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July 22, 2025

**VIA ECF**

The Honorable Julien X. Neals  
United States District Court  
District of New Jersey  
Martin Luther King Building & U.S. Courthouse  
50 Walnut Street  
Newark, NJ 07102

**Re: *In re CorMedix Securities Litigation*, No. 21-cv-14020 (D.N.J.)**

Dear Judge Neals,

We write on behalf of Defendants in connection with the Court's June 30, 2025 Opinion, which denied Defendants' motion to dismiss. ECF No. 114 (the "Opinion" or "Op.").

While Defendants do not seek reconsideration of the Opinion pursuant to Federal Rule of Civil Procedure 59(e), we wish to bring to the Court's attention a series of errors in the Opinion—including three instances in which the outcomes of cases cited in the Opinion were misstated (i.e., the motions to dismiss were granted, not denied) and numerous instances in which quotes were mistakenly attributed to decisions that do not contain such quotes—so that the Court may consider whether amendment or any other action should be taken. We also write to alert the Court that these and related issues have been raised in a parallel securities class action lawsuit pending in the District of New Jersey and are the subject of briefing in that case. *See In re Outlook Therapeutics, Inc. Sec. Litig.*, 2:23-cv-21862 (D.N.J.).

First, the Opinion cites approvingly to *Dang v. Amarin Corp. PLC*, 750 F. Supp. 3d 431 (D.N.J. 2024). The Opinion says: "In *Dang v. Amarin Corp. PLC*, the court applied the core operations doctrine where executives made misleading statements about Vascepa, the company's only product, while ignoring FDA Form 483s and audits identifying significant regulatory risks." Op. at 22. However, the *Dang* court dismissed the plaintiffs' securities fraud complaint and specifically rejected the plaintiffs' argument under the "core operations" doctrine. 750 F. Supp. 3d at 476 ("Plaintiffs' related reliance on the 'core operations' doctrine fails for the same reason."). In determining that the plaintiffs failed to allege misleading statements about Vascepa, the court explained that "the core operations doctrine does not permit imputing the requisite scienter regarding any statement made within a broad perimeter of the

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relevant core operations to an executive.” *Id.* at 477. In addition, the Opinion states that the executives in *Dang* “ignor[ed] FDA Form 483s and audits identifying significant regulatory risks,” Op. at 22, but *Dang* does not contain any discussion of FDA Form 483s or audits. Similarly, the Opinion quotes *Dang* as referring to “classic evidence of scienter,” *id.* at 20, but the case does not contain that quote.

*Second*, the Opinion relies on *In re Intelligroup Securities Litigation*, 527 F. Supp. 2d 262 (D.N.J. 2007), to support the following proposition: “Courts have repeatedly held that SOX certifications can support a strong inference of scienter when executives certify internal controls while aware of or recklessly disregarding serious deficiencies, especially when the issues pertain to core operations.” Op. at 24. The Opinion goes on to say that, “[i]n *Intelligroup*, the court found that certifying executives made actionable misstatements by signing SOX certifications despite knowledge of serious internal control failures. The certifications became ‘false statements in their own right’ where executives were aware of red flags or contradictory information.” *Id.* However, as in *Dang*, the court in *Intelligroup* granted the defendants’ motion to dismiss in its entirety. The court concluded that the plaintiffs failed to allege scienter, and explicitly concluded that “[it] does not draw any inferences of Defendants’ scienter from their SOX certifications.” *Intelligroup*, 527 F. Supp. 2d at 372. Moreover, *Intelligroup* does not contain the quotation about “false statements in their own right,” as referenced in the Opinion. Op. at 24.

*Third*, the Opinion contains the following statement in the scienter section: “Similarly, in *Stichting Pensioenfonds Metaal en Techniek v. Verizon Commc ’ns Inc.*, No. 23-05218, 2021 WL 3540968, at \*15-17 (S.D.N.Y. Aug. 10, 2021), access to internal emails and memos warning about inaccuracies supported a finding of scienter.” Op. at 19. We have not been able to identify this case from the Southern District of New York, but we believe the Court was referring to a case with the same caption from the District of New Jersey. See *Stichting Pensioenfonds Metaal en Techniek v. Verizon Commc ’ns Inc.*, 775 F. Supp. 3d 826 (D.N.J. 2025). In *Stichting*, the court granted the defendants’ motion to dismiss in its entirety and specifically rejected all of the plaintiffs’ arguments in support of scienter. *Id.* at 848 (“For the reasons indicated below, I find that all five of plaintiffs’ arguments are meritless . . . [A]n inference that defendants lacked scienter is more plausible than an inference that defendants made statements with scienter.”). Moreover, *Stichting* does not have any discussion of “internal emails” or “memos.”

*Fourth*, the Opinion attributes two quotes to *City of Warwick Retirement System v. Catalent, Inc.*, No. 23-1108, 2024 WL 3219616 (D.N.J. June 28, 2024), but they are not contained in that case. Op. at 17 (“The absence of insider trading is not dispositive.”); *id.* (“The importance of the product to the company’s financial success supports the inference of scienter.”).

*Fifth*, the Opinion also attributes a quote to *Roofer’s Pension Fund v. Papa*, No. 16-2805, 2018 WL 3601229 (D.N.J. July 27, 2018), but the quote is not found in that case. Op. at 27 (“The lack of any competing inference that is more plausible than Plaintiffs’ suggested inference . . . reinforces a strong inference of scienter.”).

*Finally*, in addition to the above case citations, the Opinion attributes two quotes to Defendants that they are not alleged to have made. Specifically, the Opinion says: (1) “Todisco publicly stated that CorMedix . . . had ‘resolved all issues related to manufacturing,’” Op. at 16 (quoting TAC ¶ 6); and (2) “CorMedix issued statements in October 2019 . . . that the company had ‘all necessary controls and processes in

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place for approval,”” *id.* (quoting TAC ¶ 7). These quotes are not contained in the TAC or the materials underlying the two cited paragraphs.

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By way of further background, on July 7, 2025, the Opinion was submitted as “Supplemental Authority” in a parallel securities class action pending in the District of New Jersey. *See In re Outlook Therapeutics, Inc. Sec. Litig.*, 2:23-cv-21862 (D.N.J. July 7, 2025), ECF No. 73 (*See* Exhibit A). Last week, the defendants in that case filed a response, which raised some of the issues addressed in this letter. *Outlook*, ECF No. 74 (*See* Exhibit B).

We are available to discuss further should the Court have any questions.

Respectfully Submitted,

/s/ Andrew Lichtman  
Andrew Lichtman