SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION

HOWARD BERNSTEIN, Individually and on Behalf of All Others Similarly Situated, Plaintiff-Appellant, v. BRISTOL-MYERS SQUIBB CO.; MARK J. ALLES; GIOVANNI CAFORIO, M.D.; SANDRA LEUNG, ESQ.; CHARLES BANCROFT; KARN M. SANTIAGO; VICKI L. SATO, PH.D.; PETER J. ARDUINI; ROBERT BERTOLINI; MATTHEW W. EMMENS; MICHAEL GROBSTEIN; ALAN J. LACY; DINESH C. PALIWAL; THEODORE R. SAMUELS; GERALD L. STORCH; and KAREN H. VOUSDEN, PH.D., Defendants-Appellees.	:	Docket No. A-002080-24 On Appeal from Order of the Superior Court of New Jersey, Law Division, Union County, dated February 7, 2025 Sat Below: Honorable John G. Hudak, J.S.C. Docket No. Below: UNN-L-003887-21 CLASS ACTION

PLAINTIFF-APPELLANT'S AMENDED OPENING BRIEF

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PRELIMINARY STATEMENT

This action alleges non-fraud, pure omission claims under Sections 11 and 15 of the federal Securities Act of 1933 (the "Securities Act") challenging offering documents issued in connection with the November 2019 merger (the "Merger") between the pharmaceutical companies Bristol-Myers Squibb Co. ("Bristol-Myers") and Celgene Corp. ("Celgene") (Bristol-Myers and Celgene, collectively with Mark J. Alles, Giovanni Caforio, M.D., Sandra Leung, Esq., Charles Bancroft, Karn M. Santiago, Vicki L. Sato, Ph.D., Peter J. Arduini, Robert Bertolini, Matthew W. Emmens, Michael Grobstein, Alan J. Lacy, Dinesh C. Paliwal, Theodore R. Samuels, Gerald L. Storch, and Karen H. Vousden, Ph.D., "Defendants"). Plaintiff Howard Bernstein ("Plaintiff") alleges that the Offering Materials (consisting of the S-4 registration statement, 424B3 prospectus, and materials incorporated therein) for new shares of Bristol-Myers common stock and 714 million contingent value rights ("CVRs") issued and sold directly to former Celgene shareholders omitted a bevy of critical facts required to be disclosed under governing U.S. Securities and Exchange Commission ("SEC") regulations—specifically, Items 303 and 105 of Regulation S-K. *See, e.g.*, Pa30-36, 73-76.

The prospect of a $6.4 billion CVR payout promised to Plaintiff and other former Celgene investors required approval from the U.S. Food and Drug

Administration ("FDA") of three legacy Celgene therapies by specified dates (the "Milestones"). One of those therapies was for a treatment called liso-cel. Bristol-Myers would not have to make the CVR payment if a single therapy missed its Milestone, even by a single day. Pa33-34, 73-76. Plaintiff alleges Defendants violated Section 11 by failing to disclose information "required to be stated" by Items 303 and 105—namely, that well before the Merger, Bristol-Myers was already taking steps that were likely to slow-roll the FDA approval process for liso-cel, and thus undercut the prospect of a $6.4 billion CVR payment promised to Plaintiff and other former Celgene investors. Pa30-33.

Unbeknownst to investors, before the Merger, Defendants had drafted defective regulatory filings and permitted operational irregularities that strayed in critical respects from both well-established industry standards and Bristol-Myers's own long-standing practices in a multitude of prior FDA filings. *See, e.g.*, Pa30-36, 73-76. Plaintiff alleges these undisclosed operational irregularities and drafting deficiencies in great detail, including, *inter alia*:

- That Bristol-Myers had drafted FDA filings that omitted volumes of basic information and critical data concerning liso-cel; and
- That Bristol-Myers had allowed its purportedly launch-ready production facilities to violate FDA and industry standards.

Id. Defendants knew that these undisclosed facts could significantly hamper FDA review, inspection, and approval of liso-cel, and that a delayed approval process

could undermine any chance of meeting the liso-cel Milestone (and ultimate payment to CVR holders).

In short, Plaintiff pleads that, undisclosed to the putative class, the promise of a $6.4 billion CVR payment was essentially illusory when Defendants issued the Offering Documents. By failing to disclose these facts, Defendants violated Items 303 and 105 and Section 11 of the Securities Act. The truth became clear after the Merger when delays caused by Defendants' deficient filings and substandard operations led the FDA to delay the liso-cel approval process beyond the Milestone date, which ultimately led to the loss of $6.4 billion CVR payment.

Accordingly, this Court should reverse the dismissal of this action and remand for further proceedings.

PROCEDURAL HISTORY

Plaintiff filed a complaint in the Superior Court of New Jersey, Union County – Law Division on November 12, 2021. Pa5, 557-604. Plaintiff asserted claims against all Defendants under Sections 11, 12(a)(2), and 15 of the Securities Act, and claims under Item 303 and 105. Pa5, 600-603. On June 25, 2024, Judge John G. Hudak of the Superior Court of New Jersey, Union County – Law Division (the "Trial Court") granted Defendants' motion to dismiss in its entirety without prejudice, finding that: (1) the statements in the Offering Materials about achieving

the CVR milestones were protected by the safe harbor for forward-looking statements in the Private Securities Litigation Reform Act ("PSLRA") and therefore not actionable under Sections 11 or 12(a)(2) of the Securities Act; (2) Bristol-Myers did not make any actionable misstatements because Plaintiff's allegations were legally deficient allegations of fraud by hindsight; and (3) the complaint did not plead any facts that show there was a plan in place prior to the Offering Materials becoming effective because Bristol-Myers disclosed that it was possible the CVRs could become worthless. Pa5, 605-633. The Trial Court also dismissed Plaintiff's pure omissions theory under Items 303 and 105 and dismissed the Section 15 claim. Pa5, 605-633. Further, though Plaintiff affirmatively disclaimed fraud and the Securities Act provides a strict liability cause of action for misrepresentation or omission, the Trial Court held that Plaintiff had to satisfy the heightened Rule 4:5-8 pleading standards for actions that sound in fraud. Pa558, 600, 629.

On August 15, 2024, Plaintiff filed the First Amended Complaint (the "FAC"). Pa5, 29-104. Plaintiff dropped his Section 12(a)(2) claim and asserted claims only under Sections 11 and 15. Pa5, 100-102. In the FAC, Plaintiff asserts a strict liability, non-fraud claim, alleging that the Offering Materials breached mandatory duties to disclose under Items 303 and 105 because they did not disclose that, before the Merger occurred, Bristol-Myers was drafting already defective FDA filings and implementing deficient operational plans. Pa5, 30-35. On February 7,

2025, the Trial Court granted Defendants' motion to dismiss in its entirety with prejudice (the "Order" or the "Order Appealed From"), finding that Plaintiff's strict liability and negligence claims sounded in fraud and, therefore, failed to satisfy the R. 4:5-8 heightened pleading standard. Pa16-28. The Trial Court further held that Plaintiff failed to state a claim under Items 303 and 105 because Bristol-Myers lacked actual knowledge that the relevant regulatory filings were or could be deficient. Pa16-28.

STATEMENT OF FACTS

I. BEFORE THE MERGER, BRISTOL-MYERS DEVELOPED FLAWED APPROVAL AND OPERATIONAL PLANS FOR LISO-CEL

Long before the Merger closed, Bristol-Myers began to plan for how it would manage the combined company. Merger negotiations between Bristol-Myers and Celgene started in early 2017, almost two years before the ultimate close of the Merger. Pa45. After a lull, negotiations began again in June 2018. Pa45-46. By September 2018, Bristol-Myers's CEO and Chairman, Giovanni Caforio, was actively working—at the direction of Bristol-Myers's Board of Directors—on a proposed offer for Celgene. Pa46-47. This work entailed a careful analysis of Celgene's drug development pipeline, including (1) the timeline for submission (2) the plans for obtaining approval, (3) the likelihood of approval and (4) the expected value of each drug if approval. Pa46-47. One of the drugs Dr. Caforio covered was

liso-cel, which was a potential blockbuster drug obtained by Celgene in March 2018, when it purchased Juno Therapeutics for $9.1 billion. Pa45-47.

By October 31, 2018, the negotiations had advanced to where Bristol-Myers began to actively plan for the management of the post-Merger company, including liso-cel. Pa50-51. At that time, Bristol-Myers's top management began working on an updated long-term financial plan for the Company that accounted for the impact of the merger. Pa50-51. This analysis required Bristol-Myers to prepare plans for the post-acquisition submission of liso-cel to the FDA for approval, including liso-cel's Biologics License Application ("BLA"). Pa50-51.

The plans Bristol-Myers formulated for managing Celgene's drug pipeline in the last quarter of 2018 were deficient. Pa50-51. For example, the Company's plans called for the submission of summary assays (i.e., tests designed to establish safety and efficacy) in support of the BLA where FDA regulations mandated that substantiating data "must be available to establish that the analytical procedures used in testing meet proper standards of accuracy, sensitivity, specificity and reproducibility and are suitable for their intended purpose." Pa50-51. The deficiencies in Bristol-Myers's liso-cel plans significantly increased the risk that the FDA would delay or deny approval, notwithstanding the treatment's promise. Pa50-51.

In November 2018, Bristol-Myers and Celgene entered into a confidentiality agreement to allow each company to access non-public information from the other for their respective due diligence efforts. Pa51-52. In late November 2018, Bristol-Myers began working with Morgan Stanley to arrange debt financing to acquire Celgene. Pa51-52. Bristol-Myers negotiated a commitment letter with Morgan Stanley Senior Funding and MUFG Bank, Ltd. for a bridge loan facility to finance the cash portion of the Merger consideration. Pa51-52. These financial transactions rested in part on Bristol-Myers's plans for Celgene's drug pipeline, including liso-cel. Pa51-52. The amount of financing and terms was dependent on the post-Merger company's expected cash flow, an issue that directly impacted the timeline for approval of liso-cel. Pa51-52. The plans and draft BLA submissions that Bristol-Myers had prepared for Celgene's drug pipeline were deficient and significantly increased the risk that the FDA would delay or deny approval for liso-cel. Pa51-52.

On December 5, 2018, Bristol-Myers's Board of Directors met to discuss the Merger negotiations and the strategic benefits of the Merger. Pa52-53. The latter rested on Bristol-Myers's then-existing plans for the post-Merger company, including its flawed plans for managing the development of Celgene's drug pipeline. Pa52-53. During the meeting, Bristol-Myers's management discussed with the Board findings from the ongoing due diligence process, including how these findings

related to key Celgene products and pipeline products. Pa53. Bristol-Myers's management provided an assessment of Celgene's pipeline assets. Pa53.

Representatives of Morgan Stanley, Evercore and Dyal Co., together with Bristol-Myers's management, discussed financial analysis related to the potential merger, including how it would impact Bristol-Myers's long term financial plan. Pa53-54. The Board also discussed potential upside variables that were not reflected in the projections. Pa53-54. Based on this analysis, the Board authorized a revised offer for Celgene. Pa53-54. Negotiations continued thereafter. *See e.g.*, Pa54-57. Bristol-Myers continued to receive non-public information from Celgene that it used to formulate its transition plan. Pa58.

On December 14, 2018, Bristol-Myers provided Celgene with a draft merger agreement. Pa60. The companies continued to revise the agreement in subsequent weeks. Pa60-61.

On December 27, 2018, following the receipt of additional confidential Celgene information from due diligence, Bristol-Myers's Board discussed a revised proposal for Celgene. Pa61. The discussion included the introduction of a CVR component to the merger consideration for purposes of bridging the gap between the companies' position on the appropriate price per share for Celgene. Pa61. Bristol-Myers's Board authorized a revised offer of $50 per share in cash, one Bristol-Myers

share, and a CVR component that would pay up to $8 per share of Celgene common stock if certain post-closing milestones were met. Pa61.

On December 28, 2018, members of Celgene and Bristol-Myers management discussed and negotiated the terms of the possible CVR, including the amounts that could be payable under the CVR and the required payment milestones. Pa62-63. To negotiate these terms, Bristol-Myers had to understand the prospects for Celgene's late-stage pipeline assets, including liso-cel. Pa62-63. Specifically, Bristol-Myers had to understand where each drug was in terms of FDA approval, Bristol-Myers's post-acquisition plan for approval of each drug, and the market potential for each drug. Pa62-63.

Celgene proposed that the CVR could pay up to $10, with $2 payable upon FDA approval of each of Celgene's late-stage pipeline assets. Pa62-63. The value of the CVR was important to Celgene management because it reflected a significant increase in value from the original $110.00 per share offer. Pa63.

In response, Bristol-Myers stated it would not agree to pay out on the CVR unless multiple milestones were achieved before a specific milestone date. Pa63-64. Under Bristol-Myers's proposal, the CVR would pay $9 only if the FDA approved all three of ozanimod, JCAR017 (aka liso-cel) and bb2121 for commercial manufacturing and marketing by December 31, 2020. Pa63-64. Again, this offer could not have been made without Bristol-Myers having a concrete plan for how it

would manage the development of these drugs post-Merger. Bristol-Myers had worked on these plans for months and had the benefit of Celgene's non-public information. Bristol-Myers's plans for liso-cel were deficient in that they contemplated submitting less data than normally called for by the FDA. This flaw substantially increased the likelihood that approval of liso-cel would be delayed or denied.

Bristol-Myers's Board met on December 30, 2018. Pa64-65. During the meeting, members of management and representatives of external advisors provided an overview of the proposed CVR component to the merger consideration under various formulations. Pa64-65. The Board approved a revised proposal for Celgene consisting of $50 in cash, one Bristol-Myers share, and a CVR that would pay $9 if the FDA approved ozanimod, JCAR017 (aka liso-cel) and bb2121 for commercial manufacturing and marketing by December 31, 2020. Pa64-65. Thereafter, the companies continued to negotiate the terms of CVR, ultimately agreeing to an extension to March 31, 2021, for bb2121. Pa66-67. On January 3, 2019, Bristol Myers and Celgene executed the merger agreement. Pa70.

II. THE OFFERING MATERIALS OMIT INFORMATION REQUIRED UNDER ITEMS 303 AND 105

On February 1, 2019, Defendants filed with the SEC a Form S-4 draft Registration Statement which would register the Bristol-Myers common stock and

CVRs to be issued in connection with the Merger. Pa70. On February 22, 2019, the SEC declared the Registration Statement effective. Pa70.

By the effective date, Bristol-Myers had already engaged in extensive planning for how it would manage Celgene's drug pipeline, not only during the negotiation process as detailed above, but also in the seven weeks since the signing of the merger agreement. Despite this planning, Defendants did not disclose any details in the Registration Statement about how Bristol-Myers would proceed vis-à-vis liso-cel. It did not, for example, disclose that Bristol-Myers had drawn up plans for a truncated BLA submission with only limited supporting data. Instead, the Registration Statement stated that "Bristol Myers Squibb has agreed to use 'diligent efforts' to achieve the CVR milestone." Pa71. By negligently failing to disclose the true facts concerning the plans for liso-cel and the significantly heightened risk of delay engendered by those plans, Defendants violated Items 303 and 105 and Section 11 of the Securities Act.

III. POST-MERGER EVENTS

The Merger became effective on November 20, 2019. Pa81. On December 18, 2019, Bristol-Myers submitted the Chemistry, Manufacturing and Controls ("CMC") portion of the liso-cel BLA. Pa81-82. The form and substances of the BLA, including the omission of reams of critical data, was consistent with the

transition plans Bristol-Myers had developed between October 2018 and February 22, 2019. Pa81-82.

Soon after completing its initial review of the liso-cel BLA, the FDA found significant omissions in the application. Pa83, 84-85. Specifically, the liso-cel BLA was deficient because Bristol-Myers had failed to submit basic data detailing (1) the tests used to ensure that liso-cel is safe and efficacious, referred to as assays and (2) the studies that assess whether those assays worked as they were supposed to, referred to as validation. Pa83, 84-85. The liso-cel BLA also violated FDA guidance that applicants "include a full description of the manufacturing process, including analytical procedures that demonstrate the manufactured product meets prescribed standards of identity, quality, safety, purity and potency" and provide that substantiating data "must be available to establish that the analytical procedures used in testing meet proper standards of accuracy, sensitivity, specificity, and reproducibility and are suitable for their intended purpose." Pa83-84.

On March 23, 2020, the FDA submitted an information request to Bristol-Myers seeking the missing data on assays and validation. Pa85. Bristol-Myers submitted the information but it was so voluminous and significant that the submission counted as a Major Amendment. Pa85. These events severely undercut the ability of Bristol-Myers to obtain approval of liso-cel in time. First, they extended the target approval deadline from August 17, 2020, to November 16, 2020,

only weeks from the liso-cel milestone. Pa86. Second, the Major Amendment prompted the FDA to reschedule its inspection of the relevant manufacturing facilities from June 2020 to October and December 2020. Pa86. Ultimately, Bristol-Myers navigated the obstacles created by its deficient BLA plans, but liso-cel was not approved by the target deadline, denying former Celgene shareholders $6.4 billion. Pa92-93.

LEGAL ARGUMENT

I. STANDARD OF REVIEW

On appeal, Rule 4:6-2(e) dismissals for failure to state a claim are subject to plenary review, with "no deference to the trial court's conclusions." *Rezem Family Assocs., LP v. Borough of Millstone*, 423 N.J. Super. 103, 114 (App. Div. 2011).

"New Jersey is a notice-pleading state, which means that only a short, concise statement of the claim need be given in the complaint, without requiring any technical forms of pleading." *Evesham Twp. Bd. of Educ. v. Vitetta Grp.*, 2008 WL 4735883, *8 (N.J. Super. Ct. App. Div. Oct. 30, 2008). On a motion to dismiss for failure to state a claim, the "inquiry is limited to examining the legal sufficiency of the facts alleged on the face of the complaint." *Printing Mart-Morristown v. Sharp Elecs. Corp.*, 116 N.J. 739, 746 (1989). The court must "assume the facts as asserted by plaintiff are true and give her the benefit of all inferences that may be drawn in her favor." *Banco Popular N. Am. v. Gandi*, 184 N.J. 161, 166 (2005) (citation

modified). The complaint is legally sufficient if any cause of action is "'suggested' by the facts" alleged. *Printing Mart-Morristown*, 116 N.J. at 746.

As the New Jersey appellate courts have repeatedly admonished, motions to dismiss should be "approach[ed] with great caution" and "granted in only the rarest of instances." *Id*. at 771-72. At this "preliminary stage" the court "is not concerned with the ability of plaintiffs to prove the allegations contained in the complaint"; rather, the court's "examination of the complaint's allegations of fact . . . should be one that is at once painstaking and undertaken with a generous and hospitable approach," affording plaintiffs "every reasonable inference of fact." *Id*. at 746. The court must "search[] the complaint in depth and with liberality to ascertain whether the fundament of a cause of action may be gleaned even from an obscure statement of claim." *Id*. "Dismissal is appropriate only if the complaint states no basis for relief and discovery would not provide one." *J-M Mfg. Co., Inc. v. Phillips & Cohen, LLP,* 443 N.J. Super. 447, 453 (App. Div. 2015) (citation modified).

Where a Plaintiff pleads causes of action under Sections 11 and 15 of the Securities Act, those claims are for negligent misrepresentation or omission. *See Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 715 (2d Cir. 2011) ("Fraud is not an element or a requisite to a claim under Section 11 or Section 12(a)(2)"); *In re Willis Towers Watson Plc Proxy Litig.*, 439 F. Supp. 3d 704, 712-13 (E.D. Va. 2020) (explaining that Section 11 "does not mention any state of mind requirement," is

"'devoid of any suggestion whatsoever of a scienter requirement,'" rather, it "'proscribes a type of disclosure or lack of it, i.e., false or misleading statements or omissions of material facts, . . . [and] enumerates specific classes of individuals who bear liability for failure to meet the required standard of disclosure'") (quoting *Gould v. Am.-Hawaiian S.S. Co.*, 535 F.2d 761, 777 (3d Cir. 1976)). A claim for *fraudulent* misrepresentation falls under Section 10 of the Securities Exchange Act of 1934 (the "Exchange Act"), which has not been pled in this case. Pa100-102.

A complaint that only alleges negligent omission claims under Section 11, and that does not allege fraudulent concealment of information, does not sound in fraud. *In re NationsMart Corp. Sec. Litig.*, 130 F.3d 309, 314-15 (8th Cir. 1997) ("We hold that the particularity requirement of Rule 9(b) does not apply to claims under §11 of the Securities Act, because proof of fraud or mistake is not a prerequisite to establishing liability under §11."); *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 272 (3d Cir. 2006) ("Securities Act claims do not sound in fraud if ordinary negligence is expressly pled in connection with those claims."); *Litwin*, 634 F.3d at 715 ("plaintiffs' complaint explicitly does not allege fraud; rather, it alleges that [defendant] acted negligently in preparing its Registration Statement and Prospectus . . . [it] is an ordinary notice pleading case").

The Second Circuit recently illustrated this point in rejecting the types of arguments raised by Defendants here. In *Pappas v. Qutoutiao, Inc.*, 2024 WL

4588491, *2-3 (2d Cir. Oct. 28, 2024), the Second Circuit reversed a district court that had incorrectly held that a Section 11 case "sound[ed] in fraud." *Id.*, at *3 ("the district court applied the wrong standard to Plaintiff's Securities Act claims"). In *Qutoutiao*, the plaintiff alleged that the company had to disclose that it "intentionally adopted profit-seeking business strategies to disseminate illegal advertisements." *Id.,* at *2. The district court held that because the underlying undisclosed conduct was intentional wrongdoing, the allegations of the case "simply do not sound in negligence." *Id.* However, as the Second Circuit explained, this was in error because "although Plaintiff alleges [the company] intentionally designed and implemented the underlying strategies, Plaintiff's Securities Act claims charge Defendants with negligently failing to disclose those strategies and their results—that a fact was known and not disclosed does not mean, as a matter of law, that the circumstances of the resulting omission sound in fraud." *Id.*, *2 (citation modified). Rather, a Section 11 claim sounds in fraud where it alleges "that defendants intentionally concealed information in the filing at issue." *Id.*, at *3.

The dismissal below was in error and should be reversed because the Complaint's detailed allegations more than suffice to "suggest" non-fraud, pure omission claims under Sections 11 and 15 of the Securities Act.

II. PLAINTIFF'S ALLEGATIONS SUFFICE TO PLEAD PURE OMISSION CAUSES OF ACTION UNDER SECTION 11. Pa1-28.

Enacted in response to the 1929 stock market crash and ensuing Great Depression, the Securities Act's "fundamental purpose" is investor protection: "to substitute a philosophy of full disclosure for the philosophy of caveat emptor." *SEC v. Cap. Gains Rsch. Bureau, Inc*., 375 U.S. 180, 186 (1963). It "protects investors by ensuring that companies issuing securities . . . make a full and fair disclosure of information relevant to a public offering." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 178 (2015). To "assure compliance," Section 11 of the Securities Act "impos[es] a stringent standard of liability on the parties who play a direct role in a registered offering," while placing only a "minimal burden on a plaintiff." *Herman & MacLean v. Huddleston*, 459 U.S. 375, 381-82 (1983).

Section 11 imposes strict liability if any part of a registration statement "contain[s] an untrue statement of a material fact or omit[s] 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). It thus supports three straightforward, but distinct, theories of liability: (1) untrue statements of material fact; (2) omission of material facts "required to be stated" under affirmative duties to disclose; and (3) omission of material facts that render other statements false and misleading. *In re Facebook, Inc. IPO, Sec. & Deriv. Litig.,* 986 F. Supp. 2d 487, 505-06 (S.D.N.Y. 2013).

This case concerns the second theory— the omission of material facts "required to be stated" in the Offering Materials pursuant to affirmative legal disclosure obligations, including Item 303 and Item 105 of SEC Regulation S-K. *See Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 120 (2d Cir. 2012). Critically, this category of claim, often referred to as a "pure omissions" theory, does not depend on any statement being rendered false or misleading. *See, e.g.*, *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 260 (2024) (explaining that "pure omission" claim under Section 11 arises from "failure to disclose information required by Item 303 . . . even if the failure does not render any statements made misleading" (citation modified); *Litwin*, 634 F.3d at 722 (construing Item 303 claims under Section 11 as "pure omissions" claims). Rather, claims under this theory turn on freestanding disclosure duties that mandate the inclusion of certain necessary information in the Offering Materials. Either the Offering Materials include the required information and thus satisfy the mandatory disclosure duties, or they do not. If not, the omission of mandatory information breaches the affirmative duties and thus constitutes a violation of the Securities Act. Liability "is virtually absolute, even for innocent" violations. *Huddleston*, 459 U.S. at 382; *see In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 923 (D.N.J. 1998) ("A plaintiff need not plead fraud, reliance, motive, intent, knowledge or scienter under Section 11.").

Plaintiff has pled that Defendants violated affirmative duties to disclose information "required to be stated" by Items 303 and 105 by failing to disclose that, before the Merger, Bristol Myers had already begun drafting FDA application documentation, approval plans, and operational protocols for the management of Celgene's drug pipeline that diverged from and were inconsistent with well-established industry standards, FDA requirements, and even Bristol-Myers's own past practice with similar applications, and further that these negligent deficiencies in Bristol-Myers's pre-Merger drafts and plans had already substantially increased the risk of a delay in the approval of liso-cel. Pa30-25. As explained more fully below, taken as true with all inferences drawn in Plaintiff's (not Defendants') favor, these allegations of fact more than suffice to suggest violation of both Items 303 and 105, and thus more than suffice to suggest a Section 11 claim. *See Silverstrand Invs. v. AMAG Pharms., Inc.,* 707 F.3d 95, 105 (1st Cir. 2013); *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1296 (9th Cir. 1998) ("Allegations which state a claim under Item 303(a) … sufficiently state a claim under Sections 11."); *Jaroslawicz v. M&T Bank Corp.,* 962 F.3d 701, 713-16 (3d Cir. 2020) (same).

A. Plaintiff Has Adequately Pled a Violation of Item 303. Pa1-28.

Item 303 required that the Offering Materials disclose "any known trends or uncertainties that . . . the registrant knows of events that are reasonably likely to cause a material change . . . unfavorable impact on . . . revenues or income from

continuing operations." 17 C.F.R. §229.303(b)(2)(ii). Under Item 303, "a disclosure duty exists" whenever such "a trend, demand, commitment, event or uncertainty" is "[1] presently known to management and [2] reasonably likely to have material effects on the registrant's financial condition or results of operation." *See Steckman*, 143 F.3d at 1296–97. It thus places the burden on the issuer's management to either rule out or disclose any reasonable likelihood of material impact from trends or risks, even if such material impact remains uncertain. *See In re Comm'n Guidance Regarding Management's Discussion and Analysis of Fin. Condition and Results of Operation*, Securities Act Release No. 8350, Exchange Act Release No. 48960, 2003 WL 22996757, at *11 (Dec. 19, 2003) ("[D]isclosure . . . is required unless a company is able to conclude . . .").

Plaintiff alleges that the Offering Materials failed to disclose that, before the Merger, Bristol-Myers was already drafting deficient plans, documentation, and protocols for the liso-cel BLA that were rife with irregularities that diverged from industry standards and their own prior practice and that would render their manufacturing facilities in blatant noncompliance with FDA standards. Pa31-35, 76-78, 84-87. These undisclosed divergences and inconsistencies significantly increased the risk that the CVR received in the Merger would be worthless. Pa32-33, 76-78, 84, 86. As such, Plaintiff alleges not only had Defendants failed to disclose these specific adverse events and uncertainties, but also failed to disclose

"whether, and to what extent a material trend has impacted ***or is expected***" to impact the Company's business and results. *See Facebook*, 986 F. Supp. 2d at 511 (citation modified). These omissions were highly material because they directly affected the value of the CVRs and Bristol Myers stock received in the Merger. Undisclosed to Celgene investors, the truncated BLA submission and deficient operational protocols formulated by Bristol-Myers before the Merger had already rendered the CVRs—which accounted for a major portion of the Merger consideration—almost worthless because the consequent delays necessary to fix the BLA would likely push the target approval deadline for liso-cel back to within (at best) weeks of the liso-cel Milestone. Pa86. These undisclosed divergences and inconsistencies in Bristol-Myers's pre-merger drafts and plans for the liso-cel BLA were already very likely to, and did, cause additional delays, such as the FDA's rescheduling of manufacturing plant inspections. *Id.* In short, due to Defendants' negligent failure to disclose critical adverse facts regarding Bristol-Myers's internal, pre-merger drafts, plans and protocols for pursuing liso-cel approval, Celgene investors were deprived of critical information about the value of the Merger consideration they received.

These allegations more than suffice to "suggest" a violation of Item 303. Defendants had an affirmative duty to disclose Bristol-Myers's internal divergences from industry and FDA standards incorporated into the pre-merger drafts and plans

for a truncated liso-cel BLA because those divergences and practices were an existing, adverse uncertainty that made timely approval of liso-cel far less likely. Many other courts have found similar allegations to state a claim under Item 303 and Section 11 of the Securities Act.

For example, in *Allison v. Oak Street Health*, *Inc.*, 2023 WL 1928119 (N.D. Ill. Feb. 10, 2023), the court considered a motion to dismiss a Securities Act case alleging that a company should have disclosed in its IPO registration statement the existence of certain marketing strategies that plaintiff alleged violated the Anti-Kickback Statute and False Claims Act. *Id.,* at *1. The court held that these allegations stated a violation of Item 303 and sustained the claims under Section 11 of the Securities Act. *Id*., at *8, *13. The court held that the company violated Item 303 by failing to disclose the "two specific practices alleged to be illegal," hindering investors' ability to judge for themselves the legal risk facing the company. *Id*., at *6 ("the alleged omission is the fact that Oak Street paid agents on a per-patient basis and offered free transportation to prospective patients, which Oak Street could have disclosed."). Here, the omission was the negligent failure to disclose that Bristol-Myers's internal pre-merger drafts and protocols already omitted reams of required data on, *inter alia*, assays and validation, and were already rife with irregularities that diverged from industry standards and their own prior practice and that were likely to render their manufacturing facilities in blatant noncompliance with FDA

standards. Pa31-35, 76-78, 84-87. Had investors been told this information and its potential consequences as required by the Securities Act, they could have judged for themselves the likelihood of success and the value of the CVRs.

Similarly, in *Panther Partners Inc. v. Jianpu Tech. Inc*., 2020 WL 5757628 (S.D.N.Y. Sept. 27, 2020), the court held that Item 303 was violated where defendant failed to disclose both then-existing internal practices already arguably in violation of regulatory rules and the "possible impact of [those regulatory] violations on [the company's] future business." *Id.,* at *13. Here, just as in *Jianpu*, a "reasonable investor would likely have considered it significant" that Bristol-Myers's internal draft plans and protocols were inconsistent with FDA guidance and regulations concerning BLAs that was already in place; investors would also have found the potential consequences of a truncated BLA material in assessing the value of the CVR and the Merger consideration in general. *Jianpu,* 2020 WL 5757628, at *13.

There are many other decisions demonstrating that Plaintiff's allegations "suggest" a case and must be sustained. *See, e.g*., *Silverstrand,* 707 F.3d at 104 (allegations that that defendants omitted information that "could have prompted FDA action" and "undoubtedly could have raised red flags with the agency" "more than suffic[ient]" to "plead plausible claims for omissions under § 11 due to undisclosed Item 303 uncertainties and undisclosed Item 503 risks"); *Twin Master Fund, Ltd. v. Akorn, Inc*., 2020 WL 564222, at *7 (N.D. Ill. Feb. 5, 2020) (holding

defendant's internal "noncompliance with FDA data integrity standards was known trend" under Item 303 and that these undisclosed "conditions could have reasonably been expected to materially impact Akorn's revenues by compromising the approval of their ANDA applications or subjecting them to FDA fines or other sanctions.").

In holding to the contrary, the Trial Court misconstrued the allegedly omitted facts and uncertainties and improperly drew adverse inferences against Plaintiff at the pleading stage.

First, the Trial Court erred in presuming that the allegedly deficient draft submission "could not have been deficient" because they "were merely drafts and were incomplete by definition" and "were not yet submitted regulatory filings and plans." Pa20. This is an error of law. As the foregoing case law clearly holds, the Securities Act requires registrants to disclose any material "trend" or "condition" or "risk." *See supra pgs*. 22-23. Thus, whether or not Bristol-Myers's plans were "drafts" or final is not relevant. The question is whether the then-existing plans and filings materially raised the risk that the CVR would not be paid. If so, they had to be disclosed. Plaintiff has satisfied these requirements by pleading that, pre-merger, Defendants were already drafting submissions, protocols, and operational plans that already omitted necessary information and already diverged from industry standards and Bristol-Myers's own past practice in a manner that directly imperiled Bristol-Myers's ability to meet the CVR milestones. Pa31-35, 76-78, 84-87.

That those pre-merger drafts were drafts, not final submissions, changes nothing. The deficiencies in Bristol-Myers's plans and submissions, whether draft or not, showed that the Company was currently on track to miss the CVR milestones. That is a material trend, condition, or risk that must be disclosed where Celegne investors agreeing to a merger in which part of the consideration is $6.4 billion tied to the achievement of these milestones. Indeed, the point of the Securities Act was to make sure investors had this sort of material information when making investment decisions.

Furthermore, the Trial Court's reasoning not only misconstrues the alleged omissions, it reverses the burdens under Item 303. Pa23-24. Item 303 does not depend on the consequences of the undisclosed events or uncertainty somehow already existing pre-merger. Rather, it is the undisclosed trend, event, or uncertainty that must exist at the time of the Merger—not its ultimate impact, which nearly always emerges later. *See In re Facebook, Inc*., 986 F. Supp. 2d at 511-12 ("Item 303 require[s] specific[] disclosure of whether, and to what extent a material trend has impacted *or is expected* to impact future revenues" (citation modified)). Here, Plaintiff alleges that Defendants' undisclosed divergences from industry standards and other irregularities were already reflected in Bristol-Myers's internal pre-merger drafts. Pa32-34, 76-78, 80, 83-84, 86-93, 97. That the ultimate impact of those undisclosed deficiencies—FDA admonition, a delayed approval timeline, missed

liso-cel milestone, etc.—necessarily arose later does not change that Plaintiff alleges the undisclosed deficiencies themselves were already present when Defendants published the Offering Materials.

Second, the potential future impact from such undisclosed events or uncertainties need not be guaranteed: Item 303 by its express terms applies to "uncertainties," the likelihood of any impact from such uncertainty is a fact question for the jury, and Item 303 places the burden on Defendants to rule any such likelihood out (or disclose it in full in the Offering Materials), not on Plaintiff to plead the likelihood of future impact was already a certainty at the time of the Registration Statement. *See Ind. Pub. Ret. Sys. v. SAIC, Inc.*, 818 F.3d 85, 96 (2d Cir. 2016) (likelihood of impact is a question not to be addressed at the motion to dismiss stage). The Trial Court's analysis gets all of this backward. Disclosure "*is required* unless a company is able to conclude either that it is not reasonably likely that the trend, uncertainty or other event will occur or come to fruition, or that a material effect on the company's . . . results of operations is not reasonably likely to occur." *Comm'n Guidance,* 2003 WL 22996757, at *11.[1]

[1] As the Ninth Circuit explained in *Steckman*, Item 303 does not require that defendants already know the likely impact, rather, it requires disclosure of the known event, trend, or uncertainty and any reasonably likely impact unless a company is able to conclude either that the trend, event, or uncertainty itself is not reasonably likely to come to fruition, or that any "material effect" therefrom "is not reasonably likely to occur." 143 F.3d at 1297.

Even accepting the Trial Court's approach, it still impermissibly draws inferences against the Plaintiff, for there is no allegation that the pre-merger drafts were materially different from the final versions later submitted, nor that Defendants had any reason to believe they would be revised to correct any divergence from industry standards and past practice. Pa22-24. Plaintiff alleges the opposite, and indeed the facts alleged show that final versions did suffer from the very same omissions and divergences from industry standards and Bristol-Myers's past practices that Plaintiff alleges were already present in the earlier drafts. Pa84-86.

The Trial Court further erred by jumping from the assumption that all drafts are "incomplete by definition" to the conclusion that Bristol-Myers could not possibly have "known of any deficiencies" until the final versions were submitted and the FDA issued notification of the deficiencies. Pa19-20. That ignores Plaintiff's allegations. It does not take notification from the FDA for Bristol-Myers to know its own internal drafts and plans have diverged from its own past practice with similar approval processes. Nor that its omissions and irregularities diverged from well-established industry standards. *Cf.* Pa23-24 (erroneously drawing inferences against Plaintiff to presume Bristol-Myers could not "know that the filings are deficient without notification from the FDA").

Nor can any of this be discounted as "hindsight" pleading simply because the alleged omissions and aberrant practices correspond to actual deficiencies later

identified after the Merger when the FDA held those submissions deficient. *Cf.* Pa20-21, 24. Under the federal securities laws, "[a]ny information" before or after the statement or omission "that sheds light on whether [they] were false or materially misleading is relevant." *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 271-72 (3d Cir. 2005). It is thus routine and proper for plaintiffs to allege "later-emerging facts"—regulatory notices, missed forecasts, company press releases, analyst downgrades, ensuing stock drops, and so on—to "provide warrant for inferences about an earlier situation." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 698-99 (5th Cir. 2005). This warrant norm is not hindsight pleading; it is simply reasonable inference drawn from common sense. *See, e.g.*, *City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 693 (3d Cir. 2023) ("later developments may allow a reasonable inference that prior statements were untrue or misleading when made").

It cannot be disputed that the scope of Bristol-Myers's own internal drafts and plans for liso-cel were plainly known to Bristol-Myers itself, particularly where, as is the case here, the Company's top management was directly involved in preparing those drafts and developing those working on those operational plans and protocols. Pa79-81. Indeed, Plaintiff meticulously alleged an array of additional facts and details, including numerous specific pre-merger dates, meetings, and other communications, during which these already-existing (but aberrant) drafts and

operational plans were being refined and reviewed at the highest levels of Bristol-Myers, in discussions with named Defendants, financial advisors to the Merger, and indeed in the very due diligence and negotiations with Celgene that led to the CVR portion of the Merger. Pa45-92. These detailed facts more than suffice to plead knowledge at this stage. *See, e.g.*, *In re Daou Sys., Inc*., 411 F.3d 1006, 1023 (9th Cir. 2005) ("allegations of direct involvement in the production" of internal reports support inference of knowledge); *In re Y-mAbs Therapeutics, Inc. Sec. Litig*., 2024 WL 451691, at *13 (S.D.N.Y. Feb. 5, 2024) (even under heightened fraud standards, "it is sufficient for plaintiffs to allege defendants knowledge of facts or access to information . . . that standard is met" where, as here, Defendants are alleged to have been "actively involved" in drafting BLA and ultimately "responsible for submitting the BLA and updated material to the FDA" (citation modified)).

Accordingly, Plaintiff specifically alleged not only that Defendants were already drafting approval plans and operational protocols that omitted necessary data and diverged from industry standards as well as Bristol-Myers's own past practice, but moreover that Bristol-Myers's management already internally knew—e.g., from their own direct involvement in those pre-merger deficient drafts, from their own divergence from well-established industry standards in preparing those drafts and protocols, and from their own prior practice with similar approval submissions and processes. Pa32-34, 76-78, 80, 83-84, 86-93, 97. Contrary to the Trial Court's

conclusion, courts routinely reject the "hindsight" label where, as here, plaintiffs do not merely allege a company's failure to predict the future but rather allege already existing internal company practices and irregularities that existed at the time of the allege omissions. *See W. Palm Beach Police Pension Fund v. DFC Global Corp*., 2015 WL 3755218, at *14 (E.D. Pa. June 16, 2015) (rejecting "hindsight" label as to defendant's allegedly deficient practices where plaintiffs alleged "contemporaneous facts" such as defendant's failure to "comply with existing regulations [and] . . . [non]compliance with its *own* stated policies and practices."); *In RAIT Fin. Trust Sec. Litig*., 2008 WL 5378164, at * 5 (E.D. Pa. Dec. 22, 2008) ("This is not 'fraud by hindsight'" because plaintiffs are not simply claiming that a defendant's "credit underwriting and monitoring processes did not perform as promised after the filing" of the registration statement, but rather allege deficiencies in defendant's "credit underwriting and monitoring processes that existed at the time of filing.").

Finally, none of Defendants' risk disclosures absolve liability for the pure omission of required information in violation of mandatory duties to disclose. Cautionary language must be "precise" and "meaningful"—i.e., specific enough "that the risk of real deception drops to nil." *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1033 (S.D. Cal. 2005) (citation modified). Even "[w]arnings of specific risks" cannot "shelter defendants from liability if they fail to disclose hard

facts critical to appreciating the magnitude of the risks described." *In re Bear Stearns Cos., Inc. Sec., Deriv., & ERISA Litig.*, 763 F. Supp. 2d 423, 495 (S.D.N.Y. 2011); *Facebook,* 986 F. Supp. 2d at 516 ("[E]ven apparently specific risk disclosures . . . are misleading if the risks are . . . stamped in internal undisclosed analyses . . . as significantly greater"). And "no amount of general cautionary language can protect a company from failure to disclose a specific, known risk." *Lin v. Interactive Brokers Grp., Inc.*, 574 F. Supp. 2d 408, 417 (S.D.N.Y. 2008). Contrary to the Trial Court's reading of a few plainly inapt snippets (Pa23-25), nothing in any of the Defendants' actual disclosures mentioned anything about the alleged omission of necessary data, divergence from industry standards and past practice, deficient operational plans, or any of the other irregularities marring Bristol-Myers's pre-merger drafts and protocols (Pa110-533). Disclosing that "likelihood of regulatory approval played a role in its diligent efforts" says nothing about undisclosed divergences from industry standards. Even if "diligent efforts" means "exercise of . . . reasonable business discretion," that in no way disclosed that Bristol-Myers was already contravening industry (and its own) best practices.

And even if "safety and efficacy" could somehow be interpreted to mean drafts "could be deficient," that disclosure would itself be misleading for mispresenting existing risks as mere future possibilities. A "company's purported risk disclosures are misleading where the company warns only that a risk may impact

its business when that risk has already materialized." *Facebook,* 986 F. Supp. 2d at 516. Again, Plaintiff alleges not that Defendants' internal plans might become deficient in the future, but rather that they were already drafting approval plans and operational protocols that already omitted necessary data and thus already diverged from industry standards as well as Bristol-Myers's own past practice. Pa31-35, 76-78, 84-87. These gross divergences from industry and past practice were not uncertain potential risks that "could" arise at some indefinite future point. They were already present before the Merger. "To warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit." *In re Stac Elecs. Sec. Litig*, 89 F.3d 1399, 1406 (9th Cir. 1996) (citation modified).

B. Plaintiff Has Adequately Pled a Violation of Item 105. Pa1-28.

Item 105 independently requires that the Registration Statement contain detailed disclosure of "the most significant factors that make an investment in the registrant or offering speculative or risky." 17 C.F.R. §229.105. It "is intended 'to provide investors with a clear and concise summary of the material risks to an investment in the issuer's securities.'" *Silverstrand*, 707 F.3d at 103. "Generic or boilerplate discussions" will *not* suffice. SEC Release No. 33-7558, 1998 WL 425894, at *14 (July 29, 1998); *see also Fecht v. Price Co.*, 70 F.3d 1078, 1082 (9th Cir. 1995) ("[i]nclusion of *some* cautionary language is

not enough to support a determination as a matter of law that defendants' statements were not misleading") (emphasis in original). Unlike Item 303, and contrary to the Trial Court's misstatement, (Pa25-26), "Plaintiff need not allege Defendants' knowledge in order to plead an Item 503 violation"; rather, "the inquiry can be boiled down to whether the Offering Documents were accurate and sufficiently candid." *Panther Partners Inc. v. Jianpu Tech. Inc*., 2020 WL 5757628, at *7 (S.D.N.Y. Sept. 27, 2020). Thus, "courts typically analyze the sufficiency of Item 503 disclosures with the familiar materiality standard." *City of Roseville Emps. Ret. Sys. v. EnergySolutions, Inc*., 814 F. Supp. 2d 395, 426 (S.D.N.Y. 2011). [2]

The Trial Court's analysis simply states that the Item 105 claim "fails for the same reasons the Item 303 claim fails." Pa25. That analysis is meritless several times over as explained above, and moreover, ignores the unique requirements of Item 105. Even where risk disclosures make passing or partial reference to arguably related risks, courts routinely hold that omission of material information from such generalized risk disclosures nonetheless violates Item 105. *Id.* at 426-27; *see also In re Adams Golf Inc. Sec. Litig.*, 618 F. Supp. 2d 343, 348-49 (D. Del. 2009) (omission of information regarding risks of "gray

[2] Originally titled "Item 503" has been retitled "Item 105," and courts variously continue to use both interchangeably. *See In re Didi Glob. Inc. Sec. Litig.*, No. 21-CV-05807, 2024 WL 1119483, *10, n.8 (S.D.N.Y. Mar. 14, 2024).

market" sales violated Item 105); *Citiline Holdings, Inc. v. iStar Fin., Inc.*, 701 F. Supp. 2d 506, 515 (S.D.N.Y. 2010) (failure to disclose increase in non-performing loans violated Item 105); *In re WorldCom Sec. Litig.*, 346 F. Supp. 2d 628, 691-92 (S.D.N.Y. 2004) (similar). Likewise, courts consistently find Item 105 violations pled where risk disclosures characterize a risk as merely contingent when, in truth, it has already started to come to fruition. *Mingbo Cai v. Switch, Inc.*, 2019 WL 3065591, at *6 (D. Nev. July 12, 2019) ("Although the prospectus includes over thirty pages of risk disclosures, defendants identify only general statements that the company faced risks associated with long selling and implementation cycles."); *Gerneth v. Chiasma, Inc.*, 2018 WL 935418, at *4 (D. Mass. Feb. 15, 2018). Plaintiff does not allege merely that the post-merger, final versions of the regulatory filings and operational plans were deficient. Pa25. Rather, Plaintiff alleges that well before the Merger close (and before the effective date of the Registration Statement), Defendants were already drafting aberrant submissions and operational plans that already reflected gross irregularities, that already omitted necessary data, and that already diverged from industry best practices and Bristol-Myers's own prior experience with similar approval processes. Pa31-35, 76-78, 84-87. These are specific undisclosed risks that Defendants' risk disclosures (and the Trial Court's flyby analysis) completely ignore.

No partial disclosure of "diligent efforts" or passing reference to "safety and efficacy" in general could ever excuse Defendants' failure to make any risk disclosure at all regarding the specific, already occurring divergences from industry standards and past practice. *Cf.* Pa24. Nor is there any reason to assume (as the Trial Court did) that "any risk of deficient regulatory filings and operational plans could only become known once the filings and plans were filed with the FDA." Pa25-26. Plaintiff alleges those risks were already reflected in, and apparent from, the pre-merger drafts of those regulatory filings and operational plans. Bristol-Myers management itself drafted those plans, and as reflected in those pre-merger drafts Bristol-Myers management itself had already diverged from industry standards and Bristol-Myers's own past experience and practice with similar approval filings. The risk already existed and was known to Bristol-Myers management.

Defendants had no answer to these allegations, so they raised a straw man before the Trial Court, truncating the alleged omitted risk as limited to the deficient final filings themselves, rather than the undisclosed practices and irregularities that led to those deficiencies and were already present in the pre-merger drafts. That is not what Plaintiff alleges. Whatever the Offering Materials may have disclosed about the term "diligent efforts" implying "efforts to carry out [] obligation in a diligent manner" and "employing such resources

normally used . . . in the exercise of [] reasonable business discretion," it disclosed absolutely nothing about risks posed by the allegedly already existing drafts that inexplicably omitted an array of necessary information, nothing of the risks posed by draft operation plans that grossly diverge from Bristol-Myers's own past practice, and certainly nothing about the specific risks posed by Bristol-Myers's undisclosed failure to comply with well-established industry standards.

City of Roseville is instructive. In that case, plaintiffs alleged that Item 105 required a company to include risk factors warning that a regulator was likely to reject a petition, that the market for a certain service program was not as represented, and that certain of the company's contracts were detrimental to future business opportunities. 814 F. Supp. 2d at 426-27. While acknowledging that the registration statement's "'Risk Factors'" section did discuss each of those topics to some degree, the court nonetheless found Item105 violations because "the plaintiffs ha[d] sufficiently alleged facts that, if true, would allow a jury to find that the Registration Statements contained material misstatements of the risks or omitted material facts in each area." *Id.* at 427.

The same is true here. As explained *supra*, not only did Defendants' risk disclosures fail to even mention (much less candidly address) the Company's already occurring yet undisclosed divergences from industry and past practice,

but even those of Defendants' risk disclosures that did ostensibly relate to "likelihood of regulatory approval" were generalized boilerplate and, in any event, were themselves materially misleading because, *inter alia*, they warned of mere potential "risks" that had, in truth, already materialized. *See, e.g.*, Pa31-35, 76-78, 84-87. While Defendants relied on their insufficient disclosures regarding "diligent efforts" *generally* to argue that they satisfied their disclosure obligations, they failed to disclose the *specific* alleged risks alleged by Plaintiff as likely to have a material impact on the Company's financials and that made the Merger speculative and risky. And Defendants' complete failure to disclose the already apparent risks of their undisclosed divergences from industry and past practice, as well as a host of material risks compounded thereby, was thus insufficient under Item 503. *See Facebook*, 986 F. Supp. 2d at 516 ("The Company's purported risk warnings misleadingly represented that this revenue cut was merely possible when, in fact, it had already materialized. The warnings only warned what might occur if certain contingencies were met; the disclosures did not make clear that such contingencies had, in fact, already occurred."); *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 415 (S.D.N.Y. 2005) (statements purporting to warn that a company's business "could" be negatively impacted "if" it failed to comply with industry regulations were

materially misleading where the company was already violating industry regulations).

C. The PSLRA Safe-Harbor Does Not Apply to Items 303 and 105. Pa1-28.

The Complaint adequately alleges pure omissions under Items 303 and 105, which are not protected by the PSLRA's "safe harbor." Pa32-33, 50-51, 70-79; *see, e.g.*, *Heinze v. Tesco Corp.*, 971 F.3d 475, 483 (5th Cir. 2020) (explaining that "the safe harbor covers only forward-looking *statements*, not *omissions*," and, thus, "it would not make sense" to apply the PSLRA safe harbor to "pure-omission claims") (emphasis in original); *Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 722 (2d Cir. 2011) (Item 303 claims are "pure omission" claims, because "disclosure of the information [is] required"); *In re Blockbuster Inc. Sec. Litig.*, 2004 WL 884308, at *7 (N.D. Tex. Apr. 26, 2004) (where plaintiffs allege "omissions that are independently actionable without reference to the protected forward-looking statements, the PSLRA safe harbor does not apply."); *see also Mallen v. Alphatec Holdings, Inc.*, 861 F. Supp. 2d 1111, 1126 (S.D. Cal. 2012), *aff'd sub nom. Fresno Cnty. Emps.' Ret. Ass'n v. Alphatec Holdings, Inc.*, 607 F. App'x 694 (9th Cir. 2015); *In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 930 (D.N.J. 1998) ("Allegations based upon omissions of existing facts or circumstances do not constitute forward looking statements protected by the safe harbor of the Securities Act."); *Curran v. Freshpet, Inc.*, 2018 WL 394878, at *4 (D.N.J. Jan. 12, 2018) (even as to "a 'mixed

present/future statement'" the PSLRA safe harbor "does not apply to . . . 'with respect to the part of the statement that refers to the present.'").[3]

Contrary to the Trial Court's determination, Pa21-22, Plaintiff's allegations fall outside the safe harbor protection.

III. PLAINTIFF PLEADS SECTION 15 CONTROL LIABILITY AGAINST ALL DEFENDANTS. Pa1-28.

Section 15 imposes liability on "[e]very person who, by or through stock ownership, agency, or otherwise . . . controls any person liable under [the Securities Act]." 15 U.S.C. §77o(a). Control is the "possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person." 17 C.F.R. §230.405. Thus, while it requires power to control, "it is not necessary to show actual participation or the exercise of actual power." *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1065 (9th Cir. 2000). Contrary to the Trial Court's determination, Plaintiff does indeed allege an array of primary violations under

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[3] *Accord In re ValuJet, Inc.*, 984 F. Supp. 1472, 1479 (N.D. Ga. 1997) (refusing to apply PSLRA's safe harbor and the bespeaks-caution doctrine because of plaintiffs' alleged failure to disclose existing facts); *City of Providence v. Aeropostale, Inc.*, 2013 WL 1197755, at *12 (S.D.N.Y. Mar. 25, 2013) ("But the safe harbor does not apply to material omissions . . . Defendants' failure to disclose that the unpopular designs … had been ordered through summer of 2011 is unprotected by the safe harbor, *regardless of whether the statements thereby rendered misleading were forward-looking*."); *In re Complete Mgmt. Inc. Sec. Litig.*, 153 F. Supp. 2d 314, 340 (S.D.N.Y. 2001) (PSLRA's safe harbor and bespeaks-caution doctrine were inapplicable because they "apply to forward-looking statements only, and not to material omissions or misstatements of historical fact.").

Section 11. Pa26; *see also In re China Valves Tech. Sec. Litig.*, 979 F. Supp. 2d 395, 416 (S.D.N.Y. 2013).

As Celgene's Chief Executive Officer and Chairman of the Celgene Board of Directors, Defendant Alles not only personally reviewed, contributed to, and signed the Registration Statement and directly solicited Plaintiff and other former Celgene shareholders to participate in the Merger and thereby exchange their Celgene shares for newly issued Bristol-Myers common stock and CVRs, but moreover he controlled Celgene, the Celgene Board, and each and every Celgene employee involved in drafting the Offering Materials, soliciting Plaintiff and other Celgene shareholders to participate in the Merger exchange, and otherwise was directly involved in the misconduct that forms the basis for all primary liability in this case. Pa46-66, 110-113. As the Third Circuit has made clear, "there is no requirement . . . that the controlled person be named as a defendant as a predicate to imposing liability upon the controlling individual defendants." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 285 (3d Cir. 2006).

Furthermore, the Trial Court does not directly address Plaintiff's allegations that Alles has power to control Celgene, its board of directors, its employees, or any other direct Celgene solicitors, and thus primary violators under Sec. 12(a)(2). Pa26. Nor could it. "Directors and officers who sign registration statements or other SEC filings are presumed to control those who draft those documents. And where a

plaintiff alleges that the directors and officers participated in the alleged primary conduct, that is sufficient to state a claim for control person liability." *City of Westland Police & Fire Ret. Sys. v. MetLife, Inc.,* 928 F. Supp. 2d 705, 721 (S.D.N.Y. 2013); *see also In re DVI, Inc. Sec. Litig.*, 2010 WL 3522086, at *11 (E.D. Pa. Sept. 3, 2010) ("a plaintiff may establish control by showing that a director signed the SEC filings at issue," for even an "outside director and audit committee member who signs an SEC filing can be presumed to have the power to control those who write the report").

CONCLUSION

Accordingly, this Court should reverse the dismissal of this action and remand for further proceedings.

Dated: July 16, 2025

Respectfully submitted,

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Superior Court of New Jersey
Appellate Division

Docket No. A-002080-24

HOWARD BERNSTEIN, Individually and on Behalf of All Others Similarly Situated, *Plaintiff-Appellant,* *(For Continuation of Caption See Next Page)*	ON APPEAL FROM AN ORDER OF THE SUPERIOR COURT OF NEW JERSEY, LAW DIVISION, UNION COUNTY Docket No. UNN-L-003887-21 Sat Below: HON. JOHN G. HUDAK, J.S.C.

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Rules

PRELIMINARY STATEMENT

In this alleged class action, plaintiff asserted claims under the Securities Act of 1933 ("Securities Act") on behalf of acquirors of contingent value rights ("CVRs") and shares of common stock issued by Bristol-Myers Squibb Company ("BMS") in its merger with Celgene Corporation in 2019. Each CVR provided a contingent right to payment of $9 if, but only if, the U.S. Food and Drug Administration ("FDA") approved applications for three different Celgene product candidates by contractual milestone dates that, at the time, were far in the future. If any of the milestone dates was missed, even by a single day, the CVRs would expire without value – which was clearly explained in the February 2019 registration statement on which plaintiff based his claims.

Tagging along to earlier complaints filed in New York federal and state courts, plaintiff filed his original complaint in November 2021 alleging Securities Act violations based on a supposed failure to disclose a secret plan to "slow-roll" the approval process for one of the three Celgene products, a cutting-edge cancer therapy called liso-cel, to ensure there would be no payment under the CVRs. Years after the registration statement, in February 2021, the FDA approved liso-cel 36 days too late for there to be payment under the CVRs in the depths of travel, governmental, and business disruptions arising from the COVID-19 pandemic. Plaintiff alleged that events in the FDA approval process

long after the registration statement became effective were evidence of this purported "plan" – paradigmatic hindsight pleading.

Given the substantial overlap with the earlier filed federal case, the trial court stayed this action pending developments in that action. Ultimately, the federal court dismissed the Securities Act claims alleged in that case with prejudice for failure to state a claim, and that ruling was affirmed on appeal by the U.S. Court of Appeals for the Second Circuit. See Mangrove Partners Master Fund, Ltd. v. Bristol-Myers Squibb Co., 2025 WL 1420914, at *2-3 (2d Cir. May 16, 2025). Plaintiff never mentions the federal proceedings or the February 2024 dismissal decision in the earlier filed New York state court case, which was not appealed.

After those decisions, the trial court lifted its stay order and addressed the defendants' motion to dismiss. The court agreed with those other courts that there was no basis for plaintiff's Securities Act claims, dismissing the complaint because its allegations were "based entirely on events that happened over a year after the [registration statement] became effective[.]" The court also rejected plaintiff's attempt to plead a Securities Act claim based on alleged violations of Items 303 and 105 of Regulation S-K, 17 C.F.R. §§ 229.105 & 229.303, finding that "there are no facts in the complaint that support [plaintiff's] argument that BMS had actually formulated" a "deficient plan to achieve the CVR milestones"

before the registration statement became effective and that "[t]he risks that could cause the CVRs to not be worth anything were disclosed."

The court granted plaintiff leave to amend his complaint, but his amended pleading did not cure the deficiencies identified in the first dismissal ruling. Rather than providing any factual allegation to support his conclusory allegation of a "deficient" but undisclosed plan for the liso-cel application, plaintiff bulked up his amended complaint with excerpts copied from the merger background section of the registration statement, which he interspersed with the same conclusory allegation of a "deficient" plan. The amended complaint still failed to allege any facts from which one might infer that BMS knew – by the effective date of the registration statement on February 22, 2019 – that the FDA would not approve liso-cel until just after the contractual milestone date almost two years later.

In granting defendants' renewed motion to dismiss, the trial court saw through this transparent attempt at hindsight pleading and dismissed the amended complaint with prejudice. Four courts have now passed upon the same Securities Act claims asserted here. All have concluded they are without basis. This Court should affirm the trial court's well-founded decision below.

PROCEDURAL HISTORY

A. The Original Complaint and the Stay in Favor of the Substantially Identical, Prior-Pending Federal Action

Plaintiff allegedly is a former Celgene stockholder. He filed his original complaint in the Superior Court on November 12, 2021, asserting claims under sections 11, 12(a)(2), and 15 of the Securities Act against BMS; several current or former BMS directors and officers; and Mark J. Alles, Celgene's chairman and chief executive officer prior to the closing of the merger with BMS. Pa5, 7, 563-65, 600-03.

By then, two other putative class actions already were pending in New York federal and state courts asserting substantially similar claims under the Securities Act. Pa4-5; Da359-407, 518-55. The first was filed on October 6, 2021, in the United States District Court for the Southern District of New York, styled SM Merger/Arbitrage, L.P. v. Bristol-Myers Squibb Co., No. 1:21-cv-8255 (JMF) (S.D.N.Y.). Pa4; Da359-407. Lead plaintiffs were appointed in accordance with the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Da408-11. The lead plaintiffs then filed an amended complaint in the consolidated action on February 23, 2022, asserting (among other things) the same Securities Act claims asserted in the complaint against substantially the same defendants, with limited exceptions. Da412-517.

The second-filed action was filed on November 2, 2021, in the Supreme Court of New York, New York County, styled Williams v. Bristol-Myers Squibb Co., Index No. 656179/2021. Pa5; Da518-55. That complaint asserted claims under sections 11 and 12(a)(2) of the Securities Act on behalf of a putative class of acquirors of CVRs based on the same disclosures as those at issue here. See Pa5. All named defendants in that action were also named defendants here.

On December 7, 2022, the defendants moved to stay this action in favor of the first-filed federal case or, in the alternative, to dismiss the complaint for failure to state a claim under Rule 4:6-2(e). Da85-87. After briefing, the trial court held a hearing on the motion on February 17, 2023; on the same day, the court entered an order staying the case pending further developments in the federal action.[1] Da556; see 1T.[2]

Approximately two weeks later, U.S. District Judge Jesse M. Furman issued an opinion and order in the federal action dismissing the consolidated amended complaint in its entirety. Pa4. In that opinion, Judge Furman

[1] Earlier, on December 10, 2021, BMS removed this action to the U.S. District Court for the District of New Jersey. See Da12-84. Plaintiff moved to remand, which defendants opposed. In an opinion and order entered on September 22, 2022, the New Jersey federal court remanded the case. The trial court reopened the docket on October 28, 2022.

[2] Defendants have submitted with this brief the transcript of the February 17, 2023 hearing, which is designated as transcript 1T. The January 10, 2025 hearing transcript submitted by plaintiff is cited herein as 2T.

dismissed the Securities Act claims with prejudice, finding that all of the challenged disclosures in the registration statement were subject to the safe harbor for forward-looking statements under the PSLRA. In re Bristol-Myers Squibb Co. CVR Sec. Litig., 658 F. Supp. 3d 220, 235-39 (S.D.N.Y. 2023). The court permitted the federal plaintiffs to replead their claims under the Securities Exchange Act of 1934 based on post-merger disclosures. The federal plaintiffs filed a second amended complaint, which BMS and the individual defendants again moved to dismiss. In an opinion and order entered on February 29, 2024, the federal court dismissed the second amended complaint with prejudice. Pa4; see In re Bristol-Myers Squibb Co. CVR Sec. Litig., 2024 WL 873436 (S.D.N.Y. Feb. 29, 2024). After plaintiffs appealed, the U.S. Court of Appeals for the Second Circuit affirmed by summary order. See Mangrove Partners Master Fund, Ltd. v. Bristol-Myers Squibb Co., 2025 WL 1420914 (2d Cir. May 16, 2025).

Also in February 2024, the court in the New York state action dismissed the Williams complaint in its entirety based on the earlier reasoning of the federal court in dismissing the Securities Act claims in that action. See Williams v. Bristol-Myers Squibb Co., 2024 WL 478018 (Sup. Ct., N.Y. Cnty. Feb. 2, 2024).

Given these developments, on March 21, 2024, the trial court in this case entered an order vacating its previous stay order for the "purpose of considering the motion to dismiss" previously filed by defendants and setting a schedule for supplemental briefing on the motion. Da1-2, 11.

B. The Trial Court Dismisses the Complaint Without Prejudice

Following supplemental briefing and oral argument, on June 25, 2024, the court granted defendants' motion to dismiss the complaint in its entirety. See Pa605-06. The court's dismissal order was accompanied by a 27-page opinion explaining the court's reasoning in detail. See Pa607-33.

First, the court found that the statements in the registration statement concerning the prospects for achievement of the CVR milestones were "protected by the safe harbor for forward-looking statements" and therefore were "not actionable under either Section 11 or Section 12(a)(2)." Pa626-28.

Second, the court concluded that the challenged disclosures "regarding the CVRs were not false," because plaintiff alleged "no contemporaneous facts" from the time of the registration statement to "show that the defendants knew that the milestones would not be met" and instead relied on events that "occurred over a year after filing of the" registration statement – "legally deficient allegations of fraud by hindsight." Pa628-29.

Third, the court found that the complaint sounded in fraud "because plaintiff argues that BMS failed to disclose that it intended to never actually meet the milestone dates" under the CVR Agreement, but plaintiff also failed to plead fraud with the particularity required under Rule 4:5-8. Pa629. The court emphasized that the complaint contained no particularized allegations to suggest "the defendants ever intended to purposefully slow-roll the FDA application process." Id.

Finally, the court rejected plaintiff's "pure omissions" theory under Items 303 and 105 because there were no allegations of fact to support the assertion of a "deficient plan to achieve the CVR milestones," and the registration statement adequately disclosed the risks associated with the CVRs. Pa631-32. As to Mr. Alles, the court found that plaintiff had "pled no facts that show that [Mr. Alles] directed the activities of BMS or had any control over the issuance of the CVRs," requiring dismissal of all claims against him. Pa633.

The trial court granted plaintiff "an opportunity to amend his complaint to allege facts that support his claims." Pa633. The court warned that "[a]ny allegations of fraud must be pled with particularity as required by R. 4:5-8." Id.

C. The Trial Court Dismisses the Amended Complaint with Prejudice

Plaintiff filed the amended complaint on August 15, 2024. See Pa103. He abandoned his claim under section 12(a)(2) of the Securities Act and asserted

claims only under sections 11 and 15. Pa100-02. Though the amended complaint was thirty pages longer, the substance of its allegations was essentially the same. The main differences between the two pleadings were: (i) 51 paragraphs of allegations about the background of the merger that were essentially copied and pasted from the registration statement, Compare Pa45-70 with Pa218-30; (ii) repetition throughout the complaint of plaintiff's conclusory allegation that, at some unspecified time before the merger closed in November 2019, unspecified individuals at BMS were allegedly already drafting "deficient" parts of the liso-cel biologics license application ("BLA") and were already developing "deficient" operational plans that they knew "were likely to slow-roll the FDA approval process" for liso-cel, see, e.g., Pa31-32; Pa50-53; Pa62-64; Pa67; Pa80-81; Pa83-84; and (iii) a multi-page explanation of Items 303 and 105, Pa72-79.

On September 30, 2024, the defendants moved to dismiss the amended complaint in its entirety with prejudice. Pa105-07. On February 7, 2025, the trial court granted defendants' motion in its entirety. Pa1-2. The court again provided a detailed explanation of its reasoning in an accompanying 26-page decision. See Pa3-28. The court concluded that, like the original complaint, the amended complaint's allegations sounded in fraud but were not pleaded with particularity under Rule 4:5-8 and, even if Rule 4:5-8 did not apply, there were

no well-pled allegations to support plaintiff's central claim that, prior to the effective date of the registration statement on February 22, 2019, BMS knew that it was drafting deficient FDA filings for the liso-cel application that would not be "finalized and submitted to the FDA until 10 months later." Pa20.

As the court correctly observed, the amended complaint engaged in the same "impermissible hindsight pleading" that plagued the original complaint. Pa21. The court rejected plaintiff's attempt to base his section 11 claim on purported omissions under Items 303 and 105 for substantially the same reason. Pa23-26. Finding that the amended complaint failed to state a primary violation of section 11, the court also dismissed the section 15 "controlling person" claim. Pa26.

Finally, the court concluded that the amended complaint should be dismissed with prejudice. Pa27-28. Noting that plaintiff's theory that "BMS intentionally omitted and/or misrepresented that it was drafting deficient FDA filings and operational plans[]" had "been rejected b[y] not just this Court, but by the 2nd [C]ircuit, federal district court, and New York Supreme Court[,]" and finding the amended complaint's similar hindsight-pleading strategy equally defective, the court concluded it could not "see any alternative route for [p]laintiff to file an amended complaint based on the facts alleged and the theories he has exhausted under the Securities Act." Id. This appeal followed.

STATEMENT OF FACTS[3]

A. The Parties

Plaintiff allegedly was a holder of Celgene common stock and as such, in November 2019, he received the merger consideration provided for under the merger agreement between Celgene and BMS dated January 2, 2019. Pa31, 35-36, 112.

BMS is a biopharmaceutical company; its common stock trades on the New York Stock Exchange. Pa36. Except for Mark J. Alles, the individual defendants are or were members of the BMS board of directors or BMS officers who allegedly signed the registration statement. Pa37-39. Mr. Alles was chairman and chief executive officer of non-party Celgene. Pa36-37. His position at Celgene was terminated upon the closing of the merger, and he did not join BMS or its board of directors. See Pa331 (identifying planned

[3] On a motion to dismiss under Rule 4:6-2(e), well-pleaded factual allegations are assumed to be true solely for purposes of evaluating the motion. Sparroween, LLC v. Twp. of W. Caldwell, 452 N.J. Super. 329, 339 (App. Div. 2017). In addition, courts can consider documents referenced in the complaint and "matters of public record" on a motion to dismiss. See, e.g., Banco Popular N. Am. v. Gandi, 184 N.J. 161, 183 (2005); E. Dickerson & Son, Inc. v. Ernst & Young, LLP, 361 N.J. Super. 362, 365 n.1 (App. Div. 2003), aff'd, 179 N.J. 500 (2004) (documents "referenced in the complaint" may be considered on motion to dismiss). The registration statement forming the basis for plaintiff's claims is found at Pa110-533.

termination/resignation of Mr. Alles "immediately following" closing of merger in registration statement). Celgene is not a defendant. See Pa37-39.

B. The Celgene Merger and the CVRs

BMS and Celgene entered into the merger agreement on January 2, 2019. See Pa70, 382. Under that agreement, subject to approval by the stockholders of both companies and other conditions to closing, BMS agreed to provide consideration consisting of $50 in cash, one share of BMS common stock, and one CVR in exchange for each share of Celgene common stock. Pa70.[4] Negotiations leading up to that agreement had begun in mid-November 2018, after BMS and Celgene agreed to "limited due diligence relating to certain Celgene intellectual property . . . ." Pa51.

The CVRs to be provided in the merger would be publicly traded securities representing a contingent right to receive payment of $9 per CVR if, but only if, the FDA approved applications for three separate Celgene product candidates by contractual milestone dates. Pa70-71. The required FDA approvals were of: (i) liso-cel, a chimeric antigen receptor T-cell ("CAR-T") for treatment of large B-cell lymphoma, by December 31, 2020; (ii) ozanimod, a drug for treatment of

[4] Even excluding the CVRs, "the cash and stock components of the merger consideration . . . represented approximately $99.37 in value per share of Celgene common stock . . . ." (based on the January 31, 2019 closing price of BMS stock). Pa128.

relapsing multiple sclerosis, also by December 31, 2020; and (iii) ide-cel, a CAR-T therapy for treatment of refractory multiple myeloma, by March 31, 2021. Id.; Pa128. If the FDA failed to approve even one of the three applications by its milestone date, then CVR holders would not be entitled to any payment. Pa32, 76. The FDA was not a party and was not bound by the milestone dates. See Pa70-71.

According to the amended complaint, negotiations leading up to the merger agreement began with an initial proposal from BMS to Celgene on December 5, 2018, offering a combination of cash and BMS common stock (but no CVR component). Pa54. Celgene responded that the offer was "not sufficiently attractive." Pa56. After BMS revised its proposal, the parties agreed to engage in "a mutual due diligence exercise," which began with meetings on December 13, 2018. Pa57-58.

The terms evolved over the following weeks, but CVRs were not suggested as a component of the merger consideration until December 27, 2018, Pa58-61, only six days before the definitive merger agreement. It was not until the next day, December 28, 2018, that negotiations began about "the terms of a possible CVR, including . . . the milestones that needed to be achieved prior to the making of such payments." Pa62.

Stockholder approval was one of the conditions to the merger. On February 22, 2019, BMS and Celgene filed a joint proxy statement / prospectus seeking approval from their respective stockholders for the proposed transaction. See Pa70. The joint proxy statement / prospectus was deemed to be a part of a Form S-4 registration statement that BMS filed on February 1, 2019. Id. With the definitive proxy statement / prospectus incorporated, the registration statement was declared effective as of February 22, 2019. Id.

The registration statement included extensive "risk factor" disclosures, including for risks specific to the CVRs. It warned that:

> **You may not receive any payment on the CVRs.**
>
> Your right to receive any future payment on the CVRs will be contingent upon the achievement of certain agreed upon U.S. regulatory milestones within the time periods specified in the CVR agreement. If the CVR milestone . . . is not achieved for any reason within the time periods specified in the CVR agreement, no payment will be made under the CVRs, and the CVRs will expire valueless. Accordingly, the value, if any, of the CVRs is speculative, and the CVRs may ultimately have no value.

Pa174. The registration statement also disclosed BMS management's estimate, in evaluating the merger consideration, that there was only a 45% probability that "the three FDA approvals required to trigger the $9 payment under the CVR agreement" would be obtained in time. Pa281. Elsewhere, the registration statement included an estimated, risk-weighted present value for each CVR of

$3.75 after taking into account "the probability of achieving all three necessary approvals." Pa192.

The stockholders of BMS and Celgene approved the merger at separate meetings held in April 2019, but the merger did not close until November 20, 2019, which is when BMS issued the CVRs. Pa71-72. The CVRs were listed on the New York Stock Exchange and were publicly traded until January 1, 2021, when they expired by their terms after the FDA failed to approve liso-cel by December 31, 2020, its contractual milestone date. Pa4, 31, 35-36, 71-72.

C. The FDA Applications

According to the amended complaint, BMS "spent months" before the merger "internally drafting deficient regulatory filings and operational plans . . . ." Pa80. Plaintiff alleged that these purported secret and undisclosed plans to "torpedo any prospect of meeting the liso-cel Milestone," Pa34, "allow[ed] Bristol-Myers to avoid the CVR payment." Pa32; see Pa76.

The amended complaint alleged that BMS allegedly began to prepare these "deficient" regulatory "plans" in October 2018, months before Celgene agreed to allow any due diligence and months before anyone first suggested using CVRs as part of the merger consideration. Pa49-50. There is no factual allegation in the amended complaint to support that speculative assertion.

Plaintiff alleged that liso-cel was a Celgene product in development, which Celgene assumed responsibility for when it acquired Juno Therapeutics in 2017. Pa39-40. But as plaintiff also admitted, Celgene remained responsible for the liso-cel application process and related communications with the FDA until the closing of its merger with BMS on November 20, 2019. See Pa81.

The merger agreement required Celgene to continue in that role through the closing. Pa431 (Merger Agreement § 6.01); see also Pa305 (describing Celgene's obligations); Pa407-08, 457 (Merger Agreement §§ 4.15, 9.02(b)(iii)) (Celgene representations and warranties, including as to liso-cel, to be true as of the closing date).

Plaintiff admitted that on September 30, 2019, Celgene – not BMS – "submitted the first component of the liso-cel BLA to the FDA[,]" Pa80, and further alleged that BMS only gained "control[]" of "the approval process for liso-cel" after the merger closing on November 20, 2019. Pa81. The amended complaint did not attempt to reconcile these allegations with plaintiff's contradictory and unsupported claim that BMS "had already drafted portions of the BLA" sometime "before the [m]erger" closed. Id.

Nearly a month after the merger closing – when BMS "assumed control of the regulatory approval process" – BMS filed the last component of the liso-cel BLA, which addressed Chemistry, Manufacturing, and Controls ("CMC").

Pa81-82. That submission triggered a 60-day period for the FDA "to conduct an initial review to determine whether the application was complete and whether to grant 'Priority Review' for liso-cel." Pa82 (emphasis added). Plaintiff conceded that at the end of that period, the FDA accepted the liso-cel BLA "and granted it Priority Review" – directly contradicting the conclusory allegation that the application "omit[ted] basic data." Pa82-83 (emphasis added). The FDA's acceptance of the liso-cel application and its decision to grant Priority Review meant that the agency's time to act on the application was "four months shorter than its typical review time" under the Prescription Drug User Fee Act. Pa82.

About a month after the BLA was accepted for filing, and during the course of the FDA's review, the FDA made a request for additional information. Pa85. On April 15, 2020, BMS submitted information in response. Id. The FDA allegedly concluded weeks later that the submission constituted a "major amendment" to the BLA, which "automatically extended the FDA's target approval deadline" to November 16, 2020 – still weeks before the contractual milestone date of December 31, 2020. Pa86. BMS promptly disclosed this development. See Pa87.

During the same general period, COVID-19 was declared a pandemic, the pandemic was declared a national emergency, and pandemic-related operating

restrictions began to significantly impact the FDA. See Da557-59, FDA Statement, "Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections," Mar. 18, 2020.[5]

Two manufacturing facilities were to be used in the production of liso-cel: a former Juno Therapeutics facility in Bothell, Washington and a Lonza facility in Houston, Texas. Pa87. The FDA required both facilities to be inspected before it would approve the application. Id. Plaintiff alleged that, sometime either "before the effective date of the Registration Statement" or "before the Merger close," BMS was drafting deficient operational plans for these facilities that would "allow [both] facilities to disregard basic FDA and industry standards." Id.

The FDA inspected both facilities after a series of pandemic-related postponements. Pa88-91. The FDA delayed the inspections until October 2020 for the Juno facility and early December 2020 for the Lonza facility, the second of these only weeks before the liso-cel milestone deadline on December 31, 2020. Pa88-90. Plaintiff admitted, contrary to his theory of "substandard operational plans," Pa78, that both inspections were completed,

[5] The Court can properly take judicial notice of these developments, which are generally known and not subject to reasonable dispute. N.J.R.E. 201(b); see, e.g., Mac Prop. Grp. LLC & The Cake Boutique LLC v. Selective Fire & Cas. Ins. Co., 473 N.J. Super. 1, 39 (App. Div. 2022).

and BMS addressed the FDA's observations, before the milestone date. Pa91-92. But that date passed without an FDA decision; the FDA approved liso-cel five weeks later, on February 5, 2021. See Pa93.

D. The Claims Asserted

The amended complaint asserted claims against all defendants under section 11 of the Securities Act of 1933, 15 U.S.C. §§ 77k, which authorizes private suits arising out of alleged material misstatements or omissions in registration statements as of their effective date. Pa100-01. Plaintiff also asserted a "controlling person" claim under section 15 of the Securities Act, 15 U.S.C. § 77o, against the individual defendants. Pa102. Plaintiff sought to assert these claims on behalf of two putative classes: (i) all persons who received BMS common stock in exchange for Celgene securities in connection with the Celgene merger; and (ii) all persons who acquired CVRs pursuant or traceable to the February 1, 2019 Form S-4 registration statement. Pa98-99.

Plaintiff alleged that the registration statement was misleading because it did not disclose the allegedly "deficient" regulatory filings and plans discussed above. Pa78-79. He alleged BMS was required to make those disclosures under Items 303 and 105 of Regulation S-K, 17 C.F.R. §§ 229.105, 229.303. Pa72, 78-79.

ARGUMENT

I. STANDARD OF REVIEW.

This Court "review[s] an order granting a motion to dismiss for failure to state a claim pursuant to Rule 4:6-2(e) de novo." Hargett v. Hamilton Park OPCO, LLC, 477 N.J. Super. 390, 395 (App. Div. 2023). A trial court's denial of leave to amend is reviewed for abuse of discretion. Morales ex rel. Martinez v. N.J. Academy of Aquatic Sciences, 302 N.J. Super. 50, 56 (App. Div. 1997). The Court may "affirm the final judgment of the trial court on grounds other than those upon which the trial court relied." Dep't of Envtl. Prot. v. Alsol Corp., 461 N.J. Super. 354, 366 (App. Div. 2019) (internal quotations omitted).

On a motion to dismiss under Rule 4:6-2(e), a trial court "examin[es] the legal sufficiency of the facts alleged on the face of the complaint." Printing Mart-Morristown v. Sharp Elec. Corp., 116 N.J. 739, 746 (1989). To survive such a motion, "the essential facts supporting plaintiff's cause of action must be presented"; "conclusory allegations are insufficient" to avoid dismissal. Scheidt v. DRS Techs., Inc., 424 N.J. Super. 188, 193 (App. Div. 2012).

The court's "examination of a complaint's allegations of fact" under this standard "should be one that is at once painstaking and undertaken with a generous and hospitable approach." Banner v. Hoffman-La Roche Inc., 383 N.J. Super. 364, 374 (App. Div. 2006). But where, as here, the plaintiff has been

given the opportunity to amend his complaint, the court need "not review plaintiff's amended complaint with the same liberality as his original complaint because it must be assumed . . . that he has alleged every fact he reasonably believes could support a" claim. Quigley v. Esquire Deposition Servs., LLC, 409 N.J. Super. 69, 76 (App. Div. 2009).

Federal decisions interpreting and applying federal law are entitled to "due deference." Fletcher v. Cessna Aircraft Co., 412 N.J. Super. 530, 534 (App. Div. 2010). In this case, that includes decisions from the Southern District of New York and the Second Circuit evaluating substantially similar Securities Act claims based on the same alleged disclosures that are at issue here. See Mangrove Partners, 2025 WL 1420914, at *2-3. Plaintiff provides no basis for this Court to disregard those decisions (nor does he mention them).

II. THE TRIAL COURT CORRECTLY HELD THAT PLAINTIFF FAILED TO STATE A SECURITIES ACT CLAIM.

To state a claim under section 11 of the Securities Act, a plaintiff must allege that the "registration statement either contain[ed] an untrue statement of material fact or omit[ted] a material fact that is required or necessary to make the other statements therein not misleading." Klein v. Gen. Nutrition Cos., 186 F.3d 338, 342 (3d Cir. 1999); see also Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 144 (3d Cir. 2004). Plaintiff has expressly disclaimed any claim under section 11 based on an allegedly misleading affirmative

misstatement. Instead, he based his claim solely on alleged "pure omissions" from the registration statement. Pa98; Pb18-19.

Claims under section 11 are "judged by the facts as they existed when the registration statement became effective." In re Initial Pub. Offering Sec. Litig., 358 F. Supp. 2d 189, 205 (S.D.N.Y. 2004) (emphasis added); see 15 U.S.C. § 77k(a) ("In case any part of the 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 . . .") (emphasis added). "It is not sufficient that, at some point after the registration statement became effective, some subsequent event made it no longer accurate." Jiajia Luo v. Sogou, Inc., 465 F. Supp. 3d 393, 406 (S.D.N.Y. 2020).

Plaintiff never has identified an undisclosed material fact that existed "when the registration statement became effective." In re Initial Pub. Offering Sec. Litig., 358 F. Supp. 2d at 205. That required dismissal, as the trial court correctly recognized.

A. The Registration Statement Did Not Omit Any Material Fact in Existence as of Its Effective Date of February 22, 2019.

Plaintiff acknowledges, as the amended complaint did, that the registration statement became effective on February 22, 2019. Pb11; Pa70. Whether it contained a material omission therefore is "judged by the facts as

they existed" on that date. In re Initial Pub. Offering Sec. Litig., 358 F. Supp. 2d at 205; see, e.g., Jiajia Luo, 465 F. Supp. 3d at 414 (rejecting claim that registration statement failed to disclose issuer's business strategy "would result" in a particular outcome).

To state a claim under the applicable standard, a plaintiff must "plead facts to demonstrate that allegedly omitted facts both existed, and were known or knowable, at the time of the offering.'" Lin v. Interactive Brokers Grp., Inc., 574 F. Supp. 2d 408, 421 (S.D.N.Y. 2008) (quoting Castlerock Mgmt. Ltd. v. Ultralife Batteries, Inc., 114 F. Supp. 2d 316, 323 (D.N.J. 2000)). The relevant question is not whether a statement "later turned out to be correct, but rather whether the defendant knew or had reason to know, at the time the offering documents were filed, that the statement was untrue." Scott v. Gen. Motors Co., 46 F. Supp. 3d 387, 394 (S.D.N.Y. 2014), aff'd, 605 F. App'x 52 (2d Cir. 2015) (cleaned up).

The trial court correctly concluded that this standard was not met. Instead of relying on allegedly omitted facts that existed at the time the registration statement became effective, plaintiff based his claims on events that occurred long after the effective date to allege material omissions with the benefit of hindsight. Pa20-21, 23-25.

First, the unifying premise of plaintiff's claim is his unfounded allegation, repeated throughout his opening brief and the amended complaint, that as early as October 2018 – months before Celgene even agreed to permit due diligence and before anyone suggested using a CVR component in the merger – BMS "was already drafting deficient regulatory filings and operational plans" for liso-cel. Pa32; see Pb2, 4, 19, 20, 24, 29, 32, 34; see, e.g., Pa50; Pa52-53; Pa58; Pa62-67; Pa76; Pa78-79. Plaintiff's own allegations demonstrated that this was a figment of plaintiff's imagination. BMS had no involvement in, or control over, the FDA approval process for liso-cel before the merger closed on November 20, 2019 – nine months after the registration statement became effective.

In his original complaint, plaintiff alleged that Celgene "controlled" the approval process for liso-cel before the merger closed and prepared and "submitted the first component of the Liso-cel BLA to the FDA on September 30, 2019[.]" Pa577; see Pa580-81. Only after the merger closed did BMS "assume[] control of the regulatory approval process for the Milestone therapy Liso-cel." Pa581-82.

Even as he has tried to distance himself from them in the amended complaint and now on appeal, plaintiff is bound by these "[f]actual assertions" in his first complaint, which are judicial admissions. Stoelting v. Hauck, 32 N.J.

87, 107 (1960); New Amsterdam Cas. Co. v. Popovich, 31 N.J. Super. 514, 520 (App. Div. 1954) ("Prior assertions made in pleadings or evidence which are inconsistent with or contradictory of present claims are admissible under the principle of self-contradiction."); see Schott v. State, 2006 WL 1911375, at *4 (N.J. Super. Ct., App. Div. July 13, 2006) ("[I]n a motion to dismiss the pleadings, a court may consider . . . judicial admissions in the record.").

Plaintiff's previous allegations demonstrate the falsity of his later conclusory allegation that BMS controlled the preparation and planning for the liso-cel BLA before the registration statement became effective in February 2019 – nine months before the merger even closed. Further, plaintiff did not address the inherent contradiction between the allegations in his pleadings in his opening brief, and he should not be permitted to do so on reply. L.J. Zucca, Inc. v. Allen Bros. Wholesale Distribs., Inc., 434 N.J. Super. 60, 87 (App. Div. 2014).

But in any event, the amended complaint itself alleged that Celgene – not BMS – "submitted the first component of the liso-cel BLA to the FDA on September 30, 2019, before the Merger closed." Pa80. And that pleading still alleged that BMS did not "assume[] control of the regulatory approval process for" liso-cel until the merger closed on November 20, 2019. Pa81. By its own allegations, in other words, the amended complaint negated plaintiff's invented

allegations about supposedly "deficient" regulatory filings and plans developed by BMS as early as October 2018.

Second, those "conclusory" allegations are "directly contradicted by" the registration statement itself, which is "integral to the complaint." Myska v. N.J. Mfrs. Ins. Co., 440 N.J. Super. 458, 471, 482 (App. Div. 2015). The registration statement disclosed that, during the period between the signing and closing of the merger agreement, Celgene would retain control over the operation of its business. Pa305; Pa431. Indeed, it was a condition to closing that Celgene's representations about the operation of its business, including its compliance with regulatory requirements with respect to its product candidates, would be true on the closing date. Pa407-08, 457. Plaintiff admitted that the CVR agreement only "became effective on November 20, 2019[,]" the day the merger closed; consequently, BMS's obligation to use "Diligent Efforts" to achieve the CVR milestones under that agreement was not an obligation at all before that date. Pa81; see Pa71.[6]

[6] Plaintiff's allegation that BMS purportedly was preparing "internal BLA submission drafts and plans" in November 2018 – months before the merger agreement was signed or the use of a CVR in the merger was even discussed – is particularly absurd. Pa50-51; see Pa61-70. His further conclusory assertion that BMS board members were aware of these "deficient" plans and "already anticipated" FDA problems is unsupported by a single factual allegation. See Pa67, 77, 80-81, 86-87.

Plaintiff's conclusory allegations that at some point before the merger, BMS already had taken responsibility for key aspects of the FDA approval process for liso-cel – by allegedly preparing "deficient" filings and operational plans that it should have known would "torpedo" timely FDA approval – is not entitled to a presumption of truth and may be disregarded. Myska, 440 N.J. Super. at 471, 482 (rejecting allegations that were "nothing more than conclusory statements[,] which are directly contradicted by documents that are integral to the complaint"); see Nikola v. Altice USA, Inc., 2025 WL 2078374, at *8 (N.J. Super. Ct., App. Div. July 24, 2025) (same).

Third, even if the Court were to entertain plaintiff's unfounded allegation, plaintiff still failed to "plead facts to demonstrate that allegedly omitted facts both existed, and were known or knowable," by the effective date of the registration statement, February 22, 2019. Lin, 574 F. Supp. 2d at 421. The amended complaint did not allege when any of the "deficient" BMS activities occurred. Plaintiff broadly asserted that they occurred sometime "before the Merger," Pa34, 48, 78-79, but in a handful of paragraphs, plaintiff alleged that they occurred "[b]etween October 31 and December 5, 2018," before BMS and Celgene had even agreed to full due diligence, Pa49-50, 52-53, 57-58.

Plaintiff's obfuscation of the timeline is significant, especially given the nine-month gap between the registration statement, on February 22, 2019, and

the merger closing, on November 20, 2019. If BMS's alleged pre-merger activities were after the effective date, then the necessary factual predicate for plaintiff's claim clearly could not have "existed" then. Castlerock, 114 F. Supp. 2d at 323. The failure to "allege facts to establish that any of these alleged events were occurring at the time of the" registration statement by itself required dismissal. In re Coty Inc. Sec. Litig., 2016 WL 1271065, at *11 (S.D.N.Y. Mar. 29, 2016). Plaintiff never addresses these dispositive points in his opening brief, and he therefore has waived any contrary argument. L.J. Zucca, 434 N.J. Super. at 87.

Fourth, the amended complaint provided no factual support for plaintiff's contention that BMS knew, by the effective date of the registration statement, not just that draft regulatory filings (which would not be submitted for another 10 months) were somehow "deficient" but also that those alleged deficiencies "would likely torpedo any prospect of meeting the liso-cel Milestone[,]" which was not until 22 months later. Pa34, 70, 78; see Yaroni v. Pintec Tech. Holdings Ltd., 600 F. Supp. 3d 385, 397 (S.D.N.Y. 2022) (the "relevant inquiry" under section 11 is whether the complaint alleges that issuer "knew or had reason to believe, at the time the [registration statement was] filed, that the statement was untrue").

The "securities laws do not require clairvoyance in the preparation of offering documents." In re TVIX Sec. Litig., 25 F. Supp. 3d 444, 452 (S.D.N.Y. 2014) (internal quotations omitted); see In re Ikon Office Sols., Inc., 277 F.3d 658, 673 (3d Cir. 2002) (same). Yet according to plaintiff's claim, BMS knew, by February 22, 2019, that unidentified but allegedly "deficient" draft filings and plans "would result" in events months or even years later that would lead to the FDA approving liso-cel 36 days after the December 31, 2020 milestone date (amidst a pandemic that was not recognized for nearly a year after the registration statement). Jiajia Luo, 465 F. Supp. 3d at 414. The trial court correctly rejected plaintiff's "far-fetched" theory. Id. at 411; Pa20-22.

In reality, plaintiff's conclusory allegations of "deficient" drafting and planning are thinly disguised hindsight – "an attempt to allege liability for disclosures not made because the material fact was unknowable or had not even occurred as of the critical date." Panther Partners, Inc. v. Ikanos Commc'ns, Inc., 538 F. Supp. 2d 662, 673 (S.D.N.Y. 2008), aff'd in relevant part, 347 F. App'x 617 (2d Cir. 2009); see Winer Family Tr. v. Queen, 503 F.3d 319, 331 (3d Cir. 2007) ("[L]iability cannot be imposed on the basis of subsequent events."). Plaintiff relies on a series of post-merger developments with respect to the liso-cel approval process as the basis for his unsupported claim that the alleged (and non-existent) drafting and planning activities must have existed and

must have been recognized to be "deficient." The amended complaint itself identified various post-merger events as proof of these alleged "deficiencies," all of which occurred long after the registration statement became effective. Pa32-33; see Pa79-92.

Plaintiff alleged, for example, that "well before the Merger, [BMS] had already drafted operational build-out plans that negligently would allow supposedly launch-ready production facilities to disregard basic FDA and industry standards." Pa84. In support of that assertion, plaintiff listed six alleged "deficiencies" in BMS's purported "operational build-out plans." Pa87-88; see Pa33, 77-78. But those alleged "deficiencies" are nothing more than the recitation of FDA observations following facility inspections that were not conducted until October and December of 2020 – nearly two years after the registration statement. See Pa89, 91.

Similarly, alleged "deficiencies" in draft portions of the liso-cel BLA that plaintiff alleged BMS prepared "before the merger" included the alleged omission of data concerning: "(i) the tests used to ensure that liso-cel is safe and efficacious, referred to as assays, and (ii) the studies that assess whether those assays worked as they were supposed to, referred to as validation." Pa81. But that supposedly omitted data is the same information that BMS submitted in

response to an FDA post-filing information request on March 23, 2020 – more than a year after the registration statement became effective. Pa84-85.

Further, even if BMS had been involved in preparing draft regulatory filings before the registration statement (which it obviously was not), the suggestion that it would have known the drafts were "deficient" could not be squared with plaintiff's allegations that the FDA accepted the liso-cel BLA after BMS filed the final module on December 18, 2019 – after the merger closed – and designated it for "Priority Review." Pa82-83. Acceptance of a BLA filing means that the FDA had determined that the application was "sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101.

Plaintiff's theory that BMS should have had the foresight to predict the FDA's decision-making with respect to a highly complex application for approval of a cutting-edge cancer treatment – in the middle of the worst pandemic in a century – rests entirely on "20/20 hindsight" and a "backward-looking assessment of the registration statement." Rubinstein v. Credit Suisse Grp. AG, 457 F. Supp. 3d 289, 295 (S.D.N.Y. 2020) (internal quotations omitted).

"This type of 'hindsight' pleading, however, falls short." Ohio Pub. Emps. Ret. Sys. v. Discovery, Inc., 715 F. Supp. 3d 483, 494-95 (S.D.N.Y. 2024) (dismissing Securities Act claims); see, e.g., In re HEXO Corp. Sec. Litig., 524

F. Supp. 3d 283, 300-01 (S.D.N.Y. 2021) (rejecting section 11 claim "based on hindsight pleading"); Zucker v. Quasha, 891 F. Supp. 1010, 1017 (D.N.J. 1995) ("[O]missions that create a misleading impression – particularly one that is misleading only in hindsight – are not sufficient . . . ."), aff'd, 82 F.3d 408 (3d Cir. 1996) (emphasis in original).

Plaintiff's claims against Mr. Alles – Celgene's former CEO and chairman and someone who never worked for BMS – are even more implausible. The amended complaint did not allege any facts "that show that [Mr. Alles] directed the activities of BMS or had any control over the issuance of the CVRs." Pa26. Even if plaintiff's central allegation were not entirely invented, there was no allegation that Mr. Alles – an outsider to BMS – knew, or could have known, that BMS allegedly drafted inadequate portions of the liso-cel BLA. To the contrary, plaintiff alleged that Celgene, the merger party led by Mr. Alles, timely submitted the first component of the BLA on September 30, 2019 (before the merger closed), Pa80, and that after closing "[t]he remainder of the approval process for liso-cel was then directly controlled by [BMS]."[7] Pa81.

[7] Plaintiff's original complaint alleged that Celgene put liso-cel on the "fast track" for FDA approval. See, e.g., Pa577-78. In the amended complaint, plaintiff sought to distance himself from his prior "fast track" allegations, but plaintiff remains bound by his assertions in the prior pleading, which are judicial admissions. See supra at 24-25.

Moreover, Mr. Alles's personal financial interests were directly aligned with Celgene stockholders' because he had significant Celgene holdings and received CVRs in the merger. See Pa327, 348 (Alles holdings). Plaintiff's conclusory allegations that BMS had a secret intent to sabotage the CVR milestones are even more outlandish as applied to Mr. Alles.

Plaintiff offers no meaningful response to these dispositive points on appeal. Pb27-30. He admits that his section 11 claim rests on "later-emerging facts" – i.e., developments occurring long after the effective date of the registration statement. Pb28. Plaintiff nevertheless suggests, mistakenly, that courts can draw an inference that those "later-emerging facts" reflect conditions that existed at the time the registration statement became effective.

But as recognized by the very case law on which plaintiff relies, the federal securities laws categorically "forbid[] reliance on speculative fraud by hindsight allegations[.]" City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc., 70 F.4th 668, 693 (3d Cir. 2023) (internal quotations omitted; emphasis in original); see Pb28 (citing City of Warren). That is all plaintiff offers here: pure speculation that there must have been "already-existing (but aberrant) drafts and operational plans" with respect to the liso-cel BLA, in February 2019, based on events that occurred many months or years later.

Pb28-29.[8] And as already discussed, that conclusory, speculative allegation not only finds no contemporaneous factual support – it is directly contradicted by plaintiff's own allegations. See supra at 24-27.

In sum, the trial court correctly dismissed the amended complaint for failure to allege any material facts in existence as of February 22, 2019 that were omitted from the registration statement. The complaint instead engaged in impermissible hindsight pleading, which courts have repeatedly and uniformly found insufficient to plead a claim under section 11. See, e.g., Singh v. Schikan, 106 F. Supp. 3d 439, 450 (S.D.N.Y. 2015) (dismissing section 11 claim that "more closely resemble[d] a criticism of the [clinical] studies' design than a claim for nondisclosure, a form of hindsight pleading not cognizable under Section 11").

[8] The substantial gap in time between the effective date of the registration statement and the "later-emerging facts" alleged in the complaint – a minimum of ten months – is another distinguishing feature of this case relative to those that plaintiff cites. See Pb28 (citing City of Warren, 70 F.4th at 693 (corrective disclosures made "eight weeks" after alleged misrepresentations); Plotkin v. IP Axess Inc., 407 F.3d 690, 698 (5th Cir. 2005) (inferring falsity of representations based on events occurring "within only three to four months" of them, in addition to facts in existence prior to representations)). Plaintiff also mistakenly relies on In re Merck & Co, Inc. Sec. Litig., 432 F.3d 261, 272 (3d Cir. 2005), which held that facts existing "prior to the commencement of the class period" could permit an inference that later representations were false.

B. The Registration Statement Disclosed the Risk That Ultimately Materialized.

The dismissal below also should be affirmed for the separate and independent reason that the registration statement included specific disclosures concerning the CVR-related risk that is the basis for plaintiff's claim, namely, that the CVRs might expire without value if any one of the three milestone therapies were not approved by the FDA by its milestone date. Pa174.

"When a registration statement warns of the exact risk that later materialized, a Section 11 claim will not lie as a matter of law." In re ProShares Tr. Sec. Litig., 728 F.3d 96, 102 (2d Cir. 2013) (cleaned up). For this principle to apply, "a registration statement need not disclose every possible permutation of the risk, nor 'predict the precise manner in which the risks will manifest themselves.'" In re ProShares Tr. Sec. Litig., 889 F. Supp. 2d 644, 655 (S.D.N.Y. 2012), aff'd, 728 F.3d 96 (2d Cir. 2013) (quoting In re AES Corp. Sec. Litig., 825 F. Supp. 578, 588 (S.D.N.Y. 1993)).

The registration statement in this case expressly warned that the CVRs would expire without value if any of the three approval milestones was missed, "for any reason," by even a single day. Pa174. That is precisely the risk that materialized, when the FDA approved liso-cel 36 days too late to meet the payment contingency under the CVRs. Pa93.

The registration statement also disclosed that BMS management estimated only a 45 percent probability that all three milestones would be achieved in time for there to be payment under the CVRs. Pa281. Given this relatively low "probability of achieving all three necessary approvals," the registration statement included an estimate of the risk-weighted present value for each CVR of just $3.75 – not even half of the possible $9 payout per CVR. Pa192.

In brief, BMS "warned of the exact risk that was threatened and later materialized." Jiajia Luo, 465 F. Supp. 3d at 411-12. Plaintiff therefore was precluded, as a matter of law, from asserting a section 11 claim about that issue. Yaroni, 600 F. Supp. 3d at 398; see, e.g., Fernandes v. Centessa Pharm. PLC, 2024 WL 3638254, at *20 (S.D.N.Y. Aug. 2, 2024) (rejecting section 11 claim based on theory that issuer misrepresented drug's "chances of success" in clinical trials where risk that drug could fail was disclosed).

C. The Trial Court Correctly Rejected Plaintiff's Attempt to Rely on Items 303 and 105 of Regulation S-K.

Plaintiff places great emphasis on an issuer's alleged disclosure obligations under Items 303 and 105 of Regulation S-K. Pa72-79; Pb19-39. But Items 303 and 105 do not provide an independent cause of action under the federal securities laws. Jaroslawicz v. M&T Bank Corp., 962 F.3d 701, 711 n.10 (3d Cir. 2020) (Item 105); In re Galena Biopharma, Inc. Sec. Litig., 336 F. Supp. 3d 378, 391 (D.N.J. 2018) (Item 303). Nor did the allegations in

the amended complaint establish that BMS failed to comply with any disclosure obligation under those regulations.

1. The Court Properly Rejected Plaintiff's Item 303 Theory.

To establish a duty to disclose under Item 303, a plaintiff must allege: "(1) that there was a known trend or uncertainty; and (2) that the trend or uncertainty had, or that the registrant reasonably expected it to have, a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Jiajia Luo, 465 F. Supp. 3d at 413. Because it only applies to "known" trends, the complaint must allege the registrant had "actual knowledge of the relevant trend or uncertainty." Indiana Pub. Ret. Sys. v. SAIC, Inc., 818 F.3d 85, 95 (2d Cir. 2016) (emphasis added); see also Howard v. Arconic Inc., 395 F. Supp. 3d 516, 569 (W.D. Pa. 2019) (denying Item 303 claim when plaintiffs failed to allege that defendant's management "had actual knowledge" of the alleged trends or uncertainties). Plaintiff did not meet any of these requirements.

Plaintiff alleged that BMS failed "to disclose that, before the Merger, [it] was already drafting deficient regulatory filings and operational plans" that were "likely to slow-roll the FDA approval process" for liso-cel and enable BMS to avoid the CVR payment. Pa76; see Pb24-25. Those conclusory allegations conflict with other allegations in the complaint, and in the registration statement,

as already discussed. See supra at 25-27. But in addition, the amended complaint did not allege actual knowledge by anyone at BMS that any draft regulatory filings or operational plans for liso-cel were so "deficient" that they "materially raised the risk that the CVR would not be paid." Pb24.

Instead of pleading the necessary facts, plaintiff relied again on hindsight pleading, but it is equally impermissible here. See Pa76-78, 86-93; Pb25; see Lopez v. Ctpartners Exec. Search Inc., 173 F. Supp. 3d 12, 34 (S.D.N.Y. 2016) (rejecting Item 303 claim based on allegations that, without "the benefit of hindsight," were "speculative and conjectural").

The trial court correctly observed that, even accepting plaintiff's false allegations of drafting and planning as true, plaintiff's characterization of that (non-existent) drafting and planning as "deficient" was based entirely on hindsight. Pa20, 23. Item 303 only requires disclosure of a known "trend, demand, commitment, event or uncertainty . . . ." In re DraftKings Inc. Sec. Litig., 650 F. Supp. 3d 120, 152 (S.D.N.Y. 2023) (quoting Litwin v. Blackstone Grp., L.P., 634 F.3d 706, 716 (2d Cir. 2011)).[9] Plaintiff identified no such

[9] The Item 303 claims at issue in the cases cited in plaintiff's opening brief involved far different facts. See Silverstrand Invs. v. AMAG Pharms., Inc., 707 F.3d 95, 103 (1st Cir. 2013) (issuer failed to disclose that, prior to offering, it knew its flagship drug, on which its "profitability entirely depended," had caused "a death, two life-threatening reactions, and fourteen hospitalizations"); Allison v. Oak Street Health, Inc., 2023 WL 1928119, at *8 (N.D. Ill. Feb. 10, 2023) (issuer failed to disclose then-existing criminal kickback scheme);

known trend, meaning there could be no Item 303 violation on which to base a section 11 claim.

But even if plaintiff had alleged "actual knowledge," the amended complaint failed to allege how any alleged "trend" or "uncertainty" was "reasonably likely" to have any material impact on BMS's operations or financial performance as of February 22, 2019, when the registration statement became effective. 17 C.F.R. § 229.303(b)(2)(ii). This standard requires "a fairly substantial probability that the known risk at issue will materialize and have a material impact – if not a more-likely-than-not standard, then something not too much below that." Willard v. UP Fintech Holding Ltd., 527 F. Supp. 3d 609, 619 (S.D.N.Y. 2021) (internal quotations omitted). Plaintiff offered no contemporaneous allegations that, at the time of the registration statement, it was reasonably likely that the liso-cel CVR milestone would be missed because of draft regulatory submissions that were not even filed for another ten months or facilities inspections that did not take place for nearly two more years.

Panther Partners Inc. v. Jianpu Tech. Inc., 2020 WL 5757628, at *10 (S.D.N.Y. Sept. 27, 2020) (issuer failed to disclose non-compliance with Chinese regulations, which was plausibly alleged to be known to issuer "given multiple public reports" at the time); Twin Master Fund, Ltd. v. Akorn, Inc., 2020 WL 564222, at *8 (N.D. Ill. Feb. 5, 2020) (issuer failed to disclose "data integrity issues" where senior executives learned that an employee "was thwarting data integrity investigations," and issues were identified "at Akorn's headquarters . . . and research facility").

Plaintiff's only response is impermissible hindsight. Pb34-36. But even hindsight could not assist plaintiff here (even if it were permissible). The FDA approved all three of the milestone therapies largely within the timeframes contemplated when BMS and Celgene entered into the merger agreement and set the milestones for payment under the CVRs. Two of the three were approved before their milestone dates; liso-cel was approved only 36 days too late – amidst the worst pandemic in a century.

Even looking back from two years in the future, it could not be said that in late-February 2019 it was "reasonably likely" that FDA approval would not be obtained in time to permit payment under the CVRs. But regardless, the registration statement disclosed the estimate by BMS management of a 45% chance that the FDA would approve all three applications in time to permit payment under the CVRs. Pa281. There was no material omission.

2. The Court Correctly Rejected Plaintiff's Item 105 Theory.

Item 105 similarly offered plaintiff no basis to avoid dismissal. That provision requires disclosure of "the most significant factors that make an investment in the registrant or offering speculative or risky." 17 C.F.R. § 229.105(a). The registration statement here expressly disclosed the risk that the CVRs might "expire valueless" if the FDA did not approve any one of the three milestone therapies "for any reason." Pa174.

But even beyond that disclosure, plaintiff did not allege any known significant risk that was not disclosed. Jaroslawicz, 962 F.3d at 713 (knowledge required); Wandel v. Gao, 590 F. Supp. 3d 630, 646 (S.D.N.Y. 2022) ("To state a claim under Item 105, an issuer must know, at the time of the [offering], about an undisclosed risk factor that could seriously affect its present or future business.") (emphasis added).[10] For the reasons already discussed, the amended complaint did not allege any facts suggesting that BMS knew, when the registration statement became effective, that alleged draft filings or plans for liso-cel were so "deficient" that they "could seriously affect" BMS's business. Wandel, 590 F. Supp. 3d at 646.

D. The PSLRA Safe Harbor Rule Protects BMS's Statements.

The trial court also properly concluded that plaintiff's claim was barred by the statutory safe harbor for forward-looking statements enacted by the PSLRA. Pa21-22. The safe harbor precludes liability "with respect to any forward-looking statement" on any Securities Act claim "based on an untrue statement of material fact or omission of a material fact necessary to make the statement not misleading," where the statement is made without "actual

[10] For this reason, the decision in City of Roseville Emps. Ret. Sys. v. EnergySolutions, Inc., 814 F. Supp. 2d 395 (S.D.N.Y. 2011), is not "instructive." Pb36. Unlike here, the complaint in City of Roseville contained well-pleaded, contemporaneous factual allegations that the defendants were aware of but misrepresented or omitted certain risks.

knowledge that it was false or misleading," is "accompanied by meaningful cautionary language," or is immaterial. 15 U.S.C. § 77z-2(c)(1); see Williams v. Globus Medical, Inc., 869 F.3d 235, 245 (3d Cir. 2017).

The challenged disclosures concerning the CVRs were protected as forward-looking statements under the PSLRA and are not actionable under section 11, as the trial court, Judge Furman of the Southern District of New York, and the Second Circuit all correctly held. Pa21-22; BMS CVR Sec. Litig., 658 F. Supp. 3d at 236; Mangrove Partners, 2025 WL 1420914, at *2; see 15 U.S.C. § 77z-2.

Plaintiff asserts that the safe harbor does not apply because his section 11 claim involves "pure omissions." Pb38-39. But the Second Circuit rejected the same argument as lacking "merit." See Mangrove Partners, 2025 WL 1420914, at *3 n. 4. In the first place, plaintiff did not allege an actionable omission that BMS was required to disclose under Items 303 or 105 for reasons already discussed. See supra at 36-41.[11]

[11] Plaintiff's "pure omissions" cases therefore are inapposite. Pb38 (citing Heinze v. Tesco Corp., 971 F.3d 475, 483 (5th Cir. 2020); Litwin v. Blackstone Grp., L.P., 634 F.3d 706, 722 (2d Cir. 2011); Mallen v. Alphatec Hldgs., Inc., 861 F. Supp. 2d 1111, 1126 (S.D. Cal. 2012), aff'd, 607 F. App'x 694 (9th Cir. 2015); In re Blockbuster Inc. Sec. Litig., 2004 WL 884308, at *7 (N.D. Tex. Apr. 26, 2004)).

Nor did the supposed "omissions" "relate to past, historical, or then-existing facts and conditions," as the amended complaint erroneously alleged. Pa98; see Pb38. Plaintiff's central (and wholly unsupported) allegation looked to the future. Pa78 (alleging BMS knew it was drafting "substandard operational plans and regulatory filings . . . that were already likely to torpedo any prospect of meeting the liso-cel Milestone") (emphasis added); see also Pa79 (alleging that omissions "rendered false and misleading" many references to known risks "that 'if' occurring 'might' or 'could' affect the Company").[12]

The BMS disclosures concerning the risks associated with the CVRs were "extensive and specific, substantive, and tailored to the risks involved." BMS CVR Sec. Litig., 658 F. Supp. 3d at 237-38. That cautionary language alone is sufficient for the safe harbor to apply. Gray v. Wesco Aircraft Holdings, Inc., 454 F. Supp. 3d 366, 394 (S.D.N.Y. 2020), aff'd, 847 F. App'x 35 (2d Cir. 2021)).

The disclosures also were meaningful. See In re Barrick Gold Corp. Sec. Litig., 341 F. Supp. 3d 358, 377 (S.D.N.Y. 2018) (court must "identify the allegedly undisclosed risk" and read cautionary language "to determine if a

[12] Plaintiff's reliance on cases involving statements of present or historical fact is therefore misplaced. Pb38-39 (citing In re Mobile Media Sec. Litig., 28 F. Supp. 2d 901, 930 (D.N.J. 1998); Curran v. Freshpet, Inc., 2018 WL 394878, at *4 (D.N.J. Jan. 12, 2018) ("mixed present/future statement")).

reasonable investor could have been misled" into believing risk did not actually exist) (quoting In re Delcath Sys., Inc. Sec. Litig., 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014)). Here, the allegedly "undisclosed risk," according to plaintiff, was that BMS was drafting "deficient" regulatory filings and plans, making timely FDA approval of liso-cel unlikely. Pa78-79. But even if those allegations could be credited, no reasonable investor would have been misled to believe there was no risk that the CVRs might "expire valueless," as the registration statement warned. Pa174; see Barrick Gold, 341 F. Supp. 3d at 377. The cautionary language "expressly warn[ed] of . . . the risk that brought about [plaintiff's] loss[.]" Halperin v. eBanker USA.com, Inc., 295 F.3d 352, 359 (2d Cir. 2002). The safe harbor squarely applied.[13]

The disclosures in the registration statement about the CVRs were forward-looking and were accompanied by meaningful cautionary language, and plaintiff has not alleged any contemporaneous fact establishing that any disclosure was at odds with what the defendants knew at the time. The trial court properly dismissed the amended complaint on this basis as well.

[13] Plaintiff does not argue on appeal either that the risk factor disclosures "were themselves misleading," Pa98, or that the defendants "had actual knowledge" that the risk factor disclosures were false, id. He therefore has waived any challenge on the basis of those assertions.

E. The Trial Court Properly Concluded That the Amended Complaint Sounded in Fraud.

Even though the trial court's judgment did not rest on the determination that the amended complaint's allegations sounded in fraud and therefore were subject to heightened pleading requirements, that determination indisputably was correct. See Pa19. Courts recognize that the heightened pleading requirements in Rule 4:5-8 apply to a claim that "sound[s] in fraud." See, e.g., Fleming v. United Parcel Serv., Inc., 255 N.J. Super. 108, 156 (Law Div. 1992).

In the amended complaint here, plaintiff alleged that BMS knowingly "drafted deficient regulatory filings and operational plans that diverged from industry practice" to "slow-roll the FDA approval process" for liso-cel and "torpedo any prospect of meeting the liso-cel Milestone, thereby "avoid[ing] the CVR payment." Pa31-32, 34; see Pa50-51, 58, 76-78, 92-93, 98. Those are the type of assertions "classically associated with fraud[.]" Rombach v. Chang, 355 F.3d 164, 171 (2d Cir. 2004); see Chubb, 394 F.3d at 160-61 (allegations "sound in fraud" where defendants are alleged to have engaged in misconduct "knowingly and intentionally").

Further, the amended complaint did not satisfy the heightened standard. It did not set forth factual allegations from which an inference could be drawn that BMS or any other defendant intentionally omitted material information from the registration statement. Indeed, the amended complaint did not include

any contemporaneous factual allegation in support of plaintiff's conclusory allegation that BMS knowingly drafted "deficient regulatory filings and operational plans" to avoid payment of the CVRs. Pa78-79.

As the trial court correctly recognized, plaintiff's allegations "[did] not include any details as to how the fraud was conceived or perpetrated aside from general dates of important meetings among BMS executives or between BMS executives and other third parties that discussed the merger." Pa19. That was not enough to plead fraud with particularity. See In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 224-25 (3d Cir. 2002) (particularity requirement not met using allegations about events post-dating alleged misrepresentations).

Plaintiff argues that his section 11 claim is based in negligence and "does not sound in fraud." Pb15-16. But even plaintiff's brief recognizes that "a Section 11 claim sounds in fraud where it alleges 'that defendants intentionally concealed information in the filing at issue.'" Pb16 (quoting Pappas v. Qutoutiao Inc., 2024 WL 4588491, at *3 (2d Cir. Oct. 28, 2024)). That is precisely what plaintiff alleged here.

In this appeal, plaintiff argues that "[i]t does not take notification from the FDA for [BMS] to know its internal drafts and plans have diverged from its own past practice with similar approval processes." Pb27. But even putting aside that there was no well-pleaded allegation that there were internal drafts and

plans, that argument illustrates that the claim is based in fraud. As the trial court correctly observed, "if you are saying [defendants] had a plan to do it you are coming back to fraud. . . . You can't plan to be negligent. You can either be fraud[ulent] or you can be negligent. You can't be both." 2T30:4-9.

In the amended complaint, plaintiff accused the defendants of intentional misconduct: the alleged preparation of "deficient regulatory filings and operational plans that blatantly strayed in critical respects" from industry standards that the defendants allegedly knew, when the registration statement became effective, "were already likely to slow-roll the FDA approval process" for liso-cel. Pa76, 79. The trial court correctly recognized that the heightened pleading requirements of Rule 4:5-8 applied to such a claim.

III. THE TRIAL COURT CORRECTLY DISMISSED THE PLAINTIFF'S "CONTROLLING PERSON" CLAIM.

Having found that plaintiff failed to state a claim under section 11, the trial court correctly dismissed plaintiff's "controlling person" claim under section 15 of the Securities Act against all of the individual defendants, Pa26, because there can be no claim for secondary liability under section 15 without a claim for primary liability under the Securities Act. Klein v. General Nutrition Cos., 186 F.3d 338, 344 (3d Cir. 1999); see 15 U.S.C. § 77o.

As for Mr. Alles specifically, the trial court correctly concluded that he "never worked for BMS[,]" and plaintiff "pled no facts to show that [Mr.] Alles

directed the activities of BMS or had any control over the issuance of the CVRs." Pa26. Plaintiff does not contest those findings on appeal. Instead, he criticizes the trial court for failing to "directly address [p]laintiff's allegations that Alles has power to control Celgene, its board of directors, its employees, or any other Celgene directors, and thus primary violators under Sec. 12(a)(2)." Pb40. Plaintiff abandoned his claims under section 12(a)(2) when he filed his amended complaint. Pa5. But in addition, allegations that Mr. Alles had "control" over Celgene are beside the point. Celgene is not alleged to have violated the Securities Act, meaning plaintiff did not plead an actionable claim against Mr. Alles for secondary liability under section 15.

Plaintiff relies in error on decisions allowing claims to proceed under section 15 when the issuer itself was not named as a defendant. Pb40-41. But in those cases, the plaintiffs still alleged an underlying securities violation by the allegedly "controlled" corporate entity. See In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 285 (3d Cir. 2006) ("The record reveals that plaintiffs did expressly name the corporation itself as the primary violator in their Section 15 and Section 20(a) counts."). There were no such allegations about Celgene here.

IV. THE TRIAL COURT DID NOT ABUSE ITS DISCRETION IN DISMISSING THE COMPLAINT WITH PREJUDICE.

Plaintiff does not contest the trial court's decision to dismiss the amended complaint with prejudice. Pa27-28. Any challenge to that decision therefore has been waived.

Regardless, the trial court's ruling was a proper exercise of its "sound discretion." Morales ex rel. Martinez v. N.J. Academy of Aquatic Sciences, 302 N.J. Super. 50, 56 (App. Div. 1997). This Court's precedents authorize dismissal with prejudice when, as here, further amendment would be a "useless endeavor." Cona v. Twp. of Wash., 456 N.J. Super. 197, 214 (App. Div. 2018). Plaintiff was given ample opportunity to allege "every fact he reasonably believes could support" a claim under the Securities Act. Quigley v. Esquire Deposition Servs., LLC, 409 N.J. Super. 69, 76 (App. Div. 2009). He was unable to do so after two iterations of his complaint and many submissions in connection with the motions related to those pleadings.

CONCLUSION

The judgment of the trial court should be affirmed in all respects.

Dated: Florham Park, New Jersey
September 16, 2025

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SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION

HOWARD BERNSTEIN, Individually and on Behalf of All Others Similarly Situated, Plaintiff-Appellant, v. BRISTOL-MYERS SQUIBB CO.; MARK J. ALLES; GIOVANNI CAFORIO, M.D.; SANDRA LEUNG, ESQ.; CHARLES BANCROFT; KARN M. SANTIAGO; VICKI L. SATO, PH.D.; PETER J. ARDUINI; ROBERT BERTOLINI; MATTHEW W. EMMENS; MICHAEL GROBSTEIN; ALAN J. LACY; DINESH C. PALIWAL; THEODORE R. SAMUELS; GERALD L. STORCH; and KAREN H. VOUSDEN, PH.D., Defendants-Appellees.	:	Docket No. A-002080-24 On Appeal from Order of the Superior Court of New Jersey, Law Division, Union County, dated February 7, 2025 Sat Below: Honorable John G. Hudak, J.S.C. Docket No. Below: UNN-L-003887-21 CLASS ACTION

PLAINTIFF-APPELLANT'S REPLY BRIEF

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I. PRELIMINARY STATEMENT

Defendants' answering brief underscores the Trial Court's clear error in prematurely dismissing Plaintiff's well pled claims. The "pure omission" claims alleged in this case are premised on straightforward facts for which Defendants have no answer. In 2019, Bristol-Myers Squibb Co. ("Bristol-Myers" or "BMS") acquired Celgene Corp. ("Celgene") in a stock-for-stock merger with a potential $6.4 billion cash payment dependent on certain drug candidates (one being liso-cel) obtaining FDA approval by certain dates. Unbeknownst to Plaintiff and other Celgene shareholders, by late 2018 (months before the February 2019 effective date of the Registration Statement at issue), Bristol-Myers was already drafting FDA application documentation and operational protocols for its post-Merger management of those drug candidates. Those internal drafts had already diverged from well-established industry standards, FDA requirements, and Bristol-Myers's own past practice with similar applications. Plaintiff alleged in great detail not only the undisclosed deficiencies and divergences themselves and how they had already substantially increased the risk of delayed liso-cel approval, but also specific 2018 dates, meetings, and other communications (again, all months before the February 2019 effective date) during which these already existing (but negligently deficient) drafts and operational plans were being reviewed at the highest levels of Bristol-Myers, in discussions with named Defendants and financial advisors to the Merger, and indeed in the very due diligence and negotiations with Celgene that led to the final terms of the Merger.

These alleged facts more than suffice to "suggest" the non-fraud, pure omission Section 11 claims asserted in this case. Nonetheless, as explained in the opening brief, the Trial Court's dismissal order disregarded all of this, committing clear error by failing to assume the truth of Plaintiff's actual factual allegations. Instead, the Trial Court credited non-existent allegations of "intentional" misconduct to justify heightened fraud pleading standards, and then improperly drew a host of adverse inferences against Plaintiff. Any one of the Trial Court's errors would warrant reversal. Together they leave no doubt.

Because the Trial Court's own analysis does not withstand scrutiny, in their answering brief Defendants make almost no effort to defend the Trial Court's reasoning. Instead, Defendants fashion flawed post-hoc justifications, none of which were raised or ruled on below. Most glaring, Defendants contend that "contradictory" allegations should be read as "judicial admissions" somehow licensing disbelief of the well-pled facts. That turns civil procedure on its head. The judicial admissions rubric Defendants cite is a function of evidence admissibility, not pleading. The concept has no bearing at the pleading stage, and even at later evidentiary stages cannot license disregard of the facts alleged. Further, the supposed "contradiction" Defendants concoct is nothing of the sort: that Celgene formally controlled the approval process before the Merger is not inconsistent with Bristol-Myers preparing internal drafts in anticipation of taking control after the Merger. The alleged facts must be assumed true and all inferences must be drawn in Plaintiff's favor.

The balance of Defendants' arguments fares no better. Measured against the correct standard, disclosure of the internally known deficiencies and divergences permeating Bristol-Myers's internal drafts and protocols, and the increased risks posed thereby, was required pursuant under Items 303 and 105 of Regulation S-K. Defendants' omission of this "required" information, therefore, supports non-fraud, strict liability claims under Section 11.

The decision below should be reversed.

II. PROCEDURAL HISTORY AND STATEMENT OF FACTS

Plaintiff relies upon the Procedural History and Statement of Facts set forth in his Opening Brief. Pb3–13.

III. ARGUMENT

Defendants led the Trial Court into error with misstatements of law, distortions of the facts, and conflation with cases alleging different theories. Defendants try the same here and compound it with several post-hoc distortions of the rules of pleading. Each of Defendants' arguments is debunked below.

A. Defendants Distort the Rules of Pleading (Pa1–28)

Nearly every argument in Defendants' answering brief rests on sheer disbelief of the facts alleged. Plaintiff alleges pre-merger drafts; Defendants say those drafts are "non-existent." Db38. Plaintiff alleges pre-Merger divergence from industry practice; Defendants call that "false allegations." *Id*. Indeed, although Plaintiff explicitly alleges that well ahead of the February 2019 effective date Bristol-Myers was internally drafting FDA approval documentation and operation protocols that diverged from industry and past

practice, Defendants categorically argue these allegations are "not entitled to a presumption of truth and may be disregarded." Db27. There is a time for Defendants to contest the facts alleged, but that time is not the pleading stage.

1. Inferences Must Be Drawn in Favor of Plaintiff (Pa1–28)

At the pleading stage, it is axiomatic that courts must "assume the facts as asserted by plaintiff are true and give her the benefit of all inferences that may be drawn in her favor." *Banco Popular N. Am. v. Gandi*, 184 N.J. 161, 166 (2005) (citation modified). It requires "a generous and hospitable approach," affording plaintiffs "every reasonable inference of fact." *Id*. If any cause of action is "'suggested' by the facts" alleged, a motion to dismiss must be denied. *Printing Mart-Morristown v. Sharp Elecs. Corp.*, 116 N.J. 739, 746 (1989).

Earlier amendments do not license the court to draw inferences against the Plaintiff. Defendants cite *Quigley v. Esquire Deposition Services, LLC*, 409 N.J. Super. 69, 76 (App. Div. 2009), Pb20–21, but in *Quigley*, the less "liberality" standard was a result of the plaintiff being given leave to amend yet opting not to. 409 N.J. Super. at 76. Here, no option to amend was refused. Plaintiff's amended complaint was dismissed with prejudice. The "generous and hospitable approach" prescribed by *Printing* controls. *See* 116 N.J. at 746.

None of Defendants' justifications warrant deviating from this black-letter standard. That Defendants contend a "contradiction" in the allegations should be interpreted as a "judicial admission" does not license courts to disbelieve the detailed facts alleged and draw inferences against Plaintiff. As a matter of law, the judicial admission rubric Defendants cite is a rule of evidence, not pleading;

it applies at later evidentiary stages to allow admission of prior inconsistent statements (in a pleading or elsewhere) in order to contest credibility. Indeed, Defendants' own citations demonstrate this. *See Stoelting v. Hauck*, 32 N.J. 87 (1960). This rubric has no application at the pleading stage, where evidence and credibility are never at issue, and rather all facts are assumed true.[1]

2. Plaintiff's Pleadings Are Not Contradictory (Pa1–28)

Moreover, the alleged "contradiction" Defendants argue is illusory. There is nothing contradictory in alleging that Celgene retained formal control over the overarching approval process before the Merger close, while at the same time alleging Bristol-Myers internally drafted its own documentation and protocols in anticipation of taking over control after the Merger close. Liso-cel was a centerpiece asset acquired in the Merger. That sophisticated companies plan ahead should be no surprise. In a merger of this size, any acquiring company would be remiss not to have detailed FDA approval plans and processes already in the works for centerpiece assets. All the more given that a mammoth $6.4 billion payout depended on timely FDA approval.

Nor is there any contradiction in Plaintiff alleging that Bristol-Myers had begun internal drafting and preparation before "full due diligence" was complete or before the CVR consideration was finalized. Plaintiff specifically alleges that

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[1] Lest there be any doubt, New Jersey allows pleading in the alternative (even if contradictory), and even where applicable the judicial admissions rubric applies only to facts and not legal conclusions. *See Higgins v. Thurber*, 413 N.J. Super. 1, 24 n.22 (App. Div. 2010), *aff'd*, 205 N.J. 227 (2011); *Van Sickell v. Margolis*, 109 N.J. Super. 14, 18 (App. Div. 1969), *aff'd*, 55 N.J. 355 (1970).

Bristol-Myers and Celgene began to exchange information in 2018, even before formal due diligence commenced, and these allegations are directly corroborated by the description of Merger negotiations included in the Registration Statement itself. For example, Plaintiff alleges preliminary financial analysis meetings and analysis of the drug development pipeline were conducted from September 11, 2018 through September 14, 2018, and that this entailed a careful analysis of: (1) the timeline for submission, (2) the plans for obtaining approval, (3) the likelihood of approval, and (4) the expected value of each drug if approved. Pa46–47. Plaintiff further alleges that between October 2018 and December 5, 2018, BMS continued to analyze the potential transaction, including preparation of plans for the post-acquisition submission of liso-cel to the FDA for approval. Pa50. These 2018 draft plans included the submission of summaries of assays and validations, but inexplicably omitted the analytical procedures and validation reports necessary for approval—a component so important that it would be considered a "major" amendment, causing a major delay, when the FDA realized it was missing. Pa50, 57. Even if, as Defendants claim, the CVR component was not suggested until December 27, 2018 (Db13), the liso-cel FDA process was a centerpiece of the Merger from the outset.

Defendants concede that due diligence began in mid-November 2018 (Db12), months ahead of the February effective date. Plaintiff specifically alleges that as part of this due diligence process, Bristol-Myers continued to review and revise FDA approval documentation and protocol in anticipation of taking over the process upon the Merger close. Plaintiff further alleges that

these drafts already negligently diverged from industry standards and omitted critical information that posed severe, undisclosed risk to timely liso-cel approval. Pa30–35. Although Defendants ask the Court to ignore these allegations, it is unrealistic that BMS would have excluded from its (even partial) due diligence review the very liso-cel application on which over $6 billion dollars would depend. Indeed, BMS's financing approval from Morgan Stanley depended on its post-acquisition submission for liso-cel. Pa51–52. Defendants' argument that BMS was somehow unaware of the details of its own internal drafts, including its inadequate plans for the assays and variations, is implausible. Cf. Db27.[2]

3. Heightened Fraud Standards Do Not Apply (Pa1–28)

Defendants cannot justify the application of heightened fraud standards by arguing non-existent allegations of "intentional misconduct." Plaintiff's explicitly and exclusively non-fraud, pure omission claims sound in negligence and strict liability. The claims turn solely on whether Defendants omitted the alleged deficiencies and divergences, not why they omitted that required information. It could be negligence or innocent mistake. Plaintiff's claims succeed or fail regardless, without any consideration of intent, reliance, or any

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[2] If accepted at their word, BMS would appear to admit that it failed to conduct proper due diligence on a drug that was to be a huge part of the Merger, which could constitute an independent violation of the federal securities laws. *In the Matter of Momentus, Inc., Stable Road Acquisition Corp., SRC-NI Holdings, LLC, and Brian Kabot*, Securities Act Release No. 10955, Exchange Act Release No. 92391 (SEC July 13, 2021) (failure to conduct adequate due diligence resulted in material omissions and misrepresentations).

other of the elements "classically associated with fraud." Cf. Db45. No matter how many times Defendants (or the Trial Court below) mischaracterize the Complaint as alleging Defendants acted "intentionally," it remains that no such allegations appear anywhere in the Complaint. To the contrary, the Complaint explicitly pleads negligence, and to avoid all doubt expressly disclaims any allegation that might be misconstrued as alleging intent to deceive or otherwise sounding in fraud. These allegations do not sound in fraud.

4. Rulings in Distinct BMS Cases Are Not Applicable (Pa1–28)

Defendants cannot import heightened federal and fraud standards by conflating this unique, pure-omissions case with distinct affirmative misrepresentation cases against BMS in New York. Defendants cite to *SM Merger/Arbitrage, L.P. v. Bristol-Myers Squibb Co.*, No. 1:21-cv-08255 (S.D.N.Y.), and its appellate decision in *Mangrove Partners Master Fund, Ltd. v. Bristol-Myers Squibb Co.*, 2025 WL 1420914 (2d Cir. May 16, 2025). Db4–6, Da360–407, Da672–76. That case is entirely distinguishable. It concerned misstatements subject to the Safe Harbor. Here, Plaintiff does not allege any misstatements, but rather alleges omissions—meaning that Safe Harbor cannot apply. Pa32–33, 50–51, 70–79; *see, e.g.*, *Heinze v. Tesco Corp.*, 971 F.3d 475, 483 (5th Cir. 2020) (explaining that "the safe harbor covers only forward-looking statements, not omissions") (citation modified). Defendants further cite to a New York County case, *Williams v. Bristol-Myers Squibb Co.*, Index No. 656179/2021. Db6, Da731. But that case simply parroted the Second Circuit case, again citing the Safe Harbor provision's application to misstatements. Thus, the New York cases did not resolve any of the

pure omission claims, Item 303 and 105 theories of relief, BMS common stock classes, or unique factual allegations asserted here.

Defendants' misdirection cannot transform this purely non-fraud, omissions case into a fraudulent misrepresentation case. But even if it could, Plaintiff's detailed allegations are pled with particularity and thus would suffice even under the inapplicable federal or fraud standards Defendants invoke.

B. Plaintiff's Detailed Factual Allegations State Section 11 Claims Premised On Pure Omission, Not Misstatement (Pa1–28)

Under the proper, well-established New Jersey pleading standards, the complaint's detailed allegations more than suffice to "suggest" non-fraud Section 11 claims on the bases of Defendants' failure to disclose information required to be stated under Items 303 and 105. And the "pure omission" nature of the claims renders much of Defendants' answering brief off the mark.

1. PSLRA Safe Harbor Does Not Apply (Pa1–28)

Because Plaintiff's claims turn solely on omissions of present and historical fact, not any affirmative statement, Defendants' safe harbor arguments are categorically inapplicable. By definition, the PSLRA Safe Harbor is limited to forward-looking *statements*. It does not apply to pure omissions of present fact. *See, e.g.*, *Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 722 (2d. Cir. 2011); *In re Blockbuster Inc. Sec. Litig.*, 2004 WL 884308, at *7 (N.D. Tex. Apr. 26, 2004). Da606. Contrary to Defendants' argument, the Second Circuit decision did not reject this contention. Indeed it makes no mention whatsoever of any claims under Items 303 and 105, *see supra*, and thus could not possibly have

addressed whether such unaddressed pure omission claims could somehow be subject to a safe harbor that "covers only forward-looking *statements*, not *omissions*." *Cf. Heinze*, 971 F.3d at 483 (emphasis in original). As discussed above, unlike the New York cases which rested on the application of the PSLRA safe harbor to affirmative misrepresentations, nothing in this case depends on any affirmative statement. It solely concerns pure omissions.

2. Plaintiff's Allegations Are Not Conclusory or Pled in Hindsight (Pa1–28)

This distinction also dispels Defendants' mischaracterization of Plaintiff's allegations as "conclusory," "hindsight," or an attempt to impose liability "on the basis of subsequent events." Db29–32. These refrains bear no resemblance to the actual Complaint, which alleges in great detail, *inter alia*, that from September through December 2018—i.e., still months ahead of the February 2019 effective date—Bristol-Myers had not only prepared draft FDA approval documentation and protocols that already negligently diverged from industry practice and already omitted critical information, but indeed that these deficient drafts were already being discussed among the highest level of Bristol-Myers management. Contrary to Defendants' cursory disparagement, these allegations indeed "identif[y] [] undisclosed material fact[s] that existed 'when the registration statement became effective.'" Db22. None of this required "clairvoyance" by Defendants. *See* Db29. These are specific allegations of omitted facts, trends, uncertainties, and risks that already existed months before the effective date. Defendants have no answer to these well-pled facts, so they

disparage them as "speculation" and beg the Court to presume them away as "obviously" untrue. That is not how the pleading stage works. These detailed facts must be accepted. Once they are, Defendants' arguments fall apart.

So too, Defendants mischaracterize the Complaint by ignoring the existing deficiencies at the time of the Merger. Db29–32. Courts nationwide reject such empty "hindsight" refrains where, as here, plaintiffs allege facts and conduct that existed and occurred before the offering at issue. *See, e.g.*, *Dudley v. Haub*, 2013 WL 1845519, at *12 (D.N.J. Apr. 30, 2013); *Zwick Partners, LP v. Quorum Health Corp.*, 2018 WL 2933406, at *7 (M.D. Tenn. Apr. 19, 2018); *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 72 (2d Cir. 2001).

Defendants' suggestion that Items 303 and 105 "do not provide an independent cause of action" is semantic misdirection. Db36. The cause of action is Section 11, which expressly creates liability for the omission of information "required to be stated" in a Registration Statement. Items 303 and 105 in turn require that certain events, trends, risks, and uncertainties be disclosed in registration statements. Defendants omitted information required by Items 303 and 105 and thus are liable under Section 11. It's that simple.

3. Defendants Misconstrue Plaintiff's Claims Under Item 303 (Pa1–28)

In addition to all the foregoing, Defendants' Item 303 arguments also fail for independent reasons. While none of Plaintiff's Item 303 allegations are "conclusory" or "conflict with other allegations," *see supra*, Defendants' knowledge arguments get the law backward. The knowledge prong of Item 303

applies only to the "known trend or uncertainty," not to the potential impact. *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1297 (9th Cir. 1998). As such, Plaintiff need only allege that Bristol-Myers's management knew of the undisclosed divergent drafts and protocols, not the likely impact that might result therefrom. *Cf.* Db38.

Regardless, Plaintiff has alleged not only that the drafts were created by Bristol-Myers itself, and discussed and reviewed by high-level Bristol-Myers management at numerous pre-Merger meetings, but moreover that the specific deficiencies were readily apparent to Bristol-Myers because they plainly diverged from Bristol-Myers's own prior experience with similar approval processes.[3] Further, pursuant to §314.101(a)(1), "[t]he filing of an NDA" is merely a minimum "threshold" for initial receipt; contrary to Defendants' argument, it is not a ruling that the application is fully complete. The filing and initial acceptance do not indicate that BMS had submitted a complete application, just that it was sufficient for initial intake. It remained substantively incomplete because, *inter alia*, BMS failed to submit the assays and validations, which would prevent the FDA from making a substantive determination. This inexplicable omission of critical data, of

[3] In its 2019 Annual Report, while listing numerous drugs in the process of being approved by the FDA, BMS touted its mission as: "To discover, develop and deliver innovative medicines that help patients prevail over serious diseases"—a mission that cannot be accomplished without FDA approval. Bristol Myers Squibb, *2019 Annual Report* at ii, 3, bms.com/assets/bms-ar/documents/2019/2019-BMS-Annual-Report.pdf (last visited Oct. 14, 2025).

course, led to a "major" amendment and a three month automatic delay.[4] Pa76, 85.

Neither does Item 303 depend on the consequences of the undisclosed events or uncertainty somehow already existing pre-merger. *Cf*. Db. 39-40. It is the undisclosed trend, event, or uncertainty that must exist at the time—not its ultimate impact, which nearly always emerges later. *See In re Facebook, Inc. IPO Sec. and Deriv. Litig.*, 986 F. Supp. 2d 487, 511–12 (S.D.N.Y. 2013). And the potential future impact need not be guaranteed or even likely: Item 303 by its express terms applies to "uncertainties," the likelihood of any impact is a fact question for the jury, and Item 303 places the burden on Defendants to rule such likelihood out (or disclose it in full), not on Plaintiff to plead that the likelihood of future impact was already a certainty. *See Ind. Pub. Ret. Sys. v. SAIC, Inc.*, 818 F.3d 85, 96 (2d Cir. 2016) (likelihood of impact is question reserved to jury).

Finally, that the FDA belatedly approved liso-cel does not absolve Defendants for failing to disclose pre-Merger deficiencies and divergences from industry and past practice, which before the effective date had already greatly increased the risk of Bristol-Myers blowing the liso-cel milestone. Cf. Db39–40. That is what ultimately occurred. The milestone was blown, the $6.4 billion CVR payment was never paid, and the price of BMS shares suffered severe declines as a result. None of this can be washed away with cursory references

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[4] In fact, a "major change" is so serious, that it is indicative of "a change that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product." U.S. Dep't of Health and Human Servs. Food and Drug Administration, *Guidance for Industry Changes to an Approved NDA or ANDA*, (April 2004), fda.gov/media/71846/download.

to the (unalleged and irrelevant) Covid-19 pandemic that occurred months after the signing of the Merger, and the filing of the Registration Statement and the BLA. Db1. Covid-19 did not cause BMS's internal drafts to omit reams of basic data nor its negligent divergence from industry standards and its own prior experience with FDA applications.

4. Defendants Misconstrue Plaintiff's Claims Under Item 105 (Pa1–28)

Defendants' Item 105 arguments also fail. Contrary to Defendants' mischaracterization, the Registration Statement did not disclose the "exact risk" "that is the basis for Plaintiff's claims." Db35. The undisclosed risks at issue were not merely "that the CVRs might expire without value" or delayed FDA approval was possible. *Cf.* Db35. Rather, Plaintiff alleges that BMS's undisclosed, internal pre-Merger drafts and plans already reflected gross deficiencies. Defendants did not disclose these risks, the increased likelihood and severity of the delays posed thereby, underlying omission of necessary data, divergence from industry standards and past practice, deficient plans, or the other irregularities marring BMS's pre-merger drafts and protocols. No "amount of general cautionary language can protect a company from failure to disclose a specific, known risk." *See Lin v. Interactive Brokers Grp., Inc.*, 574 F. Supp. 2d 408, 417 (S.D.N.Y. 2008).

Even "[w]arnings of specific risks" cannot "shelter defendants from liability if they fail to disclose hard facts critical to appreciating the magnitude of the risks described." *In re Bear Stearns Cos., Inc. Sec., Deriv., & ERISA*

Litig., 763 F. Supp. 2d 423, 495 (S.D.N.Y. 2011). That the CVRs might "expire valueless" discloses nothing about the already occurring divergence from industry practice, the deficient omission of critical data, or the unique risks of automatic FDA delays posed thereby (and alleged in detail by Plaintiff, yet unaddressed by Defendants or the Trial Court). Because these undisclosed deficiencies were already present ahead of the effective date, Item 105 required "accurate and sufficiently candid" disclosure of these specific risks. *See Panther Partners Inc. v. Jianpu Tech. Inc*., 2020 WL 5757628, at *7, *10 (S.D.N.Y. Sept. 27, 2020). Da691. Yet they remained undisclosed.[5]

C. Plaintiff Adequately Pled Section 15 Control Claims (Pa1–28)

As Plaintiff has indeed alleged primary violations, the Trial Court's Section 15 dismissals should also be reversed. And contrary to Defendants' mischaracterization, Db47–48, although Celgene is not a named defendant, Celgene is alleged to be a controlled primary violator. Pa102. Furthermore, the Complaint is replete with facts detailing Celgene and Celgene employees directly soliciting Celgene shareholders to participate in the Merger exchange.

IV. CONCLUSION

For all these reasons, the decision below should be reversed.

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[5] Unlike Item 303, the plain language of Item 105 imposes no knowledge requirement at all. *Compare* 17 C.F.R. §229.303(a) & (b)(2)(ii), *with* 17 C.F.R. §229.105(a); *See also Jianpu*, 2020 WL 5757628, at *7 (defendants' knowledge not required for Item 105); *Gutman v. Lizhi Inc.*, 633 F. Supp. 3d 681, 690 (E.D.N.Y. 2022) (same); *City of Roseville Emps.' Ret. Sys. v. EnergySolutions, Inc*., 814 F. Supp. 2d 395, 426–27 (S.D.N.Y. 2011) (analyzing Item 105 disclosures under the "familiar materiality standard," no knowledge requirement). But even if it did, Plaintiff has alleged knowledge. *See supra* at 12.

Dated: October 14, 2025

Respectfully submitted,

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