CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.
James E. Cecchi
5 Becker Farm Road
Roseland, NJ 07068
Telephone: (973) 994-1700
Facsimile: (973) 994-1744
jcecchi@carellabyrne.com

SEEGER WEISS, LLP
Christopher A. Seeger
55 Challenger Road
6th Floor
Ridgefield Park, NJ 07660
Telephone: (973) 639-9100
cseeger@seegerweiss.com

Co-Liaison Counsel for Lead Plaintiff and the Class

KESSLER TOPAZ MELTZER & CHECK LLP
Andrew L. Zivitz
Matthew L. Mustokoff
Joshua E. D'Ancona
Margaret E. Mazzeo
Nathan A. Hasiuk
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
Facsimile: (610) 667-7056
azivitz@ktmc.com
mmustokoff@ktmc.com
jdancona@ktmc.com
mmazzeo@ktmc.com
nhasiuk@ktmc.com

Lead Counsel for Lead Plaintiff and the Class

BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP
Salvatore J. Graziano
Adam H. Wierzbowski
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 554-1400
Facsimile: (212) 554-1448
Salvatore@blbglaw.com
Adam@blbglaw.com

Additional Counsel for the Class

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE CELGENE CORPORATION SECURITIES LITIGATION

Case No. 18-cv-04772 (JMV) (JBC)

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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GLOSSARY OF TERMS

AAN	American Association of Neurology
ACG	American College of Gastroenterology
ACTRIMS	American Committee For Treatment And Research In Multiple Sclerosis
ADME	Absorption, Distribution, Metabolism and Excretion
AMF	Lead Plaintiff AMF Pensionsförsäkring AB
ARR	Annualized Relapse Rate
AUC	Area Under the Curve
BD	Business Development
CD	Crohn's Disease
CDAI	Crohn's Disease Activity Index
CDEIS	Crohn's Disease Endoscopic Index of Severity
CELG	Celgene ticker symbol
CFR	Code of Federal Regulations
CPMAC	Corporate Pricing and Market Access Committee
CRP	C-reactive protein
DDW	Digestive Disease Week
DMC	Data Monitoring Committee
HEOR	U.S. Health Economics and Outcomes Research
I&I	Inflammation & Immunology
IBD	Inflammatory Bowel Disease
IIEC	Inflammation & Immunology Executive Committee
MS	Multiple Sclerosis
mRNA	Messenger RNA

MSL	Medical Science Liaison
NDA	New Drug Application
NICE	National Institute for Health and Care Excellence
PA	Psoriatic Arthritis
PBM	Pharmacy Benefits Manager
RML	Regional Medical Liaison
RMS	Relapsing Multiple Sclerosis
RTF	Refuse To File
S1P1	sphingosine-1-phosphate receptor-1
S1P5	sphingosine-1-phosphate receptor-5
SEC	Securities and Exchange Commission
SES-CD	Simple Endoscopic Score for Crohn's Disease
SOPP	Standard Operating Policy and Procedure
UC	Ulcerative Colitis
UEGW	United European Gastroenterology Week

Lead Plaintiff AMF Pensionsförsäkring AB ("AMF" or "Lead Plaintiff"), by and through its undersigned counsel, brings this action individually and on behalf of all other persons and entities who purchased or otherwise acquired the common stock of Celgene Corporation ("Celgene" or the "Company") between January 12, 2015 and April 27, 2018, both dates inclusive (the "Class Period"), and were injured thereby (the "Class").

Lead Plaintiff alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Lead Plaintiff's information and belief is based upon, among other things, the investigation conducted by and through its attorneys, which included, among other things, interviews with numerous individuals, including former employees and consultants of Celgene, a review of Celgene's public documents, conference calls concerning Celgene, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by Celgene, analyst reports and advisories about the Company, media reports concerning Celgene and information obtainable on the Internet. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. By 2015, Celgene confronted a major problem. The Company knew that in just a few years, it would lose its single largest source of revenue. Celgene's blockbuster multiple myeloma drug, Revlimid, was going to lose patent exclusivity in 2022. As Celgene knew, when that happened, less expensive generic versions of Revlimid would immediately take much of the market share that had been Revlimid's alone since 2006. Celgene would no longer be able to lean on Revlimid to provide billions in annual revenues. For more than five years running, Revlimid had delivered well over half of the net product sales for the entire Company. In 2014, the year

prior to the start of the Class Period, net product sales from Revlimid had accounted for $4.98 billion, or ***more than 65%*** of total net sales, for the Company as a whole.

2. The approaching threat to Celgene from "the Revlimid patent cliff" was recognized in 2015 and throughout the Class Period by investment analysts and national media outlets alike. For example, in July 2015, investment analysts at Morningstar discussed the Company's need to "reduce Celgene's reliance on cancer drug Revlimid beyond 2020." Celgene's over-dependence on Revlimid continued throughout the Class Period, leading one analyst to write in May 2017 that "investors have reason to be 'concerned' over the Company's revenue concentration from Revlimid."

3. Celgene needed something it could point to as the replacement for its multi-billion dollar blockbuster drug. It needed a major new source for the revenue and growth that investors had come to rely on from Revlimid. Celgene knew it. The industry knew it. Investors knew it.

4. The alleged fraud in this case begins in January 2015, when Celgene embarked on a campaign to fraudulently misrepresent that three drugs in its Inflammation & Immunology ("I&I") franchise were poised to be billion-dollar blockbusters and provide massive revenues after Revlimid went off-patent. As Defendants knew, that was nowhere near the truth.

5. The first drug was **GED-0301** (also known as Mongersen). Licensed from a small, Irish pharmaceutical company called Nogra in April 2014 for an upfront $710 million payment and tiered royalties, GED-0301 was touted as a potentially transformative treatment for the difficult-to-treat inflammatory condition Crohn's Disease ("CD") in January 2015. Celgene represented that GED-0301 was in an advanced stage of the development and regulatory approval process, and at the forefront of Celgene's new drug pipeline.

6. The second drug was **Otezla**, a pill that treats psoriasis and psoriatic arthritis ("PA"), which Celgene began to sell in 2014. Celgene marketed Otezla as the first oral therapy approved by the U.S. Food and Drug Administration ("FDA") for the treatment of adults with active PA.

7. Celgene added the third drug, **Ozanimod**, through a $7.2 billion acquisition of Receptos, Inc. ("Receptos") just months into the Class Period on July 14, 2015. Ozanimod was in development for the treatment of multiple sclerosis ("MS") and ulcerative colitis ("UC").

8. After the Receptos acquisition, on July 15, 2015, *The New York Times* reported that Celgene "has grown to be one of the most successful biotechnology companies, based largely on its blockbuster cancer drug, Revlimid. But Revlimid will eventually lose patent protection, and the company has been aggressively looking to expand its business and diversify. . . . Celgene executives said that ozanimod could have peak annual sales of $4 billion to $6 billion and would complement GED-0301 and also Otezla, a pill Celgene already sells to treat psoriasis and psoriatic arthritis."

9. Throughout the Class Period, Celgene again and again trumpeted the supposed multi-billion dollar "replacement" revenues that these three I&I drugs—GED-0301, Otezla, and Ozanimod—would deliver in the next few years, as Revlimid fell off the "patent cliff" and its revenues faded away. Unbeknownst to the market, however, from at least 2015 until the end of the Class Period, Celgene and numerous Celgene executives materially misrepresented the true facts about GED-0301, Otezla and, starting in 2017, Ozanimod.

10. In their attempt to assure the market that Celgene could fill the revenue hole Revlimid would soon leave, Celgene and the other Defendants concealed the truth from investors at almost every turn. In particular, Defendants: (i) blew past red flags and warnings from

Celgene's own employees and independent scientists, while publicly promoting sham, half-baked study data with respect to GED-0301, even after GED-0301's failure was known internally; (ii) ignored warnings of flat sales, implacable barriers to market penetration, and explicit calls to change long-standing, publicly issued sales guidance for Otezla from Celgene's senior market access executives; and (iii) disregarded warnings and guidance from Celgene's senior scientists and its primary regulator, the FDA, confirming that the Company's publicly promised application for approval of Ozanimod by the FDA in late 2017 would be rejected without required study data. Instead, Defendants misrepresented to investors the true state of affairs surrounding the growth and development status of these drugs, no matter how bleak things appeared to those within the Company.

11. By the end of the Class Period, Defendants disclosed that: (i) GED-0301 was such an outright failure that it had to be scrapped, resulting in a $1.6 billion impairment charge; (ii) the Company had reduced its revenue guidance for Otezla by over a quarter of a billion dollars; and (iii) the FDA issued a stunning "Refusal to File" ("RTF") rejection of Celgene's initial New Drug Application ("NDA") for Ozanimod. Defendants' fraud directly caused billions of dollars in losses to Celgene investors, which Lead Plaintiff seeks to recover on behalf of the putative Class through this action.

A. GED-0301

12. From at least January 2015 forward, Defendants fraudulently misrepresented material facts concerning GED-0301. Until October 2017, Defendants trumpeted GED-0301 not only as an emerging blockbuster drug, but as a potentially "miraculous" treatment for Inflammatory Bowel Disease ("IBD"), including both CD and UC. These claims were false, however, as Defendants misrepresented: (i) the strength of the GED-0301 testing data; (ii) the

robustness of the primary GED-0301 study designs; and (iii) the likelihood of GED-0301's commercial success.

13. Defendants repeatedly cited to "striking" testing data for GED-0301 throughout the Class Period. In truth, however, Celgene ***never*** had data showing, with any defensible scientific analysis, that GED-0301 worked. In fact, Celgene scientists who reviewed the GED-0301 data from the time of Celgene's licensing of the drug in 2014 onward protested that the data was rife with defects and red flags. Furthermore, post-acquisition testing during the Class Period was designed to avoid negative results, and thus never corrected these deficiencies.

14. It was a deceptive game of "kick-the-can-down-the-road," in which Celgene spuriously touted inadequate GED-0301 data as adequate, while behind the scenes avoiding proper testing that would risk proving that the drug did not work. This bought Celgene both investor optimism and time—time in which to identify another drug that could potentially deliver post-Revlimid revenues.

15. Indeed, by early 2017, GED-0301 was treated internally at Celgene as if it had already been abandoned in favor of other options. As Celgene publicly promoted GED-0301's prospects as a treatment for CD, the Company internally pivoted away from the drug and intensified its efforts to groom Ozanimod as a potential treatment for the disease. In fact, by the summer of 2017, ***Celgene personnel openly discussed in Company meetings that GED-0301 would be "scrapped."*** Despite this, Defendants' blushing public statements about GED-0301 remained unchanged until late October 2017, when Celgene finally disclosed that GED-0301 was a failure, and was being written down to zero. This belated disclosure caused a $14.63 decline in Celgene's share price in a single day.

16. Defendants' Class Period misrepresentations concerning GED-0301 began on January 29, 2015, when Defendants touted the development-stage drug as a potential blockbuster in the lucrative IBD market based, in part, on "***striking clinical data***"[1] from a Phase II efficacy study.[2] In truth, however, the Phase II study did not provide meaningful evidence of efficacy, as it did not provide endoscopic confirmation of whether GED-0301 was having a positive effect on patients. That is, the study did not determine whether clinical responses potentially attributable to GED-0301 were accompanied by actual changes in the bodily tissue affected by CD, i.e., healing.

17. While some investment analysts noted the lack of endoscopic testing in the Phase II study, Defendants dismissed any suggestion that the data was somehow compromised. Defendants reemphasized the purported strength of the Phase II clinical data, and noted that additional testing would follow.

18. Celgene's false words of comfort had the intended effect on investment analysts. For example, in a report issued on March 18, 2015, after the publication of the Phase II results, SunTrust Robinson Humphrey noted the lack of endoscopic data, but concluded, "[n]et-net, we view these results as impressive . . . ." Through 2015 and beyond, Defendants continued to fraudulently tout the supposed strength of the GED-0301 Phase II data. For example, at a

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[1] Unless otherwise noted herein, all emphasis is added.

[2] New drugs undergo three phases of pre-approval studies. During Phase I studies, researchers test the new drug in 20 to 80 healthy volunteers for safety and adjust dosing amounts to find the highest dose of the new treatment that can be given safely without serious side effects. During Phase II studies, researchers administer the new drug to a group of patients with the disease or condition for which the drug is being developed ***to test if the drug works***, while continuing to collect safety information. Phase III studies ***presume that the drug has an effect***, and are designed to assess the safety and effectiveness of the new treatment in a larger population over a longer period of time (and therefore its value in clinical practice). Phase III studies are typically randomized controlled multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition being studied) and are aimed at providing a definitive assessment of how effective the drug is, in comparison with current "gold standard" treatment.

healthcare conference in January 2016, Defendant Hugin characterized the Phase II as "incredible."

19. Multiple former employees and independent scientists who consulted with Celgene about GED-0301 recounted how these and similar statements by Defendants were false and misleading because they were not supported by the GED-0301 data that Celgene actually possessed. Indeed, as early as 2014, when Celgene acquired the due diligence data on GED-0301, including the Phase II study data, members of Celgene's GED-0301 Advisory Board, comprised of independent scientists, warned Celgene, both before and after the Company's acquisition of the drug, of significant deficiencies in the supposed efficacy data. Likewise, former employees and scientists at Celgene observed and raised openly the fact that the existing data was flawed and indeterminate, and inconsistent with the Company's public statements.

20. For example, a member of the GED-0301 Advisory Board described the Phase II evidence touted by Celgene as "***too good to be true***." Similarly, a former director in the I&I franchise reported that "***everybody***" at the Company knew the GED-0301 acquisition was "a poor science decision" as the study data existing at the time of the acquisition did not support a claim of efficacy. According to a former member of the drug's development team, "***something didn't seem right***," and aspects of the data looked "***suspicious***." Given the dubious data, Defendants' Class Period claims that GED-0301 would be "transformational" were viewed from inside the GED-0301 development team as "baffling" and scientifically "irresponsible."

21. The lack of endoscopic data was only one problem. There were other known facts that contradicted Defendants' claim that GED-0301 worked as represented. For example, by approximately March 2016, Celgene's understanding of GED-0301's "mechanism of action" (or how the drug worked in the human body) was "changing with the wind." Indeed, Celgene's

internal experiments established that the drug did not work as the seller, Nogra, had represented during the pre-acquisition diligence. Further, according to former Celgene employees and consultants: (i) GED-0301's "dose response" data "didn't add up"; and (ii) "***nothing added up***" in the pre-acquisition mechanism data Celgene reviewed.

22. As part of Defendants' efforts to publicly dismiss any remaining concerns over the lack of endoscopic confirmation in the Phase II study, the Company promised investors that it was including an endoscopic endpoint as part of a Phase Ib study that was set to commence in April 2015. Unbeknownst to investors, however, the Phase Ib study, like the Phase II study, was defective and unreliable as Celgene chose not to include a placebo control arm. That design flaw prevented any apparent efficacy results from being attributed to GED-0301 versus some other cause. As such, data from the study could not provide a valid basis for determinations concerning the efficacy of GED-0301.

23. Defendants nevertheless praised the purported robustness of the Phase Ib study design and study results when they came out later in 2016. For example, at the Morgan Stanley Global Healthcare Conference on September 12, 2016, Defendant Smith stated that the Phase Ib study results were "***validating***" of the prior Phase II study results. Defendant Callegari echoed on an October 18, 2016 conference call that "***[t]he efficacy seen in this exploratory trial . . . validates previous GED trials and reinforces the potential of GED for patients with active Crohn's disease***."

24. Despite these glowing public representations, numerous former employees and consultants with direct knowledge of GED-0301's development recognized the deficiencies in the Phase Ib study design, and recounted that these deficiencies were widely acknowledged and discussed within Celgene during the Class Period. As a former Celgene employee put it, the

decision not to include a placebo arm in the study was "a corporate decision"—Celgene "chose not to install adequate controls."

25. Furthermore, given its flawed design, data from the Phase Ib study could not support Defendants' public claims of efficacy. For example, one former Celgene employee who reviewed the Phase Ib study results and heard Defendants' October 18, 2016 statements touting GED-0301's "efficacy" based on the study, recalled that the statements "***sounded like a complete fabrication***" and "didn't make any sense."

26. As with the Phase II study's lack of endoscopic testing, certain investment analysts noted the Phase Ib study's lack of a placebo control arm and asked Defendants about the unorthodox study design. Defendants doubled-down and falsely assured them that the lack of a control arm did nothing to undermine Defendants' efficacy claims. The analysts again accepted Defendants' lulling statements. For example, in an October 18, 2016 report, analysts from RBC Capital Markets commented that the data "continue to point to a promising new oral therapy for Crohn's disease, which is a $5B market opportunity." In an April 27, 2017 report, analysts at BMO Capital Markets talked about "GED-0301's clean safety and promising efficacy profile."

27. Defendants continued to misrepresent the true state of affairs involving GED-0301 in and after the fourth quarter of 2016, assuring investors that GED-0301 remained on track for regulatory approval, when in fact, major concerns had arisen inside Celgene that GED-0301 would not even make it out of ongoing Phase III trials, due to a lack of effectiveness.

28. A former Celgene employee who participated regularly in internal quarterly review meetings of Celgene's Vice Presidents recounted that after September 2016, GED-0301 was hardly mentioned during the meetings, which was surprising because all pipeline drugs said to be advancing towards FDA approval, were discussed. Another former employee stated that, by

March or April of 2017, an internal push arose to promote Ozanimod as a potential therapy for CD. This was striking because Defendants had consistently touted GED-0301 as Celgene's CD treatment. "Frantic" efforts ensued within Celgene to show better results for Ozanimod in treating CD than those shown by GED-0301. In at least one instance, employees were directed to manipulate testing parameters to make Ozanimod look better than GED-0301 as a CD treatment.

29. Moreover, by no later than July 2017, it was openly discussed within Celgene, including by scientists with access to information concerning the Phase III trial, that ***GED-0301 would be*** "***scrapped***." The drug would not survive Phase III testing on the basis of futility. Simply put, GED-0301 didn't work. One former employee reported hearing this plainly material nonpublic information and deciding not to sell his Celgene stock out of caution. Another reported that the discontinuation of GED-0301 was discussed at an August 2017 meeting in which Celgene's most senior medical executives, including Defendant Callegari and Bob Diamond, participated.

30. Shockingly, Defendants continued to tout the purported "progress" of GED-0301 for months after its failure in Phase III had been acknowledged internally at Celgene. For example, Celgene presented slides reiterating its purported regulatory approval timeline for GED-0301 during at least three different healthcare conferences in September 2017. At one of those conferences, Defendant Alles expressly discussed Celgene's development plans for GED-0301, even though the decision to "scrap" the drug had been made months earlier.

31. Celgene delayed informing the market of the demise of GED-0301 until it could present good news, to try to drown out the bad. To that end, on October 16, 2017, Celgene issued a press release stating that Phase II studies of ***Ozanimod*** showed "meaningful clinical and endoscopic improvements in patients with . . . Crohn's disease."

32. Three days later, on October 19, 2017, Defendants issued a disclosure that corrected the months of prior misstatements about GED-0301. Celgene finally admitted that GED-0301 had exhibited futility—i.e., there was no evidence that it worked—and the Phase III trial was discontinued. As a result, Celgene disclosed that it would recognize a $1.6 billion impairment of the failed GED-0301 asset for a pre-tax charge to earnings of up to a half a billion dollars. In direct response to this news, Celgene's common stock price ***fell $14.63 per share, or nearly 11%***, in one day. A report from *Evaluate* observed, "with the company losing around $10bn of its value this morning, shareholders obviously had higher hopes for mongersen [GED-0301]."

B. Otezla

33. On January 12, 2015, the beginning of the Class Period, Celgene publicly unveiled a five year strategic growth plan. Celgene claimed that its I&I franchise would grow to deliver $3 billion in net sales by 2020—and that Otezla would lead the way. Specifically, Celgene stated that Otezla, which launched in 2014, would bring in $1.5 billion to $2 billion in net sales ***by 2017***. Defendant Hugin stated that the "progress achieved . . . with Otezla . . . gives us great confidence that we are on track to really again meet or exceed the 2017 guidance." Investment analysts cheered this representation of Otezla's strength, with SunTrust Robinson Humphrey writing that it "***should spur investor excitement***."

34. In multiple statements over the next year and a half, Defendants repeated the refrain that Otezla would achieve $1.5 billion to $2 billion in revenues by 2017, signaling to the market that the conditions necessary to hit those numbers—sustained and increasing market acceptance and sales growth—were firmly in place. Those statements were materially false and misleading when made. In reality, after the initial post-release excitement in 2014, Defendants knew that Otezla sales growth was flat, and numerous factors barred the way to further market penetration for the drug.

35. For starters, Otezla was trying to take market share away from well-established, proven psoriasis and PA drugs, which doctors knew and trusted, and also faced competition from other new entrants into the space. More fundamentally, Otezla did not work as well as the other psoriasis and PA treatments, and Defendants knew it. Reports from the field did not support competitive efficacy levels. Otezla also worked more slowly, and on a narrower range of indications, than its competitors, further limiting its potential patient population. Furthermore, while Celgene promoted the fact that Otezla was an easy-to-take pill, as opposed to the inconvenient injections of its competitors, multiple former Celgene employees confirmed that its inferior efficacy overshadowed this convenience, contributing to lower prescription rates.

36. In addition, insurers and Pharmacy Benefits Managers ("PBMs"), who greatly influence whether and when treatments are covered by insurance plans, posed another major obstacle to the growth of Otezla sales. In 2015, these entities largely refused to cover Otezla as a first-line treatment. Instead, they imposed so-called "step-edits" – requirements that patients first try less expensive treatments before being covered for Otezla.

37. To get the step-edits removed and attempt to gain market share, Celgene decided to "pay to play" and offered steep discounts and rebates to insurers for Otezla. The discounts also drove down the price that Celgene could obtain from Medicaid. The discounts, however, did not buy Celgene enough market access to offset the lower revenue generated from the discounted Otezla sales.

38. Numerous former Celgene employees reported that throughout the Class Period, these and other fundamental barriers were recognized within the Company as blocking Otezla from selling sufficiently to achieve the 2017 sales guidance, which Defendants repeatedly and unwaveringly affirmed to the public without any reasonable basis.

39. The dismal Otezla growth trends from 2015 and 2016 were recognized and discussed at the highest levels of Celgene's I&I franchise, as was the fact that ***the publicly-issued 2017 net sales guidance for Otezla could not be met***. Indeed, former high-ranking Celgene employees specifically recounted that at multiple meetings of Celgene's I&I Executive Committee ("IIEC"), of which Defendants Curran and Smith were members, in the third and fourth quarters of 2016, senior market access executives presented Otezla data and warned expressly that the 2017 net sales guidance for Otezla was not attainable.

40. By the fourth quarter of 2016, high-ranking Celgene employees, including Robert Tessarolo, the Senior Vice President of I&I, U.S., explicitly urged Curran, Smith, and the other members of the IIEC to lower the guidance. Despite the fact that, according to a senior executive in the U.S. Market Access group, "***everyone knew that the actual stated forecast was not reasonable***" and could not be met, the IIEC insisted that the public guidance would not be changed. Indeed, this executive recounts that Defendants Smith and Curran "told" the forecasting team to ***"change" the numbers***—i.e., Celgene's internal forecasts—to make Otezla's sales growth appear better than it actually was. Moreover, Defendants continued to publicly reaffirm the guidance through the end of 2016, without any reasonable basis.

41. In a public filing in January 2017, Celgene again assured investors that it was on track to meet the 2017 guidance and represented that it expected Otezla to achieve approximately 57% year-over-year sales growth to meet that guidance. Former Celgene personnel recount, however, that by early 2017, it was again recognized and openly discussed by senior market access employees within the Company that there was no way 57% growth in Otezla sales was attainable in 2017.

42. Moreover, the IIEC was once again warned, in at least one meeting in early 2017, that the Otezla net sales guidance remained too high, was unattainable, and needed to be lowered. In response, Defendant Smith cut off the presentation, saying he had heard enough.

43. After Defendants continued to falsely affirm the 2017 Otezla net sales guidance throughout the second and third quarters of 2017, on October 26, 2017, Celgene abruptly reversed course and admitted publicly that Otezla would not hit the net sales guidance the Company had long affirmed, and cut its Otezla guidance by a ***quarter of a billion dollars***. This disclosure blindsided investment analysts, and the market reeled in response to the news, with the price of Celgene's common stock ***falling $19.57***, or more than ***16% per share***, on October 26, 2017 alone.

C. Ozanimod

44. Defendants also fraudulently misrepresented the true facts about Ozanimod, when, starting in January 2017, they represented that this development-stage MS and UC drug was sailing towards regulatory approval (and subsequent product launch) in late 2017, based on successful, ongoing Phase III clinical testing.

45. In reality, in late 2016, Celgene had received results from Ozanimod tests (which Celgene had long deferred performing) that identified critical issues in areas known to be of high FDA concern. These test results were a huge setback for Ozanimod. They raised basic questions about how the drug worked in humans that would require many months, and even years, of additional testing to answer. The results virtually guaranteed that the FDA would not accept, much less approve, an Ozanimod NDA in 2017 as the Company had represented to investors. In a private meeting, the FDA told Celgene that further testing was required with the Ozanimod NDA. Yet Celgene said nothing to the market and, instead, pushed forward with the doomed Ozanimod NDA in late 2017, without the additional test results. The FDA promptly rejected the NDA, revealing Defendants' fraud to a stunned marketplace.

46. Celgene acquired Ozanimod in July 2015, when it bought Receptos, the company that first developed the drug. Strong results from advanced clinical studies made Ozanimod the "crown jewel" of the $7.2 billion acquisition, and Celgene immediately projected FDA approval and launch by 2018, and potential Ozanimod sales of up to $6 billion per year. Post-acquisition, Celgene took complete control of Receptos, installing Defendant Philippe Martin (Celgene's Vice President of Leadership & Project Management – Immunology) as *de facto* CEO.

47. If Ozanimod won FDA approval, it would compete directly with the established MS drug, Gilenya. Just three months after Celgene bought Ozanimod, however, a major patent ruling against Gilenya fundamentally changed the market outlook. In October 2015, Gilenya lost a challenge to would-be generics. Cheap, generic versions of Gilenya would thus hit the market by 2019. This ramped up the pressure on Celgene to establish Ozanimod's market share well before 2019, when competition from Gilenya generics would kick in.

48. In 2015, Celgene repeatedly told the market that Phase III trials for Ozanimod were well underway, and that the drug was on track for submission for FDA approval (for MS indications) by 2017, and a projected launch by 2018. Analysts cheered Ozanimod's progress toward launch, with RBC Capital Markets analysts, for example, reporting that Ozanimod was "ahead in timing," as of November 2015. The Gilenya generics ruling left little margin for error.

49. However, through 2015 and much of 2016, Celgene's Ozanimod development portfolio was missing a crucial component. Namely, Celgene lacked complete and adequate testing of Ozanimod's metabolites. Metabolites are essentially the chemical byproducts of the body breaking down a drug. They can be inactive or active. Active metabolites produce their own effects on the body and can impact the functioning of drugs. New Drug Applications must address drug metabolism, and in guidance dating back to at least 2008, the FDA has made clear that testing

and understanding the properties of active metabolites associated with a drug is a priority that should be undertaken "as early as possible" in drug development. The FDA warns that a failure to ascertain metabolite effects can "cause development and marketing delays." Seminal drug development literature also urges that the importance of metabolite testing "cannot be overemphasized," and that it should be done "at an early stage of clinical development, such that issues of disproportionate human metabolites may be addressed ***prior to the initiation of large-scale clinical trials***."

50. Nevertheless, Celgene had pushed forward with large scale Phase III clinical trials of Ozanimod without the requisite metabolite testing. The Company had put off performing (among other tests) the critical test to conclusively identify all active metabolites and begin to study how these metabolites affected the body—the "human radiolabeled mass balance study," which is "generally accepted" in the field as the "gold standard." Working, in effect, out of order, Celgene sought to backfill clinical pharmacology testing of Ozanimod (including metabolite testing) only ***after*** it had publicized promising results from the efficacy phases of the drug's development.

51. Celgene did not begin the necessary "mass balance" testing for Ozanimod metabolites until October 2016—more than a year after Celgene acquired Ozanimod. Unbeknownst to investors, this testing detected the disproportionate presence of a highly active metabolite, named CC112273 by Celgene (the "Metabolite"). Under FDA guidance, various forms of significant, additional testing on the Metabolite were required before submitting the Ozanimod NDA. Those tests, however, would take time.

52. These late metabolite test results, obtained in November 2016, sent shockwaves through Celgene. Defendant Martin and other Celgene senior management knew about the results

and regularly received updates on the issue. Former employees with roles in the Ozanimod development process immediately recognized the need for additional testing on the Metabolite before an Ozanimod NDA could be filed with the FDA. These former employees noted that filing the NDA without the testing would cause the FDA to issue an RTF letter—which is a rejection of the NDA as facially deficient—a fact that was conveyed to their direct management. One former clinical pharmacologist who had first-hand knowledge of the discovery of the Metabolite stated that ***the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file, and he thought other teams felt that way too from speaking with them***. A second former employee also recounted that the need for additional testing was raised in a meeting involving Celgene senior leaders, including Defendants Tran and Martin, in early 2017. However, Martin abruptly shut down the discussion.

53. Notwithstanding the discovery of the Metabolite in November 2016 and the need to conduct protracted additional ***Phase I*** testing, Defendants knowingly misrepresented that the NDA was on track to be submitted by the end of 2017 pending only the results of ongoing ***Phase III*** testing, and that Ozanimod remained on track for FDA approval in 2018. Specifically, Defendants told the market that Ozanimod was advancing through Phase III testing, and that, "contingent on that, we will file an NDA for Ozanimod in multiple sclerosis by the end of the year." And when the last Phase III trial was ultimately completed in the spring of 2017, Defendants touted the results, without ever mentioning the need to go back and perform basic Phase I testing on the Metabolite. In essence, Defendants told investors that Ozanimod was on the two-yard line for NDA submission when, ***in fact***, given the need to conduct the additional testing, it was back at the fifty-yard line.

54. Analysts relied upon on Defendants' misrepresentations. For example, in a January 2017 report, J.P. Morgan analysts wrote that an Ozanimod "NDA submission" by year-end 2017 was a "Key 2017 catalyst" for Celgene.

55. Former Celgene employees also recounted that Celgene met with the FDA in November 2017 to discuss the Ozanimod NDA and ***the FDA explicitly informed Celgene that the Metabolite test results must be included in any Ozanimod NDA***. Despite this directive from the FDA, Defendants charged ahead and filed the deficient Ozanimod NDA in December 2017. This was a reckless gamble that was also financially motivated. Former Celgene employees report that Defendant Martin and other executives received lucrative bonuses upon mere submission of the NDA to the FDA—and that they "***just wanted to get the NDA out the door***." Furthermore, as noted above, Celgene was desperate to capture market share from Gilenya before it lost patent exclusivity in 2019—and delaying submission of the NDA to complete protracted testing of the Metabolite would prevent Ozanimod's launch until after the market was saturated with cheaper generic alternatives.

56. On February 27, 2018, Celgene shocked the market when it disclosed that it had received an RTF rejection of its Ozanimod NDA application from the FDA—just as Celgene employees had warned. Celgene disclosed that, "[u]pon its preliminary review, the FDA determined that the . . . pharmacology sections of the NDA were insufficient to permit a complete review." The FDA issues an RTF only where an NDA contains glaring, facial deficiencies, including "***scientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety, purity or potency***." Notably, RTFs are exceedingly rare—industry observers estimate that RTFs have been issued just forty-five times in the past ***sixteen years*** and almost never to well-established pharmaceutical companies like Celgene.

57. Celgene's receipt of the RTF was a public debacle. Investment analysts decried Celgene's "self-inflicted wounds" and lashed the Company with criticism. When the dust settled on the February 27, 2018 disclosure, it had driven Celgene's common stock price down by $8.66 per share in a single day.

58. In late April 2018, Celgene disclosed additional information about the Metabolite. Based on this presentation, analysts from Morgan Stanley reported that completion of the required metabolite testing would delay the refiling of the Ozanimod NDA by ***up to three years***, or until 2021. In direct response to this final disclosure, which concludes the alleged Class Period, Celgene's common stock price fell an additional $4.08 on heavy trading.

II. JURISDICTION AND VENUE

59. The claims asserted herein arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78n(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

60. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and under 28 U.S.C. § 1331, because this is a civil action arising under the laws of the United States.

61. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b), because Defendant Celgene conducts business in this District and also maintains its administrative headquarters in this District.

62. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications, and the facilities of the national securities exchange.

III. PARTIES

A. Lead Plaintiff

63. Lead Plaintiff AMF is one of the largest pension companies in Sweden. AMF manages the AMF family of mutual funds, as well as separate pension, private client, and fixed income portfolios. AMF was established in 1973 as the asset management branch of the Stockholm-based AMF insurance group, and manages approximately $65 billion in assets on behalf of more than four million pension customers. As set forth in the certification attached hereto as Exhibit A, AMF purchased or otherwise acquired Celgene common stock on the NASDAQ at artificially inflated prices during the Class Period and was damaged as a result of the conduct alleged herein. On September 26, 2018, this Court appointed AMF as Lead Plaintiff for this litigation.

B. Defendants

1. Celgene

64. Defendant Celgene, a Delaware corporation headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development, and commercialization of therapies for the treatment of cancer and inflammatory diseases. The Company operates two key divisions: (i) the I&I franchise, which focuses on developing drugs for treatment of inflammatory diseases, such as psoriasis, PA, UC, MS, and CD; and (ii) the "Hematology & Oncology" franchise, which focuses on developing treatments for blood diseases and cancer. Celgene's common stock trades on the NASDAQ Global Select Market under the ticker symbol "CELG." For fiscal year 2017, Celgene reported earnings of $2.539 billion with annual revenues of $13 billion.

65. On July 15, 2015, Celgene entered into an agreement and plan of merger with Receptos, a San Diego, California-based biopharmaceutical company, pursuant to which Celgene

acquired Receptos and its development-stage drug, Ozanimod, through a series of merger transactions for $7.2 billion. On August 27, 2015, Celgene closed its acquisition of Receptos, which resulted in Receptos becoming a wholly-owned subsidiary of Celgene.

2. The Individual Defendants

66. Defendant Mark J. Alles ("Alles") has served as Celgene's Chief Executive Officer ("CEO") since March 1, 2016 and Chairman of its Board of Directors since February 6, 2018. According to the Company's 2017 Annual Report, as CEO, Alles is the chief operating decision maker, and manages and allocates resources at the global corporate level. As discussed in the Company's April 30, 2018 Proxy Statement, at the beginning of each fiscal year, Alles establishes goals and objectives with each executive officer that are designed to advance his or her functional role, while promoting achievement of overall corporate performance goals. From August 2014 until February 2016, Alles served as Celgene's Executive Vice President and Chief Operating Officer ("COO"). Alles was elected to Celgene's Board of Directors in February 2016. Prior to this time, Alles served in other senior executive positions at Celgene for over fourteen years.

67. Defendant Robert J. Hugin ("Hugin") was Executive Chairman of Celgene's Board of Directors from March 1, 2016 until his retirement on February 5, 2018. Prior to that time, from June 2011 until March 1, 2016, Hugin served as Chairman of Celgene's Board of Directors. Hugin also served as CEO from June 16, 2010 until March 1, 2016. According to the Company's 2015 Proxy Statement, as CEO, Hugin was responsible for creating, implementing, and integrating the strategic plans for both of Celgene's franchises.

68. Defendant Scott A. Smith ("Smith") served as Celgene's President and COO from April 1, 2017 until his departure from Celgene, on April 2, 2018. Prior to April 1, 2017, Smith was President of the I&I franchise. According to the Company's 2017 Proxy Statement, in this role, Smith was engaged in company-wide strategic planning and decision making aimed at

delivering on short and long-term financial goals and continuing to innovate, develop, and commercialize Celgene's products. Smith also oversaw the clinical development, global registration, and commercial sales of drugs within the I&I franchise.

69. Defendant Peter N. Kellogg ("Kellogg") currently serves as Celgene's Executive Vice President and Chief Corporate Strategy Officer. Kellogg previously served as Celgene's Chief Financial Officer ("CFO"), and Chief Accounting Officer from August 2014 until August 2018. Kellogg joined Celgene as Executive Vice President in July 2014.

70. Defendant Terrie Curran ("Curran") was promoted to President of Celgene's Global I&I franchise on April 1, 2017. From March 2016 through April 1, 2017, Curran served as Head of Worldwide Markets for Celgene's I&I franchise. From April 2013 to March 2016, Curran served as the U.S. Commercial Head of the I&I franchise. According to Celgene's Senior Management Team biographies, in this role, Curran built capabilities and recruited the teams that executed the U.S. launch of Otezla.

71. Defendant Jacqualyn A. Fouse ("Fouse") served as the Strategic Advisor to the Celgene Management Executive Committee beginning on April 1, 2017 and retired from Celgene effective June 30, 2017. Prior to assuming this role, from March 2016 through March 2017, Fouse served as the President and COO of Celgene. Fouse was also the President of the Hematology & Oncology franchise from August 2014 through February 2016, and was elected as a member of Celgene's Board of Directors effective February 11, 2016.

72. Defendant Philippe Martin ("Martin") has served as Celgene's Vice President of Leadership & Project Management - Immunology since January 2014. Martin also served as Celgene's Corporate Vice President from January 2017 to June 2018. From June 2016 to June 2018, Martin also served as Managing Director at Celgene-Receptos.

73. Defendant Nadim Ahmed ("Ahmed") was promoted to President of Celgene's Hematology & Oncology franchise on August 23, 2017. From March 2016 to August 23, 2017, Ahmed served as President of Worldwide Markets for Hematology & Oncology. From August 2014 until March 2016, Ahmed served as General Manager of the U.S. Hematology & Oncology franchise.

74. Defendant Jonathan Q. Tran ("Tran") has served as the Executive Director of Clinical Pharmacology at Receptos since its purchase by Celgene in July 2015.

75. Defendant Peter Callegari, M.D. ("Callegari") has served as Corporate Vice President of Global Medical Affairs for Celgene's I&I franchise since September 2013.

76. The Defendants referenced above in ¶¶ 66-75 are referred to herein as the "Individual Defendants."

C. Relevant Non-Parties

1. Former Employees, Consultants and Scientists[3]

77. FE 1 is an IBD and Clinical Trials expert who previously served as a consultant to Celgene, beginning prior to the Class Period. FE 1 holds an M.D. and is board certified in Gastroenterology and Internal Medicine. FE 1 is a professor of medicine and a medical director of a digestive health center at a leading university. FE 1 has published hundreds of medical articles and has overseen dozens of clinical trials. As a consultant, FE 1 advised Celgene on its acquisition of GED-0301, reviewed proposed protocols for the Phase II and Phase Ib clinical trials, and assisted in planning the Phase III GED-0301 study. These responsibilities included advising

[3] Former Employees, Consultants and Scientists ("FEs") will be identified herein by number (FE 1, FE 2, etc.). Regardless of gender, all FEs will be described in the masculine to protect their identities.

Celgene on the design of the GED-0301 Phase III clinical trial in CD, and providing input on which specific controls to use.

78. FE 2 worked in Clinical Research & Development in the Company's I&I franchise before the beginning of the Class Period to late 2016 in Summit, New Jersey. FE 2's responsibilities included long-term planning of both organizational and project-related activities, and assisting the Vice President of the I&I Clinical Research and Development department with the management of the department. Additionally, FE 2 participated in clinical development planning for I&I's compounds and managed departmental activities to ensure on-time delivery of the clinical component for regulatory submissions. FE 2 also served as a member of the GED-0301 developmental team and participated in writing a protocol for one of the GED-0301 studies. Prior to his work with GED-0301, FE 2 worked on over five NDAs for various drugs.

79. FE 3, a board certified physician in Internal Medicine, Gastroenterology, and Transplant Hematology, served as a Principal Investigator for Celgene's GED-0301 Phase Ib clinical trial. FE 3 is a professor of medicine at a major university and the Director of an IBD program at the university's hospital.

80. FE 4 worked in Translational Development, I&I at Celgene throughout the Class Period. In this role, he was responsible for the design, implementation, and analysis of pharmacodynamics and pharmacogenetics biomarker studies in Phase I and Phase II clinical trials. Additionally, FE 4 led efforts to develop compounds for inflammatory and immunological diseases. FE 4 was also a member of the research management team where he oversaw the research and development for Celgene's developmental drugs.

81. FE 5 was employed as a Director at Receptos from mid-2015 to mid-2017. While at Receptos, FE 5 oversaw and performed statistical analyses for the Ozanimod CD and UC

studies. In this role, FE 5 was a regular attendee at meetings related to Celgene's Ozanimod clinical trials, including meetings regarding the submission of Ozanimod for FDA approval as a treatment for Relapsing Multiple Sclerosis ("RMS"). FE 5 also reviewed the GED-0301 Phase Ib study results in connection with his work on Ozanimod. While at Receptos, FE 5 reported to Jeff Kopicko ("Kopicko"), the Executive Director of Biometrics. Kopicko reported to Defendant Martin, who in turn, reported to Defendant Smith.

82. FE 6 was a Regional Medical Liaison ("RML") for the Company's I&I franchise in the New England region from before the beginning of the Class Period to late 2017. In this role, FE 6 was part of the Market Access team, where he worked with Account Manager teams to identify scientific and medical support needs for accounts with marketed and pipeline products in the I&I franchise. FE 6 was also responsible for maintaining a working knowledge of all the I&I franchise's products so that he could educate the Account Managers on a product's clinical data.

83. FE 7 was a Senior National Account Manager at Celgene from 2013 to 2016. FE 7's work encompassed Market Access, in which he had 18 years of experience. FE 7 advised Celgene's senior executives on the pricing strategy and market access strategy for Otezla. These senior executives included Sal Grausso ("Grausso"), Executive Director of Market Access for I&I, Betty Jean Swartz ("Swartz"), Vice President of U.S. Market Access, Robert Tessarolo ("Tessarolo"), Senior Vice President of I&I, U.S., Gordon Willcox ("Willcox"), Vice President of Market Access, and Defendant Curran. In his role as Senior National Account Manager, FE 7 reported to Defendant Curran and Grausso, who in turn reported to Defendant Smith.

84. FE 8 was an I&I Sales Representative at Celgene from before the beginning of the Class Period to late 2017 in the Northeast Region and his focus was on selling Otezla.

85. FE 9 was a Dermatology Specialty Sales Territory Manager at Celgene from before the beginning of the Class Period to early 2017 in the Southwest Region and his focus was on selling Otezla. He was also involved in Celgene's launch of Otezla.

86. FE 10 worked as a Rheumatoid Sales Specialist for Celgene from early 2015 to late 2016. FE 10 was responsible for Otezla sales in the Northeast Region.

87. FE 11 was a Celgene District Sales Manager for the Northeast Region from before the beginning of the Class Period to late 2016. As District Sales Manager, he received weekly reports regarding Otezla sales volume and growth for the previous week, quarter, and half-year, and a year-over-year comparison. FE 11 had eleven Otezla sales representatives under his supervision—five rheumatoid representatives and six dermatology representatives.

88. FE 12 was a Sales Representative for Celgene from before the beginning of the Class Period to late 2017. FE 12 was responsible for Otezla sales in the Northeast Region.

89. FE 13 was a Regional Sales Manager at Celgene from before the beginning of the Class Period to early 2015. FE 13 was in charge of I&I sales for more than five states in the mid- and western U.S. FE 13 was responsible for the launch and sales of Otezla.

90. FE 14 was a Sales Representative at Celgene from before the Class Period to early 2017. FE 14 promoted Otezla to doctors in a large Northeast market, from the early days of Otezla's launch until he left Celgene. At least quarterly, FE 14 received a ranking report, which force ranked FE 14 against other Otezla sales personnel based on their volume of Otezla sales.

91. FE 15 was a senior member of the Pricing and Market Access group at Celgene from before the beginning of the Class Period to late 2015. In this role, FE 15 developed market access models for various drugs, including Otezla. These models were based on the drug's efficacy

compared to other medications already in the market space. FE 15 provided the models to Frank Zhang ("Zhang"), Celgene's Global Head of HEOR, who reported to Defendant Smith.

92. FE 16 was a high-ranking member of HEOR and Pricing for the U.K. and Ireland at Celgene throughout the Class Period. In this role, FE 16 was responsible for making reimbursement submissions to the National Institute for Health and Care Excellence ("NICE"), an organization in the U.K. that determines whether the government will reimburse a company for a new drug. FE 16 reported to the Head of Market Access and Corporate Affairs for the U.K. and Ireland, the Global Head of HEOR and Pricing for I&I in the U.S., who reported to Defendant Smith, and a high-ranking member of the Global Market Access group.

93. FE 17 was a senior executive in the U.S. Market Access group at Celgene from early 2016 to late 2017. In this role, FE 17 worked with the managed care team where he negotiated new contracts with health plans. FE 17 led the U.S. Market Access team responsible for optimal patient access, strategic development, and execution of Celgene's value proposition. FE 17 also prepared pricing recommendations for the IIEC, which included pricing recommendations for Otezla. FE 17 reported to Tessarolo. Tessarolo reported to Defendant Smith and Defendant Curran.

94. FE 18 was a senior executive in the U.S. Health Economics and Outcomes Research ("HEOR") group at Celgene from before the beginning of the Class Period to early 2018. FE 18 reported to Swartz.

95. FE 19 was a senior executive in U.S. Field HEOR from mid-2016 through the end of the Class Period. FE 19 worked in external Market Access to guide key decision makers with respect to patient access to specific drugs and services, efficacy, and safety. FE 19 reported up through the Executive Director of U.S. HEOR.

96. FE 20 was a senior executive in Clinical Development at Receptos from before the beginning of the Class Period to late 2016. FE 20 was responsible for conducting all the Phase II and Phase III studies for Ozanimod in MS and UC.

97. FE 21 was a Clinical Pharmacologist from late 2016 to early 2018 at Receptos and worked on the Phase I studies of Ozanimod. FE 21 contributed to the clinical pharmacology section of the Ozanimod NDA and had first-hand knowledge of the Metabolite starting at the time of its discovery. Following this discovery, FE 21 worked on studies regarding the Metabolite, including tests to identify and characterize the Metabolite.

98. FE 22 was a contractor for Receptos and worked as a Project Manager for the Ozanimod UC/CD team in San Diego between late 2017 and early 2018. As a Project Manager, FE 22 oversaw the Ozanimod UC/CD drug development through various clinical stages. FE 22's job responsibilities also required him to be kept apprised of the status of the MS Ozanimod project.

IV. FACTUAL ALLEGATIONS

A. Celgene Needed to Offset the Looming Loss of Revlimid's Patent Protection

99. After the launch of Revlimid in 2006, the drug quickly became a blockbuster for Celgene. By 2010, Revlimid accounted for ***$2.469 billion*** in annual product sales—roughly ***70.4%*** of Celgene's total annual net product sales—and, by the end of 2014, just before the start of the Class Period in January 2015, Revlimid accounted for ***$4.980 billion*** in sales.

100. Celgene's over-reliance placed significant pressure on the Company to diversify its pipeline away from Revlimid. Indeed, analysts often cited the risk inherent in Celgene's financial success being tied so closely to a single drug. On May 5, 2017, for example, Benzinga reported that "investors have reason to be 'concerned' over the company's revenue concentration from

Revlimid. . . . During the recent quarter, sales of Revlimid accounted for 64 percent of total revenue and that proportion is only growing."

101. The Revlimid patent protects the drug from generic competition, but only until the year 2022. With Revlimid's patent expiration on the horizon, and given the frequent challenges to the validity of the patent by a number of generic drug manufacturers, Celgene was under intense pressure before and during the Class Period to create and maintain a drug pipeline (including through acquisitions) to offset the anticipated loss in revenues that would result from generic Revlimid competitors entering the market.

102. For example, on July 15, 2015, *The New York Times* recognized Celgene's need to replace the revenue it historically relied upon from Revlimid in an article discussing Celgene's recent acquisition of Receptos:

> Celgene agreed on Tuesday to pay $7.2 billion in cash to acquire Receptos, which is developing a potentially promising drug for autoimmune diseases. . . . Receptos, based in San Diego, is developing a drug called ozanimod that is now in late-stage clinical trials as a treatment for multiple sclerosis and ulcerative colitis, with an approval possible for multiple sclerosis as early as 2018 and for ulcerative colitis the year after. . . .
>
> [Celgene] has grown to be one of the most successful biotechnology companies, based largely on its blockbuster cancer drug, Revlimid. ***But Revlimid will eventually lose patent protection, and the company has been aggressively looking to expand its business and diversify***. . . .
>
> Celgene has earned a reputation as willing to pay top dollar either to acquire smaller companies or to license their drugs. . . . Last year it made an eye-popping initial payment of $710 million to an obscure company based in Dublin, Nogra Pharma, for rights to GED-0301, a drug being tested for Crohn's disease, which, like ulcerative colitis, is an inflammation of the bowel. . . .
>
> Celgene will be paying more than 16 times the $14 price at which Receptos went public two years ago. Celgene executives said that ozanimod could have peak annual sales of $4 billion to $6 billion and would complement GED-0301 and also Otezla, a pill Celgene already sells to treat psoriasis and psoriatic arthritis.

103. Celgene itself also told the market that it was diversifying its pipeline away from Revlimid and situating itself to offset the anticipated loss of Revlimid patent exclusivity and the accompanying reduction in revenues with the Company's I&I franchise. On May 31, 2017, for example, Celgene touted GED-0301 as one of its most promising treatments and important assets, and Alles, after referencing the Company's historical reliance on annual Revlimid revenues, told investors that GED-0301, Ozanimod and Otezla, would serve as a "replacement for it."

B. Defendants Misrepresent the Deficient Data Supporting the Efficacy of GED-0301 and Conceal the Drug's Failure

1. Celgene Acquires GED-0301 Based on Inadequate Study Data

104. Celgene made its first foray into the IBD market through its multi-billion dollar acquisition of the rights to development-stage drug GED-0301, also known as Mongersen.

105. IBD is a term used to describe two similar disorders that involve chronic inflammation of the digestive tract: CD and UC.[4] According to the Centers for Disease Control and Prevention, an estimated 3.1 million people in the U.S. were diagnosed either with CD or UC in 2015.

106. In addition to anti-inflammatory drugs, the primary treatments for both CD and UC are immunosuppressive therapies, which inhibit patients' inflammatory response, thereby allowing for healing of the ulcers that accompany CD and UC. Two of the leading drugs—AbbVie's Humira (adalimumab), which has been available to treat PA since 2005, CD since 2007, psoriasis since 2008, and UC since 2012, and Johnson & Johnson's Remicade (infliximab), which has been available to treat CD since 1998, UC and PA since 2005, and psoriasis since 2006—are so-called

[4] Crohn's Disease is characterized by relapsing inflammation leading to ulcers in the ileum and colon. Ulcerative Colitis is characterized by long-lasting ulcers in the innermost lining of the colon and rectum.

"biologic" therapies that work by neutralizing a protein produced by the immune system. Each generated billions of dollars per year in sales during the Class Period. However, biologic treatments carry well-known drawbacks. They are administered only through injection and carry an increased risk of infection, among other side effects. Moreover, while biologic therapies such as Humira and Remicade have proven effective in relieving some patients' symptoms, they are not effective in as many as one-third of IBD patients.

107. By contrast, Celgene heralded GED-0301 as an oral medication, with a different mechanism of action than the biologics, and which targeted the root cause of IBD while potentially avoiding the side effects associated with Remicade and Humira. Celgene claimed that GED-0301 offered a potential new path to break into the lucrative IBD market.

108. On April 24, 2014, Celgene announced that it had entered into a global, royalty-bearing license agreement with Nogra Pharma Limited, a private pharmaceutical company based in Dublin, Ireland, to develop and commercialize GED-0301 for the treatment of CD and UC. As part of the deal, Celgene paid $710 million upfront and committed to almost $2 billion in additional payments based on the achievement of certain development, regulatory and sales milestones, as well as tiered royalties on sales of licensed products. The $710 million Celgene paid was the largest upfront payment any drug company had ever made to acquire a single drug.

109. In announcing the deal, Celgene described GED-0301 as "an oral antisense DNA oligonucleotide targeting Smad7 mRNA for the treatment of moderate-to-severe Crohn's disease and other indications." Whereas biologic therapies suppress the body's immune response to control inflammation, antisense therapies such as GED-0301 are supposed to work by shutting down the genes that cause diseases by binding to messenger RNA (mRNA), which is genetic material involved in the body's production of proteins.

110. At the time of the acquisition, the only publicly available clinical data on GED-0301 came from a 15-subject Phase I trial.

111. Nevertheless, Celgene—which, alone, knew the full extent and nature of the information it had reviewed in pre-acquisition due diligence—described GED-0301 in an April 24, 2014 press release as a "late-stage product" and told investors that GED-0301 had already made its way through a placebo-controlled Phase II study, and that the data from this study had been submitted to a major medical journal and would be presented at an upcoming medical congress. The press release touted the non-public Phase II trial as a "double-blind, placebo-controlled, multicenter phase II trial of three doses of GED-0301 in 166 patients with active Crohn's disease." Based upon the data it possessed on GED-0301, Celgene stated that it intended to begin recruiting patients for a Phase III clinical trial by the end of 2014.

112. In the April 24, 2014 press release, Defendant Smith, then Celgene's Senior Vice President and Global Head of I&I, stated that "GED-0301 is a potentially transformative therapy that ***demonstrated striking clinical activity in a phase II trial for Crohn's disease***." Smith added that the acquisition "strengthens our expanding pipeline of novel therapies intended to address significant unmet medical need in immune-mediated diseases."

113. During a conference call with analysts and investors that same day, Defendants—including Hugin, Alles and Smith—repeated similar claims. For example, Smith described GED-0301 as a "breakthrough compound," and cited non-public data, to which only Defendants had access, that purportedly demonstrated "consistently high response rate and rate of remission after just 4 weeks" of treatment. Defendants also highlighted the purported "significant diligence" Celgene performed as part of the acquisition. Defendants' presentation included the following slide justifying the GED-0301 acquisition:

114. Defendants continued to promote the purported strength of the GED-0301 data in discussions with analysts. For example, during the April 24, 2014 conference call, a Deutsche Bank analyst asked "what gives [Celgene] comfort in the mechanism [of action] for [GED-0]301?" In response, Defendant Smith assured investors that "[r]elative to the other oral antisense drugs, which have gone to a variety of different places, I think you see here the coupling of the antisense technology with [a] delivery system that delivers the drug right on-site in the gut for absorption at the site at the pathophysiology of the disease. ***And then we see the clinical data, the Phase II data, you can see a very robust response*** . . . ."

115. Defendants' assurances regarding their confidence in the strength of the non-public data they reviewed as part of their due diligence had the intended effect. For example, Jacob Plieth, a well-known biopharma industry commentator, observed on April 25, 2014, that "Celgene must have seen something absolutely earth-shattering in the phase II data," adding that "[u]ntil yesterday the Crohn's disease project was virtually unknown – as was Nogra itself – and only early human data on it are available." Plieth continued: "Celgene has touted the still unpublished results

of a phase II study that it saw in due diligence as one reason for handing across what *EvaluatePharma* data compute to be the largest up-front payment in biopharma history."

2. Defendants Disregard the Lack of Evidence of GED-0301's Efficacy and Other Red Flags Upon Licensing the Drug

116. Defendants' assurances that GED-0301 had shown "robust response" and "striking activity" were not supported by the data Celgene had reviewed as part of its due diligence process, including data from the non-public Phase II clinical trial. As discussed below, former Celgene employees, consultants, and IBD experts independently confirmed that Defendants' claims that GED-0301 was a potentially transformative, or even effective, treatment for CD were not supported by the existing scientific data.

117. Reports of former Celgene employees confirm this. FE 1 was a medical expert hired by Celgene to advise the Company on its acquisition and development of GED-0301. FE 1 explained that Celgene established a GED-0301 "Advisory Board," which was comprised of the "key opinion leaders" in CD and UC, including himself and several other leading experts. FE 1 stated that the Advisory Board met at least twice a year while GED-0301 was in development. Some of these meetings occurred via teleconference, but FE 1 also recalled in-person meetings with Celgene senior executives, including Celgene's Senior Medical Director, Bob Diamond ("Diamond").

118. FE 1 stated that Celgene had inadequate data from the due diligence process to determine if GED-0301 was effective and that the Company was "absolutely" aware of the lack of evidence of GED-0301's efficacy at the time of the acquisition. FE 1 was therefore surprised when Celgene purchased GED-0301 for such a steep price. FE 1 stated that Celgene received warnings—from FE 1 and other members of the Advisory Board—that there was insufficient evidence that GED-0301 was an effective treatment for IBD, both at the time the Company

acquired the rights to the drug and thereafter. FE 1 cited several conference calls that took place prior to Celgene's acquisition of GED-0301, in which FE 1 and representatives from Celgene participated. During these calls, FE 1 cautioned Celgene that the data reviewed in due diligence had major shortcomings, including, notably, the lack of endoscopic evidence[5] or bio-markers in the Phase II study to show that the drug actually works as a treatment for IBD and, thus, GED-0301 "***looks too good to be true***."

119. FE 1 explained that Celgene's claims that GED-0301 was an effective treatment for CD were based on the Phase II clinical results, which lacked endoscopic evidence of efficacy and instead relied on the Crohn's Disease Activity Index ("CDAI"), which measures the severity of symptoms as reported by study participants.[6] According to FE 1, Celgene knew that such clinical data alone, without complementary endoscopic evidence to confirm the existence of ulcers among study participants immediately prior to enrollment, and to document the remission of ulcers following treatment, was not sufficient to demonstrate "response" to GED-0301. Indeed, the scientific literature recognized that endoscopic evidence is ***necessary*** to properly assess the efficacy of a treatment for CD when compared to placebo.[7]

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[5] Endoscopy is a nonsurgical procedure used to examine a person's digestive tract. Practitioners who study CD utilize a variety of scoring systems to assess and describe the severity of CD as well as measure its remission, including CD Endoscopic Index of Severity ("CDEIS") and Simple Endoscopic Score for CD ("SES-CD"). Such endoscopic scores are also used by clinical trials to assess the efficacy of various treatment agents on inducing and maintaining mucosal healing, and are considered "the gold standard tool indicating the presence or absence of active bowel inflammation." *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4898086/.

[6] The CDAI is a research tool used in clinical trials to quantify the symptoms of patients with CD. The CDAI does not include any endoscopic assessment of disease.

[7] As explained by Laurent Peyrin–Biroulet, M.D., Ph.D. in a February 2014 editorial in *Clinical Gastroenterology and Hepatology*, a comprehensive review of placebo randomized controlled trials evaluating therapies for active CD, including the prevailing biologic treatments, infliximab and adalimumab, suggests that "***there is always a clinically relevant placebo effect [among CD study participants] when considering clinical response or remission as a primary end point***." In other words, as explained by FE 1, in order to demonstrate the efficacy of a

120. Moreover, FE 1 explained that Celgene knew there was an emphasis among regulators on endoscopic evidence as the primary measure of efficacy in clinical trials for CD treatments, and that regulatory bodies, including the FDA, had made clear that they would not accept purported proof of efficacy that did not include endoscopy. Indeed, as FE 1's colleague, William Sandborn, M.D., the Director, Inflammatory Bowel Disease Center and the Chief of the Division of Gastroenterology at the University of California, San Diego, wrote in a March 19, 2015 article in *Medpage Today*:

> CDAI-based endpoints[] are no longer acceptable to the FDA. The FDA is now requiring patients entering clinical trials in Crohn's disease to have ***objective evidence*** of active inflammation as demonstrated by a baseline colonoscopy and co-primary endpoints of patient-reported outcomes (currently stool frequency and abdominal pain) and improvement in centrally read endoscopic disease activity scores from baseline.

121. FE 2, who was part of the GED-0301 developmental team at Celgene, agreed with FE 1 that at the time Celgene licensed GED-0301, the FDA did not view the CDAI score as a valid endpoint in the absence of complementary endoscopic data. FE 2 stated that, based on internal discussions, Celgene knew that endoscopic evidence was necessary to demonstrate efficacy. FE 2 also believed that Celgene was specifically advised by the FDA of the need for endoscopic endpoints in order to support claims of efficacy.

122. FE 1 stated that without endoscopic evidence, GED-0301 was an "unproven drug," meaning that its efficacy as a treatment for GED-0301 had not been demonstrated. FE 1 stated that the Advisory Board agreed on the need for endoscopic evidence and the limitations of the Phase II study. FE 1 further stated that he communicated the need for endoscopy to Celgene prior

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treatment for CD, a study must assess endoscopic evidence of remission and not rely on clinical symptoms alone. *See* https://www.cghjournal.org/article/S1542-3565(13)01095-1/fulltext.

to the Company's acquisition of GED-0301 and, thus, Celgene was aware of the limitations of the Phase II study prior to acquiring the drug. Furthermore, FE 1 stated that after Celgene entered into the licensing agreement, he personally communicated with members of Celgene's senior management—including either Defendant Smith or Diamond—about the limitations of the Phase II data and that Celgene's senior management acknowledged these limitations. Nevertheless, Celgene decided to go forward with the high-risk deal and misrepresent the efficacy of GED-0301.

123. FE 1 was not the only industry expert to note the dubious and inconclusive nature of the GED-0301 data at the time Celgene entered into the licensing agreement. FE 3, an IBD expert who participated in Celgene's GED-0301 Phase Ib clinical trial, reviewed the available data concerning the drug—including the pre-clinical studies from animal models, small cell culture models, and the Phase II trial data—which Celgene provided to him prior to his participation in the Phase Ib study.

124. FE 3 described the remission rate reported in the Phase II study as "unbelievable" and explained that "if it looks too good to be true, you always have some reservations." In the case of the Phase II study, FE 3, like FE 1, noted that the study did not include endoscopic confirmation of disease as an inclusion criterion, meaning that participants in the study may not have even had active IBD at the time the study began. Moreover, FE 3 explained that, because the Phase II study did not include endoscopic reduction in disease as an endpoint, instead relying on the CDAI, there was no evidence that the *subjectively* reported reduction in symptoms among study participants was correlated with a *measurable* reduction in disease inside the body.

125. FE 3 explained that endoscopic confirmation was viewed as necessary because the CDAI was highly subjective. For example, FE 3 noted that a patient's mood could greatly impact the severity of reported symptoms, making clinical data reliant solely on the CDAI unreliable. FE

3 concluded that the absence of endoscopic data was a defect in the Phase II study that severely limited the significance of the results.

126. FE 4 stated that Celgene took a "big risk" when it acquired GED-0301. He recalled discussions with other scientists and investigators within Celgene, including Gerald Horan ("Horan")—one of FE 4's colleagues in the Translational Medicine department who performed pre-clinical research on GED-0301 following the acquisition—concerning the pre-acquisition GED-0301 data. FE 4 stated that the consensus was that "everybody knew the acquisition was a ***poor science decision***," in large part because the data that was used to justify it lacked endoscopic evidence of efficacy. FE 4 also recalled a discussion with a colleague at Janssen Pharmaceuticals—a subsidiary of Johnson & Johnson and the maker of Remicade—regarding Janssen's decision not to acquire GED-0301 based on the same data to Celgene reviewed. This colleague had performed due diligence on GED-0301 and agreed that the data was inadequate and did not support claims of efficacy, which was the basis for Janssen's decision not to acquire the drug.

127. FE 4 stated that despite the concerns regarding the data, Celgene decided to go forward with the acquisition as part of its effort to compete in the I&I space. Moreover, FE 4 understood, based on conversations with Celgene employees who worked on the rights acquisition of GED-0301, that Celgene was required to proceed with Phase III trials as part of its deal with Nogra. The decision to initiate a Phase III program for GED-0301 was not based on the scientific evidence Celgene had to support efficacy.

128. Similarly, FE 2, stated that "something didn't seem right" regarding GED-0301, and that people working on the GED-0301 project had concerns about the pre-acquisition data. FE 2 recalled "a lot of discussion" within Celgene among employees that Celgene had paid too much

for GED-0301, and that it had bought "a lemon." FE 2 stated that Celgene employees who were working on GED-0301 internally recognized that the pre-acquisition data was a "little suspicious," and that people within Celgene were not comfortable discussing their opinions regarding the drug.

129. FE 2 also confirmed that the Company's public praise of GED-0301 was unfounded. Consistent with FE 1 and FE 4, FE 2 explained that based upon the Phase II clinical trial data, he had no idea how anyone could make the claim that GED-0301 was "transformational." FE 2 said that such a claim was "baffling" to him and scientifically "irresponsible." In addition to the lack of endoscopic endpoints, which FE 2 agreed was a flaw in the Phase II data, FE 2 indicated that another limitation of the data was the fact that GED-0301 had an inconsistent dose response curve when assessed using the clinical CDAI data, explaining that at varying dose responses, GED-0301 either did not seem to work or appeared to work really well. FE 2 stated that GED-0301's dose response "didn't add up," and that "nothing added up" when it came to the pre-acquisition data.

130. Further, FE 2 stated that at the time of the acquisition, Celgene did not have extensive experience in GI diseases. FE 2 also explained how other companies with more experience in CD seemed to stay away from GED-0301, which FE 2 believed reinforced the questionable nature of the data for the drug.

131. In addition, Celgene ignored other red flags in the push to acquire the rights to GED-0301. For example, FE 2 recalled conversations regarding the fact that the lead investigator for the pre-acquisition data, who had developed GED-0301, Giovanni Monteleone ("Monteleone"), had a large personal financial interest in GED-0301. FE 2 explained that as its inventor, Monteleone was the one person in the world who had the most to gain from the sale of the drug and that as the lead researcher, he had the most control over the pre-acquisition data.

Indeed, Monteleone held a patent for the use of GED-0301's specific mechanism of action in CD, and thus: (i) stood to profit immensely if GED-0301 garnered the interest of a major pharmaceutical company like Celgene; and (ii) was incentivized to ensure that the pre-acquisition data did not suggest a lack of efficacy.

132. The fact that the Phase II data all came from a single country was an additional red flag. FE 2 explained that when data comes from only one country, the integrity of the data may be impacted. FE 2 recalled that in the past, there had been problems with data generated from within a single country in Europe. FE 2 also noted that the patients in that country may not be representative of patients in other countries, and in fact may be different in meaningful ways. As an example, FE 2 cited the fact that differences in diet and treatment protocols, which vary from country to country, could affect the integrity of data generated from within a single country, whereas collecting data from multiple countries lowers the chance that regional differences played a role in the outcome. FE 2 further explained that, in the case of the Phase II data, Celgene did not know if the Italian researchers working on the development of GED-0301 applied the same standards as would be applied at a research facility in the U.S.

133. Ignoring the deficiencies and inconclusiveness of the pre-acquisition data and the other red flags described above, Celgene committed to follow through with its high-risk agreement to license GED-0301.

3. Defendants Tout the GED-0301 Phase II Data and Promise Investors Endoscopic Evidence as Part of the Phase Ib Study

134. Despite the inadequacies of the pre-acquisition and Phase II data, Defendants repeatedly represented throughout the Class Period that such data supported a showing of efficacy that would be further established through a planned Phase Ib study and Phase III clinical trials.

135. Beginning on January 29, 2015, Smith touted the "***[s]triking Phase II data for GED-301***" and noted that these data would be published "in a major medical journal." Smith also noted that the Company had "received important regulatory feedback for our proposed GED-0301 clinical development plan," and that the GED-0301 clinical development program "will consist of 3 main components that will run in staggered parallel fashion. The first step is a registration enabling endoscopy study [i.e., the Phase Ib study], which is initiating currently."

136. During the call, analysts questioned the lack of information concerning the planned "endoscopy study," with one analyst stating that investors "don't really know much about the design" of the Phase Ib study. In response, Smith stated that "[t]he purpose of the endoscopic [Phase Ib] study is to match up clinical symptom resolution with positive histologic changes."[8] That is, the Phase Ib study purportedly would be designed to show both clinical remission and objective, endoscopic evidence of efficacy. Smith also promised to provide investors additional evidence of GED-0301's efficacy in short order, stating that "because of the timing of it, we have an interim analysis plan."

137. On March 18, 2015, the GED-0301 Phase II study results were published in the *New England Journal of Medicine* ("*NEJM*"). That same day, the Company issued a press release announcing the publication of the results, and stating that "[t]he newly published findings from this phase II study showed that a significantly greater proportion of patients with active Crohn's disease achieved the primary endpoint of clinical remission at both day 15 and day 28 with once daily GED-0301." The press release quoted Smith as stating: "GED-0301 offers a completely different mechanism of action that has the potential to transform the Crohn's treatment landscape.

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[8] Histology refers to the microscopic study of tissues.

We are encouraged by the phase II data and are committed to bringing innovative medicine to patients with Crohn's disease, starting with advancing the phase III trial for GED-0301."

138. While Defendants touted the GED-0301 Phase II data, some outside the Company raised questions regarding the absence of endoscopic evidence—the very same limitation that FE 1, FE 4, and FE 2 all recognized. For example, in an editorial in the same issue of the *NEJM*, Séveirne Vermeire, M.D., Ph.D., Department of Gastroenterology, University Hospitals, Leuven, Belgium, wrote that:

> [T]he inclusion criteria used by Monteleone and colleagues were based on the CDAI score and did not include more objective criteria for active disease. Endoscopic confirmation of active Crohn's disease was not an inclusion criterion, so it is unclear what proportion of patients underwent randomization without actually having mucosal lesions.

139. Dr. Vermeire also noted the fact that the Phase II study did not include endoscopic evidence that GED-0301 was effective as an endpoint, or assess biological evidence such as normalization of biomarkers that are indicative of active disease. "In short," Dr. Vermeire concluded that "there is a lack of congruence between clinical remission and biologic remission, an issue that will need to be addressed in future studies."

140. FE 1 stated that after the publication of the *NEJM* editorial, the GED-0301 Advisory Board discussed the limitations identified by Dr. Vermeire, including the lack of endoscopic confirmation of CD as an inclusion criterion and the absence of endoscopic evidence of remission as an endpoint. FE 1 stated that GED-0301's failure to reduce the level of C-reactive protein ("CRP"), which he explained was indicative of active CD, raised questions about whether the reported reduction in the CDAI scores for participants in the Phase II study was indicative of actual disease remission. Similarly, FE 3 agreed with Vermeire's conclusion that there was "a

lack of congruence" between the patient reported remission rates and the biological evidence of remission.

141. FE 1 stated that the Advisory Board agreed with the limitations identified by Dr. Vermeire. FE 1 stated that the views of the Advisory Board were communicated to Celgene, and that privately, ***Celgene acknowledged the limitations of the Phase II clinical trial data***.

142. Further, FE 2 recalled that in or around mid-2015 there were ongoing meetings among the GED-0301 development team, including with Keith Usiskin ("Usiskin"), the executive director in charge of the GI Clinical Research & Development Department and the clinical lead of the GED-0301 team, about the limitations of the GED-0301 Phase II study data. Usiskin reported to the Vice President of Clinical Research & Development, who in turn reported to Defendant Smith. These discussions were intended to inform the design and implementation of subsequent research regarding GED-0301 and FE 2 recalled that the lack of endoscopic evidence was one of the limitations discussed.

143. Publicly however, Defendants waved away any concerns over the lack of endoscopic evidence in the Phase II study, assuring investors that the data indicated a promising blockbuster drug, and that Celgene would provide such evidence through the Phase Ib study. For example, on April 30, 2015, during Celgene's first quarter 2015 conference call, Smith stated that "***[w]e are aggressively moving clinical development plans forward***" and that the "endoscopy study is underway." In response to an analyst question concerning the *NEJM* editorial, Smith stated that the editorial was "very positive and balanced. ***Unprecedented efficacy***, the opportunity to potentially change the face of treatment of Crohn's disease, and maybe the first steps in the cure and some very positive things [were addressed in the editorial]." Smith also assured investors that the Company's upcoming presentation at the annual Digestive Disease Week ("DDW") event

would answer any "questions that were raised" in the editorial, including "the relationship between dose and clinical response and remission."

144. While some analysts took note of the *NEJM* editorial "questions," they focused on Defendants' positive characterization of the Phase II data and promise to provide the missing endoscopic evidence through the forthcoming Phase Ib study. For example, in a March 18, 2015 report, SunTrust Robinson Humphrey stated that:

> Phase II results for CELG's GED-0301 in Crohn's disease were published in the *New England Journal of Medicine*. The accompanying editorial describes clinical data as "impressive" but nevertheless raises some questions on patient baselines and endpoint choice, mirroring investor concerns to date. ***We believe CELG is working to address these issues with a Phase I study (matching CDAI and endoscopy) ahead of the launch of two Phase III trials in mid-15***.

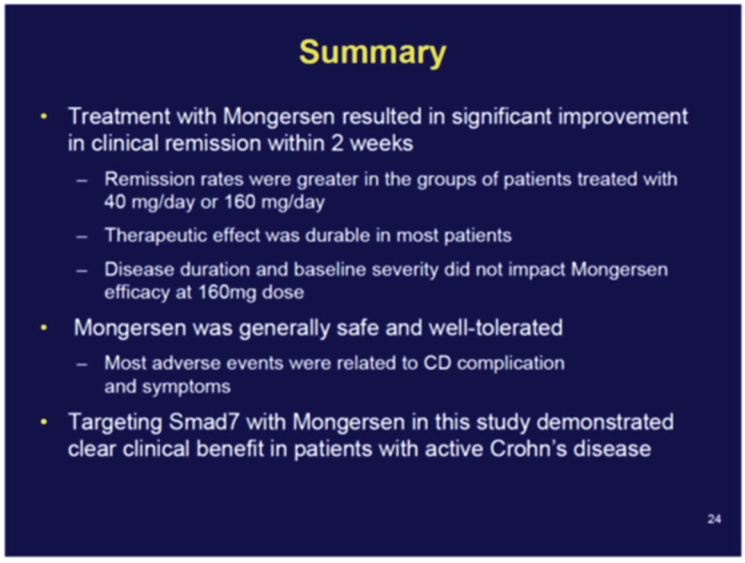
The report concluded that "***[n]et-net, we view these results as impressive and believe CELG is working to address the shortcomings of this dataset***."

145. In an April 30, 2015 report, RBC Capital Markets reported that "GED-0301 will have [a] deep dive meeting at DDW on May 17th" and that the Phase Ib study included "'endoscopy data' . . . that will be disclosed." SunTrust Robinson Humphrey also reported on this date that "[w]e anticipate DDW presentations of GED-0301 in Crohn's will address questions raised in the NEJM editorial discussing Phase II results." As reflected by these reports, Defendants' statements touting the purported quality of the results seen in Celgene's data falsely assured the market that GED-0301 was a viable and promising treatment.

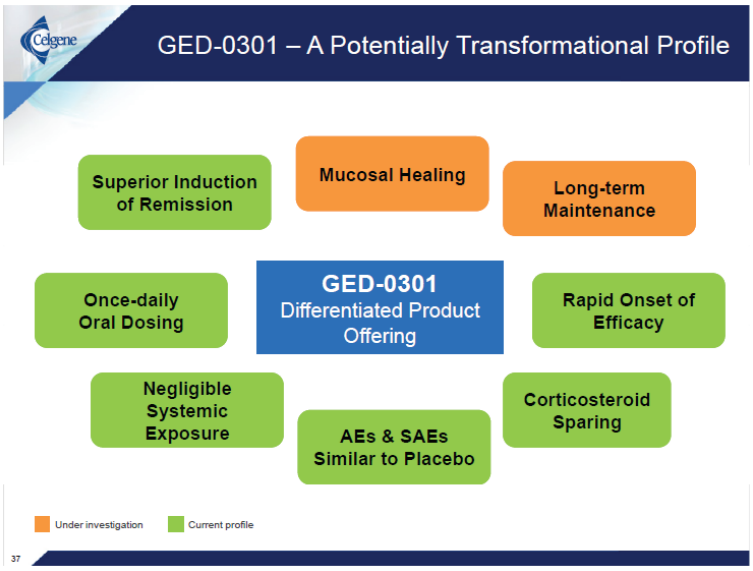
4. Defendants Continue to Praise the GED-0301 Data Throughout the Phase Ib Study

146. On April 8, 2015, approximately one month after the full Phase II study results were reported, Celgene began its Phase Ib study—also known as CD-001. On May 17, 2015, as part of Celgene's DDW Investor Event presentation, in which both Defendants Smith and Martin

participated, Celgene presented the following slide summarizing the supposed "improvement" and "clear clinical benefit" that had "resulted" from GED-0301 in Phase II:



147. Defendants' presentation also included a slide representing that in the Phase II study, "Severity of Disease or Level of Inflammation Did Not Impact the Efficacy of Mongersen 160mg Dose," effectively refuting the criticisms in the *NEJM* regarding the "lack of congruence between clinical remission and biologic remission." Indeed, Defendants represented unequivocally that, based on the Phase II data, GED-0301's efficacy had been established:



Thus, according to Defendants, the only aspects of GED-0301 which remained "Under Investigation" following the Phase II study, were its ability to cause "Mucosal Healing" and use in "Long-term Maintenance."

148. During this presentation, Defendants also provided an overview of the ongoing Phase Ib trial, highlighting the fact that the trial included an endoscopic index of CD severity as a primary endpoint. Moreover, Defendants provided an overview of the Phase III 52-week trial design. Defendants' presentation concluded by stating that "GED-0301 has the potential to transform the treatment of Crohn's disease."

149. Analysts again were reassured by the Company's positive statements. For example, in a May 18, 2015 report, SunTrust Robinson Humphrey reported that, with respect to the criticisms of the Phase II data, the "[n]ewly presented" data at DDW "suggest that GED-0301 is effective both in milder and more severe Crohn's disease patients, and that baseline CRP levels," or level of inflammation, "did not impact GED-0301 activity." The report also noted that the "key investor questions post Phase II data presentations revolved around the lack of endoscopic validation of CDAI improvement," but that Celgene "is addressing this question with the CD-001 [Phase Ib] study," which "is slated to correlate endoscopy assessments . . . with CDAI improvement." The report concluded that Celgene's "[a]d-hoc analyses of the Phase II study of GED-0301 in Crohn's disease suggest efficacy irrespective of baseline disease severity and CRP levels."

150. Similarly, following the Company's announced acquisition of Receptos (and Ozanimod, with its proposed UC indication) on July 14, 2015, Leerink Partners reported that Celgene management stated that "the acquisition of RCPT ***does not reflect a change in its confidence in GED-0301 which remains high***."

151. During the Company's July 23, 2015 conference call for the second quarter of 2015, Smith stated that Defendants expected "to see a series of blockbuster launches beginning in 2018 with Ozanimod in multiple sclerosis, ***quickly followed by GED-0301 in Crohn's disease*** and Ozanimod in UC." He added that "[t]hese launches have the potential to transform the treatment of these serious and difficult-to-treat diseases as well as setting the foundation for significant revenue growth in 2020 and beyond." Moreover, Smith characterized the GED-0301 development program as a "***late-stage development program***." Smith's statements were echoed by Hugin on January 11, 2016 at the J.P. Morgan Healthcare Conference when he touted "***the incredible Phase 2 data***."

152. Through these and other similar representations, Defendants maintained market expectations that there was a reasonable basis to believe GED-0301 was in fact a "***transform[ative]***" drug based on the then-existing data, despite the fact that multiple former Celgene employees, consultants, and IBD experts independently confirmed that the Phase II data did not support the efficacy of GED-0301 or the praise bestowed upon it by Defendants.

153. Moreover, former employees also revealed that at the same time Celgene was publicly praising GED-0301's efficacy, internally, additional doubts had arisen about the validity of the pre-acquisition data.

154. For example, FE 2 stated that that the mechanism of action for GED-0301 was obscure and unsettled while the drug was in development at Celgene, stating that Celgene's views on how the drug supposedly worked were "changing with the wind."[9] FE 2 specifically recalled a large interdepartmental meeting regarding GED-0301 that was held in or around March 2016.

[9] "Mechanism of action" refers to the biological process through which a drug produces its effect in a patient's body.

The multi-disciplinary project meeting, which included anyone involved with GED-0301 (including Manufacturing and Toxicology), lasted several days and acted as a general overall project review and update. The meeting was structured as an open-discussion about all the elements of the GED-0301 program where the participants could voice information and opinions. FE 2 stated that while executive management did not participate directly in the meeting, it was "impossible to imagine" that they were not briefed about it afterwards. As part of the meeting, FE 2 recalled a presentation by Celgene's Translational Medicine group that discussed GED-0301's mechanism of action. The presenter explained that Celgene had conducted experiments trying to elucidate GED-0301's mechanism of action and that these experiments suggested that GED-0301 did not work in the way Nogra represented at the time of the acquisition (*see supra* ¶ 109).

155. FE 2 recalled that in addition to uncertainty regarding how GED-0301 supposedly worked, the GED-0301 delivery mechanism was also obscure. FE 2 explained that the GED-0301 formulation, which was an oral therapy, was not systemically absorbed by the body, and so it had to dissolve at just the right spot in the gastrointestinal system to be effective. FE 2 analogized GED-0301 to a "***magic bullet***" that seemed "***too fantastic to be true***."

156. In addition to these undisclosed uncertainties and concerns about the pre-acquisition data, unbeknownst to investors, the Phase Ib study, like the Phase II study, was also internally recognized from inception as inadequate to support Defendants' claims of efficacy.

5. Defendants Internally Recognize that the Phase Ib Data Does Not Demonstrate Efficacy But Make Misleading, Contrary Public Statements

157. On September 12, 2016, Celgene announced interim topline data from its Phase Ib study, which purported to evaluate the effects of GED-0301 on both endoscopic and clinical outcomes in patients with active CD. In a press release issued by the Company that day, Smith was quoted as saying, "we are pleased that ***oral GED-0301 showed both endoscopic***

improvements and clinically meaningful responses and remission at an early timepoint in this study."

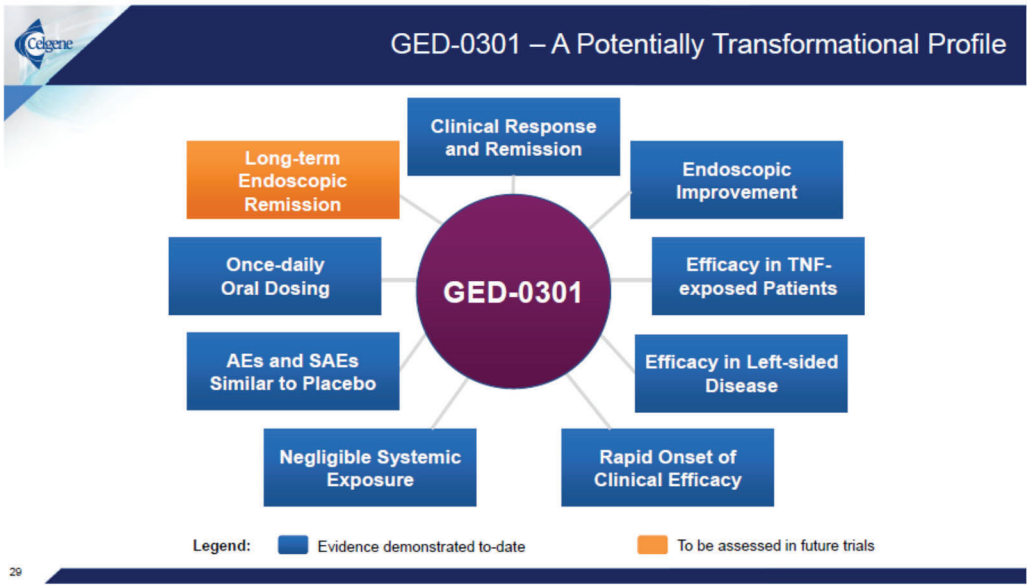
158. During the Company's presentation at the Morgan Stanley Global Healthcare Conference later that day, Smith stated that Defendants "were very, very encouraged by what we saw in the particular [Phase Ib] study" based on the fact that they "saw endoscopic improvements, clinical responses and clinical remissions across all three groups" of the study. Smith also noted that "what we found in the study" was that "the patients were starting to heal."

159. On October 16, 2016, Celgene reported the full interim results from the Phase Ib study. In the press release, Defendants again touted the fact that the Phase Ib study purportedly showed "[e]ndoscopic improvement [] across all treatment groups," stating that "[o]f the patients with evaluable endoscopies at week 12," or fifty-two participants out of the sixty-three person study, thirty-seven percent had an endoscopic response, defined as greater than a twenty-five percent reduction in SES-CD score (i.e., Simple Endoscopic Score for CD) "with no meaningful difference across treatment groups." Based on these results, the press release quoted Smith as reiterating that "oral GED-0301 showed both meaningful endoscopic improvement and clinical remission at an early time point in this study."

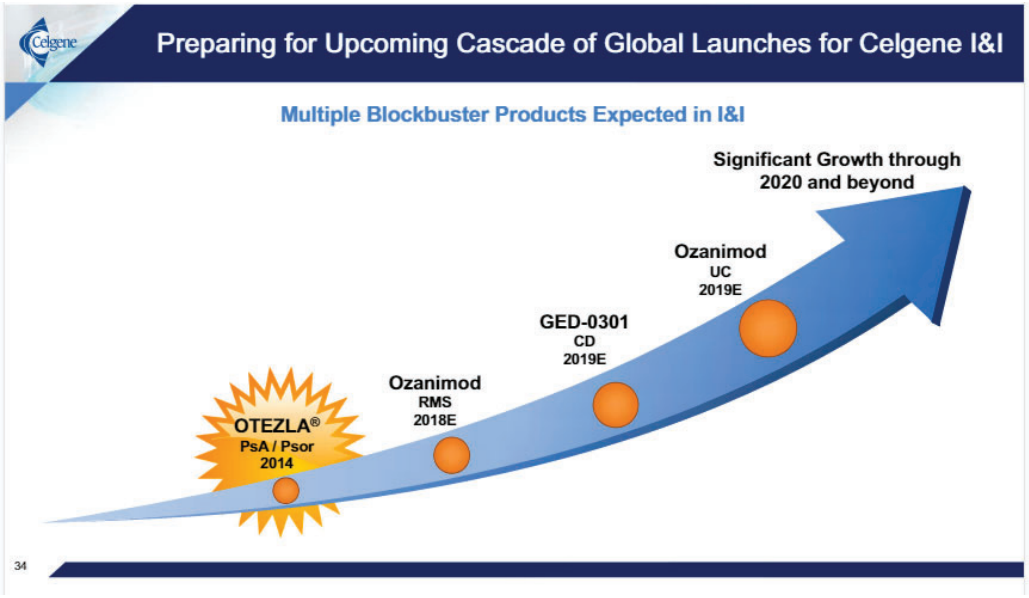
160. On October 18, 2016, Celgene held a conference call to discuss the Phase Ib study results, during which Celgene's Head of Global Medical Affairs, Defendant Callegari, stated that "***[t]he efficacy seen in this exploratory trial, in terms of clinical response, remission, and endoscopic improvement seen validates previous GED trials*** and reinforces the potential of GED for patients with active Crohn's disease."

161. Whereas Defendants had stated that GED-0301's ability to cause "mucosal healing" was still "under investigation" following the release of the Phase II study results,

Defendants now claimed that GED-0301's effectiveness in achieving endoscopic improvement was established through the Phase Ib results. Indeed, during the October 18, 2016 conference call, Defendants presented a slide in which they represented that the only open issue concerning GED-0301's efficacy was whether the drug caused "long-term endoscopic remission," which was being tested in the ongoing Phase III "Revolve" trial:



162. Also during the October 18, 2016 conference call, Smith stated that, with the interim Phase Ib results in hand, "***planning remains on track for GED submission to the FDA in 2018 and expected approval in 2019***." Defendants also presented the below slide, entitled "Preparing for Upcoming Cascade of Global Launches for Celgene I&I," which reinforced the previously stated timeline and referred to GED-0301, along with Ozanimod and Otezla, as "blockbuster products."



163. Smith further stated that "***GED-0301 represents our lead asset in Crohn's disease*** and an integral part of our industry-leading portfolio of oral therapies for the treatment of IBD."

164. In sharp contrast to the false and misleading impression created by Defendants' glowing public statements about the Phase Ib results, ***inside*** the Company, the deficiencies and dubiousness of the GED-0301 study data were recognized. For example, because the Phase Ib study had no placebo arm or acceptable alternative, it was impossible for Celgene to conclude that the observed reduction in SES-CD score was due to GED-0301 as opposed to a placebo effect. In other words, Celgene did not have a reasonable basis to tout GED-0301's efficacy following this study.

165. According to a position paper by the American College of Gastroenterology ("ACG"), "[t]reatment programs for digestive diseases should be evaluated by randomized clinical trials" and "[u]nder most circumstances, the best design for such trials requires placebo controls." The ACG states that diseases such as IBD "may have sufficiently high response rates to placebo therapy as to favor ***placebo-controlled study designs***." The ACG further notes that "when the study period is very short"—such as in Celgene's twelve week Phase Ib study—"[p]lacebo

treatment is also free of substantial risk." The ACG concluded that "[p]lacebo-controlled trials are therefore generally feasible and desirable methods for testing the safety and efficacy" of treatments for gastrointestinal diseases. Moreover, the ACG found that the only "[a]cceptable alternatives to placebo control" are "direct comparisons of new agents to standard therapy and addition of either new agents or placebo to a continuing baseline of standard therapy," neither of which occurred in the Phase Ib study.

166. As with the Phase II study data, former employees and consultants of Celgene advised and warned Defendants that the Phase Ib data did not support ***any*** conclusions about GED-0301's efficacy, let alone Defendants' emphatic public representations. Accordingly, the study data in Defendants' possession by September 12, 2016—including the Phase Ib and Phase II results—did not justify their claims of efficacy to the market.

167. For example, contrary to Defendants' representations that the Phase Ib study results "validate[d]" those of the Phase II study, FE 1 stated that Celgene's decision to conduct the Phase Ib study and include endoscopy as an inclusion criterion and an endpoint, reflected the Company's awareness of the limitations of the Phase II study that Defendants had publicly touted. FE 1, however, said that Celgene "chose not to install adequate controls" for the Phase Ib study. FE 1 also noted that from the period prior to the acquisition of GED-0301 until the time the Phase Ib study was conducted, the Advisory Board communicated the limitations of the data supporting GED-0301's efficacy to Celgene, and that the decision not to include a control arm was a "corporate decision." FE 1 stated that while he could not definitively state that Celgene's intent in designing the Phase Ib study without a control arm was to avoid a finding that GED-0301 was ineffective, the GED-0301 Phase Ib study was set up in such a way as to limit the chances of such a finding.

168. FE 1 recalled discussing the limitations of the Phase Ib study, and specifically the Phase Ib study's lack of a control arm, with other IBD experts who worked with Celgene, all of whom shared FE 1's concerns about the limitations of the study's results.

169. Specifically, FE 1 discussed this issue with Brian Feagan, M.D., the Director of Clinical Trials at the Robarts Research Center in London, who specializes in controlled trials evaluating new treatments for CD and UC, and who FE 1 explained had input into the GED-0301 Phase Ib study design. FE 1 also recalled discussing his concerns about the faulty design of the Phase Ib study with the following experts, each of whom is an authority in IBD: (i) Dr. Sandborn; (ii) Bruce Sands, M.D., Professor of Medicine, Gastroenterology, Icahn School of Medicine at Mount Sinai Hospital and Feinstein IBD Clinical Center; (iii) Jean Frederic Colombel, M.D., Professor of Medicine, Gastroenterology, Icahn School of Medicine at Mount Sinai Hospital and Feinstein IBD Clinical Center; and (iv) Geert D'Haens, M.D., Ph.D., the Head of the Academic Medical Centre, IBD Unit, University of Amsterdam, Netherlands. Notably, Dr. Sands and Dr. Colombel both participated in the Phase Ib study and therefore had first-hand knowledge of the study results. FE 1 stated that each of these experts shared his opinion that without a placebo arm, the significance of the Phase Ib study was limited. FE 1 further stated that his discussion with his colleagues confirmed his belief that the Phase Ib study was flawed and that Celgene chose not to install adequate controls when designing the Phase Ib study.

170. Given the limitations of both the Phase II and Phase Ib studies, FE 1 stated that there was a lack of evidence that GED-0301 was effective prior to the commencement of the Phase III study. FE 1 also stated that Celgene was consistently advised about the limited evidence of efficacy.

171. Similarly, FE 3 believed that Celgene decided conduct the Phase Ib study to give "credence" to the Phase II clinical results, which "***look[ed] too good to be true***." As to why Celgene chose not to include a placebo arm, FE 3 noted that having a placebo arm tends to mitigate the excitement for patients, meaning that patients will report a lesser reduction in symptoms when they know that they could be receiving a placebo. Whatever Celgene's reasoning for designing the study the way it did, FE 3 stated that without a placebo arm, the Company could not conclude on the basis of the Phase Ib results that GED-0301 was more effective than placebo, a threshold measure of efficacy.

172. With respect to the actual Phase Ib study results, FE 3 indicated that he entered four patients into the study, two of whom completed the twelve week study. FE 3 personally reviewed the endoscopic data for these patients and did not see any meaningful difference between the initial endoscopy and the ending endoscopy, and therefore concluded that there was ***no endoscopic response***. FE 3 recalled filling out forms that would have been submitted to Celgene which reported the fact that there was no endoscopic response observed at his testing site. While FE 3 did not have access to the aggregate data, he did recall a sense from his peers that they also did not see robust endoscopic results.

173. Former Celgene employees confirmed that Defendants secretly recognized the severe limitations of the Phase Ib data. FE 4 stated that following the release of the Phase Ib results, the evidence of GED-0301's efficacy became a "hot topic" inside the Company and was regularly discussed. Based on these discussions, FE 4 stated that it was known internally at Celgene that the lack of a control arm in the Phase Ib trial meant that the results did not support Celgene's claims regarding GED-0301's efficacy. FE 4 stated that in his experience at Celgene, ***the GED-0301 Phase Ib trial was the only trial that the Company conducted without a control***

group. FE 4 explained that with the exception of drugs that treat terminal illnesses like cancer, where it would be unethical to treat a patient with a placebo, a control group is always needed to evaluate the effectiveness of a treatment. Moreover, as FE 4 noted, conditions such as CD and UC often relapse and remit without any treatment, making it extremely hard to tell whether an IBD drug is effective if a study does not include a control group.

174. FE 4 characterized Defendants' statements, such as the one in Celgene's September 12, 2016 press release that "oral GED-0301 showed both endoscopic improvements and clinically meaningful responses and remission at an early timepoint in this study," as statements to promote the drug, rather than an accurate statement of what Celgene knew and believed about GED-0301's efficacy at the time.

175. Similarly, FE 5 stated that upon reviewing the results of the Phase Ib study, which were distributed by Oscar Velastegui, Senior Director, Program Management at Receptos, he was so surprised by the small sample size and lack of a control group that he approached Velastegui and Regulatory Affairs professional David Kao to discuss his concerns regarding the flawed study design. Specifically, FE 5 told Velastegui and Kao that the claimed efficacy was "***not real***" because the efficacy estimates could not be relied upon without a placebo control group. FE 5 (like FE 4) stated that CD can go into remission without treatment. The flawed study design made FE 5 "uncomfortable" with GED-0301 and, by extension, Defendants' public praise of the results.

176. FE 5 listened to Celgene's October 18, 2016 conference call while attending the United European Gastroenterology Week ("UEGW") 2016 conference in Austria. FE 5 recalled hearing Smith praise GED-0301 and the Phase Ib results, and refer to GED-0301 as a possible cure for CD, which, FE 5 said, "***pissed me off, because it wasn't***." Regarding Celgene's other representations about the evidence of GED-0301's efficacy, including Defendant Callegari's

statement during the October 18, 2016 conference call that "[t]he efficacy seen in [the Phase Ib trial], in terms of clinical response, remission, and endoscopic improvement seen validates previous GED trials and reinforces the potential of GED for patients with active Crohn's disease," FE 5 stated that, based on his review of the study data, ***"[i]t wasn't possible. It sounded like a complete fabrication. It didn't make any sense.***"

177. FE 5 raised his concerns regarding GED-0301 with Diamond, Celgene's Chief Medical Officer, Velastegui and others. However, FE 5 recalled that none of these individuals would engage substantively about GED-0301's lack of efficacy, and that several, including Velastegui, became angry with him. FE 5 stated that "I thought there was something wrong with them because it was obvious" that GED-0301 lacked evidence of efficacy. FE 5 further stated that "the hostility became pretty bad" and that he was shut down from challenging research results. This troubling response was a key reason why FE 5 ultimately left Celgene.

178. FE 2 similarly stated it was "jarring" to find out that there was no placebo arm in the Phase Ib study. FE 2 noted that even in a pediatric GED-0301 study with patients as young as two years old, it was known that a placebo was needed, meaning that study investigators would be performing invasive endoscopic testing on children who had received a placebo. FE 2 explained that such controls were necessary to demonstrate efficacy, and that the lack of a placebo meant that the Phase Ib investigators were performing invasive endoscopic testing even though the results would be inconclusive. FE 2 stated that ethically, this raised questions about the appropriateness of the Phase Ib study.

179. At the time Celgene announced the Phase Ib results, some analysts noted that the Phase Ib study lacked a control group, which raised questions about the ability to draw conclusions regarding the study. For example, Leerink Partners reported on September 12, 2016 that "there

was no control arm for the trial to demonstrate statistical significance or show if the efficacy signal was drug-induced." However, as with the concerns regarding the Phase II study results, Defendants assured investors that their efficacy claims were supported by the scientific data, concealing the doubts and criticisms about the lack of efficacy evidence discussed internally at Celgene.

180. For example, Smith defended Celgene's decision not to include a placebo arm during the September 12, 2016 Morgan Stanley Global Healthcare Conference:

> There is no placebo in this particular study, but I will ***say I would expect the placebo rate in this particular population, this study from an endoscopic perspective to be very, very low.*** This confirms significant extensive disease at baseline, ***you wouldn't expect the placebo patients to be getting better, you'd probably expect the majority of them getting worse over that 12-week period, it would be unlikely that you would get many responses. So you would expect a low placebo rate given what we've done here,*** so what you'd want is to be able to feel good that you could separate from placebo and show statistically significant effects in our large powered study than you would achieve that end point.
>
> And having looked at all, and our interpretation of data is ***we feel very comfortable around the size, the structure and the timing of the Phase III program given that we've just -- given the data that we've just seen.***

181. Celgene received similar questions from analysts during the Company's October 18, 2016 conference call. An analyst from Cowen and Company asked:

> As you guys know, you have been chided a little bit by the investment community for a lack of placebo control in this study and I guess I am wondering just what's the best defense here that there is a true drug effect as opposed to just a reversion to the mean in a patient population that's very severe at the baseline?

182. Smith responded: "If you take a look at a number of different things, [the Phase Ib study] was a little bit patient poor, but data rich, as we look at things, which was the reason for not having a placebo arm." Smith added that the "cumulative evidence really tells you that not only are you having a pretty significant effect from a response and remission standpoint, but you are also seeing everything go in the direction that you would like to see it go," citing the Phase Ib

study finding that the largest endoscopic response was associated with patients with most extensive disease as "a very positive sign of drug activity as well."

183. Defendants' public statements had the intended effect of mollifying analysts and investors. For example, RBC Capital Markets stated in an October 18, 2016 report that the Phase Ib data "continue to point to a promising new oral therapy for Crohn's disease which is a $5B market opportunity with high unmet need (only 1/3 of p[a]t[ient]s on biologics get a remission and only 1/5 of those can even keep it for a year) and no oral therapies approved." The report focused on the "[b]ig picture" that "positive efficacy so far for GED-0301 suggests even a modest/medium efficacy drug can be a potential ***$1B+ drug*** in our view."

6. Defendants Continue to Tout GED-0301 while Failing to Disclose the Dubious Viability of the Phase III Trial

184. As the Phase Ib study continued, Celgene's Phase III "Revolve" trial for GED-0301 began on December 8, 2015. The trial enrolled 701 participants across 538 study locations, and was designed to test GED-0301 compared to a placebo for a period of 52 weeks, using both clinical and endoscopic measures of remission and response. While each patient would participate for 52 weeks, because patients started at different times, the Phase III study was expected to take two years or more to be completed.

185. While investors eagerly awaited the Phase III "Revolve" study results, Defendants continued to tout the efficacy of GED-0301 based on the Phase Ib and Phase II data, as well as their confidence in its timeline for regulatory submission and approval. For example, during Celgene's fourth quarter 2016 conference call on January 26, 2017, Smith stated that "[t]his year we expect to fully enroll critical studies in our IBD program, including the large treat-through pivotal trial for GED-0301 [i.e., the Phase III "Revolve" study] in the treatment of Crohn's disease. We are very excited about the transformational potential of this novel oral treatment approach in

an area of very high unmet medical need." Similarly, during the Company's first quarter 2017 conference call on April 27, 2017, Smith assured investors that the Company was "***on track***" to launch GED-0301, stating that the GED-0301 Phase III registration program "has really accelerated over the last little while" and that "***[w]e remain on track with time lines there***."

186. Analysts echoed Defendants' confidence in GED-0301. An April 27, 2017 report by investment analysts at BMO Capital Markets stated that "[w]e believe GED-0301's clean safety and promising efficacy profile to date may position it for 1L [first-line] use and may enable Celgene to take a similar strategy to Otezla by entering the market place at a potentially lower price point to other competitors, but sequenced in earlier course of therapy and towards larger patient segments."

187. In contrast to Defendants' positive statements, significant concern persisted within Celgene that GED-0301 was ineffective and would not make it past the Phase III clinical trials. According to FE 4, these concerns were a continuation of the longstanding doubts about GED-0301's efficacy dating back to the time of its acquisition in 2014. In fact, FE 4 recalled that Celgene had effectively given up on GED-0301 after the Phase Ib study. For example, between the time that the Phase Ib data was released in September 2016 and the time that the Phase III trial was discontinued in October 2017, FE 4 did not recall GED-0301 even being ***mentioned during any of the internal quarterly review meetings*** with Celgene's Vice Presidents, in which the Company's pipeline drugs advancing to market were typically discussed. FE 4 stated that it was unusual for an actual, major development-stage drug not to be discussed at these meetings.

188. Further evidencing that Defendants had all but written off GED-0301 by this time, FE 5 stated that internally, by the spring of 2017, it was very clear that Celgene had recognized GED-0301's ineffectiveness. During a two day meeting in March or April 2017, FE 5 recalled

that at least one session focused on how Ozanimod needed to become a first line therapy for ***CD***, which was significant and unusual, given that GED-0301 was publicly represented to be Celgene's CD treatment, poised for FDA approval in 2019. FE 5 further stated that it would be strange for Celgene to have two drugs in development for the same indication. Moreover, FE 5 described how in meetings at this time, Defendant Martin, Kopicko, and Jean Louis Saillot ("Saillot"), Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos, were pushing the Ozanimod CD team to show better efficacy for CD than GED-0301. FE 5 stated it felt "frantic" like "they were digging" to produce better results with Ozanimod.

189. FE 5 also recounted that Kopicko, in particular, was very concerned about the efficacy of GED-0301, and that Kopicko's team was trying to obtain better evidence of CD efficacy for Ozanimod than GED-0301 had produced. As an example, FE 5 cited SES-CD as a metric on which Kopicko's team sought to show better results when treated with Ozanimod compared to GED-0301.

190. To accomplish this, Kopicko and others directed FE 5 to manipulate the Ozanimod Phase II CD testing protocol to achieve the desired result. At the Ozanimod Phase II CD team meetings in March or April 2017, which FE 5 regularly attended, FE 5 recalled Martin and Kopicko asking FE 5's team to widen certain testing parameters "to such a degree to make efficacy look better" in the Phase II Ozanimod CD testing. FE 5 stated that Kopicko ended up changing the testing, per Martin's request, in order to improve the apparent efficacy results for Ozanimod.

191. In addition, FE 5 stated that Martin and Kopicko directed Pharmaceutical Product Development, a third-party vendor who performed much of the statistical analysis on Ozanimod's CD efficacy, to assist in making Ozanimod appear more efficacious than it actually was.

According to FE 5, these "frantic" efforts to produce positive results in the Ozanimod CD clinical trial were reflective of Celgene's undisclosed concerns regarding the efficacy of GED-0301.

7. Defendants Determine that GED-0301 Phase III Trial Will be "Scrapped" Months Prior to the Public Announcement of Futility

192. By July 2017, Celgene employees openly discussed the fact that the Phase III CD trial would be cut short and that GED-0301 would be abandoned. For example, FE 4 stated that approximately four months prior to Celgene's October 2017 announcement of the futility determination and discontinuation, Horan, who was in a position to access the information regarding the ongoing Phase III GED-0301 trial, told FE 4 that the trial was going to be "***scrapped***." FE 4 recognized at the time that this was material, non-public information likely to negatively impact the Company's stock price. Thus, FE 4 decided not to sell any of his Celgene stock after learning this information. FE 4 noted that, like other investors in Celgene, he suffered financial losses when, four months later, Celgene announced that the Phase III GED-0301 trial was being discontinued for futility, and its stock price plummeted.

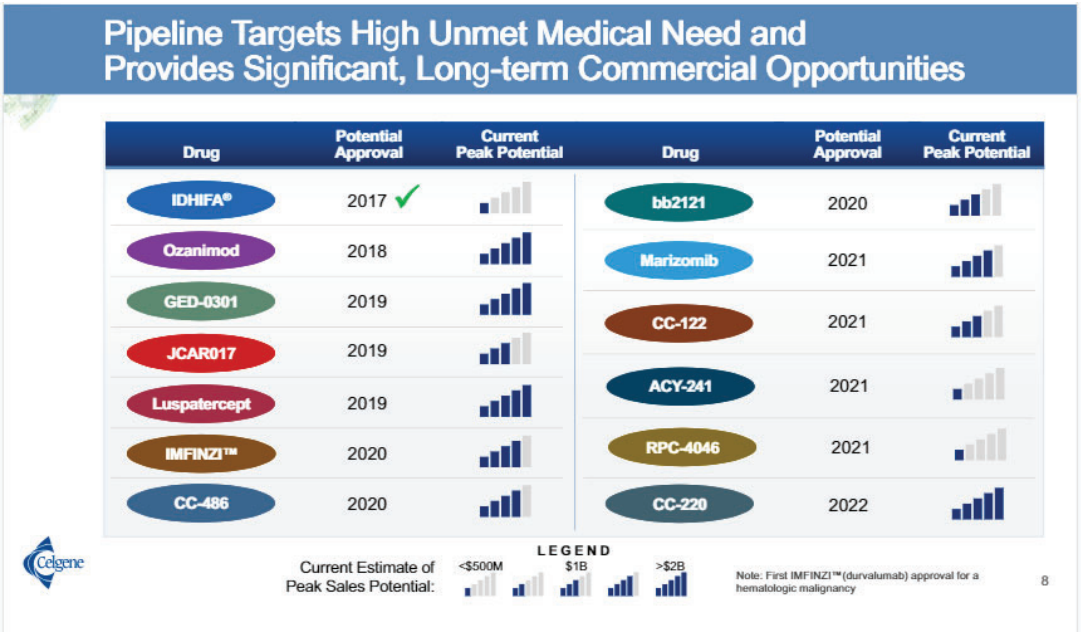
193. FE 4 explained how individuals at Celgene could have known the results of the Phase III trial while it was ongoing, stating that even though the clinical data would have been "blinded" (i.e., it was unknown which study participants received GED-0301 or placebo), people within the Company would have had access to pharmacological data that could be extrapolated to determine whether GED-0301 was having the desired effect. FE 4 stated that given Horan's role with respect to GED-0301, FE 4 believes that Horan would have had access to exactly this type of data.

194. FE 6, one of Celgene's RMLs for I&I, also was informed by a Celgene colleague in the summer of 2017 that the GED-0301 Phase III clinical trial would be discontinued. FE 6 explained that in August 2017, this colleague attended a meeting among Celgene's RMLs and

Medical Science Liaisons ("MSL") in Chicago. Both Defendant Callegari and Diamond were present at the meeting, ***during which participants discussed the fact that the GED-0301 Phase III trial would not be successful***.

195. Despite this knowledge, in and after the summer of 2017, Defendants repeatedly misrepresented GED-0301's efficacy and supposed progression toward ultimate regulatory approval and expected market launch. For example, during the Company's second quarter 2017 conference call on July 27, 2017, Defendant Curran stated that "***progress continues with GED-0301***" and that "***[w]e remain focused on progressing our next generation growth drivers, Ozanimod and GED-0301***, and look forward with anticipation to multiple data readouts in the next 12 to 24 months."

196. At the Baird Global Healthcare Conference on September 6, 2017, Defendants included the following illustration reiterating a potential 2019 FDA approval timeline for GED-0301, completely at odds with the internal recognition that the critical Phase III trial would be "scrapped":



197. Defendants also presented the identical slide at the Bank of America Merrill Lynch Healthcare Conference on September 14, 2017 and at the Cantor Fitzgerald 3rd Annual Healthcare Conference on September 26, 2017.

198. Similarly, at the Morgan Stanley Healthcare Conference on September 13, 2017, after being questioned regarding the business development plans for GED-0301, Alles responded: "***We still project GED-0301 data, in particular, in Crohn's disease in '18, with '19 being the regulatory year plus launch***."

199. Moreover, confirming FE 5's account that Defendants had pivoted to Ozanimod as a potential treatment for CD after it became clear that GED-0301 did not work, on October 16, 2017, just three days prior to Celgene's announcement of the termination of the Phase III GED-0301 trial, Defendants issued a press release touting the results of the Company's Phase II studies of Ozanimod for treatment of CD and UC. The press release stated that Ozanimod "demonstrated meaningful clinical and endoscopic improvements in patients with moderately to severely active Crohn's disease."

8. Celgene Finally Admits that GED-0301 is Not an Effective Treatment of CD and Terminates the Phase III Studies

200. On October 19, 2017, after the market closed, Celgene announced that it was discontinuing the GED-0301 Phase III "Revolve" trial (and the related "Sustain" extension trial) in accordance with an October 2017 recommendation of the Data Monitoring Committee ("DMC"), which assessed overall benefit/risk during an interim futility analysis.[10]

[10] A DMC is an independent committee established as part of large Phase III trials and which is typically comprised of clinicians with expertise in the relevant field being studied, and at least one biostatistician knowledgeable about statistical methods for clinical trials. DMCs are often given access to unblinded study data in order to assess the safety and futility of completing a Phase III trial.

201. In a Form 8-K filed on this date, Celgene announced that as a result of the decision to discontinue the Phase III GED-0301 clinical trials, the Company would recognize a ***$1.6 billion*** fourth quarter 2017 charge to earnings related to GED-0301, partially offset by a reduction in liabilities associated with its development, as well as wind-down costs associated with discontinuing the trials and certain development activities. The Company estimated the immediate net pre-tax charge to earnings to be in the range of $300 million to $500 million.

202. In response to this news, the price of Celgene common stock declined $14.63 per share, or nearly 11%, from a close of $135.96 per share on October 19, 2017, to a close of $121.33 per share on October 20, 2017.

203. News outlets directly associated the stock price decline with the negative news regarding GED-0301. For example, *Investor's Business Daily* reported that the Company's "stock fell late Thursday after the biotech discontinued a pair of trials and won't begin a third for a late-stage drug being investigated to treat Crohn's disease." Similarly, an article from *Evaluate* commented on October 20, 2017 that although "[b]ullish Celgene analysts would have investors believe that the failure of its late-stage Crohn's disease project mongersen just clears the way for an even more promising candidate, ozanimod . . . with the company losing around $10bn of its value this morning, shareholders [] obviously had higher hopes for mongersen."

204. The October 19, 2017 press release stated that Celgene was waiting to review the full dataset from the Phase II trial of GED-0301 in UC to determine next steps. However, analysts recognized that the announcement meant that GED-0301 was a failure. For example, Mizuho Securities USA analyst Salim Syed stated that "GED-301 for all practical purposes is ***dead***." Syed's prediction was correct, as Celgene has not issued any further statements regarding GED-0301's potential as a treatment for UC.

C. Defendants Fraudulently Reaffirm Otezla Sales Guidance That They Knew Was Unattainable

205. The second aspect of Defendants' three-pronged plan to replace the Company's revenue stream from Revlimid was Otezla—the most commercially advanced drug in Celgene's I&I franchise. Otezla, which the Company touted as one of its "primary commercial stage products," is an oral medication that is used to treat PA and psoriasis.[11] While many drugs used for the treatment of psoriasis and PA are biologics, Otezla is an oral medication. Celgene regularly promoted the convenience of Otezla to patients, emphasizing that Otezla is "not an injection, cream or biologic. It's a pill . . . ."

206. Otezla was approved by the FDA in March 2014 for the treatment of PA, and Celgene began recognizing revenue from the sales of Otezla during the second quarter of 2014. As early as January 13, 2014, months before the Otezla launch, Defendants primed the market that Otezla sales were poised to sky-rocket, representing that Otezla net product sales would reach $1.5 billion to $2 billion by 2017.

1. Celgene Issues 2017 Guidance for Otezla Without a Reasonable Basis

207. On January 12, 2015, Celgene issued a press release unveiling the Company's five-year strategic growth plan. According to this plan, Celgene maintained that Otezla net product sales would grow to between $1.5 billion and $2 billion in 2017 and its net product sales from the I&I franchise as a whole would exceed $3 billion by 2020. During a presentation at the J.P. Morgan Healthcare Conference that same day, Defendant Hugin highlighted the Company's 2017 Otezla sales guidance, claiming that "the progress achieved in the fourth quarter [of 2014] with

[11] Psoriatic arthritis is a type of arthritis that affects some people who have psoriasis—a chronic skin condition that speeds up the life cycle of skin cells, causing extra skin cells to build up on the surface of the skin in scales and red patches that are itchy and sometimes painful.

Otezla in our I&I franchise, gives us great confidence that we are on track to really again meet or exceed the 2017 guidance."

208. Analysts quickly seized on Celgene's reaffirmation of the 2017 Otezla and I&I guidance as well as Hugin's assurances that the Company would achieve these numbers. For example, SunTrust Robinson Humphrey wrote that "management's commentary that CELG is slated to 'meet or exceed 2017 guidance' . . . should spur investor excitement."

2. Celgene Internally Recognizes Multiple Barriers that Prevented Otezla From Achieving the 2017 Otezla Sales Guidance

209. Unbeknownst to investors, Defendants lacked a reasonable basis for their January 2015 statements reaffirming the Company's aggressive 2017 sales guidance for Otezla. In reality, after the 2014 launch, numerous barriers impeded Celgene from achieving those numbers, and Company sales representatives struggled and failed to grow their Otezla sales commensurate with the Company's projections.

210. According to FE 7, a Senior National Account Manager, as early as the March 2014 launch, Otezla's sales and revenue generating capabilities were severely impaired by several dynamics.

211. For example, FE 7 stated that, shortly after the drug's launch in 2014, Celgene offered excessive rebates and discounts to convince insurance companies to remove "step-edits"—the requirements put in place by insurers and PBMs that forced patients to try other, less expensive therapies before being permitted to use Otezla. Celgene's goal was to gain market share for Otezla by using the rebates and discounts to lower Otezla's effective. However, according to FE 7, the plan was doomed from inception.

212. As FE 7 explained, one consequence of the Company's steep rebates and discounts on Otezla was additional downward pressure on Otezla sales revenues due to the impact of these

rebates and discounts on Celgene's "best price calculation" for the drug. As FE 7 explained, rather than boosting net sales from Otezla by capturing market share through the large discounts and rebates, Celgene drove down the "best price" calculation, and was left selling the drug for what FE 7 illustratively described as one cent per pill—thus ensuring that the Company would never meet the 2017 Otezla net sales guidance.

213. In the pharmaceutical industry, a drug's "best price" refers to the price a drug manufacturer must offer to Medicaid. Specifically, the Medicaid "best price" policy requires drug manufacturers by statute to give Medicaid programs the lowest or "best" price offered to nearly all purchasers. Accordingly, because Celgene was repeatedly driving down the price of Otezla that it was offering to insurers and PBMs, it necessarily drove down the price it was required to provide to one if its largest payers, Medicaid.

214. The inherent flaw of this strategy was known to senior management, including Defendant Smith, who FE 7 stated had the final say with regard to Otezla and Market Access decisions. In fact, starting in 2014, FE 7 repeatedly warned Smith that the Company's pricing and discounting strategy for Otezla was fatally flawed and simply would not work to increase revenues. When Otezla launched, FE 7 informed Smith that he would be destroying the "best price" for the drug by offering large rebates and discounts, thereby setting Otezla up for consistently depressed net sales going forward. In response, Smith told FE 7 that Celgene would do "whatever it takes to get the business."

215. After the Otezla launch in 2014, FE 7 wrote multiple emails to Celgene's senior executive management, including Smith, documenting his concerns about the discounts and rebates that Celgene was offering for Otezla. FE 7 also told Smith that Celgene should never "pay to play"—i.e., offer rebates and deep discounts in exchange for market access—as that would

prevent Celgene from maximizing its profits. Notwithstanding FE 7's warnings, Celgene pressed ahead with its ill-fated "pay to play" plan for gaining market access.

216. FE 7 also stated that, critically, Otezla was far worse than Humira, Amgen's Enbrel (etanercept)—a biologic treatment manufactured by Amgen that has been available to treat PA since 2002 and psoriasis since 2004—and other competitors in terms of efficacy. The drug's inferiority to numerous established competitors in the marketplace made market penetration, and thus any attempt to increase revenues from Otezla sales, even more difficult.

217. FE 7 added that these impediments to growing Otezla net sales were exacerbated by the fact that, from the date of the Otezla launch, Smith hired extremely inexperienced sales representatives to sell the drug.

218. Echoing the accounts of FE 7, former Celgene sales representatives from every corner of the country all told the same story: for several fundamental reasons that remained unchanged throughout 2015, 2016 and 2017, the growth rate of Otezla sales was essentially flat.

- FE 8, a Celgene Sales Representative in the Northeast Region, confirmed that his annual Otezla sales were flat the entire time he worked for Celgene, from early 2014 through late 2017.

- FE 9, a Sales Territory Manager in the Southwest Region, recounted that by 2015, the growth of his Otezla sales had flattened and were flat from 2015 until he left Celgene in March 2017.

- FE 10, a Celgene Sales Representative in upstate New York, stated that, during his entire time with Celgene (from early 2015 until the end of 2016), it was "certainly a struggle to sell" Otezla, particularly on the rheumatology side—i.e., for patients suffering from PA. As FE 10 explained, "[o]nce the buzz [around Otezla] had dropped off by 2016, and once providers got a sense [Otezla] wasn't going to work that well," growing sales of Otezla "started to become a huge issue." Thus, FE 10 recalls that "the consensus was that the growth was not sustainable by 2016."

- FE 11, a District Sales Manager for the Northeast Region, stated that by 2016, his prescription sales had flattened for the entire year and there was a decline in annual growth (vs. 2016).

- FE 12, a Sales Representative in the Northeast Region, similarly noticed a slowing of Otezla prescription sales, particularly around October 2016.

- FE 13, a Regional Sales Manager, said that it was virtually impossible for Celgene to sell enough Otezla to meet its 2017 guidance. Specifically, FE 13 stated that the idea that Otezla could ever achieve 40% year-over-year growth in net product sales in 2017, let alone the 57% growth Defendants projected in January 2017, was absurd. FE 13 explained that he had seen no indication that would justify that kind of projection unless Celgene was expecting some huge shift in the managed care environment, and that it makes no logical sense to see those numbers domestically.

219. The Otezla sales representatives confirmed that Celgene's executives had access to information showing that the Company was unable to increase the growth rate of Otezla sales throughout the Class Period. FE 14 stated that Celgene management knew of Otezla's struggles because all of the sales results were available to management through a computer program called "Tableau." FE 12 explained that Tableau is a computer data tool that Celgene uses to compile and analyze sales data that Celgene receives from IMS—a company that collects pharmaceutical data. During the Class Period, the data available through Tableau for Otezla included straight volume, volume growth, number of prescriptions by territory, number of prescriptions by provider, and number of prescriptions attributed to each salesperson. According to FE 12, anyone from the sales side at Celgene could log on to Tableau and view the Otezla sales data. The degree of access to the data increased as you went higher up in the Company.

220. The former sales representatives also confirmed FE 7's account, uniformly attributing their struggles to grow Otezla sales to three main issues: (i) Otezla's inferior efficacy compared to its competitors, including the fact that Otezla worked slower than other drugs and was only effective for certain indications; (ii) challenges with insurance coverage for Otezla, including step-edits and preauthorization requirements; and (iii) various other obstacles that made it difficult for patients to get Otezla or negatively impacted the ability of sales representatives to sell Otezla. These persistent and widespread impediments to growing Otezla sales rendered

Celgene's 2017 Otezla guidance unattainable and Defendants' representations reaffirming that guidance materially false and misleading.

(a) Celgene Internally Viewed Otezla's Competitors As More Effective, Faster-Acting, and Covering a Broader Range of Indications

221. As numerous FEs recounted, the first fundamental barrier to growing Otezla sales throughout the Class Period was the fact that Otezla was not as effective as the other PA and psoriasis drugs from which it was attempting to capture market share.

- FE 9 explained that Humira produced positive results more quickly than Otezla. In addition, Otezla was not as effective as Humira for individuals who only suffered from psoriasis.

- FE 8 stated that Otezla's main competitors, Humira and Enbrel were simply more effective products with broader indications than Otezla. Humira and Enbrel could be prescribed to patients with mild to severe symptoms and typically worked within two to three weeks, whereas Otezla was only approved for mild to moderate indications and required up to four months to produce noticeable results. FE 8 referred to Otezla as "training wheels" compared to Humira and Enbrel.

- FE 10 confirmed that Otezla was difficult to sell because it was not as effective as its competitors, stating, for example that PA patients who had the disease for some time often did not respond well to Otezla. FE 10 received consistent feedback from rheumatologists that Otezla did not work well to treat PA.

- FE 11 added that there was an increase in competitor products entering the market during the Class Period, and in contrast to Otezla's efficacy rate of approximately 33%, these new biologic competitors had efficacy rates between 50% and 75%. As FE 11 explained, these statistics made it difficult to convince doctors and patients to switch to Otezla.

- FE 13 likewise confirmed that the efficacy of Otezla was nothing groundbreaking and not nearly as efficacious as some of the other competitors.

- FE 12 and FE 14 also indicated that there were issues with Otezla's efficacy and FE 12 specifically stated that Otezla worked slower than other competitor products and that these competitor products had more efficacy data. FE 12 further noted that there were significant deviations between patients in terms of Otezla's efficacy.

(b) Celgene Understood Internally That the Market Was Oversaturated with Entrenched Competitor Drugs

222. Celgene's attempt to capture market share and increase Otezla sales during the Class Period was further stymied by the sheer number of competitors in the PA and psoriasis treatment market and the fact that many of these drugs had been on the market for years and were well-accepted by physicians.

- FE 9 explained that the market for PA and psoriasis medications was oversaturated with competitor treatments, including established drugs like Humira. Physicians had many choices and Otezla was not at the top of the list—other, better known treatments were.

- FE 8 stated Otezla had difficulty capturing market share from its main competitors, Enbrel and Humira, as they had been on the market since 2002 and 2005, respectively.

- FE 11 similarly recounted that Humira was the "big kid on the block" and was already entrenched in the Northeast Region.

- Echoing FE 11, FE 13 indicated that the growth of Otezla sales was limited by Humira's successful saturation of the market.

- FE 13 explained that while the Company wanted Otezla to be the first in-step therapy, in light of its safety profile, ***that was just a "pipe dream***" because Methotrexate (another competitor) was so much cheaper and had been in use for so long that ***it just was never going to happen***.

- According to FE 13, Otezla was always destined to be a niche product as compared to its previously launched competitors.

(c) Insurance Coverage for Otezla Was Limited and Patients Faced Step-Edits and Preauthorization Requirements

223. Celgene's efforts to drive down pricing, in part, to avoid insurance step-edits and preauthorization requests, were largely unsuccessful until 2017, when several large PBMs finally agreed to cover Otezla as an initial PA and psoriasis treatment. As such, insurance companies threw up roadblocks that constrained Otezla's ability to gain market share and increase sales from the beginning of the Class Period through at least 2016.

- FE 9 reported issues with insurance companies, including that pre-authorization was routinely denied for Otezla and patients had to try other first-line drugs due to insurers' step-edit requirements. Insurance companies initially would not budge on coverage for Otezla.

- FE 14 stated that Otezla suffered from challenges with insurance coverage, including step-edits.

- FE 10 stated that insurance providers were unwilling for an initial period to reimburse patients for Otezla.

- FE 11 explained that several of the managed care groups in the Northeast Region had step-edits in place that required patients to use and reject Humira and Enbrel before they would approve Otezla, and the appeals process was cumbersome, so most doctors and plans opted to take the easier route by prescribing other drugs.

(d) Other Barriers to Growth

224. The growth of Otezla sales was also constricted by the fact that some patients experienced difficulties in trying to fill their Otezla prescriptions and the fact that Celgene lacked experienced sales personnel. FE 9 recounted that Otezla was considered a specialty drug, and had to be ordered from specialty pharmacies, unlike Humira and Enbrel, which were readily available in traditional pharmacies. This limit on access made it harder for patients to obtain Otezla even if their doctors prescribed it and insurance companies covered it. In addition, like FE 7, FE 14 also reported that Celgene's Otezla sales representatives were very inexperienced, which adversely impacted their ability to sell Otezla.

(e) Otezla Faced Barriers to Growth in the European Markets

225. Former Celgene employees involved with Celgene's efforts to expand Otezla into European markets similarly reported challenges to introducing Otezla into these markets and growing Otezla sales to meet the Company's unrealistic sales guidance.

226. FE 15, a senior member of the Pricing and Market Access group throughout 2015, was charged with creating pricing and market access models for reimbursement applications that

Celgene submitted to foreign national healthcare organizations in conjunction with efforts to obtain approval to market Otezla in Europe. As FE 15 explained, during the Class Period, there were two main hurdles before a drug could be marketed outside the U.S.: (i) the drug must be approved by the foreign counterpart to the FDA; and (ii) a reimbursement application must be accepted by the national healthcare organization charged with evaluating, among other things, the efficacy, cost and potential patient base for a drug.

227. In developing the models for Celgene's reimbursement applications, FE 15 struggled with Otezla's lack of compelling efficacy data because the models are usually driven by a drug's efficacy compared to other medications that are already in the market space. As he explained: "Otezla is worse than other things on the market so there was very little for me to work with." Because the data for "Otezla wasn't any better and was much worse than all of the competitors, it was very difficult to find the value" to support the reimbursement application models. FE 15 provided the Otezla models for the reimbursement applications to Zhang, Celgene's Global Head of HEOR, Pricing and Market Access, who in turn presented them to Defendant Smith.

228. Based on his review of the Otezla Phase II and Phase III trial data, FE 16, a high-ranking member of HEOR and Pricing for the U.K., stated that Otezla was inferior to its biologic competitors in terms of response rate and efficacy. It was his understanding that Otezla had a response rate that was 50% of the rate of biologics. Otezla's main advantage was that it was an oral medication, but the response rates for patients taking Otezla were "nowhere near" a biologic like Humira.

229. FE 16 confirmed that, in the U.K., Celgene's strategy was to discount Otezla to just below the price of its biologic competitors to stimulate sales and capture market share. However,

clinicians and patients were not swayed by the discount because the clinician would put the two drugs side by side, and the modest discount was not enough to make a difference with such an inferior efficacy. As FE 16 further explained, it was aggressive and foolish to assume that clinicians would use Otezla over biologics—clinicians just want to use the best product with the best data. As a result, FE 16 recounted that the Otezla sales and uptake forecasts compiled by Celgene for the U.K. and Ireland were overly aggressive. FE 16 added that his colleagues in other parts of Europe shared the same feeling that the Company's targeted sales figures were quite aggressive. FE 16 and his European counterparts at Celgene participated in discussions with independent advisory boards comprised of clinicians, local payers and various stakeholders. The advisory board members would consistently criticize Celgene, stating: "You're offering a biologic-like price without [] biologic-like efficacy."

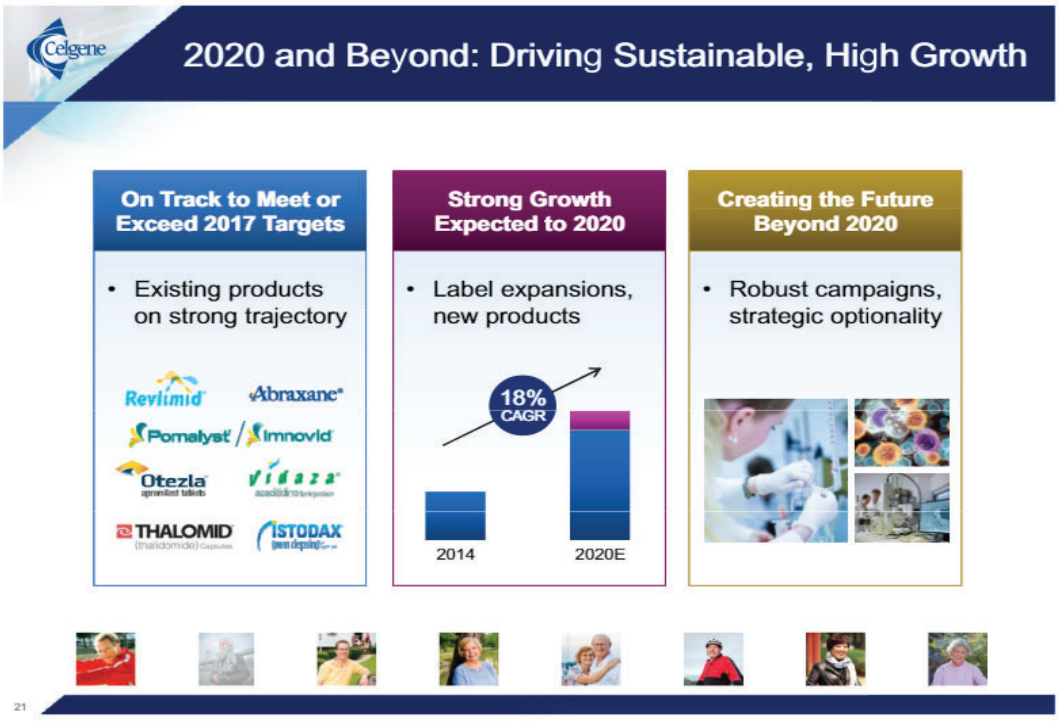
230. According to FE 16, once approval was granted by the relevant U.K. regulatory body, the NICE, in late 2016, and Otezla was introduced into the U.K. marketplace, sales and uptake were "very slow and very low." FE 16 stated that they missed sales targets for five or six quarters and were continuing to struggle as late as the middle of 2018. The early sales targets were missed by close to 50%. FE 16 confirmed that both Celgene's European and U.S. leadership were well aware of the missed targets. Indeed, there was "business review meeting after business review meeting" concerning the missed targets, including, at one point in late 2016 or early 2017, a meeting in London between Defendant Smith and Business Unit Director Rob Moore.

3. Defendants Reaffirm the 2017 Guidance and Tout Otezla's Net Product Sales Prospects Throughout 2015 and Into 2016

231. Notwithstanding the numerous barriers that were impeding Otezla's net product sales and market share growth by the beginning of the Class Period, Defendants repeatedly represented that Celgene was on track to meet its 2017 Otezla guidance—net product sales of $1.5

billion to $2 billion—over the course of the next year and a half. For example, during the May 12, 2015 Bank of America Merrill Lynch Healthcare Conference, Smith lauded the purportedly "phenomenal" "acceptance of [Otezla]" for psoriasis and PA by new patients, claiming that Otezla was "off to a great start" and that Celgene was "very, very encouraged."

232. Defendants also presented nearly identical versions of the slide set forth below discussing "sustainable, high growth" and reassuring investors that the Company was "***on track*** to meet or exceed" its 2017 Otezla sales guidance at no fewer than five separate investor conferences—on March 4, May 12, June 10, September 17 and November 10, 2015:



233. At the May 11, 2016 Bank of America Merrill Lynch Healthcare Conference, Defendant Alles claimed that Otezla's "terrific launch" gave Celgene confidence in the Company's ability to hit the Otezla 2017 guidance. Alles went on to downplay certain impediments to growth such as the step-edits imposed by the insurance companies on new users of the drug, stating, "we understand the access environment very well, so some of those barriers that gave us all a little bit

of caution for the uptake of Otezla early have started to present themselves in ways where we can manage it, understand it, and in many cases, we have great advantaged positions now because of the profile of the drug."

4. Defendants Ignore Explicit Warnings from Celgene's Market Access Team that the 2017 Otezla Net Product Sales Projections Are Unachievable

234. Despite (i) Celgene's continuing struggles to grow Otezla net sales in light of insurance barriers and Otezla's inferior efficacy vis-à-vis its competitors, and (ii) management's receipt of explicit warnings regarding the Company's doomed "pay to play" strategy for gaining market access, Defendants maintained Celgene's aggressive 2017 sales guidance throughout 2016 and 2017. Furthermore, as discussed below, between July and December 2016, Defendants disregarded explicit warnings from high-ranking finance personnel within the Company who voiced grave, specific and unequivocal concerns that the 2017 Otezla sales guidance was unachievable.

235. According to FE 17, a senior-level U.S. Market Access executive between early 2016 and late 2017, there was no Otezla revenue growth anywhere by 2016. FE 17 recalled that the lack of growth in Otezla sales and its fundamental causes were expressly communicated to the IIEC by no later than the third quarter of 2016. At this time, the IIEC was comprised of at least the following individuals: Defendant Smith; Defendant Curran; Tessarolo; Hunter Smith (Vice President, Finance); Tom Tomayko (Vice President, Commercial Development & Strategy, I&I); and Celgene's Head of Medical.

236. FE 17 and his team presented to the IIEC one to three times during each of the third and fourth quarters of 2016. Jim Kilgallon, Executive Director, U.S. Market Access, Pricing and Contracting, who worked with FE 17 and maintained much of the supporting Otezla payer and pricing statistics, presented with FE 17 at these meetings. During these presentations, which

focused on payers and pricing, FE 17 and his team expressly warned the IIEC that the 2017 Otezla guidance could not be met. FE 17 explained that the detailed research he reviewed and presented regarding payers and pricing showed that the forecasted Otezla sales for 2017 were not attainable. According to FE 17, Tessarolo also warned the IIEC in weekly meetings by the third quarter of 2016 that the 2017 Otezla guidance could not be met.

237. In the fourth quarter of 2016, FE 17 expressly advised the IIEC that the Otezla sales guidance should be lowered. FE 17 also specifically recalls that he and Kilgallon told Tessarolo directly that the guidance needed to be lowered. Tessarolo agreed and later confirmed to FE 17 that he, too, warned the IIEC that the guidance should be lowered, but the other members of the IIEC, which included Defendants Smith and Curran, insisted that the guidance would not be changed. Thus, FE 17 confirmed that by the third and fourth quarters of 2016 the IIEC was acutely aware that Celgene was not going to hit the repeatedly reaffirmed 2017 Otezla sales guidance numbers. According to FE 17, "***everyone knew that the actual stated forecast was not reasonable***" and could not be met.

238. FE 17 further recounted that the Forecasting team (which included Doug Bressette, Senior Director, Global Business Planning and Analysis for I&I) was "***told to change***" ***the numbers*** (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth.

239. FE 18, a direct report to Swartz, Celgene's Vice President of U.S. Market Access, confirmed that Smith and other Celgene executives were aware that Celgene was not going to meet its 2017 Otezla sales guidance by no later than the fourth quarter of 2016. FE 18 explained that Swartz made recommendations to the Corporate Pricing and Market Access Committee ("CPMAC")—the committee charged with monitoring and approving pricing and market access decisions—that the Company needed to reduce the 2017 guidance numbers, but she was ignored.

The CPMAC was chaired by Defendant Smith, and other members of Celgene's senior executive management would sit in as well.

240. When FE 18 first saw the 2017 Otezla sales guidance, his reaction was "***wow, there is no way in the world we were going to make [it] . . . it was crazy***." FE 18 described the guidance as a "moon shot." FE 18 indicated that the aggressive Otezla guidance did not even account for the introduction of new competition to the PA and psoriasis market—Defendants simply ignored this factor. FE 18 further explained that the guidance figures were based on the assumption that insurance reimbursement hurdles would be removed. To meet the Otezla sales numbers set by the CPMAC, Otezla would have had to completely transform the market space in less than twelve months—but this kind of transformation is unheard of, unless a company introduces a curative drug. Otezla just did not have the efficacy or novelty to bring about the market change needed to meet the Company's sales guidance. FE 18 also confirmed that Otezla sales in the fourth quarter of 2016 were very flat and had been flat for quite some time before that.

241. The admonitions of Swartz, FE 18, and their colleagues responsible for pricing concerning the unachievability of Celgene's Otezla sales guidance were outright ignored by Defendant Smith, Defendant Curran and other members of Celgene's senior management. According to FE 17, Defendants refused to lower the guidance and instead put pressure on the salespeople to hit the impossible numbers.

242. Indeed, Defendants repeatedly reaffirmed the 2017 Otezla net product sales guidance to the market. During the September 12, 2016 Morgan Stanley Global Healthcare Conference, Defendant Smith claimed: "Otezla is moving along very nicely at this point in time. Looks like $1 billion in sales this year [2016]. . . . I feel really great about where we are going and the numbers both in 2017 and 2020 that we put out there." Later, during Celgene's October 27,

2016 third quarter conference call, Defendant Smith expressed a "high degree of confidence" in Celgene's ability to meet the 2017 Otezla sales guidance, adding that "we feel very good about the targets that are out there."

243. According to FE 18, Swartz was fired in late 2017. FE 18 had reported to Swartz for a year and a half and never had any issues with her, stating that she was always very professional and was a great boss to work for. The consensus among FE 18 and his colleagues was that Swartz had been fired due to her consistent pushback regarding the unachievable Otezla sales guidance that Celgene repeatedly provided to the market. According to FE 18, Swartz was "scapegoated" and her termination was an attempt by Celgene to "pivot around her."

5. Defendants Marginally Lower the Upper Range of 2017 Guidance But Forecast Impossible 57%+ Growth in Otezla Sales

244. In January 2017, even after Defendants Smith and Curran were expressly advised by Swartz, Tessarolo and others that Celgene's publicly-stated 2017 Otezla guidance could not be met, Defendants refused to revise the low end of the range and only modestly lowered the top end from $2 billion to $1.7 billion. Critically, Defendants also misleadingly projected 57% year-over-year growth in Otezla net product sales for 2017 compared to 2016. Specifically, on January 9, 2017, Celgene filed a Form 8-K with the SEC signed by Defendant Kellogg attaching a press release with the Company's 2016 preliminary results and its outlook for 2017. In this press release, Celgene stated that it expected Otezla net product sales of "approximately $1.5 [billion] to $1.7 [billion]" for 2017, representing 57% year-over-year growth.

245. Analysts reporting on Celgene's press release, including BTIG Equity Research, wrote that the "biggest driver" of the Company's overall 2017 guidance was Otezla, "which is expected to grow ~58% YoY." SunTrust Robinson Humphrey wrote that even the narrowed Otezla guidance range "calls for significant growth." In addition, several analysts noted that

Celgene's reaffirmation of the $1.5 billion low-end of the guidance range was in line with the market's expectations. For example, RBC Capital Markets was focused on the low end of the range, writing on January 9, 2017 that the $1.5 billion figure was "already expected." Evercore ISI wrote in a January 9, 2017 report that "CELG took the top end of Otezla guidance down from $2B to $1.7B, and the midpoint of Otezla guidance now tracks with consensus 2017 estimates of $1.54B." Similarly, J.P. Morgan stated in a January 9, 2017 report discussing Celgene's updated 2017 guidance that the consensus guidance for Otezla was $1.53 billion.

246. Multiple former employees confirmed that Defendants' forecasted 57% year-over-year growth was both unrealistic and unachievable. FE 19, a senior executive in U.S. Field HEOR, recounted that based on what his Market Access group was seeing in their interactions with and analyses of large payers, there was no way that the projected 57% year-over-year Otezla sales growth for 2017 was attainable. According to FE 19, in late 2016, when Defendant Smith was assessing the 2017 Otezla market access and setting the targets, the market did not support anything close to 57% growth. FE 19 continued, "even if Market Access was able to obtain 100% coverage [from insurance companies], it was unrealistic to obtain the kind of growth in Otezla sales that Smith was forecasting for 2017."

247. As FE 19 explained, Otezla's competitors, including Humira and Remicade, were deeply entrenched in the market space, which made it increasingly difficult for the sales team to come anywhere close to Smith's projections. FE 19 stated that in light of physicians' reluctance to prescribe Otezla over well-established competitor drugs, reaching the sales projection was "not going to happen." FE 19 recalled having conversations with Swartz and Claudio Faria, Executive Director and Group Lead of U.S. HEOR, concerning the unrealistic sales projections given what Market Access was reporting to management. According to FE 19, there was no way Defendant

Smith could have interpreted what his Market Access team was saying and translated that into 57% sales growth for Otezla in 2017. In other words, Defendant Smith ignored the Market Access team's warnings.

248. FE 17 also detailed multiple impediments to Celgene meeting the Company's 2017 Otezla sales guidance, and achieving the publicly-stated 57% year-over-year growth. FE 17 attributed the overall lack of growth in Otezla sales observed throughout 2016 and into 2017 to three main factors: (i) managed care was "underwater" by April 2016; (ii) as early as April 2016, new Otezla prescriptions and patients were down; and (iii) Celgene allowed wholesalers to buy in above their demand in late 2016. With respect to managed care being "underwater," FE 17 explained that when Celgene enters into a new PBM contract that requires Celgene to issue rebates, the Company ends up paying rebates for all existing prescriptions—i.e., the rebates apply both to new prescriptions and existing prescriptions. By virtue of the massive rebates due on the existing prescriptions, the PBM contracts are deemed "underwater" and undermine sales revenues. As early as April 2016, the rebates due on existing Otezla prescriptions covered by these "underwater" contracts were "significant" and amounted to millions of dollars. FE 17 stated that Celgene management should have given a warning to investors in the fourth quarter of 2016 because the IIEC knew about the rebate issue and the impact that it was going to have on the Company's 2017 Otezla revenues. However, no warning was given.

249. Further compounding the adverse effect from the "underwater" managed care contracts in the first quarter of 2017, at the end of 2016, Celgene permitted wholesalers to buy Otezla at reduced prices in excess of their demand. As FE 17 explained, in anticipation of a planned 2017 price increase for Otezla, many wholesalers asked to purchase in December 2016 the quantities of Otezla they were slated to purchase in January 2017, in order to take advantage

of the lower price. Celgene could have refused the requests and required the wholesalers to comply with their contracts to purchase the goods in 2017, but they chose not to do so. This decision, which FE 17 stated was motivated by management's desire to make the fourth quarter 2016 Otezla numbers look great, had a negative impact on the revenues in the first quarter of 2017, and thus Celgene's ability to meet its 2017 Otezla sales guidance.

250. FE 7 likewise confirmed that achieving a 57% increase in Otezla net product sales was "***impossible***" given Celgene's "pay to play" strategy (*see supra* ¶ 215). FE 7, who identified multiple barriers to Otezla's ability to capture market share (*see supra* ¶¶ 211-217), added that "there isn't any way to grow [Otezla] revenue by 57%." FE 7 was very vocal to senior management (i.e., Alles, Smith, Curran) and specifically told them that he did not think Otezla's growth would continue because of the step-edit hurdles and the saturation of competitor drugs in the market. FE 7's warnings, however, were ignored.

251. Consistent with FE 7, FE 8 stated there was no way Celgene could meet the 57% year-over-year growth forecasted as part of the January 2017 Otezla guidance. FE 8 stated that Otezla sales continued to be flat into April 2017 and, as a result, he and his Regional Business Manager were "banging their heads against the wall."

252. The disappointing sales results and other issues rendering the 2017 Otezla guidance unachievable were again communicated to the IIEC in early 2017. However, Defendants again refused to heed the warnings. Specifically, FE 17 learned from Tessarolo that he had given a presentation to the IIEC in early 2017 concerning the disappointing Otezla sales and had warned the IIEC that the Company needed to downgrade its 2017 Otezla sales guidance. During this presentation, Defendant Smith cut off Tessarolo, stating that he had heard enough of the negative information.

6. Despite Continued Headwinds and Recognized Impediments, Defendants Reaffirm the Aggressive 2017 Guidance

253. On April 27, 2017, Defendants announced that Celgene's Otezla net product sales for the first quarter of 2017 fell short of the Company's expectations, with just a 14% year-over-year increase and a 1% sequential decline from the fourth quarter of 2016. Rather than disclose the true cause of the decline in sales, Celgene ***reaffirmed*** the forecasted 57% year-over-year growth for Otezla sales, stating that the "Updated 2017 Guidance" for Otezla was "Unchanged."

254. During the April 27, 2017 first quarter conference call, Defendant Kellogg represented that "sequential performance from Q4 to Q1 is always impacted by several items . . . Otezla is impacted by managed care dynamics that drive lower total marketplace prescriptions for psoriasis therapies in Q1." Kellogg also tried to excuse the poor first quarter results by citing to the "higher gross-to-net adjustment related to new contracts with several large payers that were implemented in January," reassuring investors that the new PBM contracts and elimination of step-edits would improve market access, and by extension, Otezla net product sales for 2017: "These new contracts approximately doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy, which has already improved OTEZLA's market share in these accounts." Smith further claimed that "[w]e initiated a number of activities that will expand the addressable population for OTEZLA worldwide, laying the groundwork for a highly successful year ahead," stating that "[w]e can see that early gains are already evident after only 1 quarter from this contracting strategy."

255. In truth, Defendants had no reasonable basis for representing that new PBM contracts and the removal of step-edits would improve Otezla sales and help the Company hit its 2017 guidance. As detailed below by multiple former employees, the removal of step-edits and the newly negotiated contracts with the insurance companies and PBMs did not offset Otezla's

struggling sales in light of the myriad other issues depressing the sales numbers and, thus, would not suffice to make up the yawning gap in sales.

(a) Removal of Step-Edits Was Not a Panacea for Otezla's Lackluster Sales

256. Defendants acknowledged internally that Celgene needed a corresponding increase in Otezla sales to counterbalance the increased expenses and lower margins associated with the new contracts to remove the step-edits imposed by the insurance companies. According to FE 12, after Celgene spent a lot of money for "payer wins" (i.e., the removal of step-edits and other requirements by insurance companies), there was a push from corporate and District Managers to increase the sales volume to offset the higher expenditures and lower margins. As discussed above, however, a laundry list of additional issues, including the lack of efficacy and increased competition, continued to negatively impact Otezla sales (*see supra* § IV.C.2) despite the increased removal of step-edits by insurance companies. As FE 9 confirmed, even if Celgene managed to remove the step-edits, it would not solve the sales issues for Otezla because, among other things, physicians had been working with competitor drugs for many years and it was easier for them to prescribe medications they were used to and knew worked well.

257. During meetings in November or December of 2016 with Defendant Curran, Tessarolo, Swartz, Grausso, Willcox, and Rob Owen ("Owen"), National Sales Director, FE 7 continued to warn these executives that paying to remove the step-edits for Otezla was not a cure for the drug's broad-based market access challenges.

258. FE 7 indicated that while Celgene did remove some step-edits for Otezla in 2017, Celgene's leadership had previously made decisions that hampered Otezla's market access and destroyed its "best price" beginning as early as the 2014 launch (*see supra* ¶¶ 212-214). In addition, not all payers agreed to remove step-edits, including United, Aetna, Cigna and Blue Cross

Blue Shield. Furthermore, FE 7 stated that even if 10 million individuals obtained access to Otezla through the removal of step-edits, not all of them would actually buy Otezla. In short, the removal of the step-edits was too little too late, and could not spur on Otezla sales enough to close the widening gap between the actual Otezla sales and the Company's knowingly unreasonable 2017 guidance.

(b) Many of the New PBM Contracts Were "Downgraded" in 2017

259. Unbeknownst to investors, Defendants' April 27, 2017 representation that the newly-entered PBM contracts would help drive the Company's 2017 Otezla sales was undermined by the fact that many of the PBM contracts took several months to generate revenues and, as a result, the Company reduced the revenue expectations associated with these contracts.

260. Specifically, FE 18 stated that several of the new PBM contracts Celgene entered into in 2017 covered patients who were receiving their Otezla prescriptions for free or at a reduced cost through various forms of patient assistance and other initiatives, such that Celgene was earning only minimal revenues related to these patients' prescriptions. Even after the new PBM contracts became effective, these patients continued to receive their Otezla prescriptions at little to no cost until their prior entitlements expired, at which point they were brought under the new reimbursement scheme. FE 18 explained that it was not until this process was complete—which could take one or two years—that Celgene started to earn revenues on these prescriptions. In other words, just because new PBM contracts went into effect in 2017, Celgene did not see increased revenues from prescriptions for many covered patients until months later.

261. FE 18 said that his Market Access team worked closely with the pricing team to assess how the new PBM contracts were performing throughout 2017. FE 18 stated that it was clear from the beginning of 2017, based on the models that his team was running monthly, that the PBM contracts were not meeting revenue expectations. FE 18 communicated the fact that the

contracts were underperforming to his boss, Swartz, and he understood that she reported this information to the CPMAC. According to FE 18, Celgene did not lower expectations for the PBM contracts even when presented with data showing that the contracts were underperforming; by contrast, when his team presented data showing that some contracts were outperforming, Celgene quickly raised the revenue expectations for those contracts.

262. Celgene eventually internally lowered the expectations on many of these PBM contracts. FE 18 recalled seeing a bar graph that depicted the original expectations, the actual numbers, and a revised, lowered expectation. The original expectation was "through the roof." While the revised expectations were closer to the current performance, this was after they had been significantly lowered—by amounts that "took [him] aback." Rather than communicate this to investors, Defendants left the market with the false impression that the new PBM contracts would help drive Otezla's 2017 sales.

7. Defendants Slash Otezla and I&I Guidance, Blaming Market-Wide Effects

263. It was not until the end of the third quarter of 2017 that Celgene finally admitted to investors what Defendants had known for years—the 2017 Otezla guidance could not be achieved. On October 26, 2017, Celgene stunned the market by announcing that, in light of the dismal Otezla sales numbers, the Company had slashed the 2017 guidance by more than $250 million—providing updated guidance of $1.25 billion compared to the $1.5 billion to $1.7 billion range Defendants reaffirmed just weeks earlier. Defendants also revised the 2020 I&I guidance down from over $4 billion to between $2.6 billion and $2.8 billion, due to the grim Otezla sales.

264. During the third quarter 2017 conference call that day, Defendants tried to blame the dramatic reduction of the Otezla guidance on slowing growth across the dermatology market and other market-wide challenges. Alles claimed: "[O]ur 2017 forecast assumptions did not

adequately anticipate the deep and persistent slowing growth of the psoriatic arthritis and psoriasis markets, especially during the entire third quarter. When combined with the discounts tied to the execution of our ongoing managed-care contracting strategy, we missed our third quarter OTEZLA sales target." Kellogg similarly attributed the reduction in the Otezla guidance to the "market-wide challenges in the U.S. dermatology market," and Curran cited the "market deceleration" and characterized the Otezla market as "increasingly dynamic and competitive."

265. Former Celgene employees knowledgeable about the real reason for the slashed guidance reported that these explanations were not accurate. FE 18, for example, rejected Defendants' claims that the Otezla miss was due to a slowing of the psoriasis and PA markets, particularly during the third quarter of 2017, as well as increasing competition, calling this purported explanation "***bullshit***." FE 18 explained that there was no way that Celgene's leadership was unaware of the fact that there would be more products entering the market in 2017. In addition, FE 18 confirmed that the market did not change rapidly in the third quarter of 2017. As he explained: "***We saw what was happening way before then***. ***We had monthly meetings with the contract and pricing teams . . . very early on in 2017***." FE 18 stated that there was "worry" and "concern" at these meetings. As FE 18 further stated: "We were in trouble with our Otezla contracts. You heard that from a lot of the pricing and contract people." Thus, according to FE 18, there was no way that Celgene's leadership was unaware of the looming guidance miss long before the third quarter of 2017.

266. The accounts of the other former Celgene employees discussed above similarly confirm that the 2017 Otezla guidance was unattainable from the start of the Class Period (*see supra* § IV.C.2).

267. Analysts reacted quickly and negatively to the Company's guidance reduction and expressed a lack of confidence in Celgene's ability to execute going forward. As J.P. Morgan wrote in an October 26, 2017 report:

> A week after a high-profile (albeit also high-risk) Phase 3 asset failed [GED-0301], the company reported a big miss for Otezla and a sizable cut to overall 2020 guidance. This is clearly not a recipe for success for an over-owned stock in a skittish market. The question now is what happens from here? . . . . Sentiment has taken a tremendous hit, management faces a major credibility issue (at least based on our investor conversations), and generalists may be running for the hills after this week that more closely resembled a Halloween horror film than a typical 3Q biotech earnings season.

268. Raymond James commented that "today's update substantially alters our outlook and confidence in the company's ability to execute":

> We previously viewed Celgene's immune & inflammatory (I&I) franchise as a key driver to facilitate a revenue diversification effort away from Revlimid. However, with GED-301 now eliminated, and Otezla appearing to stumble, revised FY20 targets indicate an increasing reliance on the hematology franchise (rather than decreasing), which is the opposite of what we'd hope to see over time. Even if ozanimod data shows differentiation, we think CELG has now become a "show me" story[.]

269. On the news of Celgene's steep guidance reduction, the price of the Company's common stock declined $19.57 per share, or more than 16%, on heavy trading volume from a close of $119.56 per share on October 25, 2017 to a close of $99.99 per share on October 26, 2017.

D. For Over a Year, Defendants Fraudulently Conceal the Need to Complete Additional Testing that Jeopardized the Ozanimod NDA

270. The third piece of Defendants' three-pronged plan to replace Celgene's revenue stream from Revlimid was Ozanimod. Ozanimod was initially developed by Receptos to treat

RMS and UC.[12] MS is the most common autoimmune disease of the central nervous system, affecting an estimated one million people in the U.S.

1. Celgene Acquires Receptos and Installs Celgene Personnel to Oversee the NDA Submission for Ozanimod

271. On July 14, 2015, Celgene agreed to purchase Receptos for $7.2 billion. In its press release announcing the acquisition, Celgene trumpeted that "[t]he transaction adds Ozanimod" which, based on clinical studies, "demonstrated several areas of potential advantage over existing oral therapies for the treatment of [UC] and [RMS] . . . ." Celgene projected potential annual Ozanimod sales of up to ***$6 billion***, and analysts commenting on the Receptos acquisition zeroed in on the drug's anticipated power to generate revenue. As one commentator later remarked, Ozanimod was "the crown jewel in Celgene's $7.2 billion acquisition of Receptos, Inc." In light of the Receptos acquisition, Celgene revised its 2020 revenue guidance for the I&I franchise up from $3 billion to over $4 billion.

272. Immediately upon acquiring Receptos, Celgene installed its own personnel at Receptos' headquarters in San Diego. As FE 20, a former senior executive in Clinical Development at Receptos, explained, after the acquisition, Celgene moved in and took over Receptos: "They [Celgene] were in charge. Receptos was not." FE 20 stated that Receptos was brought under the control of Celgene's New Jersey headquarters. From that point forward, Receptos was out of the decision-making loop and important decisions were made by Celgene in New Jersey or by on-site Celgene personnel. FE 21 stated that after the acquisition, Receptos'

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[12] MS disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss, causing communication problems between the patient's brain and the rest of the body. Most people with MS have RMS, which is characterized by a relapsing-remitting disease course, whereby a patient's symptoms may remit for a period of time but then relapse.

leadership was not allowed to make any decisions that had the potential to impact Celgene's stock price, and there were constant discussions between senior Receptos personnel and their counterparts and superiors at Celgene.

273. According to FE 20, Defendant Martin came from Celgene to Receptos to oversee the Ozanimod NDA filing. Martin formerly served as the Vice President, Head of Project Leadership, for Celgene's I&I franchise. FE 2, who worked in Clinical Research & Development in the Company's I&I franchise, described Martin as a "control freak" and Smith's right hand man, and confirmed that Martin was sent to San Diego as Managing Director for Receptos in late 2015 or early 2016. FE 2 recounted that Martin operated as the *de facto* chief executive at Receptos. FE 5, a former Director at Receptos, likewise described Martin as the CEO of Receptos after the acquisition, adding that Martin was in charge of the entire Receptos organization and reported directly to Smith.

274. FE 5 explained that once he was in power, Martin pushed out Receptos' previous upper management and replaced them with his friends from Celgene in New Jersey. Martin's best friend, Saillot, was brought in to serve as Vice President of Project Leadership, Regulatory Affairs, and Clinical Pharmacology at Receptos. FE 5 also recounted that Gary Cline, Head of Strategic Research and Innovation at Celgene, was another individual sent by Smith to San Diego to keep tabs on Ozanimod for Smith. FE 22, a Project Manager on the Ozanimod UC/CD team, corroborated that Martin reported directly to Smith and further confirmed that Saillot was Martin's second in command.

2. Celgene Touts Ozanimod's Advantages Over Gilenya

275. When Celgene acquired Receptos in 2015, the Company knew that if Ozanimod received FDA approval, its main competitor would be Gilenya (fingolimod), a drug manufactured by Novartis for the treatment of RMS. The Company therefore immediately embarked on an

aggressive campaign to hype the purported advantages of Ozanimod over Gilenya and to rush Ozanimod through the FDA approval process.

276. Gilenya has a mechanism of action that is similar to Ozanimod. Celgene, however, claimed that Ozanimod had the advantage of a much shorter half-life than Gilenya. Gilenya has a long half-life of 168 hours, or seven days—that is, half of the drug remains in a patient's body for seven days after it is taken. By contrast, Celgene claimed that Ozanimod had a much shorter half-life of just nineteen hours.

277. As one scientific paper from 2015 explained: "Having a shorter half-life and rapid peripheral lymphocyte recovery may provide [Ozanimod] with ***significant advantages***, including flexibility in treatment with other immune-modulating agents as needed or allowing for a rapid switch to alternative therapies if the patients [sic] disease flares while on therapy."

278. Immediately after acquiring Receptos, Celgene began touting the supposed advantages of Ozanimod over Gilenya and other oral RMS medications, including the drug's purportedly shorter half-life. For example, during the Robert W. Baird & Company, Inc. Healthcare Conference on September 9, 2015, Defendant Smith pointed to the "different half-life . . . that you see with the S1P1 with Ozanimod, that you don't see with Gilenya," noting that this "could potentially be some reason to differentiate."

279. Armed with this supposed competitive advantage, Celgene sought to capture Gilenya market share following FDA approval of the Ozanimod NDA, which was expected in 2018. In a landscape-altering ruling, however, in October 2015, the U.S. Patent and Trademark Office ("PTO") quashed Novartis's Gilenya patent claims in response to a challenge by generic competitors, paving the way for the entry of fingolimod generics into the RMS market by the end of 2019. As one publication characterized the PTO's decision and its impact on companies like

Celgene: "***[I]t's not good for rival pharma companies, either***. They'll also have to contend with copycat versions of Gilenya, the first oral treatment for MS."

280. Thus, despite Ozanimod's purportedly superior half-life and safety profile, the availability of cheaper generic alternatives with a similar efficacy starting in 2019 would make it more difficult for Ozanimod to gain widespread acceptance among RMS patients. As a result, Celgene was highly motivated to file its Ozanimod NDA and seek FDA approval before the end of 2017, in hopes of establishing market share before the wave of generic fingolimod competitors hit the market in 2019.

3. Celgene Disregards FDA Guidance and Industry Practice and Fails to Undertake Critical Testing for Ozanimod Metabolites

281. In announcing the Receptos acquisition, Celgene represented that it anticipated no obstacles to FDA approval. For example, the Company told investors on July 14, 2015 that the data from the two ongoing Phase III clinical trials, the RADIANCE and SUNBEAM RMS studies, "are expected in the first half of 2017 to support a RMS approval in 2018." Defendants continued to make identical representations throughout the Class Period. However, unbeknownst to investors, after Celgene discovered the Metabolite in November 2016, it failed to conduct and report critical testing required to receive FDA approval of Ozanimod in early 2018, thus dooming the drug's prospects for this rapid approval timeline.

(a) FDA Guidance and Industry Practice Standards on Metabolite Safety Testing

282. Pursuant to FDA guidance, in order to avoid significant delay in the review and approval of a new drug application, drug companies are directed to identify all metabolites early on in the drug development process and to conduct extensive safety testing of any active metabolites that are discovered during the course of these pharmacological analyses. When a drug is administered to a patient, the drug can be metabolized (i.e., chemically altered) by the patient's

body, resulting in the formation of one or more metabolites. Metabolites are characterized as either "active" or "inactive." Active metabolites continue to produce effects in the body after their formation, whereas inactive metabolites do not. Active metabolites can accumulate in the body following multiple doses of a drug and may ultimately alter both the safety and the therapeutic effects of the drug. Thus, according to a seminal article on the subject, understanding "the metabolic fate of a drug candidate in preclinical species and humans is a ***key factor*** in new drug development, registration and ultimate use."[13]

283. The importance of metabolite identification and testing has long been recognized. Since 1985, federal regulations have ***required*** that NDAs include "[a] section describing the human pharmacokinetic data" (i.e., information about how a drug moves through the body), including "[a] summarizing discussion and analysis of the pharmacokinetics and the metabolism of the active ingredients . . . of the drug product."

284. In 2002, Dr. Thomas A. Baillie (Professor of Medicinal Chemistry and Dean *Emeritus* for the University of Washington School of Pharmacy, and former Vice President and Global Head of Drug Metabolism and Pharmacokinetics at Merck & Co.), et al. authored a paper entitled "Drug Metabolites in Safety Testing" that summarized the deliberations of a multidisciplinary committee regarding the critical importance of identifying and testing metabolites as early as possible in the drug development process.[14] In this paper, often referred to as the "MIST" paper, Baillie and his co-authors recognize "the increased attention being paid by

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[13] Human Radiolabeled Mass Balance Studies: Objectives, Utilities and Limitations, Natalia Penner, Lewis J. Klunk and Chandra Prakash, May 2009. At the time of this paper, Penner, Klunk and Prakash were employed in the Department of Drug Metabolism and Pharmacokinetics at Biogen, a pharmaceutical company focused on discovering, developing and delivering therapies for people affected by serious neurological and neurodegenerative diseases.

[14] Drug Metabolites in Safety Testing, Toxicology and Applied Pharmacology 182, 188–196 (2002).

both pharmaceutical companies and regulatory agencies to the role of metabolites as potential mediators of the toxicity of new drug products."

285. Baillie, et al. highlight the fact that the early identification of metabolites in drugs at the development stage is critical to evaluation of the drug's safety. The MIST paper also stated that "it seems reasonable to expect that the sponsor would wish to develop an understanding of the metabolic fate of the drug candidate in humans ***prior*** to the initiation of large Phase III clinical trials." Baillie, et al. further stress that "the importance of the animal and human ADME [Absorption, Distribution, Metabolism and Excretion] studies [used to identify metabolites] ***cannot be overemphasized***, the results of which need to be viewed in the context of all available pharmacology and toxicology data."

286. Relying on Baillie's 2002 MIST paper, the FDA published industry guidance for the Safety Testing of Drug Metabolites in 2008 and reaffirmed this guidance in November 2016. The FDA's guidance calls for "the identification of differences in drug metabolism between animals used in nonclinical safety assessments and humans ***as early as possible*** during the drug development process." The FDA warns that "[t]he discovery of disproportionate drug metabolites late in drug development can potentially ***cause development and marketing delays***." Thus, the FDA "encourage[s] contacting the FDA early in drug development to discuss these issues."

287. As Baillie subsequently explained in a 2009 paper, the FDA's metabolite testing guidance "underscores the need for sponsors to conduct studies on the metabolic fate of drug candidates ***at an early stage of clinical development, such that issues of disproportionate human metabolites may be addressed prior to the initiation of large-scale clinical trials***."[15]

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[15] Approaches to the Assessment of Stable Chemically Reactive Drug Metabolites in Early Clinical Trials, Chem. Res. Toxicol. 2009, 263-266.

288. Testing for the presence of metabolites in humans is conducted through so-called radiolabeled mass balance studies, wherein a radioactive "label" (typically Carbon-14) is added to the drug to allow for the tracking of metabolites in the blood, plasma, urine, and feces collected from patients. As Penner, et al. explain, radiolabeled mass balance studies are "viewed as the primary source of data on human metabolites from which a decision can be made regarding the need for further safety assessment in preclinical species," stating that "[h]uman radiolabeled mass balance . . . studies are ***required*** by regulatory authorities for the registration of a new drug, and therefore, are an integral part of the majority of drug development programs." Baillie also acknowledges the importance of mass balance studies utilizing a "radiolabeled drug" in identifying metabolites, stating that these studies are "***generally [ ] accepted as the 'gold standard' method for defining the fate of a drug candidate in man***."

289. Following the identification of metabolites through appropriate studies, certain metabolites require additional testing. As the FDA explains, "when the metabolic profile in humans is similar to that in at least one of the animal species used in nonclinical studies," standard animal toxicology studies are generally deemed sufficient for FDA submission. In other words, if the metabolite is present in similar amounts in humans as in the animals used for toxicology studies, those animal toxicology studies can "stand in" for human toxicology studies. However, as the FDA guidance recognizes, there are cases when "the metabolite is formed only in humans and is absent in the animal test species or [ ] the metabolite is present at disproportionately higher levels in humans than in the animal species." In these cases where such an imbalance exists between the metabolite's presence in humans as compared to animals, the drugmaker should conduct additional testing of the metabolite ***before*** filing the NDA for the drug. In describing the type of metabolites subject to additional studies, the FDA guidance provides:

> Generally, metabolites identified only in human plasma or metabolites present at disproportionately higher levels in humans than in any of the animal test species should be considered for safety assessment.

The FDA guidance further provides that human metabolites can raise a ***safety concern*** when they "form[] at greater than 10 percent of parent drug systemic exposure at steady state."

290. Baillie likewise stresses the importance of determining whether any of a drug's metabolites are present at higher levels in humans than in animal test species. Baillie states that if an imbalance is detected, the next step is to determine whether "such 'disproportionate' human metabolites exceed 10% of the area under the plasma concentration vs time curve (AUC) of the unchanged parent"—a further red flag. The AUC, or "Area Under the Curve," percentage is significant as it reflects the actual body exposure to a drug after administration of a dose of the drug.

291. If a disproportionate metabolite is identified, the FDA guidance sets forth multiple categories of studies "to be conducted to assess the safety" of such a metabolite. This battery of tests includes: general toxicity studies, genotoxicity studies, embryo-fetal development toxicity studies, and carcinogenicity studies.

292. Penner, et al. recognize the need for further tests regarding disproportionate metabolite levels identified during drug development and, thus, the importance of early metabolite identification: "Additional toxicological testing on metabolites that display higher exposure in humans than preclinical animal species may be required. ***For such metabolites, the [FDA] Guidance recommends that they be synthesized and evaluated by direct administration to test animals and the study reports be submitted prior to commencement of large-scale clinical trials***."

(b) Celgene Fails to Conduct Critical Metabolite Testing in Contravention of Governing Guidance and Industry Standards

293. Notwithstanding the need for additional, time consuming safety studies with respect to any disproportionate metabolites that are identified, Celgene pushed forward with large-scale Phase III clinical (i.e., human) trials of Ozanimod after the Receptos acquisition in an effort to expedite submission of the Ozanimod NDA. In doing so, the Company delayed administration of the "gold standard" radiolabeled mass balance study.

294. After the Receptos acquisition, Celgene forged ahead with the Phase III SUNBEAM and RADIANCE trials and only later circled back to finish the necessary Phase I testing. As FE 21 explained, Celgene reported to the market the "sexier" efficacy findings for Ozanimod first, and then sought to backfill the results from the "non-sexy" clinical pharmacology testing that must be conducted throughout drug trials. These "non-sexy" tests examine aspects such as how a drug impacts the body or absorption rates and are typically completed during Phase I (i.e., the first in-human studies). With respect to Ozanimod, however, FE 21 reported that Celgene was still undertaking many Phase I Ozanimod studies in 2016, notwithstanding that the Company had been proceeding with large-scale Phase III clinical trials for more than a year.

295. The Code of Federal Regulations ("CFR")—a codification of the rules established by U.S. Federal Government agencies, including the FDA—confirms that Celgene's decision to push forward with the Phase III trials without first completing the threshold Phase I studies was out of sequence. As these regulations explain, "the clinical investigation of a previously untested drug is generally divided into three phases," Phase I, II and III, and "***in general the phases are conducted sequentially***." 21 C.F.R. 321.21. Phase I studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans," among other things. Phase III

studies, by contrast, "are performed after preliminary evidence suggesting effectiveness of the drug has been obtained."

296. Celgene's acceleration of the Ozanimod Phase III testing—despite not having completed Phase I testing, including the "gold standard" radiolabeled mass balance study—conditioned the market that the Company was in position to file the Ozanimod NDA by the end of 2017. For example, Celgene represented in a November 5, 2015 slide presentation given during the Company's third quarter conference call that "Ozanimod Clinical Development Continues to Progress on or Ahead of Schedule." Unaware that Celgene had not yet completed Phase I testing, analysts reporting on the conference call repeated Defendants' representations regarding the timing of the NDA for Ozanimod. Jefferies Group LLC listed the "potential launch in MS" for Ozanimod as mid-2018. Morningstar similarly reported that Ozanimod is "poised to reach the market in 2018" and also referenced Ozanimod's "potential approval in multiple sclerosis" in 2018. An RBC Capital Markets analyst also wrote that Ozanimod was "ahead in timing."

4. Celgene Belatedly Identifies a New Metabolite that Imperils the Company's Timeline for FDA Approval

297. Celgene did not undertake the testing necessary to identify all of Ozanimod's metabolites until October 2016—fifteen months after first acquiring Receptos. On October 17, 2016, Celgene began recruiting study subjects for a "**Phase I**, Single-Centre, Single Dose Oral Excretion Balance Study of [14C]-RPC1063 in Healthy Male Adults" (the "Mass Balance Study"). One of the stated primary objectives of this study was "[t]o determine how the drug [Ozanimod] moves through the body [i.e., is metabolized] and how fast it is removed from the body." Through this Mass Balance Study, which was completed on November 21, 2016, Celgene identified the Metabolite—a disproportionate and highly active metabolite, later labelled as CC-112273—which triggered the need for the additional testing described in the FDA guidance.

298. Celgene's laggard discovery of the Metabolite is confirmed by former Celgene employees. For example, FE 20 stated that the Metabolite was discovered in 2016 during a radiolabel drug study. FE 21 similarly stated that the Company identified a new metabolite approximately a year before the Company submitted the Ozanimod NDA in December 2017.

299. FE 21, who had first-hand knowledge of the discovery of the Metabolite, discussed the Metabolite with his manager and stated that its discovery was of great concern. As FE 21 explained, his manager told him not to tell anyone about the Metabolite finding—instead, FE 21's manager and the leader of Receptos, who other former employees have identified as Defendant Martin, would tell him who needed to know. FE 21 understood that the individual with his parallel role at Celgene and his manager's equivalent at Celgene both knew about the discovery of the Metabolite. FE 21 also learned that members of Celgene's senior leadership knew about the discovery of the Metabolite and received updates on the issue.

300. Upon discovering the Metabolite in November 2016, Defendants recognized that they had to conduct additional studies of the Metabolite prior to submitting the Ozanimod NDA. The results of the Mass Balance Study revealed that the concentration of the Metabolite in humans, measured by the AUC, far exceeded the 10% threshold trigger for additional testing set forth in the FDA guidance. Moreover, as the Company would later disclose after the Class Period (*see infra* ¶ 333), the Metabolite is disproportionately formed in humans and accounts for 90% of Ozanimod's activity.

301. Thus, Defendants knew in November 2016 that the Metabolite triggered ***both*** of the FDA-established thresholds for additional testing. In other words, because the Metabolite was: (i) "present at disproportionately higher levels in humans than in any of the animal test species";

and (ii) "formed at greater than 10 percent of parent drug systemic exposure at steady state," it "raised a safety concern" and should have been "considered for safety assessment."

302. In addition, the Mass Balance Study revealed that the half-life for the Metabolite was significantly longer than Ozanimod's half-life of nineteen hours, which the Company had repeatedly promoted as a competitive advantage for Ozanimod over Gilenya during the Class Period. In fact, the Company waited until after the Class Period to disclose that the half-life of the Metabolite was ***ten to thirteen days***.

303. Multiple witnesses confirm that Defendants knew that Celgene needed to conduct further testing on the Metabolite prior to filing the Ozanimod NDA. FE 21 recounted that immediately after discovering the Metabolite, he and others at Celgene began working on several additional studies. FE 21 characterized these efforts as "herculean" and "monumental," explaining that Celgene started new studies and went back and looked at closed findings to extract more data. FE 21 also indicated that Celgene's senior leadership was briefed on the discovery of the Metabolite and the ongoing characterization efforts "quite some time before the filing" of the NDA. Furthermore, FE 21 confirmed that, over time, the team working on issues surrounding the Metabolite grew.

304. Similarly, FE 5 recalled that Defendant Tran, Receptos' Head of Clinical Pharmacology, confirmed the need for additional testing and studies of the newly discovered Metabolite during an Ozanimod meeting in March or April of 2017. This meeting was attended by Martin, Saillot (who reported to Martin), Paul Frohna ("Frohna") (Vice President of Clinical Development and Translational Medicine, Receptos, who reported to Martin), Kopicko (Executive Director of Biometrics, Receptos, who reported to Martin), Darryl Penenberg ("Penenberg") (Director, Receptos, who reported to Kopicko), Aranda (Vice President of Clinical Development,

Receptos, who reported to Martin), Brett Skolnick ("Skolnick") (Executive Director of Clinical Development, Receptos, who reported to Aranda), and others.

305. FE 5 stated that, at this meeting, Tran, who worked on the radiolabeled Mass Balance Study and was responsible for analyzing the Metabolite and preparing the pharmacokinetic report, discussed the high amounts of the Metabolite that were found in humans (but not in animals) and the need to conduct further studies. According to 5, Tran directed his comments to Martin and Saillot, and Martin and Saillot quickly shut down the conversation regarding the Metabolite and moved on to a separate testing discussion.

306. Despite discovering the Metabolite and the need to complete additional testing before submitting the Ozanimod NDA to the FDA—circumstances which jeopardized Celgene's timeline for NDA submission at the end of 2017—Defendants concealed and misrepresented these material facts from investors. For example, after discovering the Metabolite and recognizing the need for additional Phase I testing, Defendants deceptively represented to investors in Celgene's Annual Report on February 10, 2017 and in its quarterly report on April 27, 2017, that the status of Ozanimod's development was "**Phase III**," when in fact, substantial **Phase I** studies on the Metabolite were now required.

307. Defendants also continued to represent that Celgene was on track to submit the NDA before the end of 2017 and was only waiting on the final results from the Phase III RADIANCE and SUNBEAM trials. For example, Alles stated during the J.P. Morgan Healthcare Conference on January 9, 2017: "We have two Phase 3 trials that have completely accrued and expect to have the data during the first half of this year . . . ***contingent on that, we will file an NDA for Ozanimod in multiple sclerosis by the end of the year***." Alles said nothing about the discovery of the Metabolite two months earlier, the need for further testing as a result, or the impact

this further testing would have on the end-of-2017 target for submission of the NDA. In reporting on the conference, J.P. Morgan analysts wrote that "NDA submission by Y[ear] E[nd] [20]17" was a "Key 2017 catalyst[]." A JMP Securities analyst similarly stated that "the submission of an NDA for ozanimod in patients with multiple sclerosis" was a "key 2017 corporate milestone[]."

308. After Celgene received the results from the SUNBEAM and RADIANCE trials in the spring of 2017, Defendants repeatedly touted the findings of these Phase III studies and assured investors that, based on these results, Celgene planned to submit the Ozanimod NDA by the end of 2017. For example, on July 27, 2017, during Celgene's second quarter 2017 conference call, Defendant Curran stated: "We announced positive results from RADIANCE, our second Phase III trial of ozanimod in MS and are on track to file the U.S. NDA by the year end." Defendant Smith added, "we feel very, very good about the data that's emerging for ozanimod," never once mentioning the Metabolite.

309. These statements were materially false and misleading because Defendants touted the completion of the Phase III studies—putting the issue of Ozanimod's development status into play—but did not disclose anything about the discovery of the Metabolite or the need to complete additional, protracted, and laborious Phase I testing which undermined Celgene's promise to submit the NDA by year-end. As far as the investing public knew, Ozanimod was well beyond Phase I. Nothing was further from the truth.

310. Further deceiving investors, on August 7, 2017, the *Journal of Clinical Pharmacology in Drug Development* published a paper authored by Defendant Tran and several other Celgene employees entitled "Cardiac Safety of Ozanimod, a Novel Sphingosine-1-Phosphate Receptor Modulator: Results of a Thorough QT/QTc Study." In this paper, Tran stated: "Metabolism studies in animals identified 3 pharmacologically active metabolites (RP101988,

RP101075, and RP101442) that have similar S1P selectivity and potency in vitro to ozanimod" and described the characteristics of these three metabolites. The article also included a Figure 1 that purported to identify the "Chemical structures of ozanimod ***and its active metabolites***."

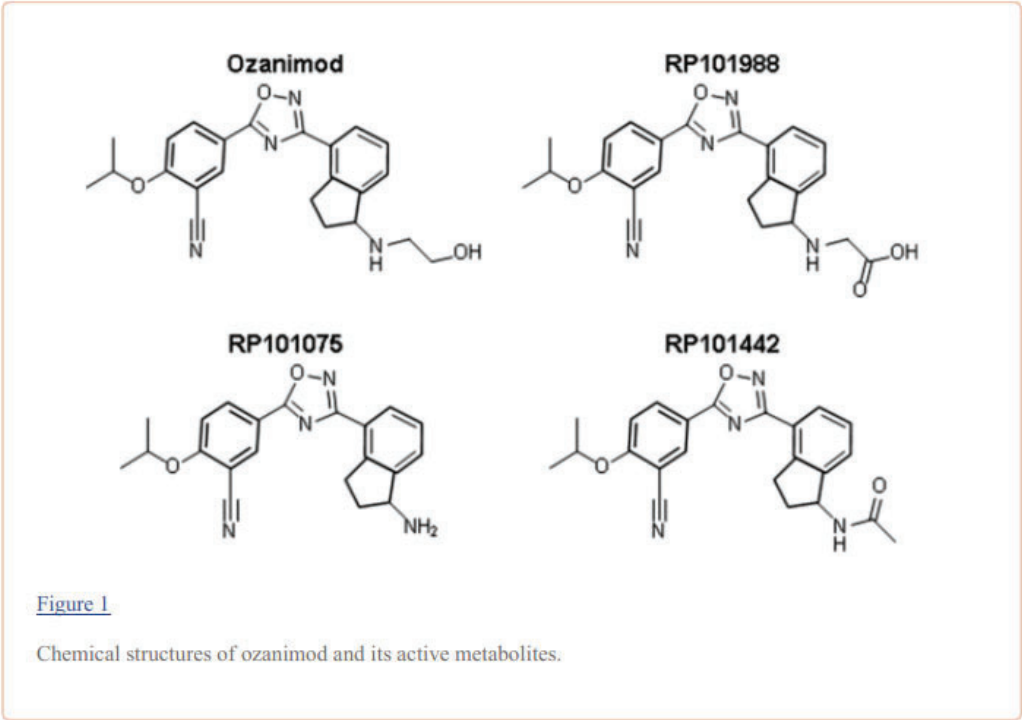


Figure 1

Chemical structures of ozanimod and its active metabolites.

311. Tran's paper made no mention of the Metabolite or the requisite additional testing, thereby misleading the scientific and investor community and perpetuating Defendants' concealment of the impact of the Metabolite on the Company's submission of the Ozanimod NDA.

5. Celgene Knowingly Submits a Facially Deficient and Incomplete NDA

312. As discussed above, Celgene was eager to rush Ozanimod to market so that it could compete directly with Gilenya and capture market share before Gilenya went off patent in 2019. Accordingly, Celgene determined not to wait until the additional Metabolite testing was complete and instead forged ahead with the NDA submission, knowing that it was deficient and almost certain to be rejected by the FDA.

313. FE 21 stated that he and his colleagues disagreed with the Company's decision to push forward with the NDA, instead believing that the Company should wait and finish all of the necessary testing and other work before submitting the NDA. He explained that he and his colleagues could not understand why the Company would not invest the additional time to perform the necessary testing prior to submitting the NDA, especially when an RTF letter, which results from a deficient NDA filing, could severely damage Celgene's reputation. According to FE 21, there was no empirical reason for pushing ahead with the deficient filing. When FE 21 shared his thoughts with his managers, he was told to keep his views to himself.

314. In or around August 2017, FE 21 discussed with his colleagues the likely outcome of the Company's decision to file the NDA without the full results of the additional Metabolite testing. Specifically, FE 21 and his colleagues concluded that Celgene would receive an RTF letter due to the absence of the requisite test results. As FE 21 explained, ***the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file, and he thought other teams felt that way too from speaking with them***. FE 21 shared his concerns with his direct management. FE 21 and his colleagues also discussed the likelihood that the Company would blame Receptos personnel and the clinical pharmacology team for the RTF, and there would be massive layoffs as part of the fallout. As FE 21 stated, he and his colleagues were concerned that an RTF would cause "heads to roll locally and up top at Celgene."

315. In spite of these grim misgivings inside the Company, on October 26, 2017, Celgene held its third quarter 2017 conference call during which Defendants painted a very different picture for the investing public. During the call, Defendant Curran reiterated the false mantra that Ozanimod "remains ***on track for regulatory submission***, beginning with the U.S. by year-end . . . ."

316. According to FE 22, in November 2017, the FDA confirmed that Celgene was required to submit the results of the additional Metabolite testing with its NDA. Specifically, prior to filing the NDA, Celgene was involved in discussions with the FDA concerning the submission, which culminated in a November 2017 in-person meeting, known as a pre-NDA meeting. FE 21 understood that the "mini-NDA" package Celgene provided to the FDA in advance of the pre-NDA meeting and months before the NDA filing included information regarding the Metabolite and Celgene's work and findings to date.

317. FE 22 later learned that, during the pre-NDA meeting in November 2017, the FDA expressly told the Company that: (i) the FDA required the study results for the Metabolite; (ii) the results were very important; and (iii) the results had to be included in the Ozanimod NDA.

318. Even after the FDA explicitly told Celgene during the Company's pre-NDA meeting that Celgene must include the results of the additional Metabolite studies as part of its NDA submission—thus confirming what the Company had already recognized internally for months—Celgene pressed ahead with its plan to file the NDA without the test results, knowing that it was almost certain that the FDA would reject the NDA.

319. FE 22 confirmed that the Company moved forward and submitted the Ozanimod NDA without the required data in December 2017. FE 22 explained that one of the additional Metabolite studies was underway in December 2017, but results of that study were not to be received until April 2018—four months after the Company's self-imposed filing deadline. Celgene nevertheless chose to submit a facially incomplete NDA without the results rather than delay the filing. FE 22 had heard that Martin and Saillot "***just wanted to get the NDA out the door***." FE 20 echoed FE 22's account, explaining that the Ozanimod NDA had been "***hustled forward***."

320. Celgene's decision to push ahead with a facially deficient NDA submission which lacked the required Metabolite test results was motivated by two principal factors. First, as discussed above, Celgene was motivated to submit the NDA prematurely in order to begin marketing Ozanimod and gain market share before generic versions of Gilenya began to enter the market in 2019.

321. Second, many of Celgene's high-ranking employees were entitled to receive bonuses upon mere submission of the NDA to the FDA. FE 22 recounted that both Martin and Saillot received bonuses for submitting the Ozanimod NDA by year-end 2017. FE 20 similarly confirmed that the compensation for the Celgene and Receptos personnel, including Martin, was tied to the Ozanimod NDA filing. FE 20 explained that this was the "carrot" for the employees, and the higher one went up the corporate chain, the greater the amount of compensation tied to the NDA filing. Confirming these accounts, as set forth in Celgene's proxy statement filed with the SEC in 2017, Defendants Hugin, Alles, Kellogg and Smith were all entitled to performance awards based in part on the "filing of a new drug application." Notably, Hugin, Alles, Kellogg and Smith received lucrative performance awards for 2017 of $2,175,000, $2,144,623, $800,352, and $845,495, respectively, along with company stock.

322. In the months following Celgene's Ozanimod NDA filing, Defendants continued to tout the NDA submission and expected FDA approval, while withholding from investors material adverse information regarding the Metabolite and the Company's decision to submit the NDA without the requisite test results, even though the FDA told the Company in November 2017 that such results were required for approval. For example, on January 8, 2018, Celgene filed a press release in a Form 8-K with the SEC that identified the "FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)" as a "2018 Expected

Operational Milestone[].” Similarly, despite the great concern that arose when Celgene found the Metabolite in November 2016 and Celgene’s decision not to perform the required testing prior to its NDA submission, the Company highlighted other testing results on a January 25, 2018 Form 8-K, but made no mention of the Metabolite and the further Phase I testing required for FDA approval. As Celgene stated: “In December, a New Drug Application (NDA) was submitted with the FDA for ozanimod in relapsing multiple sclerosis (RMS) based on data from the phase III RADIANCE Part B and SUNBEAM trials evaluating ozanimod in patients with RMS.”

6. The FDA Refuses to File the Ozanimod NDA

323. On February 27, 2018, Celgene once again stunned the market by disclosing that it had received an RTF letter in response to its Ozanimod NDA submission.

324. The FDA can refuse to file an NDA and issue an RTF letter if it identifies clear and obvious deficiencies in a company’s submission. As the FDA’s Standard Operating Policy and Procedure (“SOPP”) explains:

> ***[A]n RTF is based on omissions of clearly necessary information*** (e.g., information required under the statute or regulations) or omissions or inadequacies so severe as to render the application incomplete on its face and where the omissions or inadequacies are obvious, at least once identified, and not a matter of interpretation or judgment about the meaning of data submitted.

325. The SOPP provides that an RTF “[i]s not an appropriate vehicle for dealing with complex issues and close judgments on such matters as balancing risks and benefits, magnitude of clinical effect, acceptability of a plausible surrogate marker, or nuances of study design.” Instead, an RTF is based on “***[s]cientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety, purity and potency or provide adequate directions for use***.” Thus, an RTF indicates the FDA’s threshold rejection of an NDA based on facial inadequacies identified through a summary review of the NDA’s contents, rather than an in-depth,

all-encompassing review of the substantive data and information underlying the submission. In other words, receipt of an RTF letter sends a clear message that the identified deficiency is patently obvious and that the NDA should never have been filed in the first place.

326. There is little publicly available information regarding the frequency of RTF letters because the FDA does not release information on the subject and companies have no independent obligation to disclose RTFs. However, the limited available information suggests that RTF letters are exceedingly rare. For example, using the subscription data service BioMedtracker, *Forbes* reported that the FDA issued just forty-five RTF letters in connection with NDA applications in the sixteen-plus years between December 31, 2001 and February 28, 2018. Moreover, receipt of RTFs by experienced and well-capitalized pharmaceutical companies like Celgene is virtually unheard of. As William Blair stated in a report entitled, "While Not a Crisis for Ozanimod, FDA's RTF Letter Represents Another I&I Franchise Setback and Could Lead to a One-Year Delay," published in the wake of the FDA's RTF for Ozanimod: "In our view, well managed and high quality large-cap biotech companies do not make execution mistakes like the one disclosed on Tuesday [by Celgene]."

327. Celgene broke the news of the RTF letter to investors in a press release on February 27, 2018, stating: "Upon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review."

328. Analysts expressed both shock and concern upon the Company's revelation of the RTF. For example, Leerink Partners noted in a report entitled "How Many Self Inflicted Wounds Are Excusable? Ozanimod Delay at Least a Year," that the RTF "only adds to investors' growing unease with the company's direction and oversight of key activities" and observed that "***the company clearly made a decision to file this application at risk***, despite late information that

might have been more thoroughly disclosed and explored in the application, had the filing been postponed by a few months." As Leerink Partners further explained:

> Celgene appears to have ***gambled on the ozanimod filing in December 2017*** while knowing about the unanticipated finding from a late-stage clinical pharmacology trial [i.e., the Mass Balance Study] after the two phase IIIs read-out successfully. ***This study seemed to duplicate the type of study that would originally have been completed by Receptos, and the completion of the study itself suggests some recognition of a deficiency in the early clinical package prepared by the prior owner***.

329. William Blair also wrote: "Obviously, investors are frustrated by another setback in the autoimmune franchise, especially in light of late last year's mongersen failure in Crohn's disease, clinical delay for ozanimod in ulcerative colitis, and soft third-quarter sales for Otezla."

330. In the wake of the RTF announcement, the price of Celgene's common stock fell from $95.78 per share on February 27, 2018 to $87.12 per share on February 28, 2018. Defendant Smith, who had been promoted from head of I&I to COO in April 2017, was ushered out of Celgene in April 2018. George Golumbeski, Celgene's head of business development who was lauded as the chief architect of Celgene's acquisition strategy, also left the Company in April 2018. In addition, Defendant Martin was relieved of his responsibilities at Receptos in June 2018 and, according to FE 22, the employees within Martin's command at Receptos were let go after Celgene received the RTF. Furthermore, the 2018 proxy statement removed the "filing of a new drug application" as a factor in deciding upon senior management performance awards.

7. Celgene Admits that the RTF Was Due to Its Failure to Properly Test the Metabolite

331. On April 25, 2018, several scientists gave a presentation at the American Association of Neurology ("AAN") 2018 Annual Meeting in Las Vegas, Nevada entitled "Safety of Ozanimod Versus Interferon β-1a in Two Multicenter, Randomized, Double-Blind, Parallel-Group, Active-Controlled, Double-Dummy Phase 3 Studies in Relapsing Multiple Sclerosis

(SUNBEAM and RADIANCE Part B)." This presentation, which was partially funded by Celgene, disclosed to investors certain specifics of the Metabolite, dubbed CC-112273 by the Company, stating that: "Ozanimod is metabolized in humans to form one major active and other minor active metabolites"; "CC112273 accounts for the majority of the total activity of ozanimod in humans"; and "CC112273 is a minor metabolite in animal species."

332. Just days after the 2018 AAN annual meeting, the market learned that the additional preclinical work required to test the Metabolite could delay Celgene's refiling of its Ozanimod NDA for ***up to three years***. This is precisely the kind of significant delay that the FDA guidance cautions that drug companies should avoid by conducting the required metabolite safety testing early, before NDA submission. Specifically, on April 29, 2018, Morgan Stanley published a report entitled "More Bread Crumbs Yield Less Confidence In Ozanimod" that provided a detailed analysis comparing the recently disclosed information regarding the Metabolite to the data from the Company's earlier pre-clinical studies involving Ozanimod's other metabolites. This analysis demonstrated that Celgene would need to run additional pre-clinical toxicology studies, which could take six months to two years. Thus, when combined with the time needed to start the studies, produce the study results and refile the NDA, these additional studies would result in a total delay of one to three years. In response to the news of a further delay, Celgene's common stock fell from $91.18 per share on Friday, April 27, 2018 to $87.10 per share on Monday, April 30, 2018, the next trading day.

333. During its first quarter 2018 conference call on May 4, 2018, Celgene confirmed that the RTF arose as a result of the Metabolite and that Celgene discovered the Metabolite through the Mass Balance Study in November 2016. Jay Backstrom, Celgene's Chief Medical Officer, stated, in part: "[T]he key issues for the Refusal to Rile centered on the completeness of the clinical

pharmacology and the nonclinical portions of the NDA. These issues relate to the major active metabolite, CC-112273." Specifically, Backstrom stated that the Company conducted "a radio-labeled human mass balance study" that "identified CC-112273 as a major metabolite, accounting for approximately 90% of the activity" and that CC-112273 "disproportionately formed in humans and was not identified as a major metabolite in the nonclinical [i.e., animal] pharmacology studies." Backstrom further revealed that the half-life of the Metabolite is ***ten to thirteen days***, compared to the previously reported Ozanimod half-life of nineteen hours, thus confirming that Ozanimod had lost one of its key competitive advantages over Gilenya.

334. Celgene admitted that, upon review of the Ozanimod NDA, the FDA "requested further characterization of CC-112273." Alles claimed to be surprised by the FDA's decision, stating that: "[T]he hindsight view is that the characterization of [the] metabolite was something that we simply underestimated in the context of FDA's decision." FE 2, however, rejected Defendants' claims, stating that, based on his experience with more than five NDA submissions, it was "incomprehensible" that Celgene was surprised by the FDA's interest in the Metabolite.

335. In explaining the Company's plan for Ozanimod going forward, Backstrom stated that after the Company's meeting with the FDA in early 2018, Celgene planned to utilize data from the existing and ongoing clinical pharmacology studies to provide the requisite safety assessment for the Metabolite. Backstrom also attempted to reassure investors: "***This work is well underway and will be incorporated into a new submission now targeted for Q1 2019***."

336. Following Celgene's first quarter 2018 conference call, analysts and other commentators condemned Celgene for its decision to file the NDA without adequate characterization of the Metabolite. An *In the Pipeline* article entitled "Finger-Pointing at

Celgene," questioned: "[W]hy wasn't [the] issue [of the Metabolite] fully addressed for the FDA?" The article stated that Celgene should have discovered the Metabolite during Phase I testing:

> Analyzing blood levels of the parent compound and metabolites is one of the biggest points of Phase I, actually, so it's not like this could have been overlooked. If you find out that what you thought was your drug is apparently just a prodrug for what's really working *in vivo*, well, you have more work to do. ***But it appears that lack of data about the metabolite could have been one of the main reasons the FDA found the NDA unworkable, which just makes no sense***.

8. Celgene Attempts to Blame Receptos for the RTF

337. In an effort to deflect criticism for the RTF debacle away from Celgene itself, Defendants blamed Receptos for the deficient NDA filing, but in doing so, admitted that they knew the NDA was faulty upon submission. Specifically, Defendant Ahmed stated in a June 13, 2018 *Financial Times* article that "***I think that 99 percent of folk[s] at Celgene wouldn't have submitted [the NDA],*** but we had Receptos out on the West Coast and, for whatever reason, the decision was made to submit . . . . We learned a lesson of humility and that when you do an acquisition it's better to be more integrated rather than be completely away from the mothership." Ahmed's comments, which confirmed that Celgene knew that its NDA filing was deficient prior to submission, thoroughly undermined Alles' representation to investors that the FDA's focus on the Metabolite was unanticipated and something that the Company "underestimated." Ahmed also stated that FDA officials were "actually quite surprised" with the deficient quality of the Ozanimod NDA and that "[the FDA] kinda said 'what happened guys, this isn't what we usually expect from Celgene?' And we had to say, you know, '***mea culpa, it's on us***.'"

338. The former CEO of Receptos, Faheem Hasnain ("Hasnain"), quickly disputed Ahmed's attempt to place all the blame on Receptos and leave Celgene unscathed. Hasnain emphasized to the market that "[i]t's important to know that ***Celgene had on-site control and oversight for two-and-a-half years before this filing took place***," and made clear that at the time

of Celgene's acquisition of Receptos in mid-2015, Receptos "had mapped out the rest of the development and regulatory plans, with the rest of the pharmacology studies that needed to be done in a timely fashion." Hasnain's comments were echoed by Frohna, the former Vice President of Clinical Development and Translational Medicine at Receptos, who was "responsible for conducting positive Phase 2 clinical trials and two ongoing Phase 3 trials with Ozanimod in relapsing multiple sclerosis (RMS) and ulcerative colitis." In a user comment responding to the article in which Hasnain was quoted, Frohna stated: "***Thanks for setting the record straight Faheem! You beat me to it*** . . . ."

339. FE 21 and his colleagues were not surprised by what they called the "bullshit blame game" that followed the RTF. FE 21 further stated that the idea that the final NDA submission could be made without the approval of Celgene's leadership was nonsensical. Likewise, FE 22 explained that the NDA would not have been submitted without the approval of Celgene headquarters, as it was too important a decision to be made at the Receptos executive level. FE 2 also rejected Celgene's attempt to cast blame on Receptos.

340. FE 20 further confirmed that Celgene's statements attempting to shift blame to Receptos for the RTF were empirically false, stating that "they [Celgene] were in charge. Receptos was not." FE 20 added that when Celgene acquired Receptos, Celgene moved in and took over, installed a new head of Receptos, had control over Receptos' budget, took Receptos out of the decision-making loop, placed Receptos under the control of Celgene's New Jersey headquarters, and decisions were made by Celgene in New Jersey or Celgene personnel located onsite at Receptos.

341. As of the date of this complaint, Celgene has yet to refile its Ozanimod NDA for MS. The Company still has not completed the required testing of the Metabolite. For example,

the "Drug-drug Interaction Study of Ozanimod with Inhibitor or Inducer of CYP2C8 and/or CYP3A," a study evaluating the potential for drug interactions with Ozanimod and the Metabolite, which is specifically contemplated by the FDA's Drug Interaction Guidance, is not expected to be completed until April 15, 2019. Accordingly, the necessary Phase I testing will not be completed until more than one year after the Company repeatedly and unwaveringly assured investors that Celgene would obtain approval of the Ozanimod NDA.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

342. During the Class Period, Defendants made a series of materially false and misleading statements and omitted material facts regarding: (i) the evidence of GED-0301's efficacy, including the strength of the Phase II clinical data and the design of the Phase Ib study, and the timeline for GED-0301's regulatory approval; (ii) Otezla's ability to gain market acceptance and meet the Company's 2017 financial guidance; and (iii) the completeness of the Ozanimod NDA for MS, the sufficiency of the underlying testing data, and the undisclosed discovery of a key, active metabolite that required further testing.

A. GED-0301

343. On January 29, 2015, Celgene hosted a conference call to discuss the Company's fourth quarter 2014 financial results. During this call, Defendant Smith touted the "***[s]triking Phase II data for [sic] GED-301***."

344. On March 11, 2015, Celgene participated in the Barclays Healthcare Conference. During the presentation, Smith had the following exchange with a Barclays analyst:

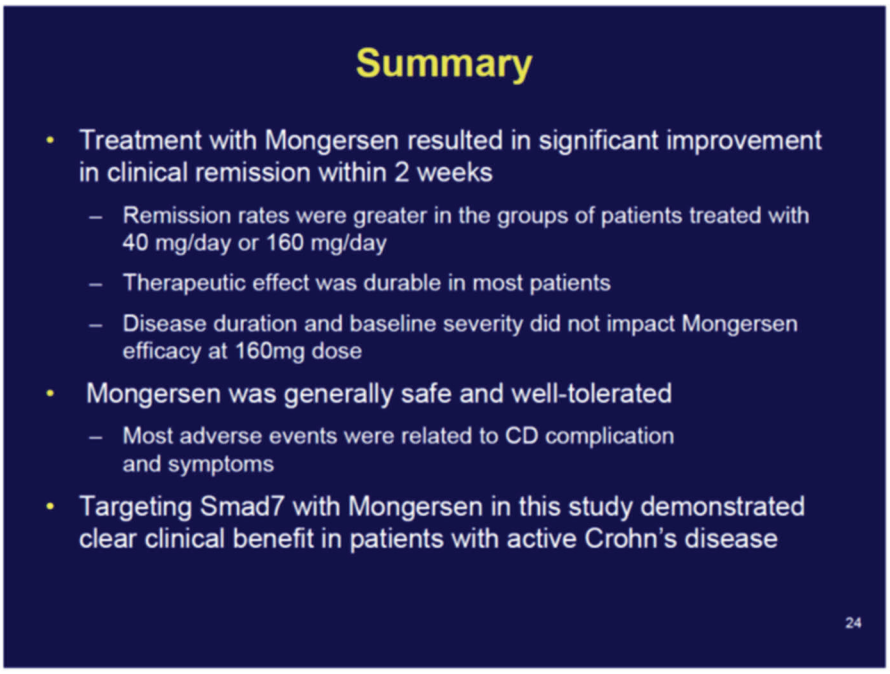
> [ANALYST:] Okay. So, on the, I guess from a biz dev front, you guys have been very, very active over the past couple of years and have some really, really compelling partnerships, but one of the deals last year was the Nogra Pharma deal for GED-301. So the data so far has been highly positive. Maybe, Scott, you could just help us out with kind of how you view the risk product profile of the drug now. How much of say endoscopy data really does add teeth to the profile? Ultimately,

> will it be sort of the basis for our regulatory endpoint or are we still back to the old sort of CDAI kind?
>
> [SMITH:] The [Phase II] data which first came out at UEGW [United European Gastroenterology Week], the abstract came out a few months ago, but just a tip of the iceberg in terms of data and we've been accepted for publication at a major medical journal and that should be happening in the next couple of weeks. So we're very excited about that because there is a lot more data in that article obviously and publication has just been shown through the abstract at UEGW. So, ***there is a real depth of information in terms of other endpoints and durability of response relative to severity of disease.*** So we're really excited to get that out and talk about it and have that in the public domain. So, I think that's great.

345. During this presentation, Smith also stated: "[F]rom the data that we saw, the Phase II data, where we have remission rates of the high dose, up in the 65%, 70% range of patients," adding that "if you can get good durability in those responses, it could completely transform the whole face of the marketplace in GI disease."

346. On March 18, 2015, Celgene issued a press release announcing the publication of the Phase II study results in the *NEJM*, stating: "The newly published findings from this phase II study showed that a significantly greater proportion of patients with active Crohn's disease achieved the primary endpoint of clinical remission at both day 15 and day 28 with once daily GED-0301." Based on these results, Defendant Smith stated that GED-0301 "has the potential to transform the Crohn's treatment landscape. We are encouraged by the phase II data . . . ."

347. In connection with the Company's presentation at the 2015 DDW conference on May 17, 2015, in which both Defendants Smith and Martin participated, Celgene issued and published a series of slides on its corporate website. One of these slides summarized the Phase II data and represented that the data showed "significant improvement in clinical remission" in study patients who were given GED-0301, "[t]herapeutic effect was durable in most patients," and the data "demonstrated clear clinical benefit in patients with active Crohn's disease":



348. Later in the presentation, Celgene presented the following slide touting GED-0301's "***Potentially Transformational Profile***," which represented that the efficacy of GED-0301 was already established by the Phase II data. Specifically, the slide represented that the "Rapid Onset of Efficacy" and "Superior Induction of Remission" are part of GED-0301's "current profile" based on existing data:

349. Analysts were reassured by the Company's statements. For example, in a May 18, 2015 report, SunTrust Robinson Humphrey accepted Defendants' defense of the Phase II data called into question in the *NEJM* editorial, stating: "Ad-hoc analyses of the Phase II study of GED-0301 in Crohn's disease ***suggest efficacy*** irrespective of baseline disease severity and CRP levels." The report also noted that the "key investor questions post Phase II data presentations revolved around the lack of endoscopic validation of CDAI improvement," but that the Phase Ib study Celgene "is slated to correlate endoscopy assessments . . . with CDAI improvement."

350. The statements in ¶¶ 343-348 above, including Defendants' statements touting the strength of the Phase II data and the evidence of GED-0301's efficacy, and defending the design of the Phase II study, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 104-204 above, Defendants' statements had the effect of concealing, and/or failing to disclose the following facts:

(i) Celgene acquired GED-0301 on the basis of efficacy data, including the Phase II data, that was recognized internally as highly questionable and indeterminate;

(ii) Celgene overlooked numerous red flags as part of its pre-acquisition due diligence, including concerns regarding both the reliability and the integrity of the Phase II data, as well as suspicions about the personal financial motive of the lead investigator who commercially developed GED-0301;

(iii) the Advisory Board recognized the limitations of the Phase II data, this fact was communicated to Celgene, and Celgene acknowledged the limitations of the data; and

(iv) in or around mid-2015, there were ongoing meetings among the GED-0301 development team, including with Usiskin, about the limitations of the GED-0301 Phase II study data, including the lack of endoscopic evidence.

By electing to speak publicly about the Phase II data, the purported evidence of GED-0301's efficacy and the design of the Phase II study—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding

these subjects so as to not mislead investors. As a result of the foregoing undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

351. On September 16, 2015, Celgene participated in the Morgan Stanley Healthcare Conference. During this conference, an analyst from Morgan Stanley asked Defendants whether the purchase of Receptos' Ozanimod, which is a potential treatment for CD, was an indication that the Company had lost confidence in GED-0301: "[W]hat does [the] Receptos [acquisition] signal about your confidence in GED given that they potentially could have overlapping indications?" In response, Alles stated:

> Let me answer it categorically, GED-0301 in Crohn's Disease is an asset that our belief from day one has only strengthened. We think the profile is miraculous and may actually be disease-altering which is why we're doing the [Phase Ib] endoscopy trial.

352. On January 11, 2016, Celgene participated in the J.P. Morgan Healthcare Conference. During this conference, Defendant Hugin reiterated that the Phase II data demonstrated GED-0301's efficacy:

> Over this past year, our progress in achieving building an[] inflammatory bowel disease franchise is significant. We had the progress made in our GED franchise with GED-0301. We are now enrolling Phase 3 patients in our programs. It's an important part of it.
>
> Millions of patients suffer from these diseases where there is not adequate therapies, and ***as you remember, we were here and told you [about] the incredible Phase 2 data. It is our mission to ensure that we replicate that in Phase 3 and we are on target to do that in the timelines that we have announced***.

353. One month later, on February 11, 2016, Celgene participated in the Leerink Partners Global Healthcare Conference. In response to a question regarding the impact of the loss of Revlimid's patent exclusivity, Alles stated:

> By itself, if I think about Crohn's disease, ulcerative colitis -- the biologics today -- somewhere in the range of $15 to $20 billion a year are being generated out of use

> in GI diseases. We think we can replace the biologics with GED-0301 and ozanimod.
>
> If we were able to do that with oral therapy, with long duration of treatment, and keeping patients in remission so they don't have to go to surgery; they don't have to cycle through multiple lines of therapy over and over and over again; that alone is enough to replace Revlimid in a window of time that is proximal to the loss of exclusivity. So if I could only just start there, ***I have line of sight -- and these are products in Phase 3 going through with Phase 2 profiles, giving them enormously high probability of success***.

354. On March 16, 2016, Celgene participated in the Barclays Global Healthcare Conference. During this conference, Defendant Kellogg responded to an analyst's question regarding GED-0301's prospects in CD and UC, stating:

> Then you come to kind of the next generation of assets. And the ones which you asked about are really kind of the next generation. And those have the trials right now in Phase III targeted at very high unmet need in GI, both GED-0301 and Ozanimod in ulcerative colitis, are oral agents. These are patients that typically progress to surgery, so the [health technology] assessment is actually quite straightforward. I mean, clearly, if you can delay or prevent future surgeries on the GI track that is a huge benefit.
>
> ***The data sets that we've seen so far are spectacular.***

355. On June 9, 2016, Celgene presented at the Jeffries Healthcare Conference. Alles again touted the evidence of GED-0301's efficacy, specifically calling out its "unique mechanism of action:"

> So, GED-0301 is a very important product, it's a small molecule oligonucleotide that ***has a unique mechanism of action that we think works quite well in the treatment of Crohn's disease***. . . . So it's very unique in that patient compliance should be very high, and we think ***the therapeutic profile so far looks like it could replace a lot of existing therapy***.

356. The statements in ¶¶ 351-355 above, including Defendants' statement touting the evidence of GED-0301's efficacy and mechanism of action, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in

¶¶ 104-204 above, Defendants' statements had the effect of concealing, and/or failing to disclose the following facts:

(i) Celgene acquired GED-0301 on the basis of efficacy data, including the Phase II data, that was recognized internally as highly questionable and indeterminate;

(ii) Celgene overlooked numerous red flags as part of its pre-acquisition due diligence, including concerns regarding both the reliability and the integrity of the Phase II data, as well as suspicions about the personal financial motive of the lead investigator who commercially developed GED-0301;

(iii) the Advisory Board recognized the limitations of the Phase II data, this fact was communicated to Celgene, and Celgene acknowledged the limitations of the data;

(iv) in or around mid-2015, there were ongoing meetings among the GED-0301 development team, including with Usiskin, about the limitations of the GED-0301 Phase II study data, including the lack of endoscopic evidence; and

(v) by March 2016, Celgene recognized internally that GED-0301's mechanism of action was not as described by its drug developer (Nogra) at the time Celgene acquired it, and that its delivery mechanism was obscure and "too fantastic to be true."

By electing to speak publicly about the Phase II data and the purported evidence of GED-0301's efficacy—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding this subject so as to not mislead investors. As a result of the foregoing undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

357. On September 12, 2016, filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to the Form 8-K, Celgene announced interim data from its GED-0301 Phase Ib study in CD. In the press release, Defendants Celgene and Kellogg stated that the interim data showed that "***in a proportion of patients treated with oral GED-0301 there was endoscopic improvement (defined as a 25 percent improvement from baseline) and clinical response and remission across all treatment groups at week 12***."

358. The press release quoted Smith as stating:

> Given the high unmet need in Crohn's disease, we are pleased that oral GED-0301 showed both endoscopic improvements and clinically meaningful responses and remission at an early timepoint in this study.

359. On September 12, 2016, Celgene also participated in the Morgan Stanley Global Healthcare Conference. During the conference, Smith doubled-down on his praise of the Phase Ib study results, stating in part:

> [W]e were very, very encouraged by what we saw in the particular study. We saw endoscopic improvements, clinical responses and clinical remissions across all 3 groups. . . . And we were very, very pleased with what we came up for results. And look forward to getting [that] out as quickly as we can on the full data.
>
> ***
>
> And that's what we've found in the study [as confirmed by endoscopy]. The patients were starting to heal.

360. Defendant Smith also touted the robustness of the Phase Ib study design, stating:

> ***It was very data heavy***, there was a ton of endpoints that we were looking at, both endoscopic endpoints and clinical endpoints. It was a patient population, which was different than we saw in the Phase II study in the past. There was [tumor necrosis factor or] TNF failures in there, there were prior surgeries in there, it was a study that was mainly done in the U.S. and we also include patients with much more sort of distal disease not just localized on the right side. So [it] was a very different patient population, a baseline [Crohn's Disease Activity Index or] CDAI was much higher than it was in Phase II. ***And so we really wanted to try the molecule out in a sort of a challenged environment***.

361. In addition, Smith represented that the lack of a control arm in the Phase Ib study did not undermine the strength of the data because a placebo group would not see a meaningful remission rate due to the severity of CD:

> There is no placebo in this particular study, but I will say I would expect the placebo rate in this particular population, this study from an endoscopic perspective to be very, very low. This confirms significant extensive disease at baseline, you wouldn't expect the placebo patients to be getting better, you'd probably expect the majority of them getting worse over that 12-week period, it would be unlikely that you would get many responses. So you would expect a low placebo rate given what we've done here, so what you'd want is to be able to feel good that you could

> separate from placebo and show statistically significant effects in our large powered study than you would achieve that end point.
>
> And having looked at all, and our interpretation of data is we feel very comfortable around the size, the structure and the timing of the Phase III program given that we've just -- given the data that we've just seen.

362. Finally, Smith described the Phase Ib study as "***validating***" of both the Phase II clinical data on which Celgene relied when it acquired the rights to GED-0301 and Celgene's decision to continue with the Phase III trial:

> What we did is I think we saw outstanding responses, clinical responses and we saw outstanding clinical remissions for this population. For any population I thought it looked very solid. ***To me this study was validating and it was validating not only of the Phase II program*** and this again is a very difficult to treat population, so seeing good responses in this population is really something extraordinary. And so that's wonderful. And then ***it's also validating of the structure of the Phase III program that we put together***. And so again, I don't anticipate taking a look at this that we would make major changes to the structure or timing of the Phase III program that is actively enrolling.

363. The statements in ¶¶ 357-362 above, including Defendants' statements touting the strength of the Phase II data, the evidence of GED-0301's efficacy and the results of the Phase Ib study, and their statements defending the design of the Phase Ib study, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 104-204 above, Defendants' statements had the effect of concealing, and/or failing to disclose the following facts:

> (i) Celgene acquired GED-0301 on the basis of efficacy data, including the Phase II data, that was recognized internally as highly questionable and indeterminate;
>
> (ii) Celgene overlooked numerous red flags as part of its pre-acquisition due diligence, including concerns regarding both the reliability and the integrity of the Phase II data, as well as suspicions about the personal financial motive of the lead investigator who commercially developed GED-0301;
>
> (iii) the Advisory Board recognized the limitations of the Phase II data, this fact was communicated to Celgene, and Celgene acknowledged the limitations of the data;

(iv) in or around mid-2015, there were ongoing meetings among the GED-0301 development team, including with Usiskin, about the limitations of the GED-0301 Phase II study data, including the lack of endoscopic evidence;

(v) by March 2016, Celgene recognized internally that GED-0301's mechanism of action was not as described by its drug developer (Nogra) at the time Celgene acquired it, and that its delivery mechanism was obscure and "too fantastic to be true";

(vi) the Phase Ib study was designed in such a way as to limit the chances that GED-0301 would be shown to be ineffective;

(vii) it was recognized internally at the Company that, due to the lack of a placebo arm in the Phase Ib study, Defendants' claims regarding GED-0301's efficacy were not supported by the Phase Ib study results;

(viii) non-public interim trial data received and analyzed by Celgene and its representatives demonstrated GED-0301's lack of efficacy, as evidenced by one of the principal investigators for the Phase Ib trial reporting to Celgene that there was no endoscopic response observed at his testing site;

(ix) Celgene's decision to license GED-0301 and proceed with the Phase III trial was a "business decision" rather than a decision based on the scientific evidence; and

(x) there was growing concern from at least September 2016 that GED-0301 would not make it past the Phase III clinical trials, as evidenced by the fact that between the time the Phase Ib data was released in September 2016 and the time the Phase III trial was discontinued in October 2017, GED-0301 was not discussed during the internal quarterly review meetings with Celgene's Vice Presidents, in which the Company's pipeline of drugs were typically discussed; Celgene was treating the drug as if it had already been written off.

By electing to speak publicly about the Phase II data, the purported evidence of GED-0301's efficacy and the design of the Phase Ib study—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding these subjects so as to not mislead investors. As a result of the foregoing undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

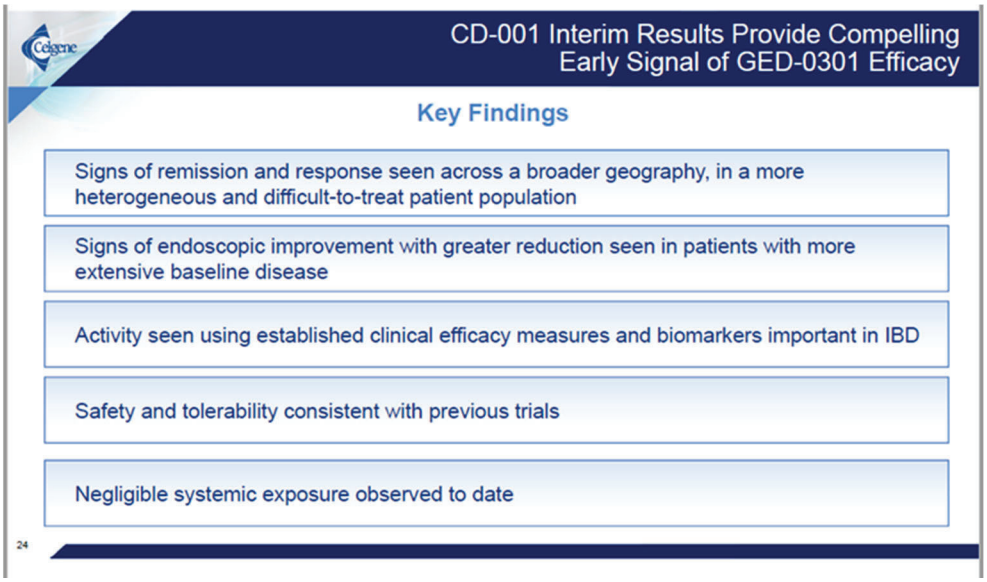
364. On October 16, 2016, Celgene issued a press release announcing the interim results from the Company's Phase Ib study for GED-0301 in CD, the headline of which stated: "***Oral GED-0301 Phase 1b Results Show Clinical Remission and Endoscopic Response at Week 12 in Patients with Active Crohn's Disease***." The press release stated: "Of the patients with evaluable endoscopies at week 12 [ ] 37 percent had an endoscopic response," which Celgene defined as equal to or greater than a 25 percent reduction in SES-CD score. The press release quoted Smith as stating: "We are encouraged that ***oral GED-0301 showed both meaningful endoscopic improvement and clinical remission at an early time point in this study***."

365. On October 18, 2016, Celgene hosted a conference call to discuss the data from the Phase Ib GED-0301 clinical study. During this call, Smith stated: "We are very encouraged by ***the validating results we have seen to date***." Smith continued:

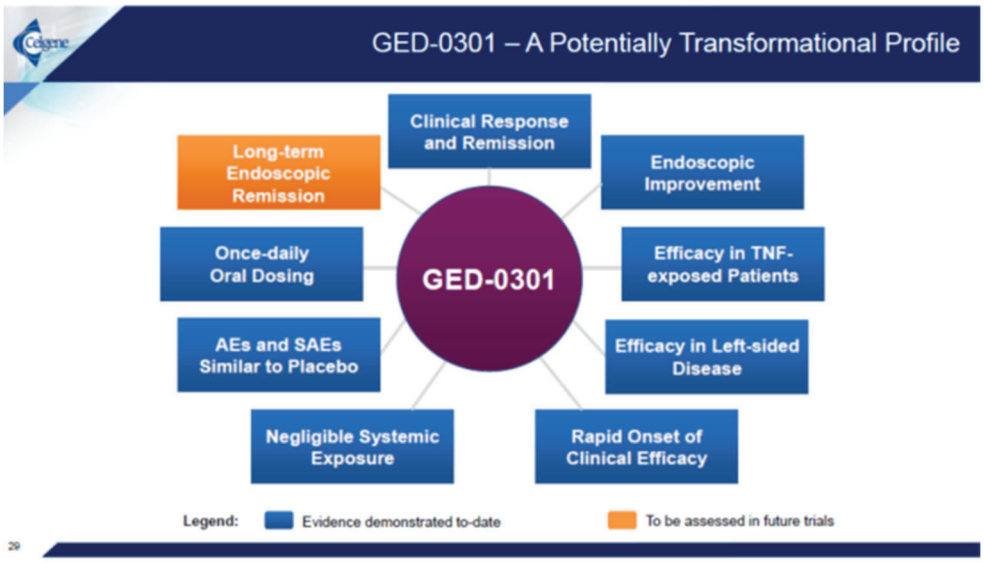
> The CD-001 [Phase Ib] trial is still ongoing, but based on the interim results, we don't anticipate needing to make any major structural changes to the phase 3 program. Keeping our assumptions for powering and time lines the same, ***planning remains on track for GED submission to the FDA in 2018 and expected approval in 2019***.

366. Defendant Callegari stated, "The efficacy seen in this exploratory trial, in terms of clinical response, remission, and endoscopic improvement seen validates previous GED trials and reinforces the potential of GED for patients with active Crohn's disease."

367. As part of Defendants' presentation to investors, Celgene issued and published a series of slides on its corporate website. One of these slides, entitled "CD-001 Interim Results Provide Compelling Early Signal of GED-0301 Efficacy," touted GED-0301's purported evidence of efficacy and claimed that the interim results of CD-001 provided a "Compelling Early Signal of GED-0301 Efficacy" and showed "Signs of endoscopic improvement":



368. Defendants also represented in a second slide that the data Celgene had accumulated to date, including the Phase II and IB studies, provided "evidence" of GED-0301's efficacy in each of the additional following areas, which Defendants claimed supported the drug's "Potentially Transformational Profile":



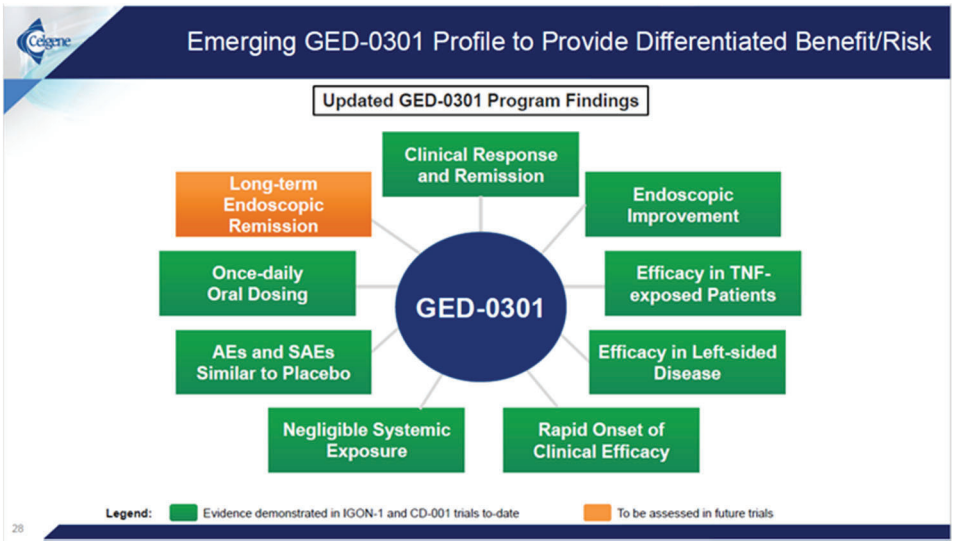
369. An analyst from Cowen and Company asked how the lack of a placebo control group impacted the validity of the Phase Ib data, asking: "[W]hat's the best defense here that there

is a true drug effect as opposed to just a reversion to the mean in a patient population that's very severe at the baseline?" In response, Smith stated:

> Again, this was a relatively small, exploratory phase 1b study. If you take a look at a number of different things, it was a little bit patient poor, but data rich, as we look at things, which was the reason for not having a placebo arm.
>
> When I take a look at this particular study, you see in a relatively heterogeneous, more severe, more difficult to treat population, you see a very positive signs [sic] in terms of clinical response and clinical remission, a ***very validating of what we have seen in the [Phase II] program***. And then when you take a look at the other markers at week 12, which is an early time point for endoscopic healing and endoscopic response, ***you see signs of endoscopic improvement in all three treatment groups*** and you see biomarkers generally going in the right direction.
>
> So that cumulative evidence really tells you that not only are you having a pretty significant effect from a response and remission standpoint, but you are also seeing everything go in the direction that you would like to see it go. And then also from an endoscopic perspective, you are seeing sort of the largest responses in the patients with most extensive disease, which I think is a very positive sign of drug activity as well.

370. Analysts relied on Defendants' assurances that the Phase Ib data supported their claims regarding GED-0301's efficacy and their apparent confidence in the timeline for GED-0301's regulatory approval, and that the lack of a placebo control group in the Phase Ib study was not a concern. For example, RBC Capital Markets stated in an October 18, 2016 report that the Phase Ib data "continue to point to a promising new oral therapy for Crohn's disease which is a $5B market opportunity with high unmet need." The report stressed that "positive efficacy so far for GED-0301 suggests even a modest/medium efficacy drug can be a potential ***$1B+ drug*** in our view." Leerink Partners reported on this date that "[m]anagement indicated this week that with the trials just getting underway now . . . the company expects to submit their registration to the FDA in 2018, with approval in 2019."

371. On October 27, 2016, as part of Celgene's third quarter 2016 earnings presentation, the Company issued and published a series of slides on its corporate website. One of these slides touted the evidence of GED-0301's efficacy:



372. On April 27, 2017, Celgene hosted a conference call to discuss the Company's first quarter 2017 financial results. During this call, Smith stated:

> There is a sort of an encore presentation of some of the GED, CD-001 data upcoming, which takes a look at the relationship between clinical remission and endoscopic improvements. And so I can't give specifics to that data, but that will be presented at DDW coming up. So we're excited about that. We're very, very -- ***we've got data for GED***, obviously, and for ozanimod. ***We're very excited about both assets. The GED registration program has really accelerated over the last little while. We remain on track with time lines there, and we think there's tremendous potential***.

373. The statements in ¶¶ 364-372 above, including Defendants' statements touting the evidence of GED-0301's efficacy and representing that GED-0301 was "***on track***" for regulatory approval, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 104-204 above, Defendants' statements had the effect of concealing, and/or failing to disclose the following facts:

(i) Celgene acquired GED-0301 on the basis of efficacy data, including the Phase II data, that was recognized internally as highly questionable and indeterminate;

(ii) Celgene overlooked numerous red flags as part of its pre-acquisition due diligence, including concerns regarding both the reliability and the integrity of the Phase II data, as well as suspicions about the personal financial motive of the lead investigator who commercially developed GED-0301;

(iii) the Advisory Board recognized the limitations of the Phase II data, this fact was communicated to Celgene, and Celgene acknowledged the limitations of the data;

(iv) in or around mid-2015, there were ongoing meetings among the GED-0301 development team, including with Usiskin, about the limitations of the GED-0301 Phase II study data, including the lack of endoscopic evidence;

(v) by March 2016, Celgene recognized internally that GED-0301's mechanism of action was not as described by its drug developer (Nogra) at the time Celgene acquired it, and that its delivery mechanism was obscure and "too fantastic to be true";

(vi) the Phase Ib study was designed in such a way as to limit the chances that GED-0301 would be shown to be ineffective;

(vii) it was recognized internally at the Company that, due to the lack of a placebo arm in the Phase Ib study, Defendants' claims regarding GED-0301's efficacy were not supported by the Phase Ib study results;

(viii) non-public interim trial data received and analyzed by Celgene and its representatives demonstrated GED-0301's lack of efficacy, as evidenced by one of the principal investigators for the Phase Ib trial reporting to Celgene that there was no endoscopic response observed at his testing site;

(ix) Celgene's decision to license GED-0301 and proceed with the Phase III trial was a "business decision" rather than a decision based on the scientific evidence;

(x) there was growing concern from at least September 2016 that GED-0301 would not make it past the Phase III clinical trials, as evidenced by the fact that between the time the Phase Ib data was released in September 2016 and the time the Phase III trial was discontinued in October 2017, GED-0301 was not discussed during the internal quarterly review meetings with Celgene's Vice Presidents, in which the Company's pipeline of drugs were typically discussed; Celgene was treating the drug as if it had already been written off; and

(xi) Celgene had recognized internally GED-0301's ineffectiveness and Defendants were frantically attempting to make Ozanimod's efficacy as a treatment

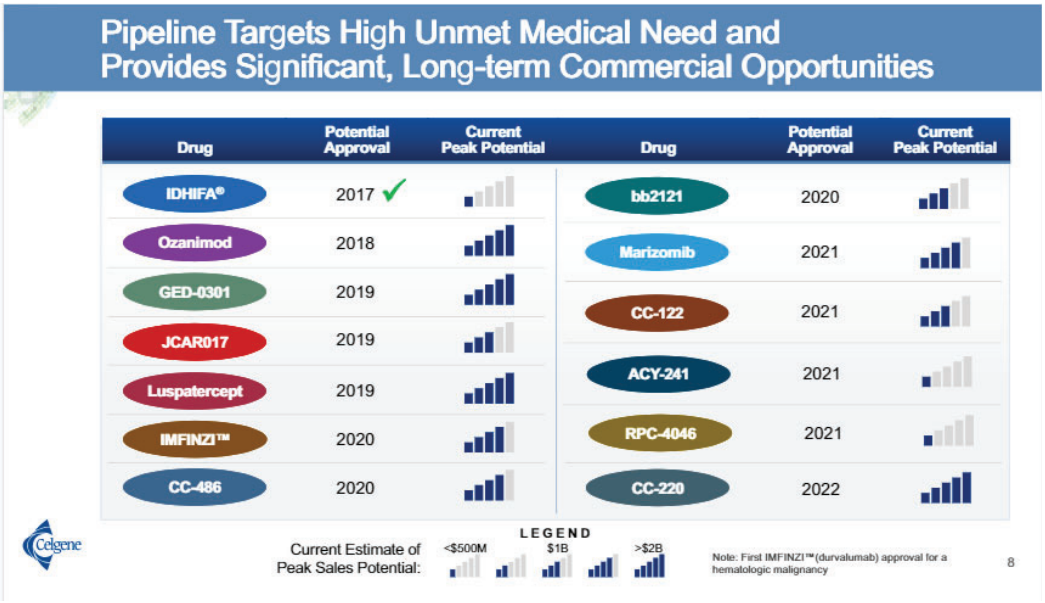
> for CD appear better than GED-0301, going so far as to manipulate the Ozanimod Phase II CD testing protocol to achieve this result.

By electing to speak publicly about the purported evidence of GED-0301's efficacy and its progress toward regulatory approval—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding these subjects so as to not mislead investors. As a result of the foregoing undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

374. On July 27, 2017, Celgene hosted a conference call to discuss the Company's second quarter 2017 financial results. During this call, Curran stated that "***progress continues with GED-0301*** and other important pipeline programs" and that "***[w]e remain focused on progressing our next-generation growth drivers, Ozanimod and GED-0301***, and look forward with anticipation to multiple data readouts in the next 12 to 24 months."

375. Analysts took note of Defendants' emphasis on GED-0301 as a "next generation growth driver." For example, Morgan Stanley reported on July 28, 2017 that "we see 2018 UC and Crohn's for ozanimod and GED0301 as the key drivers for CELG."

376. On September 6, 2017, Celgene participated in the Robert W. Baird Global Healthcare Conference. In connection with this healthcare conference, Celgene issued and published a series of slides on its corporate website. In one of these slides, presented by Kellogg, Defendants stated that GED-0301's regulatory approval was on track and targeted to occur in 2019:



377. A week later on September 13, 2017, Celgene participated in the Morgan Stanley Healthcare Conference. During this conference, Alles stated: "***We still project GED-0301 data, in particular, in Crohn's disease in '18, with '19 being the regulatory year plus launch***."

378. The next day, on September 14, 2017, Celgene participated in the Bank of America Merrill Lynch Healthcare Conference. During this conference, Kellogg again presented the slide presented on September 6, 2017 in which Defendants reiterated that Celgene planned for regulatory approval of GED-0301 to occur in 2019.

379. On September 26, 2017, Celgene presented at the Cantor Fitzgerald 3rd Annual Healthcare Conference. During this conference, Ahmed and Patrick Flanigan ("Flanigan"), Corporate Vice President of Investor Relations, presented the identical slide presented by Kellogg on September 6 and 14, 2017, in which Defendants again stated that Celgene planned for regulatory approval for GED-0301 to occur in 2019.

380. The statements in ¶¶ 374-379 above, including Defendants' statements representing that GED-0301 was "***on track***" for regulatory approval as a treatment for CD, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made.

Specifically, as set forth in ¶¶ 104-204 above, Defendants' statements had the effect of concealing, and/or failing to disclose the following facts:

(i) Celgene acquired GED-0301 on the basis of efficacy data, including the Phase II data, that was recognized internally as highly questionable and indeterminate;

(ii) Celgene overlooked numerous red flags as part of its pre-acquisition due diligence, including concerns regarding both the reliability and the integrity of the Phase II data, as well as suspicions about the personal financial motive of the lead investigator who commercially developed GED-0301;

(iii) the Advisory Board recognized the limitations of the Phase II data, this fact was communicated to Celgene, and Celgene acknowledged the limitations of the data;

(iv) in or around mid-2015, there were ongoing meetings among the GED-0301 development team, including with Usiskin, about the limitations of the GED-0301 Phase II study data, including the lack of endoscopic evidence;

(v) by March 2016, Celgene recognized internally that GED-0301's mechanism of action was not as described by its drug developer (Nogra) at the time Celgene acquired it, and that its delivery mechanism was obscure and "too fantastic to be true";

(vi) the Phase Ib study was designed in such a way as to limit the chances that GED-0301 would be shown to be ineffective;

(vii) it was recognized internally at the Company that, due to the lack of a placebo arm in the Phase Ib study, Defendants' claims regarding GED-0301's efficacy were not supported by the Phase Ib study results;

(viii) non-public interim trial data received and analyzed by Celgene and its representatives demonstrated GED-0301's lack of efficacy, as evidenced by one of the principal investigators for the Phase Ib trial reporting to Celgene that there was no endoscopic response observed at his testing site;

(ix) Celgene's decision to license GED-0301 and proceed with the Phase III trial was a "business decision" rather than a decision based on the scientific evidence;

(x) there was growing concern from at least September 2016 that GED-0301 would not make it past the Phase III clinical trials, as evidenced by the fact that between the time the Phase Ib data was released in September 2016 and the time the Phase III trial was discontinued in October 2017, GED-0301 was not discussed during the internal quarterly review meetings with Celgene's Vice Presidents, in which the Company's pipeline of drugs were typically discussed; Celgene was treating the drug as if it had already been written off;

(xi) Celgene had recognized internally GED-0301's ineffectiveness and Defendants were frantically attempting to make Ozanimod's efficacy as a treatment for CD appear better than GED-0301, going so far as to manipulate the Ozanimod Phase II CD testing protocol to achieve this result; and

(xii) by no later than July 2017, Defendants knew that the Phase III trial in CD was going to be unsuccessful and that GED-0301 would be abandoned.

By electing to speak publicly about GED-0301's progress toward regulatory approval—and thereby putting this subject into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding this subject so as to not mislead investors. As a result of the foregoing undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

B. Otezla

381. On January 12, 2015, Celgene filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to the Form 8-K, which announced certain of the Company's financial results for 2014 and its five-year strategic growth plan, Celgene stated that the 2017 net product sales for Otezla were expected to be between $1.5 billion to $2 billion.

382. On January 12, 2015, Celgene participated in the J.P. Morgan Healthcare Conference. During this conference, Hugin stated:

> I'm going to talk specifically about some of the progress achieved in the fourth quarter with Otezla in our I&I franchise, [which] ***gives us great confidence that we are on track to really again meet or exceed the 2017 guidance***. And new data is coming out across our pipeline that will strengthen our performance in this timeframe.

383. Analysts following the Company took note of Defendants' reaffirmation of the 2017 guidance. For example, SunTrust Robinson Humphrey stated in a January 12, 2015 report: "We believe that management's commentary that CELG is slated to 'meet or exceed 2017 guidance'. . . should spur investor excitement."

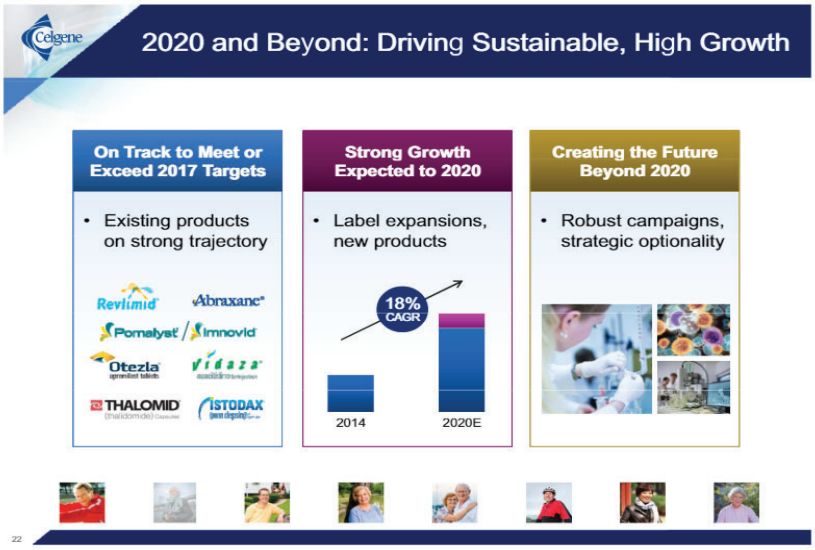
384. On January 29, 2015, Celgene filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to this Form 8-K, which announced certain of the Company's financial and operating results for the quarter and full-year ended December 31, 2014, Celgene again stated that the 2017 sales for Otezla were expected to be between $1.5 billion and $2 billion.

385. Following Celgene's January 29, 2015 press release, several analysts noted that the Company again reaffirmed the 2017 Otezla guidance. For example, J.P. Morgan Securities stated in a January 29, 2015 report that "2017 guidance reiterated. . . . Otezla sales of $1.5-2B."

386. On March 4, 2015, Celgene participated in the Cowen 35th Annual Healthcare Conference. In connection with this conference, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Kellogg, reiterated that Otezla was "on track" to meet or exceed its 2017 financial targets—i.e., $1.5 billion and $2 billion in net product sales.

387. On May 12, 2015, Celgene participated in the Bank of America Merrill Lynch 2015 Healthcare Conference. In connection with this conference, Celgene issued and published a series

of slides on its corporate website. One of these slides again reiterated that Otezla was "on track" to meet or exceed its 2017 financial targets—i.e., $1.5 billion and $2 billion in net product sales.



388. On June 10, 2015, Celgene participated in the William Blair Growth Stock Conference. In connection with this conference, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Perry Karsen, CEO of Celgene Cellular Therapeutics, again reiterated that Otezla was "on track" to meet or exceed its 2017 financial targets—i.e., $1.5 billion and $2 billion in net product sales.

389. On September 17, 2015, Celgene participated in the Bank of America Merrill Lynch Global Healthcare Conference. In connection with this conference, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Kellogg, again reiterated that Otezla was "on track" to meet or exceed its 2017 financial targets—i.e., $1.5 billion and $2 billion in net product sales.

390. On November 10, 2015, Celgene participated in the Credit Suisse Healthcare Conference. In connection with this conference, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Kellogg, again reiterated that Otezla was "on track" to meet or exceed its 2017 financial targets—i.e., $1.5 billion and $2 billion in net product sales.

391. On February 11, 2016, Celgene participated in the Leerink Partners Global Healthcare Conference. During this conference, an analyst from Leerink Partners asked, "where do you stand in your conviction about the previously-issued 2017 guidance?" Alles responded: "On a constant currency basis we are ***on track***."

392. On April 28, 2016, Celgene hosted a conference call to discuss the Company's first quarter 2016 financial results. During this call, Kellogg stated, in part:

> Now let's focus on the 2 target years specifically. Turning to 2017. . . . Both POMALYST and OTEZLA are ***on track*** and expected to achieve our previous target.

393. During this call, an analyst from RBC Capital Markets asked: "Can you walk us through what the thinking is around those other products and if those guidance you're thinking has changed in 2017?" In response, Smith stated: "On the OTEZLA side, we're reaffirming the 2017 target for OTEZLA . . . at $1.5 billion to $2 billion."

394. Analysts reporting on the Company's first quarter 2016 conference call noted that Celgene again reaffirmed the 2017 Otezla sales guidance. For example, in an April 28, 2016

report, Jeffries Group LLC commented that Celgene's "[r]eaffirmation of Otezla guidance despite the recent Rx slowdown seems to reflect the company's confidence in . . . adoption being more impacted by seasonal prior authorization dynamics rather than competition impacting demand," and RBC Capital Markets and SunTrust Robinson Humphrey similarly observed in reports issued the same day that Celgene had reiterated and reaffirmed the 2017 Otezla guidance.

395. On May 11, 2016, Celgene participated in the Bank of America Merrill Lynch Healthcare Conference. During this conference, an analyst from Bank of America Merrill Lynch asked Celgene to discuss the 2017 financial guidance for Otezla. In response, Alles stated, in part:

> Otezla has a terrific launch . . . . That gives us the confidence that, as we think about 2017 – and our earnings call a couple of weeks ago highlighted that – we are very confident that the momentum in psoriasis and then increasingly in psoriatic arthritis puts us in that range that we've talked about. So we are extremely confident that the US performance being the dominant part of that, that we have visibility, we understand the access environment very well, ***so some of those barriers that gave us all a little bit of caution for the uptake of Otezla early have started to present themselves in ways where we can manage it, understand it, and in many cases, we have great advantaged positions now because of the profile of the drug***. . . .

396. The statements set forth in ¶¶ 381-395 above, including Defendants' statements reaffirming the 2017 Otezla sales guidance and the statements indicating that Celgene was "on track" to "meet or exceed" the 2017 Otezla guidance, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 205-269 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

> (i) Defendants' Otezla pricing strategy ensured that Celgene would never attain the growth in sales and revenues necessary to meet the 2017 guidance;
>
> (ii) Celgene sales representatives from across the country were reporting flat Otezla sales growth from the date of the drug's March 2014 launch; and

(iii) Otezla was plagued by issues including step-edits, poor insurance coverage, and inferior efficacy compared to competitors that impaired its sales and attendant revenues.

By electing to speak publicly about Celgene's 2017 Otezla sales guidance and the Company's current progress in meeting this guidance—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the fact that Celgene was not positioned to meet the 2017 guidance and that this guidance could not be met given the numerous issues impacting Otezla revenues. As a result of the foregoing undisclosed material facts, Defendants' public statements lacked a reasonable basis and were materially false and misleading at all relevant times.

397. On September 12, 2016, Celgene participated in the Morgan Stanley Global Healthcare Conference. During this conference, an analyst asked about the challenges related to achieving the 2020 financial guidance. In response, Smith stated, in part:

> ***Otezla is moving along very nicely at this point in time***. Looks like $1 billion in sales this year. Again, launches all over the world next year. ***I feel really great about where we are going and the numbers both in 2017 and 2020 that we put out there. . . .***
>
> ***
>
> ***But we feel great about all the guidance it is been giving, the trajectory***, and I am just excited to get it launched geographically, and there is lots of different places we can take the molecule. So we are very, very excited about where we are with OTEZLA right now.

398. On October 27, 2016, Celgene hosted a conference call to discuss the Company's 2016 third quarter financial results. During this call, an analyst from RBC Capital Markets asked Smith about Celgene's confidence regarding the 2017 guidance. In response, Smith stated:

> I feel very confident in [the] direction of OTEZLA, not – for finishing this year and going into 2017. I think we have a lot of momentum. ***And for specifically the '17 [guidance], I think we have a high degree of confidence***. I'm very excited about the fact that we are just now starting to launch in some really major impactful

> countries, France, England and Wales, Japan early next year. There's a lot [of] geographic expansion, and we see the market shares in the U.S. continuing to grow. So we feel very good about the targets that are out there.

399. Following Celgene's third quarter conference call, RBC Capital Markets stated in an October 27, 2016 report that "CELG expressed high degree of confidence on Otezla prospects for 2017."

400. On January 9, 2017, Celgene filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to the Form 8-K, Celgene announced preliminary 2016 unaudited results and 2017 financial guidance. Celgene stated that Otezla's net product sales for 2017 would be approximately $1.5 billion to $1.7 billion with a 57% year-over-year change.

401. On January 26, 2017, Celgene filed a Form 8-K, signed by Kellogg, with the SEC, announcing results for the fourth quarter and full-year ended December 31, 2016. In the Form 8-K, Celgene stated that the 2017 total revenues for Otezla would be approximately $1.5 billion to $1.7 billion and that the Company expected a 57% "Year-over-Year Change" from 2016.

402. On January 26, 2017, Celgene hosted a conference call to discuss the Company's fourth quarter and full-year 2016 financial results. In connection with this conference call, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Kellogg, reaffirmed the 2017 Otezla revenue guidance of $1.5 billion to $1.7 billion and a 57% year-over-year change from 2016.

403. Analysts and other news outlets reiterated Defendants' forecasts of 57% year-over-year sales growth for Otezla. For example, SunTrust Robinson Humphrey noted in a January 26, 2017 report that Celgene's revised 2017 Otezla guidance of "~$1.5B-$1.7B . . . calls for +57% Y/Y growth" and *Investor's Business Daily* similarly stated in an article the same day that "Otezla,

a psoriasis med, is its product expected to have the best growth, up 57% to $1.5 billion to $1.7 billion."

404. The statements set forth in ¶¶ 397-402 above, including Defendants' statements reaffirming the 2017 Otezla sales guidance and the statements that Otezla revenues would grow by 57% year-over-year compared to 2016, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 205-269 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants' Otezla pricing strategy ensured that Celgene would never attain the growth in sales and revenues necessary to meet the 2017 guidance;

(ii) Celgene sales representatives from across the country were reporting flat Otezla sales growth from the date of the drug's March 2014 launch;

(iii) Otezla was plagued by issues including step-edits, poor insurance coverage, and inferior efficacy compared to competitors that impaired its sales and attendant revenues;

(iv) during the third and fourth quarters of 2016, Smith, Curran, and other members of the IIEC and CPMAC, were explicitly warned by both Celgene's Senior Vice President of I&I and a senior executive in the U.S. Market Access group that Celgene could not meet the 2017 Otezla guidance and that these numbers should be lowered;

(v) FE 17 recounted that the Forecasting team was "told to change" the numbers (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth; and

(vi) FE 18, confirmed that when Defendants were assessing the 2017 Otezla market access and setting the 2017 targets, the market did not support even close to 57% growth.

By electing to speak publicly about Celgene's 2017 Otezla sales guidance and the expected year-over-year growth in sales—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the fact that Celgene was not positioned to meet the 2017 guidance and that this guidance could not be met given the

numerous issues impacting Otezla revenues. As a result of the foregoing undisclosed material facts, Defendants' public statements lacked a reasonable basis and were materially false and misleading at all relevant times.

405. On April 27, 2017, Celgene filed a Form 8-K, signed by Kellogg, with the SEC announcing certain first quarter 2017 operating and financial results. In the press release attached to this Form 8-K, Celgene stated that the previously issued 2017 sales guidance for Otezla remained "Unchanged." In this press release, Alles stated: "Our significant first quarter operational, financial and strategic progress strengthen our confidence and outlook for 2017." The press release further represented with respect to Otezla:

> Despite a contraction in the overall market volume of prescriptions filled, OTEZLA share in psoriasis grew versus last quarter. In addition, net sales were impacted by increasing gross-to-net adjustments related to contracts implemented in January with several large payers that significantly broadened access for up to 100 million covered lives.

406. On April 27, 2017, Celgene hosted a conference call to discuss the Company's financial results for the first quarter of 2017. During this call, when explaining the first quarter Otezla net product sales miss, Kellogg omitted any reference to the myriad issues impacting Otezla sales recounted by Celgene former employees and falsely suggested that the new large payer contracts would improve Otezla's market share and, by extension, revenues, stating:

> As a reminder, the sequential performance from Q4 to Q1 is always impacted by several items . . . OTEZLA is impacted by managed care dynamics that drive lower total marketplace prescriptions for psoriasis therapies in Q1. In addition, a new dynamic for OTEZLA this quarter was a higher gross-to-net adjustment related to new contracts with several large payers that were implemented in January. ***These new contracts approximately doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy, which has already improved OTEZLA's market share in these accounts.***

407. In connection with this conference call, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Kellogg, reiterated that the previously issued 2017 guidance for Otezla remained "Unchanged."

Updating 2017 Guidance

	Previous	Updated
Net Product Sales		
REVLIMID®	$8.0B-$8.3B	Unchanged
POMALYST®/IMNOVID®	~$1.6B	Unchanged
OTEZLA®	$1.5B-$1.7B	Unchanged
ABRAXANE®	~$1.0B	Unchanged
Total Revenue	$13.0B-$13.4B	Unchanged
Adjusted Operating Margin	~56.5%	~57%
Adjusted Diluted EPS	$7.10-$7.25	$7.15-$7.30
Weighted Average Diluted Shares	~815M	Unchanged

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408. Smith added with respect to Otezla: "The momentum we see in Q2 across a number of fronts gives us confidence that we will deliver on our full year 2017 guidance of $1.5 billion to $1.7 billion."

409. In responding to a request from a UBS analyst that the Company "walk through what gives you confidence [that Otezla] growth will bounce back," Curran stated:

> I think there was really 3 key drivers to the performance in the first quarter. Firstly, we saw contraction in the market as we saw increased [gross to net] as a result of the contracting. But importantly, that really gives us access to double the number of insured lives going forward. And lastly, we saw a minimal drawdown in inventory. ***Importantly, if we look at the underlying dynamics of the business, they're exceptionally strong.*** If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients. And these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter 1 and into quarter 2, ***we do see the net sales rebounding and on track to deliver our 2017 guidance.***

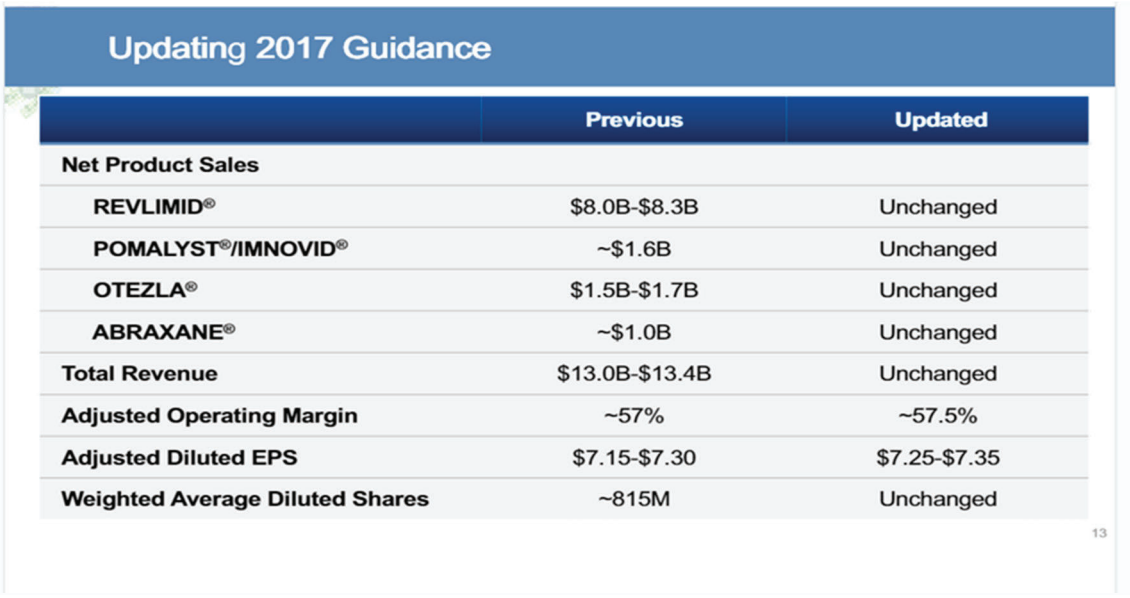
410. Analysts seized on Defendants' reaffirmation of the 2017 Otezla guidance notwithstanding the first quarter miss. For example, BMO Capital Markets noted in an April 27, 2017 report that: "Management reiterated FY2017 Otezla sales of $1.5-1.7bn." UBS stated in an report issued the same day that "Celgene reiterated confidence in achieving 2017 guidance and the longer term outlook for Otezla, citing consistent market share growth (>40% of new patients), narrowing its position behind Stelara in the psoriasis market, and new contracts that increase market access and share" and an April 28, 2017 JMP Securities report observed: "We note that previous guidance of $1.5bil to $1.7bil in net Otezla sales for 2017 remains intact despite this soft quarter."

411. On May 31, 2017, Celgene participated in the Sanford C. Bernstein Strategic Decision Conference. During this conference, Alles stated, in part:

> This is a bona fide blockbuster, and I can tell you coming out of Q1 into Q2, we've seen a nice volume recovery. We've seen the prescription volume in the market in the U.S. grow, and we're launching right now in Japan and across Europe. So a lot of momentum for OTEZLA despite a little bit of weakness in the first quarter. ***We also affirmed our guidance for the year for OTEZLA, $1.5 billion to $1.7 billion, so year-on-year great performance and a lot of momentum for the brand.***

412. On July 27, 2017, Celgene filed a Form 8-K, signed by Kellogg, with the SEC announcing certain operating and financial results for second quarter 2017. In the press release attached to this Form 8-K, Celgene stated that the 2017 net sales projections for Otezla remained "Unchanged" at between $1.5 billion and $1.7 billion.

413. On July 27, 2017, Celgene hosted a conference call to discuss the Company's second quarter financial results. In connection with this conference call, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Kellogg, again stated that the 2017 financial guidance for Otezla remained "Unchanged."



Updating 2017 Guidance

	Previous	Updated
Net Product Sales		
REVLIMID®	$8.0B-$8.3B	Unchanged
POMALYST®/IMNOVID®	~$1.6B	Unchanged
OTEZLA®	$1.5B-$1.7B	Unchanged
ABRAXANE®	~$1.0B	Unchanged
Total Revenue	$13.0B-$13.4B	Unchanged
Adjusted Operating Margin	~57%	~57.5%
Adjusted Diluted EPS	$7.15-$7.30	$7.25-$7.35
Weighted Average Diluted Shares	~815M	Unchanged

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414. Analysts once again reiterated Defendants' reaffirmation of the 2017 Otezla guidance. For example, Morgan Stanley stated in a July 28, 2017 report that: "Mgt. reaffirmed prior 2017 net product sales guidance, with . . . Otezla of $1.5B-$1.7B."

415. The statements set forth in ¶¶ 405-413 above, including Defendants' statements reaffirming the 2017 Otezla sales guidance and attributing the slow-down in first quarter 2017 Otezla sales to a "contraction in the overall market volume of prescriptions filled," "increasing gross-to-net adjustments" and "managed care dynamics," were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 205-269 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants' Otezla pricing strategy ensured that Celgene would never attain the growth in sales and revenues necessary to meet the 2017 guidance;

(ii) Celgene sales representatives from across the country were reporting flat Otezla sales growth from the date of the drug's March 2014 launch;

(iii) Otezla was plagued by issues including step-edits, poor insurance coverage, and inferior efficacy compared to competitors that impaired its sales and attendant revenues;

(iv) during the third and fourth quarters of 2016, Smith, Curran, and other members of the IIEC and CPMAC were explicitly warned by both Celgene's Senior Vice President of I&I and a senior executive in the U.S. Market Access group that Celgene could not meet the 2017 Otezla guidance and that these numbers should be lowered;

(v) FE 17 recounted that the Forecasting team was "told to change" the numbers (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth;

(vi) FE 18 confirmed that when Defendants were assessing the 2017 Otezla market access and setting the 2017 targets, the market did not support even close to 57% growth;

(vii) Defendants' decision to allow wholesalers to buy Otezla in excess of their demand in the fourth quarter of 2016 negatively impacted the first quarter 2017 Otezla sales;

(viii) Tessarolo, Senior Vice President of I&I, U.S., had again warned Defendants in early 2017 that the Company needed to downgrade its 2017 Otezla revenue guidance;

(ix) the newly-entered PBM contracts Defendants claimed "doubled the number of patient lives who can now access OTEZLA without being required to step through a biologic therapy" would not positively impact Celgene's Otezla net product sales for months or even years; and

(x) FE 18 recounted that it was clear from the beginning of 2017, based on the models that his team was running monthly, that the PBM contracts were not meeting revenue expectations and Celgene eventually lowered the expectations on many of these PBM contracts internally.

By electing to speak publicly about Celgene's 2017 Otezla sales guidance—and thereby putting this subject into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the fact that Celgene was not positioned to meet the 2017 guidance, and that this guidance could not be met given the numerous issues impacting Otezla revenues. As a result of the foregoing undisclosed material facts, Defendants' public statements lacked a reasonable basis and were materially false and misleading at all relevant times.

C. Ozanimod

416. As detailed above in ¶¶ 297-298, by no later than November 21, 2016, Defendants discovered the Metabolite. Former employees referred to the finding as a great concern, which required additional, time-consuming Phase I testing which would prevent the filing of a complete NDA in 2017. The former employees also stated that the submission of the NDA for Ozanimod without the testing would lead the FDA to reject the NDA and issue an RTF (which the FDA did). In the face of these and other undisclosed material facts, Defendants issued the following material misrepresentations and omissions during the Class Period.

417. On January 9, 2017, Celgene participated in the 35th Annual J.P. Morgan Healthcare Conference. During this conference, Alles stated, in part:

> We have two Phase 3 [Ozanimod] trials that have completely accrued and expect to have the data during the first half of this year, which will inform us. ***And contingent on that, we will file an NDA for Ozanimod in multiple sclerosis by the end of the year***.

418. In connection with this healthcare conference, Celgene issued and published a series of slides on its corporate website. Alles presented a slide entitled "Coming Soon . . . Phase III Ozanimod Data in Multiple Sclerosis" that provided in part, "***Phase III data expected in H1:17***" and "***Planning NDA submission YE:17***."

419. Analysts and other news outlets reiterated Defendants' representations regarding the timeline for Celgene's Ozanimod Phase III study results and NDA submission. For example, in a January 9, 2017 report, Evercore ISI stated: "Ph3 data readouts for Ozanimod in MS . . . appear to be on track in 2017" and *The Daily Cardinal: University of Wisconsin* reported in a January 10, 2017 article that: "The studies of ozanimod in multiple sclerosis are very intriguing trials. . . . [A]nd data should be available for investors to digest by mid-year. ***If the data is good, an FDA filing for approval is expected before the end of 2017***."

420. On January 26, 2017, Celgene hosted a conference call to discuss the Company's fourth quarter and full year 2016 financial results. During this conference call, Smith stated:

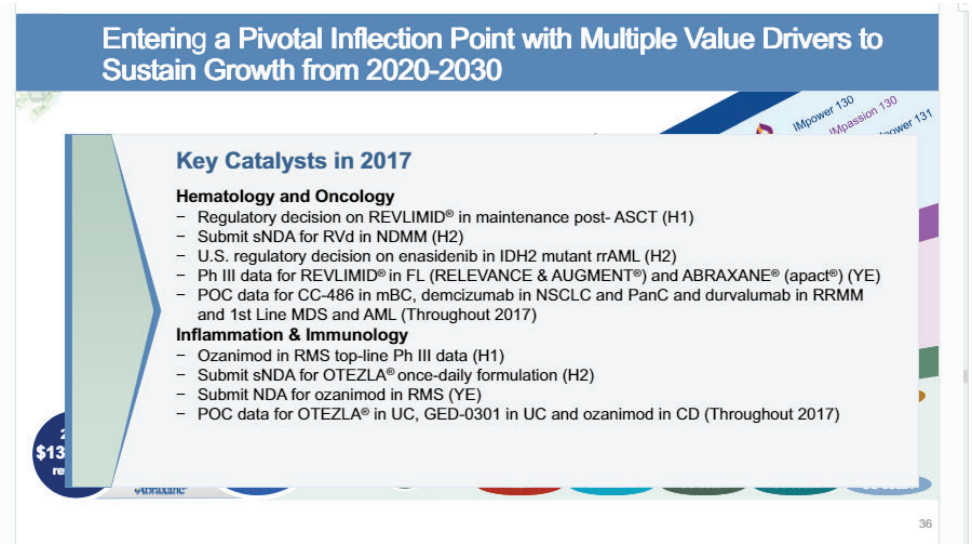
> Turning now to Ozanimod. We are very excited to be getting pivotal data from both the 12-month SUNBEAM and 24-month RADIANCE studies in the first half of 2017. ***These large Phase III active comparator trials . . . will form the core of an expected NDA submission by year-end.***

421. During the same call, an analyst from Citigroup, Inc. inquired, "maybe give us some color on your thoughts on MS market and how you're thinking about how it's evolved the acquisition and the guidance." In responding to these questions, Defendant Fouse, without saying anything about the Metabolite or the required time-consuming testing, stated:

> As Scott said, we think we are going to have a highly differentiated molecule. ***So you're going to have the data from the 2 Phase III MS trials this year, and then the team will submit that by the end of the year.***

422. In connection with the January 26, 2017 conference call, Celgene issued and published a series of slides on its corporate website. One of the slides, which was presented by Smith, stated that Celgene's I&I Franchise was on track to "***submit ozanimod U.S. NDA in RMS***" in 2017.

423. Fouse also presented a slide discussing "Key Catalysts in 2017" with respect to Celgene's growth. This slide stated that one "Key Catalyst[] in 2017" was that the I&I Franchise would "***submit NDA for Ozanimod in RMS***" by the end of 2017.



424. Analysts and other news outlets again reiterated Defendants' representations regarding the timeline for Celgene's NDA submission based on the Phase III study results. For example, BTIG Equity Research stated in a January 26, 2017 report that "the Phase III topline results for Ozanimod" were a "significant clinical catalyst[]" and Cowen and Company stated in a January 26, 2017 report that "Celgene anticipates filing an NDA for ozanimod in MS by YE." Similarly, *The Daily Cardinal: University of Wisconsin* reported: "If the [Phase III] data is positive, and the FDA eventually approves it, ozanimod could be competing in a market worth $20 billion—and growing—as soon as next year."

425. On February 10, 2017, Celgene filed a Form 10-K ("2016 10-K"), signed by Alles, Kellogg, Hugin and Fouse, with the SEC. The 2016 10-K represented, "[w]e have phase III trials underway for ozanimod in relapsing multiple sclerosis" and included a chart representing that the "Status" of Ozanimod for RMS was "Phase III" and that Celgene "Entered current status" in 2013.

426. On February 17, 2017, Celgene filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to the Form 8-K, which announced the positive results from the Ozanimod phase III SUNBEAM trial, Smith was quoted as stating, "'[w]e look forward to data from the confirmatory phase III RADIANCE trial in the second quarter as ***we advance toward planned regulatory submissions by year-end***.'"

427. Several analysts and media outlets seized on Defendants' representations regarding the Phase III trial results and the Company's timeline for submission of the Ozanimod NDA. For example, Jefferies Group LLC stated in a February 17, 2017 report that "CELG reported positive top-line data for ozanimod in MS from the first ph.III study" and Leerink Partners represented in a February 17, 2017 report that "[t]he timing and success of SUNBEAM, and the expectation for confirmatory phase III RADIANCE data in Q2, are consistent with the timeline for filing Ozanimod in H2 2017 and launching in 2018."

428. The statements set forth in ¶¶ 417-426 above, including Defendants' statements indicating that Celgene was in Phase III testing for Ozanimod and reaffirming the Company's plans to submit the Ozanimod NDA by the end of 2017, pending only the final Phase III study results, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 270-341 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants discovered a disproportionate Metabolite in November 2016;

(ii) the testing and studies regarding the Metabolite, including many Phase I studies, that needed to be conducted prior to filing the NDA put the Company's NDA filing timeline at risk and rendered it unreasonable; and

(iii) if Celgene submitted the NDA without the necessary metabolite testing and studies, the FDA was almost certain to issue an RTF.

By electing to speak publicly about the nearly complete status of Celgene's Ozanimod Phase III studies and the Company's professed ability to submit a complete NDA for Ozanimod in 2017 for FDA approval in 2018—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the discovery of the Metabolite and the need for additional Phase I testing that jeopardized Celgene's filing of a complete Ozanimod NDA in 2017 and Celgene's ability to receive FDA approval in 2018, so as to not mislead investors. As a result of the foregoing, undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

429. On March 15, 2017, Celgene participated in the Barclays Global Healthcare Conference. During the Company's presentation, Flanigan stated:

> ***So, in terms of timelines in MS, we just had the first Phase 3 readout***. This is a one-year result out of SUNBEAM. We are waiting for the two-year trial called RADIANT that should read out sometime in Q2. ***And based upon those data sets, the second study, if RADIANCE is consistent with SUNBEAM, then we package all this into an NDA and submit it to the FDA by the end of the year.***

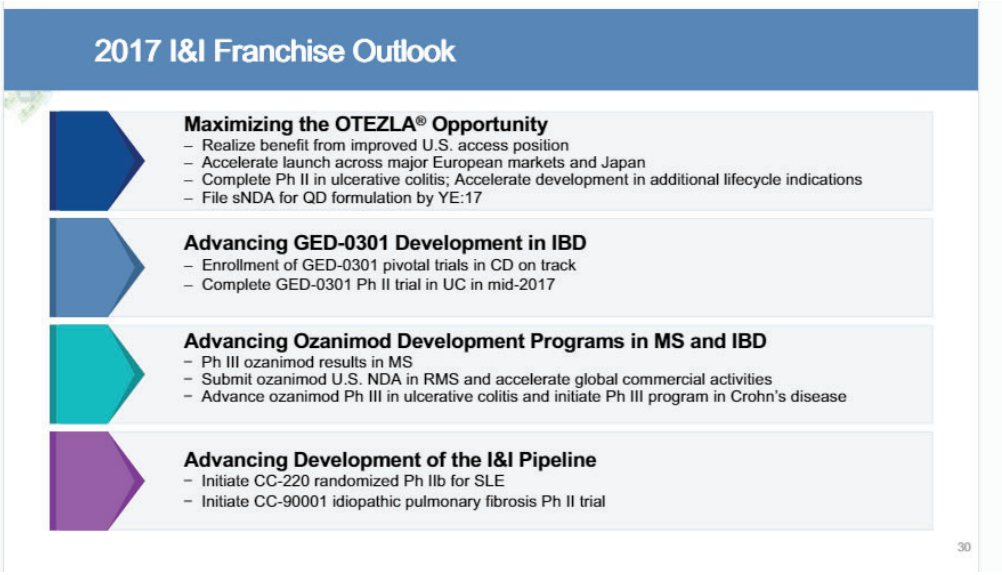
430. On April 27, 2017, Celgene filed a Form 10-Q, signed by Alles and Kellogg, with the SEC. This Form 10-Q represented: "[W]e have phase III trials underway for ozanimod in relapsing multiple sclerosis."

431. On April 27, 2017, Celgene also filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to this Form 8-K, which announced certain first quarter 2017 operating and financial results, Celgene stated:

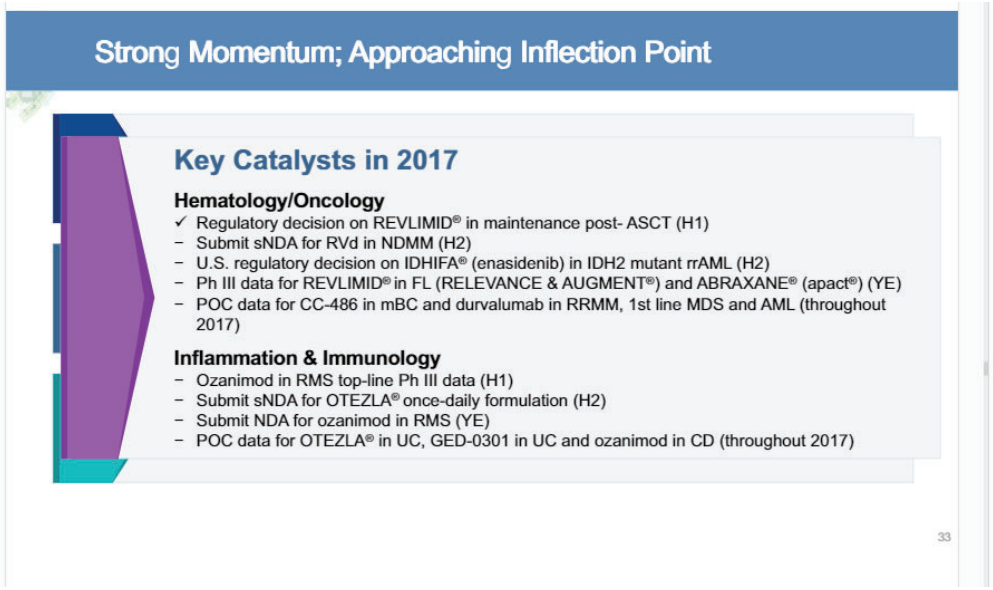
> In February, Celgene disclosed positive top-line results from the phase III SUNBEAM trial evaluating ozanimod in patients with relapsing multiple sclerosis (RMS). The trial met its primary endpoint in reducing annualized relapse rate (ARR), compared to weekly interferon (IFN) β-1a (Avonex®). Data from the confirmatory phase III RADIANCE trial are expected in the second quarter.

Celgene anticipates filing ozanimod for regulatory approval by year-end based on these data.

432. On the same date, Celgene hosted a 2017 conference call to discuss the Company's first quarter 2017 financial results. In connection with the April 27, 2017 conference call, Celgene issued and published a series of slides on its corporate website. One of the slides, entitled "2017 I&I Franchise Outlook," was presented by Defendant Smith. This slide touted "Advancing Ozanimod Development Programs in MS and IBD" and confirmed that Celgene would "***submit ozanimod U.S. NDA in RMS [in 2017]***."



433. During this call, Fouse presented a slide that listed "Submit NDA for ozanimod in RMS (YE)" as a "Key Catalyst[] in 2017" and doubled-down on confirming that Celgene would "***submit NDA for ozanimod in RMS***" by end of 2017.



434. In reporting on Celgene's April 27, 2017 conference call, analysts focused on Defendants' representations that Celgene would submit an NDA by year-end 2017. For example, Barclays stated in an April 27, 2017 report that "[n]otably, Celgene plans to submit an NDA in RMS by year-end, with a likely launch in 2018." J.P. Morgan similarly stated in an April 27, 2017 report that a "Key 2017 catalyst[]" included "Ozanimod Ph3 data in MS in May with NDA submission by YE17" and Oppenheimer acknowledged in an April 27, 2017 report that "Celgene announced it intends to file Ozanimod for regulatory approval by the end of 2017 using data from the phase III SUNBEAM and RADIANCE studies."

435. The statements set forth in ¶¶ 429-433 above, including Defendants' statements that the Phase III studies for Ozanimod were positive and nearly complete and that Celgene was set to file the Ozanimod NDA by the end of 2017 pending only the final Phase III study results, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made.

Specifically, as set forth in ¶¶ 270-341 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

> (i) Defendants discovered a disproportionate Metabolite in November 2016;
>
> (ii) the testing and studies regarding the Metabolite, including many Phase I studies, that needed to be conducted prior to filing the NDA put the Company's NDA filing timeline at risk and rendered it unreasonable; and
>
> (iii) if Celgene submitted the NDA without the necessary metabolite testing and studies, the FDA was almost certain to issue an RTF.

By electing to speak publicly about the complete status of Celgene's Ozanimod Phase III studies and the Company's professed ability to submit a complete NDA for Ozanimod in 2017 for FDA approval in 2018—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the discovery of the Metabolite and the need for additional Phase I testing that jeopardized Celgene's filing of a complete Ozanimod NDA in 2017 and Celgene's ability to receive FDA approval in 2018, so as to not mislead investors. As a result of the foregoing, undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

436. On May 22, 2017, Celgene filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to the Form 8-K, which announced the results from Ozanimod's Phase III trial, RADIANCE, Curran stated, in part:

> ***We are excited by the results seen to-date across both pivotal trials***, which further validated ozanimod's promising benefit-risk profile relative to current therapies . . . ***We plan to begin submitting global registration dossiers by the end of the year*** . . . .

437. In the wake of Celgene's Form 8-K, Canaccord stated in a May 22, 2017 report that in light of the positive RADIANCE and SUNBEAM data, "[w]e believe there is a high probability of approval," and Oppenheimer stated in a May 22, 2017 report that "Celgene announced that further analyses of the RADIANCE trial are ongoing and it plans to submit an NDA to the FDA,

based on the combined SUNBEAM and RADIANCE trials for relapsing MS by the end of 2017." In a May 22, 2017 report, Raymond James represented: "No change to plans to submit a U.S. filing by YE17."

438. On May 31, 2017, Celgene participated in the Sanford C. Bernstein Strategic Decision Conference, where Alles discussed Ozanimod's Phase III study results. Alles stated:

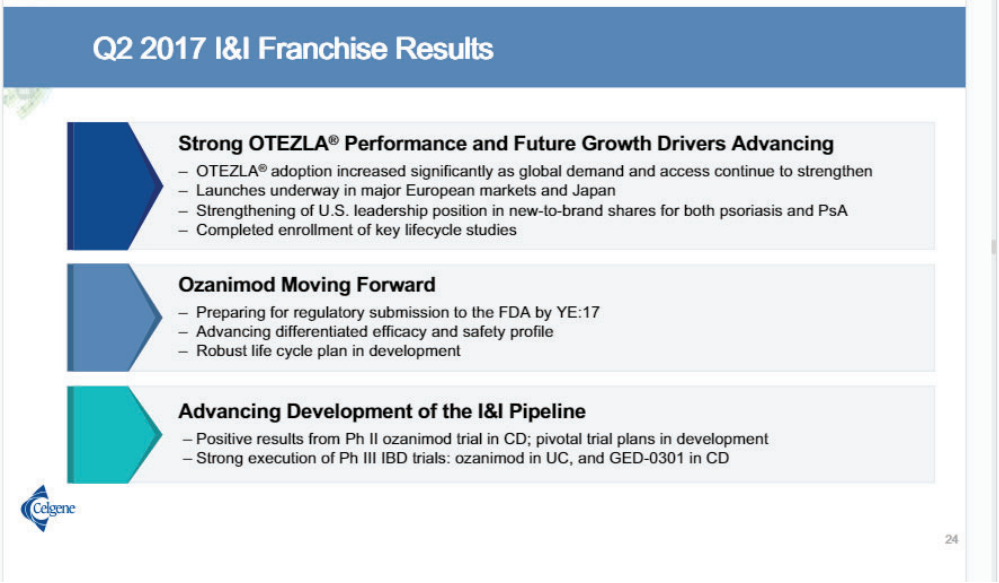
> About 22 months ago, we acquired Receptos for $7.2 billion net of cash to bring ozanimod into our portfolio, and 2 Mondays ago, ***we announced the second of 2 Phase III trials that were very positive for the drug in the setting of relapsed multiple sclerosis***. So we're quite excited about that. We're anxious for investors and the community at large to see the data. . . . We're very, very excited about the data. ***And in fact, the results of the 2 Phase III trials separately and together for relapsing MS put the product at a profile that's better than the base case we had when we did the deal to acquire the asset.***

439. On July 27, 2017 Celgene filed a Form 10-Q, signed by Alles and Kellogg, with the SEC. This Form 10-Q represented: "[W]e have phase III trials underway for ozanimod in relapsing multiple sclerosis."

440. On July 27, 2017, Celgene also hosted a conference call to discuss the Company's second quarter 2017 financial results. During this call, Curran stated:

> ***We announced positive results from RADIANCE, our second Phase III trial of ozanimod in MS and are on track to file the U.S. NDA by year end.*** We're very pleased with the progress of the program and look forward to the data being presented in upcoming major medical meetings.

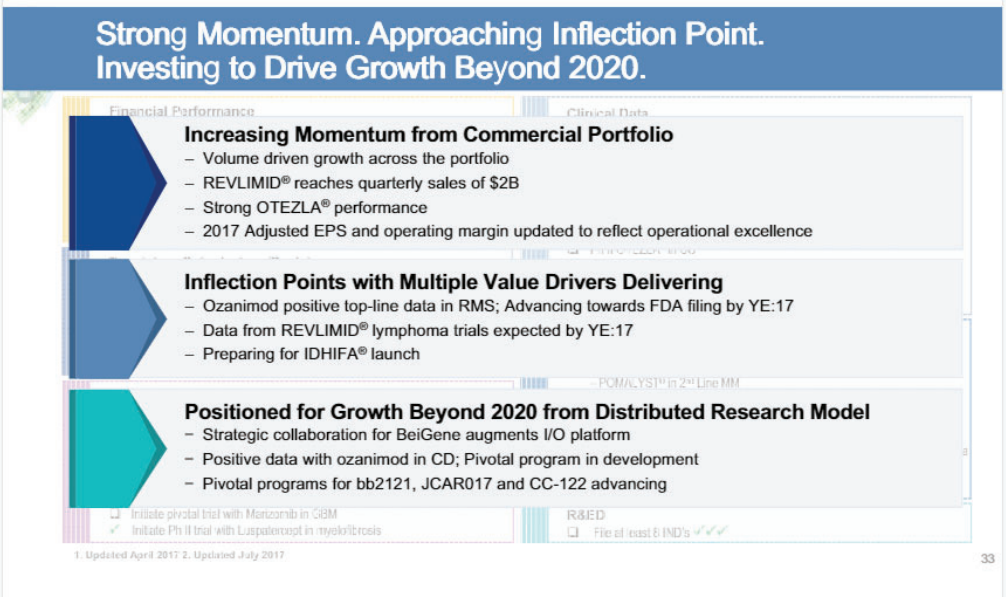
441. In connection with the July 27, 2017 conference call, Celgene issued and published a series of slides on its corporate website. One of the slides, which was presented by Defendant Curran, reiterated that Ozanimod was "***[p]reparing for regulatory submission to the FDA by YE:17***."



442. Curran presented an additional slide that stated that Celgene's I&I Franchise would "***[f]ile ozanimod U.S. NDA in RMS***" by year-end 2017.

443. Smith also confirmed that the study data from the Ozanimod testing was universally positive, stating "[j]ust to add on to the comments, ***we feel very, very good about the data that's emerging for ozanimod and looking forward to getting it out***."

444. Smith then presented a slide that discussed Ozanimod as having "***positive top-line data in RMS***" while "***[a]dvancing towards FDA filing by YE:17.***"



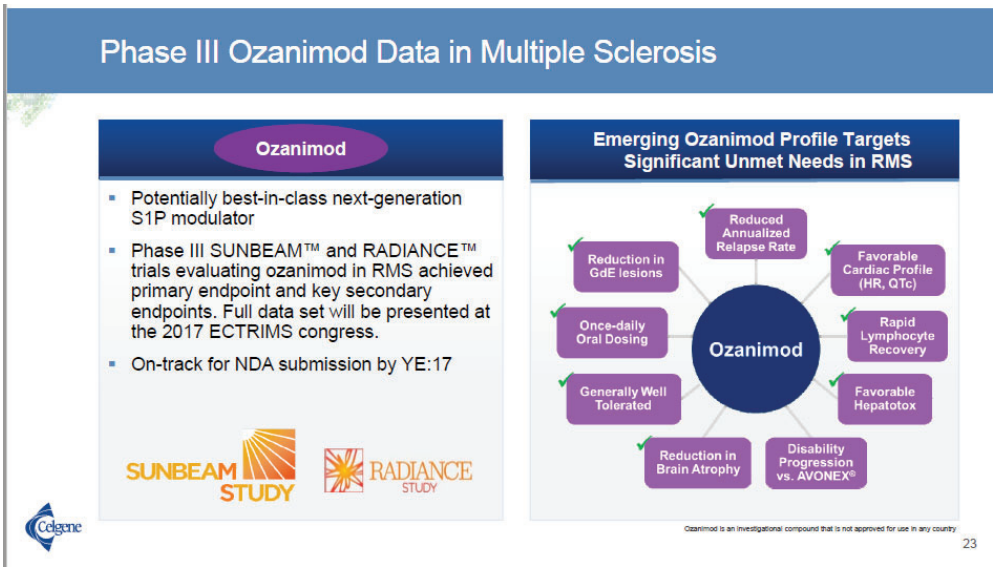
445. On July 27, 2017, Celgene filed a Form 8-K, signed by Kellogg, with the SEC. In this Form 8-K, Celgene discussed "Product and Pipeline Updates" for the I&I Franchise, and stated:

> In May, Celgene disclosed positive top-line results from the confirmatory phase III RADIANCE™ trial evaluating ozanimod in RMS. . . . ***An NDA submission to the FDA based on the combined phase III SUNBEAM™ and RADIANCE™ trials for RMS is expected by the end of 2017.***

446. On August 7, 2017, the *Journal of Clinical Pharmacology in Drug Development* published an article authored by Tran and several other Celgene employees entitled "Cardiac Safety of Ozanimod, a Novel Sphingosine-1-Phosphate Receptor Modulator: Results of a Thorough QT/QTc Study." In this article, which was sponsored by Celgene, Tran stated: "Metabolism studies in animals identified 3 pharmacologically active metabolites (RP101988, RP101075, and RP101442) that have similar S1P selectivity and potency in vitro to ozanimod" and described the characteristics of these three metabolites. Despite Celgene's discovery of the

Metabolite as early as November 2016, Tran's article made no mention of the Metabolite or the additional testing of the Metabolite that was required for Celgene's Ozanimod NDA.

447. On September 26, 2017, Celgene participated in the Cantor Fitzgerald 3rd Annual Healthcare Conference. In connection with this healthcare conference, Celgene issued and published a series of slides on its corporate website. One of these slides, which was presented by Defendant Ahmed, stated Ozanimod was "***[o]n-track for NDA submission by YE:17***."



448. On October 26, 2017 Celgene filed a Form 10-Q, signed by Alles and Kellogg, with the SEC. This Form 10-Q represented: "[W]e have phase III trials underway for ozanimod in relapsing multiple sclerosis."

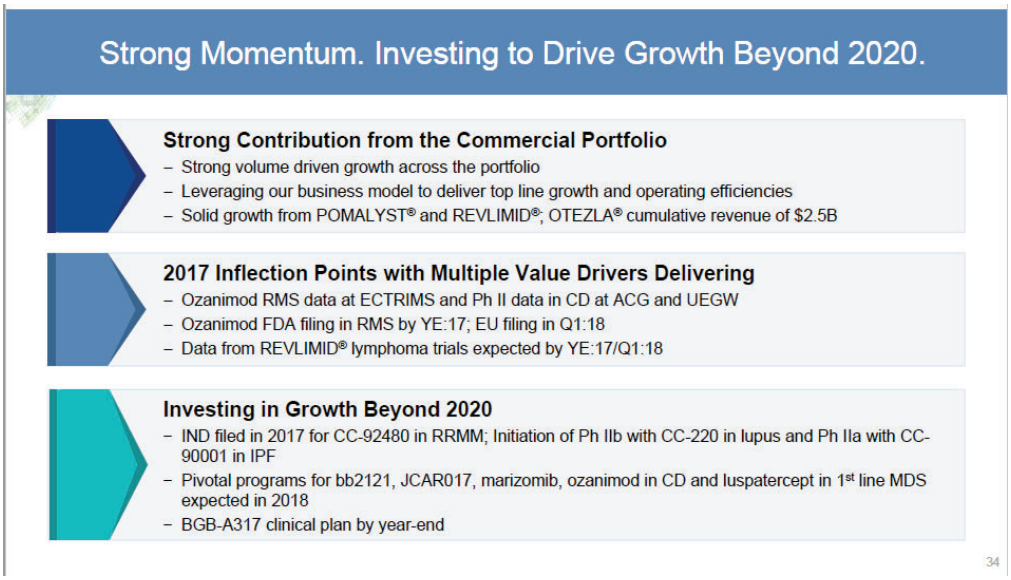
449. On October 26, 2017, Celgene also hosted a conference call to discuss the Company's third quarter 2017 financial results. During this call, Curran stated:

> We made good progress on the I&I pipeline and are very excited about the upcoming data presentation for ozanimod and MS at the ECTRIMS-ACTRIMS joint meeting in Paris later this week. ***The program remains on track for regulatory submission, beginning with the U.S. by year-end***. . . Turning now to ozanimod. ***We are highly encouraged by the results we have seen to date in both MS and IBD indications***."

450. In connection with the October 26, 2017 conference call, Celgene issued and published a series of slides on its corporate website. One of the slides, which was presented by Defendant Curran, stated that Ozanimod was "***moving forward in Multiple Sclerosis***" and Celgene was "***[p]reparing for regulatory submission [of the Ozanimod NDA] to the FDA by year-end***."

451. Defendant Curran presented an additional slide that stated that Celgene would "***[s]ubmit ozanimod U.S. NDA in RMS by YE:17***."

452. A third slide, presented by Defendant Smith, characterized Celgene's "***[o]zanimod FDA filing in RMS by YE:17***" as an inflection point in 2017 that would drive growth for Celgene.



453. On October 26, 2017, Celgene issued a press release, which announced certain of the Company's financial and operating results for the quarter ended September 30, 2017. This press release included "Product and Pipeline Updates" for the I&I Franchise and stated, "***Celgene plans to submit a New Drug Application (NDA) to the FDA for Ozanimod in RMS by year-end.***"

454. Following Defendants' October 26, 2017 statements, analysts and other media outlets again reiterated Defendants' representations regarding Celgene's timeline for submission of the Ozanimod NDA. For example, BTIG Equity Research stated in an October 26, 2017 report: "We expect ozanimod to be ***approved*** for MS during 2H2018 (US NDA sub for [R]MS YE2017)." The Dow Jones Institutional News reported in an October 26, 2017 article: "Celgene plans to submit a New Drug Application (NDA) to the FDA for ozanimod in RMS by year-end."

455. Two days later, on October 28, 2017, Celgene held an Investor Event at the MSParis2017-7th Joint American-European Committee for Treatment and Research in Multiple Sclerosis. During this event, several Individual Defendants issued misrepresentations concerning

Ozanimod. For example, in discussing the Ozanimod "development program," Defendant Martin stated:

> [T]he RADIANCE study and the SUNBEAM study will form the basis of our submission to the FDA and to [the] EMA. ***For the FDA, we are working hard as we speak to get ready to file by the end of the year***.

456. Defendant Curran represented that Celgene was "very excited by the data and looking forward to filing or submitting filing by the end of the year in the U.S. and the EMEA the first half of next year."

457. Defendant Smith stated:

> ***We announced positive top line data to ozanimod and SUNBEAM and RADIANCE earlier in the year***, and we've been very anxiously awaiting, getting to this meeting and being in a position to really get in and dig in and talk about the data. ***We're tremendously thrilled with the data and satisfied and happy***.
>
> ***
>
> So it's very, very exciting for us to be heading off in this new venture in neurology, but heading off with such an amazing, potential cornerstone product as ozanimod with what we think is a ***very, very, very positive data***.
>
> ***
>
> ***Since we went and made the acquisition and we've just continued to get more excited and more excited as we've continued to have data*** and whether that data was in MS and pivotal data, you see data firming up long term in the Phase II data, Crohn's data coming in. ***The data around this asset is very, very solid, and it's really, really exciting***.

458. In reporting on Defendants' statements at the MSParis2017 meeting, Oppenheimer focused on Defendants' repeated representations regarding the Phase III trial data and NDA submission timeline, stating: "Celgene has previously announced that further analyses of the RADIANCE trial are ongoing and it plans to submit an NDA to the FDA, based on the combined SUNBEAM and RADIANCE trials for relapsing MS by the end of 2017."

459. The statements set forth in ¶¶ 436-457 above, including Defendants' statements that the Phase III studies for Ozanimod were positive and complete and that, in light of these study results, Celgene was set to file the Ozanimod NDA by the end of 2017, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 270-341 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants discovered a disproportionate Metabolite in November 2016;

(ii) the testing and studies regarding the Metabolite, including many Phase I studies, that needed to be conducted prior to filing the NDA put the Company's NDA filing timeline at risk and rendered it unreasonable; and

(iii) if Celgene submitted the NDA without the necessary metabolite testing and studies, the FDA was almost certain to issue an RTF.

By electing to speak publicly about the complete status of Celgene's Ozanimod Phase III studies and the Company's professed ability to submit a complete NDA for Ozanimod in 2017 for FDA approval in 2018—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the discovery of the Metabolite and the need for additional Phase I testing that jeopardized Celgene's filing of a complete Ozanimod NDA in 2017 and Celgene's ability to receive FDA approval in 2018, so as to not mislead investors. As a result of the foregoing, undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

460. As discussed above (*see* ¶¶ 312-322), Celgene submitted the Ozanimod NDA for MS to the FDA in December 2017, notwithstanding that it omitted the Metabolite testing results demanded by the FDA at their November 2017 meeting with the Company.

461. On January 8, 2018, Celgene filed a Form 8-K, signed by Kellogg, with the SEC. In the press release attached to the Form 8-K, Celgene hyped their December 2017 submission of

the Ozanimod NDA for MS, identifying as one of its "2018 Expected Operational Milestones" the "***FDA decision on the submission of an NDA for ozanimod in patients with relapsing multiple sclerosis (RMS)***."

462. Following the January 8, 2018 press release, J.P. Morgan asserted in a January 8, 2018 report, that the "Key 2018 catalysts" included "potential approval of ozanimod in relapsing multiple sclerosis in 2018" and RBC Capital Markets stated in a report published the same day that "CELG confirmed they submitted an NDA for ozanimod in MS."

463. Approximately two weeks later on January 25, 2018, Celgene filed another Form 8-K, signed by Kellogg, with the SEC again highlighting that "***a New Drug Application (NDA) was submitted with the FDA for Ozanimod in relapsing multiple sclerosis*** (RMS) based on data from the phase III RADIANCE™ Part B and SUNBEAM™ trials for evaluating Ozanimod in patients with RMS."

464. Following Defendants' repeated reference to its NDA submission, SunTrust Robinson Humphrey stated in a January 25, 2018 report that "Other Late Stage Assets Also Progressing Swiftly," and specifically noted with respect to Ozanimod that "U.S. approval and launch in relapsing multiple sclerosis (RMS) expected in 4Q18 (following NDA filing in December 2017 . . .)."

465. On February 7, 2018, Celgene filed an Annual Report on a Form 10-K signed by Alles and Kellogg, with the SEC ("2017 10-K"), again representing that "***a New Drug Application (NDA) was submitted with the FDA for Ozanimod in RMS*** based on data from the phase III trials evaluating Ozanimod in patients with RMS." The 2017 10-K also included a chart representing that the "Status" of Ozanimod for RMS was "Regulatory submission" and that Celgene "Entered current status" in the fourth quarter of 2017.

466. The statements set forth in ¶¶ 461-465 above, including Defendants' statements discussing the submission of the Ozanimod NDA, were materially false and misleading, omitted material facts, and lacked a reasonable basis when made. Specifically, as set forth in ¶¶ 270-341 above, at the time Defendants issued these statements, Defendants knowingly or recklessly concealed and/or failed to disclose that:

(i) Defendants discovered a disproportionate Metabolite in November 2016;

(ii) the necessary testing and studies regarding the Metabolite, including many Phase I studies, were not complete at the time Celgene submitted the NDA and Celgene's failure to include the results from these studies in the NDA rendered it facially deficient;

(iii) Defendants knew that the Ozanimod NDA would be rejected for the reasons stated above in Section IV.D.5, including the FDA's warning during the November 2017 pre-NDA meeting that the NDA would be deemed incomplete unless Celgene included the Metabolite test results.

By electing to speak publicly about the complete status of Celgene's Ozanimod Phase III studies and the Company's submission of the NDA for FDA approval in 2018—and thereby putting these subjects into play—Defendants had a duty to fully, completely, and truthfully disclose all material facts regarding the discovery of the Metabolite and the incompleteness of the additional Phase I testing at the time Celgene filed the Ozanimod NDA in December 2017 which jeopardized Celgene's ability to receive FDA approval in 2018, so as to not mislead investors. As a result of the foregoing, undisclosed material facts, Defendants' public statements lacked a reasonable basis when made and were materially false and misleading at all relevant times.

VI. THE RELEVANT TRUTH EMERGES: ALLEGATIONS OF LOSS CAUSATION

467. Defendants' material misstatements and omissions complained of herein artificially inflated the market price of Celgene's publicly traded common stock. The artificial inflation in Celgene's stock price was removed when the facts and risks misstated and omitted by Defendants

were revealed to the market. Such corrective information was disseminated to investors through public disclosures on October 19, 2017, October 26, 2017, February 27, 2018, and April 29, 2018. Each such disclosure partially revealed relevant facts regarding the false and misleading nature of Defendants' material misstatements concerning GED-0301, Otezla, and Ozanimod. Each disclosure, more particularly described below, removed artificial inflation in the price of Celgene's publicly traded stock, causing economic injury to Lead Plaintiff and other members of the Class.

A. October 19, 2017: Celgene Discontinues Its GED-0301 Program

468. On October 19, 2017, after market close, Celgene issued a press release announcing that "the GED-0301 (mongersen) phase III REVOLVE trial (CD-002) in Crohn's disease (CD) and the extension trial (SUSTAIN, CD-004) will discontinue." The press release added that: "Celgene has decided to stop the trials following an October recommendation of the DMC, which assessed overall benefit/risk during a recent interim futility analysis" and that "[a]t this time, the phase III DEFINE trial (CD-003) in Crohn's disease will not be initiated."

469. Also on October 19, 2017, the Company filed a Form 8-K with the SEC stating that it expected to record a $1.6 billion impairment charge as a result of its decision to discontinue its GED-0301 trials, partially offset by a reduction in liabilities associated with the development program. As *Dow Jones* reported on October 19, 2017, Celgene concluded that "it will recognize a fourth-quarter 2017 charge to earnings related to the significant impairment of the approximately $1,600 million GED-0301 In-Process Research and Development asset, as well as wind-down costs associated with discontinuing the Trials and certain development activities." *Dow Jones* also reported that "[t]he exact amount of the net pre-tax charge to earnings has not yet been determined, but is estimated to be in the range of $300 million to $500 million, or $0.27 to $0.45 per diluted share after tax" and that "[a]pproximately 50 percent of the net charge will require cash payments."

470. In response to Celgene's disclosure on October 19, 2017, Celgene common stock fell by a total of $14.63 per share—nearly 11%—from a closing price of $135.96 on October 19, 2017 to a close of $121.33 on October 20, 2017 in a single trading day on extremely heavy trading volume of 27.8 million shares. This wiped out more than $11 billion in market capitalization.

471. As the *Barron's Blog* wrote on October 20, 2017, "[t]he stock fell almost 10.8% to close at $121.33 on a day when the S&P 500 posted a 0.5% gain, making Celgene the worst-performing stock in the index," which "cost Celgene $11.5 billion in market value."

472. On October 19, 2017, Morgan Stanley described the discontinuation of GED-0301 as "***a major setback***" for Celgene. Morgan Stanley reported that "[g]iven that mgt. did not identify any safety imbalances, we believe this decision was based on lack of efficacy."

473. Cantor Fitzgerald wrote the same day that Celgene's "discontinuation of GED-0301 Phase III REVOLVE trial and of the extension trial in Crohn's disease is a disappointment, taking the shares down 6% in after-hours trading."

474. Also on October 19, 2017, Raymond James wrote that "***few likely foresaw a GED-301 termination***," and that "few were expecting this development."

475. Market commentary stated that investors were then expecting Celgene's anticipated submission and approval of its Ozanimod NDA to compensate for any losses or setbacks the Company suffered as a result of the GED-0301 news. For example, Raymond James reported on October 19, 2017 that it believed the failure of GED-0301 could be offset by the potential future success of Ozanimod and Otezla, writing that "[m]anagement has sought to develop a continuum of inflammatory bowel disease products, and that strategy remains intact with ozanimod and Otezla." The same day, RBC Capital Markets similarly reported that "0301/mongersen d/c [discontinuation] is disappointing given high potential opportunity in Crohn's for unique oral, and

increases onus on ozanimod/BD [business development] for post-Revlimid revenue sustainability."

476. Negative market commentary continued into October 20, 2017. As reported by Benzinga, Baird Equity Research: (i) lowered Celgene's price target by 16% to $136 in light of Celgene's disclosure regarding GED-0301; (ii) noted "lower prospects for long-term growth, as pressure to succeed in [inflammation and immunology] is now almost exclusively on ozanimod"; and (iii) added that the "high-profile GED-0301 failure has potential to call into question the pipeline." Leerink Partners reported on October 20, 2017 that the GED-0301 discontinuation was "a painful reminder of the costs of a 'shots on goal' approach to business development, and the perils of heavily front-loaded investments into categories where the organization lacks technical and commercial expertise." In addition, the *Barron's Blog* wrote in an October 20, 2017 post called "Celgene: No Surprise? It's 10% Drop Says Different" that the news released about GED-0301 certainly "seems to be new to investors."

477. Despite the Company's October 19, 2017 disclosures concerning GED-0301 and the related stock price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to misrepresent and conceal material information from investors concerning Otezla and Ozanimod.

B. October 26, 2017: Celgene Discloses Sharply Negative Financial Results for Otezla

478. Only one week after Celgene's disclosure that it would be discontinuing its GED-0301 studies, on October 26, 2017, the Company released is third quarter 2017 financial results. Celgene reported total Otezla sales of only $308 million, a 14% decline from second quarter 2017 Otezla sales, and blamed "an increase in gross-to-net adjustments from contracts implemented in January and a slowing in overall category growth due to a more challenging market access

environment." Celgene also announced that it no longer expected 2017 Otezla net product sales to be between $1.5 billion and $1.7 billion as it had previously stated, but rather expected 2017 sales to be only approximately $1.25 billion. Celgene also stated that it was lowering its fiscal 2020 guidance as a result of the poor Otezla results.

479. In response to Defendants' disclosures on October 26, 2017, the price of Celgene common stock fell by $19.57 per share—more than 16%—from a close of $119.56 on October 25, 2017 to close at $99.99 on October 26, 2017 on abnormally high trading volume of 24.1 million shares. This wiped out more than $14 billion in Celgene market capitalization.

480. Analysts commented negatively not only on Celgene's missed and lowered guidance, but also on management's credibility. For instance, J.P. Morgan reported on October 26, 2017 that Celgene "management faces a major credibility issue." That day, Cowen and Company similarly reported that the shortfall on Otezla sales "is likely to impact the company's credibility." On October 26, 2017, *SeekingAlpha* also reported that "the Street has suddenly lost trust in Celgene's pipeline as well as the credibility of management's guidance." Raymond James downgraded Celgene stock from Strong Buy to Market Perform, and reported:

> ***[T]oday's update substantially alters our outlook and confidence in the company's ability to execute***. We previously viewed Celgene's immune & inflammatory (I&I) franchise as a key driver to facilitate a revenue diversification effort away from Revlimid. However, with GED-0301 now eliminated, and Otezla appearing to stumble, revised FY20 targets indicate an increasing reliance on the hematology franchise (rather than decreasing), which is the opposite of what we'd hope to see over time. Even if ozanimod data shows differentiation, we think CELG has now become a 'show me' story[.]

481. PiperJaffray also reported on October 26, 2017 that "despite an attractive valuation, we think management will need to start executing better commercially, clinically and strategically before this stock begins to work again." PiperJaffray further reported that:

> While some expected management to revisit 2020 guidance, given the GED-0301 failure from last week, we think ***the magnitude of the reset has clearly shaken investors***. Indeed, in one fell swoop, 2020 revenue guidance was shaved by $1.5B, with hematology accounting for >80% of revenue up from 70% of revenue. . . . With this new outlook, we can't imagine angst on this front will go away any time soon.

482. Similarly, BTIG Equity Research reported on October 26, 2017 that Celgene's third quarter results "***severely disappointed relative to expectations on Otezla***, and mgmt significantly lowered 2020 guidance due to several product forecast revisions." Jefferies Group LLC also reported that day that "***CELG put up an unusual notable revenue miss (it's been a few years since that happened by this much)*** and notably lowered 2017 revenue guidance and 2020 revenue and EPS guidance," and that "it will take some time to re-engage in credibility to hit targets and get quarters back on track and reset the situation."

483. Analysts also discussed the factors that drove Celgene's lower Otezla revenues. For example, in an October 26, 2017 report, BMO Capital Markets attributed the Otezla miss in part to discounting and competition from other psoriasis treatments, stating that "[a]lthough Otezla script growth was apparent (+4% Q/Q), it just wasn't enough to offset the aggressive discounting and slowing growth of psoriatic arthritis and ***greater competition*** in psoriasis markets."

484. Analysts reported that the magnitude of Celgene's miss was a surprise to the market. On October 26, 2017, J.P. Morgan reported that:

> In a word, CELG's print this morning was ugly. The company reported a top-line miss (total revenue of $3.28B vs. cons of $3.42B) with a bottom-line beat (non-GAAP EPS of $1.91 vs. cons of $1.87). . . . Otezla, in particular, was the standout for the wrong reasons with a bad miss ($380M vs. $411M). We believe a weak quarter was expected based on lackluster Rx trends, but not to this extent.

485. UBS similarly reported the same day that:

> While some shift in the makeup of 2020 guidance was expected (though not today), lowered guidance is a ***surprise*** – leaving the company even more dependent on Revlimid just as the focus on that[] drug['s] IP (rightly or wrongly) intensifies.

486. Also on October 26, 2017, Leerink Partners reported:

> This morning ***Celgene reported alarming Q3 2017*** with revenues 4% below consensus and pro forma EPS 2% above consensus, and the company lowered their long-term 2020 revenue targets by 5-10% after recent pipeline failures and negative market trends for Otezla. ***Investors are likely to ask whether the company's good fortune has run out, with disappointments (mongersen) and negative revisions (Otezla) left and right.*** Recently installed new management are likely to face tough questions from investors about the company's direction and leadership after the operational and guidance disappointments this quarter.

487. Even those analysts initially bullish on Celgene ultimately downgraded their ratings of Celgene shares. For example, Cantor Fitzgerald downgraded Celgene from Overweight to Neutral on October 26, 2017, and reported that:

> [T]he upside is now considerably less, given the lower visibility on the longer term. We had believed that pipeline execution would see CELG shares through the loss of REVLIMID, but the company's revisitation of guidance in the wake of GED-0301's failure creates an overhang and perhaps places greater pressure to execute on a strategic/business development option.

488. Despite Celgene's disclosures concerning Otezla results and related stock price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to misrepresent and conceal material information from investors concerning Ozanimod. For example, during the October 26, 2017 conference call, Defendant Alles tried to shift the focus from GED-0301 to Ozanimod and falsely and misleadingly claimed to investors that the "immediate shift from GED-0301 to ozanimod in Crohn's disease is a great example of the pipeline optionality and opportunity we have built and continue to build into our research model for hematology, oncology and inflammation and immunology."

C. February 27, 2018 and April 29, 2018: Celgene Receives a Refusal-to-File Letter for Ozanimod Based on Its Lack of Metabolite Testing

(a) February 27, 2018: Celgene Discloses the Refusal-to-File Letter for Ozanimod

489. After market close on February 27, 2018, just three weeks after Celgene's Form 2017 10-K touted the fact that "a New Drug Application (NDA) was submitted with the FDA for Ozanimod in RMS based on data from the phase III trials," Celgene issued a press release revealing that it had received an RTF from the FDA regarding its recently submitted NDA for Ozanimod. Celgene's press release stated:

> [U]pon its preliminary review, the FDA determined that the nonclinical and clinical pharmacology sections in the NDA were insufficient to permit a complete review. Celgene intends to seek immediate guidance, including requesting a Type A meeting with the FDA, to ascertain what additional information will be required to resubmit the NDA.

490. In response to the Company's disclosure on February 27, 2018, the price of Celgene common stock fell by $8.66 per share—more than 9%—from a close of $95.78 on February 27, 2018 to a close of $87.12 on February 28, 2018, on abnormally heavy trading volume of 27.9 million shares. This disclosure wiped out more than $6.5 billion in market capitalization.

491. Analysts responded immediately and negatively to this news, expressing shock and disappointment, particularly given management's recent positive commentary on Ozanimod. On February 27, 2018, for example, Raymond James reported that the market "didn't see this one coming," and called the RTF news an "unexpected development." *SeekingAlpha* reported the same day that the news of Celgene's RTF was "hard to accept as a reality" because receiving such a refusal to file letter from the FDA is "almost unheard of for a major company." Credit Suisse similarly reported that "we are disappointed by the timing delay related to the filing, and we think that this will continue to further concerns associated with management execution."

492. Reflecting on the critical implications the RTF would have for Celgene, RBC Capital Markets reported on February 27, 2018 that "given that [Celgene] will be requesting a Type A meeting with the FDA, it may be some time before there is additional clarity on the potential path forward. We view ozanimod as one of the most, if not the most, important pipeline programs for CELG[.]"

493. Other analyst firms also reported on February 27, 2018 that the RTF raised questions about Celgene's ability to diversify away from Revlimid. For example, PiperJaffray reported that:

> It's been a rough couple of months [for Celgene]. GED0301 failure notwithstanding, this isn't the first execution-related hurdle that I&I franchise has faced, with Otezla routinely falling short of expectations and the timeline for ozanimod in UC also recently delayed [], only raising more questions regarding CELG's efforts to diversify away from Revlimid.

494. Despite Celgene's disclosure of the RTF and the related stock price decline, the price of Celgene common stock remained artificially inflated as Defendants continued to conceal material information from investors concerning the testing required to address the Metabolite and how that testing would affect the timeline for submitting the revised NDA.

(b) April 29, 2018: Investors Learn that the Resubmission of the NDA will be Delayed up to Three Years

495. After almost two months of speculation surrounding the RTF, on April 25, 2018, in a presentation of Phase III Ozanimod Multiple Sclerosis data at an AAN meeting, a Celgene investigator disclosed new information about a "major active metabolite" of Ozanimod (CC112273), which, in fact, is behind the vast majority of Ozanimod's efficacy. Specifically, the investigator disclosed that Celgene first identified the Metabolite in a human mass balance study conducted in parallel with the Phase III Ozanimod trials, that the Metabolite levels were much

lower in the animal species used in the non-clinical studies than in humans, and that the Metabolite is responsible for approximately 90% of Ozanimod's clinical activity.

496. Despite Celgene's disclosure of the Metabolite on April 25, 2018, the price of Celgene common stock remained artificially inflated as Defendants continued to conceal material information from investors concerning the testing required to address the Metabolite and how that testing would affect the timeline for submitting the revised NDA.

497. The market's initial response to this news was mixed, as analysts tried to digest what it meant for Celgene and investors. For example, Morgan Stanley issued an analyst report after the close of trading on April 25, 2018 that concluded that the "Disclosure of active metabolite for Ozanimod is a ***net positive*** as it suggests the FDA RTF is due to lack of characterization of the metabolite." The analyst added that "[w]ith mgt. indicating it will provide an update with earnings and highlighting this disclosure at AAN, ***we suspect many investors will view this positively*** . . . ." As a result, Morgan Stanley wrote that it "would expect to see CELG ***up*** in the low-to-mid single digit % on the news."

498. The next day, April 26, 2018, RBC Capital Markets reported that "[t]hough we still do not know the exact reasons CELG received an RTF, the fact pattern suggested by yesterday's new details strongly indicates [the RTF] likely relates to ***some FDA discomfort*** around the characterization of this metabolite []" but that "[w]hether this can be quickly rectified, perhaps with add'l clinical characterization remains the key question and ***the key unknown***."

499. The ambivalence came to an end on Sunday, April 29, 2018, after Morgan Stanley issued a strongly negative report based on its detailed review of certain obscure data related to Ozanimod's other metabolites. Morgan Stanley's April 29, 2018 report entitled, "More Bread Crumbs Yield Less Confidence in Ozanimod," stated that its "analysis of prior ozanimod pre-

clinical studies suggest [that] CC112273 concentrations in prior pre-clinical work is unlikely to approximate human clinical doses" and, "[t]herefore we believe it is increasingly likely mgt. will need to complete new preclinical work on CC112273 ***setting up a 1 to 3 year delay***."

500. The Morgan Stanley analysts explained that their analysis was only made possible after they "were able to locate copies of [] posters over the weekend [April 28 and 29]" containing the "previously published ozanimod preclinical toxicology results and studies of [the two] known metabolites," i.e., other than CC112273. The posters established that the two previously identified metabolites produced levels in the animal studies that were just above the human therapeutic dose and therefore approximated the human dose. The analysts further explained that, based on their review of FDA guidance on metabolites, "the only way for mgt. to avoid synthesizing CC112273 and re-running preclinical [i.e., Phase I] toxicology [i.e., engaging in protracted testing] was by having exposure of CC112273 in animals equivalent to the human therapeutic dose" so that Celgene could simply recycle the prior testing used on the known metabolites. However, as Morgan Stanley explained, a "1 to 3 year delay" in completing the requisite testing was unavoidable given the significantly higher levels of the Metabolite in humans compared to animals. Morgan Stanley referred to its "prior review of FDA guidance on metabolites" and stressed that:

> However, given that mgt. indicated 'CC112273 levels were ***much lower*** . . . in the animal species used in the non-clinical studies than the amount produced by humans' and that ***our calculations suggest the prior set of identified (and thus studied metabolites) produced levels barely above the human therapeutic dose, we believe it is increasingly unlikely CC112273 produced levels near the human therapeutic dose in the prior preclinical work. Thus, mgt. will likely need to re-run preclinical toxicology which could take 6 months (rats) to 2 years (another carcinogenicity study). Given the timeline to start the study, produce the study reports and refile, we believe the delay is at a minimum 1 year and up to 3 years if mgt. must redo all animal work.***

The bolding and italics above appeared in the original Morgan Stanley April 29, 2018 report, to emphasize the importance of this text to its readers.

501. Celgene's stock price fell on the news of the significant additional testing required from Celgene and the significant delay for Ozanimod approval as a result of the Company's premature submission of the NDA. Specifically, Celgene's common stock dropped from a close of $91.18 on April 27, 2018 to close at $87.10 on April 30, 2018, a 4.5% decline that wiped out approximately $3 billion in market capitalization.

502. Analysts attributed this decline to the revelations that resulted from Morgan Stanley's detailed, specialized analysis and digestion of Celgene's informationally-complex AAN disclosure. For example, *The Motley Fool* wrote on April 30, 2018 that: "[S]hares of Celgene lost 4.5%. The biotech giant got negative comments from analysts at Morgan Stanley, who predicted that it could take several years for Celgene to move forward with plans to file for approval from the U.S. Food and Drug Administration for its multiple sclerosis candidate drug ozanimod." Similarly, *Citywire* reported on the same day that "Celgene shares fell 4.5% after Morgan Stanley said it expects a delay of up to three years for Celgene's key multiple sclerosis drug, ozanimod." Likewise, *Marketwatch* reported on this date that "Celgene Corp. . . . fell 4.5% after a Morgan Stanley report predicted a one- to three-year delay on any new attempt to file for U.S. approval of the company's highly anticipated drug ozanimod, which is designed to treat multiple sclerosis."

503. As a result of Defendants' misstatements and omissions, which were corrected by the disclosures discussed above, in total, the price of Celgene common stock ended the Class Period at $87.10, more than 40% below its Class Period high of $146.52 on October 4, 2017.

VII. ADDITIONAL ALLEGATIONS OF SCIENTER

504. Celgene and the Individual Defendants were active and culpable participants in the fraud, as evidenced by their knowing or reckless issuance of and/or control over Celgene's and the

Individual Defendants' materially false and misleading statements and omissions. Celgene, through its management and other senior level employees, and the Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public statements set forth in Section V above were materially false and misleading when made, and knowingly or recklessly participated or acquiesced in the issuance or dissemination of such statements as primary violators of the federal securities laws. In addition to the facts alleged in Section IV above, regarding Celgene's and the Individual Defendants' personal knowledge and/or reckless disregard of the materially false misrepresentations and omissions, Celgene's and the Individual Defendants' scienter is evidenced by the specific facts discussed below.

A. Defendants' Knowledge and Reckless Disregard of Misstatements Regarding GED-0301, Otezla, and Ozanimod

505. Defendants were directly involved in and participated in both the management and day-to-day operations of the Company at its highest levels. Accordingly, as detailed below, Defendants each had access to detailed information concerning the Company's I&I franchise generally, and GED-0301, Otezla, and Ozanimod, specifically. This information was transmitted and learned through meetings, reports and other regular communications, as detailed by numerous confidential witnesses.

1. GED-0301

506. Celgene's and the Individual Defendants' scienter with respect to the misstatements and omissions regarding the evidence of GED-0301's efficacy, the design and results of the Phase II and Phase Ib studies, and the timeline for its regulatory approval is evidenced by the following facts, among others:

(a) Defendants knew or recklessly disregarded severe deficiencies in the pre-acquisition data supporting GED-0301's efficacy

(i) Defendants secretly acknowledged the limited evidence of GED-0301's efficacy. FE 1 stated that after entering into the licensing agreement, he communicated with members of Celgene's senior management about the limitations of the pre-acquisition Phase II data, including Smith or Diamond, and that Celgene's senior management acknowledged the limitations of the Phase II data. ¶ 122.

(ii) FE 1 stated that the Advisory Board agreed on the need for endoscopic evidence and the limitations of the Phase II study, and that the need for endoscopic testing was communicated by him to the Celgene representatives who participated in the pre-acquisition due diligence conference calls. As a result, FE 1 stated that Celgene was "absolutely" aware of the limited evidence of GED-0301's efficacy based on the Phase II data. ¶¶ 118-122.

(iii) FE 2 recalled that in or around mid-2015 there were ongoing meetings among the GED-0301 development team, including with Usiskin, about the limitations of the GED-0301 Phase II study data, including the lack of endoscopic evidence. ¶ 142. FE 2 stated that based upon the Phase II clinical trial data, it was "irresponsible" for Defendants to claim that GED-0301 was "transformational." ¶ 129. FE 2 recalled "a lot of discussion" within Celgene that the Company had paid too much for GED-0301 given the limited evidence of GED-0301's efficacy. ¶ 128.

(iv) FE 4 stated that, based on discussions with other scientists and investigators within Celgene concerning the pre-acquisition GED-0301 data, "everybody [within Celgene] knew the acquisition was a poor science decision" because the data that was used to justify it lacked endoscopic evidence of efficacy. ¶ 126.

(v) FE 1 stated that after the publication of the *NEJM* editorial, the GED-0301 Advisory Board discussed the limitations in the Phase II study identified by Dr. Vermeire and communicated those views to Celgene, and Celgene acknowledged the limitations of the study data. ¶¶ 140-141.

(vi) The prevailing scientific literature at the time Celgene licensed GED-0301, of which Defendants were no doubt aware, recognized that endoscopic evidence is necessary to properly assess the efficacy of a treatment for CD when compared to placebo. ¶ 119.

(vii) FE 1 and FE 3 both stated that endoscopic evidence was viewed as the primary measure of efficacy in clinical trials for CD treatments, and that regulatory

bodies, including the FDA, had made clear that they would not accept proof of efficacy that did not include endoscopic testing. ¶¶ 119, 125.

(viii) FE 2 confirmed that it was understood internally at Celgene that the FDA viewed endoscopic evidence as necessary to demonstrate efficacy, as this guidance was considered in designing the GED-0301 Phase III trial. FE 2 also believed that Celgene was specifically advised by the FDA of the need for endoscopic endpoints in order to support claims of efficacy. ¶ 121.

(ix) FE 2 stated that internally at Celgene there was doubt and confusion concerning GED-0301's mechanism of action, noting that while the drug was in development at Celgene, Celgene's views on how the drug supposedly worked were "changing with the wind." FE 2 described a multi-disciplinary project meeting in or about March 2016 in which it was discussed that, based on experiments conducted by Celgene, the mechanism of action as described by Nogra at the time of the acquisition was not correct. ¶ 154.

(x) FE 2 also stated that there was skepticism within Celgene about whether the GED-0301 delivery mechanism worked, explaining that because the drug was an oral therapy and not systemically absorbed by the body, it had to dissolve at just the right spot in the gastrointestinal system to be effective, and it was unclear whether that happened. ¶ 155.

(b) Defendants knew of or recklessly disregarded additional red flags concerning the Phase II data

(i) Defendants knew or recklessly disregarded that Monteleone, who was the lead researcher for the Phase II study, held a patent for the use of Smad7 antisense oligonucleotides in CD and stood to personally profit if GED-0301 was successful. ¶ 131.

(ii) FE 2 stated that it was internally recognized by Celgene employees who were working on GED-0301 that the pre-acquisition data was "suspicious." ¶ 128. FE 2 also recalled conversations within Celgene regarding the fact that Monteleone had a large personal financial interest in GED-0301. ¶ 131.

(c) Defendants designed a deficient Phase Ib study, and knew or recklessly disregarded the lack of GED-0301's efficacy following the release of the flawed Phase Ib results

(i) FE 1 stated that Celgene's decision to conduct the Phase Ib study reflected the Company's awareness of the limitations of the Phase II study. Despite the Advisory Board's warnings to Celgene that the existing data did not support GED-0301 efficacy, FE 1 stated that Celgene "***chose not to install adequate controls***" in

the Phase Ib study and that the decision not to include a control arm was a "***corporate decision***," not a science-driven decision. ¶ 167.

(ii) FE 1 discussed the Phase Ib study's lack of a control arm with other IBD experts who worked with Celgene, all of whom shared FE 1's concerns about the limitations of the Phase Ib study results. These discussions confirmed FE 1's belief that the Phase Ib study was flawed and that Celgene chose not to install adequate controls when designing the Phase Ib study. ¶¶ 168-169.

(iii) FE 4 noted that patients with CD often relapse and remit without any treatment, and stated that it was known internally at Celgene that the lack of a control arm in the Phase Ib trial meant that the results did not support Celgene's claims regarding GED-0301's efficacy. ¶ 173.

(iv) FE 5 raised concerns with Martin, Diamond, and others within Celgene about the flawed Phase Ib study design, stating that the claimed efficacy was "***not real***" without a placebo control group. FE 5 noted that the senior Celgene employees with whom he spoke refused to engage substantively about the lack of evidence of GED-0301's efficacy. As a result of raising these concerns, FE 5 was subject to hostile treatment, contributing to his leaving the Company. ¶¶ 175-177.

(v) FE 3 informed Celgene that there was no endoscopic response observed at his testing site and stated that his peers also did not see any robust results. ¶ 172.

(d) Defendants were aware that the Phase III clinical trial was going to be unsuccessful at the time they touted GED-0301's timeline for regulatory approval

(i) FE 4 stated that Celgene had effectively given up on GED-0301 after the Phase Ib study, recalling that between the time the Phase Ib data was released in September 2016 and the time the Phase III trial was discontinued in October 2017, GED-0301 was not mentioned during internal quarterly review meetings with Celgene's Vice Presidents, stating that it was unusual for one of the Company's major development-stage drugs not to be discussed in such meetings. ¶ 187.

(ii) FE 5 confirmed that internally, by March or April of 2017, it was very clear that Celgene had recognized that GED-0301 would be a failure, as during this timeframe, Celgene shifted its focus to Ozanimod as a first line therapy for CD. Furthermore, Martin, Kopicko, and Saillot were frantically pushing the Ozanimod CD team to show better efficacy for CD than GED-0301, going so far as to manipulate the testing protocol for the ongoing Ozanimod CD clinical trial in order to boost Ozanimod's apparent efficacy. ¶¶ 188-191.

(iii) FE 4 stated that approximately four months prior to Celgene's October 2017 announcement of its discontinuation of Phase III testing, he was told by Horan, a Principal Investigator at Celgene who was in a position to access the information regarding the ongoing Phase III GED-0301 trial, that the trial was going to be "***scrapped***." ¶¶ 192-193.

(iv) FE 6 was similarly informed by a Celgene colleague in the summer of 2017 that the GED Phase III clinical trial would be discontinued. Specifically, in August 2017, FE 6's colleague attended a meeting among Celgene's RMLs and MSLs in Chicago, which Defendant Callegari and Diamond also attended, and during this meeting it was discussed that the GED-0301 Phase III trial would not be successful. ¶ 194.

2. Otezla

507. Celgene's and the Individual Defendants' scienter with respect to the misstatements and omissions regarding the unreasonableness and unattainability of the Company's 2017 Otezla sales guidance is evidenced by the following facts, among others:

(a) Smith, Curran and others in senior management were warned that the 2017 Otezla sales guidance could not be met and should be lowered

(i) FE 7 repeatedly warned Defendant Smith that the Company's strategy of offering deep discounts and rebates for Otezla was fatally flawed and rendered it "impossible" for the Company to achieve the 2017 Otezla guidance. ¶ 250. As early as the Otezla launch, FE 7 informed Smith—who had the final say with regard to Otezla and Market Access decisions—that he would be destroying the "best price" for the drug by offering large rebates and discounts, thereby setting Otezla up for consistently depressed net revenues going forward. ¶¶ 212-214.

(ii) FE 7 wrote multiple emails to Celgene's senior executive management, including Smith, documenting his concerns about the discounts and rebates that Celgene was offering for Otezla. ¶ 215. FE 7 also told Smith that Celgene should never "pay to play"—i.e., offer rebates and deep discounts in exchange for market access—as that would prevent Celgene from maximizing its profits. ¶ 215.

(iii) According to FE 14 and FE 12, Celgene's management had access to Otezla sales data that Celgene received from IMS through Tableau. This data reflected straight volume, volume growth, number of prescriptions by territory, number of prescriptions by provider, and number of prescriptions attributed to each salesperson. ¶ 219. Sales representatives from across the country all reported that

sales of Otezla, which were reflected in Tableau, were steady to flat from 2014 through 2017. ¶¶ 218-219.

(iv) No later than the third quarter of 2016, Tessarolo communicated in weekly meetings with the IIEC, which included Defendants Smith and Curran, that the 2017 Otezla guidance could not be met. ¶ 236.

(v) During presentations in the third and fourth quarters of 2016, FE 17 and his team informed the IIEC that the 2017 Otezla sales guidance could not be met. FE 17 recounted that "***everyone knew that the actual stated forecast was not reasonable***" and could not be met. ¶ 235-237.

(vi) In the fourth quarter of 2016, FE 17 expressly advised the IIEC that the Otezla sales guidance should be lowered. ¶ 237.

(vii) By the end of 2016, Tessarolo again warned the IIEC of the need to lower the 2017 Otezla sales guidance, but the IIEC insisted that the forecasts would not be changed. ¶ 237.

(viii) The forecasting team was "***told to change***" ***the numbers*** (i.e., the internal forecasts) by Smith and Curran to conceal the lack of growth. ¶ 238.

(ix) According to FE 17, Defendants refused to lower the Otezla guidance per his warnings and instead put pressure on the salespeople to hit the impossible numbers. ¶ 241.

(x) FE 18 indicated that the aggressive Otezla guidance did not account for the introduction of new competition to the PA and psoriasis market and that CPMAC knew of, but simply ignored, this factor. ¶ 240.

(b) Multiple former employees confirmed that Defendants knew that 57% year-over-year growth in Otezla net product sales between 2016 and 2017 was unachievable.

(i) FE 19 stated that in late 2016, when Defendant Smith was assessing the 2017 Otezla market access information that FE 19's team put together and setting the sales targets, the market did not support anything close to the 57% growth Defendants told the public. ¶ 246. According to FE 19, there was no way Defendant Smith could have interpreted what his Market Access team was reporting and translated that into 57% sales growth for Otezla in 2017. ¶ 247.

(ii) FE 17 stated that as early as April 2016, the rebates due on existing Otezla prescriptions covered by "underwater" PBM contracts were "significant." ¶ 248. In light of these outstanding rebates, FE 17 stated that Celgene management should

have given a warning to investors in the fourth quarter of 2016 because the IIEC knew about the rebate issue and the impact that it was going to have on the Company's 2017 Otezla revenues. ¶ 248.

(iii) In anticipation of a planned 2017 price increase for Otezla, Celgene's management acceded to the requests of many wholesalers to purchase in December 2016 the quantities of Otezla they were slated to purchase in January 2017, in order to take advantage of the lower price. ¶ 249. This buy-in negatively and foreseeably impacted Otezla sales in the first quarter of 2017. ¶ 249.

(iv) FE 17 learned from Tessarolo that he had given a presentation to the IIEC in early 2017 concerning the disappointing Otezla sales and had warned the IIEC that the Company needed to downgrade its 2017 Otezla guidance. ¶ 252. However, rather than heed Tessarolo's warning, Defendant Smith cut him off, stating that he had heard enough of the negative information. ¶ 259.

(v) FE 7, added that "***there isn't any way to grow [Otezla] revenue by 57%***." FE 7 was very vocal to senior management and specifically told them that Otezla's growth could not continue because of the step-edit hurdles and the saturation of competitor drugs in the market. FE 7's warnings, however, were ignored.

(c) Defendants lacked a reasonable basis for representing that new PBM contracts and the removal of step-edits would help the Company hit the 2017 Otezla sales guidance

(i) In November or December of 2016, FE 7 met with Grausso, Curran, Tessarolo, Swartz, Willcox and Owen and again warned these executives that paying to remove the step-edits for Otezla was not a cure for the drug's broad-based market access challenges. ¶ 257.

(ii) Even though the Company entered into new PBM contracts that went into effect in 2017, Celgene did not recognize revenues from prescriptions for many patients covered by these contracts until months later. ¶ 260. FE 18 stated that it was clear from the beginning of 2017 that the new PBM contracts were not meeting revenue expectations. ¶ 261. FE 18 communicated this fact to his boss, Swartz, and she reported this information to the CPMAC. ¶ 261. According to FE 18, notwithstanding the data showing that the contracts were underperforming, Celgene refused to lower expectations for the PBM contracts. ¶ 261.

(iii) FE 18 confirmed that the market for Otezla did not change rapidly in 2017: "***We saw what was happening way before then. We had monthly meetings with the contract and pricing teams . . . very early on in 2017***" and there was "worry" and "concern" at these meetings. As FE 18 further stated: "We were in trouble with our Otezla contracts. You heard that from a lot of the pricing and contract people." ¶ 265.

3. Ozanimod

508. Celgene's and the Individual Defendants' scienter with respect to the misstatements and omissions regarding the submission of the Ozanimod NDA and the status of the Company's Ozanimod clinical development, is evidenced by the following facts, among others:

(a) Upon acquiring Receptos, Celgene exercised control and decision-making authority over Receptos and Ozanimod

(i) FE 20 explained that once Celgene agreed to acquire Receptos on July 14, 2015, all decisions were made by Celgene in New Jersey or on-site Celgene personnel. ¶ 272.

(ii) FE 21 stated that after the July 14, 2015 acquisition, Celgene did not allow Receptos' leadership to partake in any decisions that could potentially impact Celgene's stock price. ¶ 272.

(iii) FE 2 recalled that Martin, who FE 2 described as a "control freak" and Smith's right-hand man, was sent by Celgene to San Diego to serve as the Managing Director for Receptos. ¶ 273. FE 2 referred to Martin as the *de facto* chief executive of Receptos. ¶ 273.

(iv) FE 5 likewise described Martin as the CEO of Receptos after the acquisition and confirmed that Martin was in charge of the entire Receptos organization and reported directly to Smith. ¶ 273. FE 5 also recounted that Smith sent Gary Cline, Head of Strategic Research and Innovation, to San Diego to keep tabs on Ozanimod for him. ¶ 274.

(v) FE 22 further corroborated that Martin reported directly to Smith and Saillot was Martin's second in command. ¶ 274.

(b) Defendants knew that the Metabolite required additional testing prior to submitting the NDA, and that the NDA was deficient upon submission

(i) On November 21, 2016, Celgene completed the Mass Balance Study and identified the Metabolite. ¶ 297. FE 20 confirmed that the Metabolite was discovered during this study. ¶ 298. FE 21 similarly recalled that Celgene identified the Metabolite approximately one year before the Ozanimod NDA was submitted in December 2017. ¶ 298.

(ii) FE 21, who had first-hand knowledge of the Metabolite, discussed the discovery with Martin and noted that it was of great concern. ¶ 299. In response,

Martin told FE 21 not to tell anyone about the Metabolite discovery and that Martin would tell him who needed to know and send people to him to work on the Metabolite. ¶ 299.

(iii) FE 21 stated that the employees in his role and Martin's role at Celgene knew about the Metabolite discovery. ¶ 299. FE 21 also stated that Celgene's senior leadership was briefed on the discovery of the Metabolite and the ongoing characterization efforts "quite some time before the filing" of the NDA. ¶ 303.

(iv) FE 5 recalled that during an Ozanimod meeting in March or April of 2017, Defendant Tran confirmed the need for additional testing and studies of the Metabolite. ¶¶ 304-305. FE 5 confirmed that Martin, Saillot (who reported to Martin), Frohna (Vice President of Clinical Development and Translational Medicine, Receptos who reported to Martin), Kopicko (Executive Director of Biometrics, Receptos, who reported to Martin), Penenberg (Director, Receptos, who reported to Kopicko), Aranda (Vice President of Clinical Development, Receptos, who reported to Martin), Skolnick (Executive Director of Clinical Development, Receptos, who reported to Aranda), and others attended this March/April 2017 meeting. ¶ 304.

(v) FE 5 further recalled that at this March/April 2017 meeting Tran directed his comments concerning the Metabolite to Martin and Saillot, but that Martin and Saillot quickly shut down the conversation. ¶ 305.

(vi) FE 21 stated that he and his colleagues discussed the need to perform additional testing after finding the Metabolite and the working team in "clinpharm" advocated that if Celgene submitted the NDA, it would get a refusal to file. FE 21 confirmed that this was said to his direct management. ¶ 314.

(vii) FE 21 and his colleagues agreed that the Company should wait to complete testing on the Metabolite before submitting the NDA as there was no empirical reason to submit without it. ¶ 313. He was never provided any reason why Celgene was rushing to submit when it was clear that more work was required. When he expressed his feelings to his leaders he was told to keep his personal feelings to himself. ¶ 313.

(viii) According to FE 22, in November 2017, Celgene met with the FDA for a pre-NDA meeting. ¶ 316. FE 22 stated that during this pre-NDA meeting, the FDA told the Company: (i) the FDA needed the study results for the Metabolite; (ii) the results were very important; and (iii) the results had to be included in the Ozanimod NDA. ¶ 317.

(ix) As detailed above, ¶¶ 282-292, federal regulations and FDA guidance, which Defendants were required to follow, had a duty to monitor, and must have

known about: (i) stress the importance of testing for metabolites before filing an NDA; (ii) require additional testing of metabolites where the results between human and animal testing differ; and (iii) mandate that NDAs address drug metabolism.

(x) Celgene's receipt of the RTF is additional evidence of Defendants' scienter because: (i) according to the FDA, "an RTF is based on omissions of clearly necessary information (e.g., information required under the statute or regulations) or omissions or inadequacies so severe as to ***render the application incomplete on its face***" (¶¶ 324-325); (ii) only 45 RTFs have been issued between December 31, 2001 and February 28, 2018 (¶ 326); and (iii) at least one market analyst noted that companies like Celgene "do not make execution mistakes like the one [involving the Ozanimod NDA]" (¶ 326).

(xi) Celgene admitted after the fact (in June 2018) that the NDA was facially deficient upon submission when it blamed Receptos for the NDA filing. ¶ 337.

(xii) FE 21, FE 22, and FE 2 all rejected the idea that the deficient NDA was submitted without the approval of Celgene's leadership, ¶¶ 339-340; and Hasnain, the former CEO of Receptos, and Frohna, the former Vice President of Clinical Development and Translational Medicine at Receptos, publicly stated that Celgene was responsible for filing the NDA. ¶ 338.

(c) Defendants were motivated to file the NDA for Ozanimod in late 2017 without the necessary Metabolite testing

(i) Defendants were motivated to submit the NDA in late 2017, rather than wait to complete the necessary Metabolite testing, because Gilenya was set to lose its patent exclusivity, paving the way for Gilenya generics that would compete with Ozanimod to enter the RMS market by the end of 2019. By submitting the NDA in late-2017 for early-2018 approval, Celgene sought to gain a year's worth of market share for Ozanimod before having to fend off cheaper competition from generics. ¶¶ 279-280.

(ii) Defendants also were motivated to hide the results of the Mass Balance Study, as they demonstrated that the Metabolite's half-life was much longer than Gilenya's, thereby wiping out a previously reported advantage of Ozanimod. ¶¶ 302, 320, 333.

(iii) Defendants also were financially motivated to submit the NDA in 2017. ¶ 321. FE 22 stated that both Martin and Saillot received bonuses for submitting the Ozanimod NDA by year-end 2017. ¶ 321. FE 20 confirmed that the compensation for the Celgene and Receptos personnel, including Martin, was tied to the Ozanimod NDA filing, and that the higher you went up the corporate chain, the greater the amount of compensation tied to the NDA filing. ¶ 321.

(iv) Celgene's annual proxy statement on Form DEF 14A, filed with the SEC on April 27, 2017, disclosed that Defendants Hugin, Alles, Kellogg and Smith were all entitled to performance awards based in part on the "filing of a new drug application." ¶ 321. Hugin, Alles, Kellogg and Smith received lucrative performance awards for 2017 of $2,175,000, $2,144,623, $800,352, and $629,125, respectively, along with company stock. ¶ 321.

B. The I&I Franchise was One of Celgene's Core Operations

509. Celgene's I&I franchise—which consisted of commercial stage Otezla and pipeline drugs Ozanimod and GED-0301—was one of the Company's core operations during the Class Period. As discussed above (*see* ¶¶ 99-103), Celgene devised a three-pronged plan to develop and market three I&I drugs—GED-0301, Otezla, and Ozanimod—in an attempt to replace the Company's revenue stream from its extremely successful cancer drug, Revlimid.

510. The first prong of Celgene's Revlimid replacement plan centered around GED-0301, which Celgene purchased from Nogra for $710 million upfront in addition to committing nearly $2 billion more in milestone payments—***the largest single-drug acquisition in pharmaceutical history***. The second prong was Otezla, which Celgene described as its "***flagship product***" driving the I&I franchise's success. Indeed, Celgene noted that the Company was "dependent upon the continued commercial success of . . . Otezla." The third prong focused on Celgene's acquisition of Receptos and with it, Ozanimod, a development-stage drug that was described by one commenter as "the ***crown jewel*** of Celgene's $7.2 billion acquisition of Receptos, Inc." Following the Receptos acquisition, Celgene revised its 2020 revenue guidance for the I&I franchise up from $3 billion to over $4 billion. Based on the importance of the three drugs to Celgene's business, Defendants must have been aware of all material facts affecting their revenue generation potential.

511. Defendants' own statements confirm that they paid particularly close attention to the status of each drug. Throughout the Class Period, Defendants repeatedly acknowledged the

importance of GED-0301, Otezla, and Ozanimod to Celgene's success. For example, in announcing the Receptos acquisition, Celgene noted that its "I&I pipeline will, upon completion of the [Receptos] transaction, consist of three high-potential commercialized or late-stage assets: OTEZLA, GED-0301 and Ozanimod." Celgene also touted all three drugs as being among the Company's "multiple potential blockbuster products in I&I," which were the keys to replacing revenue when Revlimid lost its patent exclusivity:

- On July 23, 2015, Celgene touted GED-0301, along with Ozanimod and Otezla, as being among their "multiple potential blockbuster products in I&I" which were expected to lead the company towards "significant growth through 2020 and beyond."

- On January 9, 2017, Alles stated: "As we think about these catalysts between 2020, 2030, and this window of affirming our 2020 targets, there are three launches coming. Otezla I have already talked about; . . . But Ozanimod in relapsing MS, GED-0301 in Crohn's disease, and then again Ozanimod in ulcerative colitis, a three-year run here of fantastic opportunity for us to create a multi-billion-dollar add on to our current product portfolio."

- On May 31, 2017, Alles stated that "the 3 products, OTEZLA, ozanimod and GED-0301, . . . that revenue alone, that opportunity alone can offset all of not the annual REVLIMID sales, right, but whatever the peak is. ***This is a replacement for it***."

512. The repeated statements made by the Individual Defendants throughout the Class Period touting the evidence of GED-0301's efficacy and the timeline for its commercialization, reaffirming the 2017 Otezla sales guidance, and discussing the progress of Ozanimod toward NDA submission, strongly and plausibly suggest that each Defendant had detailed knowledge of or access to material facts and information misrepresented or concealed by Celgene's and the Individual Defendants' statements. In addition, the Individual Defendants' repeated statements regarding these topics demonstrate that these were areas upon which the Individual Defendants were particularly focused, had a duty to monitor, and therefore knew or recklessly disregarded the omitted and misrepresented information.

C. Defendants Were Financially Motivated to Conceal Material Information from Investors

513. Individual Defendants Alles, Curran, and Hugin (the "Insider Trading Defendants") were financially motivated to commit securities fraud and realized substantial financial benefits from their personal sales of Celgene stock at the same time that they and the Company misrepresented and concealed from investors Celgene's material problems with GED-0301, Ozanimod, and Otezla.

514. At the same time that Celgene issued materially false and misleading statements to investors, the Insider Trading Defendants collectively sold 569,796 shares of their Celgene stock at artificially inflated prices as high as $143.89 per share, for illegal insider trading proceeds in excess of ***$68.4 million***, and profits of at least ***$27.6 million***. These sales are detailed in the chart below:

Name	Date	Shares Sold	Price	Proceeds	Cost per Share	Profit	% of Shares Sold
Alles	2/6/2015	117,099	$120.68	$14,131,156	Approx. $41.75	Approx. $9,242,272	67.30%
Curran	9/25/2017	1,727	$143.89	$248,498	Not publicly disclosed		30.56%
Hugin	6/20/2016	75,000	$100.16	$7,512,000	Not publicly disclosed		27.4%[16]
	7/28/2016	100,000	$110.00	$11,000,000	Not publicly disclosed		
	11/9/2016	100,000	$120.00	$12,000,000	Not publicly disclosed		
	6/22/2017	60,000	$134.14	$8,048,400	$29.26	$6,292,800	

[16] Prior to Hugin's first Class Period sale, he held 1,197,201 shares of Celgene common stock. Through option exercises during the Class Period, at highly favorable prices, he acquired 450,970 additional shares of Celgene common stock in connection with the sales set forth herein. These option exercises increased his cumulative common stock holdings to 1,648,171 shares. The 27.4% figure represents the cumulative sale of those 450,970 shares divided by the cumulative holdings of 1,648,171 shares.

		60,000	$134.14	$8,048,400	$33.78	$6,021,600	
		55,970	$134.14	$7,507,815	$24.81	$6,119,200	
			Total	**$68,496,269**			

515. The Insider Trading Defendants' sales of Celgene stock were suspicious in timing and amount.

516. As set forth above, Alles, Celgene's President and COO, sold 117,099 shares of Celgene stock on or about February 6, 2015, at a price of $120.68, for total proceeds of $14.1 million, and profits of approximately $9.2 million. This sale was suspiciously timed because it followed a significant run up in the price of Celgene stock following Celgene's acquisition of GED-0301 on April 24, 2014, when Celgene stock traded for as low as $68.38 per share. Alles' sales were suspicious in amount because they represented 67.3% of his currently-held shares of Celgene common stock at that time. In addition, his sales were suspicious in amount because his approximately $9.2 million in profits from the sales were approximately ***5.5 times*** greater than Alles' 2015 total salary and bonus compensation ($1,669,907). Alles' Class Period sales were also suspicious in timing and amount because Alles sold 15% more Celgene shares during the Class Period than during a period of similar length before the Class Period (the "Control Period").

517. Curran, Celgene's President of Inflammation & Immunology, sold 1,727 shares of Celgene stock on or about September 25, 2017, at a price of $143.89, for proceeds of $248,498. This sale was suspiciously timed because it occurred after Celgene secretly determined that the GED-0301 program would be discontinued, but before Celgene publicly disclosed that material adverse fact to the market on October 19, 2017. In response to that news, the price of Celgene stock fell to a price of $121.33 on October 20, 2017. Curran's sale was also suspiciously timed because it occurred after Curran and other senior executives had been warned that the 2017 Otezla

sales guidance could not be met and should be lowered, but right before Celgene publicly disclosed the lowered guidance. Indeed, just weeks after Curran's September 25, 2017 stock sale, on October 26, 2017, Celgene disclosed sharply disappointing financial results for Otezla and lowered its financial guidance as a result. In response to that news, the price of Celgene stock fell to $99.99 on October 26, 2017. Curran's sale was suspicious in amount because it represented 30.56% of her currently-held shares of Celgene common stock at that time. A comparison of these sales to Curran's annual salary and bonus compensation is not possible at this time because her salary and bonus compensation is not publicly reported in Celgene Proxy Statements. In addition, a comparison of Curran's Class Period sales to her pre-Class Period sales is not possible at this time because her pre-Class Period sales are not publicly disclosed.

518. Hugin, Celgene's Executive Chairman, sold 450,970 shares of Celgene common stock during the Class Period at artificially inflated prices ranging from $100.16 to $134.14, for total proceeds of $54.1 million and profits of at least $18.4 million. The cost basis for the 275,000 shares that Hugin sold during the Class Period in June, July, and November 2016 is not publicly available, but his profits on just his sales of 175,970 shares of Celgene stock on June 22, 2017 alone are $18.4 million. Hugin's sales were suspicious in amount because his profits of at least $18.4 million from his June 2017 sales alone were approximately ***five times*** greater than his 2017 salary and bonus compensation ($3.675 million).

519. Hugin's June 22, 2017 sales of 175,970 Celgene shares were particularly suspicious in timing because they occurred at the time that: (i) Celgene secretly determined that the GED-0301 program would be discontinued, but before the Company announced its discontinuation on October 19, 2017; (ii) Defendants knew that Celgene was not going to meet its 2017 Otezla sales guidance, but before the Company announced the shortfall on October 26, 2017; and (iii)

Defendants knew that discovery of the Ozanimod Metabolite required extensive Phase I testing that would made it impossible to file a complete NDA in 2017, which materialized with announcements in February and April 2018 when the FDA rejected the Ozanimod NDA and the likely timetable for the missing Phase I testing was revealed, respectively. In addition, Hugin's total Class Period sales were suspicious in amount because they represented 27.4% of his shares of Celgene common stock acquired and held during the Class Period after his June 20, 2016 sale. Hugin's Class Period sales were also suspicious in timing and amount because Hugin sold ***nearly three times*** more Celgene shares during the Class Period than during the Control Period.

520. Celgene Form 4 filings with the SEC indicate that the Insider Trading Defendants' Class Period sales of Celgene common stock on February 6, 2015; June 20, 2016; July 28, 2016; November 9, 2016; and September 25, 2017 were made pursuant to Rule 10b5-1 trading plans. However, those public filings do not specify when the Insider Trading Defendants entered into those plans. Accordingly, based on the currently-available record, it is quite likely that the Insider Trading Defendants entered into their Rule 10b5-1 plans governing these sales at times when they were already in possession of material adverse non-public information, thus negating the ability of such plans to immunize the Defendants' trades from securities liability.

521. Hugin's remaining sales of 175,970 shares of Celgene common stock on June 22, 2017 were apparently ***not*** made pursuant to a Rule 10b5-1 trading plan, and are therefore particularly suspicious because, in contrast to his June 20, 2016; July 28, 2016; and November 9, 2016 sales, Hugin made these sales outside of a pre-determined Rule 10b5-1 trading plan.

D. Terminations of High-Ranking Personnel Are Probative of Scienter

522. The terminations and resignations of high-ranking executives, including certain of the Individual Defendants, during or shortly after the revelation of the alleged fraud, are further indicia of scienter.

523. In June 2017—while Celgene employees internally acknowledged that the Company was likely to receive an RTF in light of its decision to push ahead with the Ozanimod NDA submission without including the results from the additional Metabolite studies—Fouse, who made repeated statements regarding the timeline for Celgene's submission of the NDA, abruptly left Celgene. Fouse's departure came just a year after she was promoted to President and COO of Celgene.

524. Swartz, the Vice President of U.S. Market Access, was terminated in November 2017, one month after Celgene announced Otezla's failure to meet its 2017 guidance. As discussed above (*see* ¶ 243), Swartz was forced out due to her pushback regarding the unachievable 2017 Otezla guidance and Defendants' repeated fraudulent statements reaffirming this guidance.

525. Smith, who was promoted from President of I&I to COO in April 2017, abruptly resigned one year later, in April 2018. Smith's unexpected exit came just months after Celgene terminated its Phase III clinical trials for GED-0301, slashed its Otezla sales guidance, and disclosed that the FDA rejected Ozanimod's NDA for failing to provide the required data regarding the Metabolite.

526. Within a few weeks of Smith's resignation, George Golumbeski, Executive Vice President of Business Development, quietly resigned from his position on April 16, 2018. Notably, Golumbeski played a leading role in several of Celgene's acquisitions, including the acquisitions of Receptos (and Ozanimod) and GED-0301.

VIII. CLASS ACTION ALLEGATIONS

527. Lead Plaintiff bring this action on its own behalf and as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all persons and entities who purchased the common stock of Celgene from January 12, 2015 through and including April 27, 2018, and were damaged thereby. Excluded from the Class are:

(i) Defendants; (ii) members of the immediate families of the Individual Defendants; (iii) the Company's subsidiaries and affiliates; (iv) any person who is or was an officer or director of the Company or any of the Company's subsidiaries or affiliates during the Class Period; (v) any entity in which any Defendant has a controlling interest; and (vi) the legal representatives, heirs, successors, and assigns of any such excluded person or entity.

528. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Celgene had more than 800 million shares of common stock outstanding and actively trading on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that the proposed Class numbers in the thousands and is geographically widely dispersed. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

529. Lead Plaintiff's claims are typical of the claims of the members of the Class. All members of the Class were similarly affected by Defendants' alleged conduct in violation of the Exchange Act as complained of herein.

530. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class. Lead Plaintiff has retained counsel competent and experienced in class and securities litigation.

531. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include:

- whether Defendants violated the federal securities laws by their acts and omissions as alleged herein;
- whether Defendants made statements to the investing public during the Class Period that contained material misrepresentations or omitted material facts;
- whether and to what extent the market price of Celgene's common stock was artificially inflated during the Class Period because of the material misstatements and omissions alleged herein;
- whether Celgene and the Individual Defendants acted with the requisite level of scienter;
- whether the Section 20(a) Defendants were controlling persons of the Company;
- whether reliance may be presumed; and
- whether the members of the Class have sustained damages as a result of the conduct complained of herein and, if so, the proper measure of damages.

532. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because, among other things, joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

IX. THE FRAUD ON THE MARKET PRESUMPTION OF RELIANCE APPLIES

533. At all relevant times, the market for Celgene's common stock was efficient for the following reasons, among others:

(i) Celgene's common stock met the requirements for listing, and was listed and actively traded on the NASDAQ Global Select Market, a highly efficient and automated market;

(ii) As a regulated issuer, Celgene filed periodic public reports with the SEC and the NASDAQ Global Select Market;

(iii) Celgene regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(iv) Celgene was followed by multiple securities analysts employed by major brokerage firms who wrote reports, which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace. Indeed, more than nine hundred analyst reports on Celgene were published during the Class Period.

534. As a result of the foregoing, the market for Celgene's common stock promptly digested current information regarding Celgene from all publicly available sources and reflected such information in the price of Celgene's stock. Under these circumstances, all purchasers of Celgene's common stock during the Class Period suffered similar injury through their purchase of Celgene's stock at artificially inflated prices and a presumption of reliance applies.

535. Further, at all relevant times, Lead Plaintiff and other members of the putative Class reasonably relied upon Defendants to disclose material information as required by law and in the Company's SEC filings. Lead Plaintiff and the other members of the Class would not have purchased or otherwise acquired Celgene common stock at artificially inflated prices if Defendants had disclosed all material information as required. Thus, to the extent that Defendants concealed or improperly failed to disclose material facts with regard to the Company and its business, Lead Plaintiff and other members of the Class are entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

X. THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE ARE INAPPLICABLE

536. The Private Securities Litigation Reform Act's statutory safe harbor and/or the "bespeaks caution doctrine" applicable to forward-looking statements under certain circumstances do not apply to any of the materially false or misleading statements alleged herein.

537. None of the statements complained of herein was a forward-looking statement. Rather, each was a historical statement or a statement of purportedly current facts and conditions at the time each statement was made.

538. To the extent that any materially false or misleading statement alleged herein, or any portion thereof, can be construed as forward-looking, such statement was a mixed statement of present and/or historical facts and future intent, and is not entitled to safe harbor protection with respect to the part of the statement that refers to the present and/or past.

539. To the extent that any materially false or misleading statement alleged herein, or any portions thereof, may be construed as forward-looking, such statement was not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statement or portion thereof. As alleged above in detail, given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Defendants were not sufficient to insulate Defendants from liability for their materially false or misleading statements.

540. To the extent that the statutory safe harbor may apply to any materially false or misleading statement alleged herein, or a portion thereof, Defendants are liable for any such false or misleading statement because at the time such statement was made, the speaker knew the statement was false or misleading, or the statement was authorized and approved by an executive officer of Celgene who knew that such statement was false or misleading.

XI. CAUSES OF ACTION

COUNT I
For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against Celgene and the Individual Defendants

541. Lead Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein.

542. This Count is asserted pursuant to Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder on behalf of Lead Plaintiff and all other members of the Class, against Celgene and the Individual Defendants.

543. As alleged herein, throughout the Class Period, Celgene and the Individual Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of national securities exchanges, made materially untrue statements of material fact and/or omitted to state material facts necessary to make their statements not misleading and carried out a plan, scheme, and course of conduct, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Celgene and the Individual Defendants intended to and did, as alleged herein: (i) deceive the investing public, including Lead Plaintiff and members of the Class; (ii) artificially inflate and maintain the prices of Celgene's common stock; and (iii) cause Lead Plaintiff and members of the Class to purchase the Company's common stock at artificially inflated prices.

544. The Individual Defendants were individually and collectively responsible for making the materially false and misleading statements and omissions alleged herein and having engaged in a plan, scheme, and course of conduct designed to deceive Lead Plaintiff and members of the Class, by virtue of having made public statements and prepared, approved, signed, and/or disseminated documents that contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading.

545. As set forth above, Celgene and the Individual Defendants made the materially false and misleading statements and omissions and engaged in the fraudulent activity described herein knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful

deceit and fraud upon Lead Plaintiff and the other members of the Class who purchased the Company's common stock during the Class Period.

546. In ignorance of the materially false and misleading nature of Celgene's and the Individual Defendants' statements and omissions, and relying directly or indirectly on those statements or upon the integrity of the market price for Celgene's common stock, Lead Plaintiff and other members of the Class purchased the Company's common stock at artificially inflated prices during the Class Period. But for the fraud, Lead Plaintiff and members of the Class would not have purchased the Company's common stock at such artificially inflated prices. As set forth herein, when the true facts were subsequently disclosed, the price of Celgene's common stock declined precipitously, and Lead Plaintiff and members of the Class were harmed and damaged as a direct and proximate result of their purchases of the Company's common stock at artificially inflated prices and the subsequent decline in the price of that stock when the truth was disclosed.

COUNT II
For Violations of Section 20(a) of the Exchange Act
Against the Section 20(a) Defendants

547. Lead Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein.

548. This Count is asserted pursuant to Section 20(a) of the Exchange Act, on behalf of the Lead Plaintiff and all other members of the Class, against Defendants Alles, Kellogg, Smith, Curran, Hugin, and Fouse (the "Section 20(a) Defendants").

549. As alleged above, the Company violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by making materially false and misleading statements and omissions in connection with the purchase or sale of Celgene's common stock and by participating in a fraudulent scheme and course of business or conduct throughout the Class Period. This fraudulent conduct was undertaken with scienter, and Celgene is charged with the knowledge and

scienter of each of the Individual Defendants who knew of or acted with deliberate reckless disregard of the falsity of the Company's statements and the fraudulent nature of its scheme during the Class Period.

550. As set forth above, the Section 20(a) Defendants were controlling persons of the Company during the Class Period, due to their senior executive positions with the Company and their direct involvement in the Company's day-to-day operations, including their power to control or influence the policies and practices giving rise to the securities violations alleged herein, and exercised the same. As such, the Section 20(a) Defendants had regular access to non-public information about Celgene's business, operations, performance, and future prospects through access to internal corporate documents and information, conversations, and connections with other corporate officers and employees, attendance at management meetings and meetings of the Company's Board and committees thereof, as well as reports and other information provided to them in connection therewith.

551. By virtue of the foregoing, the Section 20(a) Defendants each had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content of its public statements with respect to its operations, corporate governance, and compliance with regulators.

552. The Section 20(a) Defendants were culpable participants in Celgene's fraud alleged herein, by acting knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful fraud and deceit upon Lead Plaintiff and the other members of the Class who purchased the Company's common stock during the Class Period.

553. By reason of the foregoing, the Section 20(a) Defendants are liable to Lead Plaintiff and the members of the Class as controlling persons of the Company in violation of Section 20(a) of the Exchange Act.

XII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff respectfully prays for judgment as follows:

554. Determining that this action is a proper class action maintained under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, certifying Lead Plaintiff as class representative, and appointing Kessler Topaz Meltzer & Check, LLP as class counsel pursuant to Rule 23(g);

555. Declaring and determining that Defendants violated the Exchange Act by reason of the acts and omissions alleged herein;

556. Awarding Lead Plaintiff and the Class compensatory damages against all Defendants, jointly and severally, in an amount to be proven at trial together with prejudgment interest thereon;

557. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

558. Granting such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Lead Plaintiff hereby demands a trial by jury.

Dated: December 10, 2018

Respectfully submitted,

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO P.C.

/s/ James E. Cecchi

KESSLER TOPAZ MELTZER & CHECK, LLP
Andrew L. Zivitz
Matthew L. Mustokoff

James E. Cecchi
Donald A. Ecklund
5 Becker Farm Road
Roseland, NJ 07068
Telephone: (973) 994-1700
Facsimile: (973) 994-1744
jcecchi@carellabyrne.com
decklund@carellabyrne.com

SEEGER WEISS, LLP
Christopher A. Seeger
55 Challenger Road
6th Floor
Ridgefield Park, NJ 07660
Telephone: (973) 639-9100
cseeger@seegerweiss.com

Co-Liaison Counsel for Lead Plaintiff and the Class

Joshua E. D'Ancona
Margaret E. Mazzeo
Nathan A. Hasiuk
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
Facsimile: (610) 667-7056
azivitz@ktmc.com
mmustokoff@ktmc.com
jdancona@ktmc.com
mmazzeo@ktmc.com
nhasiuk@ktmc.com

Lead Counsel for Lead Plaintiff and the Class

BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP
Salvatore J. Graziano
Adam H. Wierzbowski
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 554-1400
Facsimile: (212) 554-1448
Salvatore@blbglaw.com
Adam@blbglaw.com

Additional Counsel for the Class

EXHIBIT A

CERTIFICATION

AMF Pensionsförsäkring AB ("AMF") declares, as to the claims asserted under the federal securities laws, that:

1. AMF did not purchase the securities that are the subject of this action at the direction of AMF's counsel or in order to participate in any private action.

2. AMF has been serving and will continue to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

3. AMF's Class Period purchase and sale transactions in the Celgene Corporation securities that are the subject of this action are attached in Schedule A.

4. AMF has full power and authority to bring suit to recover for its investment losses.

5. AMF has fully reviewed the Amended Consolidated Class Action Complaint and authorizes its filing.

6. I, Anders Grefberg, In-House Legal Counsel, am authorized to make legal decisions on AMF's behalf.

7. AMF will continue to actively monitor and vigorously pursue this action for the benefit of the Class.

8. AMF will endeavor to provide fair and adequate representation and work directly with the efforts of Class counsel to ensure that the largest recovery for the Class consistent with good faith and meritorious judgment is obtained.

9. AMF has served as a representative party in the following class actions filed under the federal securities laws during the three years prior to the date of this Certification:

Murphy v. Precision Castparts Corp., No. 16-cv-00521 (D. Or.).

Iron Workers Local Union No. 405 Annuity Fund v. Dollar General Corp.,
No. 17-cv-00063 (M.D. Tenn.)

In re Celgene Corp., Inc. Securities Litigation, No. 18-cv-04772 (D.N.J.)

10. AMF has not otherwise sought to serve as a representative party for a class action filed under the federal securities laws during the three years prior to the date of this Certification.

11. AMF will not accept any payment for serving as a representative party on behalf of the class beyond AMF's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

I declare under penalty of perjury of the laws of the United States of America that the foregoing is true and correct.

Executed this 7th day of December, 2018.

AMF Pensionsförsäkring AB

By: _____
Anders Grefberg
In-House Legal Counsel

SCHEDULE A

Security	Buy/Sell	Date	Quantity	Price
Common Stock	Buy	6/12/2015	6,210	$111.54
Common Stock	Buy	6/12/2015	24,203	$111.54
Common Stock	Buy	6/12/2015	121,225	$111.54
Common Stock	Buy	6/15/2015	163,494	$110.62
Common Stock	Buy	6/15/2015	32,633	$110.62
Common Stock	Buy	6/15/2015	8,362	$110.62
Common Stock	Buy	7/1/2015	5,233	$117.56
Common Stock	Buy	7/1/2015	20,191	$117.56
Common Stock	Buy	7/1/2015	101,375	$117.56
Common Stock	Buy	8/10/2015	5,507	$131.10
Common Stock	Buy	8/10/2015	21,439	$131.10
Common Stock	Buy	8/10/2015	107,270	$131.10
Common Stock	Buy	10/21/2015	5,687	$115.96
Common Stock	Buy	10/21/2015	113,904	$115.96
Common Stock	Buy	10/21/2015	22,516	$115.96
Common Stock	Buy	2/18/2016	53,113	$104.41
Common Stock	Buy	12/14/2016	37,700	$115.83
Common Stock	Buy	1/11/2017	56,569	$118.06
Common Stock	Buy	4/28/2017	24,385	$123.87
Common Stock	Buy	7/5/2017	61,723	$132.39
Common Stock	Buy	10/12/2017	39,602	$138.50
Common Stock	Sell	9/29/2016	45,704	$103.85
Common Stock	Sell	10/3/2016	29,407	$103.84
Common Stock	Sell	11/28/2016	33,401	$120.30
Common Stock	Sell	12/7/2016	107,557	$111.99
Common Stock	Sell	1/19/2017	37,414	$113.59
Common Stock	Sell	2/1/2017	10,657	$117.41
Common Stock	Sell	1/10/2018	17,101	$105.46
Common Stock	Sell	3/8/2018	29,367	$91.19
Common Stock	Sell	4/17/2018	26,704	$91.10

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11. AMF will not accept any payment for serving as a representative party on behalf of the class beyond AMF's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

I declare under penalty of perjury of the laws of the United States of America that the foregoing is true and correct.

Executed this 7th day of December, 2018.

AMF Pensionsförsäkring AB

By: _____
Anders Grefberg
In-House Legal Counsel

SCHEDULE A

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Common Stock	Buy	6/12/2015	6,210	$111.54
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