. 3d 386 (S.D.N.Y. 2016)** ................................................................. 45
Whistleblowers accuse company of improperly paying consultants to promote company’s diabetes drugs; court dismisses, concluding that plaintiffs have not pled the alleged underlying conduct with sufficient particularity.

Company moves from third-party distributors to in-house sales force and decreases revenue guidance in part as a result of this; court dismisses, holding that challenged statements were forward-looking and that plaintiffs pled no facts showing that the company knew it would miss guidance.

Company voluntarily recalls product due to concerns about contamination; court dismisses, holding that plaintiffs failed to show that contamination problem existed at the time the company made the challenged statements.

District Court Decisions: Motion to Dismiss Denied

After receiving FDA warning letter, company experiences power outage that leads to contamination in manufacturing facility and ultimately to missed revenue guidance; court denies motion to dismiss, concluding that confidential witness statements are sufficient for pleading purposes to show that contamination existed at the time of the challenged statements and that company knew about it.

Contamination in third-party manufacturing facility results in suspension of sales; court denies motion to dismiss, holding that plaintiffs have sufficiently alleged that at the time company made challenged statements in offering documents, problems had come to light through internal investigation and foreign regulatory activity.

**In re IsoRay Sec. Litig., 189 F. Supp. 3d 1057 (E.D. Wash. 2016)** ................................................................. 47
Company issues press release commenting favorably on results of study comparing its product to two other treatments; blogger publishes article accusing company of misleadingly omitting fact that other treatments also performed well in the study; court denies motion to dismiss, concluding that plaintiffs sufficiently alleged that press release created the false impression that the company’s product performed better than the alternative treatments.

Company announces that it is being investigated by government regulators in connection with possible Medicare and Medicaid fraud; company ultimately settles with government for $13.8 million; court denies motion to dismiss, holding that plaintiffs have adequately alleged a causal connection between challenged financial statements and investment losses.
DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 23-40), 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, these decisions reflect several themes favorable to defendants. Courts will generally dismiss claims where plaintiffs allege that a company’s positive statements about clinical trials or other efforts to obtain approval are based on faulty science. Courts have also repeatedly held that companies are not required to disclose all interim communications with the FDA, given the fluid nature of the regulatory process. And courts have analyzed scienter in a highly practical way, rejecting theories of fraud that include the counterintuitive premise that a company has continued to invest in approval efforts it knows are doomed. Similarly, courts reject allegations that a company knowingly concealed unfavorable events or risks when the company’s communications with investors generally show that it has embraced a culture of transparency.

The detailed summaries also show, however, that defendants do not invariably prevail in the pre-approval area. Companies may take on a duty to disclose negative regulatory feedback if they have described trial results or other steps toward approval in a uniformly positive way. Even when a company believes it is on the right side of a dispute with the FDA, it may face liability if it makes statements that mask the existence of a controversy with regulators.
**APPELLATE DECISIONS**

**Local No. 8 IBEW Ret. Plan & Trust v. Vertex Pharmaceuticals, Inc.,** 878 F.3d 76 (1st Cir. 2016), affirming dismissal. **Phase 2**

Vertex’s cystic fibrosis drug, Kalydeco, was approved for a limited patient population in 2012. The company was also engaged in trials of Kalydeco as part of a combination therapy for a broader patient population. After receiving interim results of a Phase 2 trial, Vertex announced that a high percentage of patients receiving the combination drug had experienced a 5-10 percent absolute increase in lung function, one of the principal markers used to evaluate the effectiveness of the treatment. Executives described the results as “fantastic,” and one commented “I have never seen anything like this.” The company’s stock price rose steeply and five officers or directors sold stock. Three weeks later, the company announced that it had been mistaken in its description of improved lung function, and that in reality patients had experienced only a 5-10 percent improvement relative to their previous baseline. The company’s stock price fell, although it remained higher than it had been before the company’s initial erroneous announcement.

Investors sued, claiming that the company recklessly turned a blind eye to the risk of error in its original, overly favorable interpretation of trial data. The district court granted defendants’ motion to dismiss and the First Circuit affirmed. The court observed that the company itself had noted in its original announcement that the results were unexpectedly good. But the court rejected plaintiffs’ claim that this showed recklessness in accepting the results at face value: “We suspect, too, that many studies of new pharmaceutical products result in surprises, both good and bad.” The court also rejected the argument that recklessness could be inferred from the fact that biomarkers other than lung function were inconsistent with the very favorable lung function results. These were arguments that the company “should have known” that its statements were erroneous—but “should have known” is a negligence standard, not a fraud standard. The same applied to plaintiffs’ argument that the pulmonologist reviewing the data should have detected the error. Finally, the court rejected the argument that insider sales showed conscious wrongdoing. Such sales are not unusual, as rising stock prices create an obvious incentive to sell. The court also found it notable that plaintiffs alleged only that some officers and directors sold stock, without distinguishing the sellers from others at the company who had access to the same information but did not sell stock.

**Anderson v. Peregrine Pharmaceuticals, Inc.,** 654 F. App’x. 281 (9th Cir. 2016) (unpublished), affirming dismissal. **Phase 2**

Peregrine developed cancer drugs, including bavituximab. The company made a series of positive statements in the four months following the un-blinding of its Phase 2 trials, which appeared to show statistically significant improvement in overall survival rates. As the company prepared for an end-of-Phase 2 meeting with the FDA, it discovered that the contract research organization administering the trial had mislabeled patient vials, mixing up patients on the placebo arm with those on the treatment arm. The company accordingly announced that previously reported data were unreliable, and its stock price fell 78 percent.

Investors sued, claiming that the company had breached a duty to verify that the data it reported were accurate. The district court rejected that theory and granted the company’s motion to dismiss. The Ninth Circuit affirmed. “Our case law does support a duty to verify prior to making public statements. But this is so only when failure to investigate amounts to an ‘egregious refusal to see the obvious’. We decline to extend this duty to require Defendants here to have run additional testing on the results they received from an FDA-approved third-party contractor, whose purpose was to run a procedurally valid double-blind test.”

**Tongue v. Sanofi,** 816 F.3d 199 (2nd Cir. 2016), affirming dismissal. **NDA**

Genzyme developed Lemtrada, a multiple sclerosis drug. In 2010, Genzyme was acquired by Sanofi. In addition to cash consideration, Genzyme shareholders received rights to additional payments if Lemtrada was approved by a given date. In 2011, Sanofi completed Phase 3 trials, which yielded favorable results. Because Lemtrada is administered intravenously and the drug...
on the control arm was not, the Phase 3 trials were single-blinded rather than double-blinded: Patients knew which treatment they had received, but investigators did not. In meetings before and during the trials, the FDA expressed concern over this aspect of the trial design, and suggested that the treatment effect would have to be large to justify approval. The company nevertheless made optimistic statements, predicting that in its opinion approval would occur in time for the former Genzyme shareholders to receive their contingent payout. In November 2013, the Advisory Committee evaluating the drug recommended against approval, citing issues with trial design among others. The FDA subsequently rejected the NDA and the company’s stock price fell. (Over the next year, the company continued to work with the FDA, submitting a revised application in May 2014 and ultimately winning approval of Lemtrada for certain MS patients in November 2014. More than 30 other countries had also approved the drug by that time.)

Investors sued, challenging the company’s optimistic statements about FDA approval and alleging that the company had wrongfully omitted information about the FDA’s concerns with the single-blind trial design. In addition to Section 10(b) claims, investors asserted claims under the 1933 Act in connection with statements made in the offering documents through which Sanofi acquired Genzyme. The district court granted the company’s motion to dismiss and the Second Circuit affirmed in the first appellate decision to apply Omnicare to challenged statements of opinion. Under Omnicare, the Second Circuit explained, a statement of opinion is not misleading simply because omitted information cuts the other way: Investors should assume that such information exists simply by virtue of the fact that a statement is couched as an opinion. Investors should also take industry practice into account in evaluating opinion statements. On the facts before it, the Sanofi court held that the industry context includes an understanding that companies with drugs in the development stage will be engaged in an ongoing dialogue with the FDA about the adequacy of the company’s evidence in support of approval, and that “inherent in the nature of a dialogue are differing views.” The fact that the FDA’s preference for double-blind trials is public knowledge further justified the company in omitting that information from its optimistic predictions.

In re Ariad Pharmaceuticals Sec. Litig., 842 F.3d 744 (1st Cir. 2016), dismissal affirmed in part and reversed in part. Phase 2/3

Ariad developed ponatinib, a drug designed to treat chronic myeloid leukemia. The company reported on Phase 2 trials beginning in December 2011. On October 25, 2012, the FDA sent an email to the company rejecting a proposed label on the ground that the label’s safety warnings were inadequate. The company and FDA held follow-up meetings in November 2012. On December 11, 2012, company executives commented to an analyst that they were optimistic about approval with a favorable label. Three days later, the company announced that the FDA had approved the drug but only for a limited patient population, and with a black-box label warning of the risk of adverse cardiovascular events. The company’s stock price fell. The company began commercial distribution of the drug for the limited population, and at the same time continued with Phase 3 trials seeking approval for a broader patient base. In October 2013, the company announced that it had reviewed interim data from the Phase 3 trial, and that based on those data, it was halting the trials. Several days later, the company reported that it was suspending commercial distribution at the FDA’s direction. The stock price fell again.

Investors sued, challenging statements both before and after the December 2012 limited approval. The district court granted defendants’ motion to dismiss. The First Circuit affirmed the district court’s ruling with respect to all post-approval statements and all pre-approval statements except one. With respect to pre-approval statements, plaintiffs’ theory was that the company knew about but failed to disclose the cardiovascular risks that led to the black-box warning. The court rejected that theory, concluding that plaintiffs had pled no facts establishing such knowledge. The exception was a single statement to an analyst on December 11, 2012, three days before limited approval and the black-box label were announced. At the time the company spoke to the analyst, executives knew that the FDA had rejected its proposed label, and in light of that fact, the court held that it was misleading for the company to continue to express optimism about a favorable label determination. The
court affirmed dismissal as to post-approval statements, concluding that plaintiffs had failed to plead facts showing that the company knew of the adverse events that led to the halting of Phase 3 trials. In assessing defendants’ knowledge generally, the court focused on individual speakers rather than on the company as an entity, and declined to impute knowledge of the content of FDA submissions to the executives who made the challenged statements. The court affirmed dismissal of Section 11 claims on the ground that plaintiffs had not adequately pled that they bought shares traceable to the challenged offering.1

**Schueneman v. Arena Pharmaceuticals, Inc.,** 840 F.3d 698 (9th Cir. 2016), reversing dismissal.

**Phase 3/animal studies**

Arena developed locaserin, a weight-loss drug. At the same time it was conducting Phase 3 trials, the company was running rat studies to test for carcinogenicity at doses many times in excess of those given to humans. Rats in the study developed tumors. In interpreting the rat results, the company developed the “prolactin hypothesis,” which posited that locaserin was carcinogenic in rats because of the way it interacts with prolactin, a hormone that apparently functions differently in rats than it does in humans. The FDA did not halt the Phase 3 trials in light of the rat data, but it did request additional animal testing so that the prolactin hypothesis could be further evaluated. After submitting a report including the requested follow-up rat data, the company told investors that it was confident in FDA approval, and that all studies done to date, including animal studies, had yielded positive results. Shortly before the Advisory Committee vote in September 2010, the FDA published briefing documents that revealed for the first time the agency’s concerns about carcinogenicity in the rat studies. The company’s stock price dropped 40 percent following publication of the briefing documents. The Advisory Committee voted 9-5 against approval, and the FDA denied the company’s NDA. (The company later submitted a new application and the FDA approved the drug in 2012, finding that the rat study results were not a barrier to approval both because the rat doses were many times higher than human doses and because the prolactin hypothesis was plausible.)

Investors sued following the September 2010 stock price drop. The district court granted the company’s motion to dismiss, but the Ninth Circuit reversed, reinstating the investors’ claims. The company argued on appeal, as it had at the district court, that the facts alleged showed only that the company and the FDA disagreed about the correct interpretation of the rat data. In defendants’ view, the company at all times had a reasonable basis to believe that the rat data could be explained in a benign way—via the prolactin hypothesis—and therefore plaintiffs had not shown that omission of the rat data or the FDA’s concerns about the data was misleading. The appellate court disagreed. The court held that while the company may not have had a standalone duty to disclose the rat data, it took on such a duty by affirmatively stating that all study results, both human and animal, were favorable. “Arena could have remained silent about the dispute [over the rat data] or it could have addressed its discussions with the FDA head-on. But it could not represent that there was no controversy here because all the data was favorable...It is the failure to disclose ‘issues’ and ‘concerns’ with the Rat Study and the FDA’s interest in the outcome of those studies—not who was ultimately right about the underlying science—that matters.”

**DISTRICT COURT DECISIONS**

**Motions to Dismiss Granted**


Accelerate worked to develop a system used to diagnose hospital-acquired bacterial infections. This system, called ID/AST, reduces the time needed to diagnose hospital infections. The conventional testing method is a two to three-day process involving two steps. First, a

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1 Because this First Circuit reversed dismissal with respect to only one of many challenged statements, and because the resulting class period appears to be limited to three days, we have put this decision in defendants’ column when tallying wins and losses.
patient has a blood test followed by a blood culture, meaning that bacteria are grown from the
patient’s specimen to make a quantity suitable for isolation and analysis. The second step is
isolate culturing, which involves visual identification of bacterial colonies, streaking the bacteria
onto separate petri dishes, and allowing the colonies to grow. Accelerate’s method cuts the
time needed for diagnosis by avoiding the isolate culturing step. In its SEC filings and investor
presentations, Accelerate described its system as “culture free.” In February 2015, a short seller
published an article challenging the company’s statement that its system is “culture-free.” The
short seller argued that because the system uses a blood culturing process in what would be the
first step of a conventional method, the system is not in fact “culture free.” The company’s stock
price fell following publication of the article.

Investors sued, arguing, as did the short seller, that a system that requires a blood culture cannot
be “culture free.” The court rejected the argument and granted the company’s motion to dismiss.
The court concluded that the company made clear in the challenged statements that its system
requires a blood culture, and that a reasonable investor would not have concluded otherwise.

**Zagami v. Cellceutix Corp., 2016 WL 3199531 (S.D.N.Y. June 8, 2016), motion to dismiss granted with
prejudice. Phases 1 and 2**

Cellceutix developed Brilacidin, an anti-inflammatory and antibiotic drug. In April 2015, following
Phase 2b trials of the drug, Cellceutix presented a poster at the 2015 European Congress of
Clinical Microbiology and Infectious Diseases stating that Brilacidin had “potent gram positive
activity” and “gram negative coverage.” The poster presentation also included graphs showing
the effects of the drug on the two different kinds of bacteria. Cellceutix also developed Kevetrin,
a cancer treatment intended to activate the gene p53. As the company described in public filings,
the Phase 1 trial for Kevetrin used the gene p21 as a biomarker for levels of p53. On August
6, 2015, a short-seller published an article on the Seeking Alpha investor website stating that
Cellceutix was a “sham” and accusing the company of misrepresenting facts about both Brilacidin
and Kevetrin, as well as facts about the credentials of one of its executives. The company
issued a press release the following day rebutting the accusations and providing context for the
challenged statements.

Investors sued, asserting securities fraud claims largely tracking the accusations made in the
article. The company moved to dismiss and the court granted the motion. The court rejected
plaintiff’s attack on the company’s statements about its executive’s credentials. While it was true
that the company inaccurately stated in a 2009 Form 10-K that the executive had received a Ph.D.
from Harvard rather than from Kerala University, the error had long since been corrected. As to
Brilacidin, the challenged poster statement was accurate, particularly when viewed in context:
Gram-negative “coverage” requires a lesser showing than gram positive “activity.” Nor was the
statement that Brilacidin had such “coverage” shown to be false by the company’s rebuttal to the
short-seller’s Seeking Alpha attack. The company stated there only that the drug was not likely
to be an effective treatment against a broad spectrum of gram negative bacteria. As to Kevetrin,
plaintiff’s claim in essence was that the company used an inappropriate biomarker in its Phase
1 trials. The court found that this amounted to an impermissible attack on a “non-actionable
medical opinion,” and explained that “securities law is simply not a vehicle through which courts
will police disagreements in the cancer research community or the parameters of clinical trials.”

**Huang v. Avalanche Biotechnologies, Inc., 2016 WL 6524401 (N.D. Cal. Nov. 30, 2016), motion to
dismiss granted without prejudice. Phase 2a**

Avalanche developed the drug AVA-101 to treat “wet” age-related macular degeneration, the
leading cause of blindness in the developed world. During the Phase 2a trial of the drug, the
company received and reviewed interim drug safety surveillance data. The company announced
that the data suggested that the drug continued to be well-tolerated, and that adverse events
were mild and not related to the drug. The company also made clear that it had not yet received
efficacy data or complete safety data. The company included the interim data in its IPO
registration statement. A year after the IPO, the company released one-year results from the
Phase 2a trial. The results were unfavorable insofar as they did not show a durable treatment
effect. The company’s stock price plunged. Two months later, the company announced that it
would not be proceeding to Phase 2b trials for the drug.
Investors sued, asserting both Section 10(b) claims arising from a variety of public statements and 1933 Act claims based on allegedly false statements in the IPO registration statement. Plaintiffs’ theory was that the interim safety data provided to the company should have signaled that the trial would not establish efficacy, given the overlap between indicia of safety and indicia of efficacy. The court rejected that theory and granted the company’s motion to dismiss. The court acknowledged an overlap between safety and efficacy data but concluded that plaintiffs’ theory was based on improper speculation about whether efficacy results could be predicted based on interim safety data. The court also emphasized that the company had clearly informed investors that it was not commenting on efficacy in releasing the interim safety data, and hence that no reasonable investor would have drawn conclusions about efficacy from statements about interim safety data. The court further rejected plaintiffs’ claim that the company had a duty to release complete safety data, relying on precedent holding that pharmaceutical companies need not release every safety-related result in reporting on clinical trials to investors. Finally, the court found that plaintiffs’ Section 11 claim—ordinarily a strict liability claim against issuers—was in reality a fraud claim and therefore failed for the same reason the Section 10(b) claim failed.

In re Arrowhead Research Corp. Sec. Litig., 2016 WL 6562066 (C.D. Cal. Mar. 29, 2016), motion to dismiss granted without prejudice. Phase 2a

Arrowhead developed ARC-520, a treatment for hepatitis B. The presence of hepatitis B in a person’s body is measured by the number of hepatitis B surface antigens. The benchmark for hepatitis B drugs is to achieve a 90 percent reduction in those antigens, which is referred to as a 1-log knockdown. In 2013, the company published results from a trial with chimpanzees. Animals given a single dose of 2 mg/kg had an antigen reduction of 30-60 percent. Animals given two doses, one at 2 mg/kg and one at 3 mg/kg, had an antigen reduction of 81-96 percent. The company began a Phase 2a human trial in March 2014; subjects were given a single dose of either 1 mg/kg or 2 mg/kg (or a placebo). The company announced interim results on August 12, 2014, reporting that the treatment effect was “surprisingly large,” that the results seen at the 2 mg dose were comparable to those in the animal study, and that the company therefore had confidence that it could show a “good, deep knockdown” at a 3 mg dose. In October 2014, the company announced complete Phase 2a trial results, which included a 50 percent reduction of antigen at the 2 mg dose. The company’s stock price fell by 44 percent. Investors sued, challenging statements the company made when it reported interim results on August 12, 2014. The court granted the company’s motion to dismiss. Plaintiffs had pled no facts establishing that the treatment effect at 2 mg/kg was not “surprisingly large.” As to the comparison with the chimpanzee study, this was accurate: The humans and animals did in fact fare the same at the 2 mg dose, which was the only dose that was common to the two studies. The court also dismissed challenges to the company’s statement that its goal in the Phase 2a trial was to identify a dose that would achieve a 90 percent knockdown in humans; this was a forward-looking statement accompanied by meaningful cautionary disclosures. The court also concluded that plaintiffs had failed to establish scienter on the basis of stock sales, other financial incentives and the individual defendants’ key role at the company.

Plaintiffs sought reconsideration of the court’s order and the court denied plaintiffs’ motion. 2016 WL 6681180 (C.D. Cal. Aug. 18, 2016). Plaintiffs relied primarily on the “core operations” theory, in which they sought to create a strong inference of scienter by reference to the importance of the Phase 2a trial to the company’s business and the significance of management’s role in connection with the trial. The court rejected plaintiffs’ argument on the ground, among others, that the purported falsity of the challenged statements was not so obvious that the individual defendants should be inferred to have known about it; indeed, plaintiffs had not established falsity at all.


Celladon was the developer of Mydicar, a gene therapy treatment for patient with heart failure. After successful Phase 1 and Phase 2a trials, Mydicar was granted fast-track status and designated a breakthrough therapy by the FDA. The company then proceeded to Phase 2b
trials, but failed to meet either primary or secondary endpoints. The company’s stock fell 80 percent on that announcement and its price fell further after the CEO resigned.

Investors sued, claiming that the company’s Phase 2a trial yielded a false positive, as the patients in the placebo group were sicker than those on the treatment arm. That same fact, according to plaintiffs, put the company on notice that subsequent trials would fail. Based on that theory, plaintiffs challenged favorable descriptions of the trials in the company’s IPO registration statement and subsequent SEC filings. The company moved to dismiss and the court granted the motion, concluding that plaintiffs identified no facts and no corroborating details in support of their contention that the Phase 2a trial was flawed or the company knew of flaws and what they augured for Phase 2b.


Sarepta developed eteplirsen for the treatment of Duchenne muscular dystrophy. The cells of the boys and young men suffering from this disease are unable to produce dystrophin, a protein necessary for muscle function. Eteplirsen is designed to enable cells to make a modified form of dystrophin; the cells’ ability to do so is tested via tissue biopsies. Sarepta informed investors that if it was able to produce sufficiently robust biopsy results, the FDA would be receptive to an NDA based on those results as a surrogate endpoint, rather than requiring a clinical endpoint (which would be measured by the patients’ ability to walk). On April 21, 2014, Sarepta announced that with the data it currently had, it believed an NDA was “fileable,” but that because the FDA had expressed concerns and some skepticism about the data in a guidance letter, the company planned to gather additional data over the next six to eight months and to file an NDA thereafter. The company repeated this two-part message over the next several months. In July 2014, the company received a “request for reassessment,” in which the FDA asked that the company’s primary dystrophin data be reassessed by pathologists at independent labs. The company did not immediately disclose this communication. On October 27, 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 date. The company’s stock price dropped. Three days later, on October 30, 2014, the FDA published a statement addressed to patients and physicians concerned about Sarepta’s NDA. The agency explained that it had been concerned since April 2014 that Sarepta’s then-existing dystrophin data were not sufficiently robust, had strongly encouraged Sarepta to enroll additional patients, and had been working closely with the company since then.

Investors sued, claiming that the FDA’s October 30, 2014 announcement showed that Sarepta had misled the market when it stated in April 2014 and thereafter that it had data sufficient to file an NDA. The court granted the company’s motion to dismiss. The court rejected plaintiffs’ principal hypothesis, which was that the FDA had told the company in April 2014 that it would not accept an NDA based on the existing data. Plaintiffs had pled no facts directly showing that this was the case. In addition, the company had not misled investors on the subject, as it had repeatedly disclosed that while an NDA was “fileable,” the FDA had expressed enough skepticism that the company had concluded that filing without additional data would be unwise. The court also rejected a second hypothesis—that the company had wrongly failed to disclose the FDA’s July 2014 request for a data reassessment. The court explained that this interim communication was part of an ongoing dialogue, and that companies have no obligation to disclose such indefinite feedback from regulators. The court further held that plaintiffs had failed to plead scienter, as any inference of deliberate fraud was undermined by the company’s repeated disclosures that the FDA had expressed concern about filing the NDA with its existing dataset. And the court rejected the somewhat unusual argument that the company’s failure to release the full text of the FDA’s April 2014 guidance document showed knowledge of falsity: “Generally, companies are under no obligation to disclose their written communications with the FDA to the general public.”

Esperion developed ECT 1002, a cholesterol medication developed as an alternative to statins. After an August 2015 meeting with the FDA to discuss completed Phase 2 trials, the company publicly discussed upcoming Phase 3 trials and its anticipated NDA. The company stated that the FDA would not require the completion of a cardiovascular outcome trial (CVOT) before submission of the NDA, but that the company nevertheless planned to have such a trial underway by that time, in part as an effort to seek support for a broader label. The company cautioned that it had yet to receive the FDA’s final minutes from the August 2015 meeting, and that it was possible that the company would need to alter the design of its Phase 3 trials after receiving the minutes. The FDA released its final minutes in September 2015 and the company issued an update explaining that the agency had encouraged it to initiate a CVOT promptly. Analysts perceived an inconsistency between the September 2015 announcement and the company’s August 2015 statement that the FDA was not requiring a pre-approval CVOT. The company’s stock price declined nearly 50 percent.

Investors sued, challenging the company’s August 2015 statement that the completion of a CVOT was not a precondition to FDA approval. The court granted the company’s motion to dismiss, concluding that to the extent the August statement was inconsistent with the September update, the statement fell within the PSLRA’s safe harbor for forward-looking statements. The August statement consisted of the company’s projections concerning future events in the approval process, together with the assumptions underlying those projections. The statement qualified for safe harbor protection because the company adequately disclosed exactly the risk that came to pass—that the FDA could require additional studies that might delay approval. The court also noted that in virtually all of its communications with investors, the company highlighted the risks inherent in the processes of clinical development, regulatory approval and commercialization. Finally, the court further held that plaintiffs had failed to adequately allege scienter. No facts plaintiffs pled suggested that the company knew that the FDA would deviate from its usual practice of approving cholesterol-lowering drugs without the need for a pre-approval CVOT.


Zafgen was the developer of beloranib, an anti-obesity drug. In Phase 2 trials, two patients experienced serious thrombotic events and two patients experienced superficial thrombotic events. In reporting on those trials to the investing public, the company disclosed the serious but not the superficial events. The company also stated that not all adverse events would immediately be publicized. And the company reported that no deaths or serious adverse events had been linked to beloranib. Later, in Phase 3 trials, one patient on the treatment arm died and the FDA put a clinical hold on the trials. In announcing this development, the company for the first time disclosed the superficial events from the Phase 2 trial. The company’s stock price fell by 50 percent.

Investors sued, arguing that if they had known of the superficial as well as the serious events from the Phase 2 trial, they would have been able to more fully assess the risk of a poor outcome in Phase 3. Plaintiffs challenged the statements that (1) beloranib did not increase the risk of cardiovascular disease and may be associated with reduced cardiovascular risk, (2) there were no adverse events in the Phase 2 trial “possibly, probably, or definitely associated with beloranib,” and (3) there were two serious thrombotic adverse events in the Phase 2 trial that were not associated with beloranib but that might point to a need for added vigilance in later trials. The court concluded that the first two statements were neither false nor misleading but that the third was arguably misleading insofar as defendants omitted the two superficial events. The court nevertheless dismissed the complaint in its entirety, holding that the company’s truthful disclosures about the two serious events undercut any inference that they knowingly misled investors by omitting information about the two superficial events. The court also rejected plaintiff’s argument that scienter could be inferred from the existence of scientific articles discussing potential links between drugs in beloranib’s class and elevated thrombotic risks; among other things, plaintiffs did not allege that defendants knew about the articles.

Aerie developed Rhopressa for the treatment of glaucoma. If approved, Rhopressa would face competition from two generic drugs, latanoprost and timolol, which it would need to outperform to be viable at higher prices. In a Phase 2b trial, Rhopressa was compared to latanoprost. It performed worse overall but equivalently for a certain subset of patient. In a Phase 3 trial, Rhopressa was compared with timolol. Before the trial was complete, the company made optimistic statements about expected results and pointed to a 20-year-old Scandinavian trial in which timolol performed worse than latanoprost; by extension, the company inferred that this meant that timolol would also perform worse than Rhopressa. The company also stated that Rhopressa had the potential to be a blockbuster drug. The Phase 3 trial was ultimately not a success, however, and the company’s stock price dropped on the announcement of that news. In seeking to explain why the Phase 3 trial did not mirror the earlier Scandinavian study, the company offered the following hypothesis: Rhopressa works by strengthening the eye drainage system that is compromised in glaucoma patients; timolol works by reducing the amount of fluid that needs to be drained. In the 20 years since the Scandinavian study was conducted, more patients were exposed to a class of drugs that further compromises the drainage system Rhopressa is aimed at improving. Those patients are therefore less likely to be helped by Rhopressa than the patients in the Scandinavian study, who had not experienced this extra degradation of drainage networks. That degradation did not affect the performance of timolol, which, again, works by reducing fluid rather than improving drainage, and this explained why Rhopressa did not outperform timolol. The company subsequently designed and performed a second, less ambitious Phase 3 trial, which was successful.

Investors sued, claiming that the company knew about but failed to sufficiently emphasize the differences between the Scandinavian study and the Rhopressa Phase 3 trial. The court rejected the claim and granted the company’s motion to dismiss. The company in fact did disclose the differences between the two studies, and while it did not spell out what the consequences of those differences would be, plaintiffs pled no facts showing that the company knew of those consequences in advance. The court also rejected plaintiffs’ challenge to the company’s “blockbuster” statement, which it understood as the equivalent of a statement that Rhopressa had the potential to generate $1 billion in annual revenue. Revenue forecasts of this kind are protected by the PSRLA’s safe harbors. Finally, the court rejected plaintiffs’ attack on the company’s favorable gloss on the Phase 2b trial. Viewed in context, the company was not asserting that Rhopressa was superior to the comparator drug but only that it performed as well for a certain subset of patients.

XBiotech’s lead product candidate was Xilonix, for the treatment of colorectal cancer. In July 2014, the company began enrollment for a Phase 3 trial in Europe, where it aimed to enroll 276 patients. The company retained a clinical research organization, KCR, that marketed itself as a flexible alternative to top tier CROs. KCR had more experience performing the relatively ministerial tasks usually undertaken by site management organizations, and less experience performing the full range of CRO functions, i.e., protocol design, data management and statistical analysis. In its April 2015 IPO registration statement, the company stated that 122 of the expected 276 patients for the European trial had been enrolled as of March 2015, and that the trial was expected to be completed in mid-2015. In July 2015, the company revised that timeline, stating that enrollment had gone slowly and the trial was expected to reach completion by the end of 2015. The company’s stock price dropped slightly. In November 2015, the company announced that 72 of the patients in the trial had been compromised, that insufficient steps had been taken to accommodate such data loss, and that the study would have reduced statistical power as a result. The stock price fell again, this time more steeply.

Investors sued. Although the challenged statements were contained in the company’s registration statement, plaintiffs alleged claims under Section 10(b) rather than under the 1933 Act. Plaintiffs faulted the company for failing to disclose that it had retained an inexperienced CRO and that its CEO also lacked experience with Phase 3 trials. Plaintiffs also claimed that
the original expected completion date for the trial was unrealistic and that confidential witnesses had told company executives as much. The court granted the company’s motion to dismiss on scienter grounds. The court reasoned that in challenging the company’s use of an inexperienced CRO, plaintiffs were alleging mismanagement rather than fraud. The same was true of plaintiffs’ claim that the CEO lacked experience with Phase 3 trials. As to the projected completion date, the court found plaintiff’s confidential witness allegations unpersuasive, given that the company had engaged in steps to remedy the problem the witness identified. The court also concluded that the company’s overall transparency about enrollment cut against any inference of scienter. The company provided updates tracking enrollment figures in the European trial; the company was also transparent about difficulties identifying patients to participate in a second trial, which was to take place in the United States. Finally, the company made clear to investors that its statements about when enrollment would be completed were only predictions. This too undercut an inference of deliberate misstatement.


Endocyte developed Vintafolide for the treatment of platinum-resistant ovarian cancer. The drug is personalized for each patient and is effective only for patients whose tumor cells contain folate receptors, to which the drug binds and delivers a powerful chemotherapy agent. In the company’s successful Phase 2 trials, subjects were permitted to participate whether or not their tumors contained folate receptor cells. In moving from Phase 2 to Phase 3, the company met with the FDA and made several significant changes to the trial design. Unlike the Phase 2 trial, the Phase 3 trial was limited to patients with folate receptor cells. The endpoint was also changed, from progression-free survival to progression-free survival combined with radiological assessments identifying tumor activity. The company discussed these changes in its public filings. While the Phase 3 trial was ongoing, the company also pursued approval in the European Union. After the company announced in March 2014 that it expected conditional approval in the EU, its stock price doubled. The company completed a public offering shortly thereafter. In May 2014, the company announced that the data safety monitoring board for the Phase 3 trial had conducted an interim review that showed a lack of efficacy and had accordingly recommended that the trial be stopped. The company’s stock price dropped 62 percent on this announcement.

Investors sued, alleging that the company knew that the Phase 2 trial design was flawed and that the Phase 3 trial, in which these flaws were corrected, was bound to fail. The court granted the company’s motion to dismiss, holding that the vague and uncorroborated testimony of a single confidential witness, which was the foundation of all of plaintiffs’ claims, was insufficient to demonstrate falsity. The court also found it implausible that either the company or the FDA would have persisted with the Phase 3 trial if it had been clear that the study was doomed to fail. The court rejected plaintiff’s claim that the company had concealed aspects of the FDA’s criticism of the Phase 2 trials, drawing on a line of cases holding that companies need not disclose all interim communications with regulators. Other statements were deemed inactionable because they were forward-looking, or because they were opinion statements with respect to which plaintiffs failed to meet the Omnicare standard. Finally, the court dismissed the 1933 Act claims arising from the April 2014 public offering: Plaintiffs failed to plausibly plead falsity, given the inadequacy of their allegation that the company knew all along that the Phase 3 trial would fail.


Nymox developed NX-1207, a drug designed to treat benign prostatic hyperplasia, a condition found in older men whose prostates have become enlarged. In 2009, the company started two Phase 3 studies under a Special Protocol Assessment. Enrollment was a slow process, and the company did not receive top-line results until 2014. In November 2014, the company reported that neither of the trials had met its primary endpoint. Drug safety was acceptable and efficacy was consistent with that shown in the successful Phase 2 trial. Nevertheless, the trial failed to
show a statistically significant treatment effect as a result of a higher placebo response than in the Phase 2 trial. The company’s stock price fell 82 percent the next day.

Investors sued, alleging that the company fraudulently concealed material information that would have revealed the danger of an abnormal placebo response. Investors also claimed that the company had received top-line results long before it revealed them in November 2014, but had stalled the release of the results because they were unfavorable. The court granted the company’s motion to dismiss on scienter grounds, concluding that plaintiffs had provided no factual basis for their claim that the company had delayed releasing top-line results. Although the company had stated at one point that it expected results in late 2013 or early 2014, subsequent announcements showed that the trials were completed later than initially expected—not that the company sat on results once it had them in hand. The court similarly found no factual basis for plaintiffs’ claim that the company had in essence known all along that particular aspects of the trial design would lead to a strong placebo response, which would in turn cause the trial to fail.

**Fialkov v. Alcobra Ltd., 2016 WL 1276455 (S.D.N.Y. Mar. 30, 2016), motion to dismiss granted. Phase 3**

Alcobra, an Israeli pharmaceutical company, developed metadoxine to treat adult ADHD. In July 2014, after two successful Phase 2 studies, the company announced that it had completed enrollment of a Phase 3 trial, and thanked investigators for the meticulous work they had done in enrolling subjects. The following day, the CEO told investors that over the past 15 years, there had been no successful Phase 2 trial of ADHD drugs that did not also lead to a successful Phase 3 trial. In September 2014, the company’s co-founder (who was no longer on the board), predicted that the Phase 3 trial would succeed. On October 6, 2014, the company announced disappointing results, although it also noted that if results of four patients with extreme placebo results were excluded on a post-hoc basis, the trial showed a statistically significant improvement on the treatment arm. The company’s stock price fell by more than 50 percent. Two weeks later, on October 23, 2014 the company discussed a second post-hoc analysis, in which statistically significant improvement was shown when two (rather than four) patients on the placebo arm were excluded and when eight additional patients found not to have satisfied entry criteria were excluded as well. The company’s stock price fell further over the next several days.

Investors sued, challenging both the statements made in July-September 2014, while the Phase 3 trial was ongoing, and statements made on October 6, 2014, when the company first announced Phase 3 results. The court granted the company’s motion to dismiss. The court rejected plaintiffs’ claim that the company spoke falsely when it reported that enrollment was complete and had been performed meticulously: This was a broad statement of corporate “puffery” on which reasonable investors would not rely. In addition, even if enrollment had been handled in a less than meticulous way—given that eight patients who did not satisfy trial criteria had been included—the company’s statement was not materially misleading, as the trial would have failed with or without those patients. That is, the company could show statistical significance as to efficacy only by excluding both those eight patients and an additional two patients who displayed extreme placebo effects. The court also rejected plaintiffs’ challenge to the co-founder’s optimistic prediction, which was an inactionable opinion statement and not attributable to the company in any event. Finally, the court concluded that the company’s October 6 statement about the exclusion of four patients was neither false nor inconsistent with the October 23 statement about the exclusion of two patients. The court also granted the company’s motion on scienter grounds: Plaintiffs had alleged nothing about the individual defendants’ motivations or knowledge that distinguished those defendants from any other executives of publicly traded companies.

**In re Amarin Corp. PLC Sec. Litig., 2016 WL 1644623 (D.N.J. Apr. 26, 2016), motion to dismiss granted without prejudice. Phase 3/NDA**

Amarin developed Vascepa to treat patients with high triglycerides. Amarin conducted its Phase 3 ANCHOR trial in an effort to obtain approval for a label indication covering patients who were already taking statins—a patient population of more than 30 million. The ANCHOR trial was aimed at showing that Vascepa lowers triglycerides. At the time the trial was designed and approved by the FDA under a Special Protocol Assessment, a lowered triglyceride level was deemed an acceptable surrogate endpoint for increased cardiovascular health. A second Amarin study, the long-term Phase 3 REDUCE-IT trial, was designed to show improvement in
Two of Amarin’s competitors were also conducting long-term studies of the effect of lowered triglycerides on cardiovascular health, and the FDA told Amarin that the outcomes of those trials would provide important information for the approval of Vascepa. The FDA also told Amarin that an NDA based on the ANCHOR results alone would be acceptable, but that at the time it submitted its NDA, Amarin should have the REDUCE-IT trial well underway, with approximately half of the participants enrolled. The ANCHOR trial turned out to be successful, but the competitors’ long-term trials were not. FDA staff issued a briefing document on October 11, 2013 calling into question whether Vascepa offered a meaningful clinical benefit. Five days later, the Advisory Committee evaluating the drug voted against recommending approval. The company’s stock price fell after the publication of the briefing document and fell further after the Advisory Committee vote.

Investors sued, challenging Amarin’s statements that (1) a lowered triglyceride level constituted an acceptable surrogate endpoint for cardiovascular health, (2) the FDA had agreed to the submission of an NDA without completion of the long-term REDUCE-IT study, and (3) the FDA had required that the company complete 25-50 percent of enrollment in REDUCE-IT when it submitted its NDA. The court granted the company’s motion to dismiss, concluding in each case that the challenged statement was true. Plaintiffs also claimed that the company wrongly omitted the FDA’s view that the outcome of the competitors’ long-term trials would be significant, but the court concluded that the company had made no statement inconsistent with what the FDA had told the company about its competitors’ trials.

Gillis v. QRX Pharma Ltd., 197 F. Supp. 3d 557 (S.D.N.Y. 2016), motion to dismiss granted.

Phase 3/NDA

QRX Pharma, an Australian company, developed MoxDuo, a combination drug comprised of morphine and oxycodone. Under the “Combination Rule,” the FDA generally approves such drugs when each component contributes to the claimed treatment effect and the drug is safe for a population requiring the concurrent therapy. Because MoxDuo consists of two drugs in the same class, however—opioids—the FDA ultimately imposed more stringent criteria, essentially requiring the company to show that the drug was more effective or safer than a doubled dose of either of its components (the “Superiority Requirement”). Before undertaking Phase 3 trials, QRX requested a Special Protocol Assessment from the FDA on three occasions and received denials in the form of No Agreement Letters. Without disclosing the No Agreement Letters, the company carried out Phase 3 trials in the absence of an SPA and submitted an NDA in July 2011. Although the Phase 3 trials met their primary endpoints, the FDA denied the application in a June 2012 Complete Response Letter, recommending that the company re-submit with evidence that the MoxDuo could satisfy the Superiority Requirement. The company unsuccessfully appealed that decision. In February 2013 and again in November 2013, the company submitted revised NDAs with additional data designed to show that the drug had a safety advantage over its constituent parts. In April 2014, the Advisory Committee evaluating the drug recommended against approval, finding the new safety data unpersuasive. Following the announcement of that result, the company’s stock price dropped 83 percent in a single day. The company ceased development of MoxDuo and eventually filed for bankruptcy.

Investors sued, claiming that both before and after the FDA’s June 2012 Complete Response Letter, QRX concealed the fact that the FDA was imposing the Superiority Requirement as a special application of the Combination Rule in cases where the two drug components come from the same class. The court granted the company’s motion to dismiss. The court concluded that plaintiffs had failed to plead facts showing that the company was aware before the June 2012 Complete Response Letter that the FDA would impose the Superiority Requirement. And while the company was aware of that fact after June 2012, its public statements provided sufficient information for investors to understand that fact too. The court also rejected plaintiffs’ claim that the company’s failure to disclose the No Agreement Letters constituted an actionable omission; the court drew on a line of cases holding that companies with drugs in development have no duty to disclose all interim regulatory communications. As to the company’s interpretation of the Complete Response Letter and optimistic predictions about eventual approval, these were opinion statements with respect to which plaintiffs did not meet Omnicare’s standards.
With respect to a single statement, the court concluded that plaintiffs had adequately pled falsity. This was a statement that could be understood to suggest that in June 2012, the FDA still had an open mind as to whether or not it would apply the Superiority Requirement; in reality, the FDA had told the company by that time that it would do so. The court nevertheless concluded that dismissal was mandated even with respect to this statement on scienter grounds. Defendants had little motivation to mislead the market on the point in question at the time of the challenged statement, as they believed the company in fact could satisfy the Superiority Requirement. Plaintiffs’ motive allegations were not plausible on a more general level either, as it would be counterintuitive to infer that the company would spend years on clinical trials that it knew could not meet FDA standards.

**Jasin v. Vivus, Inc.,** 2016 WL 1570164 (N.D. Cal. Apr. 19, 2016), motion to dismiss granted with prejudice. **EU approval**

Vivus developed Qsymia, a weight-loss drug approved by the FDA in July 2012. At the same time it was pursuing FDA approval, Vivus sought approval from the European Medicines Agency, which plays a similar role 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 sent in the name of one or the other of the two leaders of the committee (called rapporteurs) individually. In early reports, the two rapporteurs took different positions, with one stating that the drug could not be approved before the company conducted a cardiovascular outcome trial, and the other leaving open the possibility that such a trial could be conducted post-approval—which was what the FDA decided. In public statements, the company told investors that the issues raised by the CHMP were similar to those raised by the FDA. The company also repeatedly cautioned that approval in one jurisdiction did not guarantee approval in any other, and that the risk remained that the CHMP would require a costly pre-approval cardiovascular outcome trial. In September 2012, the company announced that it expected the CHMP to recommend against approval, and the company’s stock price dropped. 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 again, though only slightly.

Individual investors sued, challenging Vivus’ statements that the issues raised in the two regulatory processes were similar, and claiming that the company had wrongly omitted the statement by one of the rapporteurs that approval could not take place before a cardiovascular outcome trial was completed. The court granted the company’s motion to dismiss. The court distinguished between the reports issued in the name of the CHMP as a whole and the reports sent in the name of the rapporteurs individually and agreed with the company that it had no obligation to report all details of interim regulatory communications. The court emphasized the inherent fluidity of the approval process and the fact that the rapporteurs had expressed views that conflicted with one another. The court also rejected plaintiffs’ claim that it was misleading for the company to say that the CHMP “could” require a pre-approval trial when that risk had already come to fruition; the court found that the CHMP’s concerns were in fact no more serious than the company had represented. Finally, the court held that plaintiffs failed to adequately allege scienter, particularly in light of the very detailed risk disclosures the company had provided, which underscored the expense of a pre-approval cardiovascular outcome trial.


Neovasc develops and manufactures cardiovascular products. In 2009, Neovasc entered into an agreement to provide manufacturing services to another medical device company, CardiAQ. Through that relationship, CardiAQ disclosed proprietary information about its valve implantaion technology to Neovasc. In May 2010, Neovasc filed a patent application disclosing valve implantation technology; Neovasc also developed its own device using that technology (called Tiara). In 2014, CardiAQ sued Neovasc, seeking correction of ownership on Neovasc’s patent and alleging claims for fraud, breach of contract and misappropriation of trade secrets. The case
proceeded to trial, where the jury found Neovasc liable on several claims and awarded CardiAQ $70 million in damages. Neovasc’s stock price fell after the verdict was announced.

Investors sued, challenging the company’s statements during the intellectual property litigation that CardiAQ’s claims were "without merit" or "baseless." The court granted the company’s motion to dismiss, concluding that the challenged statements were forward-looking and accompanied by meaningful cautionary statements: Neovasc had warned investors about the risk and consequences of losing the CardiAQ litigation, including monetary damages and the loss of intellectual property rights. The court similarly concluded that challenged statements about the growth prospects of Tiara came within the safe harbor for forward-looking statements. In discussing the overlap between the statutory safe harbor and the law on challenged opinion statements, the court oddy drew on older First Circuit law rather than on Omnicare.

DISTRICT COURT DECISIONS
Motions to Dismiss Denied


Puma was the developer of an extended-treatment breast cancer drug, neratinib. In a press release reporting on a Phase 3 trial, the company stated that patients receiving neratinib experienced a 33 percent improvement in disease-free survival over those treated with a placebo. On an analyst call held the same day as the press release was published, executives were asked whether the disease-free survival rate for the placebo was in the range of the mid to high 80s. The executives agreed, notwithstanding the fact that the disease-free survival rate for the placebo arm was 91.6 percent, as opposed to a disease-free survival rate on the treatment arm of 93.9 percent. The company also said that Kaplan-Meier curves for the two groups were continuing to separate, which suggested the efficacy of neratinib.

Investors sued, challenging statements about both the disease-free survival rate and the Kaplan-Meier curves. The company moved to dismiss, and in a somewhat under-analyzed decision, the court denied the motion. The court concluded that disputes over whether plaintiffs had adequately pled falsity and scienter were better resolved at a later stage in the litigation.


In 2009, Aeterna bought the rights to AEZS-130, a drug designed to treat adult growth hormone deficiency, from Ardana Bioscience. After completing a Phase 3 trial initiated by Ardana, Aeterna issued several press releases announcing favorable results. The company submitted its NDA in November 2013. The company did not disclose that in analyzing trial data, it had modified the patient group by omitting results from two patients enrolled by Ardana, on the ground that those patients were not suffering from the disease. When the two patients were excluded, the data established efficacy. When the two patients were included, the data did not establish efficacy. The FDA denied the NDA and the company’s stock price dropped by 50 percent.

Investors sued, claiming the company had misled the market by omitting the fact that the trial data established efficacy only when two patients were excluded. The court agreed that the investors had stated a claim and denied the company’s motion to dismiss. The company had made numerous statements that the trial established efficacy, and those statements were rendered misleading by virtue of the omitted information that the company had modified the patient group. “Even if Aeterna had not believed this modification in the study would have adversely affected its application, the modification warranted some disclosure to investors, especially in light of the prior ongoing positive statements during the approval process. Failing to disclose at that time was reckless.”
Acadia’s leading drug candidate was Nuplazin, a treatment for Parkinson’s Disease psychosis. In April 2013, the company announced that the FDA had agreed that the data from a Phase 3 trial was sufficient to support the filing of an NDA, but that the company would not submit the application until late 2014. During the intervening time, the company said, it would complete work on drug interaction studies, stability testing, and chemistry, manufacturing and controls development. In November 2014, the company reported that it would not file the NDA until the first quarter of 2015; although it had completed drug interaction and stability testing, more work was needed. Over the next several months, through late February 2015, the company stated that it was on track for a filing before March 31, 2015. On March 11, 2015, the company announced that it would not file its NDA until the second half of 2015, and its stock price fell. The company also announced the resignation of its CEO. The company explained that it needed to delay filing because it had not sufficiently understood the amount of work necessary to begin manufacturing on a commercial scale, and needed time to prepare for the manufacturing inspection that would be part of the FDA’s review of the NDA. The company ultimately filed its NDA in September 2015.

Investors sued, challenging the company’s statements between November 2014 and February 2015 that it was “on track” for a March 2015 filing. The court denied the company’s motion to dismiss, concluding that the “on track” statements were misleading. Investors would have concluded based on that statement that the company had taken steps necessary to ensure that it would be ready by the deadline, which also meant being ready for a manufacturing inspection—and the company had not yet taken those steps at the time it made the challenged statements. The court rejected the company’s arguments that those statements were inactionable because they were forward-looking or constituted “puffery”; neither was true. The court also concluded that plaintiffs had adequately pled scienter, given the significance of the issue and the CEO’s role as the “ultimate report” for manufacturing.

STAAR designs and manufactures implantable lenses, which are Class III medical devices. A lens for treating myopia, the MICL, was approved in 2005, but only after numerous delays related to manufacturing deficiencies, which were the subject of a warning letter and a Form 483. The company subsequently began preparing for approval of an astigmatism product, the TICL. In 2013, when the company began consolidating its four manufacturing facilities, it again ran into regulatory issues. The company received a Form 483 in August 2013, and during an inspection in February 2014, was unable to produce required documentation. The latter inspection led to another Form 483 in March 2014 and to a warning letter on May 21, 2014. The company apparently did not disclose the warning letter, which became public for the first time when the FDA posted it on June 30, 2014. Among other things, the FDA stated in the warning letter that no applications for approval of new Class III medical devices—such as that for TICL—would be granted until the manufacturing issues were resolved. The company's stock price fell following the FDA's announcement.

Investors sued, challenging the company’s statements that it believed it was in compliance with FDA regulations, that the consolidation of its manufacturing operations was proceeding on track, and that the advisory committee evaluating the TICL application had recommended approval. The court denied the company's motion to dismiss. The court rejected the company’s argument that the Forms 483 and warning letter simply reflected the FDA’s position, which may have been wrong. Even if the FDA’s conclusions lacked merit, the court explained, the fact that they existed at all was an impediment to approval, and the company’s statement that it was in compliance with FDA regulations was rendered misleading in light of the omitted information. As to the challenged legal compliance opinion statement, the court applied Omnicare to conclude that the plaintiffs had sufficiently alleged that this statement was misleading in the absence of a disclosure that the FDA had taken a different position on the issue. The court also rejected the company’s argument that it had no duty to disclose interim observations of non-compliance the FDA made before issuing the warning letter. In the court’s view, while these were not final agency communications, they showed a risk that approval would be delayed, and the company’s challenged statements regarding approval were misleading in the absence of a disclosure of that risk. The court also
faulted the company for failing to disclose the May 21 warning letter and instead waiting until
the FDA posted it on June 30, particularly given the impact of the letter on TICL approval.
"While [the company] did not have to disclose the Warning Letter within seconds of receipt, [the
company] provides no support that it was free to delay as long as it did."

DECISIONS RELATED TO STOCK PROMOTION ACTIVITIES

In re Galectin Therapeutics, Inc. Sec. Litig., 843 F.3d 1257 (11th Cir. 2016), affirming dismissal.
Galectin developed a drug called GR-MD-02. The company hired four stock promotion firms
to generate favorable coverage and thereby raise stock prices leading up to two securities
offerings. Two of the four firms disclosed that they were being paid for their work. The other two
did not, and one of those two affirmatively (and wrongly) stated that it was not being paid for
its work. In offering documents for the two securities offerings, the company stated that it had
taken no action to manipulate stock prices. In post-offering SEC filings, the company described
the offerings but did not mention the fact that it had used paid stock promoters in the run-up to
the offerings. Several months after the second offering, commentators began publishing articles
about suspected links between the company and paid stock promoters, and the company’s stock
price dropped.

Investors sued, alleging that the company had made false or misleading statements and had
participated with the stock promoters in a scheme to defraud. The district court granted the
company’s motion to dismiss, rejecting both the false statement and the scheme theories.
Plaintiffs appealed the ruling as to their false statement theory only, and the Eleventh Circuit
affirmed dismissal. Like the district court, the appellate court held that the company could not
be held liable for false or misleading statements by the stock promoters: Under the Supreme
Court’s decision in Janus Capital Group, Inc. v. First Derivative Traders, liability is confined to the
“makers” of such statements, and the stock promoters themselves, rather than the company,
were the makers. As to the company’s own statements, the court concluded that these were
neither false nor misleading. The company’s statement that it did not manipulate its stock price
was true, given that the term “manipulate” refers narrowly to illusory purchases or sales, which
were not alleged in the case. Nor could the company be liable for failing to disclose its use of
stock promoters in its post-offering descriptions, as that omission did not render the accurate
statements misleading. The appellate court distinguished CytRx and Galena, two district court
decisions in which plaintiffs had been permitted to proceed with claims against companies that
had used stock promoters. In those cases, in contrast to Galectin, company executives edited
and controlled the content of the articles.

Cortina v. Anavex Life Sciences Corp., 2016 WL 7480415 (S.D.N.Y. Dec. 29, 2016), motion to
dismiss granted with prejudice.
Anavex worked to develop drugs combating Alzheimer’s disease. When the company’s stock
was uplisted from the over-the-counter market to NASDAQ, the company paid promoters to
provide favorable coverage and its stock price increased dramatically. Later, analysts began
publishing reports suggesting that the company was the beneficiary of paid stock promoters.
The company also announced an SEC investigation into stock promotion activities, and its
stock price tumbled.

Investors sued, claiming both that the company had participated in a market manipulation
scheme and that it had misleadingly omitted information about that scheme in its public filings.
The court rejected both theories. Plaintiffs’ scheme claim failed because plaintiffs did not tie the
company or its officers to the promotional articles, save in conclusory terms. The omission claim
failed because plaintiffs could not identify a duty on the part of the company to disclose that it
had paid for the articles. The relevant securities statute places the obligation to disclose such
arrangements on the author rather than the issuer of stock. The court also rejected plaintiffs’
argument that without disclosure of the paid promotion, the discussion of risk factors in the
company’s SEC filings was misleadingly incomplete; the court distinguished other cases in which
risk factors had included some but not all risks relating to market manipulation. Finally, the court
concluded that plaintiffs failed to plead scienter, having identified neither unusual insider selling nor other information suggesting that the company’s executives were aware of paid promotion activity.


Cellular Biomedicine worked on developing cell-based therapies to treat chronic and degenerative diseases. The company began using stock promoters in 2014 to create positive spin about its business. Later in 2014, a blogger posted an article in Seeking Alpha accusing the company of using stock promoters and alleging that patients had died in clinical trials and the company’s executives were dishonest. The company’s stock price dropped.

Investors sued, alleging that the company had concealed the fact that it used paid stock promoters. The court dismissed plaintiffs’ claims on causation grounds, explaining that plaintiffs had not shown that the Seeking Alpha article “corrected” any previously misstated information. Rather, the article reflected only the blogger’s opinion and aggregation of facts that were already publicly available before the article appeared. The court rejected plaintiffs’ argument that the article reflected new information insofar as it uncovered and aggregated information difficult for an ordinary investor to discover. That argument was inconsistent with the efficient market theory, under which “one presumes that all public information is incorporated into the market price, no matter how far flung it may be.”
DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 41-48), we provide detailed summaries of decisions in cases arising from developments at the post-approval stage. As discussed above, in “Trends and Analysis,” companies have prevailed in only half of these cases, a significantly lower rate than in the pre-approval setting. Two appellate decisions went against defendants on relatively technical matters of securities law. Defendants also lost in two of the three cases involving manufacturing problems, and in one case in which the company was accused of mischaracterizing the results of a post-approval trial.

On the other hand, courts remain skeptical of securities plaintiffs’ attempts to turn instances of regulatory non-compliance into securities fraud cases. In this situation, courts appropriately focus on a company’s public statements—as opposed to compliance in and of itself—as the essential core of a Section 10(b) claim.
LAUNCH ISSUES


After receiving FDA approval in 2014, MannKind began to commercialize its drug Affreza, an inhaled form of insulin used to treat patients with diabetes. Sanofi partnered with MannKind to distribute the drug. Before doctors could prescribe Affreza, their patients had to take and pass a lung function test, which requires a piece of equipment called a spirometer. This caused some complications: Most physicians do not have spirometers in their offices, so patients need to consult another provider to take the lung function test. Unfavorable treatment by insurance plan formularies caused additional problems. The company discussed the spirometer problem at various points during the first year of commercialization, but also noted apparent improvement in the area. After a slow launch, Sanofi exercised its option to terminate its relationship with MannKind, explaining publicly that prescription levels did not meet even modest expectations. The company’s stock price dropped.

Investors sued, challenging three sets of statements. First, they claimed that MannKind had falsely stated that spirometry issues were resolved. The court rejected that claim, as the company had stated only that issues were improving. Second, plaintiffs claimed that the risk disclosures in the company’s 10-K and 10-Qs were misleadingly incomplete, as they did not include a discussion of spirometry issues. The court rejected that claim too, noting that the securities laws do not impose a “duty of completeness,” and that in any event, spirometry issues were sufficiently discussed during earnings calls. Finally, plaintiffs challenged MannKind’s statement, less than two months before Sanofi terminated the two companies’ relationship, that it had no indication that Sanofi would do so. The court concluded that plaintiffs had pled no facts showing that MannKind knew what Sanofi planned to do at the time of the challenged statement.

Khoja v. Orexigen Therapeutics, Inc., 189 F. Supp. 3d 998 (S.D. Cal. May. 19, 2016), motion to dismiss granted in part with prejudice and in part without prejudice. 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 an interim review performed at 25 percent completion 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 arm. The FDA accordingly approved Contrave in November 2014 and the company began to market the drug. Issues arose, however, over the publication of the favorable 25 percent interim data. Before approval, the company had entered into a data access agreement with the FDA limiting the number of people who had access to the interim results. The FDA found the company had violated the terms of the agreement even during the pre-approval period. In March 2015, after approval, the company filed an 8-K announcing that it had succeeded in obtaining a patent covering Contrave for a new indication—cardiovascular benefit. In announcing the grant of the patent, the company discussed the favorable 25 percent data on which its patent application was based. The company also cautioned that a more complete data set would be needed to show cardiovascular benefit. Analysts responded to news about the patent favorably. The FDA, on the other hand, expressed serious concern that the 25 percent data had been publicly disclosed by means of the patent announcement. In the FDA’s view, the public dissemination of inherently unreliable interim data is problematic.

Several weeks after the 8-K announcing the patent was filed, 50 percent interim data became available. Those data showed no cardiovascular benefit from Contrave. The steering committee overseeing the trial recommended that the trial be stopped. Six weeks later, in its May 8, 2015 earnings release, the company stated 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. Minutes after the company’s announcement, the chair of the steering committee issued a press release containing the 50 percent data and...
criticizing the company for its earlier publication of the 25 percent data. In a media piece, the
steering committee chair accused the company of misleading both patients and investors. The
company’s stock price dropped.
Investors sued, alleging that the company’s public references to the favorable 25 percent data
constituted false or misleading statements as well as an unlawful scheme and a violation of the
data access plan. The court granted the company’s motion to dismiss. While the company’s
March 2015 press release may have violated the FDA’s data access plan, the court concluded
that the company had said nothing contrary to that fact—nothing suggesting that it was in
compliance with the plan. Nor did the company misrepresent the nature of the interim data;
indeed, it specifically cautioned that further data would be required to show a cardiovascular
benefit. And while analysts concluded that the 25 percent interim data were statistically
significant, the company could not be held responsible for that. As to plaintiffs’ claim that the
company needlessly publicized the interim data through the patent application process, the court
concluded that the company’s treatment of the data in that context was consistent with patent
law, and therefore could not serve as the basis of either a false statement or a scheme claim. For
different reasons, the court rejected plaintiffs’ challenge to the company’s May 8 earnings release.
The company’s statement that the trial was ongoing was not inconsistent with the fact that the
steering committee had six weeks previously recommended that the trial be stopped: Steering
committees in such situations can make recommendations but cannot stop trials. Nor did the
company have an obligation to discuss the 50 percent data at that time; indeed, under the terms
of the data access plan, it was prohibited from doing so.

MATURE PRODUCT ISSUES
Appellate Decisions

In re Pfizer Inc. Sec. Litig., 819 F.3d 642 (2nd Cir. 2016), vacating summary judgment for defendant.
Response to adverse publicity

Pfizer held the rights to two drugs used to treat chronic pain and inflammation—Celebrex, which
it acquired from Searle, and Bextra, which it acquired from Pharmacia. Like Merck’s product Vioxx,
both Celebrex and Bextra are non-steroidal anti-inflammatory drugs known as COX-2 inhibitors.
In the early 2000s, studies appeared linking COX-2 inhibitors to cardiovascular problems, and
Merck pulled Vioxx from the market in September 2004 for that reason. Pfizer responded by
issuing a series of press releases, advertisements and statements assuring investors that Celebrex
and Bextra were safe. On October 6, 2004, the New England Journal of Medicine published an
editorial questioning the safety of the two drugs, and Pfizer’s stock price fell.
Investors sued, alleging that Pfizer made false or misleading representations to conceal the safety
risks of Celebrex and Bextra, and that Searle and Pharmacia did the same before Pfizer acquired
the drugs. The core of plaintiffs’ theory was that by concealing the same risks concealed by Searle
and Pharmacia, Pfizer caused the market to maintain Pfizer’s stock price at an artificially high level.
Plaintiffs relied on this inflation-maintenance theory as a way to avoid determining whether it
was Pfizer’s alleged fraud, as opposed to that of Seale and Pharmacia, that ultimately caused the
company’s stock price to fall.

The company prevailed on summary judgment in the district court, which concluded that Pfizer
was not the “maker” of the predecessor companies’ statements, as Pfizer did not have authority
to control the content of those statements. The Second Circuit reversed, concluding that the
evidence was sufficient to permit a jury to conclude that Pfizer in fact did control the statements
of the predecessor companies before it acquired their drugs. That evidence included a fax sent
by a PR firm to Pfizer and Searle, the testimony of a Pfizer senior manager that Pfizer had the last
say on media responses, and the terms of Pfizer’s co-promotion agreement with the predecessor
companies. The Second Circuit also held that the district court had erred in excluding plaintiffs’
expert testimony on loss causation and damages. The district court had done so on the ground
that the expert could not disaggregate the inflation caused by Pfizer’s statements from that
caused by the statements of the predecessor companies. In the context of plaintiffs’ inflation-maintenance theory, the Second Circuit concluded that this was error.

*West Virginia Pipe Trades Health & Welfare Fund v. Medtronic, Inc.*, 845 F.3d 384 (8th Cir. Dec. 28, 2016), vacating summary judgment. **Payment to physician authors**

Medtronic sold Infuse, a bone growth protein approved in 2002 for use in lower back surgeries. Following approval, up to 85 percent of Infuse sales were off-label. In 2009, the FDA published warnings associating off-label use with dangerous side effects. And beginning in 2008, Medtronic was accused, in media pieces and in a Senate investigation, of paying physicians to write favorable articles in medical journals and of shaping the content of the articles to minimize the side effects of Infuse and exaggerate the disadvantages of alternative treatments. The company’s stock price fell following these accusations.

Investors sued, claiming that the company had made false or misleading statements and participated in a scheme to defraud the market. Investors also sued the physician authors of the articles as participants in the scheme. The district court dismissed the scheme claims against the physicians but permitted plaintiffs to proceed against the company. The district court subsequently dismissed all claims against the company on statute of limitations grounds. The investors appealed the dismissal of the scheme claim against the company.

The Eighth Circuit reversed, reinstating the scheme claim. The court first reversed the district court’s statute of limitations ruling, concluding that neither early unfavorable media coverage nor another investor lawsuit provided the plaintiffs with sufficient information to bring their case earlier. The court then rejected the company’s alternative ground for affirmance—that plaintiffs failed to plead a viable claim for scheme liability. The appellate court agreed with defendants that a scheme claim must be something more than a failed false statement claim in disguise. But the court concluded that the investors had identified something more than false or misleading statements: the act of paying the physician authors to induce their complicity, which lay at the heart of the scheme. Given its holding on scheme liability, the court also reached—and rejected—a second alternative argument, in which the company argued that defendants were not the “makers” of the challenged statements as required by the Supreme Court’s *Janus* decision. The Eighth Circuit held that *Janus* applies only in false statement cases, not in scheme cases. The court also rejected the company’s argument that the investors had not adequately established reliance for summary judgment purposes. The court held that the investors had compiled sufficient evidence showing that stock purchasers relied on unwarrantedly favorable information about the Infuse trials, and that the company’s allegedly deceptive conduct was what led to the dissemination of that information.

**District Court Decisions: Motion to Dismiss Granted**

*In re Biogen Inc. Sec. Litig.*, 193 F. Supp. 3d 5 (D. Mass. 2016), motion to dismiss granted with prejudice. **Adverse events/label change**

Biogen sells Tecfidera, a multiple sclerosis drug. During an October 2014 earnings call, Biogen announced that for the first time, an MS patient who had taken Tecfidera had died of progressive multifocal leukoencephalopathy (PML), a rare viral infection that is especially dangerous for those with weakened immune systems. A month later, the FDA issued a warning about the death, and Tecfidera’s label was updated to include the PML risk. On calls with analysts beginning in December 2014, company executives predicted continuing growth of Tecfidera sales in 2015. By April 2015, however, the company explained that patients were becoming increasingly hesitant about the drug, triggering a 6 percent stock price drop. In July 2015, the company cut revenue guidance based on lowered expectations for Tecfidera sales. The company also stated during a July 2015 earnings call that the PML death in 2014 had led to greater caution about the drug. The company’s stock price again fell, this time by more than 20 percent.

Investors sued, claiming that the company failed to disclose that the PML death was affecting Tecfidera sales, and that the company knew this to be the case as early as 2014. The court granted the company’s motion to dismiss, concluding that many of the challenged statements were not adequately shown to be false, or were inactionable as forward-looking statements or
as statements of opinion or “puffery.” The court concluded that plaintiffs had adequately alleged falsity with respect to statements made during a January 2015 earnings call, during which an executive said that the company had not seen a meaningful change in the discontinuation rate of Tecfidera. The court nevertheless dismissed the complaint even as to these statements, finding plaintiffs’ allegations insufficient to support a strong inference of scienter. Plaintiffs’ prompt disclosure of the PML death and label change cut against such an inference, as did the many statements executives made in earnings calls, in which they acknowledged that physicians would need to go through a process in order to get comfortable prescribing after the PML death.

*In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386 (S.D.N.Y. 2016), motion to dismiss granted with prejudice.

**Marketing practices**

Sanofi markets and sells diabetes drugs (among others). According to corporate whistleblowers, one of whom filed a complaint in state court, Sanofi was engaged in a marketing scheme beginning in 2012 to drive up sales of its diabetes drugs. The whistleblowers claimed that Sanofi made disguised payments to consultants Accenture and Deloitte, and that the consultants in turn induced retailers and hospitals to favor Sanofi’s diabetes drugs over those from competitors. The whistleblowers also contended that contracts were intentionally miscoded to conceal the payments to consultants. While these activities were allegedly taking place, Sanofi issued press releases and held calls with investors highlighting sales performance in Sanofi’s diabetes product line. The company also issued a Corporate Social Responsibility Report affirming its commitment to corporate integrity. On October 27, 2014, news sources reported that Sanofi’s board was considering replacing the CEO, and the company’s stock price fell. The next day, Sanofi reported a decline in diabetes drug sales, and its stock price fell further.

Investors sued, alleging that the company concealed an illegal marketing scheme and that the company’s CEO knew about the scheme by means of an internal investigation the company conducted in response to the whistleblowers’ accusations. The court granted defendants’ motion to dismiss. The court found that plaintiffs had not pled the underlying conduct on which they based their claims with sufficient particularity. Among other flaws, plaintiffs did not specify which contracts were miscoded, how they were miscoded, or how plaintiffs knew they were actually illegal kickback contracts. The court further concluded that the challenged statements regarding Sanofi’s commitment to compliance and corporate integrity were inactionable “puffery,” and that the CEO’s SOX certifications were inactionable statements of opinion.


**Sales and distribution**

Globus developed and commercialized spinal implants, which it sold through a network of independent distributors. When Globus became a publicly traded company in late 2013, it announced that it would gradually transition from third-party distributors to an in-house sales force. In February 2014, the company announced annual revenue guidance of $480-486 million, up from $435 million in 2013. In its August 2014 earnings call, the company decreased revenue guidance to $460-465 million. The company explained that sales were growing more slowly than it had expected for two reasons: (1) it had terminated its relationship with a distributor, Vortex, as part of its long-range plan to take the sales function in-house; and (2) it was experiencing price pressure. The company’s stock price dropped on the announcement. 2014 revenue ultimately came in at $474 million, only 1.2 percent below the lower end of the original guidance.

Investors sued, claiming that the company’s revenue projections were false insofar as they did not reflect losses stemming from the termination of the Vortex relationship. Plaintiffs also claimed that the company breached a duty to disclose its intention to terminate that relationship. The court granted the company’s motion to dismiss. The challenged revenue forecast was inactionable as a forward-looking statement; in addition, plaintiffs pled no facts showing that the company knew at the time it made the challenged statement that the loss of Vortex’s services would cause it to miss guidance. The court also rejected plaintiffs’ argument that the company had a duty to disclose that it intended to end the Vortex relationship, and that without such disclosure, the company’s risk disclosures were misleading. The court explained that plaintiffs were confusing a risk—that a distributor would choose to cease working with the company—with a business decision—that the company would voluntarily decide to cease working with the distributor.

Conformis manufactured and sold custom joint replacements, together with “iJigs,” the surgical tools used to implant them. In its IPO registration statement, the company explained that its manufacturing processes were governed by the FDA’s Quality System Regulation protocol, under which companies must adopt and enforce procedures adequate to achieve quality control. The company also stated that it believed it was in compliance with the QSR. After the company completed its IPO, it began using a new process for sterilizing the iJigs. Following three complaints that moisture had been found in the instrumentation sets, the company announced the voluntary recall of 950 iJigs. 650 of the units had already been used, with no adverse effects. The company’s stock price dropped following the announcement. Investors sued under the 1933 Act, challenging the risk disclosures in the company’s IPO registration statement. The investors claimed that the company had misleadingly disclosed that it might experience quality control issues in connection with its manufacturing and sterilization processes. According to the investors, the lax manufacturing practices that created the situation that led to the recall—moisture on the instrumentation sets—were already in place at the time of the IPO. The court rejected plaintiffs’ theory, concluding that no facts plaintiffs had alleged supported it. The court also identified a “central error” in the complaint: The company had described its quality control procedures and risks at a high level of generality, and plaintiffs erred in claiming that the company was also required to “catalog every particular future issue that could be imagined.” And the court rejected, under Omnicare, the company’s statement that it believed its facilities were compliant with the QSR: Plaintiffs had alleged nothing showing that this belief was not honestly held. Finally, the court rejected plaintiffs’ Section 10(b) claim, finding no indication of scienter—such as admissions or witness reports—suggesting that the executives knew they were misrepresenting or withholding vital information.

**District Court Decisions: Motion to Dismiss Denied**

Gauquie v. Albany Molecular Research, Inc., 2016 WL 4007591 (E.D.N.Y. July 26, 2016), motion to dismiss denied. **Manufacturing defects**

Albany Molecular Research is a contract research manufacturing company that produces drugs for the pharmaceutical industry. In 2013, the company received a warning letter from the FDA related to poor manufacturing processes and contamination issues. In 2014, the company acquired OSO Pharmaceuticals, another manufacturing facility. In July 2014, following the acquisition, the OSO facility lost power, which led to contamination in a section of the facility that accounted for 50 percent of its sales. The company did not immediately disclose the power failure and provided optimistic revenue guidance in its August 2014 10-Q and again on September 30, 2014. In its November 2014 10-Q, the company disclosed the power failure for the first time; it also announced disappointing third-quarter revenue and lowered annual revenue guidance. Analysts commented unfavorably and the company’s stock price dropped 35 percent.

Investors sued, challenging the company’s revenue guidance as false and misleading in light of the undisclosed power failure. The company moved to dismiss and the court denied the motion. The court concluded that plaintiffs had sufficiently pled both falsity and scienter in light of confidential witness allegations that placed the contamination problem in August 2014—before the challenged statements were made. The court also relied on the significance to the company of the newly-acquired OSO facility, and on the importance of contamination issues in light of the earlier FDA warning letter. The court did not, in its very brief analysis, address the fact that revenue forecasts are forward-looking statements under the PSLRA and may be entitled to protection under statutory safe harbor provisions.


Sientra developed breast implants and sold them to plastic surgeons in the U.S. The company held its IPO in November 2014. The exclusive manufacturer of Sientra’s products was Silimed,
a Brazilian company. Products manufactured by Silimed were sold both in the U.S. and in Europe. In the spring of 2015, German media published articles about regulatory investigations into possible contamination in Silimed’s Brazil plant. Silimed conducted an internal investigation and on September 4, 2015, confirmed that breast implants sold by Sientra in the U.S. were contaminated. On September 17, German regulators revoked the certificate that permitted products manufactured by Silimed to be sold in the EU. UK authorities took similar action on September 23. On October 2, Brazilian authorities suspended shipment of Silimed’s products to the US. On October 9, Sientra suspended its sales of all products manufactured by Silimed and recommended that plastic surgeons cease using them.

Sientra conducted a secondary public offering during the time that some of these events were transpiring. After requesting accelerated SEC review, Sientra filed its registration statement for the offering on September 18. The offering was conducted between September 18 and September 23—the same period during which European authorities were stopping the sale of products manufactured by Silimed within their jurisdictions. On September 24, the day after the offering closed, Sientra’s stock price fell by more than 50 percent. By October 12, Sientra’s stock was trading at roughly 25 percent of the secondary offering price.

Investors sued, challenging statements in the offering documents under both Section 10(b) and the 1933 Act. Plaintiffs also challenged statements in the two 10-Qs preceding the September 2015 secondary offering, filed in May 2015 and August 2015 respectively. The court granted the company’s motion to dismiss with respect to the 10-Qs, concluding that plaintiffs had not shown that manufacturing problems had come light at the time the documents were filed. But the court denied the defense motions in all other respects. The court found fault with the company’s risk disclosures, agreeing with plaintiffs that it was misleading for the company to warn investors that manufacturing issues could arise when in reality the issues had already risen at the time the statements were made. The court also accepted plaintiffs’ scienter allegations, notwithstanding plaintiffs’ failure to plead facts directly showing that Sientra’s executives knew about Silimed’s manufacturing problems at the time of the challenged statements. The court was willing to infer such knowledge based on the close relationship between Sientra and Silimed, the importance of manufacturing issues to Sientra, the company’s own role in quality assurance, including on-site inspections of the Brazil facility, and the financial incentives surrounding the secondary offering and the suspiciousness of its timing.

In re IsoRay Sec. Litig., 189 F. Supp. 3d 1057 (E.D. Wash. 2016), motion to dismiss denied.

Product description
IsoRay developed a cancer treatment using an isotope called Cesium-131. This treatment is a type of brachytherapy, which is a highly localized radiation therapy. On May 19, 2015, an article was published in the journal Brachytherapy describing the results of a study that compared IsoRay’s treatment to other treatment options. The next day, the company issued a press release describing the study as a success for the company’s products; for example, “IsoRay’s Cesium-131 Lung Cancer Treatment Reports…100 percent Survival At 5 Years in High Risk Patients in Newly Published Report.” On May 21, 2015, an article was published on The Street.com accusing the company of mischaracterizing the study’s findings in its press release. After the press release was issued, the company’s stock had surged; the stock price fell after the publication of the May 21 article.

Investors sued, alleging that the press release omitted material information about the study and its results. According to plaintiffs, the company had misleadingly omitted the fact that patients who received alternative treatment fared statistically the same as those who were treated with IsoRay’s product. The company moved to dismiss, arguing that reasonable investors would not have been misled, particularly in light of the fact that the text of the Brachytherapy article itself was available through a link in the challenged press release. The court rejected the company’s argument, finding that plaintiffs had sufficiently alleged that the press release created the false impression that Cesium-131 was more beneficial than alternative treatment options. The court also concluded that plaintiffs had adequately stated a claim in alleging that the company failed to disclose payments it had made to the study’s author. As to challenged statements of opinion—the company was “excited” about the “outstanding patient outcomes”—the court held that plaintiffs had stated a claim under Omnicare’s omissions analysis. In the court’s view, the
company had omitted material facts about the basis for its opinion—namely, that alternative treatments had also performed well in the trial.

**Mauss v. NuVasive, Inc.**, 2016 WL 3681831 (S.D. Cal. July 12, 2016), motion to dismiss denied in part and granted in part. **Marketing practices**

NuVasive makes products used in spinal surgery. 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. On July 30, 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. Share prices declined 12 percent following the announcement.

Investors sued and the company filed motions to dismiss successive versions of the complaint. After granting three such motions, the court permitted plaintiffs to proceed with a fifth amended complaint. In the time since plaintiffs had filed their original complaint, events flowing from the OIG investigation had continued to develop; most notably, the company had paid $13.8 million to the government to resolve the matter. The court had earlier concluded that plaintiffs failed to plead a causal link between the challenged statements and their investments losses: The announcement of an investigation does not constitute a corrective disclosure. In the final complaint, however, plaintiffs were able to allege not only that the company was being investigated but also that it had paid $13.8 million to resolve the matter. The court concluded that this was a sufficient causal link to permit plaintiffs to move forward with their claim against the company. The court dismissed claims against an individual defendant based on plaintiffs’ failure to allege scienter.
In 2016, 50 securities fraud class actions were filed against life sciences companies, an increase over the 39 actions filed in 2015 and the 42 actions filed in 2014.¹ Of the 50 new actions filed in 2016, 22 were filed against companies with development stage drugs or devices. The remaining 28 actions involve a broad spectrum of regulatory and non-regulatory issues with mature products, ranging from alleged regulatory violations in the areas of marketing and billing, to alleged financial statement fraud, to issues concerning revenue forecasting and performance.

Several trends emerge from the new filings. The number of new cases has increased, but like the cases decided in 2016, many of the new complaints appear weak, particularly in the pre-approval area. Several plaintiffs’ firms appear to be casting a very broad net, possibly reflecting a strategy that favors numerosity over quality. Notably, six of the new cases were filed against companies that are subjects of Department of Justice or state attorney general general investigations into price fixing in the generic drug industry.

The new filings are clustered in district courts in the Second and Ninth Circuits, with roughly a third of the total in each circuit. We show the breakdown graphically on the following page. New filings in 2016 by stage of drug or product development:

<table>
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<tr>
<th>PRODUCT LIFECYCLE</th>
<th>SECURITIES FRAUD CLASS ACTIONS FILED IN 2016</th>
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<tr>
<td>PRE-APPROVAL</td>
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<tr>
<td>Clinical Trials: Phases 1-3</td>
<td>15</td>
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<tr>
<td>Submission of NDA/510(k)</td>
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<tr>
<td>Total Pre-Approval</td>
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<tr>
<td>POST-APPROVAL</td>
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<tr>
<td>Alleged Regulatory Violations —</td>
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<td>Marketing and Billing</td>
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<tr>
<td>Alleged product defects</td>
<td>2</td>
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<td>Antitrust investigation</td>
<td>6</td>
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<tr>
<td>Late SEC filings</td>
<td>2</td>
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<tr>
<td>Financial statement issues</td>
<td>4</td>
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<tr>
<td>Sales forecast and demand issues</td>
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<tr>
<td>Other post-approval issues</td>
<td>5</td>
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<tr>
<td>Total Post-Approval</td>
<td>28</td>
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¹ We take this figure and list of actions from the Stanford Securities Class Action Clearinghouse. This list includes those cases categorized by Cornerstone Research as within the “healthcare sector” but excludes deal litigation and cases involving hospital management issues unrelated to any drug or medical device. Those cases are outside the scope of our analysis.
New filings related to
FINANCIAL STATEMENT issues

New filings related to
SALES FORECAST and DEMAND issues

New filings related to
OTHER POST-APPROVAL issues

New filings related to
CLINICAL TRIALS PHASES 1-3

New filings related to
SUBMISSION of NDA/501 (k)

New filings related to
LATE SEC FILING issues

New filings related to
ANTITRUST INVESTIGATION issues

New filings related to
ALLEGED PRODUCT DEFECTS

New filings related to
ALLEGED REGULATORY VIOLATIONS—MARKETING AND BILLING

New filings related to
SALES FORECAST and DEMAND issues

Decisions related to
LATE SEC FILING issues

28 NEW FILINGS RELATED TO POST-APPROVAL DRUGS OR DEVICES

15 New filings related to
CLINICAL TRIALS PHASES 1-3

7 New filings related to
SUBMISSION of NDA/501 (k)

4 New filings related to
OTHER POST-APPROVAL issues

5 New filings related to
PRE-APPROVAL DRUGS OR DEVICES

5 New filings related to
FINANCIAL STATEMENT issues

2 4
NEW FILINGS IN 2016
BY CIRCUIT

New Filings
<table>
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<th>COMPANY</th>
<th>DATE</th>
<th>COURT</th>
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<tbody>
<tr>
<td>ABEONA THERAPEUTICS, INC. (F/K/A PLASMATECH BIOPHARMACEUTICALS, INC.)</td>
<td>12/16/2016</td>
<td>S.D.N.Y.</td>
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<tr>
<td>ARROWHEAD PHARMACEUTICALS, INC.</td>
<td>11/15/2016</td>
<td>C.D. Cal.</td>
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<tr>
<td>PRONAI THERAPEUTICS INC.</td>
<td>11/9/2016</td>
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<td>INSMED INCORPORATED</td>
<td>7/15/2016</td>
<td>D.N.J.</td>
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<tr>
<td>JUNO THERAPEUTICS INC.</td>
<td>7/12/2016</td>
<td>W.D. Wash.</td>
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<tr>
<td>IMMUNOMEDICS, INC.</td>
<td>6/9/2016</td>
<td>D.N.D.</td>
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SUMMARY OF ALLEGATIONS

DEVELOPMENT STAGE  Abeona develops gene therapy and plasma-based products. Plaintiffs allege that the company failed to disclose that the science behind its proposed gene therapy treatment was not viable and that a company executive had previously worked for a biotech promoter convicted of securities fraud. Share prices dropped after an analyst published a report discussing these issues.

PHASE 2  Arrowhead is the developer of ARC-520, a hepatitis B drug. Plaintiffs allege that the company made false and misleading statements about the safety of the drug, which was fatal at certain doses, and that the company overstated the drug’s prospects for approval and commercial viability. Share prices dropped after the company issued a press release revealing that the FDA had placed a clinical hold on its Phase 2 study.

PHASE 2  ProNAi develops PNT2258, a drug for non-Hodgkin lymphoma. Plaintiffs allege that the company made false and misleading statements about the drug’s efficacy and capacity for approval. Share prices fell after the company announced that Phase 2 trials failed to establish adequate efficacy.

PHASE 2  Seres develops microbiome therapeutics; its leading product candidate is SER-109, a drug designed to prevent recurrences of c. difficile. Plaintiffs allege that the company made false and misleading statements about the drug’s efficacy and capacity for approval, and about the structure of a Phase 2 trial. Share prices declined more than 70 percent after Seres announced that the drug had failed to reach its primary endpoint in the Phase 2 trial.

PHASE 2  Insmed develops the drug Arikayce, a treatment for late stage lung disease. Plaintiffs allege that the company misrepresented the likelihood of approval in the European Union. Share prices fell after the company announced that it had withdrawn its application for approval in the EU following an unsuccessful Phase 2 study.

PHASE 2  Juno Therapeutics develops the drug JCAR015, a treatment for Acute Lymphoblastic Leukemia. Plaintiffs allege that the company failed to disclose that Phase 1 trials showed that the drug had limited value and that patients were dying from toxic side effects associated with the Phase 2 trials. Share prices plunged after the company announced that the FDA had halted trials due to patient deaths. Despite the fact that trials ultimately resumed, share prices later declined again after the disclosure of two additional deaths.

PHASE 2  Immunomedics develops IMMU-132, an antibody drug for treatment of breast and lung cancers. Plaintiffs allege that the company falsely stated that it would present updated results of a Phase 2 study at an American Society of Clinical Oncology event. Plaintiffs contend that the company instead sought to present older data, that such presentation is contrary to ASCO’s policy, that ASCO accordingly canceled the company’s scheduled presentation, and that this led to a drop in share price.
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<th>COMPANY</th>
<th>DATE</th>
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<tr>
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<td>5/12/2016</td>
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<td>ESPERION THERAPEUTICS, INC.</td>
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<td>DYNAVAX TECHNOLOGIES CORPORATION</td>
<td>11/18/2016</td>
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<td>CEMPRA, INC.</td>
<td>11/4/2016</td>
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<td>TOKAI PHARMACEUTICALS, INC.</td>
<td>8/1/2016</td>
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<td>CYTRX CORPORATION</td>
<td>7/25/2016</td>
<td>C.D. Cal.</td>
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Newlink develops cancer treatments; its leading candidate is Algenpantucel-L, a pancreatic cancer drug. Plaintiffs allege that the company misrepresented both Phase 2 trial results and the likelihood of success in Phase 3. Share prices dropped after the company announced that it would not seek approval of the drug.

Esperion develops LDL-cholesterol lowering therapies for patients with hypercholesterolemia; its leading candidate is ETC-1002, a drug intended to lower LDL cholesterol levels without the side effects of other drugs in the marketplace. Plaintiffs allege that the company falsely portrayed in a meeting with the FDA that the company would not need to complete a lengthy and expensive cardiovascular outcome trial prior to approval of the drug. Share prices plunged after the company later disclosed that the FDA had encouraged it to initiate the cardiovascular outcome trial before submitting its NDA. (This action was dismissed in December 2016, in a decision discussed on page “Dougherty v. Esperion Therapeutics, Inc., 2016 WL 7439196, motion to dismiss granted (E.D. Mich. Dec. 27, 2016). Phase 2/3” on page 30.)

Dynavax develops vaccines and therapeutics, including HEPLISAV-B, an investigational adult hepatitis B vaccine. Plaintiffs allege that the company made false and misleading statements about the number of adverse events associated with the drugs in clinical trials and the possibility of commercialization. Share prices dropped after the company announced that it had received a Complete Response Letter from the FDA requesting additional information about the product.

Cempra develops antibiotics, including the product candidate solithromycin, a treatment for bacterial pneumonia and urethritis. Plaintiffs allege that the company made false and misleading statements about the significant safety risks posed by the drug. Share prices fell after the FDA posted a preliminary review of the drug indicating the agency’s concern about a high rate of site-related reactions.

Tokai develops therapies for prostate cancer; its leading drug candidate is galeterone. Plaintiffs allege that the company failed to disclose significant problems with the Phase 3 trial design, and further failed to disclose that the drug was unlikely to meet its primary endpoint. Share prices fell after [Seeking Alpha](https://www.seekingalpha.com) published a report entitled “What’s Wrong with Tokai Pharmaceuticals,” and dropped further after the company announced plans to discontinue the galeterone Phase 3 trial.

CytRx develops the drug aldorubicin for use in oncology. Plaintiffs allege that the company failed to disclose that the clinical hold placed on the Phase 3 trial for aldorubicin would prevent sufficient follow-up for patients in that study, that nearly half of these patients would be censored from evaluation, that this would make a second analysis necessary, and that all of this would delay approval of the drug. Share prices dropped after the company announced these developments.
**SUMMARY OF ALLEGATIONS**

**PHASE 2/3** Newlink develops cancer treatments; its leading candidate is Algenpantucel-L, a pancreatic cancer drug. Plaintiffs allege that the company misrepresented both Phase 2 trial results and the likelihood of success in Phase 3. Share prices dropped after the company announced that it would not seek approval of the drug.

**PHASE 2/3** Esperion develops LDL-cholesterol lowering therapies for patients with hypercholesterolemia; its leading candidate is ETC-1002, a drug intended to lower LDL cholesterol levels without the side effects of other drugs in the marketplace. Plaintiffs allege that the company falsely portrayed in a meeting with the FDA that the company would not need to complete a lengthy and expensive cardiovascular outcome trial prior to approval of the drug. Share prices plunged after the company later disclosed that the FDA had encouraged it to initiate the cardiovascular outcome trial before submitting its NDA. (This action was dismissed in December 2016, in a decision discussed on page "Dougherty v. Esperion Therapeutics, Inc., 2016 WL 7439196, motion to dismiss granted (E.D. Mich. Dec. 27, 2016). Phase 2/3" on page 30, above.)

**PHASE 3** Dynavax develops vaccines and therapeutics, including HEPLISAV-B, an investigational adult hepatitis B vaccine. Plaintiffs allege that the company made false and misleading statements about the number of adverse events associated with the drugs in clinical trials and the possibility of commercialization. Share prices dropped after the company announced that it had received a Complete Response Letter from the FDA requesting additional information about the product.

**PHASE 3** Cempra develops antibiotics, including the product candidate solithromycin, a treatment for bacterial pneumonia and urethritis. Plaintiffs allege that the company made false and misleading statements about the significant safety risks posed by the drug. Share prices fell after the FDA posted a preliminary review of the drug indicating the agency’s concern about a high rate of site-related reactions.

**PHASE 3** Tokai develops therapies for prostate cancer; its leading drug candidate is galeterone. Plaintiffs allege that the company failed to disclose significant problems with the Phase 3 trial design, and further failed to disclose that the drug was unlikely to meet its primary endpoint. Share prices fell after Seeking Alpha published a report entitled “What’s Wrong with Tokai Pharmaceuticals,” and dropped further after the company announced plans to discontinue the galeterone Phase 3 trial.

**PHASE 3** CytRx develops the drug aldonubicin for use in oncology. Plaintiffs allege that the company failed to disclose that the clinical hold placed on the Phase 3 trial for aldonubicin would prevent sufficient follow-up for patients in that study, that nearly half of these patients would be censored from evaluation, that this would make a second analysis necessary, and that all of this would delay approval of the drug. Share prices dropped after the company announced these developments.
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<td>CTI BIOPHARMA CORP.</td>
<td>2/10/2016</td>
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<td>TRANSENERIX, INC.</td>
<td>6/2/2016</td>
<td>E.D.N.C.</td>
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<td>SPECTRUM PHARMACEUTICALS, INC.</td>
<td>9/21/2016</td>
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<td>LIPOCINE INC.</td>
<td>7/1/2016</td>
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<td>EAGLE PHARMACEUTICALS, INC.</td>
<td>5/31/2016</td>
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### New Filings

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<th>COMPANY</th>
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<th>COURT</th>
<th>SUMMARY OF ALLEGATIONS</th>
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<tr>
<td>CTI BIOPHARMA CORP.</td>
<td>2/10/2016</td>
<td>W.D. Wash.</td>
<td>CTI develops pacritinib, a drug treatment for myelofibrosis. Plaintiffs allege that the company hid from investors results of Phase 3 studies that revealed a large number of patient deaths. The FDA eventually ordered a hold on the studies. Share prices dropped after the company announced that the FDA had found excess mortality and other adverse events.</td>
</tr>
<tr>
<td>TETRAPHASE PHARMACEUTICALS INC.</td>
<td>1/28/2016</td>
<td>D. Mass.</td>
<td>Tetraphase develops Eravacycline, an intravenous to oral transition therapy for the treatment of complicated urinary tract infections. Plaintiffs allege that the company embarked on a fraudulent scheme to force oral use of the drug despite knowing the drug was not effective when taken orally. Plaintiffs also contend that the results of a Phase 3 trial were withheld from investors for four months. Share prices dropped after the company issued a press release announcing that the Phase 3 study had failed to meet its primary endpoint.</td>
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<tr>
<td>TRANSENDIX INC.</td>
<td>6/2/2016</td>
<td>E.D.N.C.</td>
<td>TransEnterix is a medical device company that develops the SurgiBot system, a laparoscopic surgical platform. Plaintiffs challenge the company’s statements concerning the anticipated clearance of its 510(k) submission for the SurgiBot system. Share prices dropped after the company disclosed that the FDA had determined that the SurgiBot system did not meet the criteria for substantial equivalence to existing robotic surgical devices.</td>
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<tr>
<td>SPECTRUM PHARMACEUTICALS, INC.</td>
<td>9/21/2016</td>
<td>D. Nev.</td>
<td>Spectrum develops apaziquone, a treatment for bladder cancer. Plaintiffs allege that the company failed to disclose the FDA’s concerns about Phase 3 trials as well as the FDA’s recommendation that the company not submit an NDA based on those trials. Share prices fell after Spectrum announced that the drug had not shown substantial evidence of a treatment effect compared to a placebo. Share prices dropped further after TheStreet.com published an article in which the company was accused of hiding a key meeting with the FDA from investors.</td>
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<td>LIPOCINE INC.</td>
<td>7/1/2016</td>
<td>D.N.J.</td>
<td>Lipocine develops the drug LPCN 1021, an oral testosterone replacement therapy. Plaintiffs allege that the company failed to disclose defects in its NDA; according to plaintiff, the proposed titration scheme in the company's Phase 3 trial differed from the scheme to be used in actual clinical practice. Share prices dropped after the company disclosed an FDA Complete Response Letter identifying the same issue with the Phase 3 trial.</td>
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<tr>
<td>CHIASMA, INC.</td>
<td>6/9/2016</td>
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<td>Chiasma develops therapies for orphan diseases; its leading drug candidate is Mycapssa, a treatment for acromegaly. Plaintiffs challenge statements concerning the methodology of a Phase 3 trial, the supervision of the company’s suppliers, and the likelihood of FDA approval. Share prices fell after the company announced that the FDA had issued a Complete Response Letter stating that the company had not provided sufficient evidence of efficacy to warrant approval.</td>
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<td>EAGLE PHARMACEUTICALS, INC.</td>
<td>5/31/2016</td>
<td>D.N.J.</td>
<td>Eagle Pharmaceuticals develops Kangio, a purportedly shelf stable liquid form of Bivalirudin, a drug previously approved by the FDA. Plaintiffs challenge the company’s statements concerning a failed attempt to secure FDA approval of the drug through the FDA’s Section 505(b)(2) regulatory pathway. Share prices dropped after the company announced that the FDA had requested further information about Kangio and that human trials of the drug might be required.</td>
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<tr>
<td>ROCKWELL MEDICAL, INC.</td>
<td>3/4/2016</td>
<td>S.D.N.Y.</td>
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<td>PTC THERAPEUTICS, INC</td>
<td>3/3/2016</td>
<td>D.N.J.</td>
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<td>CARDIOVASCULAR SYSTEMS, INC.</td>
<td>2/12/2016</td>
<td>C.D. Cal.</td>
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<td>INSYS THERAPEUTICS INCORPORATED</td>
<td>2/2/2016</td>
<td>D. Ariz.</td>
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<td>ALERE INC.</td>
<td>11/14/2016</td>
<td>S.D. Fla.</td>
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<td>MYLAN N.V.</td>
<td>10/11/2016</td>
<td>S.D.N.Y.</td>
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<td>HALYARD HEALTH, INC.</td>
<td>6/28/2016</td>
<td>S.D.N.Y.</td>
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</tbody>
</table>
SUMMARY OF ALLEGATIONS

**NDA** Rockwell develops drugs targeting renal and chronic kidney disease; its leading drug is Triferic, an iron compound delivered to dialysis patients. Plaintiffs allege that the company failed to disclose that it had submitted a separate NDA for the powder form of Triferic, which was expected to be more viable commercially than the previously approved liquid form. Share prices dropped after a fourth-quarter 2015 earnings call revealed immaterial net sales of liquid Triferic in 2015 and the company disclosed for the first time that a separate NDA had been submitted for the powder form of the drug.

**NDA** PTC Therapeutics develops therapeutics for RNA biology; its leading product is Translarna, an oral protein therapy for the treatment of muscular dystrophy. Plaintiffs allege that the company failed to disclose that the company’s NDA was not sufficiently complete to permit a substantive review. Share prices dropped after the company announced that it had received a Refuse to File Letter in which the FDA stated that it would not review the company’s NDA.

**POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS – MARKETING** Cardiovascular Systems develops, manufactures, and markets devices to treat vascular diseases. Plaintiffs allege that the company distributed illegal kickbacks to healthcare providers, engaged in off-label promotion of medical devices, and violated FDA laws and regulations in connection with its medical devices. Share prices fell after the company disclosed that the U.S. Attorney’s Office was investigating it for violations of the False Claims Act.

**POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS – MARKETING** Insys Therapeutics sells the drug Subsys, a spray approved by the FDA for the treatment of breakthrough cancer pain in opioid-tolerant patients. Plaintiffs allege that the company orchestrated a campaign to promote use of the drug for off-label prescription. Plaintiffs also allege that the company offered kickback payments to prescribers to further the scheme. Share prices dropped after Insys issued a press release announcing significantly lower revenues than previously expected.

**POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS – BILLING** Alere’s wholly owned subsidiary, Arriva, supplies diabetic testing supplies by mail order. Plaintiffs allege that the company failed to disclose that Arriva was submitting Medicare claims for deceased patients, as a result of which Arriva had its Medicare enrollment revoked. Share prices dropped after Arriva disclosed that it had received notice of the enrollment revocation.

**POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS – BILLING** Plaintiffs allege that the company made false and misleading statements by incorrectly classifying the EpiPen as a generic under Medicaid’s drug rebate program, which resulted in a lower rebate percentage that cost the government more than $100 million over five years. Plaintiffs also allege that the company lacked effective internal controls over financial reporting. Share prices fell after an Inside Health Policy article revealed that EpiPen was wrongly classified as a generic.

**POST-APPROVAL; ALLEGED PRODUCT DEFECTS** Plaintiffs allege that the company misrepresented the effectiveness of MICROCOOL surgical gowns provided to U.S. workers during the 2016 Ebola crisis. Share prices dropped after 60 Minutes reported that the company had knowingly provided defective gowns.
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<th>COMPANY</th>
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<tr>
<td>HEARTWARE INTERNATIONAL, INC.</td>
<td>1/22/2016</td>
<td>S.D.N.Y.</td>
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<td>LANNETT PHARMACEUTICALS COMPANY, INC.</td>
<td>11/16/2016</td>
<td>E.D. Penn.</td>
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<td>IMPAX LABORATORIES INC.</td>
<td>11/10/2016</td>
<td>D.N.J.</td>
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<tr>
<td>ENDO INTERNATIONAL PLC</td>
<td>11/7/2016</td>
<td>S.D.N.Y.</td>
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</table>
SUMMARY OF ALLEGATIONS

POST-APPROVAL; ALLEGED PRODUCT DEFECTS  HeartWare develops the MVAD heart pump, a ventricular assistance device implanted for patients suffering from heart failure. Plaintiffs allege that HeartWare failed to respond to an FDA Warning Letter relating to defects in manufacturing and testing the pump. Plaintiffs also allege that the company made false statements about the importance of the pump to its stock price. Share prices fell after analysts began reporting rumors of adverse events in European trials of the pump and fell again after the company announced that nearly half of the patients enrolled in those trials had experienced pump thrombosis.

POST-APPROVAL; ANTITRUST INVESTIGATION  Lannett develops and sells generic versions of brand pharmaceuticals. Plaintiffs allege that the company failed to disclose that its drug pricing practices were improper and would trigger antitrust investigations by the DOJ and Attorney General of Connecticut. Share prices dropped after the company announced that it had received interrogatories and a subpoena from the Connecticut Attorney General.

POST-APPROVAL; ANTITRUST INVESTIGATION  Impax develops and markets generic pharmaceuticals. Plaintiffs allege that the company failed to disclose that Impax was engaging in conduct that would cause the DOJ antitrust division and Connecticut Attorney General to conduct investigations likely to result in criminal charges. Plaintiffs also allege that the company lacked effective internal controls over financial reporting. Share prices fell after Bloomberg published an article describing the DOJ’s investigation into suspected price collusion among several pharmaceutical companies including Impax.

POST-APPROVAL; ANTITRUST INVESTIGATION  Plaintiffs allege that the company made false or misleading statements about its subsidiary, which purportedly was involved in price-fixing for generic drugs. Share prices plummeted after media outlets reported that prosecutors were considering filing criminal charges against Endo’s subsidiary (among others).

POST-APPROVAL; ANTITRUST INVESTIGATION  Teva develops and markets generic pharmaceuticals. Plaintiffs allege that the company failed to disclose that Teva was engaging in conduct that would result in federal and Connecticut antitrust investigations, and that these investigations would result in criminal charges. Plaintiffs also allege that Teva lacked effective internal controls over financial reporting. Share prices dropped after the company disclosed that its subsidiary had received two subpoenas in a government investigation into the marketing and pricing of generic products.

POST-APPROVAL; ANTITRUST INVESTIGATION  Plaintiffs allege that Allergan failed to disclose that it was engaging in conduct that would result in a DOJ antitrust investigation and criminal charges for price collusion. Plaintiffs also allege that Allergan lacked effective internal controls over financial reporting. Share prices dropped after the company disclosed that the DOJ antitrust division had issued a subpoena and after a Bloomberg article revealed that Allergan was under investigation for antitrust violations.
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<th>COMPANY</th>
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| TARO PHARMACEUTICAL INDUSTRIES, LTD.         | 10/25/2016 | S.D.N.Y.
| ALEXION PHARMACEUTICALS, INC.                | 11/17/2016 | S.D.N.Y.
| UNILIFE CORPORATION                          | 5/26/2016 | S.D.N.Y.
| LIGAND PHARMACEUTICALS INCORPORATED          | 11/17/2016 | S.D. Cal.
| INFUSYSTEM HOLDINGS, INC.                    | 11/8/2016  | C.D. Cal.
| MISONIX, INC.                                | 9/19/2016  | E.D.N.Y.
| GW PHARMACEUTICALS PLC                       | 1/21/2016  | S.D.N.Y.

Plaintiffs allege that the company failed to disclose that it had violated antitrust laws by colluding with other pharmaceutical companies to keep the price of generic drugs high. Share prices fell after the company disclosed that its subsidiary had received a DOJ subpoena related to potential antitrust violations.

Alexion develops therapeutic products, including Soliris, an antibody used for the treatment of a certain genetic diseases. Plaintiffs allege that defendants failed to disclose that the company employed improper sales practices and that its sales would prove to be unsustainable. Share prices dropped after Alexion cancelled an appearance at a Credit Suisse Healthcare Conference and failed to file a 10-Q within two days of its earnings announcement.

Unilife is a designer and manufacturer of injectable drug delivery systems. Plaintiffs allege that the company's CEO and former board chair were misappropriating company funds for personal use and issuing kickbacks. Share prices fell after the company disclosed that it would delay its 10-Q filing due to the discovery of these violations.

Plaintiffs allege financial statement fraud, including the alleged overstatement of Deferred Tax Assets, the mischaracterization of unsecured notes as short-term debt, and the failure to maintain effective internal controls over income tax accounting. Share prices dropped after the company filed an 8-K announcing internal control deficiencies and an upcoming restatement.

InfuSystem provides infusion pumps for home and clinical settings. Plaintiffs allege that the company overstated estimated accounts receivable (and hence revenue) and failed to disclose that it lacked effective internal controls over financial reporting. Share prices dropped after the company filed an 8-K stating that its previously issued financial statements should not be relied upon.

Misonix develops and markets ultrasonic products for surgical use. Plaintiffs allege financial statement fraud and internal controls deficiencies. Share prices fell after the company announced that it had discovered internal control deficiencies and that its quarterly filing would be delayed.

GW Pharmaceuticals develops and commercializes cannabinoid prescription medicines. Plaintiffs allege financial statement fraud and internal control deficiencies. Share prices fell after The Sunday Times published an article about the company's accounting issues.
### New Filings

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<tr>
<td>TARO PHARMACEUTICAL INDUSTRIES, LTD.</td>
<td>10/25/2016</td>
<td>S.D.N.Y.</td>
<td>POST-APPROVAL; ANTITRUST INVESTIGATION  Plaintiffs allege that the company failed to disclose that it had violated antitrust laws by colluding with other pharmaceutical companies to keep the price of generic drugs high. Share prices fell after the company disclosed that its subsidiary had received a DOJ subpoena related to potential antitrust violations.</td>
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<tr>
<td>ALEXION PHARMACEUTICALS, INC.</td>
<td>11/17/2016</td>
<td>S.D.N.Y.</td>
<td>POST-APPROVAL; DELAYED SEC FILING  Alexion develops therapeutic products, including Soliris, an antibody used for the treatment of a certain genetic diseases. Plaintiffs allege that defendants failed to disclose that the company employed improper sales practices and that its sales would prove to be unsustainable. Share prices dropped after Alexion cancelled an appearance at a Credit Suisse Healthcare Conference and failed to file a 10-Q within two days of its earnings announcement.</td>
</tr>
<tr>
<td>UNILIFE CORPORATION</td>
<td>5/26/2016</td>
<td>S.D.N.Y.</td>
<td>POST-APPROVAL; INTERNAL INVESTIGATION/DELAYED SEC FILING  Unilife is a designer and manufacturer of injectable drug delivery systems. Plaintiffs allege that the company’s CEO and former board chair were misappropriating company funds for personal use and issuing kickbacks. Share prices fell after the company disclosed that it would delay its 10-Q filing due to the discovery of these violations.</td>
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<td>LIGAND PHARMACEUTICALS INCORPORATED</td>
<td>11/17/2016</td>
<td>S.D. Cal.</td>
<td>POST-APPROVAL; CHALLENGE TO FINANCIAL STATEMENTS  Plaintiffs allege financial statement fraud, including the alleged overstatement of Deferred Tax Assets, the mischaracterization of unsecured notes as short-term debt, and the failure to maintain effective internal controls over income tax accounting. Share prices dropped after the company filed an 8-K announcing internal control deficiencies and an upcoming restatement.</td>
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<tr>
<td>INFUSYSTEM HOLDINGS, INC.</td>
<td>11/8/2016</td>
<td>C.D. Cal.</td>
<td>POST-APPROVAL; CHALLENGE TO FINANCIAL STATEMENTS  InfuSystem provides infusion pumps for home and clinical settings. Plaintiffs allege that the company overstated estimated accounts receivable (and hence revenue) and failed to disclose that it lacked effective internal controls over financial reporting. Share prices dropped after the company filed an 8-K stating that its previously issued financial statements should not be relied upon.</td>
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<tr>
<td>MISONIX, INC.</td>
<td>9/19/2016</td>
<td>E.D.N.Y.</td>
<td>POST-APPROVAL; CHALLENGE TO FINANCIAL STATEMENTS  Misonix develops and markets ultrasonic products for surgical use. Plaintiffs allege financial statement fraud and internal controls deficiencies. Share prices fell after the company announced that it had discovered internal control deficiencies and that its quarterly filing would be delayed.</td>
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<tr>
<td>GW PHARMACEUTICALS PLC</td>
<td>1/21/2016</td>
<td>S.D.N.Y.</td>
<td>POST-APPROVAL; CHALLENGE TO FINANCIAL STATEMENTS  GW Pharmaceuticals develops and commercializes cannabinoid prescription medicines. Plaintiffs allege financial statement fraud and internal control deficiencies. Share prices fell after The Sunday Times published an article about the company’s accounting issues.</td>
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<td>MANNKIND CORPORATION</td>
<td>1/15/2016</td>
<td>C.D. Cal.</td>
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<td>EMERGENT BIOSOLUTIONS, INC.</td>
<td>7/19/2016</td>
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<td>CONCORDIA INTERNATIONAL CORP.</td>
<td>8/15/2016</td>
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<td>ILLUMINA, INC.</td>
<td>12/16/2016</td>
<td>S.D. Cal.</td>
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<td>ZIMMER BIOMET HOLDINGS, INC.</td>
<td>12/2/2016</td>
<td>N.D. Ind.</td>
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<tr>
<td>KERYX BIOPHARMACEUTICALS, INC.</td>
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MannKind sells Afrezza, a rapid-acting inhaled insulin product for adults with diabetes. Plaintiffs allege that the company downplayed the impact of spirometry testing limitations in holding back sales of the drug, and that poor sales led Mannkind's distribution partner to terminate the parties' agreement. Share prices fell after MannKind announced the termination of the agreement. (This action was dismissed with prejudice in August 2016, in a decision discussed on page 42, above.)

Plaintiffs allege that Emergent, which produces the only anthrax vaccine licensed by the FDA, misrepresented the U.S. government's growing demand for the vaccine. Share prices dropped after the company announced that the Department of Health and Human Services had issued solicitation notices implying lowered demand for the company's vaccines.

Plaintiffs allege that Concordia failed to disclose a substantial increase in competition against its drug Donnatal, which would depress revenue performance and lead to a suspended dividend. Share prices fell after the company announced that it was lowering its 2016 guidance to reflect the impact of unexpected competition.

Illumina provides products and services used in genetic analysis. Plaintiffs allege that defendants made false and misleading statements about the decline in sales of one of the company's gene sequencing instruments. Share prices fell after the company announced that it would not meet its third quarter revenue projections.

Zimmer develops and manufactures medical equipment, including implants and surgical products. Plaintiffs allege that the company failed to disclose that supply chain problems led to a decrease in order fulfillment rates, which in turn led the company to miss revenue and profit forecasts. Share prices dropped after the company issued reported lower net sales than previously expected due to the supply chain infrastructure issue.

Keryx sells Auryxia, a treatment for chronic kidney disease. Plaintiffs allege that the company failed to disclose that production difficulties would lead to the exhaustion of supplies of the drug. Share prices dropped after Keryx announced that a supply interruption of Auryxia would occur and that the company had exhausted its reserve of finished drug product.

Neovasc is a medical device company that manufactures the Tiara, a device used to treat mitral valve disease that can be implanted through minimally invasive surgery. Plaintiffs allege that the company failed to disclose that the Tiara device was developed through the misappropriation of trade secrets from the company CardiAQ. Share prices fell after a jury awarded CardiAQ $70M in damages after determining that Neovasc had misappropriated trade secrets.
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<tr>
<td>MannKind Corporation</td>
<td>1/15/2016</td>
<td>C.D. Cal.</td>
<td>POST-APPROVAL; DEMAND ISSUES MannKind sells Afrezza, a rapid-acting inhaled insulin product for adults with diabetes. Plaintiffs allege that the company downplayed the impact of spirometry testing limitations in holding back sales of the drug, and that poor sales led Mannkind’s distribution partner to terminate the parties' agreement. Share prices fell after MannKind announced the termination of the agreement. (This action was dismissed with prejudice in August 2016, in a decision discussed on page 42, above.)</td>
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<tr>
<td>Emergent Biosolutions, Inc.</td>
<td>7/19/2016</td>
<td>D. Mar.</td>
<td>POST-APPROVAL; DEMAND ISSUES Plaintiffs allege that Emergent, which produces the only anthrax vaccine licensed by the FDA, misrepresented the U.S. government's growing demand for the vaccine. Share prices dropped after the company announced that the Department of Health and Human Services had issued solicitation notices implying lowered demand for the company's vaccines.</td>
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<tr>
<td>Concordia International Corp.</td>
<td>8/15/2016</td>
<td>S.D.N.Y.</td>
<td>POST-APPROVAL; SALES FORECASTING Plaintiffs allege that Concordia failed to disclose a substantial increase in competition against its drug Donnatal, which would depress revenue performance and lead to a suspended dividend. Share prices fell after the company announced that it was lowering its 2016 guidance to reflect the impact of unexpected competition.</td>
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<tr>
<td>Illumina, Inc.</td>
<td>12/16/2016</td>
<td>S.D. Cal.</td>
<td>POST-APPROVAL; SALES FORECASTING Illumina provides products and services used in genetic analysis. Plaintiffs allege that defendants made false and misleading statements about the decline in sales of one of the company’s gene sequencing instruments. Share prices fell after the company announced that it would not meet its third quarter revenue projections.</td>
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<tr>
<td>Zimmer Biomet Holdings, Inc.</td>
<td>12/2/2016</td>
<td>N.D. Ind.</td>
<td>POST-APPROVAL; SALES FORECASTING Zimmer develops and manufactures medical equipment, including implants and surgical products. Plaintiffs allege that the company failed to disclose that supply chain problems led to a decrease in order fulfillment rates, which in turn led the company to miss revenue and profit forecasts. Share prices dropped after the company issued reported lower net sales than previously expected due to the supply chain infrastructure issue.</td>
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<tr>
<td>Keryx Biopharmaceuticals, Inc.</td>
<td>8/2/2016</td>
<td>S.D.N.Y.</td>
<td>POST-APPROVAL; OTHER (SUPPLY CHAIN ISSUES) Keryx sells Auryxia, a treatment for chronic kidney disease. Plaintiffs allege that the company failed to disclose that production difficulties would lead to the exhaustion of supplies of the drug. Share prices dropped after Keryx announced that a supply interruption of Auryxia would occur and that the company had exhausted its reserve of finished drug product.</td>
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<tr>
<td>Neovasc, Inc.</td>
<td>6/6/2016</td>
<td>D. Mass.</td>
<td>POST-APPROVAL; OTHER (COMPETITION/TRADE SECRETS) Neovasc is a medical device company that manufactures the Tiara, a device used to treat mitral valve disease that can be implanted through minimally invasive surgery. Plaintiffs allege that the company failed to disclose that the Tiara device was developed through the misappropriation of trade secrets from the company CardiAQ. Share prices fell after a jury awarded CardiAQ $70M in damages after determining that Neovasc had misappropriated trade secrets.</td>
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<td>INTREXON CORPORATION</td>
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<td>NATERA, INC.</td>
<td>3/24/2016</td>
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<td>NANTKWESt, INC.</td>
<td>3/22/2016</td>
<td>N.D. Cal.</td>
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**SUMMARY OF ALLEGATIONS**

**POST-APPROVAL; OTHER (UNFAVORABLE COVERAGE IN INVESTOR BLOG)** Intrexon is a synthetic biology company that uses gene regulation programs to assist in the engineering of cells. Plaintiffs allege that the company failed to disclose that weaknesses in its portfolio of core technologies. Share prices fell after Seeking Alpha published an article whose author criticized Intrexon’s technology and claimed that the technology did not enable users to develop and commercialize cancer therapies.

**POST-APPROVAL; OTHER** Natera develops non-invasive DNA testing and generates revenue primarily from Panorama, a non-invasive prenatal test. Plaintiffs assert claims under the 1933 Act alleging that the company’s IPO registration statement contained false financial data insofar as Panorama sales had flat-lined. (This case was removed to federal court from state court and subsequently remanded to state court. The district court’s remand order is on appeal to the Ninth Circuit.)

**POST-APPROVAL; OTHER** NantKwest develops cancer therapies that use natural killer cells to treat cancer and other infectious diseases. Plaintiffs allege that the company’s IPO registration statement misleadingly omitted facts concerning executive compensation, a lease, and internal control weaknesses. Share prices fell after NantKwest disclosed these issues.
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. And 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, 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

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

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

ROBERT PIETRZAK
+1 212 839 5537
rpietrzak@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