UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMAD ODEH, individually and on behalf of all others similarly situated, Plaintiff, v. IMMUNOMEDICS, INC., et al., Defendants.	Civil Action No. 18-17645(MCA)(LDW) Return Date: April 20, 2020 ***Oral argument requested***

BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED COMPLAINT

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PRELIMINARY STATEMENT

Defendants learned about a Data Integrity Breach[1] at Immunomedics' Morris Plains manufacturing facility on January 31, 2018. This breach, which involved the deliberate, fraudulent manipulation of bioburden samples, the misrepresentation of test procedures in batch records, and the improper backdating of batch records, went to the heart of Immunomedics' forthcoming Biologic License Application ("BLA"), which sought FDA approval of its biologic targeted therapy for treating breast cancer. Consistent, accurate manufacturing is critical for biologics, and the Data Integrity Breach was a huge red flag.

Given the seriousness of the breach, Company staff immediately brought it to the attention of Senior Management and the Board. However, Defendants misled investors and concealed the breach and its effects on Immunomedics. Defendants provided false information about why Immunomedics was delaying the filing of its BLA; omitted to reveal that the FDA issued a Form 483 about the breach; that Defendants failed to remediate the issues raised in the Form 483 to the satisfaction of the FDA while simultaneously advising investors of a hypothetical that an unresolved Form 483 could lead to regulatory issues and delays; and that an employee *might* violate the law by recording false information in systems used by

[1] Defined terms have the same meaning as Plaintiffs' Amended Complaint (ECF No. 41). ¶__ references throughout the brief are to the numbered allegations in the Amended Complaint.

Immunomedics to report to regulators even though this already occurred.

Plaintiffs rely upon contemporaneous records, published by the FDA after the Class Period ended, which establish that Defendants knew the statements they made during the Class Period were false and misleading when made.

Defendants seek dismissal by creating a strawman: that Plaintiffs are merely seeking to hold Defendants' liable for failing to be clairvoyant about the FDA's ultimate rejection of Immunomedics' BLA. This grossly mischaracterizes Plaintiffs' allegations. Defendants made false statements and misled investors about its BLA for IMMU-132, misled investors about the Data Integrity Breach, its effect on the BLA and its interactions with the FDA. This is not about predicting what the FDA might do, it is about misrepresenting what already occurred.

Defendants' motion to dismiss also rests on disputing the Complaint's well-pled facts. The heart of Defendants' motion is an argument that Defendants remediated the Data Integrity Breach. This is not what was pled. To the contrary, the Complaint pleads that the FDA informed Defendants that because the Company refused to provide documentary evidence of the remediation efforts—which were withheld on grounds of attorney-client privilege—the matter was not remediated.

FACTUAL BACKGROUND

Immunomedics discovered the Data Integrity Breach on January 31, 2018. ¶¶9, 82. Immunomedics personnel immediately notified Pehl and the Board of

Directors. ¶79. The breach was no small matter. Small deviations in the manufacturing process can alter the effectiveness of a biologic since the manufacturing process is notoriously sensitive and closely controlled. ¶¶71–72. In response to this crisis, Defendants brought in outside counsel to investigate and "immediately" informed the FDA. ¶79. But Defendants repeatedly issued misstatements to conceal the crisis and to obscure the severity of it. A mere six business days after the discovery of the Data Integrity Breach, Immunomedics publicly announced that it would be delaying IMMU-132's BLA filing date by two months. ¶80. Immunomedics failed to reveal that the delay was because of intentional fraud at its manufacturing facility, nor did it disclose that there had been a Data Integrity Breach *at all*. *Id.* Despite having learned *just the prior week* that manufacturing personnel were manipulating samples and records, ¶93, Pehl instead expressed that he was "pleased with the overall progress across clinical and manufacturing work streams, including successful validation runs" despite having learned *just the prior week* that manufacturing personnel were manipulating samples and records. ¶93. When an analyst asked what "gave rise to" the delay, Pehl stated that the initial timeline was too aggressive and that there was a need to validate additional assays. Rosenberg characterized it as a "check-the-box exercise." ¶95. Neither mentioned that they had recently discovered egregious fraud that undermined the integrity of the manufacturing process and the data. *See* Compl. Ex.

C, at 42. In response to a question at a later conference about what "next steps" would be necessary to advance IMMU-132's regulatory submission, Pehl omitted to reveal the need to remediate the Data Integrity Breach. ¶98.

Immunomedics sold $300 million of its stock in a June 2018 secondary offering. ¶¶102–04. Neither the Registration Statement nor the Prospectus mentioned the problems in Morris Plains or the Data Integrity Breach. *Id.*

The FDA inspected the Morris Plains facility in August 2018, and issued a Form 483 violation singling out issues related to the Data Integrity Breach. ¶82. The FDA noted it could not assess whether Immunomedics had remediated the problems because Defendants withheld necessary documentation. *Id*. According to the FDA: "[t]he firm indicated at the inspection close-out that they understood the seriousness of the observation." Compl. Ex. C, at 42. Despite receiving the Form 483, Defendants submitted their 2018 Form 10-K with a risk disclosure acknowledging that "if" the FDA were to issue a Form 483—something the FDA *had already done nine days earlier* – it "could" cause delays in approval and other material adverse impacts. ¶106. Defendants simultaneously acknowledged the materiality of the information being withheld and continued to conceal that information. *Id*.

In December 2018, the truth began to reach the market. ¶¶18, 120, 123. Even after the existence of the Form 483 was disclosed by an analyst, Defendants falsely told analysts, to reverse Immunomedics' stock price decline, that the Data Integrity

Breach had been remediated. ¶¶113–17. Later, Pehl responded to a question about the Form 483 by telling his audience that Immunomedics "did take care of [the issues] very early." ¶118. Yet Defendants knew Immunomedics was withholding documentary evidence and that—as the FDA could not therefore confirm remediation—this remained an open issue that could sink the BLA. ¶82.

After the market closed on January 17, 2019, Immunomedics announced it had received a Complete Response Letter ("CRL") from the FDA rejecting IMMU-132's bid for approval. ¶124. Defendants acknowledged that the rejection stemmed from manufacturing issues. *Id*. The FDA found the scope of the Data Integrity Breach to be much broader than Immunomedics initially represented to the FDA in January 2018 and reaffirmed that remediation could not be confirmed so long as Defendants continued to withhold documentary proof. ¶¶84, 86, 88, 89, 91.

LEGAL ARGUMENT

I. Legal Standard

When deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court accepts all the pleadings' allegations as true and draws all reasonable inferences in the favor of the plaintiff. *See Phillips v. Cnty. of Allegheny,* 515 F.3d 224, 231 (3d Cir. 2008); *Curran v. Freshpet, Inc.*, Civ. No. 16-2263, 2018 WL 394878, *3 (D.N.J. Jan. 12, 2018)). A complaint challenged "by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations," but must

simply allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). And, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

II. Plaintiffs state a valid claim under Section 10(b).

Defendants challenge two elements of Plaintiffs' §10(b) claim: the existence of "a material misrepresentation or omission," and "scienter." *City of Edinburgh Council v. Pfizer, Inc*., 754 F.3d 159, 167 (3d Cir. 2014). Both challenges fail.

A. The Complaint properly alleges Defendants' misleading statements and material omissions.

To satisfy the PSLRA's pleading requirement for falsity and Fed. R. Civ. P. 9(b), a plaintiff needs to specify each statement alleged to be misleading and why the statement is misleading, setting out the "first paragraph of a newspaper story—that is, the who, what, when, where and how" concerning the statements at issue. *Freshpet,* 2018 WL 394878, at *3 (quoting *In re Alpharma,* 372 F.3d 137, 147 (3d Cir. 2004)); 15 U.S.C. §78u-4(b)(1). Defendants do not dispute that the Complaint identifies who made the alleged misstatements, what those statements were about, when the statements were made, where the statements were made, and how the statements were false and misleading. Instead, Defendants quibble with the structure of the Complaint and argue that their statements were not materially misleading. Def

Br. at 9-24. The Court should reject Defendants' arguments concerning falsity.

1. The Complaint is not a "puzzle pleading."

Defendants wrongly contend the Complaint should be dismissed because it is a "puzzle pleading." Def Br. at 12. A "puzzle pleading" reflects a "'great web of scattered, vague, and redundant and often irrelevant allegations.'" *In re Honeywell Int'l Inc. Sec. Litig.* 182 F. Supp. 2d 414, 426 (D.N.J. 2002) (quoting *Wegner v. Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1243 (N.D. Cal. 1998)). Here, the Complaint plainly alleges Plaintiffs' theories of falsity and Defendants' direct knowledge that their statements were misleading when.[2] Under Rule 9(b), the Complaint specifically identifies Defendants' alleged misleading statements in ***bold and italics*** (other than the pure omissions alleged at ¶¶102-103).[3] *See* ¶¶93-99, 101, 106, 108, 110-111,

[2] Defendants' cases on puzzle pleading are distinguishable. In *Boca Raton Firefighters & Police Fund v. Bahash*, 506 F. App'x 32, 37-38 (2d Cir. 2012), the panel concluded the operative complaint was a puzzle pleading because it was 280 pages long and contained a single paragraph of allegations describing why all alleged statements were misleading. In *OFI Asset Mgmt. v Cooper Tire & Rubber*, 834 F.3d 481, 491-92 (3d Cir. 2016); *Xiaojiao Lu v. Align Tech., Inc.*, 2019 WL 5579520, at *5 (N.D. Cal. Oct. 29, 2019); and *In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2005), the plaintiffs conceded that their pleadings did not accurately identify misleading statements and lacked proper organization. Here, the Complaint is only 54 pages and Plaintiffs concede nothing other than it is a clear and plain statement of the case.

[3] Defendants complain that the Complaint block quotes too much of their alleged misstatements. Def Br. at 13. The Court should reject that argument. *See In re ArthroCare Corp. Sec. Litig.*, 726 F. Supp. 2d 696, 710 (W.D. Tex. 2010) (noting "it is logical that in many instances Plaintiff set forth the relevant portions of a press release or investor call *in toto*, in order to give an idea of what was said and, just as importantly, what was omitted.").

113-115, 117-118. Pursuant to Rule 9(b), the Complaint specifically identifies the facts explaining how and why Defendants' Class Period statements were misleading when made. ¶¶105, 119. *See also* ¶¶79-91 (detailed allegations providing the sources and bases of falsity and Defendants' intent to deceive investors). Rather than repeat verbatim allegations of misleading disclosure language quoted earlier in the Complaint, Plaintiffs appropriately cross-reference the identical language when it appeared in subsequent regulatory filings. *See* ¶¶100, 102-103, 106, 109. Defendants' direct attacks against the allegations, moreover, reflect they have notice of Plaintiffs' theories of fraud. *See In re MF Glob. Holdings Ltd. Sec. Litig.*, 982 F. Supp. 2d 277, 310 (S.D.N.Y. 2013). The Complaint provides the Court and Defendants with a clear roadmap of what statements are actionable and why. *See In re Honeywell*, 182 F. Supp. 2d at 416 (even if the pleading was complex, it could be understood by a child).

2. Defendants' made actionable misstatements and omissions between February 8, 2018 and June 4, 2018.

Defendants claim that the Complaint "utterly failed" to identify a single actionable statement made by any of the Defendants during the Class Period. Def Br. at 12. As demonstrated below in a chronological, statement-by-statement analysis of the allegations, Defendants are wrong.

On February 8, 2018, Pehl made the following statements in an Immunomedics press release and during the Company's 2Q18 earnings conference

call concerning the status of manufacturing processes at the Morris Plains manufacturing facility:

> ***I am pleased with the overall progress across clinical and manufacturing work streams, including successful validation runs. Our focus continues to be on compiling a BLA package that efficiently brings [IMMU-132] to market, and one that anticipates and addresses potential FDA requests going forward. As such, we now expect to file the BLA by the end of May 2018.***
>
> * * *
>
> ***I'm very pleased with the overall status and quality and can confirm that all critical work streams, including, for example, the previously discussed manufacturing validation runs, are yielding positive results. We are tracking slightly behind our previously communicated time schedule, as we seek to compile the most complete package possible that anticipates future FDA requests.***[4]

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[4] Defendants argue that various statements about being "pleased" with the progress at the Morris Plains facility (¶¶93-94), being "extremely well-prepared" to supply demand with the Morris Plains plant (¶98), and being in a "good state" to supply demand from Morris Plains (¶111), are inactionable puffery or corporate optimism. Def Br. at 16-17 & n.3, 21-22. But to be dismissed as puffery, the statements must be immaterial. *See In re Enzymotec Sec. Litig.*, 2015 WL 8784065, at *14 (D.N.J. Dec. 15, 2015). The Complaint alleges that these statements (along with Defendants' other Class Period statements) were misleading because Defendants failed to disclose that the Morris Plains facility had suffered a serious Data Integrity Breach. ¶¶105, 119. Defendants' statements, together with their material omissions, led investors to believe that all was well with Immunomedics' IMMU-132 manufacturing capabilities. *See Freshpet*, 2018 WL 394878, at *4-5 (holding statement that "[w]e are pleased with our initial test of Freshpet's new baked product" actionable because when it was made, the defendants failed to disclose the company had experienced "manufacturing issues, including a fire at Freshpet's Baxter Springs facility..."); *see also Carmignac Gestion, S.A. v. Perrigo Co. PLC*, 2019 WL 3451523, at *9 (D.N.J. July 31, 2019) ("The ultimate issue of materiality should not be decided as a matter of law unless 'the disclosures or omissions are so clearly unimportant that reasonable minds could not differ.'") (citation omitted).

* * *

> ***And that I can really confirm that all the critical submission-related work streams, including, for example, the previously discussed manufacturing validation runs, are providing positive results.***

* * *

> ***We adjusted our original [BLA filing] schedule to allow sufficient time to validate these assays and incorporate the data into our BLA submission package. So that was reason number one. Reason number two is that we had very aggressive initial time lines associated with the validation of the bioanalytical assays and testing for literally thousands of animal and human PK samples.***

¶¶93-95. On February 8, 2018, in the aftermath of discovering the Data Integrity Breach and having to report it to the FDA, Pehl chose to speak about the overall progress and status of the Morris Plains manufacturing facility, claiming that "all" manufacturing processes were yielding positive results, and that Immunomedics needed an extra two months to file the BLA due to past or anticipated interactions with the FDA. *Id.* These statements triggered Pehl and Immunomedics' duty to disclose complete and accurate information about the manufacturing issues and BLA delay. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 (2011) ("companies can control what they have to disclose under these provisions by controlling what they say to the market"); *Stichting Pensioenfonds ABP v. Merck & Co. Inc.*, 2012 WL 3235783, at *4 (D.N.J. Aug. 1, 2012) (when a defendant puts an issue "in play," it triggers a legal duty to disclose material information relating to

that topic).[5] Pehl and Immunomedics violated their duty to disclose accurate and complete information.

The Complaint specifically identifies the material facts Pehl failed to disclose. By the end of January 2018, Defendants had full knowledge that the Morris Plains manufacturing facility was experiencing a severe and un-remediated Data Integrity Breach due to Company personnel unlawfully manipulating and falsifying manufacturing data. ¶105. *See also* ¶¶79-80, 92. When Pehl made his February 8, 2018 statements, he knew that Immunomedics had informed the FDA about the Data Integrity Breach and had first-hand knowledge of its severity. ¶105. Despite the Data Integrity Breach being "a matter deserving [his] utmost attention" (¶79), Pehl deliberately withheld these facts from investors even as he elected to speak about the manufacturing process and the IMMU-132 BLA.[6] ¶¶10, 73, 105. Defendants

[5] Defendants also incorrectly claim the Complaint fails to allege any facts showing they were under a duty to disclose any of the alleged omitted facts. Def. Br. at 15-16. When a defendant chooses to speak, sells stock or is under some regulatory imposed duty to disclose, there is a legal obligation to disclose all material information. *Pfizer*, 754 F.3d at 173-174. Here, the Complaint is filled with allegations that triggered the duty to disclose. *See* ¶¶93-96, 98-99, 101, 108, 111-115, 117 (identifying Defendants who chose to speak and the topics they spoke of); ¶¶102-103 (Defendants making material omissions in offering documents subject to the Securities Act of 1933); and ¶104 (Immunomedics selling $300 million in stock).

[6] Defendants' claim that they did not need to disclose the Data Integrity Breach because "the Company believed [it] had been resolved," is both improper and inaccurate. Def Br. at 16. As explained in the Complaint, the Data Integrity Breach was not "resolved." Defendants repeatedly refused to provide real proof to the FDA of the scope of Data Integrity Breach and its purported remediation. ¶¶82, 84, 86-87, 89-90. The Complaint alleges that the FDA did not believe the Data Integrity

cannot viably claim that the Data Integrity Breach was immaterial and, at the same time, concede that the truth about the Data Integrity Breach was not publicly disclosed at the time of their statements. *See Perrigo Co. PLC*, 2019 WL 3451523, at *9 (materiality should not be decided as a matter of law unless reasonable minds cannot differ about the materiality of the omitted facts). As a result, the Complaint adequately alleges them to be false and misleading. *Williams v. Globus Med. Inc.*, 869 F.3d 235, 241 (3d Cir. 2017) (once a defendant speaks on a matter, "even an issue it had no independent obligation to address," that defendant cannot omit material facts about that subject).

During the February 8, 2018 earnings conference call, Rosenberg made the following statement about purported progress at the Morris Plains manufacturing facility and the Company's interactions with the FDA about IMMU-132's manufacturing: "***So this is very much sort of a check-the-box exercise. Nonetheless, we have to go through validation and incorporate the data into the BLA***." ¶95. When Rosenberg made this statement, he too had direct knowledge of the Data Integrity Breach, and the fact that Immunomedics immediately alerted the FDA about the problem. ¶105. *See also* ¶¶79-80, 92. Despite the severity of the Data

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Breach was remediated before the end of the Class Period and that Defendants knew this. At this stage of the case, accepting as true all the facts in the Complaint and drawing all reasonable inferences in favor of the plaintiff, Defendants' purported belief that the Data Integrity Breach was resolved (and therefore immaterial) must be rejected. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

Integrity Breach—an issue that was no "check-the-box" matter—Rosenberg made an unlawful decision to conceal the breach from investors. ¶¶95, 105. *See Roofer's Pension Fund v. Papa*, 2018 WL 3601229, at *8 (D.N.J. July 27, 2018) (omissions are actionable where "there is a substantial likelihood that a reasonable investor would consider it important in deciding how to act") (quotation and citation omitted).

During the February 8, 2018 earnings conference call, Garone spoke about his and the Company's communications with the FDA:

> ***So the FDA does have a lot of visibility. So we've had a couple of face-to-face meetings with them and written communications with them. We – they have seen our proposed release assays. They have seen our whole manufacturing process, the process flow diagrams and so forth. They have seen our proposed release assays, and it was in that discussion, actually, that they made the suggestion for the 3 additional assays. We discussed it with them and agreed with them that we should put those in place and are doing that.***

¶96.[7] When Garone made that statement, he too knew the Company had identified the Data Integrity Breach in January 2018 and had immediately informed the FDA—in writing—about the issue. ¶105. *See also* ¶¶79-80, 92. Like Pehl and Rosenberg, Garone deliberately withheld these facts from investors when he chose to speak about the Morris Plains manufacturing facility and processes. Garone's statement is

[7] As Defendants note, the Complaint inadvertently misattributes Garone's February 8, 2018 answer to a securities analyst's question, to Rosenberg. ¶96; Def Br. at 23. Garone was, in fact, the speaker who made the statement in ¶96 in response to a securities analyst's question during February 8, 2018 earnings conference call.

actionable. *Freshpet*, 2018 WL 394878, at *4; *In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 472 (E.D. Pa. 2014) (quoting *In re Merck & Co., Inc. Sec., Deriv. & ERISA Litig.*, 2012 WL 3779309 (D.N.J. Aug. 29, 2012) (noting "[w]hen a company 'put[s] an issue in play,' it acquires a duty to disclose information relating to that topic.").

On February 8, 2018, Immunomedics filed its 2Q18 Form 10-Q, signed by Pehl and Garone, with the SEC. ¶97. The Complaint specifically identifies the following misleading risk disclosure in the 2Q18 Form 10-Q:

> ***Our Information Systems may be subject to interruption or damage from a variety of causes, including power outages, computer and communications failures, system capacity constraints, catastrophic events (such as fires, tornadoes and other natural disasters), cyber risks, computer viruses and security breaches.***

Id. That risk disclosure was materially misleading when it was made because Immunomedics, Pehl, and Garone already knew that the Company's information system had suffered from a severe Data Integrity Breach. ¶105. *See also* ¶¶79-80, 92. In the Third Circuit, warning about a material risk that has already come to fruition is securities fraud. *Williams*, 869 F.3d at 242. *See also Wilson v. Merrill Lynch & Co., Inc.*, 671 F.3d 120, 130 (2d Cir. 2011) (noting "[c]autionary words about future risk cannot insulate from liability the failure to disclose that the risk has

transpired.").[8] The identical risk disclosure language quoted in ¶97 is alleged to be misleading in subsequent Immunomedics SEC filings: (a) ¶¶100 (May 9, 2018 3Q18 Form 10-Q); (b) ¶¶102-103 (incorporated by reference into the June 2018 Registration Statement and Prospectus); (c) ¶106 (August 23, 2018 Form 10-K); and (d) ¶109 (November 7, 2018 1Q19 Form 10-Q). Each subsequent utterance of this risk disclosure is equally actionable for the same reasons.[9] ¶105. *See In re Enzymotec*, 2015 WL 8784065, at *15 (duty to disclose under §10(b) triggered where risk had already materialized).

On February 22, 2018, Pehl stated the following about the status of the Morris Plains manufacturing facility, the delay in the filing of the BLA, communications with the FDA, and Immunomedics' preparedness for the FDA's inspection of the Morris Plains facility:

> ***We had previously communicated a timeline that was a couple of [months] earlier, but there is some additional work ongoing in terms of assays that the FDA has been asking us to do.***

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[8] *See also Rubinstein v. Collins*, 20 F.3d 160, 171 (5th Cir. 1994) ("To warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable event to happen when they have already occurred is deceit."); *In re Prudential Secs. Inc. P'ships Litig.*, 930 F. Supp. 68, 72 (S.D.N.Y. 1996) (no protection for someone who "warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away.").

[9] Pehl and Garone signed the 3Q18 Form 10-Q (¶100), Pehl, Garone, Aghazakeh, Canute, Hutt and Islam signed the June 11, 2018 Registration Statement (¶102), Pehl, Garone, Aghazakeh, Canute, Hutt and Islam signed the 2018 Form 10-K (¶106), and Pehl and Malik signed the 1Q19 Form 10-Q (109).

* * *

The other work stream that is ongoing and where we have really made great progress is process validation.

* * *

We hired someone as our head of quality who has eight years of experience as an FDA inspector. She turns basically every stone between New Jersey and New York, I can tell you. And she also brought in a lot of consultants with an FDA background, so we feel that we are extremely well prepared.[10]

Again, in choosing to speak about these topics, Pehl triggered a legal duty to be complete and accurate. *Matrixx*, 563 U.S. at 45 (when defendants chose to speak, they were under a duty to disclose those facts necessary to make the statements made, not misleading). Pehl did not disclose material facts. When he spoke about the BLA filing deadline being pushed out, Pehl failed to inform investors that it had been delayed because the Company was addressing a serious Data Integrity Breach. ¶105. When he spoke about the "great progress" Immunomedics was making in its manufacturing process work streams, Pehl remained silent about the fact that Immunomedics' manufacturing process had suffered a Data Integrity Breach. *Id.* Similarly, Pehl did not inform investors that it would be necessary for

[10] Despite Defendants' protestations, that statement is not mere puffery. Def. Br. at 16 n.3. Indeed, it is not a statement of general optimism, but is a statement of historical fact set in the context of addressing FDA preapproval issues at the Morris Plains manufacturing facility: Particularly, the then unstated and un-remediated Data Integrity Breach caused by Immunomedics employees' deliberate falsification of manufacturing processes and data.

Immunomedics (and its newly hired head of quality) to resolve the Data Integrity Breach to ensure the Company was "extremely well prepared" for the upcoming (and ultimately disastrous) FDA inspection. *Id.* In speaking about communications the Company had recently had with the FDA, moreover, Pehl failed to disclose that Immunomedics had been forced to notify the agency of the Data Integrity Breach. There is no basis to believe that investors would not have found these undisclosed facts about the Data Integrity Breach and Immunomedics' manufacturing process important and altering the total mix of information that existed at the time. *See Shah v. Zimmer Biomet Holdings, Inc.,* 348 F. Supp. 3d 821, 839 (N.D. Ind. 2018) (failure to disclose internal audit made pre-inspection statements misleading because results made it "entirely predictable" that company would receive a Form 483 once the inspection occurred).

On May 9, 2018, Pehl made a PowerPoint presentation to investors and analysts stating that the FDA pre-approval inspection of the Morris Plains facility was a "***Key 2018 Business Objective[]***," "***[p]re-approval inspection activities continue***" and that manufacturing "***[p]rocess [v]alidation***" was ongoing in anticipation of the FDA's pre-approval inspection. ¶99. But again, Pehl did not inform investors about the un-remediated Data Integrity Breach and the fact that Immunomedics had to alert the FDA about the breach, let alone what if anything the Company was doing to remedy the situation. ¶105. These statements are actionable.

In June 2018, Defendants caused Immunomedics to file a Form S-3ASR Registration Statement and Prospectus for the sale of over 13 million shares of the Company's common stock. ¶¶102-103. Defendants Pehl, Garone, Aghazakeh, Canute, Hutt, and Islam signed the Registration Statement pursuant to the Securities Act of 1933. *Id*. While the Form S-3ASR incorporated the misleading risk disclosure about potential threats to the Company's information systems, it did not disclose any facts about the Data Integrity Breach. ¶¶102, 103. The Securities Act of 1933 prohibits the omission of "a material fact required to be stated" in the Registration Statement. 15 U.S.C. §77k(a). The SEC's instructions to Form S-3 required Defendants to disclose "any and all material changes in [Immunomedics] affairs which have occurred since the end of the latest fiscal year for which certified financial statements were included … and which have not been described in a report on Form 10-Q or Form 8-K filed under the Exchange Act." Instructions to Form S-3, Item 11(a). The requirements of the registration forms, prescribed by the SEC, are an integral part of disclosure law. *See* 17 C.F.R. §§230.400, 230.401 (the issuer's registration statement and prospectus shall conform to the applicable rules and forms), 239.0-1, *et seq*. *See also Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1222 n.37 (1st Cir. 1996) ("[I]n the context of a public offering, plaintiffs who (through the market) rely upon the completeness of a registration statement or prospectus may sue under Section 10(b) [of the Exchange Act] for nondisclosures of material facts

omitted from those documents in violation of the applicable SEC rules and regulations").

Immunomedics, Pehl, Garone, Aghazakeh, Canute, Hutt and Islam, did not disclose the Data Integrity Breach in any SEC filing dated between January 1 and May 31, 2018. And they failed to comply with their legal duty to disclose the Data Integrity Breach in the June 2018 Registration Statement and Prospectus.[11] ¶¶102-103, 105. As a result, the omissions of material fact in Immunomedics' June 2018 offering documents are actionable under Section 10(b).[12]

3. Defendants made actionable misstatements and omissions between August 23, 2018 and January 17, 2019.

On August 23, 2018, Immunomedics filed its 2018 Form 10-K Form with the SEC, and Pehl, Garone, Aghazakeh, Canute, Hutt, and Islam signed the document. ¶106. The Complaint specifically identifies misleading risk disclosure language in

[11] Defendants make the erroneous argument that they cannot be held liable for misleading statements in the June 2018 Prospectus because nobody signed it. Nobody signed the June 2018 Prospectus because it was issued pursuant to the June 2018 Registration Statement, which Defendants did sign. *See Fed. Hous. Finance Agency v. Nomura Holding America, Inc.*, 104 F. Supp. 3d 441, 546 n.154 (S.D.N.Y. 2015).

[12] In June 2018, Immunomedics sold 13.225 million shares of common stock for total net proceeds of $300 million. ¶¶102-104. Along with the duty to disclose triggered by the requirements of the Securities Act of 1933, this $300 million in insider sales of stock by Immunomedics triggered the Company's, as well as Pehl, Garone, Aghazakeh, Canute, Hutt, and Islam's, duty to disclose the existence of the Data Integrity Breach and the Company's immediate notification to the FDA of that issue. *Pfizer,* 754 F.3d 173-74 (a duty to disclose arises where a defendant sells stock or otherwise falls under a regulatory duty to speak the full truth).

the Form 10-K:

> ***If we, or any of our collaboration partners, or our or their contract manufacturers, cannot successfully and efficiently manufacture the compounds that make up our products and product candidates, our ability, and the ability of our collaboration partners, to sell products and conduct clinical trials will be impaired.***
>
> * * *
>
> ***The FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections, to which the facility must adequately respond in order to avoid escalated regulatory concerns. If our manufacturing facility or those facilities of our collaboration partners and our respective contract manufacturers or processors do not comply with applicable cGMPs and other regulatory requirements, in addition to regulatory enforcement, we may be subject to product liability claims, we may be unable to meet clinical demand for our products, and we could suffer delays in the progress of clinical trials for products under development and of potential approval and commercialization.***

¶106. Notably, the disclosures concern potential future events: "***If*** we … cannot successfully and efficiently manufacture … our ability … to sell products and conduct clinical trials will be impaired" and "[t]he FDA generally will issue a notice on Form 483 ***if*** it finds issues with respect to its inspections…" *Id.* Both risk disclosures were misleading because the FDA had already issued a Form 483 to Pehl and Immunomedics management on August 14, 2018, and, the same day, FDA inspectors orally chastised Immunomedics personnel (including Rosenberg) for repeatedly refusing to prove the breach had been remediated. ¶119. *Merck,* 2012 WL 3235783, at *4 (when a defendant puts an issue "in play," it triggers a legal duty to

disclose material information relating to that topic); *Freedman v. St. Jude Med., Inc.*, 4 F. Supp. 3d 1101, 1114 (D. Minn. 2014) (failure to disclose Form 483 actionable where defendants' statements otherwise led to impression that the company did not have any adverse interactions with the FDA). A reasonable investor would want to know these facts so she could make an informed decision about whether the Company could meet demand for IMMU-132 in the future or whether Immunomedics would suffer potential delay in FDA approval as a result of the un-remediated Data Integrity Breach. *See In re Enzymotec,* 2015 WL 8784065, at *15 (duty to disclose under Section 10(b) triggered where risk warned of had already materialized).

Further, if the FDA could not assess whether Data Integrity Breach at Morris Plains facility had been corrected (¶¶82, 119)—and given the breach was the result of Immunomedics' deliberate falsification of manufacturing processes and data—there was heightened risk the FDA would not be approving IMMU-132's manufacture at Morris Plains. Defendants seek to slough off those material facts, citing to *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31 (1st Cir. 2014), and argue "courts have found receipt of a Form 483 to be immaterial." Def Br. at 21. But in *Genzyme*, the First Circuit noted that the purported materiality of the Form 483 in that case "need not be reached," and clarified that a Form 483 may very well be material depending on the facts of the case. *In re Genzyme*, 754 F.3d at 42 & n.4.

The identical risk disclosure language quoted in the Company's 2018 Form 10-K (¶106) is also alleged to be misleading as stated in Immunomedics' 1Q19 Form 10-Q (filed November 7, 2018, and signed by Pehl and Malik). ¶109. The Form 483 risk disclosure language in the 1Q19 Form 10-Q is misleading for the same reasons it is misleading in the 2018 Form 10-K. ¶119.

Defendants' motion conspicuously avoids arguing that the August 2018 Form 483, given the facts here, was immaterial. It would be baseless to do so given the circumstances surrounding the Form 483 in this case, which was issued chiefly because of Defendants' repeated refusal to provide sufficient evidence to the FDA to prove remediation of a significant and serious Data Integrity Breach at the Morris Plains manufacturing facility. *See Pub. Pension Fund Grp. v. KV Pharma. Co.*, 679 F.3d 972, 982-83 (8th Cir. 2012) (receipt of a Form 483 can be a material depending on the facts of the case); *McGuire v. Dendreon Corp.*, 2008 WL 5130042, *6 (W.D. Wash. Dec. 5, 2008) (receipt of a Form 483 can have a material impact on market expectations); *In re Enzymotec*, 2015 WL 8784065, at *14 (only where alleged omission is so obviously unimportant to an investor can court can find it immaterial as a matter of law).

Defendants' invocation of *In re Egalet Corp. Sec. Litig.*, 340 F. Supp. 3d 479, 508 (E.D. Pa. 2018) is unavailing; in fact, it supports Plaintiffs' position. "By way of illustration, . . . if the FDA had already decided the scope of [exclusivity] and

[defendant] were speculating about the effect of the FDA's determination, [defendant] would be expected to provide accurate, or at least not misleading, information about the effect of the FDA's determination." *Id.* Here, at the time of the statement, the FDA had determined that Immunomedics had failed to adequately respond. Thus, the risk of escalating regulatory concerns had already materialized.

On November 7, 2018, Pehl made the following statement concerning steps necessary for FDA approval, including approval of the Morris Plains manufacturing facility, during a conference call with analysts and investors: ***Based on recent mid-cycle discussion with the FDA, the company will continue to work closely and collaboratively with the agency to address outstanding review issues*** . . ." ¶108. By the time Pehl made this statement, Defendants had not only received the Form 483, they had also repeatedly refused to provide proof of either the scope or remediation of the Data Integrity Breach to the FDA. ¶119. This is a classic case of a material omission. *See e.g.*, *Williams*, 869 F.3d at 241 (once a defendant speaks on a matter, "even an issue it had no independent obligation to address," that defendant cannot omit material facts about that subject); *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1100, 1129 (C.D. Cal. 2005) (failure to disclose receipt of Form 483 actionable when made in relation to statements about FDA approval).

On November 7, 2018, Immunomedics filed its 1Q19 Form 10-Q, and Pehl and Malik signed the document. ¶110. The 1Q19 Form 10-Q contained a new risk

disclosure about employees engaging in fraud that may violate FDA rules:

> ***Our employees and our independent contractors, principal investigators, consultants or commercial collaborators, as well as their respective sub-contractors, if any, may engage in misconduct or fail to comply with certain regulatory standards and requirements, which could expose us to liability and adversely affect our reputation.***
>
> ***Our employees … may engage in fraudulent or other illegal activity, which may include intentional, reckless or negligent conduct that violates, among others, (a) FDA laws and regulations, or those of comparable regulatory authorities in other countries, including those laws that require the reporting of true, complete and accurate information to the FDA, (b) manufacturing standards[.]***
>
> * * *
>
> ***Any misconduct or failure by our employees and our independent contractors, principal investigators, consultants or commercial collaborators, as well as their respective sub-contractors, if any, to comply with the applicable laws or regulations may expose us to governmental investigations, other regulatory action or lawsuits. If any action is instituted against us as a result of the alleged misconduct of our employees or other third parties, regardless of the final outcome, our reputation may be adversely affected and our business may suffer as a result. If we are unsuccessful in defending against any such action, we may also be liable to significant fines or other sanctions, which could have a material and adverse effect on us.***

¶110. But Defendants already knew that Immunomedics employees had engaged in the unlawful falsification of data and documents about manufacturing processes at the Morris Plains facility. ¶¶110, 119. *Williams*, 869 F.3d at 242 (warning about the possibility of a material risk that has already occurred is, at a minimum, misleading).

Defendants claim that all the Complaint's allegations of misleading risk disclosures are inactionable because, when the statements were made, the FDA had

not rejected the IMMU-132 BLA. Def Br. at 18. This argument lacks merit: the "risk disclosure" Defendants selected to highlight in their motion (the risk that the FDA would withhold approval of IMMU-132) is not the risk disclosure being challenged in this case. The Complaint alleges that Defendants warned investors about the consequences to Immunomedics' clinical information and patient data ***if*** a security breach happened, but that information and data was already compromised by the undisclosed Data Integrity Breach. Defendants also warned investors about possible ramifications ***if*** Immunomedics received a Form 483 or ***if*** Company employees engaged in misconduct involving manufacturing standards. Yet, when those warnings were made, Defendants knew those risks had already materialized.

On November 13, 2018, Defendant Malik stated the following about the Company's manufacturing capabilities at a Credit Suisse Healthcare Conference: "***Where we are today is we're in a good state to supply the market for the next few years based on the current [Morris Plains manufacturing] infrastructure that we have***." ¶111. But, as Malik knew, by November 13, 2018, Defendants already received the Form 483, responded to it, and again refused to provide the FDA with any documentation to prove up scope and purported remediation of the Data Integrity Breach. ¶¶89, 119. An FDA rejection of the BLA would preclude Immunomedics from commercially manufacturing IMMU-132 at the Morris Plains facility, either permanently or at least until Immunomedics proved that it had

remedied the problems. ¶¶73, 119(c)-(d).[13] Malik disclosed none of these material, negative facts when he claimed the Morris Plains facility was "in a good state" to supply the market with IMMU-132. So Malik's statement is actionable. *See Freshpet*, 2018 WL 394878, *4 ("[w]e are pleased with our initial test of Freshpet's new baked product" actionable because defendants failed to disclose manufacturing issues); *see also In re Sprint Corp. Sec. Litig.*, 232 F. Supp. 2d 1193, 1218 (D. Kan. 2002) (failure to disclose material information can render even optimistic statements actionable).

On the morning of December 20, 2018, news about the Form 483 and Data Integrity Breach was disclosed in an analyst report. ¶¶112, 122. Defendants tried to temper the disclosure through statements made through Company-friendly analysts. Among the statements published in analyst reports on December 20, 2018 were:

> ***We spoke with management who pointed out to us that this Form-483 was already received 4 months ago, this August, and the company believes it has addressed manufacturing issues cited in the form.***
>
> ***Mgt. believes they have communicated with the FDA about the issues prior to the 483 and have worked to remediate all the key issues. Mgt. further indicated that if these issues, including the 483, were material they would have issued a release highlighting the issues.***
>
> ***We have spoken with management this morning regarding observations and understand that they occurred as part of a pre-approval inspection in early August following BLA acceptance and***

[13] These well-pled facts undermine Defendants' contention that the Complaint does not identify how Malik's November 13, 2018 statement would have misled investors. Def Br. at 20-21.

> ***granting of priority review status in July and that the observations are "old news" and a remediation has long been put in place.***
>
> ***While IMMU, appropriately, will not characterize FDA response to remediation efforts so close to a PDUFA date the company suggested that if there are major risks to the filing it would have to disclose more specifics.***
>
> ***As above, the company confirmed that it received the inspection reports in August of this year, and feel that it has addressed all of the issues raised during the inspection. While mgmt did not disclose specific content, they were outwardly confident that everything was adequately addressed, and further that they are confident in a positive decision by the FDA on or before the Jan PDUFA date.***

¶¶113-117. Pehl and Malik were the only members of Immunomedics' management (and the only people at the Company) that had the authority to make these statements to securities analysts. ¶¶29, 32. They had ultimate authority and control over the dissemination of these statements to the analysts. ¶¶30, 33. And, the undisputed text of the reports makes it clear that the analysts merely repeated these Defendants' statements.[14] Defendants do not deny that Pehl and Malik had ultimate control over those statements and cannot argue that Immunomedics would not be liable for the

[14] Defendants' reliance on *Janus Capital Grp., Inc. v. First Deriv. Traders*, 564 U.S. 135 (2011), for the proposition that they cannot be liable for statements made by others is misplaced. That Pehl and Malik's statements were published in analyst reports does not insulate them from liability. When a third-party rearticulates a statement made by a defendant, the defendant is a speaker for §10(b) liability. *Janus*, 564 U.S. at 142-43.

statements made to analysts by the Company's senior management.[15] Here, the Complaint sufficiently pleads the statements made to and published by analysts as actionable. *See Washtenaw Cnty. Emps.' Ret. Sys. v. Walgreen Co.*, 2019 WL 4597518, at *5 (N.D. Ill. Sept. 23, 2019) (holding that statements made by senior management to analysts, then parroted by those analysts, are actionable under §10(b)).

The Complaint alleges that when these statements were made to the analysts, Defendants knew they repeatedly refused to provide the FDA with the requested and necessary proof about the scope of the Data Integrity Breach and whether it had ever been remediated (with the final such refusal occurring on September 4, 2018). ¶119. The FDA informed Defendants that the agency could not confirm whether Immunomedics remediated the Data Integrity Breach because Defendants repeatedly failed to prove it. ¶¶82, 84, 86-87, 89-90. For these reasons, the statements to analysts assuring investors that the manufacturing issues identified in the Form 483 had been resolved, that a remediation for the Data Integrity Breach had long been put into place, and that the Form 483 issues posed no major risks to FDA approval, were all materially misleading when made and thus actionable.

Lastly, on January 10, 2019, Pehl told investors: "***We've got the [Form] 483s***

[15] *See Glickenhaus & Co. v. Household Int'l, Inc.,* 787 F.3d 408, 426 (7th Cir. 2015) (nothing in *Janus* "undid the long-standing rule" that a corporation is liable for the statements made by employees who have authority to make them).

in August. We did take care of [the issues] very early."[16] ¶118. But Pehl knew that the critical issues raised in the Form 483 were not resolved: Defendants refusal to provide the FDA with evidence identifying the actual scope of Data Integrity Breach or whether it was ever remediated. ¶¶82, 84, 86-87, 89-90. When Pehl elected to speak about the status of the Form 483, he was required to disclose all the material information about that status. He did not do that. *See Gov't of Guam Ret. Fund v. Invacare Corp.*, 2014 WL 4064256, at *6 (N.D. Ohio Aug. 18, 2014) (defendants false statement that it "ha[d] addressed" the FDA's concerns from a Form 483 actionable).

B. The Complaint adequately alleges scienter.

To plead scienter, a plaintiff must "allege facts giving rise to a strong inference of either reckless or conscious behavior." *Inst. Inv. Grp. v. Avaya, Inc.*, 564 F.3d 242, 267 (3d Cir. 2009). Recklessness is conduct that constitutes "an extreme departure from the standards of ordinary care, . . . which presents a danger of

[16] Defendants claim that Pehl's January 10, 2019 statement that Immunomedics purportedly "[took] care of the [Form 483] very early" militates against a finding of falsity about "the data integrity issue." Def Br. at 20-21. Not only is the argument incorrect, but it is pure misdirection. The Complaint alleges that Defendants did not "take care of" the Form 483 issues with the Data Integrity Breach. To the contrary, during the August 2018 inspection and in Immunomedics' September 4, 2018 final written response to the Form 483, Defendants repeatedly refused to provide the FDA with any written evidence to back up their claims about the reach of the Data Integrity Breach and whether it had been remediated. ¶¶82, 84, 86-87, 89-90. For these reasons, the statement "we did take care of issues very early" (¶118) was either false or, at minimum, incomplete and misleading to investors.

misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Id*. at 267 n.42 (quotation omitted). A plaintiff "must sufficiently plead defendants' knowledge of facts or access to information contradicting their public statements… [*i.e*., that] Defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *In re Elec. For Imaging, Inc. Sec. Litig.*, 2019 WL 397981, at *6 (D.N.J. Jan. 31, 2019) (quotation omitted). The inference "need not be irrefutable, *i.e.* of the smoking-gun genre, or even the most plausible of competing inferences," but must merely be "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 324 (2007). The question is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id*. at 323 (emphasis in original). Plaintiffs here have plead a strong inference of scienter based on allegations about both Defendants knowledge of the true, undisclosed facts about Immunomedics' Data Integrity Breach and Form 483 issues and the Defendants' motive and opportunity to commit the fraud.

1. Defendants' knowledge and reckless disregard of Immunomedics' Data Integrity Breach and the Form 483 Issues supports scienter.

Where, as here, the fraud hinges on the non-disclosure of material information, "evidence that the defendants had actual knowledge of the facts is

sufficient to show scienter." *In re Great Atlantic and Pacific Tea Co.*, 103 Fed. App'x 465, 468-69 (3d Cir. 2004); *see also In re CenturyLink Sales Practices and Sec. Litig.*, 2019 WL 3431600, at *10 (D. Minn. July 30, 2019) ("One classic fact pattern giving rise to a strong inference of scienter is that defendants made statements when they knew or had access to information suggesting that these public statements to be materially inaccurate.")

Plaintiffs specifically allege that each Defendant had direct knowledge of the facts underlying the Data Integrity Breach and the FDA's reaction to it. As set forth in the Complaint, "Pehl and the Board of Directors" (*i.e.*, Defendants Aghazadeh, Canute, Hutt, and Islam) were "notified of the Data Integrity Breach" on January 31, 2018 and its details in the "days immediately following." ¶¶79, 83. Defendant Rosenberg was a consultant and then specifically hired to address Chemistry, Manufacturing and Controls ("CMC") issues at Immunomedics' Morris Plains facility, was present during the FDA's pre-approval inspection between August 6-14, 2018, and answered (or refused to answer) the FDA's questions about the Data Integrity Breach. ¶¶37, 82, 86-87. Pehl and Immunomedics management also received and responded to the FDA's Form 483 in August 2018. ¶¶82-83, Exs. B and C. And both Malik and Garone, senior members of Immunomedics' management, were required in accordance with the Company's Senior Officer Code of Ethics and Communications Policy, to be aware of material information and

ensure that it was reported to investors. ¶¶32, 35. These allegations identifying actual knowledge of and access to the facts Defendants are alleged to have misstated and omitted establish a strong inference of scienter. *See, e.g., Freshpet*, 2018 WL 394878, at *5 ("Plaintiffs properly allege scienter based on Defendants' conscious decision to omit presently known facts."); *Monk v. Johnson & Johnson*, 2011 WL 6339824, at *8 (D.N.J. Dec. 19, 2011) (allegations of "defendants knowledge of facts or access to information contradicting their public statements" establishes a strong inference of scienter). The Complaint also pleads that IMMU-132 was Immunomedics only viable product and that, as a biologic, the ability to demonstrate an ability to successfully manufacture IMMU-132 was vital. ¶¶4, 54, 68-74. *See SEB In. Mgmt. AB v. Endo Int'l, PLC*, 351 F. Supp. 3d 874, 905 (E.D. Pa. 2018) ("Knowledge under a recklessness theory can be established by demonstrating that the fact was so obviously material that defendant must have been aware both of its materiality and that its non-disclosure would likely mislead investors.").[17]

Defendants argue that "Plaintiffs [do not] point to any documents, reports, or

[17] Given the specific allegations about Defendants' knowledge of the true facts when they made the alleged false and misleading statements, their suggestion that this is just a case of "fraud by hindsight" is a non-starter. Def Br. at 25. Defendants did not need to be "clairvoyant." *Id*. They needed to be honest. When Defendants made their statements to investors, they had the facts about the Data Integrity Breach and Form 483 issues that they misstated and omitted. *See*, *e.g.*, *In re NeoPharm, Inc. Sec. Litig.*, 2003 WL 262369, at *14 (N.D. Ill. Feb. 7, 2003) (scienter found where allegations show that defendants made their false statements while in possession of non-public information that directly contradicted their statements).

other information" to support their scienter allegations. Def Br. at 25. That is not true. Plaintiffs not only detail the documents and reports underlying Defendants receipt of information about the Data Integrity Breach and Form 483 issues (including Defendants refusal to provide the FDA with information about the Data Integrity Breach) (¶¶9-10, 17, 79-91, 105, 119), they attach those documents to the Complaint. *See* Compl., Exs. A-C. The "Initial Response to the Inspectional Observations," for example, states "[t]he allegations [regarding the Data Integrity Breach] were first raised on Wednesday, January 31, 2018, and in the days immediately following the Company escalated the matter up to the CEO, engaged counsel to investigate... [and] briefed board leadership." Compl. Ex. A, at 2. The FDA's August 14, 2018 Form 483 was specifically issued to Defendants Pehl and Immunomedics. Compl. Ex. B, at 1. And the FDA's EIR identified Defendant Rosenberg as "the most responsible person at the [Morris Plains] facility." Compl. Ex. C, at 1. Indeed, none of the Defendants dispute that they were aware of the Data Integrity Breach as of January 2018. And none of the Defendants dispute that they were aware of the Form 483 issues, including Immunomedics refusal to provide the FDA with requested information about the Data Integrity Breach, as of August 2018.

Defendants also argue that scienter cannot be plead "merely by virtue of their positions at the Company." Def Br. At 30. But Plaintiffs do not "merely" rely on the Defendants' executive positions at Immunomedics. As discussed, Plaintiffs identify

how the information about the Data Integrity Breach and Form 483 issues were provided and available to each of the Defendants. That this information concerned the Company's only viable drug candidate and the critical manufacturing process for that drug, and that Defendants made statements assuring investors about that manufacturing process, when considered together with the Defendants executive and director positions, supports a strong inference of scienter. *See Perrigo Co. PLC*, 2019 WL 3451523, at *16 ("misrepresentations concerning 'core matters of central importance to a company may support an inference of scienter when accompanied by some additional allegation of specific information conveyed to management and related to the fraud.'" (quoting *Martin v. GNC Holdings, Inc.*, 757 F. App'x 151, 155 (3d Cir. 2018) (additional quotation and citation omitted)); *Mill Bridge Inc. v. Benton*, 2009 WL 4639641, at *31 (E.D. Pa. Dec. 3, 2009) ("[W]hile a court may not infer that a defendant was aware of information merely by virtue of his or her position within a company, where the information relates to the organization's core business, such facts are powerful circumstantial evidence of scienter."). As one court recognized, "it is 'absurd' to think that the CEO and CFO of a pharmaceutical company would be unaware of the alleged substandard, non-compliant conditions pervading their company's manufacturing and quality control divisions—the heart of a company whose main business is manufacturing pharmaceuticals for public consumption." *Mulligan v. Impax Labs., Inc.*, 36 F. Supp. 3d 942, 970 (N.D. Cal.

2014); *see also In re Dr. Reddy's Lab. Ltd. Sec. Litig.*, 2019 WL 1299673, at *16 (D.N.J. Mar. 21, 2019) (executives' knowledge about manufacturing problems inferred because "as a pharmaceutical company, a core aspect of [the] business 'is ensuring compliance with safety and manufacturing quality standards.'"). The importance of IMMU-132 and the biologic's manufacturing process and Defendants' roles at Immunomedics simply buttress the undisputed allegations that Defendants knew about the Data Integrity Breach before February 2018 and knew about the Form 483 issues as of August 2018.

Unable to dispute that they knew about the Data Integrity Breach and Form 483 issues during the Class Period, Defendants fall back on their strawman. They argue that Plaintiffs case is simply that Defendants "must have known that the data integrity issue would cause the FDA to withhold approval of IMMU-132." Def Br. at 25. Those are not Plaintiffs' allegations. The wrongdoing here is that Defendants failed to disclose the Data Integrity Breach, the Form 483 issues, and the fact that Immunomedics refused to provide the FDA with requested information about the Data Integrity Breach, ***not*** that Defendants failed to predict the outcome of the IMMU-132 BLA. ¶¶105, 119. Whatever Defendants may have personally thought about the prospects of FDA approval, it does not change that they misstated and omitted material facts about the Data Integrity Breach and Form 483 issues, and the Complaint specifies that they knew or recklessly disregarded these material facts.

That satisfies the requirement to plead a strong inference of scienter.

Defendants also accuse Plaintiffs of "group pleading" and claim "Plaintiffs lump together all Defendants by claiming that… they, collectively, 'withheld' information from investors." Def. Br. At 26. Again, not true. The Complaint identifies (and attaches documents establishing) that, among other things, Defendants Pehl, Aghazadeh, Canute, Hutt, and Islam were all directly notified of the Data Integrity Breach in January 2018, Defendant Rosenberg was identified as "the most responsible person" at the Morris Plains facility, Defendants Malik and Garone had direct responsibility for the accuracy of the statements to Immunomedics investors, and Pehl and Immunomedics management received and responded to the FDA's Form 483. These allegations of knowledge are buttressed by allegations about the statements made by specific Defendants about Immunomedics manufacturing process and the IMMU-132 BLA. *See*, *e.g.* ¶¶93-98. As the Third Circuit held in *Avaya*, "[a]mong the facts alleged by Shareholders, the most powerful evidence of scienter is the content and context of [defendants'] statements themselves." 564 F.3d at 269; *see also Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) (allegations that "defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter."). And the allegations about the Individual Defendants' scienter are enough to support a strong inference of scienter for Immunomedics. *See*

Sun v. Han, 2015 WL 9304542, at *12 (D.N.J. Dec. 21, 2015) (finding corporate scienter where "'pleaded facts [] create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter.'"); *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc.*, 531 F.3d 190, 195 (2d Cir. 2008) ("the most straightforward way to raise such an inference [of scienter] for a corporate defendant will be to plead it for an individual defendant.").

2. Defendants' motive and opportunity also supports the strong inference of scienter.

While these facts regarding Defendants' knowledge are more than enough to evidence a strong inference of scienter, and "[t]he absence of a motive allegation is not fatal" (*Tellabs*, 551 U.S. at 325), the Complaint also identifies Defendants' motive to mislead the market. Plaintiffs allege that, as a result of their fraudulent conduct, Defendants were able to sell $300 million of Immunomedics stock in a June 2018 Secondary Offering. ¶¶102-104, 129-130. These allegations, taken together with the specific allegations of knowledge, support a strong inference of scienter.

Defendants' do not even respond to the allegations concerning the stock sale; instead they claim that Plaintiffs only allege Immunomedics was under "financial pressure" and argue that "all that is alleged here" is a "corporation's desire to increase its stock value" or "meet analyst and market expectations." Def. Br. at 28-29. But Defendants fail to address the allegation that Defendants sold $300 million of Immunomedics stock while keeping the truth about the Data Integrity Breach

from investors. ¶¶15, 102-104, 129-130. That stock was sold at a price only $2 below Immunomedics Class Period (and all-time) high, and over $10.00 per share higher than the Company's stock price traded immediately after the Class Period. ¶¶129, 135. These facts support the already strong inference of scienter. As the Court held in *Freshpet*, 2018 WL 394878, at *6, "plaintiffs have pled motivation" where "[t]hey allege that the Individual Defendants timed their Secondary Offering at just below [the] peak price." *See also In re Enzymotec*, 2015 WL 8784065, at *19 ("Crucially, Lead Plaintiffs specifically tie together the time of [the Secondary Offering] with core of the alleged misrepresentations"); *In re Portal Software, Inc. Sec. Litig*, 2005 WL 1910923, at *12 (N.D. Cal. Aug. 10, 2005) ("[P]laintiffs' contention that defendants were motivated to inflate artificially [the company's] stock price in the short term in order to conduct a successful secondary public offering and obtain much-needed operating capital does allege facts of a palpable motive for fraud.").[18]

[18] Plaintiffs also allege that Defendants Pehl and Garrone were both forced to resign as the consequences of their deception became known. Defendants contest the importance of these allegations. Def Br. at 31. But these allegations do not stand in isolation. Rather, Plaintiff identifies that Pehl resigned only "three weeks after the FDA sent a written communication to Immunomedics, which included a copy of the FDA's [EIR] concerning, among other things, the Data Integrity Breach at the Morris Plains manufacturing facility" (¶¶28, 92), and Garone resigned on August 24, 2018, just ten days after Immunomedics received the Form 483. ¶107. "[G]iven the timing of the announcement[s]," these resignations provide "some probative value" in inferring a strong inference of scienter (and certainly cannot support any opposing inference of non-fraudulent intent). *Papa*, 2018 WL 3601229, at *20. *See also W. Palm Beach Police Pension Fund v. DFC Glob. Corp.*, 2015 WL 3755218, at *17 (E.D. Pa. June 16, 2015) ("[W]hen considering the totality of Plaintiffs'

"Though it is not necessary to plead motive to establish that a defendant acted with scienter," the allegations regarding Defendants' stock sale is "persuasive when conducting a holistic review of the evidence." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 245 (3d Cir. 2013). Viewed holistically, Plaintiffs' allegations of Defendants' knowledge, motive, and opportunity, give rise a strong inference of scienter.

III. The Complaint properly alleges § 20(a) control person liability.

To allege a §20(a) violation, the pleading must show an underlying violation of Section 10(b), circumstances establishing a defendants' control over the entity's actions, and the defendant's culpable participation in the fraud. *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 284-285 n.16 (3d Cir. 2006).[19]

Defendants contend the Complaint fails to allege that any defendant was a control person during the Class Period. Def Br. at 33. Not so. Defendants ignore that Pehl, Malik, Garone, and Rosenberg were not only Immunomedics' highest-ranking executives, they were personally responsible for reviewing the Company's public

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scienter allegations, the Court concludes that the resignation of key executives, including the President and COO responsible for implementing new regulations, bolsters the evidence of conscious or reckless behavior.").

[19] The Complaint states a 10(b) claim for the discussed reasons. While culpable participation need not be pled, *Papa*, 2018 WL 3601229, at *24, n.24; *Belmont v. MB Inv. Partners Inc.*, 708 F.3d 470, 484, n.20 (3d Cir. 2013) (declining to address district split on question), it is present here. Each Defendant had direct knowledge of the Data Integrity Breach, the company's inadequate response, and the Form 483. Yet the Individual Defendants deliberately and repeatedly concealed the truth from investors while selling 13.225 million shares of Company stock.

statements for accuracy and possessed the authority to make alleged misleading statements on behalf of Immunomedics (and, in fact, did so). ¶¶28-30. Defendants do not dispute that Immunomedics' Board members Aghazadeh, Canute, Hutt, and Islam each had authority over the Company and controlled the dissemination of the Company's alleged misleading statements by signing the Company's June 2018 Registration Statement, causing the June 2018 Prospectus to be filed pursuant to the Registration Statement, as well as signing the Company's 2018 Form 10-K (all of which contained misleading statements and material omissions). ¶¶102-103, 106. Further, Aghazadeh, Canute, Hutt, and Islam deliberately sat idle while the person they were charged to oversee—Pehl—continued to mislead investors and securities analysts about the Data Integrity Breach and Form 483 issues in January 2019. ¶¶113-115, 117. *See Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 478 (3d Cir. 2013) (when a defendant knows about the alleged fraud, secondary liability may be imposed on control persons where their inaction prevented the discovery of the unlawful conduct). Defendants Aghazadeh, Canute, Hutt, and Islam were not just "facade[s] for fraud," they were "culpable confederate[s]" in the unlawful deception of investors. *See Straub v. Vaisman & Co.*, 540 F.2d 591, 596 (3d Cir. 1976).

CONCLUSION

Defendants' motion should be denied.

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Respectfully submitted,

/s/ James E. Cecchi

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