UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

METZLER ASSET MANAGEMENT GMBH and ERSTE-SPARINVEST KAPITALANLAGEGESELLSCHAFT MBH, on Behalf of Themselves and All Other Similarly Situated Parties,	)	**Civil Action No. 16-12101-FDS**
Plaintiffs,	)	
v.	)	
STUART "TONY" A. KINGSLEY, GEORGE A. SCANGOS, PAUL C. CLANCY, and BIOGEN, INC.,	)	
Defendants.	)	

MEMORANDUM AND ORDER
ON DEFENDANTS' MOTION TO DISMISS

SAYLOR, J.

This is a putative class action involving alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and SEC Rule 10b-5. Lead plaintiffs Metzler Asset Management GmbH and Erste-Sparinvest Kapitalanlagegesellschaft mbH have brought suit, on behalf of a class of similarly situated persons, against biopharmaceutical company Biogen Inc. and three Biogen executives. Plaintiffs contend that class members were harmed when they purchased Biogen's common stock at prices that were artificially inflated by the company's materially misleading statements and omissions about Tecfidera, its leading multiple sclerosis drug.

The amended complaint relies heavily on statements by 17 former Biogen employees

acting as confidential witnesses. It alleges that defendants withheld material information about Tecfidera's safety profile and declining Tecfidera sales, and made misleading positive statements about future revenue. It further asserts that several Biogen executives made 31 materially false misrepresentations and omissions during various earnings calls and conferences over a one-year period between July 23, 2014, and July 23, 2015.

Defendants have moved to dismiss the complaint for two principal reasons. First, they contend that plaintiffs' claims are barred by the doctrine of claim preclusion, or *res judicata*, in light of this Court's dismissal of a suit raising similar claims in *In re: Biogen Inc. Sec. Litig. ("Biogen I")*, 193 F. Supp. 3d 5 (D. Mass. 2016), *aff'd* 857 F.3d 34 (1st Cir. 2017). While the claims in this suit are largely identical to those in *Biogen I*, because the *Biogen I* putative class was never certified, lead plaintiffs in this suit are not bound by this Court's earlier decision. Claim preclusion therefore does not bar this action.

Second, defendants have moved to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6) and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. §§ 78u-4, 78u-5. Defendants contend that the complaint fails to set forth plausible allegations that the individual defendants' statements contain actionable misrepresentations or omissions. Specifically, defendants argue that the alleged misrepresentations, including nine that are newly alleged and were not included in the original action, are not adequately alleged to be false at the time they were made. In addition, they contend that the complaint fails to allege specific facts that give rise to a strong inference of scienter.

As the First Circuit has observed, "[n]ot all claims of wrongdoing by a company make out a viable claim that the company has committed securities fraud." *Fire and Police Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 231 (1st Cir. 2015). The amended complaint does

not, for example, allege that Biogen's current or historical financial statements are misleading because of fictitious sales, off-label marketing, inventory parking, or any similar act of corporate fraud. Rather, it alleges in substance that Biogen executives made statements about Tecfidera's risks and future sales that were misleading because they were unduly optimistic and minimized the impact of adverse events.

Although most of the newly alleged misrepresentations do not appear to be actionable, after drawing all reasonable inferences on behalf of plaintiffs, the complaint alleges a plausible claim that at least six statements (or omissions) constitute material misrepresentations—three that are repeated from *Biogen I*, and three that are newly alleged. However, the complaint's allegations that defendants acted with the requisite degree of scienter fail to clear the relatively high hurdle of the PSLRA. In other words, even assuming that defendants made a materially false or misleading statement, plaintiffs have not sufficiently alleged that defendants made those statements with a "conscious intent to defraud or 'a high degree of recklessness.'" *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008) (quoting *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 82 (1st Cir. 2002)). Instead, the most compelling inference that can be drawn from the complaint as a whole is that defendants were, at worst, negligent, or engaged in permissible puffery. *See Auto. Indus. Pension Trust Fund v. Textron Inc.*, 682 F.3d 34, 39 (1st Cir. 2012) ("negligence or puffing are not enough").

Accordingly, and for the reasons set forth below, defendants' motion to dismiss will be granted.

I. Factual Background

Unless otherwise noted, all facts are stated as set forth in the amended complaint.[1]

[1] Defendants' motion to dismiss is accompanied by 24 exhibits, including SEC filings and transcripts of earnings calls and securities-research conferences. While ordinarily "any consideration of documents not attached

Because the vast majority of the amended complaint overlaps with the complaint in *Biogen I*, this section will largely address new witnesses and allegations.

A. The Parties and Tecfidera

Lead plaintiff Metzler Asset Management GmbH ("Metzler") is a German capital investment company located in Frankfurt, Germany. (Compl. ¶ 36).[2] Lead plaintiff Erste-Sparinvest Kapitalanlagegesellschaft mbH ("Erste-Sparinvest") is an Austrian investment company located in Vienna, Austria. (*Id.* ¶ 37). The complaint alleges that Metzler and Erste-Sparinvest purchased Biogen securities at artificially inflated prices during the class period, which is July 23, 2014, through July 23, 2015. (*Id.* ¶¶ 1, 36-37).

Biogen Inc. is a publicly-traded corporation based in Cambridge, Massachusetts. (*Id.* ¶ 38). It is a biopharmaceutical company that develops, manufactures, and markets treatments for certain neurological, autoimmune, and hematological diseases, including multiple sclerosis ("MS"). (*Id.* ¶ 48). Biogen's securities trade on NASDAQ under the symbol "BIIB." (*Id.* ¶ 38).

Tecfidera is one of Biogen's four principal drugs for the treatment of MS. (*Id.* ¶ 48). It is an oral pharmaceutical approved for use in the United States and European Union. (*Id.*).[3] It competes with other oral MS drugs as well as injectable MS treatments. (*Id.* ¶¶ 2, 14, 67). After the FDA approved Tecfidera for use in March 2013, Biogen began selling it in the United States

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to the complaint, or not expressly incorporated therein, is forbidden . . . courts have made narrow exceptions for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint." *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993). It has become standard for courts considering motions to dismiss in securities fraud cases governed by the PSLRA to consider financial statements and transcripts referred to in the complaint. *See, e.g.*, *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 232 n.2. Accordingly, the Court will consider the submitted exhibits. In presenting defendants' allegedly fraudulent misrepresentations, bold text indicates emphasis added by plaintiffs in the complaint. All additional language from the exhibits is provided for contextual purposes.

[2] All citations are to the amended complaint.

[3] According to a recent Form 8-K, Biogen now appears to develop and market at least five MS drugs (Tecfidera, Avonex, Plegridy, Tysabri, and Fampyra). (Def. Ex. 24 at 16).

in mid-2013. (*Id.* ¶¶ 2, 48). In 2015, the wholesale cost of the drug was approximately $70,000 per patient per year. (*Id.* ¶ 48).

From its 2013 launch, Tecfidera was a significant source of revenue for Biogen, and it fueled much of the company's growth. In 2015, Tecfidera was Biogen's highest grossing product, producing $1 billion in revenue more than the second-place product. (Def. Ex. 24 at 16).[4] Defendants have publicly acknowledged Tecfidera's importance to the company. In Biogen's quarterly reports and annual report released during the class period, the company stated that it "may be substantially dependent on sales from our principal products for many years, including an increasing reliance on sales of [Tecfidera] as we expand into additional markets." (Compl. ¶ 50).

On October 22, 2014, Biogen publicly announced, for the first time, that an MS patient who had taken Tecfidera for more than four years as part of a clinical study had died of progressive multifocal leukoencephalopathy ("PML"). (*Id.* ¶ 10). PML is an infection that is particularly dangerous for individuals with a weakened immune system, including those with low white blood cell counts. (*Id.*).[5]

A month later, on November 25, 2014, the FDA issued a warning to the public about the patient who died from PML while using Tecfidera. (*Id.* ¶ 83). The FDA stated that the patient was not taking any other drugs associated with PML, and it advised physicians and patients to monitor Tecfidera patients for side effects. (*Id.*). It further noted that "[a]s a result, information describing this case of PML . . . is being added to the Tecfidera label." (*Id.*). Tecfidera's label

[4] Tecfidera generated $3.64 billion in revenue, whereas Avonex, Biogen's next-best selling MS drug, generated $2.63 billion in revenue.

[5] The complaint does not allege that Biogen failed to announce the PML death promptly.

was updated in the United States to include the PML risk on December 3, 2014. (Def. Ex. 13 § 5.2). Tecfidera's original label, dated March 27, 2013, had already disclosed the risk that "Tecfidera may cause lymphopenia." (Def. Ex. 1 at 1).[6]

On July 24, 2015, Biogen cut its guidance for revenue growth in half, attributing the change to the decline in Tecfidera's recent financial performance. (Compl. ¶ 159). That day, Biogen's stock price fell over 20%, and there was unusually heavy trading volume in the stock. (*Id.* ¶ 161).

B. New Witness Allegations

The amended complaint alleges claims against Biogen and individual defendants George Scangos (the Chief Executive Officer), Paul Clancy (the Chief Financial Officer and Executive Vice President, Finance), and Stuart Kingsley (the former Executive Vice President, Global Commercial Operations). (*Id.* ¶¶ 39-41).

The complaint essentially alleges that defendants knew from both internal data and discussions with physicians that Tecfidera potentially weakened patients' immune systems and that the PML incident materially affected Tecfidera sales—effects that their public statements fraudulently or recklessly misrepresented and concealed. In support of its allegations, the complaint relies heavily on statements from 17 confidential witnesses ("CWs") who were formerly employed by Biogen in various capacities across the country.[7] Many of the

[6] Lymphopenia is a condition where an individual has low levels of lymphocytes, which are a type of white blood cell. (Def. Ex. 1 § 5.1).

[7] Under the PSLRA, a plaintiff may rely on a confidential witness and need not provide his or her name as long as the witness is "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 51 (1st Cir. 2008) (internal quotation marks omitted). Courts must evaluate confidential witnesses based on factors such as "the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id.* (internal quotation marks omitted).

confidential witnesses were Biogen Area Business Managers ("ABMs"), defined by Biogen as a "specialty sales representative position [that is] called upon to sell our [n]eurology products [including Tecfidera] with key stakeholders in the [MS] community: including [n]eurologists, allied health professionals, and local MS chapters." (*Id.* ¶ 68 n.2).

1. New Confidential Witnesses

Plaintiffs in *Biogen I* offered statements from ten confidential witnesses. The *Biogen II* complaint adds seven additional confidential witnesses. The statements of the seven new witnesses may be summarized as follows.

CW 11 was a Biogen senior territory business manager responsible for Pennsylvania from September 2012 to January 2016. (*Id.* ¶ 88). His largest client was the University of Pennsylvania Medical Center. (*Id.*). He provided "several internal Biogen documents that corroborate" plaintiffs' claims. (*Id.*). His "sales of Tecfidera dropped precipitously immediately after the [PML death] announcement." (*Id.* ¶ 90). In addition, his 2015 mid-year review quoted an internal Biogen e-mail from "early 2015 stating that the company was cutting sales goals for Tecfidera . . . for the second quarter." (*Id.* ¶ 94).[8] CW 11's Tecfidera sales goals were lowered throughout 2015; by Q3 2015, his sales goal was 44 units, whereas it had been 95 units one year before. (*Id.* ¶ 95). By contrast, his sales goal for another Biogen MS drug, Tysabri, remained stable throughout the class period. (*Id.* ¶ 96).

In mid-2015, CW 11 also received a slide deck titled "2015 Q2 Quarterly Business Review—Philadelphia West." (*Id.* ¶ 97). The slide deck stated:

[8] The e-mail stated: "The residual impact of the safety event from 2014 along with competitive pressure has continued to impact Tecfidera performance in Q2, but several leading indicators of success are encouraging, such as physician intent to prescribe, and an improving efficacy perception. To support your focus on executional excellence and establishing Tecfidera as the first choice, Tecfidera goals will be reduced by 15% across all territories and regions for Q2." (Compl. ¶ 94).

> In the oral market Tecfidera is down and Gilenya is up.[9] Major factors: SAFETY is a major concern at Penn. PML and low lymphocyte counts (in the upwards of 4 months after being [discontinued]) seem to have the most impact on their use of Tecfidera. In addition, they have seen breakthrough with Tecfidera patients and believe Gilenya is more efficacious. Copaxone is considered their safest alternative.[10]

CW 12 was a Biogen ABM responsible for the Atlanta area from March 2009 to July 2015. (*Id.* ¶ 68). The complaint does not specify to whom CW 12 reported, although his 2014 year-end review was written by Regional Director Craig Brown. (*Id.*). According to the complaint, Brown wrote "that CW 12's performance took a negative [turn] 'due to a non-commercial event which impacted your number one MS volume and influencer account [Shepherd Center]." (*Id.*). Around that time, Brown also wrote that

> Dr. Ben Thrower [of the Shepherd Center] and his partners began **removing patients from Tecfidera, and the number of new starts and referrals subsequently plummeted**. Dr. Thrower's actions **began a domino effect in the territory** which caused some of your community based neurologist[s] to also **change their prescribing patterns away from Tecfidera.** At the conclusion of Q3, you fell short of your Tecfidera new patient start goal . . . .

(*Id.*). Brown later added, "your Atlanta South territory is one of [the] few in the nation that has a BIIB [Biogen] share above 50%." (*Id.* ¶ 87).

CW 13 was a Biogen employee located in the company's Raleigh, North Carolina office from September 2012 to July 2016. (*Id.* ¶ 124). His titles during that time period included MS Case Manager, Active Support Coordinator, and Patient Services Coordinator. (*Id.*). As an MS Case Manager, he supported Biogen's MS sales team. (*Id.*). He was at least five managerial levels below the named defendants. (*Id.*). CW 13 stated that immediately following the PML death, "new start[s]" of Tecfidera dropped and there were regular meetings with his immediate

[9] Gilenya is another drug used to treat MS and is sold by a Biogen competitor, Novartis. (Compl. ¶ 93 n.4).

[10] "Breakthrough" in this context means that "diseases were 'breaking through.'" (Compl. ¶ 98). Copaxone is another drug used to treat MS and is sold by a Biogen competitor, Teva Pharmaceuticals.

supervisors to discuss turning around the situation. (*Id.* ¶ 125). CW 13 further believed that senior company executives had extensive sales reports on key metrics, and received them on at least a quarterly basis. (*Id.* ¶ 134).

CW 14 was a Biogen ABM responsible for parts of New York and Pennsylvania from July 2012 to February 2016. He was five managerial levels below Kingsley. (*Id.* ¶ 126). CW 14 recalled "lots of discontinuations" of existing Tecfidera patients immediately after the PML death was announced. (*Id.* ¶ 127). He further stated that there were non-regularly scheduled conference calls in the "East Division," in which his territories were located, following the PML announcement. (*Id.* ¶ 129). Such calls were attended by ABMs from his division, and many reported declining Tecfidera sales. (*Id.*).

CW 15 was a Biogen employee located in the company's Cambridge, Massachusetts headquarters from February 2012 to November 2014. (*Id.* ¶ 60). He was the Manager of Medical Research in Global Medical and previously served as a medical affairs scientist, scientific writer, and senior scientific writer. (*Id.*). He was five reporting levels below Scangos. (*Id.*).

CW 15 stated that when he was a senior scientific writer (August 2013 to July 2014), he worked on a prepared response "for any PML case associated with Tecfidera." (*Id.* ¶ 61). According to him, the company's marketing and communication departments decided to prepare a response to such an incident soon after Tecfidera's approval and release to the public in 2013. (*Id.*). He stated that "a Tecfidera-linked PML case was a matter of 'when, not if.'" (*Id.*). The prepared response was approved by "G8," which was Scangos's term for his senior executive leadership team, approximately three months before the first PML case linked to Tecfidera was reported. (*Id.* ¶ 62).

CW 16 was a former Senior Vice President for Biogen's Worldwide Medical Organization. (*Id.* ¶ 142). He was the Head of Medical Affairs from January 2014 to March 2016. (*Id.*). He stated that Biogen senior executives knew of "external communication measures" that the company's medical teams were undertaking in response to the PML death. (*Id.*).

CW 17 was a former Executive Territory Business Manager and Field Trainer for Biogen from September 2007 to November 2015. (*Id.* ¶ 130). He reported to Regional Director Karen Grant. (*Id.*).[11] CW 17 sold pharmaceutical products for Biogen, including Tecfidera, and stated that his sales dropped by at least 25% following the PML death. (*Id.*).

2. New Allegations by Previously Identified Confidential Witnesses

In addition, plaintiffs offer additional supporting allegations from four previously identified confidential witnesses. Their new statements may be summarized as follows.

CW 1 was a Biogen ABM responsible for parts of southern Florida and Puerto Rico from November 2010 to June 2015. (*Id.* ¶ 100).[12] He was five reporting levels below Scangos. (*Id.*). According to CW 1, by December 2014, Biogen's neurologist customers were taking their patients off Tecfidera. (*Id.* ¶ 101). He stated that Tecfidera had some immune-suppressive properties and that after the PML death, the drug was considered an immune-suppressive agent. (*Id.*).

Similar to other ABMs, CW 1's sales of Tecfidera declined toward the end of 2014. (*Id.* ¶ 102). He first became aware of "a severe drop in Tecfidera sales" when there were

[11] In total, CW 17 was five reporting levels below Scangos. (Compl. ¶ 123) (stating that Grant was four reporting levels removed from Scangos).

[12] CW 1's biggest customer was the MS Center at the University of Miami. (Compl. ¶ 104). CW 1 "recalled doctors telling him that they were discontinuing a 'significant number' of patients . . . because of the first PML case." (*Id.*).

"emergency" Biogen conference calls in December 2014 and January 2015. (*Id.* ¶ 103). These calls were led by Senior Vice President of U.S. Commercial Joe Ciaffoni and Senior Sales Director Keith Ferguson. (*Id.*). CW 1 recalled that slide decks were distributed in advance of these calls, and that they showed an increase in discontinuations nationally. (*Id.*). In addition, CW 1 personally saw a decline in Tecfidera sales in his area, including his largest customer, the MS Center at the University of Miami. (*Id.* ¶ 104). He also spoke with other ABMs, who similarly stated that Tecfidera prescriptions were down at other MS treatment centers. (*Id.* ¶ 106).

CW 3, like CW 1, was a Biogen ABM responsible for parts of southern Florida and Puerto Rico from May 2012 to June 2015. (*Id.* ¶ 108). He was also five reporting levels below Scangos. (*Id.*). CW 3 saw a decline in prescriptions of Tecfidera after the PML announcement, and recalled neurologists at the University of Miami telling him in November 2014 that they "were not going to write Tecfidera prescriptions for new patients unless the patient specifically asked to be put on Tecfidera." (*Id.*). Beginning in January 2015, he participated in regularly scheduled conference calls for the Southeast Region, during which other ABMs also reported large declines in Tecfidera sales. (*Id.* ¶¶ 109, 113).

Both CW 1 and CW 3 stated that Biogen instructed ABMs "to downplay the significance of the PML death in order to convince doctors to continue to prescribe Tecfidera." (*Id.* ¶¶ 110-11). In particular, "medical science liaisons" made appointments with neurologists to discuss the PML death. (*Id.* ¶ 110). These meetings reflected Biogen's efforts at "damage control." (*Id.* ¶ 111).

CW 7 was a Biogen ABM responsible for parts of Virginia, West Virginia, and Maryland from April 2011 to June 2015. (*Id.* ¶ 119). CW 7 reported to a regional sales manager, who

reported to the Senior Sales Director—East. (*Id.*).[13] According to the complaint, although CW 7 "could not recall exact numbers," the drop in Tecfidera sales "was big enough that he and his territory team consistently missed their sales goals . . . ." (*Id.*). He further recalled attending a National Sales Meeting in March 2015, during which declining Tecfidera sales were discussed and acknowledged. (*Id.* ¶ 121).

CW 8 was the senior director of commercial operations for Biogen, a position "equivalent to chief of staff for the head of commercial operations," from August 2014 to November 2015. (*Id.* ¶ 122). CW8 reported to the Senior Vice President of U.S. Commercial. (*Id.*).[14] According to CW 8, Tecfidera sales were adversely impacted immediately following the PML death. (*Id.*). He added that Ciaffoni would meet Scangos's "G8" at least once a month. (*Id.* ¶ 140).

3. New Allegations by Dr. Thrower and Dr. Zamvil

In addition to the new confidential witness allegations, plaintiffs offer statements by two physicians in support of the complaint.

Dr. Ben Thrower is the medical director of the Shepherd Center, a private, not-for-profit hospital in the Atlanta area. (*Id.* ¶ 63). Between 2010 and 2013, he was involved in a clinical trial that Biogen conducted for Tecfidera. (*Id.*). He also serves as a clinical instructor of neurology at Emory University, and as a Senior Medical Advisor to the Multiple Sclerosis Foundation. (*Id.* ¶ 64).

The Shepherd Center was the "leading prescriber of Tecfidera in the United States among MS centers" as of August 1, 2014. (*Id.* ¶ 65). On that date, the Shepherd Center had

[13] CW 7 was five reporting levels below Kingsley. The complaint states that CW 7 was two reporting levels removed from Senior Sales Director—East Stephen Hulse (Compl. ¶ 119), who in turn was believed to be three reporting levels removed from Kingsley (*Id.* ¶ 126).

[14] CW 8 was two reporting levels below Scangos. The complaint states that CW 8 reported to Ciaffoni (Compl. ¶ 122), who in turn reported to Scangos (*Id.* ¶ 100).

approximately 400 patients taking Tecfidera. (*Id.*). However, during spring 2014, the center had begun monitoring for possible side effects of MS patients taking Tecfidera by taking additional blood tests. (*Id.*). Doctors noted that "there was an elevated risk of developing low lymphocyte counts among patients on Tecfidera." (*Id.*). In August 2014, Dr. Thrower notified Biogen employees Keith Ferguson, a senior sales director, and Eric Hall, a medical science liaison, that Tecfidera was causing declining lymphocyte counts in about 30% of patients taking Tecfidera. (*Id.* ¶ 66).

Afterward, physicians at the Shepherd Center stopped prescribing Tecfidera for new MS patients, and discontinued it for at least half of the 400 patients already taking the drug. (*Id.* ¶ 67). The center informed Ferguson, Hall, and an individual named Todd Burks of this development. (*Id.*).[15]

Dr. Scott Zamvil is a neurologist at the University of California-San Francisco Medical Center who specializes in MS treatment. (*Id.* ¶ 69). He has conducted extensive research and published studies about MS and MS treatments. (*Id.*). He recalled Shepherd Center doctors telling him in summer 2014 about the lymphocyte-count decline in patients taking Tecfidera. (*Id.* ¶ 70). In addition, he recalled Dr. Guy Buckle of the Shepherd Center telling him in March 2015 that the center had alerted Biogen about its findings. (*Id.*).

Dr. Zamvil also asserts that he was one among many doctors who went through "Biogen brainwashing" concerning Tecfidera's safety profile. (*Id.* ¶ 71). After the drug was launched in spring 2013, he prescribed it for many of his MS patients, believing it was a safe option. (*Id.*). However, in February 2015, he conducted his own study, and like the Shepherd Center, found that Tecfidera lowered patients' lymphocyte counts and left them susceptible to PML. (*Id.* ¶

[15] The complaint does not identify the title or position of Burks.

72).[16] His findings were published in an article released on February 12, 2015. (*Id.*). Following the PML death and the release of his study, Dr. Zamvil stopped prescribing Tecfidera and discontinued the drug for many of his patients. (*Id.* ¶ 74).

C. Overview of the Class Period Timeline

Plaintiffs in this case have alleged an extended class period: the *Biogen I* class period was from December 2, 2014, to July 23, 2015, but the *Biogen II* class period is from July 23, 2014, to July 23, 2015. (*Id.* ¶ 1).

The complaint alleges that "[o]n July 23, 2014, the first day of the class period . . . Biogen held an earnings call with analysts." (*Id.* ¶ 166). Defendants Scangos, Clancy, and Kingsley participated in the earnings call. (*Id.*). That same day, Biogen also issued a press release touting its 2014 second-quarter financial results, increasing its "full-year financial guidance" because of "the growth of Tecfidera in the U.S. and the E.U." (*Id.* ¶ 170-71).

Another press release was issued on September 11, 2014. (*Id.* ¶ 176). Like the July 23 press release, this statement "continued to extol the safety profile of Tecfidera." (*Id.*). However, on October 22, 2014, Biogen released third-quarter 2014 financial results and announced the PML incident. (*Id.* ¶ 178). CFO Clancy spoke on an investor conference call on December 2, 2014. (*See id.* ¶¶ 192-93). CEO Scangos spoke during a healthcare conference on January 12, 2015. (*See id.* ¶¶ 194-95).

On January 29, 2015, Biogen announced fourth-quarter results, reporting Tecfidera revenues of $916 million, up 16.4 percent from the third quarter, which was 34.7 percent of total Biogen revenue. (*Id.* ¶¶ 48, 143). As part of its practice to issue projected revenue guidance twice per year, defendants projected annual Biogen revenue growth of 14 percent to 16 percent

[16] By the point, the PML death had already been announced.

for 2015. (*Id.* ¶ 144). Biogen's stock rose 0.6 percent on January 29, 2015, and 10.2 percent the next day. (*Id.* ¶ 209). Scangos, Clancy, and Kingsley all spoke during the earnings call. (*See id.* ¶¶ 197-208). Analysts reacted positively to Biogen's fourth-quarter earnings and defendants' statements during the call. (*See id.* ¶¶ 210-16).

After fourth-quarter earnings, Kingsley spoke during a February 25, 2015 healthcare conference. (*See id.* ¶¶ 147-49). Scangos also spoke during a March 2, 2015 healthcare conference. (*See id.* ¶ 257).

On April 24, 2015, Biogen released disappointing 2015 first-quarter earnings, announcing Tecfidera revenues of $825 million, which were below the market's consensus estimates and a 9.9 percent decrease from the previous quarter. (*Id.* ¶ 150). On a company level, Biogen's total revenue decreased 3.2 percent from the previous quarter. (*Id.* ¶ 48). The complaint alleges that the earnings call on April 24 was the "first time [that] defendants partially acknowledged that the PML death was impacting Tecfidera sales." (*Id.* ¶ 150). In response, Biogen's stock price decreased 6.6 percent on April 24. (*Id.*). However, maintaining their practice of providing revenue guidance only twice a year, defendants did not change the projected annual revenue growth for Biogen of 14 to 16 percent that they had released after announcing fourth-quarter results in January. (*Id.* ¶ 151). Instead, Clancy stated, "If [Tecfidera's] U.S. trajectory does not improve, we may come in at the lower end of our previously provided [annual] revenue growth." (*Id.* ¶ 222).

After announcing first-quarter earnings, Clancy spoke during a healthcare conference on May 6, 2015. (*See id.* ¶¶ 227-28). A week later, Executive Vice President of R&D Doug Williams (not a named defendant in this action) spoke during a May 13 healthcare conference. (*See id.* ¶ 229-30). Two weeks later, Clancy spoke during a May 27 strategic-decisions

conference. (*See id.* ¶¶ 231-33). On May 27, 2015, Biogen's stock price increased 2.5 percent from the previous day, closing at $402.92. (*Id.* ¶ 158).

On July 24, 2015, the day after the end of the class period, Biogen released second-quarter earnings. It announced Tecfidera revenue of $883 million, a 7.1 percent increase from the first quarter, but still less than the $916 million in revenue earned during the fourth quarter of 2014. (*Id.* ¶ 48). Biogen's total revenue increased 1.4 percent from the first quarter. (*Id.*).

At that point, Biogen revised its full-year 2015 revenue guidance, stating that "[r]evenue growth is expected to be approximately 6 percent to 8 percent compared to 2014 [down from the January estimate of 14 percent to 16 percent], a decrease from prior guidance based largely on revised expectations for the growth of Tecfidera." (*Id.* ¶ 159). "Our balance of year forecast assumes limited patient growth for Tecfidera in the United States." (*Id.* ¶ 28).

During the earnings call, Scangos stated, "We had expected to see a reacceleration of Tecfidera, but that did not happen to any appreciable extent." (*Id.* ¶ 236). Kingsley also stated:

> We believe the safety event reported in late 2014 has created greater caution on the part of both physicians and patients about switching to orals. Our US market research indicates a moderation in physician intent to prescribe, though in Q2, Tecfidera continued to gain patients in the US.

(*Id.* ¶ 236).

During the call, Kingsley responded to a question by stating, in part, "[the first PML case was a pretty] significant change statement for the profile of Tecfidera, given its very pristine safety profile at the time." (*Id.* ¶ 238). An analyst asked "when you thought about Tecfidera and flat sales, how much—to what extent do you think there will be people stopping [the] drug versus just minimal growth?" Williams responded:

> [We didn't expect] a modest but not trivial increase in discontinuations in Tec[fidera] in the United States [in particular].

(*Id.* ¶ 239).

The market and analysts reacted negatively, and Biogen's stock price decreased $85, or 22 percent, on July 24. (*Id.* ¶¶ 237-45). The 22 percent decline occurred on unusually heavy trading volume, with 16.6 million shares traded compared with an average daily trading volume over the class period of 1.6 million shares. (*Id.*).

After the class period, during a September 18, 2015 healthcare conference, Kingsley stated "[i]t was clear to us that we were going to get a—some kind of a downtick in the safety profile that would have some kind of an impact on physician behavior, but we couldn't tell." (*Id.* ¶ 163). He added that "the [Tecfidera] label was so clean [before the PML incident], the first PML event was a pretty big change statement for a broad base of physicians who were very comfortable with having essentially no safety issues." (*Id.*).

On October 9, 2015, Biogen announced that Kingsley was leaving the company. (*Id.* ¶ 164). Twelve days later, the company announced that it would eliminate approximately 11 percent of its workforce. (*Id.* ¶ 165).

D. Additional Statements During the Class Period

Below are some of the alleged materially false misrepresentations and omissions that defendants made during the class period. The majority of the statements were previously addressed by this Court in *Biogen I*, and will not be duplicated here. However, plaintiffs in this suit have added nine purportedly false and misleading statements occurring on five dates between July 23, 2014, and April 24, 2015. Bolded text indicates emphasis added by plaintiffs. Additional text is provided for context.

1. July 23, 2014—Kingsley and Scangos on Earnings Call

The complaint alleges that Kingsley and Scangos made the following two false and

misleading statements about Tecfidera's "safety profile" and "growth rate" during an earnings call on the first day of the class period, July 23, 2014.

> Kingsley: **T[ecfidera] in the US continued on a solid trajectory.** T[ecfidera] has been broadly used across numerous patient segments. Dually diagnosed, switches prompted by efficacy and non-efficacy reasons as well as patients returning to the market.
>
> **We believe T[ecfidera] is generally viewed by physicians and patients as efficacious with an attractive safety profile** and a manageable tolerability profile. **Importantly, patient retention rates have been similar to other marketed MS therapies and in line with our expectations.**
>
> . . . .
>
> Scangos: Tecfidera continues to gain market share and we believe it's on track to become the leading MS therapy in the U.S.

(Compl. ¶ 166-67).

The complaint alleges that Kingsley's statement regarding Tecfidera's "solid trajectory" and Scangos's statement that Tecfidera "continues to gain market share" were false and misleading because, among other things, physicians at the Shepherd Center had already stopped new prescriptions of the drug for its patients, creating a "domino effect" on other prescribers in the Atlanta area. (*Id*. ¶¶ 168-69).

2. July 23, 2014—Q2 Press Release

The complaint alleges that Biogen's July 23, 2014 press release touting its second-quarter financial performance included the following misleading statement:

> Press Release: This past quarter highlighted significant accomplishments across our business, from the approval of Eloctate for hemophilia A, **to the continued patient uptake of Tecfidera in the U.S.** and new markets worldwide, to strong clinical results for important emerging MS treatments.

(*Id.* ¶ 170). The release also indicated that Biogen was increasing its "full year financial guidance . . . owing primarily to the growth of Tecfidera in the U.S. and E.U." (*Id.* ¶

171).

The complaint alleges that the bolded statement was false and misleading because Biogen "knew that the Shepherd Center . . . had already begun taking patients off of Tecfidera." (*Id.* ¶ 172). It further alleges that Biogen knew of this development, the risks to Tecfidera's safety profile, and that other neurologists were "changing their prescription patterns away from Tecfidera." (*Id.*).

3. September 11, 2014—Press Release

On September 11, 2014, Biogen issued a press release that "continued to extol the safety profile of Tecfidera." (*Id.* ¶ 176). Specifically, Biogen's Chief Medical Officer Alfred Sandrock (who is not a named defendant) was quoted:

> Sandrock: Tecfidera continues to provide patients with effective oral treatment for MS that is supported by a growing body of data reinforcing its benefits and favorable safety profile.

(*Id.*). The complaint alleges that the statement was false and misleading because Dr. Thrower told Biogen executives in August 2014 that the drug was "compromising patients' immune systems in approximately 30 percent of the Shepherd Center's patients who were taking the drug." (*Id.* ¶ 177).

4. October 22, 2014—Kingsley on Earnings Call

Biogen's third-quarter financial results were announced on October 22, 2014, and the company held an earnings call with defendants Scangos, Clancy, and Kingsley participating. (*Id.* ¶ 178). It was during this call that the PML death was announced for the first time. When the call was opened to questions from research analysts, the first question focused on Tecfidera's future growth rate. The complaint alleges that the following additional false and misleading statements were made.

> Question: Maybe for Tony [Scangos] or Paul [Clancy] on Tecfidera, looks like the growth on a quarter on quarter basis either absolute dollars or percentage basis, it looks a little bit lower in Q3 than, say, over any of the last four or five prior quarters.
>
> Was there anything one time nature that you want to call out? Or should we just assume that drug is on a different trajectory?
>
> Kingsley: **Nothing big on a one time nature. Inventories are moderating, I think a little bit in the channel.**
>
> As always a little probably difficult to predict exactly, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that.
>
> But **we are very comfortable with the trajectory of the product right now. We're very comfortable as we talked about the portion of new starts and switches we are getting.**
>
> **Nothing significantly off plan from our standpoint.** I think we feel pretty good about the performance.

(*Id.* ¶ 183; Def. Ex. 8 at 7-8). The complaint alleges that the bolded statements were false and misleading because physicians at the Shepherd Center had stopped prescribing Tecfidera in August 2014 and that there had been a "domino effect" on other prescribers. (Compl. ¶ 185).

Additional stock analysts then asked various questions to the Biogen executives. In particular, one analyst asked about Tecfidera discontinuation rates:

> Question: So we've done some of our own work on the discontinuation rate, and from at least from what docs are telling us, it looks like it's fairly flat and consistent with what define and confirm showed. Can you guys maybe talk about the trends you are seeing there? Are we right? Or is there some other dynamic we should think about?
>
> Kingsley**: I think that is consistent with what we are seeing.**
>
> As we have said before, **the discontinuation rates are, we expect to be similar to other inline therapies, over time.** We think we believe the physicians are learning to manage the GI intolerability issues, but you are still going to get some off that. **So we believe your analysis is probably in line with what we are**

seeing.

(Compl. ¶ 186; Def. Ex. 8 at 18-19). The complaint alleges that these statements were false and misleading because the company did not disclose that physicians at the Shepherd Center were discontinuing half of its existing MS patients that were taking Tecfidera. (Compl. ¶ 187).

5. January 29, 2015—Kingsley on Earnings Call

The complaint further alleges that Kingsley made several false and misleading statements about Tecfidera's "growth" during Biogen's fourth-quarter earnings call on January 29, 2015.

> Kingsley: In 2014, we continued to grow our global MS market share, fueled by the continued roll-out of Tecfidera worldwide, improving performance from Tysabri, and continued strength from our interferon business, including the recent launch of Plegridy. Over the past six months, our data suggests that our portfolio has consistently captured roughly half of all newly diagnosed patients and switch patients in the US.
>
> Tecfidera continued to demonstrate its strong performance, which we believe is a testament to its attractive product profile, combining strong efficacy, favorable safety and tolerability, and the convenience of oral administration. **We believe Tecfidera is on track to become the most-prescribed therapy for MS worldwide.**
>
> In the US, we saw continued growth through the fourth quarter, with its market share near 20%. **As you may have seen through IMS, we observed moderating new starts for Tecfidera in the fourth quarter. We believe several factors have impacted the recent performance of Tecfidera, including a decline in the overall market switch rate, the US label update in December, and the recent launch of Plegridy, which is capturing some interferon switches that otherwise may have gone to Tecfidera.**
>
> Importantly, we have not noticed a meaningful change in Tecfidera discontinuation rates. We are actively engaging physicians to ensure proper education on the label update. And we believe in the continued growth potential of the product in the US.

(*Id.* ¶ 199; Def. Ex. 15 at 5).

One analyst then asked why Tecfidera sales had declined.

> Question: [Y]ou mentioned three different reasons Tecfidera was weaker—it was weaker or slowing down, in terms of new patient adds. And it was a decline in

> switching, US label change, and the Plegridy launch? Of the three, which one was the most important? Thank you.
>
> Kingsley: Look, Copaxone—I think we've been consistent on that. We think, in the US private payer market, the impact of a generic Copaxone is largely unbranded Copaxone.
>
> It's difficult for payers to see—or certainly, to convince physicians—that there is therapeutic substitutability between glatiramer acetate and the interferon. So I think that's where we are on that, and that's pretty consistent with what we said in the past.
>
> On Tecfidera—look. Actually, hard to piece apart. Probably, the—as Paul said, **we expect the product to grow. But we would see some moderation in growth next year.**
>
> I think we would have said that in any case for the first reason, which is switch rate in the market in the US has come down over the last three or four quarters. We've talked about that, I think, again, pretty consistently. When Tecfidera launched in the US—and we're seeing this repeat outside the US—it doubled or tripled the switch rate for a period of time. And that's been working its way down over time.

(Compl. ¶ 200; Def. Ex. 15 at 11-12).

The complaint alleges that the bolded statements were false and misleading because Kingsley was then aware that Tecfidera sales were down across the United States. (Compl. ¶ 201). In particular, the complaint contends that Biogen knew that physicians at the Shepherd Center in Atlanta and the University of Pennsylvania Medical Center were no longer prescribing the drug. (*Id.*). In addition, the complaint states Kingsley "admitted after the class period that defendants knew the PML death had led to a significant change to the safety profile and physicians' views of Tecfidera." (*Id.*).

6. April 24, 2015—Williams on Earnings Call

On April 24, 2015, Biogen held its first-quarter earnings call. It announced that Tecfidera and Biogen revenues that had declined 9.9 percent and 3.2 percent, respectively, from the previous quarter. According to the complaint, defendants only "partially disclosed the truth

regarding the PML incident's negative impact on Tecfidera sales." (*Id.* ¶ 220). It alleges that "defendants continued to mislead the market regarding the true extent of the PML death's impact on Tecfidera sales" and that they made false and misleading statements "regarding Tecfidera performance while failing to update or correct earlier-issued FY 2015 guidance (and thus confirming it)." (*Id.* ¶ 222).

The complaint presents one new purportedly false or misleading statement from the April 24, 2015 earnings call, which was made by Williams in response to an analyst's question.

> Question: Perhaps to start off with Tecfidera, you highlighted the case of PML last year in your comments. But of course, there was the other case written up that was with a different form of MF, not Tecfidera, this year. And first of all, do you think that that will have any impact on the out—in the future for Tecfidera? And secondly, I would just be curious as to what advice you are now giving physicians, with respect to patients who are JCV positive? Do you think the case this year alters the sentiment you had after last year's case, where of course the patient was heavily pre-treated and lymphopenic?
>
> . . . .
>
> Kingsley: We just spent much of this week in talking to physicians and understanding what their perspective is. So just to highlight, between the tech event and the (inaudible) BML report late last year, what they are seeing is more hesitancy among patients. We talked about market growth as one of the issues in switch rates.
>
> Not clear that the physicians, at least that I talked to, which was the anecdotal, had a dramatically different perspective themselves. But they see some hesitance in the conversations that they are having with patients. I think it's a little early to tell what the kind of the impression result or perception result from the recent New England journal articles will be.
>
> Williams: I think the simple answer to your question is that it's our assessment that **there is no real change in the benefit-risk profile of the drug for patients with MS. So it's pretty much status quo at the moment.**

(*Id.* ¶ 222; Def. Ex. 18 at 7). The complaint alleges that the bolded statement was materially false and misleading again because Biogen was aware that physicians at the Shepherd Center in Atlanta and the University of Pennsylvania Medical Center were no longer prescribing Tecfidera

and were discontinuing patients off the drug. (Compl. ¶ 226). The complaint further alleges that Biogen was aware of Dr. Zamvil's February 2015 study showing Tecfidera lowered patients' lymphocyte counts, leaving them susceptible to PML. (*Id.*).

E. Additional Scienter Allegations

In addition to the statements from the confidential witnesses and Drs. Thrower and Zamvil, the complaint includes other allegations that plaintiffs contend bolster the inference that defendants had the requisite scienter (that is, that they had the conscious intent to defraud investors or acted with a high degree of recklessness).

First, the complaint alleges that because the individual defendants made several specific statements concerning Tecfidera sales, they were receiving specific information regarding the drug and either fabricated the information they provided to investors or deliberately ignored the information they possessed. (*Id.* ¶¶ 249-250).

Second, the complaint contends that Tecfidera was Biogen's main revenue source throughout the class period, accounting for approximately one-third of the company's total revenue. (*Id.* ¶ 251).[17] In the company's SEC filings and public statements, defendants repeatedly stated that Tecfidera was the company's "principal product," "major business driver" and "largest contributor to overall revenue growth." (*Id.* ¶¶ 254-56). The complaint reasons that the individual defendants were necessarily aware of facts concerning Tecfidera's safety profile, new starts, and discontinuation rates. (*Id.* ¶ 258). It also alleges that Kingsley, as a result of his close proximity to Biogen's sales force, "was aware of, or was reckless in not being aware of, the fact that safety-related concerns had materially impacted Tecfidera sales and caused physicians to stop prescribing Tecfidera and switch patients to other therapies." (*Id.* ¶ 259).

[17] This contention was also made in the *Biogen I* complaint.

Third, the complaint contends that because Biogen's products are highly regulated by American and foreign government entities, it can be inferred that defendants "closely monitored the Company's 'most critical business activities,' including 'adverse event reporting' and 'product risk management,' as they pertained to Tecfidera." (*Id.* ¶ 262).

Fourth, the complaint alleges that the "disparity between Defendants' words to the market and the actual state of affairs within Biogen further supports a strong inference of scienter." (*Id.* ¶ 263).

Finally, the complaint contends that two post-class period events augment a strong inference of scienter. Kingsley abruptly left Biogen in October 2015, and the complaint suggests that his departure was linked to declining Tecfidera sales. (*Id.* ¶ 266). In addition, Scangos took a substantial pay cut between 2014, when he received a bonus of more than $4 million, and 2015, when he received only $1.2 million in compensation. (*Id.* ¶ 267). The complaint suggests that Scangos's pay was linked to Tecfidera sales, creating a clear motive for him to conceal the truth about the drug's safety profile and financial performance. (*Id.*).

II. Procedural Background

The complaint in *Biogen I* was filed on August 18, 2015. On November 18, 2015, the Court appointed GBR Group, Ltd. as lead plaintiff in that case. An amended complaint was filed on January 19, 2016. Defendants moved to dismiss the complaint with prejudice on March 1, 2016, under Fed. R. Civ. P. 9(b) and (12)(b)(6), and the PSLRA, 15 U.S.C. §§ 78u-4, 78u-5. The Court granted the motion on June 23, 2016, finding that three statements identified by plaintiffs were plausibly misleading or false. However, the complaint failed to give rise to a "strong" inference of scienter required by the PSLRA.

After the court's dismissal, the *Biogen I* plaintiffs filed a proposed second amended

complaint on July 21, 2016. That day, plaintiffs also moved to vacate the Court's order of dismissal, contending that they had uncovered new evidence which could not have been discovered earlier with due diligence. The Court denied the motions on September 28, 2016.

Subsequently, a new set of plaintiffs filed the complaint in this action on October 20, 2016. The 230-paragraph complaint raised substantially the same factual allegations as plaintiffs in *Biogen I*. On February 1, 2017, the Court appointed Metzler Asset Management GmbH and Erste-Sparinvest Kapitalanlagegesellschaft mbH as lead plaintiffs in this case. A 299-paragraph amended complaint was filed on April 27, 2017. Defendants then moved to dismiss the complaint with prejudice.

Simultaneously, plaintiffs in *Biogen I* appealed the Court's dismissal to the First Circuit. On May 12, 2017, the First Circuit affirmed the Court's dismissal, finding on *de novo* review that the "amended complaint fail[ed] to plead particularized facts giving rise to a strong inference of scienter, as required by the PSLRA." *Biogen I*, 857 F.3d at 37. In addition, the First Circuit found "there was no error or abuse of discretion in the [Court's] denial of the motion to vacate the judgment and for leave to file a second amended complaint." *Id.*

III. Legal Standard

On a Rule 12(b)(6) motion to dismiss a claim brought under Section 10(b) and Rule 10b-5, courts must, as with any such motion, accept plaintiffs' allegations as true. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). However, Congress has raised the standard of pleading for Section 10(b) and Rule 10b-5 securities fraud claims.[18]

[18] "In 1995, Congress enacted legislation attempting to wrest control over securities fraud class action lawsuits from the plaintiffs' bar devoted to such litigation and confer it upon counsel for larger institutional investors. Such a measure, it was believed, would cut down on frivolous litigation as counsel for institutional investors were thought to take a more balanced cost-benefit view of such litigation. While at it, Congress raised the hurdle a plaintiff would have to jump before being permitted to present her case to a jury." *Lirette v. Shiva Corp.*, 27 F. Supp. 2d 268, 271 (D. Mass. 1998) (internal citations omitted).

When a plaintiff alleges misrepresentation or omission of a material fact, the PSLRA requires that the complaint "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1); *accord Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240. "A fact is material when there is 'a substantial likelihood' that a reasonable investor would have viewed it as 'significantly alter[ing] the total mix of information made available.'" *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 756 (1st Cir. 2011) (alteration in original) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988)). "A statement can be 'false or incomplete' but not actionable 'if the misrepresented fact is otherwise insignificant.'" *Id.* at 756-57 (quoting *Basic*, 485 U.S. at 238). However, "[w]hile a company need not reveal every piece of information that affects anything said before, it must disclose facts, 'if any, that are needed so that what was revealed [before] would not be so incomplete as to mislead.'" *In re Cabletron Sys., Inc.*, 311 F.3d 11, 36 (1st Cir. 2002) (quoting *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (en banc)).

"'The PSLRA also separately imposes a rigorous pleading standard on allegations of scienter.'" *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240 (quoting *ACA Fin.*, 512 F.3d at 58). To plead scienter, the complaint must "with respect to each act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). A strong inference is "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent." *Tellabs*, 551 U.S. at 314. "A complaint will survive a motion to dismiss only if it states with particularity facts giving rise to a 'strong inference' that defendants acted with a conscious intent 'to deceive or defraud investors by controlling or artificially affecting the price

of securities' or 'acted with a high degree of recklessness.'" *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240 (quoting *Waters Corp.*, 632 F.3d at 757). "Recklessness, as used in this context, 'does not include ordinary negligence, but is closer to being a lesser form of intent.'" *Id.* (quoting *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 188 (1st Cir. 1999)).

In evaluating the adequacy of a complaint, a court "cannot hold plaintiffs to a standard that would effectively require them, pre-discovery, to plead evidence." *Miss. Pub. Emps. Ret. Sys. v. Boston Sci. Corp. I*, 523 F.3d 75, 90 (1st Cir. 2008) (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1225 (1st Cir. 1996)). However, a plaintiff may not simply rely on a "fraud by hindsight" theory of scienter—that is, "a plaintiff may not simply contrast a defendant's past optimism with less favorable actual results, and then contend that the difference must be attributable to fraud." *Shaw*, 82 F.3d at 1223 (internal quotation marks and alteration omitted), *abrogated on other grounds by* 15 U.S.C. § 78u-4(b)(2). Courts should consider the complaint "as a whole" and weigh "competing inferences" in a "comparative evaluation" of plaintiffs' allegations and alternative inferences from those allegations. *ACA Fin.*, 512 F.3d at 59; *see also Tellabs*, 551 U.S. at 314. If "there are equally strong inferences for and against scienter," then the tie goes to the plaintiff. *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 45 (1st Cir. 2008) (quoting *ACA Fin.*, 512 F.3d at 59).

IV. Claim Preclusion

Defendants first contend that this action should be dismissed because it is barred by the doctrine of claim preclusion, or *res judicata*. "The [claim preclusion] analysis is governed by federal law since the original action was litigated in this Court." *Andrews-Clarke v. Lucent Techs.*, 157 F. Supp. 2d 93, 99 (D. Mass. 2001). "[Claim preclusion] is a valid defense to a later suit if (1) there is a final judgment on the merits of an earlier action, and (2) there is identity of

the parties and (3) identity of the claims in both suits." *Reppert v. Marvin Lumber & Cedar Co.*, 359 F.3d 53, 56 (1st Cir. 2004) (citing *United States v. Cunan*, 156 F.3d 110, 114 (1st Cir. 1998)).

The parties do not dispute that the Court's dismissal of *Biogen I* constitutes a final judgment on the merits. Rather, the parties dispute whether there is sufficient "identity of the claims" and "identity of the parties."

Plaintiffs contend that their case is "materially different" from *Biogen I*. (Mem. in Opp. at 4). In essence, plaintiffs state that *Biogen II* involves a "distinct theory" whereby "defendants misled the market about Tecfidera's safety profile and doctors' willingness to prescribe the drug *before* the PML death was disclosed." (*Id.*) (emphasis in original). That argument is unconvincing. The First Circuit has repeatedly stated that courts are to adopt a "transactional approach" in determining whether "causes of action are sufficiently related to support a *res judicata* defense." *In re Iannochino*, 242 F.3d 36, 46 (1st Cir. 2001) (quoting *Mass. Sch. of Law, Inc. v. Am. Bar Assoc.*, 142 F.3d 26, 38 (1st Cir. 1998)). Factors that courts are to consider include "whether the facts are related in time, space, origin or motivation," "whether [the claims] form a convenient trial unit," and "whether [the claims'] treatment as a unit conforms to the parties' expectations." *Id.* It is difficult to envision a case where a finding of "identity of the claims" is more warranted. The bulk of the factual allegations and claims in both suits are identical, as plaintiffs substantively allege that defendants made materially false statements and omissions concerning Tecfidera's safety profile and sales. In addition, new factual allegations do not affect the claim-preclusion analysis when they could have been raised in the earlier action. *See* Restatement (Second) of Judgments § 25, cmt. b (1982). It is clear that most, if not all, of the new factual allegations could have been brought in *Biogen I*. *See Biogen I*, 857 F.3d at 46

("Without showing that the plaintiffs could not in the exercise of reasonable diligence have obtained this new evidence earlier, GBR's argument that the district court abused its discretion by failing to account for the time the plaintiffs needed to vet the evidence to meet their Rule 11 obligations has no force.").

However, the parties in *Biogen I* and this suit are not identical. Although both suits are purported class actions, the proposed class in *Biogen I* was never certified, and "a plaintiff who files a proposed class action cannot legally bind members of the proposed class before the class is certified." *Standard Fire Ins. Co. v. Knowles*, 568 U.S. 588, 593 (2013); *see also Dempsey v. Vieau*, 130 F. Supp. 3d 809, 813 (S.D.N.Y. 2015) (finding "nothing in the plain language of the [PSLRA] that would preclude later litigation by an absent class member of a previously dismissed putative class action prior to certification, so long as the statute of limitations has not run.").

Defendants, citing *Taylor v. Sturgell*, 553 U.S. 880, 896-97 (2008), contend that plaintiffs in *Biogen I* provided "adequate representation" such that claim preclusion should nonetheless apply. However, the Supreme Court has taken a "constrained approach to nonparty preclusion." *Id.* at 898. It later stated that "[w]e could hardly have been more clear [in *Taylor*] that a properly conducted class action, with binding effect on nonparties, can come about in federal courts in just one way—through the procedure set out in Rule 23." *Smith v. Bayer Corp.*, 564 U.S. 299, 316 (2011) (internal quotation marks omitted).

Accordingly, it is clear that "in the absence of a [class action] certification" in *Biogen I*, claim preclusion does not apply. *Id.* at 315. Defendants' motion to dismiss will not be granted on the basis of claim preclusion.

V. Failure to State a Claim for Violation of Securities Laws

The Court has analyzed the majority of the allegedly false or misleading statements in its prior memorandum and order in *Biogen I*. For the sake of brevity, the Court will not repeat that extensive history and analysis here.

In substance, the *Biogen II* complaint alleges that Biogen was aware of safety concerns with Tecfidera, that Tecfidera sales dropped steeply because physicians became reluctant to prescribe the drug, that Biogen failed to disclose those facts, and that defendants made affirmative misstatements to investors. Based on statements from confidential sources, among other things, it alleges that defendants must have known—and, indeed, did know—that Tecfidera was not as safe as publicized and the PML death had a large adverse effect on sales. It further alleges that "at no time during the class period [from July 23, 2014 through July 23, 2015] did defendants provide any indication that the PML death, or the underlying cause of the PML death, had materially impacted Tecfidera sales, or caused physicians to stop prescribing Tecfidera or switch patients onto other therapies in light of safety concerns with the drug." (Compl. ¶ 22).

The complaint thus essentially alleges that defendants' statements during the class period were materially false by misrepresentation and omission, and that defendants knew or recklessly disregarded that their statements were materially false and misleading. In addition to the claim under Rule 10b-5 (Count One), the complaint also asserts a claim against the individual defendants as control persons under Section 20(a) of the Exchange Act (Count Two).

Defendants contend that Count One should be dismissed for two principal reasons. First, they contend that the Rule 10b-5 claim should be dismissed because the complaint fails to plead an actionable misstatement or omission. Specifically, defendants contend that the newly alleged statements are not actionable because they are not sufficiently false or misleading. Second, they

contend that Count One should be dismissed because the complaint fails to allege specific facts giving rise to a strong inference of scienter. Defendants also contend that Count Two should be dismissed for failure to plead a predicate Exchange Act violation.

A. Count One: Rule 10b-5 Generally

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). Pursuant to that section, the SEC promulgated Rule 10b-5, which makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. "To state a claim for securities fraud under Section 10(b), a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) in connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 40 (1st Cir. 2014); *accord Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240.

Only the first two elements are at issue here. The Court will address the complaint's allegations of material misrepresentations and omissions before turning to the issue of scienter.

B. Allegations of Material Misrepresentations and Omissions

The complaint alleges that defendants made 31 misrepresentations and omissions that

materially understated the actual effect that the PML death was having on Tecfidera sales. The Court has already found that 19 of the 22 purported misrepresentations and omissions—which were also identified in *Biogen I*—were not actionable, either because they were (1) forward-looking statements, (2) protected statements of optimism or puffery, or (3) not adequately alleged as false or misleading. Drawing all reasonable inferences in plaintiffs' favor, the Court also found that three of the 22 alleged misrepresentations and omissions were plausibly misleading or false.[19] However, the Court concluded that the three statements "did not give rise to the strong [inference] required by the PSLRA." *Biogen I*, 857 F.3d at 40.

As to the nine newly alleged misrepresentations and omissions, defendants contend that the complaint does not adequately allege that the statements were false or misleading when made.[20] Again, bolded text indicates emphasis added by plaintiffs.

1. Statements 1 and 2—Kingsley and Scangos on Earnings Call

As discussed earlier, plaintiffs allege that Kingsley and Scangos made the following allegedly false or misleading statements during a Q2 earnings call on July 23,

[19] Those three statements were the following:

> Kingsley, on the January 29, 2015 earnings call: "Importantly, we have not noticed a meaningful change in [Tecfidera] discontinuation rates."
>
> Kingsley, on the same earnings call: "[T]he lack of any meaningful change that we see—or we believe we're seeing—in the discon[tinuation] rate is encouraging, because it doesn't suggest there's such a change in the profile that people are anxious to pull patients out, but on the contrary."
>
> Kingsley, at the February 25, 2015 healthcare conference: "We have not seen any change in the discontinuation rate. There is a natural discontinuation rate for a product like Tecfidera in terms of tolerability and other things. You'd obviously get very concerned if you saw a spike in the discontinuation rate. No evidence of that . . . . [The discontinuation rate has] been consistent with—I mean, we look at it relative to the growth of the product. There's nothing that's a signal that says it's not consistent with historical averages."

[20] However, as set forth below, the Court also finds that several of these newly alleged statements are not actionable because they are protected statements of optimism or puffery or forward-looking statements protected by the PSLRA safe harbor provision.

2014:

> Kingsley: **T[ecfidera] in the US continued on a solid trajectory.** T[ecfidera] has been broadly used across numerous patient segments. Dually diagnosed, switches prompted by efficacy and non-efficacy reasons as well as patients returning to the market.
>
> **We believe T[ecfidera] is generally viewed by physicians and patients as efficacious with an attractive safety profile and a manageable tolerability profile. Importantly, patient retention rates have been similar to other marketed MS therapies and in line with our expectations.**
>
> . . . .
>
> Scangos: Tecfidera continues to gain market share and we believe it's on track to become the leading MS therapy in the U.S.

(Compl. ¶ 166-67).

Plaintiffs contend that these statements were false and misleading because physicians at the Shepherd Center had already stopped new prescriptions of the drug for its patients, creating a "domino effect" on other prescribers in the Atlanta area. (*Id.* ¶ 169). That argument fails for two reasons.

First, a reasonable investor would conclude that Tecfidera sales were in fact on a "solid trajectory" in July 2014; between Q1 and Q2 2014, Tecfidera and overall company revenues increased 38.5% and 13.7%, respectively. (*Id.* ¶ 48). Tecfidera sales had almost quadrupled between its release in Q2 2013 and Q2 2014. (*Id.*).[21] The following quarter, the drug's growth slowed, but Tecfidera revenue still increased by 12.4%. (*Id.*). Plaintiffs have not provided any data that contradicts defendants' statements on this date.

Second, and perhaps more importantly, the complaint contains no allegations that defendants and other Biogen executives were aware in July 2014 of the Shepherd

[21] Tecfidera revenue was $192.1 million in Q2 2013 and $700.4 million in Q2 2014. (Compl. ¶ 48).

Center's concerns about "blood work [ ] conducted on MS patients taking Tecfidera." (*Id.* ¶ 169). In fact, the complaint states that Dr. Thrower did not even notify Biogen that "Tecfidera was causing this impact" until "approximately August 2014." (*Id.* ¶ 66).[22]

These statements are thus not actionable misrepresentations.

2. Statement 3—Q2 2014 Press Release

The complaint further alleges the following excerpt from Biogen's July 23, 2014 press release was misleading:

> This past quarter highlighted significant accomplishments across our business, from the approval of Eloctate for hemophilia A, **to the continued patient uptake of Tecfidera in the U.S.** and new markets worldwide, to strong clinical results for important emerging MS treatments.

(Compl. ¶ 170). Plaintiffs contend that the statement was misleading because Biogen "knew that the Shepherd Center" and "other neurologists" "had already begun taking patients off of Tecfidera." (*Id.* ¶ 172).

Again, there is a "significant timing problem." *Biogen I*, 857 F.3d at 42. The complaint specified that Dr. Thrower did not inform anyone at Biogen about Tecfidera's impact on lymphocyte counts until August 2014, at least one week after the July 23, 2014 press release. (Compl. ¶ 66). In addition, Biogen financials indicate that there was "continued patient update" throughout the first half of 2014. (*Id.* ¶ 48). Therefore, this statement is similarly not an actionable misrepresentation.

3. Statement 4—Q3 2014 Press Release

Next, the complaint alleges that the following quote by Chief Medical Officer Sandrock

[22] In their opposition memorandum, plaintiffs contend that Dr. Thrower informed Biogen that Tecfidera "was causing low lymphocyte counts *by* (i.e. no later than) *August 2014*." (Mem. in Opp. at 32) (emphasis in original). This is contradicted by the complaint's multiple explicit statements that Biogen was first aware of risks to Tecfidera's safety profile in August 2014. (Compl. ¶¶ 6, 66, 177).

from Biogen's September 11, 2014 press release was misleading:

> Tecfidera continues to provide patients with effective oral treatment for MS that is supported by a growing body of data reinforcing its benefits and favorable safety profile.

(*Id.* ¶ 176). It is plausible that this statement was false or misleading, because by that date Dr. Thrower had informed Biogen about Tecfidera's impact on patients' immune systems in 30% of Shepherd Center patients taking the drug. (*Id.* ¶ 177).

It is true that there are other inferences that can be drawn from Sandrock's statement. For example, other physicians and institutions more generally may not have had similar safety concerns about Tecfidera. The complaint does not allege that corroborating evidence confirming the effect of Tecfidera on lymphocyte counts existed until February 2015, when Dr. Zamvil conducted his own independent study. (*Id.* ¶ 17). The complaint does not state what percentage of MS patients taking Tecfidera nationwide were treated at the Shepherd Center. And Tecfidera's label already included a warning that the drug would reduce lymphocyte counts in March 2013, well before the class period began. (Def. Ex. 1 § 5.1).[23] Nevertheless, drawing all reasonable inferences on behalf of plaintiffs, there is a sufficient basis to conclude that this statement was a material misrepresentation or omission.

4. Statements 5 and 6—Kingsley on Earnings Call

Plaintiffs allege that Kingsley made the following allegedly false or misleading statements during the Q3 earnings call on October 22, 2014:

> Question: Maybe for Tony [Scangos] or Paul [Clancy] on Tecfidera, looks like the growth on a quarter on quarter basis either absolute dollars or percentage basis, it looks a little bit lower in Q3 than, say, over any of the last four or five

[23] The label stated: "Tecfidera may cause lymphopenia. A recent CBC should be available before initiating treatment with Tecfidera. A CBC is recommended annually, and as clinically indicated. Consider withholding treatment in patients with serious infections." (Def. Ex. 1 at 1).

prior quarters.

Was there anything one time nature that you want to call out? Or should we just assume that drug is on a different trajectory?

Kingsley: **Nothing big on a one time nature. Inventories are moderating, I think a little bit in the channel.**

As always a little probably difficult to predict exactly, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that.

But we are very comfortable with the trajectory of the product right now. We're very comfortable as we talked about the portion of new starts and switches we are getting.

Nothing significantly off plan from our standpoint. I think we feel pretty good about the performance.

(Compl. ¶ 183; Def. Ex. 8 at 7-8).

Question: So we've done some of our own work on the discontinuation rate, and from at least from what docs are telling us, it looks like it's fairly flat and consistent with what define and confirm showed. Can you guys maybe talk about the trends you are seeing there? Are we right? Or is there some other dynamic we should think about?

Kingsley**: I think that is consistent with what we are seeing.**

As we have said before, **the discontinuation rates are, we expect to be similar to other inline therapies, over time.** We think we believe the physicians are learning to manage the GI intolerability issues, but you are still going to get some off that. **So we believe your analysis is probably in line with what we are seeing.**

(Compl. ¶ 186; Def. Ex. 8 at 18-19).

These statements are generic expressions of corporate optimism, or "puffery," that are immaterial as a matter of law. It is well-established that "not every unfulfilled expression of corporate optimism, even if characterized as misstatement, can give rise to a genuine issue of materiality under the securities laws." *Shaw*, 82 F.3d at 1217.

In particular, courts have demonstrated a willingness to find immaterial as a

> matter of law a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace—loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available.

Id. "The corporate puffery rule applies to loose optimism about both a company's current state of affairs and its future prospects." *In re Boston Sci. Sec. Litig.*, 2011 WL 4381889, at *11 (D. Mass. Sept. 19, 2011), *aff'd*, 686 F.3d 21 (1st Cir. 2012) (citation omitted). However, "[b]ecause 'the recent trend is to consider expressions of corporate optimism carefully' . . . claims of puffery now require a court to consider (1) 'whether the statement is so vague, so general, or so loosely optimistic that a reasonable investor would find it unimportant to the total mix of information' and (2) 'whether the statement was also considered unimportant to the total mix of information by the market as a whole.'" *Id.* (quoting *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 250 (D. Mass. 2006)).

The quoted statements above are not factual assertions (other than "[i]nventories are moderating"), but essentially subjective, optimistic statements that a reasonable investor would not consider material.[24] Because they are expressions of corporate optimism or puffery, they are therefore not actionable.

5. Statements 7 and 8—Kingsley on Earnings Call

Plaintiffs further allege that Kingsley made the following allegedly false or misleading statement during a Q4 earnings call on January 29, 2015:

> **We believe Tecfidera is on track to become the most-prescribed therapy for MS worldwide.**
>
> In the US, we saw continued growth through the fourth quarter, with its market share near 20%. **As you may have seen through IMS, we observed**

[24] The statement "Nothing big on a one time nature. Inventories are moderating," was made in response to an analyst's comment about slower Tecfidera sales growth in Q3 2014. Therefore, in context, the statement was an expression of corporate optimism that Tecfidera sales growth would resume in subsequent quarters.

> **moderating new starts for Tecfidera in the fourth quarter. We believe several factors have impacted the recent performance of Tecfidera, including a decline in the overall market switch rate, the US label update in December, and the recent launch of Plegridy, which is capturing some interferon switches that otherwise may have gone to Tecfidera.**

(Compl. ¶ 199; Def. Ex. 15 at 5). Plaintiffs contend that "Kingsley knew that Tecfidera sales were down in almost every region in the United States" and that he "knew the PML death had led to a significant change to the safety profile and physicians' confidence in Tecfidera." (*Id.* ¶ 201).

At least four facts contribute to a plausible inference that the statement "We believe that Tecfidera is on track to become the most-prescribed therapy for MS worldwide" was misleading. First, Tecfidera revenue for the first quarter of 2015 did not just experience slowing growth; it actually decreased $91 million, or 9.9 percent, from the fourth quarter of 2014. (*Id.* ¶ 48). Second, multiple confidential witnesses stated that there were "emergency" nationwide Biogen conference calls in late 2014 and early 2015 to address declining Tecfidera sales. (*Id.* ¶¶ 103, 109). Third, confidential witnesses stated that in early 2015, "physicians were transferring patients off Tecfidera and onto different therapies." (*See, e.g.*, *id.* ¶ 115). Fourth, after the class period, during the Q2 2015 earnings call on July 24, 2015, Biogen's executive vice president of research and development stated that there was "a modest but not trivial increase in discontinuations in Tec[fidera] in the United States in particular." (*Id.* ¶ 239).[25] Because Kingsley's statement suggested that new starts and switches remained positive and consistent with historical numbers, it is at least plausible that this statement was false or misleading.

[25] Those are not the only inferences that can be drawn from Kingsley's statements. For example, the statement was made on January 29, 2015, only one month into the first quarter. Accordingly, the fact that Tecfidera produced lower revenue for the first quarter as a whole and Williams' acknowledgement almost seven months later that the company had seen a modest, but not trivial, increase in the discontinuation rate does not necessarily prove that the statements were false when made.

Plaintiffs also allege that during that same earnings call, Kingsley made the following allegedly false or misleading statement:

> On Tecfidera—look. Actually, hard to piece apart. Probably, the—as Paul said, **we expect the product to grow. But we would see some moderation in growth next year.**
>
> I think we would have said that in any case for the first reason, which is switch rate in the market in the US has come down over the last three or four quarters. We've talked about that, I think, again, pretty consistently. When Tecfidera launched in the US—and we're seeing this repeat outside the US—it doubled or tripled the switch rate for a period of time. And that's been working its way down over time.

(Compl. ¶ 200; Def. Ex. 15 at 11-12).

Those statements, however, are not actionable. Putting aside the fact that Kingsley cautioned that Biogen expected growth to "moderate," to the extent he predicted that Tecfidera sales would increase, it was essentially a financial projection that squarely falls within the statutory safe harbor for "forward-looking" statements concerning projected earnings and "future economic performance." *See* 15 U.S.C. § 78u-5(i)(1)(A), (C); *In re Biogen IDEC, Inc. Sec. Litig.*, 2007 WL 9602250, at *10 (D. Mass. Oct. 25, 2007) (citations omitted), *aff'd sub nom. N.J. Carpenters Pension & Annuity Funds*, 537 F.3d 35.[26]

6. Statement 9—Kingsley on Earnings Call

Finally, plaintiffs allege that Executive Vice President of R&D Doug Williams made the following misleading statement on an April 24, 2015 earnings call in response to an analyst's question on the impact of the PML death on Tecfidera's safety profile:

[26] "Forward-looking statements are often contained in financial filings. Congress, in providing the limited safe harbor protection, sought to encourage market efficiency by encouraging companies to disclose future projections without fear that those projections, if they did not materialize, would result in an action for fraud." *In re Biogen IDEC, Inc. Sec. Litig.*, 2007 WL 9602250, at *10 (D. Mass. Oct. 25, 2007) (citations omitted). "When faced with an arguably forward-looking statement, the future projections must be identified and separated from the present facts upon which those projections are based." *Id.* (citing *In re Stone & Webster*, 414 F.3d 187, 212-13 (1st Cir. 2005)). "The statutory protection will only apply where the claim of fraud is based upon the future projection." *Id.*

> Williams: I think the simple answer to your question is that it's our assessment that **there is no real change in the benefit-risk profile of the drug for patients with MS. So it's pretty much status quo at the moment.**

(Compl. ¶ 222; Def. Ex. 18 at 7).

Multiple factors lead to a plausible inference that this statement was misleading. First, the complaint alleges that by April 2015, Biogen was aware not only of Dr. Thrower's findings at the Shepherd Center, but also of Dr. Zamvil's study confirming that Tecfidera reduced lymphocyte counts in patients. (Compl. ¶¶ 63-67, 69-74). Second, at least one ABM reported that Tecfidera sales declined in Q4 2014 and Q1 2015 due to safety concerns with the drug. (*Id.* ¶¶ 93-97). Third, as discussed earlier, Tecfidera sales declined in Q1 2015 by $91 million, or 9.9 percent, from the previous quarter. (*Id.* ¶ 48). And fourth, several Biogen executives made statements on the last day of the class period suggesting that physicians became wary of prescribing Tecfidera in the wake of the PML death. (*Id.* ¶¶ 236-40).[27] Drawing all reasonable inferences in plaintiffs' favor, it is plausible that this statement was materially false or misleading.

7. Conclusion

In summary, the majority of the newly alleged statements do not appear to be actionable under the PSLRA, whether considered separately or taken as a whole. However, the complaint includes sufficient allegations to conclude that at least three of the newly alleged statements were material misrepresentations or omissions. Together with the three alleged misstatements or omissions identified in *Biogen I*, a total of six such statements qualify as misleading statements or omissions under the PSLRA.

[27] Again, it is possible to draw other inferences from Williams's statement. For example, physicians' analyses of Tecfidera's benefit-risk profile may have stabilized by April 2015, approximately six months after the PML death was announced. In support of that inference, Tecfidera sales increased during Q2 2015, when the statement was made. (Compl. ¶ 48).

C. Allegations of Scienter

To be actionable under the PSLRA, a statement must be more than merely material and misleading; it also must have been made with the requisite scienter. *See ACA Fin.*, 512 F.3d at 58-59. "Scienter is 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Id.* (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)).

"A complaint will survive a motion to dismiss only if it states *with particularity* facts giving rise to a *strong inference* that defendants acted with a conscious intent to deceive or defraud investors by controlling or artificially affecting the price of securities[,] or acted with a high degree of recklessness." *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 240 (citations and internal quotation marks omitted) (emphasis added); *accord ACA Fin.*, 512 F.3d at 58-59; *see also* 15 U.S.C. § 78u-4(b)(2). "It does not suffice that a reasonable factfinder plausibly could infer from the complaint's allegations the requisite state of mind." *Tellabs*, 551 U.S. at 314. Instead, the court must "engage in a comparative evaluation" and weigh "competing inferences" to determine whether the inference of scienter is "cogent and compelling." *Id.* at 314, 324. A "'strong inference' of scienter 'must be more than merely plausible or reasonable—it must be cogent and *at least as compelling as any other opposing inference* of nonfraudulent intent.' In other words, where there are equally strong inferences for and against scienter, *Tellabs* now awards the draw to the plaintiff." *ACA Fin.*, 512 F.3d at 59 (citations omitted) (emphasis in original) (quoting *Tellabs*, 551 U.S. at 314, 324).

"In this circuit, a plaintiff may satisfy the scienter requirement with a showing of either conscious intent to defraud or 'a high degree of recklessness.'" *Id.* at 58 (quoting *Aldridge*, 284 F.3d at 82); *accord Greebel*, 194 F.3d at 198-201. "Recklessness in this context means 'a highly unreasonable omission, involving not merely simple, or even inexcusable[] negligence, but an

extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it.'" *Miss. Pub. Emps. Ret. Sys. v. Boston Sci. Corp. II*, 649 F.3d 5, 20 (1st Cir. 2011) (quoting *SEC v. Fife*, 311 F.3d 1, 9-10 (1st Cir. 2002)); *see also Greebel*, 194 F.3d at 188 (noting that recklessness in this context "does not include ordinary negligence, but is closer to being a lesser form of intent"). "Even if plaintiffs wish to prove scienter by 'recklessness,' they still must allege with sufficient particularity, that defendants had full knowledge of the dangers of their course of action and chose not to disclose those dangers to investors." *Maldonado v. Dominguez*, 137 F.3d 1, 9 n.4 (1st Cir. 1998).[28] "Knowingly omitting material information is probative, although not determinative, of scienter." *Miss. Pub. Emps. Ret. Sys. I*, 523 F.3d at 87; *see also Aldridge*, 284 F.3d at 83 ("[T]he fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter.").

Scienter "should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations." *ACA Fin.*, 512 F.3d at 59; *see also Tellabs*, 551 U.S. at 310 ("[T]he inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.") (emphasis in original). "There is no set pattern of facts that will establish scienter; it is a case-by-case inquiry." *ACA Fin.*, 512 F.3d at 66. Compelling evidence of scienter most often includes "clear allegations of admissions, internal records or witnessed discussions" that suggest that defendants were "aware that they were withholding vital information or at least were warned

[28] It is also well-established that "[p]leading 'fraud by hindsight,' essentially making general allegations 'that defendants knew earlier what later turned out badly,' is not sufficient." *Ezra Charitable Trust v. Tyco Int'l, Ltd.*, 466 F.3d 1, 6 (1st Cir. 2006) (quoting *Gross v. Summa Four, Inc.*, 93 F.3d 987, 991 (1st Cir. 1996)).

by others that this was so" when they made the misleading statements. *In re Boston Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012).

Courts have "considered many different types of evidence as relevant to show scienter," including

> insider trading . . . ; closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent information; evidence of bribery by a top company official; existence of an ancillary lawsuit charging fraud by a company and the company's quick settlement of that suit; disregard of the most current factual information before making statements; disclosures of accrual basis in a way which could only be understood by a sophisticated person with a high degree of accounting skill; the personal interest of certain directors in not informing disinterested directors of impending sale of stock; and the self-interested motivation of defendants in the form of saving their salaries or jobs.

Greebel, 194 F.3d at 196 (citations omitted). In addition, various other "facts and circumstances indicating fraudulent intent—including those demonstrating motive and opportunity"—may also combine to satisfy the scienter requirement. *In re Cabletron Sys.*, 311 F.3d at 39 (citation and internal quotation marks omitted). The "presence of [contemporaneous] insider trading can be used, in combination with other evidence, to establish scienter." *N.J. Carpenters Pension & Annuity Funds*, 537 F.3d at 55. However, "[i]nsider trading cannot establish scienter on its own, but rather can only do so in combination with other evidence." *Miss. Pub. Emps. Ret. Sys. II*, 649 F.3d at 29.

Here, plaintiffs' theory of scienter has two basic components. The first relies on allegations of 17 confidential witnesses and Drs. Thrower and Zamvil to establish that defendants intentionally or recklessly misled investors about the risk Tecfidera posed to lymphocyte counts and the subsequent impact of the PML death. The second component, referred to as "additional scienter allegations" in the complaint, includes allegations that defendants must have known the true state of Tecfidera sales, because they made numerous

statements concerning Tecfidera's discontinuation rates and safety profile. Among other things, the complaint alleges that Tecfidera's status as Biogen's most important product, or part of its "core operations," contributes to an inference of scienter.

Defendants counter with proposed inferences that (1) Tecfidera's risks were known in summer 2014 and that sales growth began to slow in late 2014—facts that defendants disclosed both before and throughout the class period—and (2) the PML death—again, a risk that they disclosed—had a greater and longer-lasting impact on Tecfidera than they anticipated.

There is little doubt that plaintiffs' allegations of scienter are plausible. That is not, however, the relevant question; rather, it is whether the allegations support a "strong inference" of scienter, as the law requires. As set forth below, the allegations of the confidential witnesses and Drs. Thrower and Zamvil are not sufficient to support a strong inference of scienter on their own, and the complaint's "additional scienter allegations" add little and are not sufficient to tip the balance. Accordingly, and for the following reasons, the complaint's allegations are insufficient to support a strong inference of scienter.

1. Confidential Witness Allegations

The confidential-witness allegations, although multiple and generally corroborative, are insufficient to support a strong inference of scienter. Many of the statements attributed to confidential witnesses 1 through 10 were already rejected by this Court and the First Circuit in *Biogen I*.

First, those allegations are not specific enough to support a strong inference that defendants acted with intent to defraud or even with recklessness. *See In re Cabletron Sys.*, 311 F.3d at 30, 39 (concluding that confidential witness allegations about company's fraudulent inventory practices supported a strong inference of scienter because they "ma[de] adequate

particularized allegations of large-scale fraudulent practices over time," and "specific descriptions of the precise means through which [the fraud] occurred"); *Coyne v. Metabolix, Inc.*, 943 F. Supp. 2d 259, 267, 271 (D. Mass. 2013) (concluding that confidential-witness allegations were "both conclusory and too vague" and included "no specific facts capable of demonstrating that [d]efendants knew the information that [plaintiff] alleges contradicted their public statements"). Certainly "[t]he Court cannot construe the PSLRA's pleading requirement to mean that confidential witnesses, who are former employees of the [c]ompany, must recall all possible details from their former positions," nor are plaintiffs required to plead evidence. *Collier v. ModusLink Glob. Sols., Inc.*, 9 F. Supp. 3d 61, 73 (D. Mass. 2014). Nonetheless, the PSLRA requires that the confidential witnesses allege "with *particularity* facts giving rise to a *strong* inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added).

The analysis begins with the allegations from the ten ABMs (CW 1, CWs 3 through 7, CW 9, CWs 11 and 12, and CW 14) concerning Tecfidera sales. According to the ABMs, the following occurred around late 2014 and early 2015: sales "dropped precipitously;" sales "took a negative"; sales "dropped steeply and immediately"; there was a "large drop in new prescription sales"; there was a "sharp decline" in sales; "sales dropped dramatically"; there was "a large drop in new prescription sales"; there was a "big slowdown" in market expansion; there was a "serious downturn" in "start forms"; "new prescriptions significantly slowed down"; sales "took a hit"; and new prescriptions came to a "screeching halt." (Compl. ¶¶ 68, 90, 100, 108, 114, 116-19, 127).

Those allegations do not set forth *specific* facts about the sales, such as a measurement of the sales decline, why sales were declining, whether the decline was due to lower new starts and

switches or higher discontinuations, or how the sales decline affected the company's financial guidance. *See Coyne*, 943 F. Supp. 2d at 266-67 (concluding that "vague (and largely conclusory) allegations of struggling sales, problems with production, and difficulty retaining repeat clients" were insufficient to demonstrate that company was "*incapable* of meeting its predicted target"); *see also Biogen I*, 857 F.3d at 45 n.9 (stating that CW 11's statements were "inadequate" to prove scienter). At most, the CW statements are generalized comments that Tecfidera sales dropped in Q4 2014 after the PML death was announced, and that in response Biogen attempted to address physicians' concerns with the drug, convened meetings and/or sales calls to discuss the situation, and lowered its marketing team's sales goals.

The other newly presented CWs—CW 13 and CWs 15 through 17—also offer no substantive information that would lead to a strong inference of scienter. Like the ABMs, CWs 13, 15, and 17 were five levels removed from the named defendants.[29] CW 13 and 17's statements merely echo what the ABMs already stated: namely, that after the PML death, Tecfidera sales dropped and Biogen executives were aware of that development. (Compl. ¶¶ 125, 130, 134). CW 15's statement that in 2013 Scangos's "G8" prepared a public statement for a potential PML-related death does not contradict defendants' public statements, particularly where Tecfidera's label already included a lymphopenia warning back in March 2013. (*Id.* ¶ 61; Def. Ex. 1 § 5.1). Likewise, although the complaint suggests that CW 16 was fewer reporting levels removed from the named defendants, the fact that senior company executives were aware of "external communication measures" in response to the PML death adds little to the scienter

[29] The complaint does not allege that any of the ten ABMs—most of whom were regional sales employees many levels removed from any of the defendants—or any of the other confidential witnesses ever spoke with one of the named defendants. *See Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 245 (noting that the confidential witnesses were not in "senior management positions, and they appear to have had relatively little ongoing contact with senior management"). There is similarly no allegation that any of the CWs witnessed a fraudulent act, or created or read a false document.

analysis. (Compl. ¶ 142).

Plaintiffs contend that requiring them to allege more would require them to plead evidence of fraud. But particularized facts about the Biogen's misrepresentation of Tecfidera's safety profile and sales decline after the PML death (and more specifically, discontinuations) are necessary here, where defendants specifically included the lymphopenia risk on the Tecfidera label in March 2013 and warned investors about slowing Tecfidera growth throughout the class period. Taken altogether, the CW statements do not "purport to contradict any of the financial information released by Biogen in its quarterly and yearly reports." *Biogen I*, 857 F.3d at 42. Indeed, on October 22, 2014—before the PML death had any impact on Tecfidera sales, and while revenues were still growing at a healthy rate—Kingsley warned the market about Tecfidera's slowing growth: "We have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that." (Def. Ex. 8 at 8). On January 29, 2015, during the same call that Biogen announced record annual and quarterly revenue for Tecfidera (and the company as a whole), Kingsley stated that he was seeing slowing Tecfidera sales due, in part, to the PML death:

> As you may have seen through IMS, we observed moderating new starts for Tecfidera, including a decline in the overall market switch rate, *the U.S. label update in December*, and the recent launch of Plegridy, which is capturing some interferon switches that otherwise may have gone to Tecfidera.
>
> Importantly, we have not noticed a meaningful change in Tecfidera discontinuation rates . . . .

(Def. Ex. 15 at 5) (emphasis added). On February 25, 2015—the same day that the complaint alleges he intentionally or recklessly misled investors about Tecfidera's discontinuation rates—Kingsley again noted the "slowing of the growth rate," told investors that the PML death was a "meaningful event that [Biogen] ha[s] to manage through," and stated that he thought Tecfidera

was "resilient" in the face of "hesitancy" among physicians. (Def. Ex. 17 at 4).

In other words, absent more particularized details and stripped of their generalities, the confidential-witness allegations about Tecfidera sales are not clearly inconsistent with what defendants were publicly disclosing to the market. *See N.J. Carpenters Pension & Annuity Funds*, 537 F.3d at 52 (concluding that a confidential source's vague allegation that patients being treated with defendants' pharmaceutical product suffered "several" infections during trial was not inconsistent with what defendants publicly disclosed and therefore did not "contribute anything additional to plaintiffs' case"); *Auto. Indus. Pension Trust Fund*, 682 F.3d at 40 ("If [defendant] knowingly understated the number of cancellations . . . this would be classic evidence of scienter. But . . . on the crucial question of when cancellations began piling up, [defendant's] statement and the confidential witness' description of cancellations increasing 'suddenly' in 'late summer' are not in conflict." (citation and internal quotation marks omitted)). Accordingly, the relatively vague statements of the confidential witnesses, absent more particularized details, lend support to an inference of scienter, but not a strong one. *See Biogen I*, 857 F.3d at 42 ("The statements do not even begin to quantify the magnitude of the sales decline at the company level.").

New allegations attributable to Drs. Thrower and Zamvil do not affect the outcome of this analysis. In substance, Dr. Thrower states that Shepherd Center personnel noted that MS patients taking Tecfidera had a higher risk of developing lower lymphocyte counts. (Compl. ¶ 65). In August 2014, Dr. Thrower notified two Biogen employees, Keith Ferguson and Eric Hall, of this development. (*Id.* ¶ 66). Putting aside the fact that Dr. Thrower had no contact with Scangos, Clancy, or Kingsley, the risk of Tecfidera reducing patients' lymphocyte counts had already been disclosed nearly 18 months before. (Def. Ex. 1 § 5.1). The risk was also disclosed

in various SEC filings. (Def. Ex. 3 at 22 (2013 Form 10-K); Ex. 4 at 50 (2014 Q1 Form 10-Q); Ex. 6 at 52-53 (2014 Q2 Form 10-Q); Ex. 16 at 25 (2014 Form 10-K)). In addition, while approximately 200 patients at the Shepherd Center discontinued using Tecfidera, there were more than 100,000 patients worldwide taking the drug. (Compl. ¶ 67; Def. Ex. 8 at 3). The number of discontinued Shepherd Center patients thus constituted less than 0.2% of all Tecfidera patients.

Dr. Zamvil's statements fail to support a strong inference of scienter for similar reasons. Dr. Zamvil alleged that he spoke with Shepherd Center doctors in summer 2014 about the risk Tecfidera posed to patients' lymphocyte counts. (Compl. ¶ 70). He then conducted his own study in February 2015 confirming the findings, and discontinued the drug for many of his patients. (*Id.* ¶¶ 72-74). While those allegations certainly corroborate those of Dr. Thrower, they again do not contradict defendants' public statements, particularly where Dr. Zamvil never spoke with defendants and failed to quantify the number of discontinued patients.

The allegations that there were conference calls concerning declining Tecfidera sales, a March 2015 national sales meeting, and Biogen's lowering of employees' sales goals likewise add relatively little to the inference of scienter. The complaint alleges that CW 3 and CW 14 participated in conference calls during which ABMs reported lower Tecfidera sales. (*Id.* ¶¶ 113, 129). The complaint further alleges that CWs 1, 3, and 7 attended a national sales meeting in March 2015 (after Kingsley's statements about the discontinuation rates, and well after the company's January projections). (*Id.* ¶¶ 112, 114, 121). According to the allegations, unidentified "senior Biogen leaders" at the meeting acknowledged that the PML death "definitely was impacting Tecfidera sales," an unidentified person described the death as a "market event," and an unidentified person stated that "sales [presumably of Tecfidera] would

need to pick up again if [Biogen] was going to meet expected 14-16% revenue growth." (*Id*. ¶¶ 112, 114).

Missing from those allegations are any details about the magnitude of the impact on sales, the change in the discontinuation rate, who made the statements, or whether any of the defendants attended the meeting. The allegations also support an inference that Tecfidera growth was slowing due to a number of factors, including the PML death, as defendants disclosed. CWs 1, 5, and 11 allege that Biogen lowered sales goals for ABMs around January 2015, and that a Biogen vice-president sent an e-mail stating that the adjustment was due to "lower guidance due to unforeseen market events." (*Id.* ¶¶ 94-96, 138-39). A "concealed change in company policy might, depending on the circumstances, assist an inference of scienter." *Auto. Indus. Pension Trust Fund*, 682 F.3d at 39. However, there are no allegations that defendants took any steps to conceal the change, and again, the allegations do not include particularized details about the magnitude of the change or defendants' involvement in it. Biogen's efforts to assist its sales employees to reach compensation goals while also warning the market about slowing Tecfidera growth do not warrant a strong inference of fraud.

Finally, the complaint alleges that CW 2 attended a November 2014 Biogen "town hall" meeting led by Scangos. According to CW 2, Scangos's presentation stated that "the overall sense of the trajectory [at Biogen] was changing," and another presentation addressed "potential organizational changes as a result of the PML death." (Compl. ¶ 107). Again, those allegations are consistent with competing inferences. CW 2 does not explain what the potential changes were, or any details about how Biogen's "trajectory" was changing. Even viewing CW 2's allegations in light of the entire complaint, they require the Court to make several assumptions to

piece together an inference of fraudulent intent or recklessness, let alone a compelling one.[30]

Moreover, those allegations are consistent with the competing inference of a lack of scienter. Biogen had experienced meteoric revenue growth in 2014, and in November 2014 it was only weeks away from announcing 232 percent annual revenue growth for Tecfidera. Nevertheless, the "trajectory" of Tecfidera's growth was changing, as the company disclosed beginning in October 2014. (*See* Def. Ex. 8 at 8). Kingsley, in response to question about moderating Tecfidera growth in the third quarter of 2014, stated: "As always[,] a little probably difficult to predict exactly, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that." (*Id.*). Also, during the same January 2015 call in which Biogen announced that annual Tecfidera revenue had more than doubled, Kingsley explicitly acknowledged that the PML announcement was having an impact on performance. (*See* Def. Ex. 15 at 5) ("We believe several factors have *impacted* the recent performance of Tecfidera, including a decline in the overall market switch rate, the US label update in December . . . ." (emphasis added)). He also addressed Biogen's sales approach after the PML announcement, an approach that could be reasonably inferred to mean "organizational changes":

> I think the *educational initiatives* are underway, which is, we have sales forces out, talking to a broad set of physicians. Our medical team is providing support where there are requests. So I think we are [executing on this]—educating people to the label and what the label says. And answering those questions.

[30] The complaint's allegations as to CW 10 and CW 8 add little to the mix. CW 10 was an executive assistant for Sundaram, the "program director of Tecfidera," who allegedly met frequently with Kingsley and Scangos. (Compl. ¶¶ 131-33). Although CW 10 alleges that various executives and sales teams met to discuss Tecfidera sales and that Biogen representatives spoke with physicians, there is no detail about the content of those discussions. (*Id.*). Indeed, the only allegation CW 10 adds is that Sundaram "knew that the label change would immediately lead to lost sales." (*Id.* ¶ 133). The complaint does not allege how CW 10 *knew* that Sundaram *knew* that fact; anything Sundaram allegedly said; any detail on the magnitude of lost sales; or whether Sundaram's apparent knowledge was shared by defendants. CW 8 was Biogen's senior director of commercial operations from August 2014 to November 2015. He merely alleges that Tecfidera "was on a growth trajectory when he joined," but that the "trajectory changed after the October 2014 PML death was announced." (*Id.* ¶ 122).

(*Id.* at 13) (emphasis added).

In short, the various allegations of the confidential witnesses and Drs. Thrower and Zamvil, taken as a whole, certainly support a plausible inference of scienter. However, without more, they are not sufficient to support a *strong* inference of scienter, as the law requires, and they are consistent with the competing non-fraudulent inferences.

2. Additional Scienter Allegations

The complaint's "additional" scienter allegations do not add much, if anything, to the new confidential witness allegations.[31] The complaint alleges that defendants had both the motive and opportunity to misrepresent Tecfidera's growth projections. However, some of the allegations make little sense in the factual context of Biogen's purported fraud, and they are otherwise too generic to support an inference of scienter. "'[C]atch-all allegations' which merely assert motive and opportunity, without something more, fail to satisfy the PSLRA." *In re Cabletron Sys.*, 311 F.3d at 39 (quoting *Greebel*, 194 F.3d at 197). Instead, motive and opportunity allegations must state "more than the usual concern by executives to improve financial results." *Id.*

First, plaintiffs contend that specific statements made by the individual defendants "reflect" that they received "specific information regarding Tecfidera." (Compl. ¶ 250). Therefore, plaintiffs suggest that defendants "either fabricated the information they provided to investors and the market or they deliberately ignored information they possessed or had access to relating to such matters." (*Id.*). This is plainly a conclusory assertion that lacks the specific allegations necessary to support an inference of scienter.

Second, the complaint restates the "core operations" allegations from *Biogen I*. The

[31] Notably, plaintiffs have ignored the "defendants' compensation structure and stock holdings," which "weaken any inference of scienter." *Biogen I*, 857 F.3d at 44.

complaint alleges that because Tecfidera was Biogen's main revenue source during the class period, accounting for approximately one-third of total company revenue, defendants knew or were reckless in not knowing that their statements about Tecfidera were misleading. (*Id.* ¶¶ 48, 251-59). Certainly, under *Tellabs*, the "core operations" allegations and Tecfidera's importance to Biogen must be taken into account as part of the Court's assessment of the scienter allegations. However, courts have been hesitant to apply significant weight to "core operations" allegations without other significant evidence of a defendant's intent or recklessness, or a "plus factor." *See In re A123 Sys., Inc. Sec. Litig.*, 930 F. Supp. 2d 278, 285 (D. Mass. 2013) ("Plaintiffs cite [*Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 19 (D. Mass. 2004)] for the proposition that 'facts critical to a business's core operations or an important transaction generally are so apparent that their knowledge may be attributed to the company and its officers.' *Crowell*, . . . [however,] involved allegations of the improper booking and accounting of fraudulent sales, buttressed by a 'plus factor'—an e-mail pointing to the company's vice president as the author of the scheme."); *see also Lenartz v. American Superconductor Corp.*, 879 F. Supp. 2d 167, 183 n.9 (D. Mass. 2012) (finding the core operations theory inapplicable in accounting fraud case because the facts were "less clear" than the "particularized facts" of *Crowell*). Here, there is no "smoking gun" evidence or "plus factor" as in *Crowell*.[32]

Next, plaintiffs contend that because Biogen's "key activities" are highly regulated, defendants "monitored the Company's 'most critical business activities,' including 'adverse event reporting' and 'product risk management,' as they pertained to Tecfidera." (Compl. ¶

[32] It appears that the First Circuit has not yet directly addressed the proper weight to give "core operations" allegations, and even courts that have applied it have not done so unless the product is "central to [the company's] continued survival as a business entity." *See Lenartz*, 879 F. Supp. 2d at 183 n.9. Here, Tecfidera was certainly important to Biogen and probably the company's most important product, but even plaintiffs do not contend that it was central to the company's "continued survival as a business entity."

262). Plaintiffs further allege that the "patent inconsistencies between Defendants' public pronouncements and what was known internally within Biogen provide further evidence of scienter." (*Id.* ¶ 265). Here, plaintiffs again offer merely conclusory allegations and fail to provide any further specifics necessary to support a strong inference of scienter where defendants disclosed Tecfidera's risks and sales data to investors.

Finally, plaintiffs allege that two post-class period developments support an inference of scienter. First, Kingsley "abruptly left his position at Biogen only two months after the company's July 2015 admissions concerning Tecfidera." (*Id.* ¶ 266). Second, Scangos "took a substantial pay cut due, in large part, to the performance of Tecfidera during 2015." (*Id.* ¶ 267). Plaintiffs reason that there was "a clear motive for Scangos to conceal the truth about the drug's safety profile, as his compensation was tied directly to Tecfidera's success in the marketplace." (*Id.*). Neither supports a strong inference of scienter.

The complaint fails to plead with any particularity that Kinglsey's employment was terminated because of declining Tecfidera sales. Accordingly, this allegation alone cannot support an inference of scienter. *See Abrams v. Baker Hughes, Inc.*, 292 F.3d 424, 434 n.28 (5th Cir. 2002) ("Scienter may not be inferred from resignation of company officials 'for personal reasons.'") (citation omitted).

In addition, the allegation concerning Scangos's compensation makes little sense in this context. Even though plaintiffs suggest that Scangos had an incentive to pump up Tecfidera sales, and by extension Biogen's stock price, by concealing the risk of lymphopenia, that risk was disclosed by defendants well before the start of the class period. Furthermore, the complaint largely reiterates the argument from *Biogen I* that defendants attempted to minimize the PML death's effects on Tecfidera sales. However, it does not allege that Biogen's revenue *reporting*

was false or misleading in any way. Instead, the complaint alleges that Biogen's future revenue *projections* were misleading.

In sum, the complaint's "additional" allegations of motive, opportunity, and "core product," taken as a whole, do not make the complaint's otherwise plausible inference of scienter strong enough to satisfy the PSLRA.

3. Opposing Inferences

Based on the complaint as a whole, plaintiffs' asserted inference of scienter may be plausible, but it is not strong, cogent, or compelling. Moreover, the Court "must weigh 'not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged.'" *N.J. Carpenters Pension & Annuity Funds*, 537 F.3d at 45 (quoting *Tellabs*, 551 U.S. at 314). There are at least three facts that further weaken the inference of scienter here.

Most obviously, defendants disclosed the risk that Tecfidera would reduce lymphocyte counts more than a year before the class period began, were somewhat cautious in projecting Tecfidera's growth, and repeatedly warned investors about the downside risks, including moderating growth and the PML label change. As the First Circuit has consistently noted, "'attempts to provide investors with warnings of risks generally weaken the inference of scienter.'" *Waters Corp.*, 632 F.3d at 760 (quoting *Ezra Charitable Trust*, 466 F.3d at 8); *see Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 243 (concluding that plaintiffs' contention that defendants made statements about pharmaceutical revenues with reckless disregard as to whether investors would be deceived was "undercut by the fact that [the defendant company] *explicitly* warned investors" that an FDA enforcement action "'could result in reduced demand for our products and would have a material adverse effect on our operations and prospects'"); *Genzyme Corp.*, 754 F.3d at 42-43 (noting that a corporation's informative disclosures "undercut

any inference of fraudulent intent on the part of defendants").

For example, during a call on October 22, 2014, Biogen announced the PML death and stated that it "reported the case to the regulatory authorities" and that it would "work with them to confirm that the language on [Tecfidera's] label provides patients and their physicians appropriate information regarding lymphopenia." (Compl. ¶ 75; Def. Ex. 8 at 3). During the same call, Kingsley responded to an analyst's question (about third-quarter Tecfidera growth being the lowest of the previous five quarters) by noting that growth was moderating and difficult to predict. (Compl. ¶ 183; Def. Ex. 8 at 7-8) ("As always a little probably difficult to predict exactly, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that.").[33]

Clancy later stated on December 2, 2014, that investors should be "mindful" of Tecfidera's discontinuation rates, which were in the "teens" and higher than the company would have hoped for an oral MS therapy. (Def. Ex. 12 at 2-4).[34] On January 29, 2015, after announcing record quarterly revenue for Tecfidera, Kingsley stated that the company had observed "moderating new starts for Tecfidera in the fourth quarter" and that it "believe[d] several factors have impacted the recent performance of Tecfidera, including a decline in the overall market switch rate, [and] the U.S. label update in December . . . ." (Compl. ¶ 199; Def. Ex. 15 at 5). He also stated that the reasons for slowing growth were "[a]ctually hard to piece apart." (Compl. ¶ 200; Def. Ex. 15 at 11-13). In the same breath that he stated that he did not "believe" he was seeing a "meaningful change" in Tecfidera's discontinuation rate, he was again

[33] Notably, the complaint alleges that "[a]nalysts accepted defendants' *statements that the PML death would not have a material impact on Tecfidera*." (Compl. ¶ 78) (emphasis added). None of the defendants made any such statements during the call.

[34] On the same call, Clancy stated that Biogen "expect[ed] a label change" due to the PML death. (Def. Ex. 12 at 3).

cautious: "Look—I think that, naturally, in a case like this, as people are processing the new label, you'll see softness in switch rate for a period of time." (Def. Ex. 15 at 13).

In February 2016, Kingsley again noted the effect that the PML death was having on Tecfidera, despite the drug's resilience:

> Fourth quarter, we had the report of one PML incident and I think we talked about this in earnings call and toward the end of the year which is that's a *meaningful event that you have to manage through*, right? *There's a lot of communication that has to happen to physicians*. You would expect to see *some hesitancy among some set of physicians before you get to them to have a conversation*. But that would—the product's been quite resilient, I think, is our view in light of that. 2015, we think it's still a meaningful growth driver.

(Compl. ¶ 217; Def. Ex. 17 at 4) (emphasis added). When directly asked to predict whether "a lot of the [] PML noise or news" had come out in the fourth quarter of 2015 after the December label change, or whether it would carry over into the first quarter, Kingsley was again, at the very least, cautious:

> Yes, so the information certainly got out in the fourth quarter. Looking at analogous situations with other products, *we typically think you might have a 2, 3 month time frame where this presses*, but that's looking at analogies. So *impossible to predict with great accuracy*.

(Compl. ¶ 217; Def. Ex. 17 at 4-5) (emphasis added).

During the first-quarter-earnings call in April 2015, Scangos noted that "Tecfidera had a more challenging quarter, due to a number of issues, including . . . the single PML case reported last year." (Compl. ¶ 150; Def. Ex. 18 at 3). Kingsley again noted the PML death when he stated, "We believe [moderation in growth rates] is occurring as expected, but also believe that the [Tecfidera] safety event in October further dampened market growth and switch rates in Q1." (Def. Ex. 18 at 4). Finally, Clancy warned that "[i]f the U.S. [Tecfidera] trajectory does not improve, we may come in at the lower end of our previously provided revenue growth [range of 14 to 16 percent]." (Compl. ¶ 222; Def. Ex. 18 at 6). In May 2015, Clancy stated that the

"unfavorable impact" that the PML death had on physicians' attitudes toward Tecfidera had "stabilized" but that it "hasn't turned around as quick as we had wanted it to turn around." (Def. Ex. 19 at 2).

Other factors appear to support the inference that defendants, at worst, negligently overestimated Tecfidera's short-term revenue growth after the PML death. After Biogen announced record Tecfidera quarterly revenue of $916 million in the fourth quarter of 2014, Tecfidera revenue dropped in the first quarter and demonstrated tepid growth in the second quarter due, in part, to the PML death. Notably however, after the class period, Tecfidera revenue rebounded to $937 million in the third quarter and $993 million in the fourth quarter of 2015, contributing to annual growth rates of 25.1 percent and 10.9 percent for Tecfidera and Biogen, respectively. (*See generally* Def. Ex. 24). That demonstrates the "meaningful" but "moderating" growth that defendants expected. Moreover, the complaint contains no allegation that defendants concealed the lymphopenia warning, or hid or otherwise delayed in announcing the PML death to investors (or the subsequent label change). *See Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 243 (noting that medical company defendant "did not withhold information about the FDA's concerns once the FDA issued a Warning Letter" and "did not promise a positive resolution of the matter").

In short, "[t]hese are not the actions of a company bent on deceiving investors as to their future earnings prospects." *See id.* Defendants warned the public about Tecfidera's potential impact on lymphocyte counts well in advance of the class period and issued timely notifications about the PML death. Accordingly, their conduct falls far short of recklessness and does not support an inference of scienter. Rather, they support the inference that defendants were, at

worst, overly optimistic in attempting to predict the PML death's effect on revenues.[35]

4. Conclusion

Considered as a whole, the complaint presents new allegations of scienter that fall far short of the "strong inference" required under the PSLRA. At best, the allegations are plausible, but not "cogent and compelling." *Tellabs*, 551 U.S. at 324; *see also ACA Fin.*, 512 F.3d at 59 (noting that scienter "should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations"). Again, the allegations from confidential sources and Drs. Thrower and Zamvil—none of whom personally spoke to defendants or witnessed any overtly fraudulent behavior—contribute somewhat to plaintiffs' asserted inference of scienter. However, they are too unspecific and conclusory to create a strong inference of recklessness or intent. Indeed, the allegations concerning Tecfidera's safety profile, physicians' discomfort after the PML death, and declining Tecfidera sales are at least partly consistent with defendants' repeated public disclosures. Furthermore, the complaint's "additional" motive and core-product allegations provide very little support to an inference of scienter. Without more, plaintiffs' circumstantial case of scienter is not strong or compelling.

In sum, even after drawing all reasonable inferences on behalf of plaintiffs, the most compelling inference to be drawn from the complaint as a whole is that defendants did not publicize further the lymphopenia warning already on the Tecfidera label and were unduly optimistic—at worst, negligently so—in predicting how quickly Tecfidera sales would recover from the PML announcement. "Still, 'allegations of corporate mismanagement are not

[35] As Kingsley warned investors, that effect was inherently difficult to predict. (*See* Def. Ex. 8 at 7-8) (Kingsley: "As always a little probably *difficult to predict exactly*, but look, we have always expected Tecfidera's growth rate would moderate over time. I think we are seeing a natural case of that." (emphasis added)); (*see* Def. Ex. 17 at 4-5) (Kingsley: "[S]o the [PML death] information certainly got out in the fourth quarter. Looking at analogous situations with other products, we typically think you might have a 2, 3 month time frame where this presses, but that's looking at analogies. So *impossible to predict with great accuracy*." (emphasis added)).

actionable under Rule 10b-5. Nor are allegations of mere negligence.'" *Fire and Police Pension Ass'n of Colo.*, 778 F.3d at 246 (quoting *Waters Corp.*, 632 F.3d at 760) (alteration omitted). Without evidence sufficient to support a strong inference of intent, or at least recklessness, defendants' failure to predict the future does not support a claim for securities fraud; accordingly, under the heightened pleading standard of the PSLRA, Count One will be dismissed.

E. Count Two: Section 20(a) Liability

Count Two asserts a claim against the individual defendants under Section 20(a) of the Exchange Act, which imposes joint and several liability on persons in control of entities that violate securities laws. 15 U.S.C. § 78t. However, violations of Section 20(a) depend on an underlying violation of the Exchange Act. 15 U.S.C. § 78t-1(a); *see Waters Corp.*, 632 F.3d at 762 ("Because the plaintiff's Section 20(a) claim was derivative of the Rule 10b-5 claim, it was properly dismissed as well."); *ACA Fin.*, 512 F.3d at 67-68. Because the complaint fails to state a claim for an underlying violation of the Exchange Act, Count Two will be dismissed.

VI. Conclusion

For the foregoing reasons, defendants' motion to dismiss is GRANTED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: March 27, 2018