UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JOHN J. GERNETH, Individually and on Behalf of All Others Similarly Situated **Plaintiff,** **v.** **CHIASMA, INC., et al.,** **Defendants.**	**Civil Action No.: 16-11082**

MEMORANDUM AND ORDER

CASPER, J. **February 15, 2018**

I. Introduction

Plaintiff John Gerneth ("Gerneth") brings claims against Defendants Chiasma, Inc. ("Chiasma"), Mark W. Leuchtenberger ("Leuchtenberger"), Mark J. Fitzpatrick ("Fitzpatrick"), Todd Foley ("Foley"), John Scarlett ("Scarlett"), Ansbert Gadicke ("Gadicke"), Dror Brandwein ("Brandwein"), Bard Geesaman ("Geesaman"), Scott Minick ("Minick"), David Stack ("Stack"), Vincent Miles ("Miles"),[1] William Blair & Company, LLC ("William Blair"), Cowen and Company, LLC ("Cowen"), Barclays Capital Inc. ("Barclays") and Oppenheimer & Co. Inc. ("Oppenheimer") (collectively, "Defendants"), alleging that Defendants violated Section 11 of the Securities Act, 15 U.S.C. § 77k ("Section 11") (Count I), and that the Individual Defendants

[1] The Court shall refer to Leuchtenberger, Fitzpatrick, Foley, Scarlett, Gadicke, Brandwein, Geesaman, Minick, Stack and Miles as the "Individual Defendants."

violated Section 15 of the Securities Act (Count II). D. 30. Defendants now move to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(6). D. 62. For the reasons stated below, the Court DENIES the motion.

II. Standard of Review

The Court will grant a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) if the complaint fails to plead sufficient facts that "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). When considering a motion to dismiss, the Court is tasked with "separat[ing] the factual allegations from the conclusory statements in order to analyze whether the former, if taken as true, set forth a 'plausible, not merely a conceivable, case for relief.'" Juárez v. Select Portfolio Servicing, Inc., 708 F.3d 269, 276 (1st Cir. 2013) (quoting Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 12 (1st Cir. 2011)). In conducting this examination, the court must not "attempt to forecast a plaintiff's likelihood of success on the merits," id. (internal quotation marks omitted), but instead "give the plaintiff the benefit of all reasonable inferences." Ruiz v. Bally Total Fitness Holding Corp., 496 F.3d 1, 5 (1st Cir. 2007) (citing Rogan v. Menino, 175 F.3d 75, 77 (1st Cir. 1999)).

III. Factual Background

The following summary is based upon the allegations in the amended complaint, D. 30, which are accepted as true for the consideration of the motion to dismiss. Chiasma is a late-stage biopharmaceutical company with its principal place of business in Newton, Massachusetts. D. 30, ¶ 16. The company's primary business since 2001 has been applying its proprietary Transient Permeability Enhancer ("TPE") technology to develop and sell drugs for oral delivery that were previously only available in injectable form. D. 30, ¶¶ 3, 53-55. Chiasma was focused on

developing the first oral drug for the treatment of acromegaly, a hormonal growth disorder that causes excess production of growth hormone. D. 30, ¶¶ 4, 48, 55.

Chiasma's oral acromegaly treatment, Mycapssa, is an oral capsule form of octreotide, a previous injectable treatment, using the TPE technology. D. 30, ¶¶ 3-4, 47, 52-53. Mycapssa would be the first oral treatment for acromegaly available on the market. D. 30, ¶ 51. Upon Mycapssa's approval and success, Chiasma intended to use its TPE technology to develop oral delivery treatments of other drugs that are now only available as injections. D. 30, ¶¶ 4, 53.

Chiasma decided to seek approval for Mycapssa using the FDA's 505(b)(2) hybrid New Drug Application ("NDA") pathway. D. 30, ¶ 77. 505(b)(2) allows the applicant to rely partially upon previously submitted clinical studies submitted by prior applicants in support of other drugs. D. 30, ¶ 40. Chiasma performed Phase 1 trials for Mycapssa, D. 30, ¶ 62, and relied upon previously conducted clinical studies of octreotide's injectable drugs in lieu of a Phase 2 trial, D. 30, ¶¶ 55, 111.

Between March 2012 and November 2014, Chiasma conducted a single-arm, open label, multi-center, baseline-controlled Phase 3 trial to observe whether patients with acromegaly maintained safe and effective responses to treatment when switched from injectable octreotide to Mycapssa. D. 30, ¶ 64. The Phase 3 trial was not conducted in the United States because the FDA required six months of monkey toxicity data to approve enrollment in a U.S. site and Chiasma only had three months of monkey toxicity data. Id. The Phase 3 trial was conducted in two phases: a seven-month "Core Treatment Phase," followed by an optional six-month "Extension Phase." D. 30, ¶ 65. Out of 155 patients enrolled in the Phase 3 trial, 102 completed the Core Treatment Phase and 82 completed the Extension Phase. D. 30, ¶ 67.

In February 2013, Chiasma entered into a licensing agreement with F. Hoffman-La Roche Ltd. and Hoffman-La Roche Inc. (collectively, "Roche"). D. 30, ¶ 5. Roche promised a $65 million upfront payment and possible future payments based on development and commercial milestones of up to $530 million in exchange for the right to develop and commercialize Mycapssa after FDA approval. D. 30, ¶¶ 5, 71. In May 2014, having received the finalized Phase 3 data, Roche and Chiasma met with the FDA to identify any "major unresolved problems" before submitting the NDA. D. 30, ¶¶ 6, 74, 77, 84, 100, 105, 112-113, 115, 119. In July 2014, Roche terminated its licensing agreement with Chiasma, D. 30, ¶¶ 6, 74, but Chiasma stated that Roche's executives were pleased with the Phase 3 trial results, and that its termination was a strategic decision to avoid becoming "more deeply involved in the endocrinology sector," D. 30, ¶ 75.

On April 17, 2015, Chiasma submitted its draft Registration Statement on Form S-1 to the Securities and Exchange Commission ("SEC"), along with a preliminary prospectus. D. 30, ¶ 83. Chiasma submitted its registration statement on Form S-1 to the SEC, along with a prospectus on Form 424(b)(4), D. 64-1 (the "Prospectus"). D. 30, ¶ 85. Chiasma submitted the Mycapssa 505(b)(2) NDA to the FDA on June 15, 2015. D. 30, ¶¶ 77-78. Chiasma submitted an amendment to its registration statement on Form S-1/A on July 6, 2015. Id. Chiasma's initial public offering took place on July 15, 2015. D. 30, ¶ 85. By the time the IPO was complete on July 21, 2015, Chiasma had received net proceeds of approximately $106.5 million. Id. On November 18, 2015, after the markets closed, Roni Mamluk ("Mamluk") of Chiasma disclosed during a quarterly earnings conference call that during the May 2014 pre-NDA meeting, the FDA had raised specific questions about (1) Chiasma's ability to get approval of its NDA for Mycapssa under the 505(b)(2) pathway; (2) the duration of the Phase 3 trial; and (3) the durability of Mycapssa's effect on its Phase 3 trial patients. D. 30, ¶ 115. On the same call, Malmuk assured investors that Chiasma

had addressed these FDA concerns and that there were "no question[s] any more" with respect to durability or the 505(b)(2) pathway. D. 30, ¶ 116. Malmuk stated that Chiasma had "a clear path forward with the FDA." Id.

On April 14, 2016, the market became aware of news that the FDA would reject the Mycapssa NDA, D. 30, ¶ 117, causing negative effects on analysts' price targets, D. 30, ¶¶ 10, 120-123. On April 15, 2016, Chiasma announced that the FDA had issued a Complete Response Letter ("CRL") explaining its denial of the Mycapssa NDA. D. 30, ¶ 87. On April 18, 2016, Chiasma offered more detailed reasoning from the CRL, including that the FDA did not believe the NDA had offered substantial evidence of efficacy and that Chiasma would need to conduct another clinical trial to resolve this deficiency. D. 30, ¶ 88. Chiasma also explained that the FDA had "expressed concerns" about "certain aspects" of the Phase 3 trial, and among other recommendations it suggested that Chiasma conduct its new trial in the United States, and that the trial have a longer duration. D. 30, ¶ 89. On another conference call on April 18, 2016, before the markets opened, Leuchtenberger said that during a second pre-NDA meeting in December 2014, the FDA had expressed that Chiasma's Phase 3 trial, as constructed, would not be as informative as some alternatives, but that these issues would not preclude Chiasma from filing the Mycapssa NDA. D. 30, ¶ 119. The same day, Chiasma's common stock price dropped more than 63%, falling to $3.75 per share from its first closing price of $10.17. D. 30, ¶¶ 11, 124.

IV. Procedural History

The original complaint was filed on June 9, 2016. D. 1. After being appointed as lead plaintiff for the putative class, Gerneth filed an amended complaint on February 10, 2017. D. 30. Defendants have now moved to dismiss the complaint. D. 62. The Court heard the parties on the pending motion and took this matter under advisement. D. 73.

V. Discussion

A. Section 11 of the Securities Act

Section 11 makes liable any issuer of a security, or certain individuals involved in the Registration Statement or prospectus, that in "any part of [a] registration statement, when such part became effective, 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). "'Section[ ] 11 . . . [is an] enforcement mechanism[ ] for the mandatory disclosure requirements of the Securities Act.'" Silverstrand Investments v. AMAG Pharm., Inc., 707 F.3d 95, 102 (1st Cir. 2013) ("Silverstrand I") (alteration in original) (quoting Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996)). Section 11 "imposes strict liability on issuers of a security, and any 'remaining [ ] defendants . . . may be held liable for mere negligence.'" Silverstrand I, 707 F.3d at 102 (alteration in original) (quoting In re Morgan Stanley Info. Fund Secs. Litig., 592 F.3d 347, 359 (2d Cir. 2010)). Unlike Section 10(b) of the Securities Exchange Act of 1934, there is no scienter or reliance requirement, and the Court does not apply any heightened pleading standard unless the plaintiff's claim sounds in fraud. Silverstrand I, 707 F.3d at 102.

To state a Section 11 claim, a plaintiff must adequately allege "(1) the existence of either a misstatement or an unlawful omission; and (2) materiality [of that statement or omission]." In re Morgan Stanley Info. Fund Secs. Litig., 592 F.3d at 360. Materiality is measured by "'[w]hether the defendants' representations, taken together and in context, would have misled a reasonable investor.'" Id. (quoting Rombach v. Chang, 355 F.3d 164, 172 n.7 (2d Cir. 2004)). Materiality is a mixed question of law and fact, and thus "will rarely be dispositive in a motion to dismiss," In re Morgan Stanley Info. Fund Secs. Litig., 592 F.3d at 360, unless the statements "are so obviously

unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance," ECA v. JP Morgan Chase, 553 F.3d 187, 197 (2d Cir. 2009) (quoting Ganino v. Citizens Utils. Co., 228 F.3d 154, 162 (2d Cir. 2000)).

1. Plausible Allegations of Material Misstatements and Omissions

For the reasons explained below, several of Gerneth's allegations in the amended complaint satisfy the requirements to state a claim under Section 11. However, other allegations contained in the amended complaint do not. Accordingly, Defendants' motion to dismiss is denied as to Count I, but some of the misstatements or omissions alleged by Gerneth cannot plausibly support that claim.

a) Gerneth Has Adequately Pled Some Material Misstatements or Omissions in Chiasma's Item 503 Disclosures

Regulation S-K, 17 C.F.R. § 229.10 *et seq.*, issued pursuant to the Securities Act, "governs the disclosure requirements of registration statements, periodic reports and annual reports filed with the SEC" pursuant to Section 11. Silverstrand Investments v. AMAG Pharm., Inc., 12 F. Supp. 3d 241, 246 (D. Mass. 2014) ("Silverstrand II") (citing 17 C.F.R. § 229.10). One of the "items" an issuer is obligated to disclose under Regulation S-K is Item 503, which requires a prospectus to include "a discussion of the most significant factors that make the offering speculative or risky." 17 C.F.R. § 229.503(c). Item 503 disclosures must "describe the most significant factors that may adversely affect the issuer's business . . . or its future financial performance," Silverstrand I, 707 F.3d at 103 (quoting Securities Offering Reform, SEC Release No. 8501, 2004 WL 2610458, at *86), and "explain how the risk affects the . . . securities being offered. Generic or boilerplate discussions do not tell the investors how the risks may affect their investment." Id. (quoting Statement of the Commission Regarding Disclosure of Year 2000 Issues

and Consequences by Public Companies, Investment Advisers, Investment Companies, and Municipal Securities Issuers, SEC Release No. 7558, 1998 WL 425894, at *14 (July 29, 1998)).

In essence, to survive a motion to dismiss, a complaint alleging violation of Section 11 in Item 503 disclosures must "allege sufficient facts to infer that a registrant knew, as of the time of an offering, 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.

Defendants argue that Chiasma's prospectus complied with Item 503, including multiple disclosures of risk factors relating to, *inter alia*, (1) dependence on the regulatory approval of Mycapssa; (2) that Chiasma had never had a drug approved by regulatory authorities; (3) that even if Mycapssa received regulatory approval in the United States, that it could be delayed; (4) that Chiasma would only be able to generate revenue if there was regulatory approval; (5) that it would be incurring expenses to secure regulatory approval; and (6) that the FDA might disagree with the design or conduct of Chiasma's clinical trials, including different interpretation of the clinical trial data or that the data was insufficient to justify reliance on prior studies. D. 64-1 at 16-61. Further, the prospectus disclosed that these risk factors could negatively impact the stock price. D. 64-1 at 57-58. While the issues raised by the FDA during the pre-NDA meeting were not among those Item 503 risk factors that Chiasma disclosed, Defendants argue they are beyond the scope of what Item 503 requires. In other words, Defendants dispute their materiality.

Although Gerneth makes a number of arguments that the amended complaint plausibly alleges materiality, his argument is persuasive at least to the extent that he asking the Court to read the Item 503 disclosures contextually. Gerneth argues that the disclosures were couched as possibilities of risk, rather than certainties that had already come to pass. For example, Gerneth

points to Chiasma's warning that the FDA might disagree with the design or conduct of its clinical trials, including disagreement about interpretation of data, D. 64-1 at 17, when in fact the amended complaint alleges that the FDA had already stated its disagreement with the Phase 3 trial design by that time, see, e.g., D. 30, ¶¶ 89, 119. "[C]autionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired." In re AOL Time Warner Sec. & "ERISA" Litig., 381 F. Supp. 2d 192, 223 (S.D.N.Y. 2004). It was not until the phone calls on November 18, 2015, April 14, 2016, and April 18, 2016, that Chiasma executives admitted that the possible disagreement by the FDA they had disclosed had not only occurred, but was later listed in the CRL as a partial basis for denial of the NDA. See, e.g., D. 30, ¶¶ 87-89, 115-16, 119.

While the parties hotly dispute the severity of the FDA's reservations at the pre-NDA meetings and thus their materiality, the Court cannot consider that disputed issue of fact on a motion to dismiss. As alleged in the amended complaint, a reasonable investor could have been misled by the failure to include details about the timeliness and accuracy of Chiasma's disclosed Item 503 risks regarding warnings by the FDA at the pre-NDA meetings, which Chiasma failed to heed before filing the NDA. While the FDA never "specifically requested that [Chiasma] postpone its NDA submission" due to its concerns stated at the pre-NDA meetings, Sanders v. AVEO Pharmaceuticals, Inc., No. 13-cv-11157-DJC, 2015 WL 1276824, at *6 (D. Mass. Mar. 20, 2015), the allegations reflect "'subjective scientific disagreement over the efficacy' of the drug [that] should be disclosed to investors." Id. (quoting In re Alkermes Sec. Litig., No. 03-cv-12091-RCL, 2005 WL 2848341, at *16 (D. Mass. Oct. 6, 2005)). Accordingly, Gerneth has stated a Section 11 claim that the Item 503 disclosures were materially misleading.

b) Gerneth Has Plausibly Alleged That Some Statements Describing The Phase 3 Trial Were Materially Misleading

Defendants argue that Regulation S-K does not require a prospectus to disclose the particular and granular details of a clinical trial, but rather the general business strategy that may include clinical trials. In particular, Defendants argue that they did not have a duty to disclose additional details about the Phase 3 trial, which Gerneth alleges were material omissions, such as methods of statistical analysis or methodological comparison to other studies for acromegaly treatments. See D. 30, ¶¶ 92-97, 99. Issuers have a duty to "provide investors with a clear and concise summary of the material risks." Silverstrand I, 707 F.3d at 103. However, granular details from a NDA meeting about a clinical trial are not material if they are "not particularly predictive" of the FDA's ultimate decision. Washtenaw Cty. Employees' Ret. Sys. v. Princeton Review, Inc., No. 11-cv-11359-RGS, 2012 WL 727125, at *5 (D. Mass. Mar. 6, 2012); see Glassman, 90 F.3d at 632.

Nonetheless, the Court finds other allegations relating to the Phase 3 trial to be materially misleading. For example, Gerneth alleges that Chiasma failed to disclose that, at the pre-NDA meeting, the FDA offered guidance to Chiasma that it would prefer that the company enroll in sites in the United States to run the Phase 3 trial, D. 30, ¶¶ 93, 102, 104-105, and that this shortcoming was another explicit reason for the ultimate denial of the NDA, D. 30, ¶¶ 102, 123. While "ultimate FDA disapproval . . . could not have been known at the time of the . . . omissions, certainly the FDA had expressed concerns" that made Chiasma's claim that it would be able to secure approval for Mycapssa with shorter development timelines materially misleading when it was made, Sanders, 2015 WL 1276824, at *6, because the omitted fact made approval on any timeline less likely. In Sanders, 2015 WL 1276824, at *7, this Court determined that a later statement by an

executive of the defendant that "he was aware that the FDA expressed concerns" during a pre-NDA meeting was sufficient to allege plausibly that his statements to the contrary were materially misleading. Id.[2] Accordingly, Gerneth has stated a Section 11 claim that omissions relating to the FDA's stated concerns about the Phase 3 trial, as well as related misstatements about the timeline and likelihood of NDA approval, were materially misleading.

2. Certain Allegations Do Not State a Section 11 Claim

While, as explained above, Gerneth has stated a claim as necessary for Count I to survive Defendants' motion to dismiss, some of the misstatements and omissions alleged in the amended complaint fail to support a claim under Section 11.

a) Alleged Omissions That Were Disclosed

Defendants argue that the prospectus includes information about the Phase 3 trial that Gerneth alleges was omitted. Defendants point to Gerneth's allegation that the prospectus failed to disclose that the percentage of patients in the Phase 3 trial who successfully controlled their acromegaly using Mycapssa was calculated using last observation carry forward statistical method, rather than worst-observation carried forward statistical method, which Gerneth alleges is preferred by the FDA and would have resulted in a lower percentage of "successful" patients in the Phase 3 trial. D. 30, ¶¶ 95-96. As Defendants identify, the prospectus appeared to do exactly

[2]Even if, as Defendants argue elsewhere, their statement claiming to be able to secure approval for Mycapssa on a shorter time horizon was an opinion, "[a]n opinion may still be misleading if it does not represent the actual belief of the person expressing the opinion, lacks any basis or knowingly omits undisclosed facts tending seriously to undermine the accuracy of the statement." Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 775 (1st Cir. 2011). In this instance, Gerneth has alleged plausibly that Defendants "knowingly omit[ted] undisclosed facts tending to undermine the accuracy of the statement," id., that the Mycapssa NDA could be approved with shorter development timelines.

that. After disclosing its 65% rate of patients who had "achieved the primary endpoint," it states that ""[a]pplying a worst-case imputation method, whereby all patients who withdrew from the study prematurely . . . are treated as nonresponders, 53% of patients were classified as responders." D. 64-1 at 103. To the extent the FDA preferred the worst-observation carried forward method, it was made available as an alternative calculation.

Similarly, Defendants point to Gerneth's allegation that the prospectus was materially misleading because it stated that the responder rate in the Phase 3 trial was 62% after the Extension Phase, when only 58.2% of patients participated in the Extension Phase and 54.3% finished it. D. 30, ¶ 99. The information necessary to derive these percentages is either disclosed or calculable based on information on the same page of the prospectus. D. 64-1 at 103. Furthermore, participation in each subsequent stage of the study, discussed in the first paragraph on that page, id., is not the same calculation as responder rate, which referred to the patient's response to a particular treatment, see, e.g., D. 64-1 at 101 (classifying patients as "responder[s] to a long-acting injectable somatostatin analog"). In other words, the Phase 3 responder rate of 62% refers to a subset of those who participated in the Extension Phase who responded to Mycapssa.

Defendants also point to Gerneth's allegation that a statement attributed to endocrinologists contained in the prospectus stating that a minimum effectiveness rate among patients of 50% would be sufficient for an oral treatment to be successful. D. 30, ¶ 98. Defendants argue this statement was provided under a section addressing "Commercialization Strategy," and related to the effectiveness rate necessary to ensure success in convincing doctors to prescribe the drug, rather than relating at all to the FDA. The amended complaint similarly reads this disclosure out of context, which does not make it misleading. See Washtenaw, 2012 WL 727125, at *6. A plain reading of the amended complaint shows that the 50% patient rate came from "Chiasma's market

research" intended to show what effectiveness rate in patients "would be sufficient for an oral treatment to be successful." D. 30, ¶ 98.

Defendants also point to Gerneth's allegation that the Prospectus omitted a "standard" quantity of measurement for treatment efficacy (the "ULN endpoint measurement") of 1.0, instead only disclosing that Chiasma used a 1.3 ULN endpoint measurement for the Phase 3 trial. D. 30, ¶ 101. A prospectus is not required to disclose "alternative methods for measuring the data," In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 879 (9th Cir. 2012), or otherwise disclose "information from optimal studies" in contrast to the company's own stated methods of measurement, Padnes v. Scios Nova Inc., No. 95-cv-1693, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996). In essence, Gerneth asks the Court to evaluate the prudence of the Phase 3 trial as alleged in the amended complaint, rather than the material falsity of its representation in the Prospectus. The use of any alternative measurement, stated clearly in the prospectus, would be part of the mix of information an investor could use in deciding whether to purchase the security.

Finally, Defendants argue Gerneth's allegations that Roche terminated its licensing agreement with Chiasma after the pre-NDA meeting because of questions raised by the FDA, D. 30, ¶ 113, is contradicted by a plain reading of disclosures contained in the prospectus. In particular, Defendants point to a paragraph in which the prospectus states:

> "[I]n July 2014, Roche elected to terminate our license agreement for oral octreotide after reviewing the data from the seven-month core treatment period of our Phase 3 clinical trial and after a May 2014 pre-NDA meeting with the FDA. Roche cited no reason for its decision in its formal notice of termination, but stated publicly at the time that it had elected to make this decision after receiving additional information about our Phase 3 clinical trial and after further consultation with regulatory authorities."

D. 64-1 at 18. Gerneth argues that the prospectus was misleading because its claim that "Roche cited no reason for its decision in its formal notice of termination" was not true. No facts alleged in the amended complaint make this disclosure misleading or false by alleging that Roche did give a reason for its termination in its formal notice, or what the reason was.

b) Speculative Alleged Omissions

Further, Defendants argue that a series of Gerneth's allegations of other misstatements are baseless speculation and, therefore, cannot form the basis of a Section 11 claim. Defendants point to Gerneth's allegation that the prospectus was misleading because it did not disclose that the FDA preferred the WOCF method to account for withdrawing patients in the mITT study. D. 30, ¶ 96. However, Defendants argue that the amended complaint does not allege that the FDA expressed this preference to Chiasma at any time before the prospectus was filed, instead relying only on an analyst report that was published a year after the prospectus was filed [and did not itself imply that any FDA statement was made before the prospectus was filed]. D. 30, ¶ 121. Information the plaintiff alleges to have been omitted must have "existed at the time the prospectus became effective" to state a claim under Section 11 of the Securities Act. Cooperman v. Individual, Inc., 171 F.3d 43, 47 (1st Cir. 1999).

While Gerneth argues that Section 11 claims do not require him to plead scienter to state a claim, this fails to rebut Defendants' argument. Defendants argue that the information must have existed when the prospectus was issued for its omission to be misleading. In other words, Defendants cannot have misled the market by omitting information that "when such [Registration Statement] became effective," 15 U.S.C. § 77k(a), did not exist. For motion to dismiss purposes, Gerneth cannot be said to have stated a claim that the prospectus was misleading without adequately pleading that information was available to be disclosed when the prospectus was

issued, which in this instance he has failed to do. At the very least, Gerneth must plead that the information did exist to allege plausibly that Defendants should have disclosed it. See Gross v. Summa Four, Inc., 93 F.3d 987, 995 (1st Cir. 1996) (superseded by statute on other grounds) (rejecting argument that press release was misleading by referencing information contained in board minutes created after the press release was issued).

Finally, Defendants contend that Gerneth's allegation concerning Chiasma's disclosure that "oral octreotide has the potential to become a standard of care in the treatment of acromegaly" is not actionable because Gerneth has not alleged that Defendants had any opinion or knowledge to the contrary, and that the product failed to reach its stated potential does not rise to the level of being misleading. The statements referenced by Gerneth as misleading on this subject are all couched in opinion language. The prospectus talks about Chiasma's "belie[f]" that they have sufficient data to seek 505(b)(2) approval, or that Chiasma "expect[s] to be able to rely on information from previously conducted studies." D. 30, ¶ 105.

B. Count II Is Not Time-Barred

Defendants argue that the claims against the Individual Defendants, which were added in the amended complaint, are untimely and should alternately be dismissed on this basis. Claims brought under the Securities Act have a one-year statute of limitations. 15 U.S.C. § 77m. This period is measured from "the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence." Id. This discovery rule has been analogized to finding "the later date on which an investor, alerted by storm warnings and therefore exercising reasonable diligence, would have discovered the fraud." Capital Ventures Int'l v. UBS Sec. LLC, No. 11-cv-11937-DJC, 2012 WL 4469101, at *13 (D. Mass. Sept. 28, 2012). The "relevant question for statute of limitations purposes is 'whether a plaintiff could have

pled '33 Act claims with sufficient particularity to survive a 12(b)(6) motion to dismiss.'" Id. (quoting In re Bear Stearns Mortg. Pass-Through Certificates Litig., 851 F. Supp. 2d 746, 762-63 (S.D.N.Y. 2012)).

Defendants contend that the Court should find that the claims began to accrue on November 18, 2015, when Gerneth alleges Chiasma first revealed publicly material information that had been omitted from the prospectus. D. 30, ¶ 115. Presently, however, the Court cannot conclude there is "no doubt that [the claims] are time-barred." Warren Freedenfeld Assocs. V. McTigue, 531 F.3d 38, 46 (1st Cir. 2008) (citation omitted). As explained above, the Court considers Gerneth's allegations from the April 14 and 18, 2016 phone calls as relevant to the materiality of omissions from the Prospectus. Moreover, these April 2016 allegations were referenced in Gerneth's original complaint filed in June 2016. See D. 1, ¶ 36. Defendants have not met their burden that Gerneth discovered or should have discovered facts revealed in the April 2016 phone calls in November 2015. See In re Bear Stearns, 851 F. Supp. 2d at 763.

VI. Conclusion

For the aforementioned reasons, the Court DENIES Defendants' motion to dismiss, D. 62.

So Ordered.

/s/ Denise J. Casper
United States District Judge