Life Sciences Securities Litigation Activity in Q1 2018: Digest of Notable Decisions, Settlements, and New Filings

April 26, 2018

Notable Decisions

Federal Courts of Appeals

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

On February 22, the Fourth Circuit reversed the Eastern District of North Carolina's dismissal of the plaintiff's second amended complaint against TranS1, Inc. and several of its officers ("TranS1") in this putative class action. The plaintiff alleges that TranS1 concealed a fraudulent scheme to help doctors who used TranS1's system for minimally invasive spinal surgery (the "System") to secure reimbursement from health insurers and government-funded healthcare programs. According to the plaintiff, after the American Medical Association assigned a new billing code to the System, TranS1 instructed and encouraged physicians to submit reimbursement requests using an incorrect billing code and failed to disclose this practice to its shareholders when informing them that it was training surgeons on how to obtain reimbursement in light of the recent billing-code change. The district court dismissed the complaint on the grounds that the plaintiff had not adequately alleged that TranS1 did not sufficiently disclose its reimbursement practices or that TranS1 knew that its reimbursement practices were illegal. The district court also found the plaintiff's scienter allegations insufficient because they did not allege when and how TranS1 knew that its disclosures were false or misleading, much less support a powerful or cogent inference of scienter.

A split panel reversed on appeal, holding that the plaintiffs sufficiently alleged that TranS1 had omitted key facts when disclosing the assistance and training it was providing to surgeons regarding reimbursement—namely, that it was instructing surgeons to unlawfully code the System. The panel majority concluded that, because TranS1 chose to inform the market that it was training surgeons how to code the System and that the new code was causing only minimal losses, TranS1 had a duty to disclose its alleged fraudulent reimbursement scheme. Although the company argued that it could not be expected to disclose supposedly illegal conduct that no court or other adjudicative body has found to be illegal, the court rejected that argument, holding that its choice to speak about its reimbursement requirements triggered an obligation to tell "the whole, material truth." Additionally, the court rejected TranS1's argument under the Sixth Circuit's 2009 decision in *Omnicare*[1] that it did not have a duty to disclose its reimbursement practices because it did not specifically assert that it was complying with a particular law. The panel majority explained its view that *Omnicare* did not establish a rule that there is never a duty to disclose illegal activity absent a specific assertion of compliance with the relevant law and was inapposite in these circumstances. The court also held that the plaintiff pleaded scienter through allegations that TranS1's officers knew of the scheme simply by alleging that they were the ones running the scheme. Finally, the court determined that the plaintiff had pleaded loss causation through an "amalgam" of the corrective-disclosure and materialization-of-the-concealed-risk theories based on a combination of TranS1's announcement that it had received a subpoena from the Department of Health and Human Services and an analyst report speculating that the subpoena could be due to the company's reimbursement communications with doctors. The matter has been remanded to the Eastern District of North Carolina for further proceedings.

[1] *Indiana State Dist. Council of Laborers & HOD Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935 (6th Cir. 2009), *petition for writ of certiorari dismissed*, 562 U.S. 1027 (2010).

Federal District Courts

West Virginia Pipe Trades Health & Welfare Fund v. Medtronic, Inc.,
No. 0:13-cv-01686-JRT-FLN, 2018 WL 620383 (D. Minn. Jan. 30, 2018).

On January 30, the U.S. District Court for the District of Minnesota certified a class in this lawsuit alleging that Medtronic, Inc. ("Medtronic") downplayed problems with a bone-graft product and paid hundreds of millions of dollars to authors of studies to manipulate study findings to boost Medtronic's stock price. The plaintiffs claim that Medtronic paid the authors of early clinical studies $210 million to conceal known adverse side effects, while disclosing only that they were paid "in excess of $10,000" in any given year in connection with the studies. In certifying the class, the court held that the "thrust" of plaintiffs' liability claim was omission rather than any affirmative statements—specifically, Medtronic's alleged failure to disclose its "own quid pro quo arrangements" with the authors of the studies—and that each class member would use the same evidence to make a prima facie showing of liability. After undertaking an extensive discussion about whether it could, under relevant law, consider the merits of the plaintiffs' proposed class period as part of the certification motion, the court concluded that it was compelled to decide when a corrective disclosure was made and set an end point for the class period. The court determined that the truth about the studies being conducted by clinicians with significant financial incentives was revealed in a journal article published in June 2011, more than a month earlier than the end of the proposed class period. The court therefore shortened the class period to end on the date of the June 2011 journal article.

Gerneth v. Chiasma, Inc.,
No. 1:16-cv-11082-DJC, 2018 WL 935418 (D. Mass. Feb. 15, 2018).

On February 15, the U.S. District Court for the District of Massachusetts denied defendants' motion to dismiss in this putative class action involving allegations that Chiasma, Inc. ("Chiasma") omitted material information from its IPO prospectus in violation of Section 11 of the Securities Act. The plaintiff alleges that Chiasma failed to disclose information about the sufficiency of the trial methodology used in the development of its lead product candidate, which the FDA allegedly questioned when providing interim feedback. The FDA allegedly warned Chiasma during pre-NDA meetings that it disagreed with the Phase III trial design, warnings which Chiasma failed to disclose and did not heed prior to filing its NDA. In seeking dismissal, Chiasma argued that it had disclosed that there was a risk that the FDA would deny approval. The court rejected that argument on the basis that a certainty that has already come to pass cannot be couched as a mere possibility, and therefore Chiasma needed to more fully disclose the interim feedback it had received. Further, the court held that a reasonable investor would have been misled by the failure to disclose that the FDA had communicated substantive scientific disagreements about the drug's efficacy. The court concluded that certain other alleged omissions were not well-pleaded because the allegedly omitted information was actually disclosed in the prospectus or the alleged omissions related to information that Chiasma did not obtain until after the IPO prospectus was filed.

Hoey v. Insmed Inc.,
No. 3:16-cv-04323-FLW-TJB, 2018 WL 902266 (D.N.J. Feb. 15, 2018).

On February 15, the U.S. District Court for the District of New Jersey dismissed this putative class action involving allegations that Insmed Inc. ("Insmed") misrepresented and omitted information regarding its lead product candidate, a lung-disease drug administered through a nebulizer, in violation of Section 10(b) and Rule 10b-5. Specifically, the plaintiff alleged that Insmed misrepresented the outcome of a Phase II trial involving the drug and the drug's prospects for European approval, and failed to disclose to investors sufficient details about the methodology of that trial and the European regulators' concerns regarding the methodology. The court held that the plaintiff's allegations were not actionable for a number of reasons. First, the court held that omissions regarding alleged shortcomings in the design and structure of a trial, so long as the results of the trial are accurately represented, are not material and thus not actionable—a holding that the court viewed as comporting with those of "numerous courts" throughout the country. Second, the court held that

biopharmaceutical companies are under no obligation to share a regulatory agency's criticisms or concerns regarding a trial, so long as those communications do not represent a final determination on approval and the company's statements regarding the trial and interactions with regulatory authorities are not otherwise false or misleadingly optimistic. Third, the court held that a number of Insmed's statements were inactionable because they constituted opinions, corporate puffery, or forward-looking statements, introduced with phrases such as "I believe" or "in my judgment." Finally, the court held that the plaintiff failed to plead scienter with sufficient particularity. The Court dismissed the case without prejudice and granted the plaintiff leave to amend within 30 days.

Rabkin v. Lion Biotech., Inc.,
No. 3:17-cv-02086-SI, 2018 WL 905862 (N.D. Cal. Feb. 15, 2018).

On February 15, the U.S. District Court for the Northern District of California granted in part and denied in part a motion to dismiss this putative class action involving allegations that Lion Biotechnologies, Inc. ("Lion"), through a number of its executives, artificially inflated its stock price by commissioning articles published to investment websites that allegedly contained materially false and misleading statements regarding both the company and the impartiality of the reports. After the SEC announced a $100,000 settlement with Lion and a $3,000,000 settlement with its former CEO, the lead plaintiff filed this suit claiming that Lion's shareholders were harmed as a result of the company's failure to disclose its secret promotional efforts and its failure to correct the false and misleading statements made as a result of those efforts. The Court granted dismissal without prejudice with respect to claims under Sections 11 and 12 of the Securities Act on the grounds that the lead plaintiff had failed to sufficiently allege that he owned stock connected to the offering period at issue. The court otherwise rejected the defendants' motion, finding that the claims under Section 10(b) and Rule 10b-5 and Section 20(a) were plausibly alleged.

Costabile v. Natus Medical Inc.,
No. 17-cv-00458-JSW, 2018 WL 1071041 (N.D. Cal. Feb. 26, 2018).

On February 26, the U.S. District Court for the Northern District of California dismissed this putative class action against Natus Medical Inc. ("Natus") involving allegations that Natus made misleading statements regarding a contract to sell medical equipment, supplies, and services to the Venezuelan Ministry of Health. The plaintiff alleged that the company repeatedly misrepresented that the contract had been executed and misled investors about when payments were due under the contract (allegedly to disguise that they were not being made on a timely basis). The complaint relied upon a confidential witness who claimed that the contract had not actually been executed at the time. The court determined that reliance on the confidential witness was insufficient to meet the requirement to plead fraud with particularity because the witness joined the Venezuelan Ministry of Health after the time period in question and because the plaintiff did not provide enough information to evaluate the credibility of information that had been conveyed to the witness by his or her predecessor. The court held that the plaintiff had adequately pleaded misstatements about when payments under the contract were due, rejecting the defendants' argument that the statements were protected as "forward-looking" because they omitted presently existing facts. Nevertheless, the court concluded that the complaint must be dismissed because plaintiff had failed to raise a reasonable inference of scienter. In the absence of sufficient allegations supporting the theory of scienter based on the contract not being executed and in the absence of "direct falsehoods," the plaintiff could not plead scienter based on the mere existence of allegedly false statements. The court decided that the plaintiff's additional basis for inferring scienter—that Natus executives sold company stock for large proceeds during the relevant period—was similarly unavailing because the percentages sold were not unusual in light of the defendants' past trading behavior.

Gregory v. ProNAi Therapeutics Inc.,
No. 1:16-cv-08703-PAE, 2018 WL 1358387 (S.D.N.Y. Mar. 13, 2018)

On March 13, the U.S. District Court for the Southern District of New York granted the motion to dismiss in this putative class action involving allegations that ProNAi Therapeutics Inc. ("ProNAi")

made 70 false or misleading statements regarding the company's sole drug candidate, a potential cancer therapy. At the core of the plaintiff's complaint were allegations that ProNAi misled investors by overstating the drug's prospects, downplaying or failing to disclose negative test results, and identifying as risk factors events that had already come to pass. The District Court dismissed the plaintiff's claims in their entirety for several reasons. First, the court concluded that many of the identified statements largely constituted "mere puffery," as they were "too general to cause a reasonable investor to rely upon them." Second, the court held that other general statements were not actionable because they were "forward-looking statement[s] accompanied by sufficient cautionary language." Third, the court determined that more specific statements regarding the drug's clinical trials and efficacy were sufficiently informative, in the context of the entirety of the information available. Finally, the court held that the plaintiff failed to plead scienter for the only otherwise-actionable statements—non-forward-looking opinion statements about potential novel applications of the drug made after the company receive universally negative results of internal preclinical studies—because the plaintiff failed to plead motive where they alleged only a generalized motive of having a successful IPO and also failed to plead recklessness.

In re HeartWare Int'l, Inc. Sec. Litig.,
No. 1:16-cv-00520-RA (S.D.N.Y. Mar. 16, 2018).

On March 16, the U.S. District Court for the Southern District of New York denied (in a ruling from the bench) the defendants' motion to dismiss this putative class action involving allegations that HeartWare International, Inc. ("HeartWare") misled investors about the safety and commercial viability of the company's flagship heart-pump product before revealing that half the patients enrolled in clinical trials experienced adverse events. The plaintiff alleges that HeartWare falsely claimed that it was making progress on addressing the FDA's concerns about how the device was being tested and produced, pointing to statements by the company's CEO that he was personally overseeing the remediation effort to ensure that the devices would be ready for clinical trials. In moving to dismiss, HeartWare asserted that the suit relied on improper hindsight statements from former employees who were not aware of all the relevant facts and that the CEO's statements were nonactionable forward-looking statements of corporate optimism and opinion. In deciding that the complaint adequately alleged actionable misstatements, the court credited alleged quotations from former employees who stated that HeartWare's processes "didn't change" and that "we were just doing exactly what we were doing before" after receiving the FDA's concerns in writing. The court also determined that it was unlikely that HeartWare's CEO was unaware of quality issues when he made optimistic public statements during the relevant period. Ultimately, the court permitted the plaintiff's case to proceed because the complaint's allegations of fraud were at least as compelling as the opposing inferences that could be drawn in favor of the defendants.

Cohen v. Kitov Pharm. Holdings, Ltd.,
No. 1:17-cv-00917-LGS, 2018 WL 1406619 (S.D.N.Y. Mar. 20, 2018).

On March 20, the U.S. District Court for the Southern District of New York granted in part and denied in part the defendant's motion to dismiss this putative class action involving allegations that Kitov Pharmaceuticals Holdings, Ltd. ("Kitov") misled investors regarding the results of a Phase III trial of a drug in development for the combined treatment of pain and hypertension. Specifically, the plaintiff alleged that Kitov falsified the results of the study in order to hide the fact that the study had failed to show statistically significant evidence of the drug's efficacy, and subsequently failed to disclose that the prior-announced results were inaccurate. Information regarding this conduct came to light after the Israel Securities Authority (the "ISA") arrested Kitov's CEO in connection with the publication of false information and the company announced that the ISA had launched a formal investigation into Kitov's public disclosures regarding the drug. The court denied defendant's motion to dismiss as to statements made specifically regarding the results of the Phase III trial, as Kitov's failure to disclose that the results had been falsified was a material omission in that context. The court dismissed those claims based on allegations that various statements in Kitov's public filings about its business generally were misleading for their failure to disclose the falsified results because those statements were completely unrelated to the allegedly falsified data—as the court explained, "the subject of the

omissions and the subject of the statement[s] are too attenuated" to support a claim. The court also denied the claims as against the company's CFO for lack of sufficiently pleaded scienter.

Erste-Sparinvest Kapitalanlagegesellschaft MBH v. Seres Therapeutics, Inc.,
No. 1:16-cv-11943, 2018 WL 1567614 (D. Mass. Mar. 30, 2018).

On March 30, the U.S. District Court for the District of Massachusetts dismissed this putative class action involving allegations that Seres Therapeutics, Inc. ("Seres") made false and misleading statements regarding the development of a pill-based therapy intended to treat a particular kind of recurring colon infection. The plaintiff alleged that Seres knew or had reason to know that a Phase II trial of the drug would fail, and yet continued to make misleadingly optimistic statements regarding the trial's "high probability of success" up until its completion. When it was eventually announced that the trial had failed to achieve its primary endpoint with statistical significance, Seres's stock price dropped 72 percent. The court dismissed the complaint because the plaintiff failed to plausibly allege that Seres knew, or should have known, that the trial was not going as expected. Given that the trial was conducted on a double-blind basis, the information available to Seres was minimal and did not conflict with the optimistic outlook conveyed to investors. The court also ruled that a number of other alleged misstatements were not actionable because they were made by third parties that were not sufficiently "entangled" with the company, because they were made outside the class period, or because the plaintiff had not adequately alleged that they were false or misleading.

Notable Settlements

Rihn v. Acadia Pharm. Inc.,
No. 3:15-cv-575-BTM-DHB (S.D. Cal. filed Mar. 13, 2015).

On January 22, the U.S. District Court for the Southern District of California granted final approval of the parties' proposed settlement in which Acadia Pharmaceuticals Inc. ("Acadia") will pay $2.925 million to settle all claims brought by a putative class of Acadia shareholders. The lawsuit alleged that Acadia's statements that it was "on track" to submit an NDA for a new drug were materially misleading under the *Omnicare* omissions standard because the company failed to disclose that it had not yet undertaken a meaningful assessment of its manufacturing and quality-assurance systems, a critical component of the NDA approval process. On September 19, 2016, the court denied Acadia's motion to dismiss, concluding that a reasonable investor would have expected the company to have undertaken such an assessment prior to stating that it was "on track." Thereafter, the parties entered into private mediation and reached the settlement, which the court approved preliminarily on June 9, 2017.

Esposito v. Am. Renal Assocs. Holdings, Inc.,
No. 1:16-cv-11797-ADB (D. Mass. filed Aug. 31, 2016).

On January 31, the parties filed a joint motion for approval of a settlement in which American Renal Associates Holdings, Inc. ("ARAH") agreed to pay $4 million to resolve a proposed class action involving allegations of insurance fraud around the time of ARAH's IPO. According to plaintiffs, ARAH, a dialysis-clinic operator, participated in a scheme to funnel Medicare- and Medicaid-qualified patients into private insurance to increase ARAH's reimbursement rates. The suit cited claims made in a 2016 lawsuit filed by UnitedHealth against ARAH alleging that ARAH convinced Medicare- and Medicaid-eligible patients to enroll in UnitedHealth plans by referring them to a charity called the American Kidney Fund, which offered to pay for their private insurance. The UnitedHealth suit alleged that ARAH funded the American Kidney Fund in order to steer more patients to private insurance to increase ARAH's reimbursement rates. ARAH's stock fell 10% on announcement of the UnitedHealth suit and another 10% when the Centers for Medicare and Medicaid Services launched an investigation into ARAH and other dialysis centers that were funneling patients away from Medicare and Medicaid. The district court granted preliminary approval of the settlement on February 8. The settlement is awaiting final approval.

In re CTI BioPharma Corp. Sec. Litig.,
No. 2:16-cv-00216-RSL (W.D. Wash. filed Feb. 12, 2016).

On February 1, 2018, the U.S. District Court for the Western District of Washington granted final approval of a settlement requiring CTI BioPharma Corp. ("CTI") to pay shareholders $20 million. The suit alleged that CTI made positive statements about the ongoing clinical trials of pacritinib, a drug to treat myelofibrosis, while failing to report serious safety concerns. In particular, CTI allegedly proceeded into a second phase of trials despite advice from an independent monitoring committee to halt the study due to safety concerns and failed to disclose that it had received this advice. A motion to dismiss had been fully briefed but the matter settled before a hearing or order on the motion. The court had previously granted preliminary approval of the settlement on October 24, 2017.

In re AVEO Pharm., Inc. Sec. Litig.,
No. 1:13-cv-11157-DJC (D. Mass. filed May 9, 2013).

On February 2, the parties filed a joint motion for approval of a settlement in which AVEO Pharmaceuticals, Inc. ("AVEO") agreed to pay $17.7 million to resolve a class action suit involving allegations that AVEO hid FDA concerns about a drug for treating kidney cancer. According to plaintiffs, in a May 2012 meeting the FDA recommended that AVEO conduct a second clinical trial due to concerns raised by the first trial. The plaintiffs allege that AVEO omitted the FDA's recommendation from all public disclosures about the first trial. When the FDA's concerns were made public a year after the May 2012 meeting, AVEO's stock fell by nearly 50%. AVEO intends to satisfy the settlement amount by paying $15 million into a settlement fund and issuing warrants for the purchase of 2 million shares of its common stock, which plaintiffs estimate to be worth about $2.73 million. The motion for preliminary approval, which the court has not yet decided, comes about two months after the district court granted class certification. In 2016, AVEO agreed to pay $4 million to settle SEC allegations that it hid concerns about the same drug from investors.

In re CytRx Corp. Sec. Litig.,
No. 2:16-cv-05519-SJO-SK (C.D. Cal. filed July 25, 2016).

On February 5, the parties in this putative class action against CytRx Corp. ("CytRx") filed a joint notice of settlement and joint request to stay proceedings in anticipation of a stipulation of settlement to be filed on or before May 2, 2018. The U.S. District Court for the Central District of California granted the stay request on February 7. No details on the settlement agreement are available at this time. The plaintiffs had previously moved to certify a class on November 17, 2017. That motion was still pending before the court at the time that the notice of settlement was filed. The plaintiffs have alleged that CytRx made misleading statements about (i) its compliance with a Special Protocol Assessment (an "SPA") governing a Phase III trial for a cancer drug; (ii) the timeline for the trial; and (iii) the progress of the trial. The plaintiffs' original complaint was dismissed in June 2017 for failure to plead falsity and scienter,[2] prompting plaintiffs to file an amended complaint adding an allegation that the defendants knew *both* that the company had failed to comply with the SPA *and* that its failure to do so could render the SPA non-binding and thereby obviate the FDA's obligation to approve the drug even if the trial was successful. In August 2017, the court permitted some of the plaintiffs' claims to proceed, holding again that a number of the plaintiff's allegations were not actionable but also concluding that the new allegations regarding the consequences of the failure to comply with the SPA adequately pleaded a securities violation.[3]

[2] *See Crihfield v. CytRx Corp.*, 2017 WL 2819834 (C.D. Cal. June 14, 2017).

[3] *See In re CytRx Corp. Sec. Litig.*, 2017 WL 5643161 (C.D. Cal. Aug. 14, 2017).

Arkansas Teacher Ret. Sys. v. Insulet Corp.,
No. 1:15-cv-12345 (D. Mass. filed May 5, 2015).

On February 9, the parties filed a joint motion for approval of a settlement in which Insulet Corporation ("Insulet") agreed to pay $19.5 million to resolve a proposed class action involving allegations that Insulet misled investors about the success of an insulin infusion pump and about certain performance metrics. According to the plaintiffs, Insulet changed the way it calculated and reported how many new patients started using its device in order to hide that sales and patient growth were lagging. After the district court rejected Insulet's motion to dismiss in March 2017, the parties engaged in private mediation before David Geronemus, Esq. of JAMS beginning in July 2017. The parties continued settlement negotiations as discovery progressed and reached an agreement in principle in November 2017. The court has not yet ruled on the motion for preliminary approval.

In re PTC Therapeutics, Inc. Sec. Litig.,
No. 16-cv-11224-KMM-AH (D.N.J. filed Mar. 3, 2016).

On March 2, the parties jointly moved for preliminary approval of a proposed settlement in which PTC Therapeutics ("PTC") would pay shareholders $14.75 million. Previously, on August 28, 2017, the U.S. District Court for the District of New Jersey partially granted and partially denied a motion to dismiss the claims against PTC.[4] The suit was brought after the FDA found the company's NDA for a drug in development to treat genetic mutations was facially inadequate for review. The court dismissed claims asserting that the company knew but failed to disclose that it would not be able to meet certain FDA requirements, concluding that the plaintiffs failed to allege with specificity who supposedly knew that information or what they knew. At the same time, however, the court held that the plaintiffs had pleaded facts sufficient to demonstrate that certain statements by the company—that the "totality" or "consistency" of the data showed that the product had a clinically meaningful benefit to patients—were misleading because the product had not been successful for most patients. The court has not yet ruled on the motion for preliminary approval.

Notable New Filings

Kheder v. Aradigm Corp., et al.,
No. 3:18-cv-00261-VC (N.D. Cal. filed Jan. 11, 2018).

On January 11, the plaintiff filed a putative class action securities suit against Aradigm Corporation and its CEO and CFO ("Aradigm"). Aradigm develops novel pulmonary drug-delivery systems designed to enhance existing and development-stage drugs and to reduce the need for injectable drug therapy. In July 2017, Aradigm filed an NDA for a drug comprising a proprietary formulation of an antibiotic delivered by inhalation for the management of infections associated with respiratory diseases. The plaintiff alleges that Aradigm and the officer defendants made false or misleading statements about whether results from the drug's clinical trial adequately supported the NDA. First, the plaintiff challenges the methodology underlying the drug's Phase III clinical trials as not well tailored to yield consistent efficacy findings. The plaintiff also alleges that the endpoint of the trials was unlikely to demonstrate a clinically meaningful benefit because patients would likely be taking the drug for a much longer duration. The plaintiff claims that Aradigm's share price fell 38.12% on January 9, 2018, when the FDA released a briefing document noting its concerns with the trials. The case was filed by Pomerantz LLP and Bronstein, Gewirtz & Grossman, LLC.

[4] *See In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801 (D.N.J. Aug. 28, 2017).

Bowers v. Tesaro Inc., et al.,
No. 1:18-cv-10086-ADB (D. Mass. filed Jan. 17, 2018).

On January 17, the plaintiff filed a putative class action securities suit against Tesaro Inc. and its CEO and CFO ("Tesaro"). Tesaro identifies and develops cancer therapeutics and oncology supportive care products. One of Tesaro's products was approved by the FDA in 2015 as an oral treatment for chemotherapy-induced nausea and vomiting. In March 2016, Tesaro filed an NDA for an intravenous version of the product, which gained FDA approval in October 2017. The plaintiff alleges that on January 12, 2018, Tesaro updated the labeling for the intravenous version due to reports of anaphylaxis and anaphylactic shock, some instances of which required hospitalization. The plaintiff thus alleges that the defendants made false or misleading statements by failing to disclose those health risks associated with the intravenous formulation throughout the relevant period, causing Tesaro's share price to fall by 5.85% on the new-label announcement. The case was filed by Pomerantz LLP, Bronstein, Gewirtz & Grossman, LLC, and Andrews DeValerio LLP.

Kakkar, et al. v. Bellicum Pharm., Inc.,
No. 4:18-cv-00338 (S.D. Tex. filed Feb. 6, 2018).

On February 6, the plaintiff filed a putative class action against Bellicum Pharmaceuticals, Inc. and its CEO and CFO ("Bellicum") alleging that they made misleading statements by failing to disclose certain risks associated with the company's lead product candidate, a treatment for patients undergoing stem-cell transplants who lack a matched donor. The product is currently undergoing Phase I and II clinical trials. In January 2018, the company announced that the FDA had placed the trials on hold as a result of three cases of encephalopathy (i.e., brain damage) deemed possibly related to the product. The plaintiff alleges that the defendants failed to disclose that there was a substantial risk of encephalopathy associated with the product, which rendered their statements false and misleading at all relevant times. The suit was filed by The Briscoe Law Firm, PLLC, Pomerantz LLP, and Bronstein Gewirtz & Grossman, LLC. A similar suit was filed in the Southern District of Texas on March 14, with the caption *Rudy v. Bellicum Pharm., Inc.*, No. 4:18-cv-00795. The parties' joint motion to consolidate the two cases is currently pending before the district court.

Lee v. Synergy Pharm. Inc.,
No. 1:18-cv-00873 (E.D.N.Y. filed Feb. 8, 2018).

On February 8, a shareholder brought a putative class action suit against Synergy Pharmaceuticals Inc. and its CEO and CFO ("Synergy") alleging that the company made misleading statements regarding a $300 million senior secured loan it received from a third-party lender. The company allegedly needed the loan as part of its "go-it-alone" strategy to develop, distribute, and market a new drug for the treatment of chronic constipation without a major drug manufacturer partner. The plaintiff alleges that the company disclosed the loan as "non-dilutive" of shareholders' interests while providing a material boost to the company's cash position, but failed to disclose certain onerous loan terms that negatively affected shareholders and rendered the loan insufficient to fund the company's operations, requiring the company to conduct a dilutive secondary equity offering to fund its operations through 2019. The suit was filed by WeissLaw LLP. Two similar suits were filed in the Eastern District on February 14 and March 2, with the captions *Countryman v. Synergy Pharm., Inc.*, No. 2:18-cv-00990, and *Rose v. Synergy Pharm., Inc.*, No. 2:18-cv-01344.

Giugno v. Bristol-Myers Squibb Co.,
No. 3:18-cv-00878-VC (N.D. Cal. filed Feb. 9, 2018).

On February 9, the plaintiff brought a putative class action suit against Bristol-Myers Squibb Company and numerous executives ("BMS") alleging that the company made misleading statements regarding the likely results of trials it was conducting on the use of a BMS medication as a first-line therapy in patients with advanced non-small cell lung cancer. The suit alleges that BMS represented having "great confidence" in the treatment, but that this misrepresented the likely success of the trials. The suit also alleges that after disclosure of some negative results, BMS continued to express undue

optimism about the treatment's prospects. The suit was filed by Glancy Prongay & Murray LLP. A similar suit was filed in the Southern District of New York on February 21 with the caption *Tung v. Bristol-Myers Squibb Co.*, No. 1:18-cv-01611.

Khanna v. Ohr Pharm., Inc., et al.,
No. 1:18-cv-01284-LAP (S.D.N.Y. filed Feb. 14, 2018).

On February 14, the plaintiff filed a putative class action securities suit against Ohr Pharmaceutical, Inc. and three executives ("Ohr"). Ohr is a clinical-stage biotechnological company that develops novel therapies for ophthalmic diseases. Ohr's lead product candidate throughout the relevant period was a non-invasive ophthalmic solution aimed at improving vision outcomes. In March 2016, Ohr entered into an SPA with the FDA over the design of Phase III trials to treat age-related macular degeneration with the lead product candidate. On January 4, 2018, Ohr issued a press release stating that the product did not meet its primary efficacy endpoint in connection with the Phase III trials. Ohr's stock price dropped by 81.2% the next day. The plaintiff asserts that Ohr made false and/or misleading statements about the progress of the Phase III trials in that Ohr failed to disclose that the product would not produce vision improvements and was not commercially viable. The case was filed by Levi & Korsinsky, LLP.

Hustig v. Obalon Therapeutics, Inc.,
No. 3:18-cv-00352-AJB-WVG (S.D. Cal. filed Feb. 14, 2018).

On February 14, the plaintiff filed a putative class action complaint against Obalon Therapeutics, Inc. and two executives ("Obalon") alleging that the company made misleading statements regarding its finances and accounting because it recognized certain revenue in violation of GAAP accounting principles. Obalon is a medical-device company that develops and commercializes devices for the treatment of obesity by facilitating weight loss. The complaint, which was filed after Obalon issued a press release announcing that the company's auditor, KPMG, received a communication from a purported whistleblower regarding the company's revenue-recognition practices, is sparse on details regarding the alleged violations. The thrust of the plaintiff's allegations is that the company issued financial statements that did not comply with GAAP, which renders those statements false and misleading under Regulation S-X. The suit was filed by Glancy Prongay & Murray LLP. A similar suit was filed in the Southern District of California on February 22 with the caption *Cook v. Obalon Therapeutics, Inc.*, No. 3:18-cv-00407.

Gordon v. MiMedx Grp., Inc.,
No. 18-cv-01831-ER (S.D.N.Y. filed Mar. 1, 2018).

On March 1, the plaintiff brought a suit against MiMedx Group, Inc. and two executives ("MiMedx") alleging that the company made misleading statements regarding its finances and accounting. MiMedx is a biopharmaceutical company focusing on biomaterials for soft-tissue repair and other medical applications, which it distributes through numerous distributors, including at least one federal contractor that permitted the company to distribute products to hospitals operated by the Department of Veteran Affairs "at will." The plaintiff alleges that MiMedx conducted a "channel-stuffing" scheme to improperly recognize revenue that had not yet been realized in order to meet forecasts, failed to disclose its financial payments to at least 20 physicians as required by federal law, and lacked adequate internal controls over financial reporting. In 2016, the company was involved in litigation with two former employees regarding alleged channel stuffing. The instant suit was filed after the company postponed release of its fourth quarter 2017 results due to an internal investigation into company practices. The suit was filed by Pomerantz LLP. A similar suit was filed by Block & Leviton LLP on February 23 in the Northern District of Georgia, with the caption *MacPhee v. MiMedx Group, Inc.*, 1:18-cv-00830.

Joshi Living Trust v. Akorn, Inc., et al.,
No. 1:18-cv-01713 (N.D. Ill. filed March 8, 2018).

On March 8, the plaintiff filed a putative class action securities suit against Akorn, Inc. and three executives ("Akorn"). The plaintiff alleges that Akorn, a pharmaceutical company that develops and manufactures branded and generic medications, made false and misleading statements about its compliance with FDA data-integrity requirements. The plaintiff claims that Akorn's failure to comply with the FDA requirements jeopardized Fresenius SE & Co. KGaA's acquisition of Akorn, which was announced in April 2017. When Fresenius announced on February 26, 2018, that it was investigating alleged breaches of FDA data-integrity requirements at Akorn, Akorn's stock price dropped 38%. The case was filed by The Rosen Law Firm, P.A., and Heffner Hurst.

Watkins v. Solid Biosciences, Inc., et al.,
No 1:18-cv-10587-MLW (D. Mass. filed Mar. 27, 2018).

On March 27, the plaintiff filed a putative class action securities suit against Solid Biosciences, Inc. ("Solid Biosciences"), two executives, and the underwriters for the company's IPO. During the relevant period, Solid Biosciences' lead product candidate was a treatment for Duchenne muscular dystrophy that uses an adeno-associated virus (an "AAV") to deliver a transgene into the patient. In January 2018, the company's stock price fell 5% after a study co-authored by a former Solid Bioscience advisory-board member highlighted the risks of using gene therapies delivered using an AAV. On March 14, 2018, the company issued a press release announcing that the FDA had placed a clinical hold on Phase I/II trials for the treatment because a patient had suffered a Suspected Unexpected Serious Adverse Reaction. The company's stock price fell by 60% the day following the press release. The plaintiff alleges that the Registration Statement for the company's IPO was materially false and misleading because it failed to disclose that the treatment had a high likelihood of causing adverse events in patients and misled investors about the toxicity of the treatment. The case was filed by Andrews DeValerio LLP and Glancy Prongay & Murray LLP.

City of Warren Gen. Employees' Ret. Sys. v. Celgene Corp., et al.,
No. 2:18-cv-04772-JMV-JBC (D.N.J. filed Mar. 29, 2018).

On March 29, the plaintiff filed a putative class action securities suit against Celgene Corporation and various Celgene executives ("Celgene"). Celgene specializes in the discovery, development, and commercialization of therapies for treating cancer and inflammatory diseases. The plaintiff alleges that because Celgene's most profitable drug is due to lose its patent exclusivity in the coming years, it was important to investors that Celgene develop and commercialize new drugs to diversify and ultimately replace its reliance on revenues from its main drug. Three of the most promising drugs in Celgene's portfolio were (i) GED-0301, a treatment for Crohn's disease, (ii) Otezla, a psoriasis treatment approved by the FDA in 2014, and (iii) Ozanimod, a developmental treatment for multiple sclerosis and ulcerative colitis. The plaintiff alleges that Celgene made false and misleading statements about all three drugs, which caused the company's stock price to be artificially inflated during the class period. First, the plaintiff alleges that interim GED-0301 trials suffered from fatal flaws, including the lack of a placebo, such that there was an undisclosed risk and high likelihood that the drug would not be commercially viable. The plaintiff next alleges that Celgene failed to disclose that Otezla sales had dramatically slowed in the third quarter of 2017. Finally, the complaint alleges that the data in Ozanimod's NDA was insufficient to permit a complete review by the FDA, resulting in the FDA issuing a refusal to file letter to Celgene regarding the drug. The case was filed by Carella, Byrne, Cecchi, Olstein, Brody & Agnello, P.C., Robins Geller Rudman & Dowd LLP, and VanOverbeke, Michaud & Timmony, P.C.

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