UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

QUINTESSA HUEY, individually and on behalf of all others similarly situated, Plaintiff, v. ANAVEX LIFE SCIENCES CORPORATION and CHRISTOPHER U. MISSLING, Defendants.	Case No. 1:24-cv-01910-CM

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE AMENDED COMPLAINT

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Acadia	Acadia Pharmaceuticals
AC	Amended Complaint
Anavex	Anavex Life Sciences Corporation
Class Period	February 1, 2022 to January 1, 2024, inclusive
CGI-I	Clinical Global Impression of Improvement Scale
FDA	U.S. Food and Drug Administration
NDA	New Drug Application
Neuren	Neuren Pharmaceuticals, Ltd.
PSLRA	Private Securities Litigation Reform Act of 1995
RSBQ	Rett Syndrome Behavioural Questionnaire
RSBQ AUC	Rett Syndrome Behavioural Questionnaire (RSBQ) Area Under the Curve (AUC)

PRELIMINARY STATEMENT

This is a classic case of a financial loss in search of a claim. This action began as presenting what the Court aptly described as "a very, very discrete theory": that Defendant Anavex Life Sciences Corporation ("Anavex" or the "Company") knew that it would use particular endpoints in its "Excellence" study but told the market otherwise until the end of the Class Period. Unfortunately for Plaintiff, that theory is demonstrably unfounded, as Defendants repeatedly disclosed the Excellence endpoints within the Class Period. Recognizing this reality, Plaintiff now abandons this theory and instead uses her (doubled in size) Amended Complaint to concoct a new way in which investors were supposedly misled.

Plaintiff invents—based purely on multiple layers of unfounded and counterfactual inferences—a universal "requirement" by the FDA as to what endpoints must be used in any type of Rett Syndrome study and asserts that this requirement *must have been* communicated to Defendants. But the Amended Complaint falls far short of providing the necessary particularized allegations to support that any such requirement exists, let alone that Defendants knew about and disregarded it. In fact, Plaintiff's own allegations and the documents upon which she relies directly undercut her assertions.

The Amended Complaint should be dismissed because (I) it does not plead with particularity the central premise as to why Defendants' statements were allegedly misleading, instead relying on circular reasoning and unfounded conclusions; (II) it is entirely bereft of any sufficiently pled scienter allegations; and (III) the allegations of market decline are divorced from the theory of fraud and therefore do not plead loss causation.

BACKGROUND[1]

I. Anavex and Its Rett Syndrome Studies

Anavex is a biopharmaceutical company working to develop treatments for certain nervous system diseases, including Rett Syndrome. AC ¶¶ 2-3.[2] Clinical trials for the drug ANAVEX 2-73 included the Avatar study (results announced February 1, 2022) and the Excellence study (results announced January 2, 2024). AC ¶¶ 26, 30, 43, 63. These studies each had "endpoints," i.e., measures used to determine success. The endpoints include the Rett Syndrome Behaviour Questionnaire ("RSBQ"), completed by the patient's caregiver, and the Clinical Global Impression Improvement ("CGI-I"), which is physician measured. AC ¶ 55. As is typical in the biopharmaceutical industry, the studies were double-blinded (i.e., the Company did not know who received treatment and who received placebos). Ex. 13 (2023 Form 10-K) at 9-10.

When Anavex announced results of the Avatar study on February 1, 2022 (the first day of the Class Period), it used an endpoint method referred to as "RSBQ AUC." AC ¶ 51. In describing it, Dr. Missling noted known limitations with RSBQ as a stand-alone endpoint based on its propensity for error as a score measured by a patient's caregiver, and explained:

> The FDA hence recommended, and it's also provided in the guidelines from the FDA and recommended specifically in these cases because you don't have many choices of endpoints to pick from, which have been validated for rare diseases like Rett Syndrome, to use instead the RSBQ with an anchor. That's called anchor-based responder method, which links the score from one clinical outcome assessment, the RSBQ in this case, with scores from a simple reference anchor, which is the outcome assessment with a clinically meaningful threshold, which is the CGI-I. And that

[1] This section accepts as true the non-conclusory allegations in the Amended Complaint ("AC") and cites materials the Court can properly consider, including "statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007). Such materials are exhibits to the Declaration of Stephen G. Topetzes, referred to herein as "Ex. __".

[2] In one example of demonstrably false "factual" allegations, Plaintiff mistakenly alleges Anavex is a Delaware corporation (AC ¶ 13) when it is incorporated in Nevada. Ex. 2 (2022 Form 10-K).

> facilitates the interpretation of what constitutes a meaningful within and between patient change in clinical outcome assessment. And so, this RSBQ AUC was born.

Ex. 3 (Feb. 1, 2022 transcript) at 4. Presentation slides reiterated that the FDA recommended an "anchor-based responder method," citing an agency guidance document. See Ex. 4 (presentation) at 8, Ex. 5 (FDA Guidance).[3] The slide identified RSBQ AUC as an example of such method.

The Excellence study was underway when Avatar results were released. Anavex initially disclosed an intent to also use RSBQ AUC as an endpoint, including during the February 1, 2022, conference call disclosing Avatar results. In response to a question concerning whether Excellence will also use RSBQ AUC, Dr. Missling responded by referring to his earlier discussion about the FDA guidance to use an anchor-based methodology: "So that's right, the Excellence study will use the same endpoint because as just described, it is just the preference of the FDA." Ex. 3 at 13.

During the Class Period, Anavex told investors that it would be discussing the study design with the FDA. Ex. 6 (May 10, 2022 transcript) at 3; Ex. 7 (Aug. 9, 2022 transcript) at 12. Partway through the Class Period, Anavex announced that, after further consultation with the FDA, it would not use RSBQ AUC and instead would use RSBQ. On a February 7, 2023, earnings call, Dr. Missling explicitly told analysts that the endpoint would *not* be RSBQ AUC and thus would differ from Avatar, and instead the plan was for the primary endpoint to be RSBQ with CGI-I as key secondary endpoint. AC ¶ 97; Ex. 8 (Feb. 7, 2023 transcript) at 5. Further, on June 6, 2023, the Company issued a press release that said:

> In communication with the FDA, the Company received the Agency's input on the study endpoints, which were utilized in this clinical study. The [RSBQ] total score and [CGI-I] score are co-primary endpoints in the statistical analysis plan with

[3] The slide presentation is referenced in the transcript and attached to a Form 8-K filed with the SEC. When "the Complaint quotes and relies upon statements made in press releases and investor calls, the Court may properly consider the complete referenced press releases, the full transcripts of those calls, and the SEC filings referenced and incorporated therein…." Koplyay v. Cirrus Logic, Inc., No. 13-cv-790 (CM), 2013 WL 6233908, at *4 (S.D.N.Y. Dec. 2, 2013).

> specified linear mixed-effects models for repeated measures (MMRM) as the primary analysis methods.

Ex. 9 (June 6, 2023 press release). Later press releases further confirmed these endpoints. Ex. 10 (June 12, 2023 press release); Ex. 11 (Aug. 8, 2023 press release).

II. Competitor Studies and Plaintiff's Invented FDA "Requirement"[4]

While the Anavex studies were underway, a competitor, Neuren Pharmaceuticals, Ltd. ("Neuren"), developed its own Rett Syndrome drug, which it licensed to Acadia Pharmaceuticals ("Acadia"). AC ¶¶ 34, 37. Neuren had a private meeting with the FDA in October 2017, in which, among other things, the FDA advised about multiple concerns with RSBQ as a primary endpoint. AC ¶¶ 35-36. At the "encouragement" of the FDA, Neuren agreed to study CGI-I "as an anchoring functional measure as a co-primary endpoint with RSBQ." AC ¶ 36. Acadia's "Lavender" study utilized those endpoints, and results were announced December 2021. AC ¶¶ 38, 40.

Plaintiff characterizes this "encouragement" as a mandate that "FDA required RSBQ and CGI-I to be used as co-primary endpoints for any pivotal Rett Syndrome" study and would not accept the RSBQ AUC measure. ¶ 58. Unnamed persons at FDA allegedly conveyed this endpoint "requirement" to unnamed persons at Anavex during a "pre-IND meeting" between December 2017 and February 2018 and in unspecified communications after February 2020. AC ¶¶ 59, 76.[5]

III. Defendants' Relevant Class Period Disclosures

A. Risk Disclosures and Cautionary Statements

During the Class Period, Anavex disclosed to investors many risks associated with a pre-revenue pharmaceutical company whose products are still undergoing clinical trials and subject to

[4] The allegations in this section are not well-pled for reasons explained herein, but are recited nevertheless for purposes of putting into context Plaintiff's claims.

[5] In reality, Anavex had already submitted its IND to the FDA by December 11, 2017, so the timing of this non-particularized allegation is demonstrably suspect. Ex. 1 (2017 Form 10-K) at 3.

FDA approval. The risks were listed in each Form 10-K annual report under the bolded heading: "Even if we are able to develop our potential drug compounds, we may not be able to receive regulatory approval…." Ex. 12 (2021 Form 10-K) at 23. The Company disclosed:

> All of our potential drug compounds will require extensive additional research and development, including non-clinical testing and clinical trials, as well as regulatory approvals, before we can market them. In particular, human therapeutic products are subject to rigorous non-clinical and clinical testing and other approval procedures of the FDA and similar regulatory authorities in other countries. […] There are many reasons that we may fail in our efforts to develop our potential drug compounds. These include:
>
> - the possibility that non-clinical testing or clinical trials may show that our potential drug compounds are ineffective and/or cause harmful side effects; […]
>
> - our potential drug compounds may fail to receive necessary regulatory approvals … in a timely manner, or at all [….]

Id. at 23-24; see also Ex. 2 at 31-32 (similar); Ex. 13 at 35-36 (similar). In addition, the Form 10-K also made clear that statements regarding "anticipated future clinical and regulatory milestone events… are forward-looking statements." Ex. 12 at iv.

Each at-issue press release and analyst call included similar statements with reference to more extensive annual report disclosures. See, e.g., Ex. 14 (Feb. 1, 2022, press release) at 6 (noting that non-historical statements are forward looking and "involve a number of risks and uncertainties," including as referenced in the Form 10-K); Ex. 3 (Feb. 1, 2022, transcript) at 2 (noting that statements involve "a number of risks and uncertainties" and encouraging review of SEC filings that identify specific factors to cause actual results to differ, including "uncertainty in the results of clinical trials or regulatory approvals"); Ex. 24 (Jan. 12, 2023 presentation) at 2.

B. Plaintiff's New Theories of Alleged False Statements and Omissions

The original theory of this case was that Defendants always intended to use RSBQ and CGI-I as co-primary endpoints in Excellence, but did not disclose that until the end of the Class Period and instead lied that RSBQ AUC would be the endpoint. ECF No. 1; ECF No. 27 at 5.

Recognizing that the clear disclosures listed above undercut that theory, Plaintiff now adopts an entirely new case. Cutting through the substantial chaff, Plaintiff essentially alleges:

- Defendants represented, implied, and/or created the impression that RSBQ AUC adhered to regulations and/or was approved by the FDA, when in fact the FDA required RSBQ and CGI-I as co-primary endpoints for any clinical trial used to support an NDA for ANAVEX 2-73. AC ¶¶ 76, 77, 79, 84, 93, 95, 98.
- Defendants, to make it seem that RSBQ AUC was acceptable, falsely represented that Excellence would use that endpoint when they knew otherwise. AC ¶¶ 76, 82, 87, 90.
- Defendants misrepresented the strength of data during one conference call. AC ¶ 101.

As explained below, none of these are pled as actionable false statements or omissions.[6]

C. The Alleged "Corrective Disclosure"

On January 2, 2024, Anavex announced the Excellence study results using the RSBQ and CGI-I co-primary endpoints and a MMRM method (AC ¶ 63), as it had disclosed it would. The study showed improvement on RSBQ, but the CGI-I endpoint was not met. AC ¶ 63. The press release did not mention RSBQ AUC or anything about FDA's views regarding endpoints. Ex. 20.

Plaintiff alleges that analysts responded negatively to the announcement of the results (AC ¶ 70), but does not allege any analyst commented or reacted in any way with respect to the choice of endpoints or the validity of RSBQ AUC.[7] Instead, the allegations emphasize the disappointing results of the Excellence study and commentary provided by the Company. AC ¶¶ 70-71.

[6] Much of the Amended Complaint is extraneous and does not relate to any alleged Class Period misstatement. For example, Plaintiff devotes pages to purported attempts to "manipulate" or "spin" Avatar results (AC ¶¶ 42-61), but that all predates the Class Period. Similarly, several paragraphs criticize the manner in which the Excellence results were presented (AC ¶¶ 65-69), but this is the purported *corrective* disclosure—not anything alleged to be misleading during the Class Period.

[7] Plaintiff describes Adam Feuerstein as an "analyst," but he is an internet journalist and some of his commentary (including the entirety of ¶ 54) comes from posts made on Twitter. Ex. 15.

STANDARD OF REVIEW

"To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" ATSI, 493 F.3d at 98 (citation omitted). "Allegations that are conclusory or unsupported by factual assertions are insufficient." Id. at 99. "A securities fraud complaint must also meet the heightened pleading standards of [Rule] 9(b) and the [PSLRA]." Kleinman v. Elan Corp., plc, 706 F.3d 145, 152 (2d Cir. 2013). The "circumstances constituting fraud" must be "state[d] with particularity," including the reasons *why* a statement is misleading. Id.

ARGUMENT

The Amended Complaint suffers from fatal flaws, nearly all of which relate to Plaintiff's decision to use her own subjective characterizations and unfounded inferences, rather than particularized, well-pled allegations. As shown below, the Amended Complaint fails to establish nearly all of the required elements of a Section 10(b) and Rule 10b-5 claim, i.e., misstatements or omissions of material fact, made with scienter, in connection with the purchase or sale of securities, upon which the plaintiff relied, and proximate causation of injury. Koplyay, 2013 WL 6233908, at *4 (citing Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 172 (2d Cir. 2005)). Count I and Count II (which is derivative of Count I) should be dismissed.

I. The Amended Complaint Does Not Adequately Allege Any False or Misleading Statement or Omission of Material Fact

A. Plaintiff's Allegations Do Not Establish the Central Premise of Her Complaint: A Non-Existent FDA "Requirement" Regarding Endpoints

Nearly all of the allegations of misstatement or omission rest on a scenario concocted in the Amended Complaint whereby the FDA declared that there was a single, correct way to conduct all Rett Syndrome studies by using specific "FDA-approved endpoints," that Defendants were told

this "requirement," and that they ignored it. These allegations lack any particularity, which is inevitable because the supposed FDA "requirement" is entirely and demonstrably fabricated.

1. Plaintiff Fails to Allege with Particularity the Supposed FDA "Requirement"

A plaintiff "must do more than simply assert that a statement is false—[it] must demonstrate with specificity why that is so." In re Lululemon Sec. Litig., 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014), aff'd, 604 F. App'x 62 (2d Cir. 2015) (internal quotation marks omitted). Here, that requires Plaintiff to allege with particularity that the supposed FDA endpoints "requirement" actually exists. See Gamm v. Sanderson Farms, Inc., 944 F.3d 455, 463 (2d Cir. 2019) ("Under Rule 9(b) and the PSLRA, the circumstances of a fraud include 'the basis' for that contention."); In re JP Morgan Chase Sec. Litig., 363 F. Supp. 2d 595, 632 (S.D.N.Y. 2005) (granting motion to dismiss because "there [were] no particular factual allegations that support the conclusory assertion that" the allegedly omitted facts actually occurred); In re Allergen PLC Sec. Litig., No. 18-cv-12089 (CM), 2019 WL 4686445, at *16 (S.D.N.Y. Sept. 20, 2019) (looking past conclusory allegations and explaining that "[w]hen a securities fraud action rests on the failure to disclose a given fact, the complaint must state a plausible claim that the underlying fact actually exists").

The absence of particularity is striking here. The alleged source of the supposed FDA "requirement" is that certain unnamed persons at the FDA informed certain unnamed persons at Neuren – Defendant's competitor – of "concerns" with using RSBQ as a standalone primary endpoint in Neuren's separate trial for a different drug to treat Rett Syndrome. AC ¶¶ 4, 36. So, at the "encouragement" or "recommend[ation]" of the FDA, Neuren agreed to also study CGI-I as an anchoring function and co-primary endpoint. AC ¶ 36. From this "encouragement" during a private meeting with a competitor, Plaintiff takes the unsupported leap to conclude there was a universal FDA "requirement" to *only and in all cases* use RSBQ and CGI-I as co-primary

endpoints, AC ¶ 38, asserting without foundation that any other endpoints "were not permitted by the FDA," including RSBQ AUC (which itself anchors RSBQ to CGI-I due to limitations with RSBQ as a stand-alone measure). AC ¶¶ 3, 4. This conclusory and logically unsound statement of a requirement does not satisfy the pleading standards. Cf. Fort Worth Emps. Ret. Fund v. Biovail Corp., 615 F. Supp. 2d 218, 227-28 (S.D.N.Y. 2009) (rejecting plaintiff's argument that an FDA "recommendation" or "preferred approach" equated to a "requirement"); Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co., 28 F.4th 343, 353-54 (2d Cir. 2022) (rejecting allegation that an endpoint described as "strong expression" misleadingly implied a certain threshold, because plaintiff did not establish that there was a general understanding of "strong expression").

Also missing is anything supporting the basis of Plaintiff's allegations. "Where, as here, factual allegations are made on information and belief, the complaint must allege adequate bases for the allegations. It 'must identify sufficiently the sources upon which [plaintiff's] beliefs are based and those sources must have been likely to have known the relevant facts.'" In re Pfizer, Inc. Sec. Litig., 538 F. Supp. 2d 621, 628 (S.D.N.Y. 2008) (citations omitted); see also Gamm, 944 F.3d at 464 (a complaint must "provid[e] documentary evidence and/or a sufficient general description of the personal sources of the plaintiffs' beliefs" (citation omitted)). The Amended Complaint contains none of that – no allegations of witness accounts, internal reports, or other evidence that would identify how Plaintiff arrived at her conclusion regarding this "requirement."[8]

[8] Despite not citing anything in support of her allegations, the apparent source of Plaintiff's knowledge of the private Neuren-FDA meeting is a drug application submitted by Neuren that further confirms the FDA only "recommended" and "encourage[d]" use of CGI-I as an anchoring measure and co-primary endpoint. Ex. 16 (Acadia NDA) at 26, 50. This publicly available document can properly be considered on a motion to dismiss, as it is one Plaintiff knew about and by all accounts relied upon when drafting her pleading. AC ¶ 41. See n.1, supra. Indeed, summaries of the Neuren-FDA meeting on page 26 of Ex. 16 and ¶ 36 of the Amended Complaint are virtually identical. Nevertheless, for the reasons explained above, Plaintiff's allegations fail regardless of whether the Court were to consider this document.

Accordingly, Plaintiff has not established the existence of her invented FDA endpoints "requirement." Without that, nearly all of her claims of false statement or material omission fail.

2. Plaintiff's Own Allegations Undermine the Existence and Violation of the Supposed FDA "Requirement"

Plaintiff also confusingly alternates between descriptions of the "required" FDA endpoints, making incomprehensible any assessment of compliance and demonstrating her fundamentally flawed understanding of the subject matter. At different points, Plaintiff alleges that the FDA required "RSBQ anchored with CGI-I" (AC ¶¶ 4, 64, 79) *and* "RSBQ with CGI-I as a co-primary endpoint" (AC ¶¶ 5, 58). These are different measures. RSBQ anchored with CGI-I yields a single score, with both RSBQ and CGI-I as inputs (e.g., RSBQ AUC). By contrast, RSBQ and CGI-I as co-primary endpoints leads to two separate scores. Yet Plaintiff uses these terms interchangeably. Compare AC ¶ 63 (reciting press release explaining Excellence co-primary endpoints RSBQ and CGI-I) with AC ¶ 64 (describing the same as "RSBQ anchored with CGI-I"). In other words, RSBQ AUC—an endpoint that anchors RSBQ to CGI-I—is exactly what Plaintiff at various points alleges the FDA required. Cf. Abely v. Aeterna Zentaris Inc., No. 12 Civ. 4711, 2013 WL 2399869, at *8 (S.D.N.Y. May 29, 2013) (dismissing complaint alleging pharmaceutical company misled investors as to study design, finding that the complaint did not allege with particularity how defendant's approach to conducting a study materially contravened supposed FDA guidance).

In addition, various of the documents Plaintiff cited in the Amended Complaint undermine a single FDA endpoint requirement. For example, Plaintiff recites statements from a "key opinion leader" quoted in an analyst report. AC ¶ 57. That report describes a "key takeaway[]" from the key opinion leader: "there does not seem to be a single ideal efficacy endpoint so any FDA approval will likely be based on outcomes from multiple measures in combination with good safety and tolerability." Ex. 17 (analyst report) at 1.

B. Defendants' Statements Do Not Create a False Impression of FDA Approval

1. The Pleaded Facts Do Not Support Plaintiff's Unfounded Conclusions

The Amended Complaint repeatedly includes long block quotes followed by conclusory paragraphs that mischaracterize the statements, seeking to transform them into something they are not. A plaintiff's unfounded, subjective characterizations do not warrant any weight. See Fraternity Fund Ltd. v. Beacon Hill Asset Mgmt. LLC, 376 F. Supp. 2d 385, 395 (S.D.N.Y. 2005) ("[T]he underlying factual allegations must justify the inference that plaintiffs urge." (citations omitted)); Polar Int'l Brokerage Corp. v. Reeve, 108 F. Supp. 2d 225, 241 (S.D.N.Y. 2000) ("[T]he court need not adopt plaintiffs' subjective characterizations of documents properly before it.").

Plaintiff seeks to turn any time Defendants discussed study designs into an implicit promise that the FDA would approve a NDA that relied on studies using the RSBQ AUC endpoint. Even a cursory review of the statements (some of which do not even reference RSBQ AUC) reveals that Defendants never made any representations about FDA approval. AC ¶¶ 77, 79, 84, 93, 95, 98.

To help accomplish her goal, Plaintiff repeatedly takes quotes out of context and employs unfounded and speculative interpretations of the statements made. For example, she asserts that Dr. Missling said during a February 1, 2022, call that RSBQ AUC was the "preference" of the FDA. AC ¶ 77. The full transcript reveals why that is misconstrued. Earlier in the call, Dr. Missling explained that, due to limitations on RSBQ as a stand-alone measure, the FDA recommended to use an anchor (i.e., essentially the same comment Plaintiff alleges FDA told Neuren). AC ¶ 78; Ex. 3 at 4. Dr. Missling referred (verbally and in his slides) to a guidance document from the FDA about such a method. Id.; Ex. 4 at 8.[9] He then said: "And so this RSBQ

[9] Defendants cite the FDA guidance document not for its truth, but to show what Defendants cited when making the allegedly misleading statements and for what the FDA said about anchor-based methods. Accordingly, it is proper for consideration on a motion to dismiss. See Abdin v. CBS

AUC was born." Ex. 3 at 4. The slide makes clear that RSBQ AUC is one example of an anchor-based responder method ("(e.g., RSBQ AUC)"). Ex. 4 at 8. Later in the call, Dr. Missling again made clear that the discussion with FDA related to using an anchoring method: "But the discussion with FDA led to a conviction that the RSBQ alone is not sufficient as a standalone to measure… So the anchor-based correlated threshold[-]based RSBQ was then chosen, which is the RSBQ AUC." Ex. 3 at 10. The question-and-answer in paragraph 75 followed all of that and, in his answer about the FDA's "preference," Dr. Missling referred back to his earlier statements.[10]

Relatedly, Plaintiff repeatedly and without foundation misconstrues references by Dr. Missling to FDA "guidance" as necessarily meaning Plaintiff's invented "requirement." AC ¶¶ 84, 87, 93. The context makes clear, though, that the reference is to the FDA document (aptly titled "Guidance for Industry") Dr. Missling discussed and cited in the February 1, 2022, call. Ex. 3.

Plaintiff also argues that, because Dr. Missling began his response to a compound question with the word "yes," he explicitly said that the FDA approved RSBQ AUC. AC ¶ 98. In reality, Dr. Missling's response clarified that Excellence (unlike Avatar) would *not* use RSBQ AUC (answering the analyst's question in the negative). AC ¶ 97; Ex. 8. He then had a further exchange to make sure the analyst understood the response.[11] Plaintiff also makes the additional unfounded conclusion that, in this exchange, Dr. Missling "impl[ied] falsely that the measures [in Avatar and Excellence] were equivalent to one another" (AC ¶ 98), which is not in the transcript.

Broadcasting, Inc., 971 F.3d 57, 60 n.2 (2d Cir. 2020) (court can properly take judicial notice of documents for the fact of publication and relevant discussion in the community).

[10] Plaintiff's excerpt in Paragraph 75 contains a mistake. The audio recording makes clear that Dr. Missling's response is: "Good question. Thank you. So that's right, the Excellence study will use the same endpoint because as just described, it is just the preference of the FDA." Ex. 3 at 13.

[11] In another example of unfounded conclusory characterization of a document before the Court, Plaintiff tries to spin this series of clarifying statements where the call participants were talking over each other as some nefarious attempt to avoid a question. AC ¶ 99.

Plaintiff relies on other unsupported inferences and conclusions throughout the Amended Complaint. For example, she argues that Dr. Missling "refused to answer" a question, even though his response clearly contained a direct answer and the analyst did not follow-up. AC ¶¶ 81-82. Similarly, Plaintiff asserts (without basis) that the "existing design" submitted to the FDA was what was reflected on ClinicalTrials.gov (AC ¶ 90), despite Company statements specifically telling investors not to rely on that website. AC ¶ 81, Ex. 18 (Feb. 9, 2022 transcript) at 8.

2. Defendants' Risk Disclosures and Cautionary Statements Rebut the Unfounded Characterizations Drawn by Plaintiff

Defendants' disclosures throughout the Class Period squarely negate any allegation of an implicit or explicit promise that the FDA would approve a NDA based on particular study designs.

The PSLRA shields from liability forward-looking statements identified as such and accompanied by meaningful cautionary statements. 15 U.S.C. § 78u–5(c)(1)(A)(i). Similarly, under the bespeaks caution doctrine, alleged misrepresentations are immaterial if "it cannot be said that any reasonable investor could consider them important in light of adequate cautionary language." Halperin v. eBanker USA.com, Inc., 295 F.3d 352, 357 (2d Cir. 2002). "Consequently, when cautionary language is present, [a court] analyze[s] the allegedly fraudulent materials in their entirety to determine whether a reasonable investor would have been misled." Id. Statements about the possibility of FDA approval are "classically forward-looking." In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 535 (S.D.N.Y. 2015), aff'd sub nom. Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016). This Court has found that risk disclosures "expressly identif[ying] the risk of FDA non-approval…indisputably satisfy the PSLRA safe harbor." Biovail, 615 F. Supp. 2d at 231-33.

Here, Anavex repeatedly warned investors in its annual reports, press releases, and conference calls that its drug products "may fail to receive necessary regulatory approvals." See pg. 5, supra. This language "explicitly identifies the salient risk, namely, that a regulatory authority

such as the FDA could deny or delay approval of" the drug and identifies important factors that could lead to such result. Sanofi, 87 F. Supp. 3d at 536. No reasonable investor could have interpreted Defendants' statements, taken as a whole, to mean the FDA would definitely approve a drug that relied on a particular study design.

Relatedly, any attempt to fault Defendants for expressing optimism about clinical studies or potential FDA approval or conveying results in a "positive light" (AC ¶¶ 101-102) also fails because courts have repeatedly found that such statements are inactionable. See In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004) ("[A] complaint alleging violations of the securities laws may not rely upon statements that … constitute puffery or ordinary expressions of corporate optimism."); Kleinman, 706 F.3d at 153 ("Subjective statements can be actionable only if the defendant's opinions were both false and not honestly believed when they were made." (internal quotation marks omitted)). As explained herein, Plaintiff "has not pled a single non-conclusory allegation that would support the inference that [defendant] held a subjective belief" contrary to any public statement of optimism. Bettis v. Aixtron SE, No. 16-cv-25 (CM), 2016 WL 7468194, at *11 (S.D.N.Y. Dec. 20, 2016).

C. Plaintiff Does Not Allege Factual Falsity as to Any Study Results

Apart from her invalid allegation of the supposed FDA endpoint "requirement," Plaintiff does not allege that anything communicated to the market about the study plans, endpoints, or results was factually inaccurate. For example, although Plaintiff marks in bold two paragraphs describing study results in ¶ 101, she does not allege that any of this description was inaccurate.

To the extent the Amended Complaint can otherwise be read as making general criticisms of Defendant's choice of endpoints or design of the clinical trial, such quibbles do not state a securities fraud claim. Numerous cases reject claims against biopharmaceutical companies that second-guess how data is presented. See, e.g., Kleinman, 706 F.3d at 154–55 (dismissing a

complaint that argued the company's changing of measures to present data in a different format must have been misleading, explaining that defendants had no obligation to present results in any particular format); Biovail, 615 F. Supp. 2d at 221 (dismissing claims of misleading investors by not disclosing that studies used a method that allegedly increased the risk of FDA non-approval); In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011) ("Plaintiffs cannot premise a fraud claim upon a mere disagreement with how Sanofi chose to interpret the results."); Abely, 2013 WL 2399869 at *2-3, 6-9 ("The Second Circuit and other tribunals have concluded that the securities laws do not recognize a fraud claim premised on criticisms of a drug trial's methodology, so long as the methodology was not misleadingly described to investors.").

D. The Endpoints for the Excellence Study Were Accurately and Repeatedly Disclosed During the Class Period

The clear intra-Class Period disclosures identified above undermine the allegations that Defendants knowingly did not reveal until the end of the Class Period the endpoints for Excellence. Plaintiff in fact explicitly acknowledges that on February 7, 2023, Defendants disclosed Excellence would not use RSBQ AUC. AC ¶ 115. Therefore, at a minimum, Plaintiff's case falls apart as of that date. See In re Progress Energy, Inc., 371 F. Supp. 2d 548, 552 (S.D.N.Y.2005) ("[I]t is indisputable that there can be no omission where the allegedly omitted facts are disclosed."); Okla. Firefighters Pension & Ret. Sys. v. Student Loan Corp., 951 F. Supp. 2d 479, 500 (S.D.N.Y. 2013) ("[D]efendants disclosed precisely the type of information plaintiffs claim was withheld."); Bettis, 2016 WL 7468194 at *11 ("[O]n several occasions, [the company] made exactly the disclosures that Plaintiff claims were withheld from investors."); Ganino v. Citizens Utils. Co., 228 F.3d 154, 167 (2d Cir. 2000) ("[A] misrepresentation is immaterial if the information is already known to the market because the misrepresentation cannot then defraud the

market."). No reasonable investor needed to wait until the end of the Class Period to know what the Excellence endpoints would be.

II. Plaintiff Utterly Fails to Meet Her High Burden to Plead Scienter

The Amended Complaint is striking for the paltry effort undertaken to plead scienter. A plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," i.e., an "intention to deceive, manipulate, or defraud." Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 313-14 (2007) (citations and internal quotation marks omitted). The "court must consider plausible, nonculpable explanations for the defendant's conduct." Id. at 324. For an inference of scienter to be strong, "a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged." Id. (emphasis added). Plaintiff fails both methods to plead scienter in the Second Circuit. See ATSI, 493 F.3d at 99.

A. Plaintiff Only Pleads Non-Actionable Generalized Motives

Plaintiff's half-hearted effort to plead motive and opportunity fails, as all she can muster are motives universal across all companies and executives, which courts routinely and universally find "do not suffice" to plead securities fraud. Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001). Indeed, the only alleged motives are to prevent jeopardizing needed equity raises and continuing individual compensation. AC ¶¶ 19, 108. Such generalized motives do not establish scienter. See, e.g., Biovail Corp., 615 F. Supp. 2d at 226 ("The Second Circuit has held that the alleged motives to maintain a company's stock price or 'sustain [ ] the appearance of corporate profitability' do not constitute sufficient evidence of motive to support a securities fraud claim." (citation omitted)); Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1130 ("[A] plaintiff must do more than merely charge that executives aim to prolong the benefits of the positions they hold."); Caiafa v. Sea Containers, Ltd., 525 F. Supp. 2d 398, 412-43 (S.D.N.Y. 2007) ("The alleged desire[] to raise

additional capital in a private placement…[is] inadequate to support an allegation of intent to commit fraud." (citation omitted)).

Plaintiff's motive theory also does not make sense, as Anavex would have inevitably needed to disclose the real endpoints when releasing the Excellence results and there is no alleged reason to conceal the results only for the short period of time alleged. Cf. Shields, 25 F.3d at 1130 ("It is hard to see what benefits accrue from a short respite from an inevitable day of reckoning."); In re PXRE Grp., Ltd., Sec. Litig., 600 F. Supp. 2d 510, 533 (S.D.N.Y. 2009) (considering "the seeming futility of Defendants' alleged scheme"), aff'd sub nom. Condra v. PXRE Grp. Ltd., 357 F. App'x 393 (2d Cir. 2009).

B. The Absence of Particularized Allegations Fails to Create a Strong Inference of Conscious Misbehavior or Severe Recklessness

Plaintiff fares no better in trying to satisfy the high bar to plead conscious misbehavior or recklessness (i.e., deliberate, illegal behavior or conduct constituting "an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it"). In re Lululemon, 14 F. Supp. 3d at 573 (citation omitted); see also Kalnit, 264 F.3d at 142-43 (noting that the strength of the allegations must be correspondingly greater absent allegations of motive). To satisfy this standard, plaintiff must *specifically* identify the reports or statements from which defendants learned facts contrary to the public representations. Novak v. Kasaks, 216 F.3d 300, 309 (2d Cir. 2000). A plaintiff's "failure to do so is sufficient to end the inquiry." Shetty v. Trivago N.V., 796 F. App'x 31, 35 (2d Cir. 2019) (summary order).

Plaintiff does not cite any internal document, describe any internal meeting, or recite a single witness (let alone a credible one). Instead, she relies entirely on oft-rejected allegations such as that Defendants "must have known" due to corporate positions or so-called "core

operations." AC ¶¶ 15, 105-106. This is insufficient. See City of Brockton Ret. Sys. v. Shaw Group Inc., 540 F. Supp. 2d 464, 473 (S.D.N.Y. 2008) (rejecting general allegation that defendants must have known of accounting improprieties due to involvement in daily operations, absent factual allegations supporting inference of knowledge such as "access to particular, identified internal reports that would have alerted them"); Koplyay, 2013 WL 6233908, at *7 (dismissing complaint that "never makes reference to any internal reports, statements by confidential witnesses, or other specific facts showing that Defendants had access to" the allegedly undisclosed contrary data); see also Okla. Firefighters, 951 F. Supp. 2d at 497-98.

1. Plaintiff Does Not Plead Any Facts with Particularity to Show Defendants Knew of Allegedly Concealed Information

Even if (counterfactually) the FDA communicated to *Neuren* a "requirement" for all Rett Syndrome study designs to only and exclusively use RSBQ and CGI-I as co-primary endpoints, no well-pled allegations support that anyone at Anavex knew of it. Plaintiff attempts to tie knowledge to Anavex by asserting that, because *unspecified* persons at Anavex allegedly met with *unspecified* persons at the FDA *sometime* "between December 2017 and February 2018" (two years after the Neuren-FDA meeting) and *must have* also had *some number* of conversations with *unnamed* persons at the FDA "at various times thereafter," the FDA *must have* informed Anavex of the supposed endpoint "requirement." AC ¶ 59; see also AC ¶¶ 76, 95. The complete lack of detail and unfounded assumptions and logical leaps utterly fail to satisfy her pleading requirements. See San Leandro Emerg. Med. Grp. Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 812 (2d Cir. 1996) ("Plaintiffs' unsupported general claim of the existence of confidential company… reports that revealed [contrary information] is insufficient to survive a motion to dismiss.").

Moreover, the Amended Complaint does not allege any *basis* for Plaintiff's supposed knowledge of what the FDA privately told Anavex. Even when (unlike here) a plaintiff identifies a source of alleged inside information, the allegations must show the source likely knows the relevant facts. Cf. Pfizer, 538 F. Supp. 2d at 630 (dismissing allegations based on alleged internal confidential witness because, "[i]n addition to identifying the source, the source must be shown to have been likely to know the relevant facts"). Here, Plaintiff does not even try to ascribe a source of her allegations, let alone show the source to be reliable. Instead, she relies entirely on conjecture. The mere fact that Defendants later disclosed different endpoints for Excellence does not support anything as to their earlier knowledge or intent as to the study. See In re Lululemon, 14 F. Supp. 3d at 571 ("A violation of Section 10(b) and Rule 10b–5 premised on misstatements cannot occur unless an alleged material misstatement was false *at the time it was made*.") (emphasis in original); Okla. Firefighters, 951 F. Supp. 2d at 497-98 ("[P]laintiffs allege no facts whatsoever to support their argument that defendants did not honestly believe" statements at time they were made, noting the absence of any alleged internal communications or witness accounts).

Plaintiff similarly alleges not a single source or other support for the allegation that Dr. Missling knew in August 2023 that the Excellence trial failed to meet its co-primary endpoints and that he had "data unblinded and in-hand." AC ¶ 102. This alone renders the allegation insufficient. See Quinones v. Frequency Therapeutics, 106 F.4th 177, 182-83 (1st Cir. 2024) (dismissing claim that individual executives knew of study results prior to public release, explaining that plaintiffs did not allege when information was conveyed to them so as to establish a strong inference of scienter); Abely, 2013 WL 2399869 at *19 (rejecting allegations that defendant had access to contrary data that lacked specificity including particular reports the defendant received). In fact, this is directly contradicted by Dr. Missling's own remarks that Anavex was still "looking forward

to the top line dat[a]" (Ex. 19 at 2) and how he described standard practices as to unblinding data after a study. See Ex. 18 at 12.

2. Plaintiff's Laundry List of Subjective Characterizations Does Not Create a Strong Inference of Scienter

A plaintiff's failure to *specifically* identify how defendants learned facts contrary to the public representations is sufficient to end the scienter inquiry. Plaintiff's other general attempts to impugn Defendants as dishonest do not salvage her claims. Indeed, consistent with her overall approach, the allegations are not factual and instead consist only of conclusory interpretations of various events that are not entitled to any weight. For example, Plaintiff alleges that Dr. Missling attempted to "evade" or "refus[e] to answer" analyst questions (AC ¶ 107), but the transcripts belie that, showing that Dr. Missling clearly stated the endpoints (e.g., Ex. 6 at 3; Ex. 18 at 9). Plaintiff similarly characterizes Anavex attempts to "spin" data in a positive light, but does not allege hiding of the methods used to measure the data—instead, they were openly disclosed. AC ¶ 111.

Plaintiff bizarrely points to three press releases as indicative of scienter merely because she believes they had "little-to-no substantive value" and must have been issued to inflate the stock price. AC ¶ 113. She does not allege any were false or unusual compared to past practices. Nor does she allege *why* these releases—relating to a regulatory submission, study data, and entering an agreement—had no substantive value or how worthless releases caused stock price increases.

Finally, Plaintiff cites a "pattern of delaying the announcement of bad news," but nowhere pleads facts to support that Defendants had data ready to present earlier. Instead, she baldly asserts unspecified "industry standards and customary practices" and compares Anavex to Acadia, without any foundation that the timeframes should be the same. Indeed, many variables could factor into when data are ready to prepare, including the size and resources of the company, the location of the data subjects, and the amount of data refinement needed. The Company also

explained the timing, which was consistent with earlier disclosures that data analysis takes "several months." See Ex. 21 (Nov. 27, 2023 transcript) at 6 ("After the last 12-week readout, there was an additional safety follow up and that's basically why the timings may be a little bit different from expectations, but we are in – on track to release this data once we have it."); Ex. 18 at 12.

C. The Substantially More Plausible Alternative Reveals No Fraudulent Intent

In contrast to Plaintiff's speculative scenario built on conclusory assertions and layers of unsupported inferences, the alleged facts instead present a more compelling and non-fraudulent alternative: that the FDA did not tell Anavex that it needed to only use a certain type of endpoint and that Anavex adjusted the study design during the Class Period as disclosed. The FDA had concerns about a study that only used RSBQ and privately encouraged Neuren to anchor RSBQ to CGI-I, which Neuren decided to do by using co-primary endpoints. For the Avatar study, Anavex, also based on FDA guidance and concern that RSBQ by itself was prone to error, decided to anchor CGI-I to RSBQ by using the RSBQ AUC measure. Anavex publicly announced Avatar results using the RSBQ AUC metric (not hiding it from the FDA). Anavex also intended to use that endpoint for Excellence, as it communicated publicly, but partway through the Class Period Anavex met further with the FDA and, based in part on those discussions, decided to instead use RSBQ and CGI-I as co-primary endpoints. Anavex disclosed this on multiple occasions during the Class Period, without negative market reaction (see Section III, infra). When Anavex announced somewhat disappointing Excellence results in January 2024, the negative market reaction was due to that, not the (already disclosed) endpoints.

Plaintiff's theory is also logically incoherent, further reinforcing why it is not at least as strong as the non-fraud alternative. She claims Defendants harbored a secret intent not to use RSBQ AUC in the Excellence study because they knew they could not present that to the FDA, yet Defendants openly used RSBQ AUC in the Avatar study, which the Company also presented

to the FDA. Relatedly, if the major avenue to create the false impression was to make the market believe Excellence would use RSBQ AUC, then why would Defendants disclose repeatedly during the Class Period that Excellence would in fact *not* use that endpoint?

III. The Allegations Fail to Establish Loss Causation

Plaintiff also fails to plead loss causation (i.e., that a decline in stock price was caused by disclosure of the alleged previously unknown misrepresentation or omission). See Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 345-46 (2005); In re Omnicom Grp., Inc. Sec. Litig., 597 F.3d 501, 510 (2d Cir. 2010). The alleged "corrective" disclosure is divorced from her theory of liability and earlier disclosures undermine proximate causation.

A. Defendants' Mid-Class Period Announcement of the Excellence Endpoints Did Not Reveal Fraud or Create Any Negative Market Movement

Disclosure regarding the actual Excellence endpoints did not lead to any investor losses, let alone any attributable to the alleged fraud. Plaintiff alleges that Defendants intentionally misrepresented that Excellence would use the RSBQ AUC endpoint in order to continue to perpetuate a false impression that the FDA approved use of that endpoint. Although Plaintiff originally argued that identification of the actual endpoints was hidden until the end of the Class Period, she now (correctly) admits such information was disclosed on February 7, 2023. AC ¶ 115. Accordingly, disclosure of the actual endpoints used in Excellence could not have caused the stock price decline at the end of the Class Period. See Okla. Firefighters, 951 F. Supp. 2d at 503 (citing Lentell, 396 F.3d at 173).

Plaintiff is also mistaken that the intra-Class Period endpoint disclosure caused a stock price decline or related to the alleged fraud. First, she claims that, in making this announcement, Anavex "thereby indicat[ed] that the AVATAR trial results were potentially not as positive or

supportive as initially represented." AC ¶ 115. But she pleads no support for such conclusory characterization that is not entitled to any deference. See Polar Int'l, 108 F. Supp. 2d at 241.

Moreover, she incorrectly alleges that such disclosure "sent Anavex's share price tumbling," referencing downward movement from the February 7 close to the prices over the next two trading days. AC ¶ 115. However, the disclosure occurred during a morning earnings call on February 7. Ex. 25 (Feb. 7, 2023 press release). The relevant focus is therefore the stock price movement on February 7, when the stock closed up nearly six percent above the previous day's close. Ex. 23 (stock data).[12] Failure to allege negative market reaction when elements of the alleged "concealed risk" were exposed to the market undermines loss causation. See In re New Energy Sys. Sec. Litig., 66 F. Supp. 3d 401, 405-06 (S.D.N.Y. 2014).

To the extent Plaintiff argues that analyst reports over the next two days were necessary to understand this new information, the Amended Complaint undermines her. Plaintiff alleges that Anavex traded as part of an efficient market that "promptly digested current information regarding Anavex from all publicly available sources and reflected such information in the price of the stock." AC ¶ 120. Plaintiff cannot have it both ways: arguing for the presumption of reliance based on an efficient market while also arguing that clearly disclosed information during an earnings call – among the most watched events for any company – was not promptly absorbed into the price. See SRM Global Fund L.P. v. Countrywide Fin. Corp., No. 09-cv-5064, 2010 WL 2473595, at *10 (S.D.N.Y. June 17, 2010). Moreover, courts exclude analyses of publicly available information that simply repackage already-public information. Sapssov v. Health Mgmt.

[12] The Court can properly consider stock price data on a motion to dismiss. Ganino, 228 F.3d at 166 n.8. Regardless, because the relevant inquiry is as to February 7, about which Plaintiff says nothing, the Amended Complaint fails to allege any loss causation.

Assoc., Inc., 608 F. App'x. 855, 863 (11th Cir. 2015). In addition, analyst reports issued over the next two days viewed the disclosure of endpoint positively. See, e.g., Ex. 22 (BTIG).

B. The End of Class Period Announcement Was Not "Corrective" of the Alleged Fraud

The press release on January 2, 2024, does not correct any prior alleged misstatements or omissions. Plaintiff alleges that the new information presented that day is that "Defendants finally revealed that the EXCELLENCE trial did not meet its co-primary endpoints of RSBQ and CGI-I." AC ¶ 116. But the central premise of her case is that Defendants misled the market as to whether the FDA would accept studies using RSBQ AUC. On January 2, 2024, Defendants did not reveal *anything* on this topic, as nearly a year before they had made clear the primary endpoints of the Excellence study.

That Anavex's stock price declined that day is more appropriately and logically attributable to investors' disappointment with the Excellence results. Cf. Biovail, 615 F. Supp. 2d at 229 ("The all-but-inevitable decline in the price of Biovail's stock price following the company's announcement that the FDA had not approved the [drug application] was caused by the agency's failure to approve the drug—not by any 'corrective' disclosure of some prior untruth."). Like in Biovail, nothing in the January 2024 announcement about the Excellence results "'corrected' or otherwise revealed the 'actual truth' behind any prior alleged misrepresentation by Defendants." Id. at 229; see also In re New Energy, 66 F. Supp. 3d at 405 ("[T]o establish loss causation, 'a plaintiff must allege ... that the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered.'" (citation omitted) (emphasis in original)).

Indeed, under Plaintiff's theory, no corrective disclosure occurred even at conclusion of the Class Period. When announcing the Excellence results, Defendants touted the "successful" Phase 3 Avatar study, which used RSBQ AUC. In other words, the Company continued to make

the same type of statements that Plaintiff has characterized as falsely implying that the FDA would accept RSBQ AUC. Cf. Biovail, 615 F. Supp. 2d at 229 (explaining that, even after the alleged corrective disclosure, defendants maintained their public stance about proper study design, and thus "persisted in their purported 'misstatements' after the expiration of the class period").

Plaintiff appears to be an investor with a loss casting about in search of a claim. Her original theory failed, so she concocted a new one. But the new one is also untied to her loss. Although the release of the Excellence study results led to a market reaction that she did not like, "private securities fraud actions are available, not to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause." In re New Energy, 66 F. Supp. 3d at 406 (cleaned up and citation omitted).

CONCLUSION

For all of the reasons outlined above, the Court should dismiss the Amended Complaint.

Date: August 23, 2024

Respectfully submitted,

/s/ Stephen G. Topetzes

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