

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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MIMEDX GROUP, INC.,

Plaintiff,

v.

OSIRIS THERAPEUTICS, INC.,

Defendant.
-----X

16 Civ. 3645 (KPF)

OPINION AND ORDER

KATHERINE POLK FAILLA, District Judge:

This case involves a dispute among rivals in the wound care biologics market about their competing tissue-graft products. Plaintiff Mimedx Group Inc. alleges that Defendant Osiris Therapeutics Inc. issued false or misleading statements that Defendant’s product is better in various ways than Plaintiff’s. Specifically, Plaintiff asserts claims of false advertising in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and of deceptive trade practices and false advertising in violation of New York General Business Law §§ 349 and 350. Defendant moves to dismiss the Second Amended Complaint (the “SAC”) for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth in this Opinion, the Court finds that although not all of Plaintiff’s claims are adequately pled, most of them are, and Defendant’s motion to dismiss is therefore denied.

BACKGROUND¹

A. Factual Background

1. The Parties and the Study

Plaintiff is a Florida corporation based in Georgia that develops, manufactures, and markets healing products and devices for tissue regeneration, including “regenerative bioactive products and bioimplants processed from placental human amniotic membrane.” (SAC ¶ 10; *see also id.* at ¶¶ 3, 11). At issue here is Plaintiff’s “EpiFix” product, “a tissue graft processed from [a dehydrated] human amniotic membrane that is derived from donated placentas using [Plaintiff’s] proprietary technology, including its Purion process.” (*Id.* at ¶ 20; *see also* Study 5). EpiFix is designed to help “reduce inflammation, enhance healing, and reduce scar tissue formation.” (*Id.* at ¶ 21).

¹ This Opinion draws on facts from the Second Amended Complaint (the “SAC” (Dkt. #69)), the well-pled facts of which are taken as true for purposes of this motion. *See Morrison v. Nat’l Austl. Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). The Opinion also draws on three additional sources: (i) the study entitled “A Comparative Outcomes Analysis Evaluating Clinical Effectiveness in Two Different Human Placental Membrane Products for Wound Management,” which is attached as Exhibit A to the SAC (the “Study” (Dkt. #69-1)); (ii) Defendant’s press release entitled “Grafix Demonstrates Superior Clinical Outcomes Compared with EpiFix in Real World Study,” which is attached as Exhibit B to the SAC (the “Press Release” (Dkt. #69-2)); and (iii) Defendant’s brochure entitled “When Treating Chronic Wounds: Know The Facts,” which is attached as Exhibit C to the SAC (the “Brochure” (Dkt. #69-3)). *See Goel v. Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016) (recognizing documents attached to the complaint as within the “narrow universe of materials” that may be considered in connection with a Rule 12(b)(6) motion).

For convenience, Defendant’s moving brief is referred to as “Def. Br.” (Dkt. #72); Plaintiff’s opposition brief as “Pl. Opp.” (Dkt. #73); and Defendant’s reply brief as “Def. Reply” (Dkt. #74).

Plaintiff “has spent many millions of dollars researching and developing EpiFix.” (SAC ¶ 23). Specifically, Plaintiff “has conducted countless experiments and tests, grounded in scientific methods, to rigorously establish the safety and efficacy of EpiFix, and spent years and millions of dollars on research and development to discover and perfect its product.” (*Id.* at ¶ 25). Plaintiff has also “devote[d] significant financial resources each year to marketing its product.” (*Id.* at ¶ 23). In turn, Plaintiff “receives substantial revenue from EpiFix” and “has established a considerable market in the United States for EpiFix.” (*Id.* at ¶ 22).

Defendant is incorporated and based in Maryland, and likewise develops, manufactures, and markets wound care products; as noted, it is a direct competitor of Plaintiff’s in the wound care biologics market. (SAC ¶¶ 29-30). Defendant’s competing product is Grafix, “a cryopreserved placental membrane” used to treat acute and chronic wounds. (*Id.* at ¶ 32).

Plaintiff’s EpiFix and Defendant’s Grafix wound care products were the subject of a comparative study entitled “A Comparative Outcomes Analysis Evaluating Clinical Effectiveness in Two Different Human Placental Membrane Products for Wound Management” (the “Study”). (SAC ¶ 33). The Study was led by Dr. Eric Johnson and others, and it relied on a patient population at the Bozeman Health Deaconess Hospital, Wound and Hyperbaric Center in

Bozeman, Montana. (Study 5; Press Release 3). The Study was eventually published in the peer-reviewed journal *Wound Repair and Regeneration*. (*Id.*).²

2. Defendant's Press Release

On or about May 2, 2016, Defendant published a press release (the "Press Release") on its website touting the results of the Study. (SAC ¶ 34). In fact, Plaintiff alleges, the Press Release distorts the Study's findings and makes false claims regarding the superior efficacy of Grafix over EpiFix. (*Id.*). Plaintiff points specifically to two alleged misrepresentations in the Press Release.

First, Plaintiff targets the Press Release statement that "unclosed EpiFix-treated wounds demonstrated a deterioration in clinical condition." (SAC ¶ 34; Press Release 2). Plaintiff alleges that this statement is unsupported by the Study because "[t]he Study does not state that the unclosed wounds treated with EpiFix demonstrated clinical deterioration. Rather, the Study states that 'there was no clinical improvement' in the unclosed EpiFix-treated wounds within the defined timeframe." (SAC ¶ 35). "The Press Release's statement therefore falsely implies that treatment with EpiFix caused the wounds to deteriorate, which is not supported by the underlying Study." (*Id.*).

Second, Plaintiff points to the Press Release statement that "clinical outcomes for patients seen and treated ... at [Study investigator Dr. Eric Johnson's] clinic in Bozeman [Montana] have shown that Grafix has

² The attached Study notes in fine print that it is an "Accepted Article" version as opposed to the "Version of Record," meaning the "article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process which may lead to differences between [the Accepted Article] version and the Version of Record." (Study 1). Neither party places any significance on this nuance. Nor does the Court.

demonstrated superior outcomes to EpiFix.” (SAC ¶ 36; Press Release 3). Plaintiff alleges that this statement is unsupported by the Study because “[t]he Study does not show that Grafix demonstrated superior outcomes to EpiFix. Rather, the Study shows that EpiFix closed the same number of, if not more, diabetic foot ulcer, arterial ulcer and pressure ulcer wounds by the end of treatment as the Grafix product.” (SAC ¶ 37). “Additionally,” Plaintiff continues, “the Study shows that, on average, patients receiving treatment with Grafix received at least 1.5x to 2x the number of graft applications than those patients receiving treatment with EpiFix and that EpiFix worked more quickly than Grafix (an average treatment duration of 28.5 days for EpiFix compared to 50 days for Grafix) for closed wounds.” (*Id.* at ¶ 38).

3. Defendant’s Brochure

Since at least early October 2015, Defendant has been distributing to prospective U.S. and overseas customers a brochure entitled “When Treating Chronic Wounds: Know the Facts, Preserving Placental Membrane in Its Native State Matters” (the “Brochure”). (SAC ¶ 54). Plaintiff alleges that the Brochure “make[s] false or misleading statements regarding the superior processing of Grafix as compared to EpiFix.” (*Id.* at ¶ 53). Plaintiff points specifically to three allegedly false or misleading statements in the Brochure.

First, Plaintiff objects to the Brochure’s representation that “[a] Chronic Wound Needs ... Viable Cells,’ and that viable cells are contained in Osiris’ Grafix allograft but are lacking in EpiFix.” (SAC ¶ 61 (quoting Brochure 1)). This creates the impression “that Grafix — which contains live cells — is more

effective at healing chronic wounds than EpiFix as a result of these viable cells.” (*Id.*). Plaintiff contends that this statement is misleading because “[w]hile viable cells can be beneficial for wound healing, viable cells in a placental derived tissue graft like Grafix are not necessary for effective wound healing.” (*Id.* at ¶ 62). In fact, Plaintiff claims upon information and belief, “viable cells added to a chronic wound through an allograft die quickly upon introduction to the wound or migrate away from the wound site” and thus have a “minimal contribution on the effectiveness of the allograft.” (*Id.* at ¶ 63).

Second, Plaintiff alleges that the Brochure’s statements that EpiFix “contains high levels of Matrix Metaloproteases (‘MMPs’) as a result of Purion processing” and that “this high level of MMPs ‘is not a desirable component for wound repair’” (Brochure 3), are misleading because they “impl[y] to the consumer that these high levels of MMPs in the EpiFix product inhibit wound closure, which is false” (SAC ¶ 64). Plaintiff complains that Defendant omits information related to the activity of MMPs in EpiFix, “which is the most relevant parameter in assessing impact on wound closure ... because if MMPs are not active they cannot inhibit wound closure.” (*Id.* at ¶ 65). Defendant also “fails to indicate that EpiFix contains a high level of Tissue Inhibitors of Matrix Metaloproteases (‘TIMPs’), which are known to inhibit the activity of MMP[s].” (*Id.* at ¶ 66).

Finally, Plaintiff alleges that the Brochure’s statement that EpiFix’s Purion process “‘causes significant alterations’ to the extracellular structural matrix (‘ECM’) of the amniotic cells, such that the ECM is no longer ‘intact’”

(Brochure 2-3), is literally false because “the dehydration of the Purion process leaves the ECM of the amniotic cells intact” (SAC ¶ 68).

B. Procedural Background

Plaintiff filed the Complaint on May 16, 2016 (Dkt. #1) and the First Amended Complaint (the “FAC”) on May 24, 2016 (Dkt. #14). At the time of the FAC’s filing, the Study had not yet been accepted for publication; nor was it made available in draft form to Plaintiff and, so, was not attached to Plaintiff’s pleading as an exhibit. (*See id.*). On June 23, 2016, the Court held a joint initial pretrial and pre-motion conference, at which Defendant informed the Court, *inter alia*, that publication of the Study was forthcoming. (Tr. of June 23, 2017 Conf., Dkt. #37, at 19:5-12). After significant delays (*see* Dkt. #34, 40, 53, 59), the Study was accepted for publication and an “Accepted Article” version of the Study, *i.e.*, a non-formatted, non-proofed, but otherwise approved version of the manuscript, was produced to Plaintiff on or about December 13, 2016. (*See* Dkt. #62, 65). Thereafter on January 4, 2017, Plaintiff filed the Second Amended Complaint — the operative complaint in this action — attaching a copy of the Study as an exhibit. (Dkt. #69).

The SAC asserts claims under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and New York General Business Law §§ 349 and 350, for Defendant’s false or misleading statements that Grafix has demonstrated superior outcomes as compared to EpiFix (SAC ¶¶ 76-99) and for Defendant’s false or misleading statements that Grafix has undergone superior processing as compared to EpiFix (*id.* at ¶¶ 100-122).

Defendant filed its motion to dismiss the SAC and supporting materials on February 13, 2017 (Dkt. #70-72); Plaintiff its opposition brief on March 15, 2017 (Dkt. #73); and Defendant its reply brief on March 29, 2017 (Dkt. #74).³

DISCUSSION

A. Motions to Dismiss Under Rule 12(b)(6)

When considering a motion to dismiss under Rule 12(b)(6), a court should “draw all reasonable inferences in [the plaintiff’s] favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief.” *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (internal quotation marks omitted) (quoting *Selevan v. N.Y. Thruway Auth.*, 584 F.3d 82, 88 (2d Cir. 2009)). Thus, “[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

“While *Twombly* does not require heightened fact pleading of specifics, it does require enough facts to ‘nudge [a plaintiff’s] claims across the line from conceivable to plausible.’” *In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 (2d Cir. 2007) (per curiam) (quoting *Twombly*, 550 U.S. at 570). “Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of entitlement to

³ Defendant also requested an opportunity to present oral argument in connection with its motion (Dkt. #75), but the Court has found oral argument unnecessary.

relief.” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557). Moreover, “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.*

“In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint.” *DiFolco v. MSNBC Cable LLC*, 622 F.3d 104, 111 (2d Cir. 2010). “Even where a document is not incorporated by reference, the court may nevertheless consider it where the complaint ‘relies heavily upon its terms and effect,’ which renders the document ‘integral’ to the complaint.” *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (quoting *Int’l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995) (per curiam)).

Here, the Study, the Press Release, and the Brochure are all attached to the SAC (see SAC, Ex. A-C), and accordingly are considered in connection with the instant motion. See *Goel v. Bunge, Ltd.*, 820 F.3d 554, 558-59 (2d Cir. 2016) (including exhibits attached to the complaint as among the documents that may properly be considered in resolving a motion to dismiss).

B. Defendant’s Motion to Dismiss Plaintiff’s Lanham Act Claims Is Denied

1. Section 43(a) of the Lanham Act

Plaintiff asserts two claims of false advertising pursuant to § 43(a) of the Lanham Act, which provides:

Any person who ... uses in commerce any ... false or misleading description of fact, or false or misleading representation of fact, which ... in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities ... shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1).

To be actionable under the Lanham Act, statements must constitute “commercial advertising or promotion.” *Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004). A § 43(a) false advertising claim must also establish that the challenged message is (i) “either literally or impliedly false”; (ii) “material,” that is, a “misrepresentat[ion] [of] an inherent quality or characteristic of the product”; (iii) “placed in interstate commerce”; and (iv) “the cause of actual or likely injury to the plaintiff.” *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48, 65, 70 (2d Cir. 2016) (citing *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255-56 (2d Cir. 2014)).

Defendant moves to dismiss Plaintiff’s Lanham Act claim on the grounds that (i) the challenged statements in the Press Release and the Brochure are

not “commercial advertising or promotion” and (ii) the Press Release and the Brochure do not contain statements that are “literally or impliedly false.”⁴

2. The Press Release and the Brochure Qualify as Commercial Advertising and Promotion

The threshold § 43(a) question implicated here is whether the allegedly false or misleading statements in the Press Release and the Brochure constitute “advertising and promotion.” In the Second Circuit, that inquiry is governed by the three-part test outlined in *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 58 (2d Cir. 2002): The contested representation must be (i) “commercial speech,” (ii) “made for the purpose of influencing consumers to buy [the defendant’s] goods or services,” and (iii) “disseminated sufficiently to the relevant purchasing public.” *Id.* at 56 (quoting and partially adopting the test from *Gordon & Breach Sci. Publishers S.A. v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1536 (S.D.N.Y. 1994)); *accord Boule v. Hutton*, 328 F.3d 84, 90-91 (2d Cir. 2003).

“The touchstone of whether a defendant’s actions may be considered ‘commercial advertising or promotion’ under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market.” *Enigma Software Grp. USA, LLC v. Bleeping Computer LLC*,

⁴ As Plaintiff notes, Defendant’s motion does not challenge any of the remaining elements of Plaintiff’s § 43(a) claim. (See Pl. Opp. 7 n.1 (“[Defendant] does not contend in its Motion to Dismiss that [Plaintiff] has failed to plead adequately ... that the false or misleading statements have actually deceived or have the capacity to deceive the intended audience, that the deception is material, that injury to [Plaintiff] is likely, or that the goods at issue have traveled in interstate commerce.”)).

194 F. Supp. 3d 263, 293 (S.D.N.Y. 2016) (internal quotation marks omitted) (quoting *Fendi*, 314 F.3d at 57).

Here, Defendant argues that the Press Release and the Brochure do not qualify as “advertising and promotion” because they do not satisfy the first and third elements of the *Fendi* test. These arguments are addressed, and rejected, in turn.

a. Plaintiff Adequately Pleads That the Press Release and the Brochure Are Commercial Speech

Defendant argues that the Press Release and the Brochure “constitute scientific discourse that is entitled to First Amendment protection, not commercial speech.” (Def. Br. 10). Defendant maintains that the Second Circuit’s decision in *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013), “is dispositive here.” The Court disagrees and, given *ONY*’s prominence in Defendant’s argument, discusses that decision in some detail below.

ONY involved competing producers of “surfactants,” biological substances that line the surface of human lungs and are critical for breathing. See *ONY*, 720 F.3d at 492. The defendants conducted a study of the relative efficacy of the competing products and concluded that their own product was generally more effective than the plaintiff’s. *Id.* at 493-94. They then hired physicians to present the study’s findings and to publish those findings in a peer-reviewed journal article. *Id.* at 494-95. Thereafter, the defendants issued a press release publicizing the article’s conclusions and distributed promotional materials that cited the article’s findings. *Id.* at 495. The plaintiff

sued, *inter alia*, under the Lanham Act, alleging that the published article contained several incorrect statements about the relative efficacy of the parties' competing products. *Id.* The district court ultimately dismissed the complaint and the Second Circuit affirmed. *Id.* at 492.

The Second Circuit began with the premise that Lanham Act interpretation is informed by free speech principles because the law proscribes conduct “that, but for its false or misleading character, would be protected by the First Amendment.” *ONY*, 720 F.3d at 496. “[S]tatements of pure opinion — that is, statements incapable of being proven false — are [generally] protected under the First Amendment.” *Id.* Still, the Circuit recognized that “[s]cientific academic discourse poses several problems for th[is] fact-opinion paradigm[.]” *Id.* That is because while “[m]ost conclusions contained in a scientific journal article are ... capable of verification or refutation by means of objective proof,” “it is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision[.]” *Id.* The panel continued:

Importantly, those conclusions are presented in publications directed to the relevant scientific community, ideally in peer-reviewed academic journals that warrant that research approved for publication demonstrates at least some degree of basic scientific competence In a sufficiently novel area of research, propositions of empirical “fact” advanced in the literature may be highly controversial and subject to rigorous debate by qualified experts. Needless to say, courts are ill-equipped to undertake to referee such controversies. Instead, the trial of ideas plays out in the pages of peer-reviewed journals, and the scientific public sits as the jury.

Id. at 497-98. The Circuit ultimately held that “the [contested] article’s contents [we]re not actionable under the Lanham Act” because statements in scientific literature “are more closely akin to matters of opinion, and are so understood by the relevant scientific communities.” *Id.* at 497.

Defendant’s reliance on *ONY* is thus misplaced. Plaintiff has no quarrel with the Study, be it methodology, conclusions, or otherwise.⁵ Plaintiff instead complains about the Press Release, which Plaintiff contends “misrepresents the conclusions in the Study.” (Pl. Opp. 9). Plaintiff likewise argues that the Brochure, far from serving as a scientific article or even reporting the findings of such an article, is “designed and drafted to persuade customers to purchase the Grafix product.” (*Id.* at 10). Plaintiff is correct. Its lawsuit attacks statements in commercial materials directed principally to consumers, not statements in scientific materials directed to scientists.

And if the Second Circuit’s aforementioned reasons for shielding scientific articles were not enough, the Court’s express delineation of its holding confirms that *ONY* does not necessarily immunize commercial materials such as the Press Release and the Brochure here:

It is important to note that plaintiff does not allege, nor did it at any point during the proceedings before the district court seek to amend its complaint to allege, that the promotional materials misstated the article’s conclusions. Thus, plaintiff’s objection is not that [the defendants] distorted the article’s findings; rather, its theory is that by presenting accurately the article’s allegedly inaccurate conclusions, [the defendants]

⁵ The Court refers of course to the operative complaint, the SAC. It is immaterial to the instant analysis that a prior version of Plaintiff’s complaint may have preemptively challenged the integrity of the then-unpublished Study.

committed a separate tort, for which plaintiff is entitled to relief.

ONY, 720 F.3d at 499; *see also Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230, 236 (5th Cir. 2014) (distinguishing *ONY* on the grounds that *Eastman* did not involve a challenged scientific journal article and holding that brochures and similar marketing materials qualified as commercial speech).

Moreover, the mere fact that the Press Release and the Brochure touch on topics of scientific debate does not trigger *ONY* immunity and disqualify them as commercial speech. As the Fifth Circuit has observed in a similar context: “Advertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate. Otherwise, the Lanham Act would hardly ever be enforceable — ‘many, if not most, products may be tied to public concerns with the environment, energy, economic policy, or individual health and safety.’” *Eastman Chem.*, 775 F.3d at 236-37 (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 563 n.5 (1980)).

Fixated on *ONY* (*see* Def. Br. 10-13), Defendant largely ignores traditional indicia of commercial speech. “Pure commercial speech ‘does no more than propose a commercial transaction.’” *Enigma Software Grp. USA*, 194 F. Supp. 3d at 293-94 (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983)). Meanwhile, “a ‘hybrid’ communication, *i.e.*, one that combines commercial and non-commercial elements, may nonetheless be ‘commercial’ where [i] it is an advertisement; [ii] it refers to a specific product or service; and [iii] the speaker has an economic motivation for the speech.” *Id.*; *see Bolger*,

463 U.S. at 66-67 (holding that pamphlets containing information about sexually transmitted disease were “properly characterized as commercial speech,” despite their discussion of important social issues, because they were advertisements that referenced the publisher’s products and the publisher had a commercial motivation for disseminating them).

Here, the statements in the Press Release and the Brochure qualify as commercial speech: They tout the benefits of Defendant’s product over Plaintiff’s competing product and they are principally directed to a consumer audience, not a scientific one. Contrary to Defendant’s assurance, *ONY* does not alter the calculus here.

b. Plaintiff Adequately Pleads That the Press Release and the Brochure Were Sufficiently Disseminated

Defendant also argues that Plaintiff has failed “to allege facts demonstrating that the challenged statements were sufficiently disseminated to the purchasing public.” (Def. Br. 14; *see id.* at 13). For example, Defendant criticizes the SAC for failing to “identify the relevant market, intended audience, or extent of dissemination of the Brochure[,] ... the relative number of copies distributed, the extent to which members of the target audience actually received the challenged materials, or even who that target audience in fact was.” (Def. Br. 14). “Nor,” Defendant continues, does the SAC “include a description of the relevant market itself.” (*Id.*).

“Proof of widespread dissemination within the relevant industry is a normal concomitant of meeting [the commercial advertising and promotion] requirement. Thus, businesses harmed by isolated disparaging statements do

not have redress under the Lanham Act; they must seek redress under state-law causes of action.” *Fendi*, 314 F.3d at 57. The “touchstone” of the inquiry “is that the contested representations are part of an organized campaign to penetrate the relevant market.” *Id.*; see also *Prof’l Sound Servs. v. Guzzi*, 349 F. Supp. 2d 722, 729 (S.D.N.Y. 2004) (Chin, J.) (holding isolated statement to a single customer insufficient to state Lanham Act claim).

Although the SAC would have benefited from additional factual material on this point, the Court finds that it has alleged enough facts to plead plausibly that the Press Release and the Brochure were sufficiently disseminated.

Plaintiff has identified that the relevant market for the parties’ competing products is “the wound biologics market.” (SAC ¶ 29). Plaintiff has further alleged that Defendant

has distributed and continues to distribute the Press Release ... to current or prospective customers, including ... healthcare and wound treatment centers [such as] Presence St. Joseph Hospital’s Center for Wound Care and Hyperbaric Medicine in Elgin, Illinois; Alexian Brothers Wound Healing Center in Elk Grove Village, Illinois; Cedar Park Regional Wound Care Center in Cedar Park Texas; Lakes Region General Hospital in Laconia, New Hampshire; and Portsmouth Regional Hospital in Portsmouth, New Hampshire.

(*Id.* at ¶ 43). Likewise, Plaintiff has alleged, upon information and belief, that “since at least as early as October 2015, [Defendant] has been distributing, and is continuing to distribute [the Brochure] to prospective customers in the U.S. and abroad.” (*Id.* at ¶ 54).

The SAC need not allege all of the particular details identified by Defendant; indeed, many of those details would be difficult to ascertain absent

discovery. The question at this stage is one of plausible pleading and, drawing all reasonable inference in Plaintiff's favor, the Court finds that the SAC contains sufficient facts to render plausible that the Press Release and the Brochure "are part of an organized campaign to penetrate" the wound biologics market. *See Fendi*, 314 F.3d at 57; *see also Sussman-Automatic Corp. v. Spa World Corp.*, 15 F. Supp. 3d 258, 272 (E.D.N.Y. 2014) (finding at the motion to dismiss stage that allegations of an "unspecified number of phone calls and interactions between the [d]efendants' employees and prospective [product] consumers and the online display of the [p]laintiff's products on the [defendants'] website, both albeit without a clear time frame, is sufficient to infer an 'organized campaign' on the part of the [d]efendants").⁶ In sum, the Court finds that Plaintiff has adequately pled that Defendant's Press Release and Brochure were sufficiently disseminated and, in conjunction with its earlier "commercial speech" holding, that they therefore qualify as "commercial advertising or promotion" under the Lanham Act.

3. Plaintiff Plausibly Alleges That the Press Release and the Brochure Contain False or Misleading Statements

Defendant argues that Plaintiff fails adequately to allege that the challenged statements in the Press Release and the Brochure are false or misleading. The Court disagrees and finds that Plaintiff has adequately alleged

⁶ The *Sussman-Automatic Corporation* court nonetheless dismissed the plaintiff's Lanham Act claim because the plaintiff "ma[de] no attempt to define or allege a 'relevant market' for purposes of the false advertising claim," *Sussman-Automatic Corp. v. Spa World Corp.*, 15 F. Supp. 3d 258, 272 (E.D.N.Y. 2014), an issue not present here, as discussed above.

that certain of the statements in the Press Release and the Brochure are either false or misleading.

a. Applicable Law

There are two ways to show that a statement is “false” under the Lanham Act. See *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63 (2d Cir. 2016). “Falsity may be established by proving that [i] the advertising is literally false as a factual matter, or [ii] although the advertisement is literally true, it is likely to deceive or confuse customers.” *Merck Eprova AG*, 760 F.3d at 255 (internal citation and quotation marks omitted).

“One kind of literally false claim is a claim of test-proven superiority.” *Apotex*, 823 F.3d at 63. “The premise is that the ‘defendant’s ad[vertisement] explicitly or implicitly represents that tests or studies prove its product superior’ and ‘plaintiff satisfies its burden by showing that the tests did not establish the proposition for which they were cited.’” *Id.* (quoting *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992)). “Alternatively, a plaintiff can show that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers.” *Id.* (internal quotation marks omitted) (quoting *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 153 (2d Cir. 2007)). “[O]nly an unambiguous message” may be literally false. *Time Warner Cable*, 497 F.3d at 158. Thus, “if the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally

false” and the advertisement is actionable only upon a showing of actual consumer confusion. *Id.*⁷

“The difference between the two classes of falsity is the comparison that each invites. A determination of literal falsity invites a comparison ‘between the statement and ... reality,’ while a determination of implicit falsity invites a comparison between the ‘impression on the listener’ and reality.” *Reed Const. Data Inc. v. McGraw-Hill Cos., Inc.*, 49 F. Supp. 3d 385, 411 (S.D.N.Y. 2014) (quoting *Time Warner Cable*, 497 F.3d at 153), *aff’d*, 638 F. App’x 43 (2d Cir. 2016) (summary order). Thus, “whereas ‘plaintiffs seeking to establish a literal falsehood must generally show the substance of what is conveyed, ... a district court must rely on extrinsic evidence [of consumer deception or confusion] to support a finding of an implicitly false message.’” *Apotex*, 823 F.3d at 63 (quoting *Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 229 (2d Cir. 1999)).

b. Certain Statements in the Press Release May Be Considered False or Misleading

Plaintiff challenges two statements in the Press Release as misrepresentative of the Study’s conclusions. (Pl. Opp. 13). The Court addresses each in turn.

⁷ Literal falsity may also be proven by implication. *See Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007). Under the false-by-necessary-implication doctrine, “[i]f the words or images, considered in context, necessarily imply a false message, the advertisement is literally false.” *Id.* Consumer deception is presumed when a plaintiff demonstrates the literal falsity of an advertisement. *Id.* at 153. Consumer deception is also presumed when the defendant “intentionally set out to deceive the public, and the defendant’s deliberate conduct in this regard [was] of an egregious nature.” *Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992).

i. The Deterioration of Unclosed EpiFix-Treated Wounds

Plaintiff alleges that the statement, “[U]nclosed EpiFix-treated wounds demonstrated a deterioration in clinical condition” (Press Release 2), inaccurately describes the Study’s outcome. (SAC ¶ 35). By Plaintiff’s account, the Study merely concludes “that ‘there was no clinical improvement’ in the unclosed EpiFix-treated wounds within the defined timeframe.” (*Id.*). But reviewing both the Press Release statement and the Study’s finding in their respective contexts reveals that Plaintiff is incorrect.

The Study’s “Results” section reports the pertinent data concerning unclosed wounds:

Additional analyses included the changes in overall wound dimensions for non-closed wounds ... A mean 43.1% surface area reduction and a mean 39.6% volume reduction was demonstrated in the [Grafix]-managed wounds compared to a mean 72.6% increase in surface area and a mean 135.7% increase in volume for [EpiFix]-managed wounds.

(Study 8). Later, in its “Discussion” section, the Study summarizes the same point:

For all non-closed wounds in the [Grafix] group (n=17), reductions in both surface area and volume indicate clinical improvement. In contrast, there was no clinical improvement observed in the non-closed [EpiFix] population (n=45) *based on an overall increase in wound dimensions after management with [EpiFix].*

(*Id.* (emphasis added)).

Plaintiff’s interpretation of the Study’s conclusions is demonstrably incomplete. The Study finds not merely that “no clinical improvement [was]

observed,” as Plaintiff’s allegations would indicate. Rather, the Study explains that this conclusion was “based on an overall increase in wound dimensions” after the use of EpiFix. The increase in wound size is detailed in the Results section: a mean 72.6% increase in surface area and a mean 135.7% increase in volume for EpiFix-treated unclosed wounds.

Meanwhile, the challenged Press Release statement, read in context, is supported by this same evidence. The Press Release includes a series of “Study Highlight” bullet-points, including this one:

For wounds that did not reach complete closure during the study period, a mean 43% surface area reduction and a mean 40% reduction in volume was recorded for Graftix-treated wounds versus a mean 73% increase in surface area and a 136% increase in volume for EpiFix-treated wounds.

(Press Release 2). The immediately ensuing paragraph, which contains the allegedly unsupported statement, states in pertinent part:

The Graftix-treated wounds that did not achieve closure during the study period demonstrated clinically effective improvement with an average surface area and volume reduction of greater than 40%. By comparison, the unclosed EpiFix-treated wounds demonstrated a deterioration in clinical condition as evidenced by an average increase in surface area and volume of greater than 104%.

(*Id.*). Understood in context, the deterioration statement is expressly based on the Study’s data and conclusion. Notably, Defendant’s moving brief references these supporting statements (*see, e.g.*, Def. Br. 16), but Plaintiff’s opposition brief nowhere squarely addresses why Defendant’s supporting reference is

inapplicable or its argument otherwise incorrect. Plaintiff's principal response is merely to repeat the same quoted refrain. (*See, e.g.*, Pl. Opp. 14).

In sum, reading the Press Release's deterioration statement "in full context," *Apotex*, 823 F.3d at 63, and evaluating the referenced data and conclusion from the Study, the Court finds that Plaintiff has failed plausibly to allege that this Press Release statement inaccurately describes one of the Study's conclusions.

ii. Grafix's Superior Outcomes over EpiFix

The second Press Release statement alleged by Plaintiff to be unsupported by the Study is that "clinical outcomes for patients seen and treated ... at [Dr. Eric Johnson's] clinic in Bozeman [Montana] have shown that Grafix has demonstrated superior outcomes to EpiFix." (SAC ¶ 36; Press Release 3).

Plaintiff argues this Press Release statement is an overstatement because the Study in fact shows that "for certain types of wounds, EpiFix was able to close the wound more quickly and with fewer applications than the Grafix product." (Pl. Opp. 14). Specifically, "EpiFix closed the same number of, if not more, diabetic foot ulcer, arterial ulcer and pressure ulcer wounds by the end of treatment as the Grafix product." (SAC ¶ 37). Moreover, Grafix patients on average "received at least 1.5x to 2x the number of graft applications than [EpiFix] patients" and "EpiFix worked more quickly than Grafix (an average treatment duration of 28.5 days for EpiFix compared to 50 days for Grafix) for closed wounds." (*Id.* at ¶ 38).

Defendant counters that this parsing of data does not change the Study's express conclusion "that '[w]hen compared, [Grafix] demonstrated clinical effectiveness, as evidenced through a significantly higher closure rate (63.0% vs. 18.2%) in much larger wounds (9.4cm² vs. 2.1cm²) compared to [EpiFix].'" (Reply Br. 3 (quoting Study 8)). Moreover, "[t]he difference in the number of graft applications and treatment durations for [Grafix] correlated with the statistically larger size of wounds closed in this group[.]" (Def. Br. 7 (quoting Study 7)).

Plaintiff has the better of the argument here, if only barely. The Study indeed reveals that as to certain types of ulcer wounds, EpiFix closed the same number as or slightly more than did Grafix; that is, for some wounds EpiFix is arguably equally if not slightly superior to Grafix, according to this metric. Whether the challenged statement in fact "deceive[s] or confuse[s] customers," *Merck Eprova AG*, 760 F.3d at 255, cannot be adjudicated at this stage. *Cf. Conopco Inc. v. Wells Enterprises, Inc.*, No. 14 Civ. 2223 (NRB), 2015 WL 2330115, at *4 (S.D.N.Y. May 14, 2015) (holding that even if a narrow reading of the challenged statement were literally true, "[I]t is nevertheless plausible that consumer studies would show that consumers interpret [the challenged statement] on the [product's] packaging to indicate [a deceptive message. The plaintiff's] allegations are thus sufficient to permit it to further develop facts on this theory.").

Drawing all inferences in Plaintiff's favor at this stage, the Court finds that Plaintiff has plausibly alleged that the Press Release's broad claim that

Grafix has “demonstrated superior outcomes to EpiFix” may be construed as a false overstatement unsupported by the Study.

c. Statements in the Brochure May Be Considered False or Misleading

Plaintiff challenges three statements in the Brochure as false or misleading. (See SAC ¶¶ 60-69). Defendant does not retort point for point, but responds generally that the SAC “distorts the actual statements made in the Brochure and then characterizes those contorted statements as false and misleading.” (Def. Br. 17). Defendant further argues that Plaintiff’s allegations are conclusory and fail plausibly to plead “the falsity of the statements in the Brochure.” (*Id.* at 18). On this point, Defendant criticizes Plaintiff for “cit[ing] no studies, literature, or other basis for suggesting that the scientific statements are false or misleading.” (*Id.*).

In response, Plaintiff’s opposition brief explicates why, for each challenged statement, the SAC adequately alleges falsity or likelihood to mislead consumers. (Pl. Opp. 15-17). Moreover, Plaintiff appropriately emphasizes the overarching point that Defendant incorrectly “attempts to conflate the ultimate burden of proof with the plausibility standard for pleadings. Ultimately, [Plaintiff] must demonstrate that the challenged representations tend to mislead or confuse consumers. However, at the pleadings stage, the Court must accept [Plaintiff’s] factual allegations as true and draw all inferences in [Plaintiff’s] favor.” (Pl. Opp. 17 (internal citations omitted)).

Plaintiff has the better argument here, as well. The Court finds that Plaintiff has plausibly pled that each of the three challenged statements in the Brochure is false or likely to deceive or confuse consumers. *See Merck Eprova AG*, 760 F.3d at 255.

i. The Presence and Role of Viable Cells in Tissue Grafts

Plaintiff first challenges the Brochure’s representation regarding the role of viable cells in efficacious tissue grafts and EpiFix’s comparative disadvantage in this regard. The Brochure states that (i) “A Chronic Wound Needs: ... Viable Cells” (Brochure 2); (ii) EpiFix’s Purion process “destroys endogenous tissue viable cells” (*id.*) and lacks the “presence of viable cells” (*id.* at 4); and (iii) “Grafix provides everything you need for treating chronic wounds” such as “viable cells” (*id.*).

The SAC alleges that these statements create the impression “that Grafix — which contains live cells — is more effective at healing chronic wounds than EpiFix as a result of these viable cells.” (SAC ¶ 61). Plaintiff claims that this impression is incorrect and that the Brochure’s statements are misleading because “[w]hile viable cells can be beneficial for wound healing, viable cells in a placental derived tissue graft like Grafix are not necessary for effective wound healing.” (*Id.* at ¶ 62). In fact, Plaintiff contends upon information and belief, “viable cells added to a chronic wound through an allograft die quickly upon introduction to the wound or migrate away from the wound site,” and thus have a “minimal contribution on the effectiveness of the allograft.” (*Id.* at ¶ 63).

The Brochure can be read to suggest that viable cells play an important — if not vital — role in the efficacy of tissue grafts and, further, that EpiFix lacks such cells while Grafix contains them. Assuming the truth of Plaintiff’s factual allegations that “viable cells in a placental derived tissue graft like Grafix are not necessary for effective wound healing,” and drawing all reasonable inferences in Plaintiff’s favor, the Court agrees with Plaintiff that consumers may “receive the impression from [the Brochure] that Grafix is more effective at healing chronic wounds because of the presence of live cells in ... Grafix.” (Pl. Opp. 15). *See Schering Corp.*, 189 F.3d at 229 (“[P]laintiffs alleging an implied falsehood are claiming that a statement, whatever its literal truth, has left an impression on the listener that conflicts with reality. This latter claim invites a comparison of the impression, rather than the statement, with the truth.”). Accordingly, the Court finds that Plaintiff has plausibly alleged that the Brochure’s statements regarding the presence and role of viable cells in the parties’ competing products are “false ... or ... likely to deceive or confuse consumers.” *Merck Eprova AG*, 760 F.3d at 255.

ii. The Presence and Effect of Matrix Metalloproteases in Tissue Grafts

Plaintiff likewise challenges the Brochure’s representation about the effect of Matrix Metalloproteases (“MMPs”) in tissue-graft efficacy and EpiFix’s comparative disadvantage on this front. The Brochure states (i) “A Chronic Wound Doesn’t Need ... High Levels of Matrix Metalloproteases (MMPs)” (Brochure 2); (ii) “Grafix is comprised of ... Low Levels of MMPs” (*id.*; *see also id.* at 4 (“Low ... MMP content”)); and (iii) “Purion-process tissue,” that is

EpiFix, contains a “high level of MMPs[, which] is not a desirable component for wound repair” (*id.* at 4; *see also id.* (“High ... MMP content”)).

Plaintiff alleges that these statements create the impression that “high levels of MMPs in the EpiFix product inhibit wound closure,” which is false. (SAC ¶ 64). Plaintiff contends that the notion that EpiFix will be ineffective at healing wounds due to its high MMPs-levels is false because the MMPs in EpiFix are not active. (Pl. Opp. 16 (citing SAC ¶ 65)). Once again, the SAC adequately alleges that the Brochure creates a misimpression about the effect of MMPs in EpiFix tissue grafts; assuming the truth of the SAC’s factual allegations concerning the *actual* effect of MMPs, the Court easily finds that Plaintiff has plausibly alleged the false or misleading nature of the Brochure’s MMPs allegations. *See Dependable Sales & Serv., Inc. v. Truecar, Inc.*, No. 15 Civ. 1742 (PKC), 2016 WL 79992, at *4 (S.D.N.Y. Jan. 6, 2016) (partially denying motion to dismiss Lanham Act false advertising claim on falsity grounds because “[a]t the motion to dismiss stage, the Court cannot decide whether [the defendant’s] ‘Guaranteed Savings Certificate’ actually guarantees customer savings or does not involve negotiation. [The defendant] has raised ‘a factual dispute that is inappropriate for resolution on a motion to dismiss.’” (quoting *Fin. Guar. Ins. Co. v. Putnam Advisory Co., LLC*, 783 F.3d 395, 405 (2d Cir. 2015)).

iii. The Effect of EpiFix’s Purion Process on the Extracellular Structural Matrix of Amniotic Cells

Finally, Plaintiff alleges that the Brochure’s statement that EpiFix’s Purion process “causes significant alterations’ to the extracellular structural

matrix ('ECM') of the amniotic cells, such that the ECM is no longer 'intact'" (Brochure 2-3; *see id.* at 3 (indicating the absence of an "[i]ntact structural matrix" in EpiFix)), is literally false because "the dehydration of the Purion process leaves the ECM of the amniotic cells intact" (SAC ¶ 68; *see also* Pl. Opp. 17). Defendant cites no authority for its proposition that in order for Plaintiff to allege adequately that this Brochure statement is literally false, Plaintiff must identify "studies, literature, or other [scientific] bas[e]s." (Def. Br. 18). Neither does the Court impose such a requirement here. "A determination of literal falsity invites a comparison 'between the statement and ... reality'" and "[w]hether a statement is literally false is, generally speaking, a matter of fact." *Reed Const. Data Inc.*, 49 F. Supp. 3d at 412 (quoting *Time Warner*, 497 F.3d at 153). At this stage the Court assumes the truth of Plaintiff's well-pled factual allegations; so doing, the Court finds that the SAC plausibly alleges that the Brochure's statement about the compromising effect of the Purion process on the intactness of EpiFix's ECM is literally false.

C. Defendant's Motion to Dismiss Plaintiff's State-Law Claims Is Denied

Plaintiff asserts two causes of action under §§ 349 and 350 of the New York General Business Law that mirror Plaintiff's Lanham Act claims. Defendant moves to dismiss these state-law claims on the same grounds as the federal ones. (Def. Br. 19). It also moves to dismiss the state-law claims "for two additional independent reasons": (i) the SAC fails to allege harm to the public at large and (ii) the Court should decline supplemental jurisdiction after

dismissing Plaintiff's federal claims. (Def. Br. 19-20).⁸ For the reasons discussed below, the Court denies Defendant's motion to dismiss Plaintiff's state-law claims.

1. Sections 349 & 350 of the New York General Business Law

Section 349 prohibits “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state,” N.Y. Gen. Bus. Law § 349(a), while § 350 prohibits “[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state,” *id.* § 350.

Under §§ 349 and 350, a plaintiff must allege that “[i] the defendant’s act, practice or advertisement was consumer-oriented; [ii] it was materially deceptive and misleading; and [iii] that [the movant] was injured as a result.” *MDB LLC v. Hussain*, No. 14 Civ. 9281 (VEC), 2016 WL 1267793, at *5-6 (S.D.N.Y. Mar. 29, 2016) (internal citations and quotation marks omitted); *see also New World Solutions, Inc. v. NameMedia Inc.*, No. 11 Civ. 763 (KMK), 2015 WL 8958390, at *25 (S.D.N.Y. Dec. 15, 2015) (“The standard for recovery under General Business Law § 350, while specific to false advertising, is otherwise identical to section 349.”). Although §§ 349 and 350 are designed to protect consumers, competitors may recover under these sections if there is “some harm to the public at large.” *Boule*, 328 F.3d at 94.

⁸ The latter argument is of course not “independent,” as labeled by Defendant; indeed, it is expressly contingent on the dismissal of Plaintiff's federal claims.

2. Analysis

The parties agree that Plaintiff's claims under New York General Business Law §§ 349 and 350 are analyzed using the same standard as Plaintiff's Lanham Act claims and each cite then-Judge Sotomayor's decision in *Avon Products, Inc.* for this proposition. (See Def. Br. 19; Pl. Opp. 17-18 (citing *Avon Prods., Inc. v. S.C. Johnson & Son, Inc.*, 984 F. Supp. 768, 800 (S.D.N.Y. 1997) (Sotomayor, J.) ("The standards for bringing a claim under § 43(a) of the Lanham Act are substantially the same as those applied to claims brought under the New York common law for unfair competition and §§ 349 and 350 of the New York General Business Law.")); see also *Playtex Prod., LLC v. Munchkin, Inc.*, No. 14 Civ. 1308 (RJS), 2016 WL 1276450, at *3 (S.D.N.Y. Mar. 29, 2016) (applying same standards for false advertising claims under the Lanham Act and New York law)); *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14 Civ. 585 (AJN), 2015 WL 4002468, at *17 n.14 (S.D.N.Y. July 1, 2015) (same).

Judge Oetken has observed that "[o]ne element in common among [§ 43(a) of the Lanham Act and § 349 of the New York General Business Law] is that the defendant's conduct must be, in some sense, directed towards consumers." *Samsung Display Co. v. Acacia Research Corp.*, No. 14 Civ. 1353 (JPO), 2014 WL 6791603, at *5 (S.D.N.Y. Dec. 3, 2014). As earlier noted, under the Lanham Act, cognizable misrepresentations must be "in the context of commercial advertising or commercial promotion," which in turn requires that those misrepresentations were "disseminated sufficiently to the relevant

purchasing public to constitute ‘advertising’ or ‘promotion’ within that industry.” *Id.* (collecting cases). “In a similar vein, a plaintiff suing under § 349 of the General Business Law must allege ‘consumer oriented’ conduct on the defendant’s part.” *Id.* (citing *Shapiro v. Berkshire Life Ins. Co.*, 212 F.3d 121, 126 (2d Cir. 2000)). “While a defendant’s competitors have standing to bring claims under § 349, ‘the gravamen of the complaint must be consumer injury or harm to the public interest.’” *Id.* (quoting *digiGAN, Inc. v. Invalidate, Inc.*, 02 Civ. 420 (RCC), 2004 WL 203010, at *6 (S.D.N.Y. Feb. 3, 2004)).

Although Plaintiff fails to address Defendant’s two ostensibly “additional[,] independent reasons,” as it should have, the Court upholds the SAC’s state-law claims for substantially the same reasons it upholds the federal claims. As described in Discussion Section B.2., *supra*, the allegedly false and misleading statements in the Press Release and the Brochure constitute “commercial speech” that was “disseminated sufficiently to the relevant purchasing public.” *Fendi*, 314 F.3d at 58. The SAC adequately alleges that the literally or impliedly false statements in the Press Release and the Brochure have misled consumers, caused them confusion as to “the relative quality, effectiveness, and reliability” of the parties’ competing products, and harmed the public, in addition to Plaintiff itself. (SAC ¶¶ 39, 41, 78, 81, 90, 92). The Court finds that the SAC adequately states a claim under §§ 349 and 350, including “harm to the public at large,” *Boule*, 328 F.3d at 94, and accordingly denies Defendant’s motion to dismiss Plaintiff’s state-law claims.

CONCLUSION

For the foregoing reasons, Defendant’s motion to dismiss is DENIED. Defendant shall file an answer or other response to the SAC within 21 days of the date of this Order. Within 7 days thereafter, the parties shall submit a joint status letter and a proposed Civil Case Management Plan and Scheduling Order, as outlined in the Notice of Initial Pretrial Conference in this matter (Dkt. #17). The Court will then enter the proposed Case Management Plan. The parties are forewarned that the Court will be disinclined to extend discovery deadlines, once those deadlines are proposed by the parties and endorsed by the Court.

SO ORDERED.

Dated: July 21, 2017
New York, New York



KATHERINE POLK FAILLA
United States District Judge