Supreme Court of the State of New York
Appellate Division, First Judicial Department

Webber, J.P., Singh, González, Shulman, JJ.

13702 CHESTER COUNTY EMPLOYEES RETIREMENT FUND, etc., Plaintiff-Respondent,

-against-

ALNYLAM PHARMACEUTICALS, INC., et al., Defendants-Appellants.

Index No. 655272/19
Case No. 2020-04534

Skadden, Arps, Slate, Meagher & Flom LLP, New York (Alaxander C. Drylewski and Michael S. Hines of the Bar of the State of Massachusetts, admitted pro hac vice, of counsel), for Alnylam Pharmaceuticals, Inc., John M. Maraganore, Michael P. Mason, Dennis A. Ausiello, Michael W. Bonney, John K. Clarke, Marsha H. Fanucci, Steven M. Paul, David E.I. Pyott, Paul R. Schimmel, Amy W. Schulman, Phillip A. Sharp and Kevin P. Starr, appellants.

Shearman & Sterling LLP, New York (Daniel Lewis of counsel), for Goldman Sachs & CO. LLC, J.P. Morgan Securities LLC, Barclays Capital Inc., Credit Suisse Securities (USA) LLC, Piper Jaffray & Co., JMP Securities LLC, Needham & Company, LLC, Chardan Capital Markets, LLC and B. Riley FBR, Inc., appellants.

Robbins Geller Rudman & Dowd LLP, Melville (Douglas Wilens of counsel), for respondent.

Order, Supreme Court, New York County (O. Peter Sherwood, J.), entered November 2, 2020, which denied defendants' motion to dismiss the complaint, unanimously modified, on the law, to grant the motion as to the Section 12 claims against the individual defendants, and otherwise affirmed, without costs.

Defendants have failed to utterly refute plaintiff's factual allegations and conclusively establish a defense to the asserted claims as a matter of law (CPLR

3211[a][1]; CPLR 3211[a][7]). Plaintiff has sufficiently alleged causes of action based on Federal Securities Law sections 11, 12(a)(2), and 15 (*see also Litwin v Blackstone Group., L.P.*, 634 F3d 706, 716 [2d Cir 2011], *cert denied* 565 US 878 [2011]). Notably, at this stage of litigation, there is no basis to find, as a matter of law, that plaintiff has failed to assert valid claims by alleging that in the circumstances here, the registration statements, prospectus or oral communication included either untrue statements of fact concerning the APOLLO Study or statements of opinion about that study that were misleading to a reasonable investor by omission of material facts concerning the lack of cardiac efficacy data, as later confirmed by the FDA. Therefore, defendants fail to establish that plaintiff's claims of false or misleading statements or material omissions used by defendant Alnylam Pharmaceuticals, Inc. in a public offering are premised on nonactionable statements of opinion.

However, the Section 12(a)(2) claim should be dismissed as against the individual defendants, because the complaint alleges only that they reviewed and signed the registration statements, which is insufficient to establish that they are statutory sellers (*Emerson v Mutual Fund Series Trust*, 393 F Supp 3d 220, 259-260 [ED NY 2019]).

THIS CONSTITUTES THE DECISION AND ORDER
OF THE SUPREME COURT, APPELLATE DIVISION, FIRST DEPARTMENT.

ENTERED: April 29, 2021

Susanna Molina Rojas
Clerk of the Court

SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY

PRESENT: HON. O. PETER SHERWOOD **PART** IAS MOTION 49EFM

Justice

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CHESTER COUNTY EMPLOYEES RETIREMENT FUND, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

- v -

ALNYLAM PHARMACEUTICALS, INC., *et al.*,

Defendants.

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INDEX NO. 655272/2019

MOTION DATE 12/20/2019

MOTION SEQ. NO. 001

DECISION + ORDER ON MOTION

The following e-filed documents, listed by NYSCEF document number (Motion 001) 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 43, 45, 46, 47, 48, 50

were read on this motion to/for DISMISS.

Upon the foregoing papers, it is ordered that this motion to dismiss (Motion Sequence Number 001) is decided in accordance with the accompanying decision and order.

10/30/2020
DATE

O. PETER SHERWOOD, J.S.C.

CHECK ONE:	[ ]	CASE DISPOSED		[X]	NON-FINAL DISPOSITION		
	[ ]	GRANTED	[X] DENIED	[ ]	GRANTED IN PART	[ ]	OTHER
APPLICATION:	[ ]	SETTLE ORDER		[ ]	SUBMIT ORDER		
CHECK IF APPROPRIATE:	[ ]	INCLUDES TRANSFER/REASSIGN		[ ]	FIDUCIARY APPOINTMENT	[ ]	REFERENCE

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: COMMERCIAL DIVISION PART 49

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CHESTER COUNTY EMPLOYEES RETIREMENT FUND, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

-against-

ALNYLAM PHARMACEUTICALS, INC, JOHN M. MARAGANORE, MICHAEL P. MASON, DENNIS A. AUSIELLO, MICHAEL W. BONNEY, JOHN K. CLARKE, MARSHA H. FANUCCI, STEVEN M. PAUL, DAVID E.I. PYOTT, PAUL R. SCHIMMEL, AMY W. SCHULMAN, PHILLIP A. SHARP, KEVIN P. STARR, GOLDMAN SACHS & CO. LLC, J.P. MORGAN SECURITIES LLC, BARCLAYS CAPITAL INC., CREDIT SUISSE SECURITIES (USA) LLC, PIPER JAFFRAY & CO., JMP SECURITIES LLC, NEEDHAM & COMPANY, LLC, CHARDAN CAPITAL MARKETS, LLC and B. RILEY FBR, INC.,

Defendants.

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DECISION AND ORDER

Index No.: 655272/2019
Motion Sequence Number: 001

O. PETER SHERWOOD, J.:

I. BACKGROUND

This case is brought, pursuant to sections 11, 12(a)(2) ad 15 of the Securities Act of 1933 (the 1933 Act), as a class action on behalf of all parties who purchased common stock of Alnylam Pharmaceuticals (Alnylam or the Company) in the Company's public offering on November 14, 2017. According to the amended complaint ("Complaint", NYSCEF Doc. No. 29), the Company used a Registration Statement which contained untrue statements of material fact and omitted material information about a drug it was developing and which was closest to production, patisiran. Specifically, the Company had no scientific evidence to support obtaining approval of patisiran to treat cardiomyopathy, thereby limiting the market potential of the drug.

Defendants include all of the underwriters of the offering (Goldman Sachs& Co, JP Morgan Securities, Barclays Capital Inc., Credit Suisse Securities (USA) LLC, Piper Jaffray & Co., JMP Securities LLC, Needham & Co., LLC, Chardan Capital Markets, and LLC, B Riley FBR, Inc. (the Underwriters). Plaintiff also names individual defendants who were officers at the Company and who signed off on the Registration Statement: John Maraganore (CEO and director on the board of directors), Michael Mason (VP of Finance and Treasurer), Dennis Ausiello (director), Michael Bonney (director), John Clarke (director), Marsha Fanucci (director), Steven Paul (director), David Pyott (director) Paul Shimmel (director), Amy Schulman (director), Phillip Sharp (director), Kevin Starr (director) (together the Individual Defendants).

As additional background to the issues in the case, according to the Complaint, "Clinical trials have three types of endpoints: (i) primary (ii) secondary; and (iii) exploratory. According to the Food and Drug Administration, a primary point is the outcome that establishes "the effectiveness, and/or safety features, of the drug in order to support regulatory action." Secondary end points are used to "provide evidence that a particular mechanism underlies a demonstrated clinical effect." Exploratory endpoints "are included [in clinical trials] to explore new hypotheses" (Complaint, ¶ 62) ("Compl. ¶ __").

II. FACTS

As this is a motion to dismiss the amended complaint, the facts are taken from the amended complaint (Compl, NYSCEF Doc. No. 29) and are assumed to be true.

The Company is a pharmaceutical company that develops new drugs based on RNA interference (RNAi). At the time of the public offering, the Company did not have any drug on the market and was making no money. It was trying to develop drugs in three different areas (genetic medicines, cardio-metabolic diseases, and hepatic infectious diseases). The Company filed a shelf Registration Statement with the SEC on or about May 5, 2017 (Compl. ¶ 40). In August of 2017, the Company presented its most promising drug as patisiran, which targets a specific gene to treat a very rare and fatal disease (about 50,000 people, worldwide, have it).

The Registration Statement for the offering cautioned investors to only rely on information in the Registration Statement in evaluating the offering, and to rely on later filed documents, if they conflicted with earlier filed documents (Compl. ¶ 46). On or about November 14, 2017,

Underwriters purchased and sold 5.6 million shares of Company stock in connection with the offering (*id.* at ¶ 49). The offering generated $785 million for the Company and over $20 million for the Underwriters.

The Registration Statement featured patisiran as the drug closest to receiving regulatory approval. Patisiran was in a phase III clinical trial (the Apollo Study). Phase III trials are usually the final hurdle before a company submits a new drug application to the FDA. Patisiran was being tested primarily as treatment for polyneuropathy but its efficacy for treating cardiomyopathy was also being assessed (Compl. ¶¶ 3, 65-66). In September 2017, the Company announced the top line results from the Apollo Study, but did not release the data, even thought it had the data. The Company claimed the Apollo Study met its primary and secondary endpoints (that it is effective and has a clinical effect) (see *id.*, ¶ 71). The Company described the study as supporting the use of patisiran to treat cardiomyopathy and indicated it would use that study to support its application to the FDA to use patisiran to treat cardiomyopathy (*id.*, ¶¶ 71-78). In fact, the Apollo Study did not generate any cardiac efficacy data and so provided no support for gaining FDA approval for that use (*id.*, ¶ 83).

Plaintiff also alleges the Registration Statement failed to disclose information required to be disclosed by regulation.

- Item 303 of Regulation S-K [17 CFR s 229.303] requires disclosing material events and uncertainties which would cause reported financial information to not be indicative of future results, and that known events, demands, or uncertainties must be disclosed unless the company concludes the event, or a material impact from that event, is not reasonably likely to occur (*id.*, ¶¶ 87-88). Plaintiff claims the Company knew the Apollo Study did not provide any support for an attempt to gain approval for the drug for cardiomyopathy.
- Item 503(c) of Regulation S-K [17 CFR s 229.303(c)] requires an issuer to disclose "risk factors" that make the stock risky (*id.*, ¶¶ 91-92). Factors that could cause the drug nearest approval to fail to get that approval are risk factors that should have been disclosed.

The Company submitted its application to approve patisiran for both conditions to the FDA in November 2017. On August 10, 2018, the FDA approved the drug for polyneuropathy, but denied the application regarding cardiomyopathy (*id.*, ¶ 97). On September 7, 2018, a report from the FDA's Center for Drug Evaluation and Research (the FDA Report) became available which revealed the lack of support from the Apollo Study (*id.*). The FDA did not provide any explanation or insight into why it did not approve patisiran to treat cardiomyopathy (*id.*, ¶ 98).

Plaintiff asserts:

1) Violations of Section 11 of the 1933 Act, against all defendants for the misleading Registration Statement;

2) Violation of Section 12(a)(2) of the 1933 Act, against all defendants, for the untrue or undisclosed material facts in the Registration Statement, and their failure to exercise reasonable care to determine the misstatements and omissions; and

3) Violation of Section 15 of the 1933 Act against the Company and the Individual Defendants, as persons in control of the Company.

III. ARGUMENT

A. Defendants' Motion to Dismiss

Defendants move jointly to dismiss the Complaint pursuant to CPLR 3211(a)(1), (5), and (7), based on documentary evidence, arbitration/release/res judicata, and failure to state a claim for which relief can be granted. Defendants argue CPLR 3016(b)'s heightened pleading standard applies here because the claims are based upon misrepresentation, but also notes that, even under CPLR 3013's general pleading standard, "vague and conclusory" allegations cannot avoid dismissal (Memo at 8, *see Lynch v Upper Crust, Inc.*, 294 AD2d 237, 238 [1st Dep't 2002]).

Defendants argue that the first two claims, for violations of sections 11 and 12(a)(2) of the 1933 Act, are time-barred, as the FDA report relied on by plaintiff was published on September 7, 2018, more than a year before plaintiff filed this action, and the 1933 Act has a one year statute of limitations (Memo, NYSCEF Doc. No. 38, at 3, 8-9). The FDA Report was published on the FDA's website on September 7, 2018 (*id.* at 9-11). That is what starts the statute of limitations running, not the republication of the report by securities analysts on September 12, where it was noticed.

The first claim, based on section 11, fails as plaintiff has not identified a specific false or misleading statement in the Offering materials. In fact, defendants argue all of the required information was provided *(id.* at 12-13). The Apollo Study did produce cardiac efficiency data (*id.* at 12-13, citing Excerpts from Alnylam Pharmaceuticals, Inc., Quarterly Report for Q3 2017 [Form 10-Q] [the Q3 Report], filed November 7, 2017, attached as Exhibit E to Drylewski aff, NYSCEF Doc. No. 33, at 19). The FDA Report noted the results of the study included "highly statistically significant positive results on all of the trial's pre-specified secondary efficacy endpoints" (Memo at 13 quoting FDA Report, attached as Exhibit D to Drylewski aff, NYSCEF

Doc. No. 34 at 56). The Company's statements in the Registration Statement were accurate. The Registration Statement also warned investors that the FDA could interpret the data differently, which could have an adverse impact on the approval process (Memo at 13-14). The two statements identified by plaintiff as allegedly misleading are not actionable because they are the Company's opinions as to the interpretation of the Apollo Study data and "[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.'" (*id.* at 15 quoting *In re Sanofi Sec. Litig.*, 87 F Supp 3d 510, 543 [SDNY 2015] [alteration in original] [citation omitted], *aff'd sub nom Tongue v Sanofi*, 816 F3d 199 [2d Cir 2016]). Even if the Apollo Study data could not support FDA approval of the cardiomyopathy usage, there are no allegations the Company knew that when the Registration Statement was filed. Defendants contend plaintiff fails to allege the statements are false or not made with an honest belief of their truth. Nor could a reasonable person interpret the statements in the Registration Report as a guarantee the drug would be approved for cardiomyopathy (Memo at 16-17). Plaintiff's dispute is really about the design of the Apollo Study (*id.* at 17). Nor does the Complaint allege "Alnylam's disclosures did not comply with Items 303 and 105 of SEC Regulation S-K" (*id.* at 18, citing 17 C.F.R. §§ 229.303, 229.105). There is no allegation the omitted information was known to the Company or was a reasonably likely uncertainty. In fact, the Registration Statement fully disclosed the risks (*id. at* 18-19).

The second claim, based on section 12(a)(2), fails because that imposes liability on certain sellers for misstatements or omissions and plaintiffs have failed to identify actionable misstatements or omissions or to allege the defendants to be statutory sellers (*id.* at 20- 23). According to the defendants, "[u]nder Section 12(a)(2), a plaintiff may only bring suit against its "statutory seller," meaning "the person who either 'passed title . . . to the buyer for value' or 'successfully solicited the purchase of a security'" (Memo at 22, quoting *Stadnick v Vivint Solar, Inc.*, Nos. 14-cv-9283 (KBF), 14-cv-9709 (KBF), 2015 WL 8492757, at *16 [SDNY Dec. 10, 2015][citation omitted], *aff'd*, 861 F.3d 31 [2d Cir. 2017]). Merely alleging the Individual Defendants reviewed and signed the Registration Statement is not enough.

The third claim, based on section 15, imposes liability on people or entities which control a person who is liable under sections 11 or 12 (Memo at 23). Because plaintiff has failed to state a claim under the first two claims, claim three also fails. Further, plaintiff fails to allege culpable

conduct by any of the Individual Defendants beyond their merely being a director or officer of the Company.

B. Plaintiff's Opposition

Plaintiff argues only notice pleading is required, and is fulfilled by the Complaint, arguing "Commercial Division courts in this county have found CPLR 3016(b) does not apply to 1933 Act claims (Opp, NYSCEF Doc. No. 39, at 7, citing I*n re Netshoes Sec. Litig.*, 64 Misc3d 926, 931 [Sup Ct NY County 2019]; *In re Densply Sirona, Inc. S'holders Litig.*, 2019 WL 4695724, at *4 [Sup Ct NY County Sept. 26, 2019, J. Borrok]). "Plaintiff need only allege that the Registration Statement: (i) contained an untrue statement of material fact; (ii) omitted to state a material fact that was necessary to make the statements not misleading; or(iii) omitted to state a material fact that was required to be disclosed" (Opp at 8, citing 15 USC §77k[a]; 15 USC §77l [a][2]). "Liability is 'virtually absolute, even for innocent misstatements'" (*id.* quoting Herman & MacLean v Huddleston, 459 US 375, 382 [1983]). "Plaintiff 'need not allege scienter, reliance, or loss causation' for 1933 Act claims" (*id.* quoting *N.J. Carpenters Health Fund v Royal Bank of Scotland Grp., PLC*, 709 F3d 109, 120 [2d Cir 2013]).

Plaintiff alleges the "Registration Statement inaccurately stated that patisiran achieved significant effects in the [APOLLO] study's cardiac subpopulation" (Opp at 8, quoting Complaint, ¶80). Plaintiff also alleges "the FDA Report unequivocally states that the cardiomyopathy-related exploratory endpoints "do not measure a clinical benefit"" (Opp at 8, quoting Complaint, ¶101). Accordingly, both the original announcement and the Registration Statement's representation that the Apollo Study "generated "positive complete results" – meaning for all primary, secondary, and exploratory endpoints, i.e., for both polyneuropathy and cardiomyopathy – were also false" (Opp at 8, quoting Complaint ¶¶82-83). "Both sets of statements also omitted material information by failing to disclose that APOLLO's exploratory endpoints did not measure cardiac efficacy, meaning they could not support using patisiran to treat cardiomyopathy even if they were positive" (Opp at 9, citing Complaint, ¶¶81, 83). As far as defendants claim immunity from liability based on cautionary language which they claim protects them under the "bespeaks caution" doctrine, that protection only applies to prospective statements, and not to the fact that the Apollo Study did not provide cardiac data (Opp at 11). Nor are the statements that "patisiran achieved significant effects in the [APOLLO] study's cardiac subpopulation" (Complaint paragraph 80) and that the study

generated "positive complete results" (*id.* ¶ 82) opinions. They are presented as facts, without the signals "I believe" or "I think" to show they are only opinions (Opp at 12). "[N]umerous courts have construed misstatements about clinical trials to be actionable non-opinions" (*id.* at 13). Even if the statements are opinions, such opinions can be actionable if the opinion "(i) is not sincerely held by the speaker (135 S. Ct. at 1326); (ii) contains an embedded or "underlying" fact that is false (id.at 1327); or (iii) omits a fact that renders it misleading to an ordinary investor (id.at 1329)" (*id.* at 13). The Company reviewed the Apollo Study data and understood how to properly measure cardiomyopathy efficacy, so could not have sincerely believed the Apollo Study supported using the drug to treat cardiomyopathy (*id.* at 13-14).

Plaintiff alleges defendants violated Item 303 by "failing to disclose that Alnylam knew by at least November 2, 2017 that APOLLO generated no cardiac efficacy data, meaning even if the exploratory endpoints were positive they could not support using patisiran to treat cardiomyopathy and, as a result, the market for patisiran would be significantly curtailed" *(id.* at 15, citing Compl., ¶ 90). As far as defendants argue the Company did not know the Apollo Study generated no cardiac data, plaintiff points to defendants' multiple pre-offering statements about the results and data of the study, showing their familiarity with the study (*id.* at 15).

Plaintiff argues the Registration Statement violates Item 503 and a claim based on Item 503 requires them to allege "a registrant knew . . . that (1) a risk factor existed; (2) the risk factor could adversely affect the registrant's present or future business expectations; and (3) the offering documents failed to disclose the risk factor." (*id.* at 15-16, quoting *Silverstrand Invs. v AMAG Pharms., Inc.*, 707 F3d 95, 103 [1st Cir. 2013]). Plaintiff contends the Registration Statement does not address the failure of the Apollo Study to establish cardiac application, the market potential of the drug was the biggest risk facing the Company, and the statements relied upon by defendants as disclosure did not mention cardiac or cardiomyopathy (*id.* at 16).

As to Claim 2, plaintiff points out defendants agree that if plaintiff has stated a claim pursuant to section 11, it has also alleged a claim under section 12(a)(2) (Opp at 16). Therefore, defendants only argue the Individual Defendants are not statutory sellers pursuant to section 12(a)(2). They concede the Company and the Underwriters are alleged to be statutory defendants (*id.* at 16-17). Plaintiff alleges the Individual Defendants signed the Registration Statement, which

is sufficient to hold them responsible for the document. As signatories, the Individual Defendants solicited the investors under Section 12(a)(2) (*id.* at 17).

As to Claim 3, pursuant to Section 15, defendants argue it fails for lack of a primary violation. As there was a primary violation, that argument fails (*id.* at 17). Further, as far as defendants argue it is improper to plead the Company and the Individual Defendants have both primary and secondary liability, plaintiff is permitted to plead in the alternative (*id.* at 16-17). Nor is "meaningful culpable conduct" required, as that is not required for 1933 Act claims (*id.* at 18).

As far as defendants claim the complaint is untimely, the statute of limitations for 1933 Act claims is one year from when the misstatement or omission should have been discovered using reasonable due diligence, and even a reasonably diligent plaintiff need not have discovered the Report and the references to cardiac efficiency in it (*id.* at 19). Further, the defendants had repeatedly assured plaintiff of the positive results, so a reasonably diligent plaintiff would not have looked at the FDA Report's findings (*id.* at 19-20 citing *In re Morgan Stanley Mortg. Pass-Through Certificates Litig.*, 810 FSupp 2d 650, 665 [SDNY 2011]). Nor is the evidence definitive that the FDA Report was available on the FDA website on September 7, 2018 (*id.* at 20). While federal regulations require the report to be published by September 10, 2018, there is no evidence it was, and the date the FDA Report was available is under dispute. Nor could the claim have been asserted until after the analyst reports were issued, causing the stock price to drop (*id.* at 21). Further, *Leavitt*, a 1934 Act claim, was filed on September 26, 2018, which tolled the statute of limitations on this claim (*id.* at 12-22).

C. Defendants' Reply

Defendants contend plaintiff is effectively arguing the Company had no basis for seeking approval of the drug for cardiomyopathy because the FDA later determined the Apollo Study data did not support that use, and this is merely about different interpretations of the clinical trial data and different opinions (Reply, NYSCEF Doc. No. 43, at 1, 3-5). Defendants argue the FDA's later determination not to approve the drug for this purpose does not mean there was no reason to seek approval (*id.* at 5-6). The fact that a prior trial on a different drug was not successful does not support a determination that defendants must have known at the time of the offering that the FDA would not approve the drug at issue here (*id.* at 6).

Further, the Apollo Study did include some "exploratory endpoints measuring cardiac health" *(id.* at 2, quoting Complaint, ¶ 66). That the FDA had a different opinion and decided that data was not sufficient to give the drug a cardiac indication does not make the statement false (*id.* at 6-7). There was some cardiac data in the Apollo Study, which is admitted in the Complaint (*id.* at 7, quoting Complaint at para 66 ["the exploratory endpoints of the APOLLO [s]tudy included, among other things, measures of cardiac structure and function"]). The FDA Report did not dispute the accuracy of the data, the FDA only interpreted the results differently (*id. at* 7-8). As far as plaintiff argues the Registration Statement's cautionary language does not immunize the statements pursuant to the "bespeaks caution doctrine," Defendants do not argue the statements at issue are forward-looking or that that doctrine applies. Rather, the Company disclosed the relevant risks and no reasonable investor could conclude the Company was guaranteeing FDA approval (*id.* at 8).

The Company's disclosure was consistent with the requirements of SEC Regulation S-K (*id.* at 8-9). The Company cannot be held responsible for knowing how the FDA would view the study in the future. The Registration Statement disclosed the risks and uncertainties of the FDA approval process (*id.* at 9).

Defendants argue the plaintiff has failed to overcome their showing that the action is barred by the statute of limitations, or that the latter two claims have been sufficiently pled (lacking allegations the Individual Defendants were statutory sellers and lacking a primary violation, respectively) (*id.* at 2, 10). Plaintiff concedes the claim against the Individual Defendants is based solely on their having signed off on the prospectus, which courts have found insufficient to support this claim (*id.* at 10, quoting *Emerson v Mut. Fund Series Tr.*, 393 F Supp. 3d 220, 259-60 [EDNY 2019]).

Plaintiff's arguments about the statute of limitations also fail because the filing of the complaint in *Leavitt v Alnylam Pharma. Inc.* does not toll the running of the statute of limitations. This case is not consolidated with *Leavitt* and the cases cited by plaintiff do not support their position (Reply at 10-11). Second, the argument that the action is timely because FDA Report was not released until after September 12, 2018, cannot stand, since that does not leave time for the analyst to review the FDA Report before releasing the analyst report on September 12, and that the FDA Report must have been available on September 10, 2018, at the latest (*id.* at 11-12).

Further, once the FDA decision had been made, no reasonable, diligent investor could have relied upon the Company's statements in the Offering Report, so claims after that date cannot stand (*id.* at 12).

As to the third claim, pursuant to Section 15, there is no primary liability (as the first two claims fail) and plaintiff has failed to allege culpable conduct by the allegedly controlling person (*id.* at 13).

IV. DISCUSSION

A. Standards

Defendants move to dismiss pursuant to CPLR 3211(a)(1), (5), and (7).

To succeed on a motion to dismiss pursuant to CPLR § 3211 (a) (1), the documentary evidence submitted that forms the basis of a defense must resolve all factual issues and definitively dispose of the plaintiff's claims (*see 511 W. 232nd Owners Corp. v Jennifer Realty Co.*, 98 NY2d 144, 152 [2002]; *Blonder & Co., Inc. v Citibank, N.A.*, 28 AD3d 180, 182 [1st Dept 2006]). A motion to dismiss pursuant to CPLR § 3211 (a) (1) "may be appropriately granted only where the documentary evidence utterly refutes plaintiff's factual allegations, conclusively establishing a defense as a matter of law" (*McCully v. Jersey Partners, Inc.*, 60 AD3d 562, 562 [1st Dept. 2009]). The facts as alleged in the complaint are regarded as true, and the plaintiff is afforded the benefit of every favorable inference (*see Leon v Martinez,* 84 NY2d 83, 87-88 [1994]). Allegations consisting of bare legal conclusions as well as factual claims flatly contradicted by documentary evidence are not entitled to any such consideration (*see e.g. Nisari v Ramjohn,* 85 AD3d 987, 989 [2nd Dept 2011]).

CPLR § 3211 (a) (1) does not explicitly define "documentary evidence." As used in this statutory provision, "'documentary evidence' is a 'fuzzy term', and what is documentary evidence for one purpose, might not be documentary evidence for another" (*Fontanetta v John Doe 1,* 73 AD3d 78, 84 [2nd Dept 2010]). "[T]o be considered 'documentary,' evidence must be unambiguous and of undisputed authenticity" (*id.* at 86, citing Siegel, Practice Commentaries, McKinney's Cons. Laws of N.Y., Book 7B, CPLR 3211:10, at 21-22). Typically, that means "judicial records, as well as documents reflecting out-of-court transactions such as mortgages, deeds, contracts, and any other papers, the contents of which are 'essentially undeniable,'" (*id.* at

84-85). Here, the documentary evidence is the FDA Report. The parties discuss the Registration Statement, which would qualify, but it does not appear to be attached here. The parties also cite to several other documents, such as the FDA patisiran website (for the date of the publication of the FDA Report), which will be discussed as needed.

On a motion to dismiss a plaintiff's claim pursuant to CPLR § 3211 (a) (7) for failure to state a cause of action, the court is not called upon to determine the truth of the allegations (*see, Campaign for Fiscal Equity v State,* 86 NY2d 307, 317 [1995]; *219 Broadway Corp. v Alexander's, Inc.*, 46 NY2d 506, 509 [1979]). Rather, the court is required to "afford the pleadings a liberal construction, take the allegations of the complaint as true and provide plaintiff the benefit of every possible inference [citation omitted]. Whether a plaintiff can ultimately establish its allegations is not part of the calculus in determining a motion to dismiss" (*EBC I v Goldman, Sachs & Co.*, 5 NY3d 11, 19 [2005]). The court's role is limited to determining whether the pleading states a cause of action, not whether there is evidentiary support to establish a meritorious cause of action (*see Guggenheimer v Ginzburg,* 43 NY2d 268, 275 [1977]; *Sokol v Leader,* 74 AD3d 1180 [2d Dept 2010]).

Defendants also move on the grounds that this suit is barred by the statute of limitations, pursuant to CPLR 3211(a)(5).

B. Statute of Limitations

"On a motion to dismiss a cause of action pursuant to CPLR 3211(a)(5) on the ground that it is barred by the statute of limitations, a defendant bears the initial burden of establishing, prima facie, that the time in which to sue has expired. In considering the motion, a court must take the allegations in the complaint as true and resolve all inferences in favor of the plaintiff" (*Island ADC, Inc. v Baldassano Architectural Group, P.C.* 49 AD3d 815, 816 [2008] [citations omitted]). The statute of limitations for claims brought under Sections 11 and 12(a)(2) of the '33 Act is "within one year after the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence" (15 USC § 77m). This case was filed on September 12, 2019. The drug was approved on August 10, 2018. The FDA Report as posted on the FDA website lists September 7, 2018, as the date the Report was created (see Doc. No. 38, n. 5). Plaintiff disputes that the Report was posted on that date. There is no documentary evidence showing the date the document was made available. The amended complaint alleges the FDA

Report was unavailable before the analyst report discussing the FDA Report was published on September 12, 2019. As plaintiff's response on a motion to dismiss under CPLR 3211(a)(5) "must be given their most favorable intendment" (*Arrington v New York Times Co.*, 55 NY2d 433, 442 [1982]), the court holds that defendants have not met their burden of showing the statute of limitations has run.

C. Claim 1- Violations of Section 11 of the 1933 Act,

"To state a claim under Section 11, plaintiffs must allege that the registration statement ... contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading..." (15 U.S.C. § 77k[a]). "The truth of a statement made in the registration statement is judged by the facts as they existed when the registration statement became effective" (*In re Initial Pub. Offering Sec. Litig.*, 358 FSupp2d 189, 205 [SDNY 2004]).

Defendants argue CPLR 3016(b)'s heightened pleading standard, which requires the "circumstances constituting the wrong [to] be stated in detail" when the claim involves fraud or misrepresentation, applies here. Decisions from the New York State Supreme Court, Commercial Division are split on whether the heightened standard applies in this type of claim (see *Hoffman v AT & T Inc.*, 67 Misc 3d 1212(A) [Sup Ct 2020] ["plaintiff alleges that the Offering Documents contain misrepresentations. Accordingly, CPLR § 3016(b) applies and plaintiffs must state the circumstances constituting the misrepresentations in detail"]; *Densply Sirona, Inc.*, 2019 N.Y. Slip Op. 32849[U] at 8 ["While it is true that the CAC alleges that Defendants made materially false and misleading statements, it does not contain claims for fraud or misrepresentation but instead alleges strict liability and negligence claims pursuant to Sections 11, 12(a)(2) and 15 of the '33 Act. Therefore, the heightened pleading standard of CPLR 3016(b) does not apply"]; *Netshoes Sec. Litig.*, 64 Misc 3d at 931 ["Although the complaint alleges that Netshoes made materially false and misleading statements, it does not specifically allege any claim for fraud or misrepresentation and only alleges claims based on negligence and strict liability. Accordingly, a heightened pleading standard is not warranted"]).

The court need not decide whether the heightened pleading standard applies here. The allegedly misleading statements are stated with great specificity in the Registration Statement.

There is no dispute about who said what and when. The statements taken from the Registration Statement are alleged to be untrue or misleading.

According to plaintiff, "[t]he Registration Statement inaccurately stated that 'patisiran achieved significant effects in the [APOLLO] study's cardiac subpopulation'" and made "repeated claims that APOLLO generated 'positive complete results' – meaning for all primary, secondary, and exploratory endpoints, i.e., for both polyneuropathy and cardiomyopathy" (Opp at 9, quoting Complaint, ¶¶ 80, 82-83, apparently quoting the Registration Statement, but without citation). Defendants contend these are opinions. The Registration Statement also cautioned potential investors that the FDA could see the data differently.

As far as defendants argue these statements are non-actionable opinions, the United States Supreme Court has noted "a sincere statement of pure opinion is not an untrue statement of material fact, regardless whether an investor can ultimately prove the belief wrong. That clause, limited as it is to factual statements, does not allow investors to second-guess inherently subjective and uncertain assessments. In other words, the provision is not, as the Court of Appeals and the Funds would have it, an invitation to Monday morning quarterback an issuer's opinions (*Omnicare, Inc. v Laborers Dist. Council Const. Indus. Pension Fund*, 575 US 175, 186 [2015]). Here, the statements attributed to the Registration Statement are statements of fact, although they are vague facts.

The parties debate the impact of the "bespeaks caution" doctrine. That is:

> "one of a set of rules coping with the problem that forward-looking information poses for securities disclosure laws. For decades, the disclosure of forward-looking information was generally prohibited by the Securities and Exchange Commission (SEC). That policy changed in the 1970s. To encourage disclosure of forward-looking information notwithstanding certain vulnerabilities, including the tendency of predictions to be embarrassed by the passage of time, regulators developed safe harbors. The SEC promulgated a safe harbor in 1970, *see SAFE HARBOR RULE FOR PROJECTIONS,* Securities Act Release No. 532, 1979 WL 181199 (June 25, 1979) (codified as amended at 17 CFR §§ 230.175, 240.3b-6); and Congress followed suit in 1995 [with the Reform Act]. Bespeaks caution is the courts' contribution.
>
> Under the doctrine, alleged misrepresentations in a stock offering are immaterial as a matter of law where it cannot be said that any reasonable investor could consider them important in light of adequate cautionary language set out in the

> same offering. When such cautionary language is included, courts analyze the allegedly fraudulent materials in their entirely to determine whether a reasonable investor would have been misled. The touchstone of the inquiry is not whether isolated statements within a document were true, but whether defendants' representations or omissions, considered together and in context, would affect the total mix of information and thereby mislead a reasonable investor regarding the nature of the securities offered"

(Netshoes Sec. Litig., 64 Misc 3d at 935-36 [internal quotations omitted]). The Registration Statement is not attached here, so it cannot serve as documentary evidence and the court cannot evaluate the statements alleged to be in it. As far as defendants argue the claim should fail for lack of allegations about defendants' knowledge of the falsity of the statements, that is not an element of a Section 11 claim. The cause of action depends only on whether the factual statement was untrue, based on the facts as they existed when the statement became effective. Accordingly, plaintiff's claim based on section 11 should survive.

D. Section 12 Claim

Defendants argue this claim should be dismissed because plaintiff failed to allege a misstatement and because plaintiff failed to allege the Individual Defendants were statutory sellers. As discussed above, plaintiff has alleged an actionable misstatement. As to the Individual Defendants, plaintiff's Section 12 claim against them is based solely on their having signed the Registration Statement (Opp at 17). "An individual is a 'statutory seller'—and therefore a potential section 12(a)(2) defendant—if he: (1) 'passed title, or other interest in the security, to the buyer for value,' or (2) 'successfully solicit[ed] the purchase [of a security], motivated at least in part by a desire to serve his own financial interests or those of the securities['] owner'" (*In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F3d 347, 359 [2d Cir 2010] quoting *Pinter v Dahl*, 486 US 622, 642, 647 [1988]). "Numerous courts in [the Second] circuit hold that on a motion to dismiss, officers or directors of the stock issuer who signed its registration statement are deemed to have solicited the purchase of the offered stock" (*Briarwood Investments Inc. v Care Inv. Tr. Inc.*, 07 CIV. 8159LLS, 2009 WL 536517, at *4 [SDNY Mar. 4, 2009]; see e.g. *In re Flag Telecom Holdings, Ltd. Sec. Litig.,* 352 FSupp2d 429, 454 [SDNY 2005]["An officer or director who signs a Registration Statement containing materially false or misleading statements or omissions is deemed, for pleading purposes, to have solicited a purchase within the meaning of [§ 12(a)(2)]"). Accordingly, plaintiff has stated a claim pursuant to Section 12.

E. Section 15- against the Company and Individual Defendants

Section 15 (15 USCA § 77o), provides:

> "Every person who, by or through stock ownership, agency, or otherwise, or who, pursuant to or in connection with an agreement or understanding with one or more other persons by or through stock ownership, agency, or otherwise, controls any person liable under sections 77k or 77*l* of this title, shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person had no knowledge of or reasonable ground to believe in the existence of the facts by reason of which the liability of the controlled person is alleged to exist."

As discussed above, plaintiff has pled primary liability. Accordingly, the only remaining issues are whether plaintiff may plead both primary and control person liability against the same defendants for the same alleged conduct, and whether plaintiff has properly pled culpable conduct by the Individual Defendants.

Defendants argue this claim must be dismissed as to the individual defendants based on *Kalnit v Eichler* (85 F Supp 2d 232, 246 [SDNY 1999]) in which the court determined an allegation of those defendants being control persons failed because that plaintiff's theory of the case included them as primary violators. However, that case is distinguishable, as that plaintiff failed to plead a primary violation. Further, there are many cases in "which the courts have found claims adequately asserted against a single defendant for violations of securities laws as both primary violator and controlling person" (*In re Harmonic, Inc., Sec. Litig.*, C 00-2287 PJH, 2006 WL 3591148, at *6 [ND Cal Dec. 11, 2006], listing I*n re Daou Sys., Inc., Sec. Litig,* 411 F.3d 1006, 1029-30 [9th Cir.2005], *cert. denied,* 126 S.Ct. 1335 [2006]; *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1235 [9th Cir.2004]; *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920, 937-46 [9th Cir.2003]; and *In re North Point Communications Group, Inc., Sec. Litig.*, 221 F.Supp.2d 1090, 1105-06 [N.D.Cal.2002]).

As to culpable conduct, defendants rely on *Ladmen Partners, Inc. v Globalstar, Inc. (*07 CIV. 0976 (LAP), 2008 WL 4449280, at *10 [SDNY Sept. 30, 2008]), which states: "[i]n order to state a Section 15 claim, a plaintiff must adequately allege "(1) a primary violation by a controlled person; (2) control of the primary violator by the defendant; and (3) 'that the controlling person was in some meaningful sense a culpable participant' in the primary violation" (quoting *In re Prestige Brands Holdings, Inc. Sec. Litig.*, 2006 U.S. Dist. LEXIS 81980, *6–7 [SDNY November 9, 2006] quoting *Boguslavsky v Kaplan,* 159 F.3d 715, 720 [2d Cir.1998]. The question of whether

such conduct is required appears to be the subject of a split in the Second Circuit. Other courts, and the apparent majority, do not require culpable conduct (see *McKenna v Smart Tech. Inc.*, 11 CIV. 7673 KBF, 2012 WL 1131935, at *30 [SDNY Apr. 3, 2012], collecting cases). This Court accepts the reasoning of the majority and declines to impose the additional "culpable participation" requirement.

V. CONCLUSION

For the reasons discussed above, the motion to dismiss is hereby denied. Counsel shall appear virtually for a preliminary conference on November 17, 2020 at noon. A link for a Microsoft Teams Videoconference will be provided.

This constitutes the decision and order of the court.

DATED: October 30, 2020

ENTER,

O. PETER SHERWOOD J.S.C.