

[PUBLISH]

In the
United States Court of Appeals
For the Eleventh Circuit

No. 21-11246

NEIL EINHORN,
Individually and on behalf of all others similarly situated,

Plaintiff,

POLICE AND FIRE RETIREMENT SYSTEM
OF THE CITY OF DETROIT,
Individually and on behalf of all others similarly situated,

Plaintiff-Appellant,

versus

AXOGEN, INC.,
KAREN ZADEREJ,
PETER J. MARIANI,
GREGORY G. FREITAG,
JAMIE M. GROOMS,

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ROBERT J. RUDELIUS,
MARK GOLD,
GUIDO NEELS,
AMY WENDELL,
LEERINK PARTNERS LLC,
JMP SECURITIES LLC,
JEFFERIES LLC,
WILLIAM BLAIR & COMPANY, L.L.C.,

Defendants-Appellees,

JOHN HARPER, et al.,

Defendants.

Appeal from the United States District Court
for the Middle District of Florida
D.C. Docket No. 8:19-cv-00069-TPB-AAS

Before LAGOA, BRASHER, and TJOFLAT, Circuit Judges.

BRASHER, Circuit Judge:

The Police and Fire Retirement System of the City of Detroit lost money when a short seller's report concluded that Axogen, Inc., had overstated the market for its products, resulting in a precipitous decline in Axogen's stock price. Specifically, Axogen said that its human nerve repair products had potential because "each year" 1.4 million people in the United States suffer nerve damage, leading to over 700,000 nerve repair procedures. The Retirement System filed this lawsuit against Axogen and related entities, which presents the following question: Were Axogen's public statements forward looking? If so, as the district court held, the statements are eligible for a safe harbor from liability. *See* 15 U.S.C. § 77z-2(c). After careful review and with the benefit of oral argument, we conclude that the challenged statements are forward looking and affirm the judgment of the district court.

I.

An individual plaintiff filed a securities class action on behalf of all persons and entities that purchased or otherwise acquired Axogen stock during a class period between August 7, 2017, and December 18, 2018. The district court eventually appointed the Retirement System as lead plaintiff. Once in charge, the Retirement System filed an amended class complaint alleging violations of the 1933 Securities Act ("the '33 Securities Act"), 15 U.S.C. §§ 77k, 77l(a)(2), 77o, and the 1934 Securities Exchange Act ("the '34 Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a). The district court granted the defendants' first motion to dismiss, and the Retirement System filed a second amended complaint. The following allegations are

recited from the second amended complaint, as we must take them as true for the purposes of this decision.

Axogen is a medical technology company specializing in “nerve repair” products. Axogen claims an “exclusive focus on peripheral nerve repair and protection solutions” and sells “just a handful of products.” One of those products is the Avance Nerve Graft, a segment of nerve tissue derived from human cadavers used to “support and guide nerve regeneration” and “bridge gaps created in peripheral nerves as a result of trauma.” Avance is Axogen’s leading product, accounting for around half of the company’s total revenues during the class period. Axogen claimed that between thirty-three and forty percent of its total market related to Avance.

During the class period, Axogen billed itself as a company with explosive growth potential, particularly for Avance. By the end of the class period, it estimated that its potential market had ballooned to 2.7 billion dollars. This estimate was made against a background of modest revenues—thirteen years after launching its core product, Axogen’s 2017 revenue totaled only sixty million dollars, and it was operating at a loss. The result was a company that claimed untapped “long-term sustainable growth” potential, which was an attractive narrative to the plaintiffs.

Axogen conducted two public offerings of common stock during the class period that raised more than 170 million dollars. Documents related to those offerings contained statements in support of Axogen’s purported growth potential. Axogen stated that it “believed” several things concerning the number of peripheral

nerve injuries and procedures that occurred “each year” in the United States.¹ The offering documents incorporated statements made in Axogen’s 2016 and 2017 Form 10-K. The 2016 10-K stated that:

Axogen believes each year in the U.S. more than 1.4 million people suffer traumatic injuries to peripheral nerves. Axogen estimates that traumatic injuries to peripheral nerves result in over 700,000 extremity nerve repair procedures.

Similarly, the 2017 10-K stated:

We believe that each year in the U.S., more than 1.4 million people suffer damage or discontinuity to peripheral nerves resulting in over 700,000 extremity nerve repair procedures.

These statements appeared in the general business overview section of Axogen’s Form 10-K, under a subheading entitled “Peripheral Nerve Regeneration Market Overview.”

Some of the offering documents repeated Axogen’s belief concerning the number of injuries and procedures that occur each

¹ To support its ’34 Exchange Act claims, the Retirement System’s complaint also relies on two public statements that estimated the number of nerve repair procedures during the class period without using the phrase “each year.” Because the Retirement System does not appeal the district court’s dismissal of its ’34 Exchange Act claims, we do not address those statements.

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year. A prospectus prepared in support of the November 2017 offering stated:

We believe that, each year in the United States, more than 1.4 million people suffer traumatic injuries to peripheral nerves, resulting in over 700,000 extremity nerve repair procedures.

The same document contained similar statements concerning the size of the market for a different Axogen product:

[R]esearch . . . has indicated approximately 80,000 [peripheral nerve injuries] occur in the U.S. each year that are related to third molar extractions, anesthetic injections, dental implants and benign pathology.

And a registration statement filed prior to the May 2018 offering stated:

We believe that each year in the U.S. more than 1.4 million people suffer damage or discontinuity to peripheral nerves resulting in over 700,000 extremity nerve repair procedures.

In December 2018, Seligman Investments, a short seller that had been investigating Axogen, published a research report challenging Axogen's claims about the frequency of peripheral nerve injury repair procedures and the size of Axogen's market. The report concluded that, far from the number Axogen touted, there were only 28,000 peripheral nerve injury repair procedures each year in the United States. It also concluded that Axogen's total

market for Avance in trauma cases was only fifty-two million dollars, almost twenty times less than the market Axogen represented to investors during the class period. The release of the Seligman Report caused a market shock. Axogen's share price fell from \$27.53 per share at closing the day before the report was released to \$21.36 per share at close of the next trading day and \$17.09 per share at closing three days after that. Axogen's stock price has yet to recover to pre-Seligman levels.

The Retirement System later retained its own experts to examine Axogen's claims about peripheral nerve injury frequency. These experts argued that Axogen's claims about its market and the prevalence of repair procedures were inaccurate. The Retirement System also contacted several former Axogen employees who served as confidential witnesses in the complaint. These confidential witnesses expressed further skepticism about Axogen's market estimates. And although the Retirement System alleged that Axogen executives knew that the estimates were false to support its claims under the '34 Exchange Act, it "expressly disclaim[ed] any allegations of fraud or intentional misconduct in connection with [the '33 Securities Act] claims."

After the Retirement System filed the second amended complaint, the defendants moved to dismiss again. The district court granted the defendants' renewed motion and dismissed the complaint with prejudice, holding that the challenged statements were: (1) forward looking and protected by the safe-harbor provision, 15 U.S.C. § 78z-2, and in the alternative (2) non-actionable statements

of opinion under *Omnicare, Inc. v Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175 (2015). The court also held that the amended complaint failed to satisfy the heightened standard for pleading *scienter* under the Reform Act, rendering the ‘34 Exchange Act claims fatally deficient.

The Retirement System timely appealed, challenging only the district court’s dismissal of its claims under the ‘33 Securities Act. The question before us is further narrowed by the Retirement System’s briefing, which disclaims any challenge to Axogen’s estimates of the size of its market. Thus, the only question on appeal is whether Axogen’s statements concerning the frequency of nerve injuries and peripheral nerve injury repair procedures are shielded from liability.

II.

We review a district court’s order granting a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) *de novo*, accepting the complaint’s well-pleaded factual allegations as true and construing them in the light most favorable to the plaintiff. *See S. Fla. Water Mgmt. Dist. v. Montalvo*, 84 F.3d 402, 406 (11th Cir. 1996). But “conclusory allegations, unwarranted deductions of facts or legal conclusions masquerading as facts will not prevent dismissal.” *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002). To survive a motion to dismiss, a complaint must allege “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “A

claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

III.

The ‘33 Securities Act creates a cause of action against persons and entities that cause an “untrue statement of a material fact” or omit a material fact from a public filing related to an offering of securities. *See* 15 U.S.C. §§ 77k, 77l, 77o. But the law recognizes a “safe harbor” for ‘33 Securities Act liability for “forward-looking” statements. 15 U.S.C. § 77z-2. A forward-looking statement is, among other things, “a statement containing a projection of revenues” or “income” or “a statement of future economic performance.” 15 U.S.C. § 77z-2(i)(1)(A) & (C). Any “statement of the assumptions underlying or relating to any statement” about such projections is also a “forward-looking statement.” *Id.* at (D). As relevant here, the safe harbor provides a defense to liability if the plaintiff fails to prove that the forward-looking statement was “made with actual knowledge . . . that the statement was false or misleading.” *Id.* §77z-2(c)(1)(B)(i).

For our part, we have held that the key characteristic of a forward-looking statement is that its “truth or falsity is discernible only after it is made.” *Harris v. Ivax Corp.*, 182 F.3d 799, 805 (11th Cir. 1999) (interpreting the safe-harbor provision covering claims under the ‘34 Exchange Act). To differentiate “historical

observations,” which are not forward looking, from “assumptions about future events,” which are forward looking, we rely on the context in which the statement appears. *See id.* A statement need not be entirely forward looking to receive safe-harbor protection. Even a statement that depends in part on present-tense observations is due safe-harbor protection so long as the conclusion it supports is forward looking. *Id.* at 806. Put another way, “when a forward-looking statement is of the sort that, by its nature, rolls in present circumstances—that is, when a statement forecasts in a tentative way a future state of affairs in which a present commitment unfolds into action—the statement isn’t barred from safe-harbor protection solely on that ground.” *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1329 (11th Cir. 2019). Nonetheless, if a statement includes a “distinct present-tense . . . component” that is “readily severable” from the forward-looking portion of the statement, the safe harbor protects only the forward-looking part. *Id.* at 1328.

We must apply these principles to Axogen’s statements about the number of nerve injuries and peripheral nerve injury repair procedures performed in the United States “each year.” The Retirement System argues that the statements are not forward looking. In the alternative, the Retirement System argues that the statements are still actionable even if they are forward looking.

Starting with the Retirement System’s first argument, we conclude that the challenged statements are forward looking. As a reminder, the critical phrase in the challenged statements is Axogen’s assertion that a certain number of peripheral nerve injuries

and procedures occur in the United States “each year.” The Retirement System argues that Axogen’s “each year” statement is about a present, existing, or historical fact. Axogen argues that the phrase “each year” reflects an ongoing state of affairs that extends from the present into the future, not a historical state of affairs that existed at a particular point in time.

We agree with Axogen. Although there is certainly an element of present or historical fact in the phrase “each year,” the phrase is also forward looking. The “each year” statement is, at least in part, a prediction about the number of injuries requiring nerve repair procedures that are likely to occur “each year” in the future. Forward-looking statements “often rest both on historical observations and assumptions about future events.” *Harris*, 182 F.3d at 806. By making a claim about the number of injuries and procedures “each year,” Axogen made an assertion about the likely number of injuries and procedures in the current year and the year after that and the year after that.

To be sure, we can imagine using the phrase “each year” to refer solely to an existing or historical fact. A study could conclude, for example, that a specified number of injuries occurred “each year *for the ten years observed*.” That usage makes a claim about past conditions based on the study’s observations. Or a company could say that it pays an employee \$100,000 each year. That statement is a claim about the employee’s existing compensation structure, not a prediction of what the employee will be paid in the future. But, as Axogen used the phrase, it is inherently forward

looking; it was addressed to future years just as much as to past years or the present year.

If there were any doubt about whether the statement was forward looking, the context resolves it. *See Harris*, 182 F.3d at 805. The plaintiffs concede that the statements were used to support Axogen’s predictions about the size of the market that “could be serviced” by its products. Those market-size predictions are about “future economic performance” and are defined as forward-looking statements under the statute. *See* 15 U.S.C. ¶ 77z-2(i)(1)(C). Axogen’s “statement of [its] assumptions underlying or relating to” its market predictions—*i.e.*, that “each year” a certain number of injuries occur and medical procedures are performed—are definitionally forward looking. *See* 15 U.S.C. ¶ 77z-2(i)(1)(D); *Harris*, 182 F.3d at 806. Indeed, the only reason Axogen made the statements—and the only reason the Retirement System found them material—is that the statements could be used to predict the size of the going-forward or anticipated market for Axogen’s products.

Having concluded that there is a forward-looking aspect to the statements, we must address whether their forward-looking aspect is severable from their present-tense or historical implications. The Retirement System contends that we can “pars[e]” the statements’ present-tense observations and separate them from their forward-looking components. The problem for the Retirement System is that no portion of the statements are “readily” or “easily” severable. *Carvelli*, 934 F.3d at 1328-29. The statement we found severable in *Carvelli* was “lengthy” and had two distinct clauses,

one addressing a present condition and one an “expect[ation].” *See id.* at 1328. On the other hand, we explained in *Carvell* that “a present-tense declaration is, in some cases, an inextricable part, rather than an easily severed ancillary, of a forward-looking statement.” *Id.* The mere fact that “a forward-looking statement is of the sort that, by its nature, rolls in present circumstances” does not mean it falls outside the safe harbor. *Id.*

Here, we have only one clause, “each year.” It has both present-tense and forward-looking implications because it says something about the past and something about the future. But, to the extent the phrase “each year” may have two aspects—one that is forward looking and one that is backward looking—the phrase is not readily severable into “distinct present-tense and forward-looking components.” *Id.* at 1328. We can sever the forward- and backward-looking “portion[s]” of a statement, *id.*, but we cannot sever the meanings of a single phrase.

Turning now to the issue of Axogen’s liability for its forward-looking statements, we agree with the district court that the Retirement System has not stated a claim upon which relief may be granted. As relevant here, the safe harbor does not apply to forward-looking statements if “the plaintiff fails to prove that the forward-looking statement . . . if made by a business entity, was . . . made by or with the approval of an executive officer of that entity and made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.” 15 U.S.C. § 77z-2(c)(1)(B).

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The district court concluded that the Retirement System failed to plead “actual knowledge that the statements were false or misleading,” and we agree. Aside from cursorily alleging that Axogen “knew the statement[s] w[ere] materially false or misleading,” the Retirement System failed to allege any facts suggesting Axogen’s actual knowledge of the statements’ falsity. In fact, it disclaimed any allegation that Axogen “intentional[ly]” misrepresented anything.

The Retirement System does not argue on appeal that it met the “actual knowledge” standard. It contends instead that the statement is not eligible for the safe harbor under a separate test because it was unaccompanied by “meaningful cautionary statements.” 15 U.S.C. § 77z-2(c)(1)(A)(i). This argument is beside the point. We have explained that “[e]ven if [a] forward-looking statement has no accompanying cautionary language, the plaintiff must prove that the defendant made the statement with ‘actual knowledge’ that it was ‘false or misleading.’” *Harris*, 182 F.3d at 803 (quoting an identical provision covering ‘34 Exchange Act claims, 15 U.S.C. § 78u-5(c)(1)(B)). So the Retirement System cannot get around the “actual knowledge” standard by pointing to the alleged lack of cautionary statements.

Confronting the issue for the first time in its reply brief, the Retirement System again does not argue that it meets the statutory “actual knowledge” standard. Instead, it contends that the Supreme Court’s decision in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175 (2015),

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relieves it of that burden. The Retirement System’s argument mis-understands the safe-harbor statute and *Omnicare*. For its part, the “actual knowledge” standard is a non-negotiable part of the statute. The safe-harbor provision expressly requires a plaintiff to prove that a forward-looking statement was made with “actual knowledge that the statement was false or misleading.” 15 U.S.C. § 77z-2(B)(ii)(II). *Omnicare*, on the other hand, addressed whether an *opinion* may be an actionable misstatement of fact under 15 U.S.C. § 77k(a). *See* 575 U.S. at 178 (“This case requires us to decide how [Section 77k(a)] applies to statements of opinion.”). The Court did not address the safe-harbor provision, let alone alter the plain text of the statute. Thus, the Retirement System’s failure to plausibly allege—or even attempt to argue on appeal—Axogen’s actual knowledge dooms its ’33 Securities Act claims.

IV.

For the foregoing reasons, the district court’s judgment is

AFFIRMED.

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LAGOA, J. Concurring

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LAGOA, Circuit Judge, concurring in judgment:

While I concur in the judgment, I write separately because I would have affirmed the district court on the basis that the statements at issue are clear examples of nonactionable statements of opinion under the framework the Supreme Court articulated in *Omnicare v. Laborers District Council Construction Indus. Pension Fund*, 575 U.S. 175 (2015), without addressing whether the statements constitute forward-looking statements.

I.

As the majority opinion explains, certain statements within a variety of offering-related documents form the foundation of the legal challenge brought by the Retirement System (i.e., the plaintiff-appellant). While the Retirement System challenges several statements made by Axogen (i.e., the defendant-appellee), many of these statements are materially similar if not identical in either plain language or in context.

For my purposes then, I focus on the following statement from Axogen’s 2017 Form 10-K, which was incorporated into Axogen’s 2018 public offering documents:

We believe that each year in the U.S., more than 1.4 million people suffer damage or discontinuity to peripheral nerves resulting in over 700,000 extremity nerve repair procedures (“Health”, United States, 2011, Publication of U.S. Department of Health & Human Services; Noble, et al. J of Trauma Injury Infection and Critical Care 1998; Kurt Brattain, MD,

Magellan Medical Technology Consultants, Inc., Minneapolis, Minnesota 2013).

At bottom, the Retirement System argues that this statement, and similar statements about the incidence of peripheral nerve injuries and procedures, falsely misrepresented the incidence of such injuries and procedures, as well as contained omissions of material facts that, in turn, misled investors—all in violation of the Securities Act of 1933 (the “Securities Act”). As part of its argument, the Retirement System also challenges the citation to the various studies within this broader statement.

Relevant to this appeal, Section 11 of the Securities Act provides a purchaser of a security a cause of action to sue an issuer of a security (and certain other actors) if the issuer’s registration statement: (1) “contained an untrue statement of a material fact”; or (2) “omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.”¹

¹ In addition to bringing claims under Section 11 of the Securities Act, 15 U.S.C. § 77k(a), the Retirement System also brought claims under Section 12(a)(2) of the Act, *id.* § 77l(a). “Claims under sections 11 and 12(a)(2)” have been described as “Securities Act siblings,” with a slight difference being that Section 11 pertains to untrue statements and omissions in registration statements while Section 12(a)(2) pertains to untrue statements and omissions in prospectuses and oral communications. *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 358–59 (2d Cir. 2010). Section 12(a)(2) contains materially similar language as Section 11 and provides a cause of action for a purchaser of a security to sue an offeror or seller of a security if a relevant prospectus or oral communication: (1) “include[d] an untrue statement of a material fact”; or (2) “omitt[ed] to state a material fact necessary in order to make the

U.S.C. § 77k(a). The Supreme Court has termed these two provisions the “false-statement provision” and the “omissions provision,” respectively. *Omnicare*, 575 U.S. at 184, 186. Thus, under these two provisions, Section 11 “creates two ways to hold issuers liable for the contents of a registration statement—one focusing on what the statement says and the other on what it leaves out.” *Id.* at 179.

Under the first way to establish liability pursuant to Section 11’s false-statement provision, an inquiry must be made into whether the statement at issue constitutes an opinion. This is because “statements of opinion are generally nonactionable because liability attaches only in the case of an ‘untrue statement of a material *fact*,’” and there is a distinction between an *objective fact* and a *subjective opinion*. *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1322 (11th Cir. 2019) (emphasis in original) (quoting *Omnicare*, 575 U.S. at 183). But an opinion statement may still be actionable because even an opinion statement “explicitly affirms one fact: that the speaker actually holds the stated belief.” *Omnicare*, 575 U.S. at 184. “Thus, a statement of opinion that ‘falsely describe[s] [the speaker’s] own state of mind’ is an untrue statement of fact—as to

statements, in the light of the circumstances under which they were made, not misleading.” § 77l(a)(2). The parties do not substantively distinguish between the Section 11 and Section 12(a)(2) claims in their briefings. And the Retirement System noted in its operative complaint that Axogen’s May 2018 registration statement “contained” a prospectus, which “incorporated by reference” Axogen’s 2017 Form 10-K. Thus, for purposes of this concurrence, I see no need to draw a distinction, as well.

what the speaker actually believes—and accordingly will ‘subject the issuer to liability (assuming the misrepresentation were material).’” *Carvelli*, 934 F.3d at 1322 (alterations in original) (quoting *Omnicare*, 575 U.S. at 184). Additionally, an opinion statement may be actionable if the opinion statement contains “embedded statements of fact” in which liability may be established “not only if the speaker did not hold the belief she professed but also if the supporting fact she supplied were untrue.” *Omnicare*, 575 U.S. at 185–86.

Under the second way to establish liability pursuant to Section 11’s omissions provision, an “objective” inquiry must be made into whether the opinion statement at issue would, against the broader context of the registration statement, mislead a “reasonable investor.” *Id.* at 186–87, 190–91. Thus, for an investor to bring a claim alleging a material omission in violation of Section 11, “[t]he investor must identify particular (and material) facts going to the basis for the issuer’s opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.” *Id.* at 194. And as the Supreme Court has noted, this “is no small task for an investor.” *Id.*

With this background in mind, I turn to the dispositive issue at hand—whether the statement from Axogen’s 2017 Form 10-K (and others like it) constitutes a statement of opinion and, if so, whether it is a nonactionable statement of opinion.

II. Nonactionable Statement of Opinion

As discussed above, there are two ways to establish liability under Section 11—i.e., by showing that the statement at issue (1) included a materially untrue statement under Section 11’s false-statement provision or (2) omitted a material fact needed to make the statement not misleading under Section 11’s omissions provision. Assuming materiality for purposes of this concurrence, I first discuss why the statement at issue is an opinion statement, rather than a statement of fact, and why such an opinion statement is not actionable under Section 11’s false-statement provision. I then conclude by discussing why such an opinion statement also is not actionable under Section 11’s omissions provision.

1. False-Statement Provision

The first step in the inquiry under Section 11’s false-statement provision is to determine whether the statement at issue is a statement of fact or a statement of opinion. This is because the general rule is that a statement of opinion is a nonactionable statement under the false-statement provision. *Carvelli*, 934 F.3d at 1322.

The Supreme Court has explained that “[a] fact is ‘a thing done or existing’ or ‘[a]n actual happening’” whereas “[a]n opinion is ‘a belief[,] a view,’ or a ‘sentiment which the mind forms of persons or things.’” *Omnicare*, 575 U.S. at 183 (some alterations in original) (quoting *Webster’s New International Dictionary* 782, 1509 (1927)). In perhaps the seminal example of the difference

between a fact and an opinion, the Supreme Court distinguished between the phrase “the coffee is hot” and the phrase “I think the coffee is hot.” *Id.* The phrase “the coffee is hot” is a statement of fact because it “expresses certainty about a thing.” *Id.* On the other hand, the phrase “I think the coffee is hot” is a statement of opinion—not a statement of fact—because it “does not” “express[] certainty about a thing.” *Id.*

To distill the Supreme Court’s example down even further, a person definitively knows, and it is unquestionably certain, that “the coffee is hot” if that person just brewed a pot of coffee in a well-functioning machine and poured the coffee into a mug. But a person does not definitively know, and it is uncertain, that “the coffee is hot” if a person arrives at her office thirty-minutes late and spies a pot of coffee in the breakroom. The person might “think the coffee is hot” based on her educated belief, but ultimately there is uncertainty about whether the “coffee is hot” given her late arrival to the office, the fact that she did not brew the coffee herself, and so on.

Such a difference between a statement of fact and a statement of opinion is “ingrained in our everyday ways of speaking.” *Id.* And words like “believe” and “think,” or phrases like “In my opinion,” trigger the listener or reader to be aware that the speaker is giving a statement of opinion. *Carvelli*, 934 F.3d at 1322. Indeed, this is why “[t]he common law recognized that most listeners hear ‘I believe,’ ‘in my estimation,’ and other related phrases as *disclaiming* the assertion of a fact. Hence the (somewhat overbroad)

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LAGOA, J. Concurring

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common-law rule that a plaintiff cannot establish a misrepresentation claim ‘for misstatements of opinion, as distinguished from those of fact.’” *Omnicare*, 585 U.S. at 197–98 (Scalia, J., concurring in part) (emphasis in original) (quoting W. Keeton, D. Dobbs, R. Keeton & D. Owen, Prosser and Keeton on Torts § 109, at 755 (5th ed. 1984) (Prosser & Keeton)).

Turning to this case, we must decide whether the statement at issue—i.e., “We believe that each year in the U.S., more than 1.4 million people suffer damage or discontinuity to peripheral nerves resulting in over 700,000 extremity nerve repair procedures”—expresses certainty. It does not. The statement is predicated on the phrase “We believe” just as the statement found to be an opinion in *Omnicare* was predicated on the same exact phrase. *See id.* at 179–80. Plain text aside, the statement does not have a definitive number—e.g., “there are 784,322 nerve procedures”—or a definitive timespan—e.g., “there were 784,322 nerve procedures last year”—rather the statement includes the phrase “over 700,000” and a nebulous term “each year.” To be sure, the fact that the statement does not use a definitive number or a definitive timespan does not render the statement an opinion automatically, but the use of the phrase “We believe” coupled with the use of inherently imprecise phrasing should trigger the purchaser to realize that Axogen is reciting an opinion in the form of an estimate. After all, the inquiry into whether a statement is a statement of opinion or statement of fact is an “everyday” inquiry, *id.* at 183, where words like

“believe” have long been known to “disclaim[] the assertion of a fact,” *id.* at 197 (Scalia, J., concurring in part) (emphasis removed).

The fact that the statement at issue contained a citation does not inherently change the larger statement into a statement of fact. Indeed, the statement at issue still contains the qualifying phrase “We believe.” And just like the example with the employee late to work who spies a pot of coffee in the breakroom and believes the coffee may be hot based on her past experiences, Axogen may believe in the recited figures based on its sources. But, in neither situation, is the employee or Axogen expressly certain. Indeed, here, Axogen has not made “a determinate, verifiable” statement, *id.* at 184, in the form of a sentence like: “*There are* over 1.4 million nerve injuries each year and *there are* over 700,000 nerve procedures each year according to specific studies.” Rather, Axogen has alerted the purchaser that it is expressing an opinion through the words “We believe.” *See id.* at 183–84 (emphasis in original) (distinguishing between a CEO stating “The TVs we manufacture have the highest resolution available on the market” as a statement of fact and a CEO stating “I *believe*” or “I think” “the TVs we manufacture have the highest resolution available on the market” as a statement of opinion).

In sum, the statement at issue is a statement of opinion, not a statement of fact. But “simply because a statement is couched as opinion . . . doesn’t foreclose a finding that it constitutes an express or implied misrepresentation of fact.” *Carvelli*, 934 F.3d at 1322. There is “still . . . some room for [Section 11’s] false-statement

provision to apply to expressions of opinion.” *Omnicare*, 585 U.S. at 184.

As noted above, Section 11’s false-statement provision first applies to opinions because an opinion statement “explicitly affirms one fact: that the speaker actually holds the stated belief.” *Id.* at 184. So in all but the most unusual circumstances, a statement of opinion is actionable under the false-statement provision if the speaker has lied in stating an untrue belief. *Carvelli*, 934 F.3d at 1322; *see also Omnicare*, 585 U.S. at 185 n.2 (emphasis in original) (explaining that there could be a “rare set of facts,” not applicable here, where “a director could think he was lying while actually (*i.e.*, accidentally) telling the truth about the matter addressed in his opinion,” which would not lead to Section 11 liability). But the Retirement System cannot establish liability under this first pathway of the false-statement provision because the Retirement System “expressly disclaim[ed] any allegations of fraud or intentional misconduct in connection with the[] non-fraud claims” of the Securities Act in its operative complaint. The Supreme Court said as much in *Omnicare* when the Court explained that the relevant investors could not challenge the particular statements at issue because “their complaint explicitly ‘exclude[d] and disclaim[ed]’ any allegation sounding in fraud or deception” and therefore the investors “d[id] not contest that [the issuer’s] opinion was honestly held.” *Omnicare*, 585 U.S. at 186.

With the first pathway to liability under the false-statement provision foreclosed, the Retirement System is left with the second

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pathway—trying to establish that “embedded statements of fact” within the statement of opinion are “untrue.” *Id.* at 185–86. Here, a parsing of the full statement in question is, again, necessary, and it reveals only two embedded statements of fact within the larger statement of opinion. First, the statement of opinion inherently contains an embedded fact that Axogen and those responsible for the statement of opinion “[held] the stated belief” that over 1.4 million peripheral nerve injuries occur each year and that there are over 700,000 medical procedures addressing these injuries each year. *Id.* at 184. As discussed above, the Retirement System cannot challenge this, as it has expressly disclaimed any allegations that Axogen’s opinion was not honestly held. Second, the statement of opinion cites to the three studies at issue, thereby requiring the factual inquiry into whether those studies exist and whether Axogen, in some form, reviewed those studies. This is because it is a fact that the referenced studies exist or do not exist, and it is a fact as to whether Axogen reviewed or did not review the studies. And, here, the Retirement System does not challenge whether those studies exist (they do) or whether Axogen reviewed those studies (it did).

By challenging what it pegs as the “objectively verifiable then-existing facts concerning the numbers of nerve injuries and nerve procedures”—i.e., over 1.4 million injuries and over 700,000 procedures—the Retirement System is not challenging facts at all. This is because those figures are predicated on the opinion-oriented phrase “We believe.” And while the Retirement System argues

that “there was nothing subjective about the figures in [Axogen’s] statements” because “the number of nerve injuries or nerve procedures . . . are ‘fixed’ and ‘definite,’” in reality the Retirement System’s own proffered estimates for those figures show that there is inherent subjectivity in these figures. *Id.* In fact, by its own admission, the Retirement System proffered three different estimates of the prevalence of peripheral nerve injuries and procedures in its operative complaint—one each from its medical expert, an outside consulting firm, and the original short-seller report.

And therein lies the rub for the Retirement System. The Retirement System has framed its argument about the figures in the statement constituting embedded facts as a battle of experts and estimates. The Retirement System therefore is asking this Court to agree with the Retirement System that its subjective estimates, while relatively close in range, are better than Axogen’s subjective estimates of the incidence of peripheral nerve injuries and procedures. But that does not comport with the mandate established by *Omnicare*. Indeed, Section 11 neither allows investors to “second-guess inherently subjective and uncertain assessments” nor allows investors to “Monday morning quarterback an issuer’s opinions.” *Omnicare*, 575 U.S. at 186. And the Retirement System attempts to do just that by arguing that its experts are better than Axogen’s experts and by framing Axogen’s estimates not as part of an opinion but as objectively verifiable facts. While Axogen’s overall opinion about the incidence of peripheral nerve injuries and procedures could “turn[] out to be wrong,” it is still an opinion—not a fact. *Id.*

Thus, the Retirement System’s challenge to Axogen’s opinion must fail under the second pathway to liability of Section 11’s false-statement provision.

2. Omissions Provision

Section 11 provides another means of establishing liability under its omissions provision. To pursue a claim that a statement “omitted to state a material fact required to be stated therein or necessary to make the statement[] therein not misleading,” § 77k(a), an investor “must identify particular (and material) facts going to the basis for the issuer’s opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context,” *id.* at 194. This is a contextual inquiry and because “[r]egistration statements as a class are formal documents . . . [i]nvestors do not, and are right not to, expect opinions contained in those statements to reflect baseless, off-the-cuff judgments, of the kind that an individual might communicate in daily life.” *Id.* at 190. But “an investor cannot state a claim by alleging only that an opinion was wrong; the complaint must as well call into question the issuer’s basis for offering the opinion.” *Id.* at 194.

Similar to the thrust of its arguments under the false-statement provision, the Retirement System again argues that Axogen’s peripheral nerve injury and procedure figures are flawed. Here, the Retirement System takes aim at the citation to the three studies after the figures. The Retirement System contends that there are

various flaws in the three studies and that the estimates proffered by its experts are more accurate than the studies relied upon by Axogen. The Retirement System takes particular issue with Axogen not explicitly using a certain prevalence rate for peripheral nerve injuries that is cited in one of the studies. For these reasons, the Retirement System argues that Axogen “falsely represented the basis of [its] assertions” and omitted facts about its knowledge of the studies underlying its assertions. *Id.*

Despite these arguments, the Retirement System has failed to meet its burden to state a claim under the omissions provisions, which, from the outset, is “no small task for an investor.” *Omnicare*, 585 U.S. at 194. While reasonable investors “are right not to . . . expect opinions contained in . . . statements to reflect baseless, off-the-cuff judgments,” reasonable investors cannot “expect that *every* fact known to an issuer supports its opinion statement.” *Id.* (emphasis in original); *see also Tongue v. Sanofi*, 816 F.3d 199, 212 (2d Cir. 2016) (“*Omnicare* does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed in the registration statement.”). Axogen set forth an opinion about the incidence of peripheral nerve injuries and procedures. Axogen then cited three studies for investors. The Retirement System challenges this opinion because the Retirement System believes that its own estimates about the incidence of peripheral nerve injuries and procedures, based on various studies reviewed by its own experts, are better than Axogen’s estimates.

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But as noted by the district court, in coming to this assertion, the Retirement System neither “allege[d] omitted facts regarding the nature of the inquiry conducted by [Axogen] in creating the estimates that would render the statements misleading to reasonable investors” nor made “any allegation regarding what reasonable investors would expect regarding the particular sources consulted or the methodology used by a company to create estimates of this type.” And the Retirement System did not “alleg[e] that [Axogen], at the time [it] issued the challenged estimates, possessed the data or analyses that [the Retirement System] now argues show [Axogen’s] estimates were incorrect.” The Retirement System simply alleges that Axogen’s cited studies are flawed and questions those studies based on its own studies and experts. That does not satisfy the tall task to state a claim under Section 11’s omissions provision. *Omnicare*, 575 U.S. at 194 (“[A]n investor cannot state a claim by alleging only that an opinion was wrong.”).

III. Conclusion

For these stated reasons, I believe that the statements at issue are clear-cut examples of nonactionable statements of opinion. As a result, I would have affirmed the district court on this ground without reaching the question of whether the statements constitute forward-looking statements.