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**Docket: 1584CV02665-BLS2**

**Date: February 21, 2017**

**Parties: ANTHONY FORTUNATO, Individually and on Behalf of All Others Similarly Situated v. AKEBIA THERAPEUTICS, INC., and Others[1]**

**Judge: Kenneth W. Salinger**

MEMORANDUM AND ORDER ALLOWING DEFENDANTS' MOTION TO DISMISS

Anthony Fortunato asserts claims on behalf of himself and a putative class of investors in Akebia Therapeutics, Inc. The amended complaint alleges that Akebia's final registration statement and prospectus for its initial public offering were misleading because they did not disclose interim results from an ongoing clinical drug trial. Fortunato claims that as a result Akebia, senior executives and directors who signed the offering materials, and the investment banks that acted as underwriters for the IPO all violated the federal Securities Act of 1933.

Defendants move to dismiss this action on the grounds that: (1) the federal courts have exclusive jurisdiction over Securities Act class actions; (2) Fortunato's claims sound in fraud and he has failed to state the factual basis for his claims with sufficient particularity; and (3) if particularity is not required, Fortunato has failed to allege facts that plausibly suggest he and the putative class are entitled to relief.

The Court concludes that the first two arguments are without merit. State courts have concurrent jurisdiction to hear Securities Act class actions; the Securities Litigation Uniform Standards Act of 1998 did not take that power away. And Fortunato need not meet the heightened pleading standard that applies to fraud claims because he alleges only negligent misrepresentations and expressly disclaims any claim of intentional or reckless fraud.

But the Court will ALLOW the motion to dismiss because the facts alleged by Fortunato do not plausibly suggest that he is entitled to any relief under the

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[1] John P. Buler, Jason A. Amello, Muneer A. Satter, Campbell Murray, M.D., Jack Nielsen, Anupam Dalal, M.D., Giovanni Ferrara, Kim Dueholmd, Ph.D, Duane Nash, M.D., Morgan Stanley & Co. LLC, Credit Suisse Securities (USA) LLC, UBS Securities LLC, and Nomura Securities, International.

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Securities Act. Fortunato claims that the offering materials issued by Akebia for its March 2014 IPO were misleading because they failed to disclose preliminary information from Akebia's ongoing Phase 2b clinical trial of its first potential pharmaceutical product suggesting that patients receiving the test drug were more likely to experience serious adverse events than patients who received a placebo. But the complaint and the materials it cites make clear that this Phase 2b study was a double-blind, placebo controlled, randomized trial. They also indicate that this trial was not completed, and thus the study results were not unblinded to reveal which patients received the trial drug and which received a placebo, until six months or more after the IPO. Fortunato alleges no facts plausibly suggesting that Defendants knew or could have known any material information about the double-blind Phase 2b trial before Akebia's IPO or, indeed, at any time before Akebia publicly released the final trial results in October 2014.

1. Subject Matter Jurisdiction. Fortunato asserts claims on behalf of himself and a proposed class of more than fifty investors under sections 11,

12(a)(2), and 15 of the federal Securities Act of 1933; these provisions are codified as 15 U.S.C. §§ 77k, 77l, and 77o, respectively. "The Securities Act 'was designed to provide investors with full disclosure of material information concerning public offerings.' " In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 755 (1st Cir. 2016), quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185 (1976). "Section 11 advances this goal by creating virtually strict liability for any 'untrue statement' or misleading omission of material fact in a registration statement." Id., quoting 15 U.S.C. § 77k(a). "[S]ection 12(a)(2) imposes similar liability on sellers who make such statements in a prospectus or oral communication." Plumbers' Union Local No. 12 Pension Fundy. Nomura Asset Acceptance Corp., 632 F.3d 762, 766 (1st Cir. 2011), citing 15 U.S.C. § 77.40(2). "Section 15 creates liability for any individual or entity that 'controls any person liable' under sections 11 or 12." Id., quoting 15 U.S.C. § 77o. Thus, "a liability finding under either §§ 11 or 12 is a prerequisite for success under § 15." Silverstrand Investments v. AMAG Pharm., Inc., 707 F.3d 95, 107 (1st Cir. 2013).

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Defendants argue that the Securities Act gives federal courts exclusive jurisdiction and deprives the Massachusetts courts of subject matter jurisdiction over Fortunato's class claims. (Defendants have actually moved to dismiss all of Fortunato's claims for lack of subject matter jurisdiction. But their jurisdictional argument only pertains to the claims he seeks to assert on behalf of the putative claims, not to his personal claims under the federal Securities Act.)

Fortunato makes two responses. First, he points out that Akebia made the same jurisdictional argument after attempting to remove this action to federal district court; notes that Judge Saris rejected the jurisdictional argument and remanded the case to the Superior Court; and argues that Judge Saris's ruling is binding and may not be revisited. Second, Fortunato asserts in the alternative that Judge Saris's ruling was correct and that state and federal courts have concurrent jurisdiction over class actions brought under the federal Securities Act.

The Court concludes that it must make its own determination as to its subject matter jurisdiction, and not merely defer to Judge Saris's prior ruling. It would also be inappropriate to skip over the jurisdictional question and decide whether Fortunato has stated a viable claim without first determining whether the Court has the power to resolve that question. Turning to that question, the Court concludes that state courts retain concurrent jurisdiction to hear and decide Securities Act class actions.

1.1. Law of the Case. Defendants tried to remove this action to federal court. They ran afoul of a Securities Act provision that bars removal of any case under the federal statute that is "brought in any State court of competent jurisdiction." See 15 U.S.C. § 77v(a). Fortunato sought a remand under this provision. Defendants opposed the remand request on the ground that the Superior Court is not a "court of competent jurisdiction" because Congress has given federal courts exclusive jurisdiction over class actions under the federal Securities Act. Judge Saris disagreed. She held that the state and federal courts have concurrent jurisdiction over Fortunato's class claims. She therefore ordered that the case be remanded to the Suffolk County Superior Court. See Fortunato v. Akebia Therapeutics, Inc., 183 F.Supp.3d 326 (D.Mass. 2016). By law, Defendants cannot

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appeal or otherwise seek review of this remand order. See Kircher v. Putnam Funds Trust, 547 U.S. 633, 640-644 (2006).

Fortunato insists that, under the "law of the case" doctrine, the prior jurisdictional ruling by Judge Saris "controls here" and therefore "precludes" and "prevents" any further consideration of the issue. That is not correct.

The decision to remand this case has no preclusive effect, with respect to Judge Saris's jurisdictional ruling or otherwise, because Defendants had no right to seek any appellate review. Kircher, *supra*, at 646-647; see also *Alicea v. Commonwealth*, [466 Mass. 228](#), 234 (2013) (whether federal court judgment or order has preclusive effect in state court proceeding "is governed by Federal common law," not by state law). "While the state court cannot review the decision to remand in an appellate way, it is perfectly free to reject the remanding court's reasoning[.]" Kircher, at 647. Furthermore, a federal judge has no more power to "confer jurisdiction" on Massachusetts courts than does the secretary of a state agency, and her "opinion with respect to the existence of jurisdiction" is similarly "neither controlling nor entitled to special weight." Cf. *Cummings v. Secretary of Exec. Office of Env'tl. Affairs*, [402 Mass. 611](#), 613-14 (1988) (state agency cannot confer jurisdiction on courts by regulation).

The law of the case doctrine does not prevent a second judge from revisiting "an earlier ruling by another judge." *Martin v. Roy*, [54 Mass. App. Ct. 642](#), 644, (2002); accord *Gleason v. Hardware Mut. Cas. Co.*, [331 Mass. 703](#), 710 (1954). Since final judgment has not entered, the Court has "broad discretion" to revisit any prior ruling in this case. *Genesis Technical & Fin., Inc. v. Cast Navigation, LLC*, [74 Mass. App. Ct. 203](#), 206 (2009); accord *Herbert A. Sullivan, Inc. v. Utica Mut. Ins. Co.*, [439 Mass. 387](#), 401 (2003) ("it is within the inherent authority of a trial judge to `reconsider decisions made on the road to final judgment.' ") (quoting *Franchi v. Stella*, [42 Mass. App. Ct. 251](#), 258 (1997)).

There are several reasons why it makes sense for the Court to make its own determination as to whether it has subject matter jurisdiction, rather than merely adopt Judge Saris's thoughtful decision.

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As Judge Saris recognized, there is a sharp disagreement among federal district judges as to whether federal courts have exclusive jurisdiction over federal Securities Act class actions or, alternatively, whether state courts share concurrent jurisdiction over such claims. *Fortunato*, 183 F.Supp.3d at 328; accord, e.g., *Rosenberg v. Cliffs Natural Resources, Inc.*, No. 1:14CV1531, 2015 WL 1534033, \*2 - \*3 (N.D. Ohio 2015); *Toth v. Envivo, Inc.*, No. C 12-5636 CW, 2013 WL 5596965, \*1 n.1 (N.D. Cal. 2013). It appears that no federal appellate court has addressed the issue.[2] The Supreme Court is considering whether to step in and resolve this split among federal district judges.[3] It has invited the Acting Solicitor General to express the views of United States as to whether certiorari should be granted.[4] But at present the issue remains hotly contested and unsettled.

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[2] Defendants quote the United States Court of Appeals for the Second Circuit as saying that the 1998 amendments to the Securities Act "made federal court the exclusive venue for class actions alleging fraud in the sale of certain securities." *California Pub. Employees' Ret. System v. WorldCom, Inc.*, 368 F.3d 86, 98 (2d Cir. 2004) ("CalPERS"). But that is pure dictum. See *Fortunato*, 183 F.Supp.3d at 33. The CalPERS case had nothing to do with securities class actions. The issue before the Second Circuit was whether individual actions brought in state court around the country under the Securities Act could be removed to federal bankruptcy court (under the bankruptcy removal statute) even though they could not otherwise be removed to federal district court (because it was undisputed that state courts had concurrent jurisdiction over the claim and thus removal was barred under the Securities Act removal provision). See *CalPERS*, 368 F.3d at 91-95. This appellate decision had nothing to do with jurisdiction over class actions under the Securities Act. In any case, Massachusetts courts are not bound to follow either holdings or dicta by United States Courts of Appeals. Cf. *Commonwealth*

v. Pon, [469 Mass. 296](#), 308 (2014) (Massachusetts courts "give respectful consideration to such lower Federal court decisions as seem persuasive," but "are not bound by decisions of Federal courts except the decisions of the United States Supreme Court on questions of Federal law.") (quoting Commonwealth v. Hill, [377 Mass. 59](#), 61 (1979), and Commonwealth v. Montanez, [388 Mass. 603](#), 604 (1983)). As explained below, the CalPERS dictum quoted by Defendants is incorrect.

[3] See Petition for Writ of Certiorari filed in Cyan, Inc. v. Beaver Cnty Employees Ret. Fund, No. 15-1439, available at <http://www.scotusblog.com/wpcontent/uploads/2016/06/15-1439-petition.pdf> (last visited February 10, 2017).

[4] See case docket at <https://www.supremecourt.gov/search.aspx?filename=/docketfiles/15-1439.htm> (last visited February 21, 2017).

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Furthermore, since "the question of subject matter jurisdiction may be raised by the parties at any time," is therefore "certain to reappear" on appeal if Fortunato were to prevail on the merits, and has been fully briefed and argued by the parties, it makes little sense to allow the case to proceed without considering the merits of Defendants' assertion that Massachusetts courts lack subject matter jurisdiction over Fortunato's claims. See Maxwell v. AIG Domestic Claims, Inc., [460 Mass. 91](#), 99 (2011) (deciding interlocutory challenge to subject matter jurisdiction, even though Defendant had no right to seek interlocutory review on that ground).

1.2. Subject Matter Jurisdiction as Prerequisite. The Court must decide Defendants' jurisdictional challenge under Mass. R. Civ. P. 12(b)(1) before it can address their arguments for dismissal under Rule 12(b)(6) "[b]ecause the question of subject matter jurisdiction goes to the power of the court to hear and decide the matter." Ginther v. Commissioner of Ins., [427 Mass. 319](#), 320 n.4 & 322 n.6 (1998). "Courts ... have both the power and the obligation to resolve questions of subject matter jurisdiction whenever they become apparent[.]" HSBC Bank U.S.A., N.A. v. Matt, [464 Mass. 193](#), 199 (2013), quoting Nature Church v. Assessors of Belchertown, [384 Mass. 811](#), 812 (1981). "The question at the heart of subject matter jurisdiction is, 'Has the Legislature [or the Constitution] empowered the [court] to hear cases of a certain genre?' " Ten Persons of the Commonwealth v. Fellsway Development LLC, [460 Mass. 366](#), 375 (2011), quoting Doe, Sex Offender Registry Bd. No. 3974v. Sex Offender Registry Bd., [457 Mass. 53](#), 56-57 (2010), and Wachovia Bank, Nat'l Ass'n v. Schmidt, 546 U.S. 303, 316 (2006). "Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause." Steel Co. v. Citizens for a Better Environment, 523 U.S. 83, 94 (1998), quoting Ex parte McCardle, 74 U.S. (7 Wall.) 506, 514 (1868).

Massachusetts courts sometimes skip over difficult jurisdictional issues, and instead resolve a case on the merits, where doing so will make "no difference in the result." See Boston Gas Co. v. Department of Pub. Utils. [368 Mass. 780](#), 805 (1975); accord Mostyn v. Department of Env'tl. Prot., [83 Mass. App. Ct. 788](#), 792 & n.12

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(2013). The plaintiffs in Boston Gas and Mostyn were seeking to challenge decisions by administrative agencies. The defendant agencies argued that the plaintiffs did not have standing. Whether a plaintiff has standing raises an "issue of subject matter jurisdiction." Indeck Maine Energy, LLC v. Commissioner of Energy Resources, [454 Mass. 511](#), 516 (2009). In a case involving judicial review of an administrative decision, however, it often does not matter whether the claim fails because no plaintiff has standing or

because the plaintiffs have not asserted a meritorious claim. Either way, the result is typically the same: a judgment will enter that leaves the agency decision intact, and strict statutory time limits will bar anyone else from seeking judicial review thereafter. Compare *Indeck*, supra (affirming judgment that dismissed action for lack of standing) with *Mostyn*, supra (affirming judgment that affirmed agency's decision).[5]

In this case, however, it would make a big difference whether the Court dismisses the action for lack of subject matter jurisdiction or does so because Fortunato has failed to state any claim upon which relief can be granted. A dismissal for lack of subject matter jurisdiction would be without prejudice, leaving Fortunato free to refile this class action in federal court. See *Abate v. Fremont Inv. & Loan*, [470 Mass. 821](#), 836 (2015)

("Dismissals for lack of subject matter jurisdiction are ordinarily without prejudice because dismissal for lack of jurisdiction is typically not an adjudication on the merits."). But a dismissal for failure to state a claim would be with prejudice, and bar any further claim by Fortunato personally. See *Mestek, Inc. v. United Pacific Ins. Co.*, [40 Mass. App. Ct. 729](#), 731, rev. denied, 423 Mass. 1108 (1996) ("Under Massachusetts law, as elsewhere, a dismissal for failure to state a claim, under Mass. R. Civ. P. 12(b)(6), operates as a dismissal on the merits, see Mass. R. Civ. P. 41(b)(3), with res judicata effect") (quoting *Isaac v.*

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[5] Federal courts, in contrast, must resolve any question of subject matter jurisdiction, including whether a plaintiff has standing, before deciding whether a plaintiff has asserted a viable cause of action or otherwise reaching the merits. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. at 93-102. The Supreme Court has held that reaching the merits without having subject matter jurisdiction would violate Article III of the Constitution and therefore is not permitted even where "the merits question is more readily resolved" and "the prevailing party on the merits would be the same as the prevailing party were jurisdiction denied." *Id.* at 93.

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*Schwartz*, 706 F.2d 15, 17 (1st Cir. 1983)). Since no class has been certified, such a dismissal would not have preclusive effect with respect to the putative class. See *Massachusetts General Hosp. v. Rate Setting Comm'n*, [371 Mass. 705](#), 713 (1977).

It would be inappropriate to decide whether this action must be dismissed with prejudice under Rule 12(b)(6) for failure to state a claim without first deciding whether the Court has subject matter jurisdiction adjudicate the merits. If the Court lacked subject matter jurisdiction, any judgment dismissing Fortunato's claims with prejudice would be void and have no effect. See *Everett v. 357 Corp.*, [453 Mass. 585](#), 612 (2009) (vacating judgment entered after jury trial and ordering dismissal because Superior Court lacked subject matter jurisdiction).

1.3. State Court Jurisdiction. So let's turn to the jurisdictional question. According to Defendants, Congress established concurrent state and federal court jurisdiction over suits brought to enforce the Securities Act of 1933, but then eliminated state court jurisdiction over larger Securities Act class actions when it amended that statute in 1998. Defendants say that Congress originally established concurrent jurisdiction by providing that "[t]he district courts of the United States . . . shall have jurisdiction . . . , concurrent with State and Territorial courts, of all suits in equity and actions at law brought to enforce any liability or duty created by this subchapter." See 48 Stat. 86, § 22(a) (now codified at 15 U.S.C. § 77v(a)); see also *Wilko v. Swan*, 346 U.S. 427, 433 n.16 (1953). Congress amended this provision in 1998. It now says that federal district courts "shall have jurisdiction . . . , concurrent with State and Territorial courts, except as

provided in section 77p of this title with respect to covered class actions, of all suits . . . brought to enforce any liability or duty created by this subchapter" (emphasis added). 15 U.S.C. § 77v(a), as amended by the Securities Litigation Uniform Standards Act of 1998, Pub. L. No. 105-353, § 101(a)(3) 112 Stat. 3227 (1998) ("SLUSA"). Defendants say this amendment "extinguished" state court jurisdiction over Securities Act class actions seeking damages on behalf of more than fifty people.

The Court disagrees. Congress did not have to and did not in fact establish concurrent state and federal jurisdiction over Securities Act claims, because state courts have the inherent power under our federal system to decide such claims.

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And nothing in the 1998 statutory amendment deprives state courts, either expressly or by necessary implication, of concurrent jurisdiction to hear and decide class actions of any size brought under the Securities Act.

1.3.1. Concurrent Jurisdiction Is Presumed. State courts do not need permission from Congress to hear and decide questions of federal law, including causes of action created by federal statute. As the Supreme Judicial Court explained long ago, "Wile jurisdiction assumed by the state courts, in matters arising under the United States laws, has not been limited to the case where jurisdiction has been expressly conferred upon them by the statute itself." *Ward v. Jenkins*, 51 Mass. (10 Metcalf) 583, 588 (1846). So long as no statutory or constitutional provision gives federal courts exclusive jurisdiction, "the fact that the cause of action arose under certain rights acquired by a statute of the United States [is] no sufficient objection to the jurisdiction of a state court." *Id.* The United States Supreme Court has long agreed. See *Clain v. Houseman*, 93 U.S. (3 Otto) 130, 136137 (1876); *Houston v. Moore*, 18 U.S. (5 Wheat.) 1, 32 (1820). It has "consistently held that state courts have inherent authority, and are thus presumptively competent, to adjudicate claims arising under the laws of the United States." *Tallith v. Levitt*, 493 U.S. 455, 458 (1990) (state courts may decide civil actions under the Racketeer Influenced and Corrupt Organizations Act); accord, e.g., *Yellow Freight Sys., Inc. v. Donnelly*, 494 U.S. 820, 821(1990) (state courts may decide civil actions under Title VII of the Civil Rights Act of 1964).

This presumption that "State courts are adequate forums for the vindication of federal rights" is "a foundational principle of our federal system." *Burt v. Titlow*, 134 S. Ct. 10, 15 (2013). "Federal law is enforceable in state courts . . . because the Constitution and laws passed pursuant to it are as much laws in the States as laws passed by the state legislature. The Supremacy Clause makes those laws 'the supreme Law of the Land,' and charges state courts with a coordinate responsibility to enforce that law according to their regular modes of procedure." *Mulhern v. MacLeod*, [441 Mass. 754](#), 756 (2004), quoting *Howlett v. Rose*, 496 U.S. 356, 367 (1990), quoting in turn U.S. Const. art. W. "State courts have jurisdiction over federal causes of action not because it is 'conferred' upon them by the Congress"

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(emphasis added), but instead because the Constitution contemplates that federal claims and questions may be decided in state judicial proceedings. *Tallith*, 493 U.S. at 469 (Scalia, J., concurring).

"It therefore takes an affirmative act of power under the Supremacy Clause to oust the States of jurisdiction—an exercise of what one of our earliest cases referred to as 'the power of congress to withdraw federal claims from state-court jurisdiction" (emphasis in original). *Id.* at 470, quoting *Houston*, 18 U.S. (5 Wheat.) at 26; accord *Yellow Freight Sys.*, 494 U.S. at 823 ("To give federal courts exclusive jurisdiction over a federal cause of action, Congress must, in an exercise of its powers under the Supremacy Clause, affirmatively divest state courts of their presumptively

concurrent jurisdiction."). "Only 'an explicit statutory directive, [an] unmistakable implication from legislative history, or ... a clear incompatibility between state-court jurisdiction and federal interests' will rebut the presumption" of concurrent jurisdiction. *Ha thorn v. Lovorn*, 457 U.S. 255, 266 (1982), quoting *Gulf Offshore Co. v. Mobil Oil Corp.*, 453 U.S. 473, 478 (1981).

1.3.2. Parsing the Statutory Text. Nothing in the Securities Act expressly says or even clearly suggests that federal courts have exclusive jurisdiction over claims brought under that statute. Like any statute, the Securities Act must be construed in accord with the ordinary meaning of its words, considered in the context of the relevant statutory scheme as a whole, to produce a meaning that best reflects the apparent purpose of the statute. *Securities and Exchange Comm'n v. C. M Joiner Leasing Corp.*, 320 U.S. 344, 350-351 (1943); see generally *Abramski v. United States*, 134 S.Ct. 2259, 2267 (2014); *Commonwealth v. Hanson H.*, [464 Mass. 807](#), 810 (2013). When read in this manner, the 1998 amendment relied upon by Defendants did not withdraw federal Securities Act claims from state-court jurisdiction.

As noted above, Defendants' jurisdictional argument is based on a provision in section 22 of the Securities Act of 1933 stating that federal district courts "shall have jurisdiction . . . , concurrent with State and Territorial courts, except as provided in section 77p of this title with respect to covered class actions, of all suits . . . ." See 15 U.S.C. § 77v(a), as amended by SLUSA § 101(a)(3)(A). Section 77p,

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in turn, provides that "kilo covered class action based upon the statutory or common law of any State or subdivision thereof in any State or Federal court by any private party alleging" certain broad categories of securities fraud. 15 U.S.C. § 77p(b), as amended by SLUSA § 101(a)(1). The term "covered class action" is defined in § 77p(f)(2) to mean, in substance, "a lawsuit in which damages are sought on behalf of more than 50 people." *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 83 (2006) ("Dabit") (construing 15 U.S.C. § 78bb(f)(5)(B) of the Securities Exchange Act of 1934, as amended by SLUSA § 101(b)(1)(B), which is identical to § 77p(f)(2) of the Securities Act). Thus, § 77p has the effect of doing away with larger securities fraud class actions brought under state law, by providing that neither state nor federal courts may hear such claims. *Id.*[6]

On its face, the plain language of § 77v(a) does nothing to restrict the subject matter jurisdiction of state courts. To the contrary, the first sentence of this provision is a grant of authority to federal district courts that was amended in 1998 to specify that the federal courts may not hear certain categories of securities fraud class actions that are brought under state law. "[T]he reference to § 77p in the amendment to the concurrent jurisdictional provision in § 77v(a) does not constitute an 'explicit statutory directive' " barring state courts from hearing class actions under the federal Securities Act. *Fortunato*, 183 F.Supp.3d at 332 (Saris, J.), quoting *Gulf Offshore*, 453 U.S. at 478. When Congress wants to grant exclusive jurisdiction to federal courts, it knows how to say so expressly. It did so, for example, in section 27 of the Securities Exchange Act of 1934, which provides that:

The district courts of the United States and the United States courts of any Territory or other place subject to the jurisdiction of the United States shall have exclusive jurisdiction of violations of this chapter or the rules and regulations thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by this chapter or the rules and regulations thereunder (emphasis added).

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[6] "SLUSA does not actually pre-empt any state cause of action. It



simply denies plaintiffs the right to use the class-action device to vindicate certain claims. The Act does not deny any individual plaintiff, or indeed any group of fewer than 50 plaintiffs, the right to enforce any state-law cause of action that may exist." *Dabit*, 547 U.S. at 87.

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15 U.S.C. § 78aa(a). No similar language or any other express abrogation of state court jurisdiction over class actions appears anywhere in the Securities Act, which creates different obligations and therefore different potential causes of action than the Securities Exchange Act. The omission from the Securities Act of any statutory provision "that expressly confines jurisdiction to federal courts or ousts state courts of their presumptive jurisdiction . . . is strong, and arguably sufficient, evidence that Congress had no such intent." *Yellow Freight Sys.*, 494 U.S. at 823.

Defendants protest that reading § 77v(a) as defining the jurisdiction of federal courts, but not limiting the jurisdiction of state courts, makes the language added by the 1998 amendment superfluous. They point out that § 77v(a) only grants federal courts jurisdiction over federal Securities Act claims, not over state law claims, and that there was thus no need for Congress to add language stating that federal courts now lack jurisdiction over certain kinds of state law claims. Defendants are implicitly invoking the principle that courts should try to "interpret a statute to give effect to all its provisions, so that no part will be inoperative or superfluous." *Shirley Wayside Ltd. Partnership v. Board of Appeals of Shirley*, [461 Mass. 469](#), 477 (2012), quoting *Connors v. Amino*, [460 Mass. 790](#), 796 (2011) (internal quotation marks omitted); accord, e.g., *Clark v. Rameker*, 134 S.Ct. 2242, 2248 (2014). The Supreme Court calls this principle the "canon against surplusage" or the "canon against superfluity." *Marx v. General Revenue Corp.*, 133 S.Ct. 1166, 1177 (2013) (surplusage); *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 107 (2011) (superfluity).

The fact that § 77v(a) does not itself create federal court jurisdiction over state law claims does not make superfluous the clause stating that federal courts do not have jurisdiction over state law securities fraud class actions on behalf of more than fifty people. We cannot interpret § 77v in isolation, but instead must read it in the context of other statutes that give the federal courts jurisdiction over state law securities claims. Cf. *Branch v. Smith*, 538 U.S. 254, 281 (2003) ("courts do not interpret statutes in isolation, but in the context of the corpus furls [body of law] of which they are a part"). Federal courts can hear securities fraud claims arising under state law by exercising supplemental jurisdiction in cases involving related

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claims arising under federal law, or by exercising diversity jurisdiction where there is the requisite diversity of citizenship among the parties. See *Anderson v. Aon Corp.*, 614 F.3d 361, 364 (7th Cir. 2010) (supplemental jurisdiction under 28 U.S.C. § 1367(a)), and *Hargrave v. Oki Nursey, Inc.*, 646 F.2d 716 (2d Cir. 1980) (diversity jurisdiction under 28 U.S.C. § 1332). When Congress decided in 1998 to bar federal courts from exercising jurisdiction over larger securities class actions brought under state law, it had to put that provision somewhere. Though Congress could have amended the general statutes authorizing supplemental and diversity jurisdiction, it was free instead to add the new language to a statute addressing federal jurisdiction over securities claims. The mere placement of this provision does not drain it of all meaning and thus make it superfluous.

Although the phrase "except as provided in section 77p of this title with respect to covered class actions" is not superfluous for the reason argued by Defendants, on the Court's reading of § 77v(a) this phrase is nonetheless duplicative. Section 77v(b) expressly deprives both federal and state courts of any power to hear a "covered class action based upon the

statutory or common law of any State." There was no need for Congress to say the same thing a second time by adding parallel language to § 77v(a).

But the inclusion of parallel provisions in two different sections of the same statutory chapter does not mean that one of the provisions should be read in a manner inconsistent with the plain language used by Congress, just to give it some independent meaning. See *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253254 (1992). When "interpreting a statute a court should always turn first to one, cardinal canon before all others. . . . [C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Id.* "Redundancies across statutes are not unusual events in drafting, and so long as there is no 'positive repugnancy' between two laws, . . . a court must give effect to both." *Id.* at 253, quoting *Wood v. United States*, 41 U.S. (16 Pet.) 342, 363 (1842). Statutory "provisions that, although 'technically unnecessary,' are sometimes 'inserted out of an abundance of caution—a drafting imprecision venerable enough to have left its mark on legal Latin (*ex abundantia cautela*).'" *Smith v. City of*

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*Jackson, Miss.*, 544 U.S. 228, 252 (2005) (Scalia, J., concurring in part and concurring in the judgment), quoting *Fort Stewart Schools v. Federal Labor Relations Auth.*, 495 U.S. 641, 646 (1990). Thus, a statutory phrase is not superfluous if Congress "simply intended to remove any doubt" about an issue, or make sure that a legal rule is not overlooked by repeating it in several relevant statutes. *Ali v. Federal Bureau of Prisons*, 552 U.S. 214, 226 (2008); accord *Marx*, 133 S.Ct. at 1176-1177. "Congress could sensibly have seen some practical value in the redundancy." *Corley v. United States*, 556 U.S. 303, 325 (2009), quoting *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 445-446 (1995) (Souter, J., dissenting).

In any case, Defendants' proposed interpretation of § 77v(a) would itself make the language at issue superfluous. Defendants argue that the relevant provision should be read as establishing concurrent state and federal court jurisdiction over suits brought to enforce the federal Securities Act, and thus that the 1998 amendment should be understood as extinguishing state court jurisdiction over class actions on behalf of fifty or more people brought under the Securities Act. As discussed above, however, state courts have inherent power to decide claims brought under the federal Securities Act. "Because there was, consequently, no need for Congress to specify that [state] courts have this power," the relevant clause in § 77v(a) "is superfluous" if read as conferring jurisdiction on state courts. Cf. *Marx*, 133 S.Ct. at 1177; accord *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S.Ct. 1749, 1758 (2014) (fee shifting statutes would be superfluous if construed narrowly to apply only where losing party acted in bad faith, because courts have inherent power to order fee-shifting in such cases). "[T]he canon against surplusage 'assists only where a competing interpretation gives effect to every clause and word of a statute.'" *Marx*, supra, quoting *i4i Ltd. Partnership*, 564 U.S. at 107. Since "no interpretation" of § 77v(a) "gives effect to every word," it makes sense to read the statute as written even if doing so makes one clause redundant. *Marx*, supra.

1.3.3. Legislative History and the Federal Interest in Uniform Standards. Reading § 77v(a) in the manner described above is consistent with the legislative history and expressly stated purpose of the Securities Litigation Uniform

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Standards Act. There is neither an "unmistakable implication from the legislative history" that the SLUSA amendment to § 77v(a) was intended to bar state courts from hearing class actions brought under the federal Securities Act, nor any "clear incompatibility between state-court jurisdiction and federal interests" and having uniform standards apply to

all larger securities fraud class actions. Cf. *Ha thorn*, 457 U.S. at 266.

The relevant legislative history is as follows. "SLUSA is part of a series of reforms targeted at costly securities litigation. Congress first passed the Private Securities Litigation Reform Act of 1995 (PSLRA)[7] to deter the filing of so-called strike suits—frivolous securities class actions that put defendants to the unappealing choice of settling claims, however meritless, or risking extravagant discovery and trial costs." *Freeman Investments, L.P. v. Pacific Life Ins. Co.*, 704 F.3d 1110, 1114 (9th Cir. 2013). This statute "placed special burdens on plaintiffs seeking to bring federal securities fraud class actions." *Dabit*, 547 U.S. at 82. "Its provisions limit recoverable damages and attorney's fees, provide a 'safe harbor' for forward-looking statements, impose new restrictions on the selection of (and compensation awarded to) lead plaintiffs, mandate imposition of sanctions for frivolous litigation, and authorize a stay of discovery pending resolution of any motion to dismiss." *Id.* at 81 (citing 15 U.S.C. § 78u-4). It "also imposes heightened pleading requirements" in private securities fraud actions brought under § 10(b) of the Securities Exchange Act[8] or SEC Rule 10b-5.[9] *Id.*

The PSLRA had the "unintended consequence" of encouraging lawyers to bring securities fraud "class actions under state law, often in state court." *Dabit*, 547 U.S. at 92. "By bringing state law class actions in state courts," lawyers representing securities fraud plaintiffs "avoided the procedural steeplechase erected by the PSLRA." *Freeman Investments*, *supra*.

So in 1998 Congress enacted SLUSA to "curtain] plaintiffs' ability to evade the PSLRA's limitations on federal securities-fraud litigation by bringing class-

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[7] Pub. L. 104-67, 109 Stat. 737, codified at 15 U.S.C. § 77z-1 and § 78u-4.

[8] Codified at 15 U.S.C. § 78j(b).

[9] Codified at 17 C.F.R. § 240.10b-5.

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action suits under state rather than federal law." *Amgen Inc. v. Connecticut Ret. Plans & Trust Funds*, 133 S. Ct. 1184, 1200 (2013). The stated purpose of SLUSA is "to prevent certain State private securities class action lawsuits alleging fraud from being used to frustrate the objectives" of PSLRA by "enact[ing] national standards for securities class action lawsuits involving nationally traded securities[.]" SLUSA § 2(5), 112 Stat. 3227. That is why this 1998 statute was called a "uniform standards" act.

In sum, the purpose of SLUSA was to limit the use of securities class actions brought under state law, whether in state or federal court; it was not enacted to bar state courts from hearing larger class actions brought under the federal Securities Act. This is apparent from the legislative history, and made explicit by Congress in § 2 of the legislation as enacted and signed into law.

Defendants' assertion that trying federal Securities Act class actions in state court is incompatible with achieving uniform national standards for such claims is without merit. That Congress enacts a federal law to establish a "uniform system of regulation" does not mean that state courts lack jurisdiction to apply that statute; the Supreme Court's "ability to review state court decisions of federal questions . . . sufficiently protect[s] federal interests" in developing and applying uniform national standards. *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Manning*, 136 S. Ct. 1562, 1574 (2016). Defendants' argument to the contrary is "unsound." *Pan Am. Petroleum Corp. v. Superior Court of Del. In and For New Castle County*, 366 U.S. 656, 665 (1961), quoting *Great Northern R. Co. v. Merchants*

Elevator Co., 259 U.S. 285, 290 (1922). State court judgments in federal Securities Act class actions will not "result in any more inconsistency than [the] multimembered, multi-tiered federal judicial system already creates." Taft in, 493 U.S. at 465 (rejecting uniformity argument against state court jurisdiction over civil RICO claims).

2. Plaintiffs Claims Do Not Sound in Fraud. Defendants next argue that Fortunato's allegations and claims sound in fraud and that the amended complaint is therefore subject to, but fails to meet, the requirement under Mass. R. Civ. P. 9(b) that "averments of fraud ... shall be stated with particularity." The Court disagrees.

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Fortunato does not allege that Akebia's final registration statement and prospectus were purposefully misleading. Rather, he claims that Defendants had a duty to determine whether any interim results from the ongoing Phase 2b clinical trial might be inconsistent with or cast doubt upon the Phase 2a results that were disclosed in the offering materials, and that they negligently failed to do so. The amended complaint expressly states that Fortunato makes no claim that Defendants engaged in "fraud or [other] intentional or reckless misconduct."

Since Fortunato has alleged only negligent misrepresentation and expressly disclaimed any allegation of intentional or reckless fraud, the heightened pleading standard of Rule 9(b) does not apply. See *Hutchison v. Deutsche Bank Securities Inc.*, 647 F.3d 479, 484 (2d Cir. 2011) (motion to dismiss Securities Act claim); *Lenartz v. American Superconductor Corp.*, 879 F.Supp.2d 167, 189 (D.Mass. 2012) (Young, J.) (same). "Although the complaint does assert that defendants actually possessed the information that they failed to disclose, those allegations cannot be thought to constitute 'averments of fraud,' absent any claim of scienter and reliance." *Shawv. Digital Eqpt. Corp.*, 82 F.3d 1194, 1223 (1st Cir. 1996).

Under Massachusetts law, the heightened pleading requirements of Rule 9(b) apply to claims for intentional or reckless misrepresentation but not to claims of negligent misrepresentation. See *DeWolfe v. Hingham Centre, Ltd.*, [464 Mass. 795](#), 798 n.8 (2013) (construing complaint that alleged "material misrepresentation" as stating claim for negligent misrepresentation because "fraud has not been pleaded with sufficient particularity to state a claim for intentional or reckless misrepresentation"). And Massachusetts procedural rules apply when a plaintiff brings federal claims in a Massachusetts court, "unless those rules are pre-empted by federal law." *St. Fleur v. WPI Cable Sys./Mutron*, [450 Mass. 345](#), 352 (2008), quoting *Howlett*, 496 U.S. at 372.

3. The Complaint Does Not State a Viable Claim. This brings us to the substantive meat of Defendants' motion to dismiss under Mass. R. Civ. P. 12(b)(6): whether Fortunato's amended complaint states a claim upon which relief can be granted. The Court concludes that it does not.

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3.1. Legal Standard. To survive a motion to dismiss under Rule 12(b)(6), a complaint must allege facts that "plausibly suggest" the plaintiff has a viable claim. *Lopez v. Commonwealth*, [463 Mass. 696](#), 701 (2012), quoting *Iannacchino v. Ford Motor Co.*, [451 Mass. 623](#), 636 (2008), and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007). When deciding a motion to dismiss under Rule 12(b)(6), a judge must "accept as true the facts alleged in the . . . complaint"—or that are apparent from documents attached to, referenced in, or otherwise relied upon in framing the complaint[10]—"as well as any favorable inferences that reasonably can be drawn from them." *Partanen v. Gallagher*, [475 Mass. 632](#), 635 (2016), quoting *Galiastro v. Mortgage Elec. Registration Sys., Inc.*, [467 Mass. 160](#), 164 (2014). However, "[c]onclusory allegations" that a defendant has acted illegally are not enough; judges must disregard such assertions and "focus on whether the factual allegations plausibly suggest an entitlement to

relief." *Maling v. Finnegan, Henderson, Farabow, Garrett & Dunner, LLP*, [473 Mass. 336](#), 339 (2015), quoting *Curtis v. Herb Chambers I-95, Inc.*, [458 Mass. 674](#), 676 (2011).

3.2. Factual Allegations. The following facts are either alleged in Fortunato's amended complaint or are apparent from documents cited in the complaint.[11]

Akebia is a biopharmaceutical company. To date it has focused on trying to develop and obtain Food and Drug Administration ("FDA") approval of a single product that Akebia calls AKB-6548. This drug aims to treat anemia in patients with chronic kidney disease or "CKD" by increasing the production of red blood cells

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[10] See *Melia v. Zenhire, Inc.*, [462 Mass. 164](#), 166 (2012) (documents attached to the complaint); *Johnston v. Box*, [453 Mass. 569](#), 581 n.19 (2009) (documents referenced in complaint) (dictum); *Golchin v. Liberty Mut. Ins. Co.*, [460 Mass. 222](#), 224 (2011) (documents used in framing complaint).

[11] In addition to the complaint itself, the Court has also considered the Akebia press releases, Akebia's final prospectus issued on March 19, 2014, the transcript of Akebia's public call with press and investors on October 27, 2014, regarding the results of the Phase 2b trial results, and two guidance documents published by the Food & Drug Administration regarding clinical drug trials. All of these documents are referred to in the complaint and expressly used by Fortunato as the basis for his key allegations. As a result, the Court may consider them without converting Defendants' motion to dismiss into a motion for summary judgment. See, e.g., *Golchin*, 460 Mass. at 224.

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and hemoglobin. There are FDA-approved and commercially available drugs that treat anemia in CKD patients. All of those drugs have known side effects that are sufficiently serious that the FDA requires that prescription information for those drugs contain so-called "black box warnings" that prominently list those risks. Akebia is hoping that AKB-6548 will prove not just to be an effective treatment but to be safe enough not to require any black box warning.

Akebia had a successful initial public offering ("IPO") on March 20, 2014. It sold 6.762 million shares of common stock for \$17.00 per share, allowing it to raise over \$100 million of capital. Fortunato and the other putative class members have all purchased Akebia common stock pursuant or traceable to the prospectus issued and registration statement filed by Akebia in connection with its IPO (which Fortunato refers to as the "Offering Materials").

Akebia's Offering Materials made various representations and disclosures to prospective investors regarding past and continuing clinical testing of AKB-6548. Akebia told investors that this drug "has compelling clinical data demonstrating a best in class profile with several potential safety and efficacy advantages" over current drugs used to treat anemia resulting from CKD. It explained that Akebia had "successfully completed a Phase 2a proof of concept study" involving 91 patients, that "No drug-related serious adverse events were reported," and that "dosing was well-tolerated." The Offering Materials also disclosed that as of March 2014 Akebia was "currently conducting a Phase 2b clinical trial for AKB-6548." Akebia warned potential investors that "[s]erious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole." It also warned that further clinical testing could reveal a pattern of serious adverse events related to taking the drug rather than the placebo, but stated that, "[do

date, no such pattern has emerged in our AKB-6548 trials."

The Phase 2b trial conducted by Akebia was a double-blind, placebo-controlled, randomized clinical trial. The study enrolled 209 patients, each of whom were given either the drug or a placebo once daily for twenty weeks. The study patients were all non-dialysis subjects with CKD stages 3, 4, or 5. Two-thirds of

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these patients were chosen at random to receive active treatment using AKB-6548. The other third received a placebo. The "double-blind" nature of the study meant that neither the patients nor the investigators (i.e. physicians and other clinicians providing treatment) knew whether any particular patient was being given the drug or a placebo. The first patient was dosed in late July 2013. Eighty percent of the patients were enrolled in the study by the end of February 2014. All the patients were enrolled by April 15, 2014. Thus it appears that the dosing of patients in the Phase 2b study was completed in late September or early October 2014.

On October 27, 2014, some seven months after the IPO, Akebia publicly reported efficacy and safety results from the now-completed Phase 2b trial. It reported positive efficacy results. Over half (54.9 percent) of the patients who received the drug (the "active treatment group") met the study's hemoglobin improvement endpoint, while only 10.3 percent of the patients who received a placebo (the "placebo group") did so. But Akebia also disclosed that the Phase 2b study had identified potential safety risks not seen in the earlier trial. Specifically, Akebia's press release reported that: (i) "[t]here was a higher incidence of serious adverse events (SAEs) reported in the active treatment group versus the placebo group (23.9 percent and 15.3 percent, respectively)," and (ii) "[o]f the 49 SAEs reported in the active treatment group, one was considered probably related to active treatment and two were considered possibly related, including one death." During a conference call for investors and journalists the day this press release was issued, Akebia indicated that one of the two SAEs that was possibly related to the drug involved a patient "who developed abnormal liver function tests three months into the study:" this appears to mean that the patient showed liver function problems within three months after first receiving the drug, which could have been either before or some months after Akebia's IPO.

This public report of differences in SAEs between the treatment and placebo groups caused Akebia's stock price to fall by the end of trading on October 27 from \$18.72 to \$13.97 per share. The stock price continued to fall. When the amended complaint was filed in August 2016 Akebia was trading at around \$8.00 per share.

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Fortunato alleges that, under the FDA rules and regulations cited in the complaint, Akebia had an ongoing obligation throughout the Phase 2b trial to monitor serious adverse events and assess whether there was a reasonable possibility that the drug caused the event. He notes that the FDA requires drug companies like Akebia to perform an "aggregate analysis" of adverse events to determine whether they occur more frequently in the treatment group than in the placebo group. And he points out that FDA rules allow clinical trial sponsors like Akebia to establish an independent "Data Monitoring Committee" that, unlike the trial sponsor and investigators, can look at unblinded results (i.e. results identifying patients as part of the treatment or the placebo group) and monitor while the trial progresses whether patients receiving the drug are experiencing a disproportionate number of serious adverse events. Akebia concedes that it had in fact established such a Data Monitoring Committee to review interim and final results of its Phase 2b trial.

Fortunato asserts that, "[g]iven that the Phase 2b study had already made substantial progress by the time of the IPO, and that a significant

number of patients in the study suffered serious adverse events, it is a reasonable inference that many of those serious adverse events occurred before the IPO." He further asserts that, since study investigators were required to report serious adverse events to Akebia, "[l]t is therefore a reasonable inference that Akebia should have been aware of the serious adverse events in the Phase 2b study as of the IPO," including "that the proportion of patients in the drug group who had suffered serious adverse events was greater than the proportion of such patients in the placebo group." On this basis, Fortunato claims that Akebia's Offering Materials "were materially false and misleading because they failed to disclose the heightened safety risks for AKB-6548 already uncovered in the ongoing Phase 2b study" by the time of the IPO.

3.3. Facts Not Known or Knowable. The facts alleged by Fortunato do not plausibly suggest that Akebia knew or could have known about the number or proportion of serious adverse events experienced by Phase 2b patients who were receiving AKB-6548 by the time of the IPO in March 2014.

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Since the Phase 2b trial was a double-blind study, there is no reason to believe (and Fortunato alleges no facts plausibly suggesting) that Akebia knew or had any way of knowing until after the study was completed which SAEs were experienced by patients receiving AKB-6548, which were experienced by those receiving the placebo, and whether there was any disproportion between the two groups in the incidence of SAEs. As the FDA's "Guidance for Clinical Trial Sponsors" explains, "[k]nowledge of unblinded interim comparisons from a clinical trial is generally not necessary for those conducting or sponsoring the trial; further, such knowledge can bias the outcome of the study by inappropriately influencing its continuing conduct or the plan of analyses." [12] The reason to have a data monitoring committee or "DMC", as Akebia did with respect to the Phase 2b trial, is to have an independent body that can review unblinded data throughout the trial to ensure that the drug being studied is not causing adverse events. But the FDA instructs "that any part of the interim report to the DMC that includes comparative effectiveness and safety data presented by study group," i.e. that identifies which patients are in the treatment group and which are in the placebo group, "whether coded or completely unblinded, [should] be available only to DMC members during the course of the trial, including any follow-up period—that is, until the trial is completed and the blind is broken for the sponsor and the investigators." [13] "In other words, the purpose of having an independent data monitoring committee is to protect the validity of the double-blind trial results by avoiding disclosure of trial data to the sponsors and investigators prior to the trial's completion." Weinstein v. Kirkman, No. C13-0769-JCC, 2013 WL 12121125, \*3 (W.D. Wash. 2013).

Fortunato alleges no facts plausibly suggesting that Akebia disregarded, or that it should have disregarded, the FDA rules requiring double-blind clinical trial data to remain blinded until the study is finished. The mere fact that Akebia learned and reported after the Phase 2b study was complete that drug recipients experienced a higher incidence of serious adverse events than patients in the

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[12] Food & Drug Admin., Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees, § 4.2 at 10 ("Data Monitoring Committee Guidance").

[13] Id. § 4.2.2. at 11.

placebo group, and that three out of the 49 serious adverse events may have

been related to the taking of the study drug, does not suggest that Akebia knew or should have known materially adverse interim study results at the time of its IPO.

An allegation that serious adverse events occurred during a double-blinded, placebo-controlled drug study does not plausibly suggest that the study sponsor was or could have been aware of that information, in the absence of some further alleged reason to believe that the study results had been unblinded and thus that the sponsor had reason to know that any of the SAEs had been experienced by subjects who received the drug being studied rather than the placebo. See *Weinstein*, supra (dismissing shareholder derivative action with prejudice); *In re Intrabiotics Pharm. Inc. Sec. Litig.*, No. C 04-02675 JSW, 2006 WL 2192109, \*10-\*11 (N.D. Cal. 2006) (dismissing Securities Act claims with prejudice); *In re Columbia Labs., Inc. Sec. Litig.*, 144 F.Supp.2d 1362, 1370 (S.D. Fla. 2001) (same); see also *Twinde v. Threshold Pharms, Inc.*, No. C 07-4972 CW, 2008 WL 2740457, \*12 (N.D. Cal. 2008) (dismissing portion of Securities Act claims without prejudice).

Fortunato cannot state a claim merely by pointing out that FDA regulations require study investigators to report all serious adverse events to the study sponsor. In a double-blind study neither the investigator nor the sponsor will know which patients are receiving the placebo rather than the study drug. A sponsor nonetheless has an obligation to make an independent assessment of a serious adverse event to determine whether there appears to be a reasonable possibility that the study drug—rather than, say, the patient's pre-existing medical condition or totally unrelated factors—caused the SAE and thus that the outcome qualifies as a "serious and unexpected adverse reaction." In such cases the sponsor must unblind the data as to that single event, and if it turns out that the patient was receiving the trial drug then the sponsor must report the episode to the FDA. See 21 C.F.R. § 312.32; Food & Drug Admin., Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE Studies, App. B. But Fortunato does not allege that ever occurred during Akebia's Phase 2b trial.

Fortunato has therefore failed to state a viable Securities Act claim. Plaintiffs pleading Sections 11 and 12 claims must "at a minimum, plead facts to demonstrate

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that allegedly omitted facts both existed, and were known or knowable, at the time of the offering." *Scott v. General Motors Co.*, 46 F.Supp.3d 387, 394 (S.D.N.Y. 2014) (dismissing securities act claims with prejudice), quoting *Lin v. Interactive Brokers Grp., Inc.*, 574 F. Supp. 2d 408, 421 (S.D.N.Y. 2008), quoting in turn *Castlerock Mgmt. Ltd. v. Ultralife Batteries, Inc.*, 114 F. Supp. 2d 316, 323 (D.N.J. 2000) (dismissing securities act claims with prejudice). Thus a plaintiff may not state a viable claim "by relying solely on hindsight to prove a misstatement." *Scott*, supra. "Defendants are not expected to know the un-knowable, nor are they expected to disclose it." *Panther Partners, Inc. v. Ikanos Communications, Inc.*, 538 F.Supp.2d 662, 670 (S.D.N.Y. 2008) (dismissing securities act claim), *affd*, 347 Fed. App'x 617 (2d Cir. 2009). As noted above, "a liability finding under either §§ 11 or 12 is a prerequisite for success under § 15." *Silverstrand Investments*, 707 F.3d at 107. Thus, where a complaint fails to state a viable claim under § 11 or § 12, a related § 15 claim must be dismissed as well. *In re Ariad Pharmaceuticals, Inc.*, 98 F.Supp.3d 147, 179 (D.Mass. 2015) (*Young, J.*), *affd*, 842 F.3d 744, 756 n.8 (1st Cir. 2016).

Fortunato's assertion that Defendants breached their duty of disclosure under Item 303 of SEC Regulation S-K fails to state a claim for much the same reason. That rule requires that a registrant disclose "any known trends or uncertainties" that are likely to have a material impact on future sales, revenues, or income from continuing operations. 17 C.F.R. §



229.303(a)(3)(ii). It therefore "only imposes a duty to make forward-looking projections regarding information known to the registrant." *J & R Mktg., SEP v. General Motors Corp.*, 549 F.3d 384, 392 (6th Cir. 2008) (affirming dismissal of complaint for failure to state a claim).

3.4. Dismissal With Prejudice. The pending motion to dismiss was served over four months ago. Fortunato has had ample time to serve and file a motion to further amend his complaint, if he believed that he could cure any defect in his pleading by augmenting the factual allegations of his first amended complaint. In his memorandum of law, Fortunato says in a footnote that if the Court were to grant the motion to dismiss then he would like the opportunity "to replead." But Fortunato has never sought leave to file a second amended complaint nor done anything else to identify or describe any potential further

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amendment that would state a viable claim. Given the double-blind nature of the Phase 2b clinical trial, it appears that any further amendment Fortunato might propose would be futile because he still would be unable to identify any facts plausibly suggesting that Defendants could have known material adverse information regarding interim Phase 2b trial results at the time of Akebia's initial public offering.

Under these circumstances, the Court concludes in the exercise of its discretion that Fortunato's claims should be dismissed with prejudice. See *Johnston v. Box*, [453 Mass. 569](#), 582-584 (2009) (where complaint fails to state a viable claim, plaintiff has neither moved to amend its complaint nor "adequately describe[d] [any] contemplated amendment" in enough detail to allow "court to determine the merits of the motion," and in any case filing an amended complaint "would likely have been futile as a matter of law," court may dismiss action with prejudice and without first giving plaintiff opportunity to seek leave to amend complaint) (quoting *Nettv. Bellucci*, [437 Mass. 630](#), 645 (2002)).

As noted above, however, since no class has been certified the dismissal of this action will have no preclusive effect with respect to the putative class. See *Massachusetts General Hosp.*, 371 Mass. at 713.

ORDER

Defendants' motion to dismiss is ALLOWED. Final judgment shall enter dismissing with prejudice Plaintiffs claims on behalf of himself. Since no class has been certified, the final judgment only applies to Plaintiff individually.

Kenneth W. Salinger  
Justice of the Superior Court

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