UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

DONALD MARTIN MEYER, MANISHKUMAR H. BHAGAT, and DUSTIN L. LINEWEBER, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ORGANOGENESIS HOLDINGS INC., GARY S. GILLHEENEY, SR., and DAVID C. FRANCISCO,

Defendants.

Case No. 1:21-cv-06845-DG-MMH

AMENDED COMPLAINT

CLASS ACTION

JURY TRIAL DEMANDED

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Court-appointed Lead Plaintiff Donald Martin Meyer, and named Plaintiffs Manishkumar H. Bhagat and Dustin L. Lineweber (collectively, "Plaintiffs"), by and through their undersigned counsel, bring this federal securities class action, on behalf of themselves and a class consisting of all persons and entities that purchased or otherwise acquired the common stock of Organogenesis Holdings Inc. ("Organogenesis" or the "Company") from August 10, 2020 through August 9, 2022, inclusive (the "Class Period"), and were damaged thereby (the "Class"). Plaintiffs assert their claims under the Securities Exchange Act of 1934 (the "Exchange Act") against Defendants (defined in ¶¶ 33-35). As alleged in this Amended Complaint ("Complaint"), Defendants made a series of statements that they knew or recklessly disregarded were materially false or misleading at the time the statements were made, and omitted material information necessary to make the statements, in light of those material omissions, not materially false or misleading.

Except as to allegations specifically pertaining to Plaintiffs, all allegations in this Complaint are based upon the investigation undertaken by Plaintiffs' counsel ("Lead Counsel"), which included, but was not limited to, the review and analysis of: (i) public filings made by Organogenesis with the U.S. Securities and Exchange Commission (the "SEC"); (ii) press releases and other public statements issued by Defendants; (iii) research reports issued by securities and financial analysts; (iv) media and news reports and other publicly available information concerning Organogenesis and Defendants; (v) transcripts of Organogenesis's earnings and other investor conference calls; (vi) publicly available presentations, press releases, and interviews by Organogenesis and its employees; (vii) documents obtained pursuant to the Freedom of Information Act ("FOIA"); (viii) economic analyses of the movement and pricing of Organogenesis's publicly traded common stock; (ix) discussions with relevant consultants and experts; and (x) interviews of former employees ("FEs") of Organogenesis and documents

received from the FEs. Plaintiffs believe that substantial additional evidentiary support will exist for this Complaint's allegations after a reasonable opportunity for discovery.

I. NATURE AND SUMMARY OF THE ACTION

1. Organogenesis claims that its products, which include skin substitutes used in the treatment of chronic and acute wounds, "provide integrated healing solutions that substantially improve medical outcomes ***while lowering the overall cost of care***."[1] In truth, during the Class Period, Organogenesis engaged in a scheme to game the Medicare reimbursement system for two of its most expensive and profitable products—Affinity and PuraPly XT—to induce physicians to choose Organogenesis's products over cheaper alternatives. This scheme included marketing the lucrative reimbursement "spread" between the cost Organogenesis charged physicians for Affinity and PuraPly XT and the amount that certain Medicare Administrative Contractors ("MACs") reimbursed physicians for these products without requiring invoices that documented the actual cost incurred.

2. Organogenesis's undisclosed reimbursement-based marketing practices were not only illegal—similar schemes have resulted in companies paying hundreds of millions of dollars in fines and penalties for violations of the False Claims Act and other healthcare laws—they also allowed the Company to report rapid revenue ***growth*** just as investors were expecting revenue ***decreases*** resulting from a change in reimbursement for the Company's legacy products.

3. As explained below, prior to the Class Period, Organogenesis's revenues were driven by so called "pass-through" reimbursement for two of its wound care products, PuraPly and PuraPly AM, in hospitals and Ambulatory Surgery Centers ("ASCs"). In these treatment settings, reimbursement is typically "bundled" with the overall cost of the procedure, meaning that higher-

[1] Unless otherwise indicated, all emphasis is added.

cost products may be reimbursed for less than their cost. Pass-through status provides a temporary exemption for certain new, high-cost products which allows hospitals and ASCs to be separately reimbursed for using these products, thereby promoting their use. With the benefit of this temporary reimbursement tailwind, PuraPly sales increased ***529%*** year-over-year in 2016 and ***75%*** year-over-year in 2017, quickly overtaking Organogenesis's legacy products to become the main driver of the Company's revenue. In fact, as a result of PuraPly's pass-through status, Organogenesis's revenues more than doubled from 2015 to 2017.

4. However, PuraPly's pass-through status expired on December 31, 2017, leading to lower demand and causing Organogenesis's PuraPly product revenues to decline ***49%*** year-over-year in the first three quarters of 2018. Fortunately for the Company, in March 2018, Congress reinstated PuraPly's pass-through status for another two years, effective October 1, 2018. Once the pass-through extension took effect, Organogenesis's PuraPly product revenues immediately rebounded, growing 82% year-over-year in 2019 and 17% year-over-year in the first nine months of 2020.

5. By 2020, with the expiration of PuraPly's pass-through status again looming, Organogenesis needed an offset for the impending loss of revenue. Market analysts were keenly aware of Organogenesis's dependence on PuraPly's pass-through reimbursement, and braced for "hamper[ed] revenue growth," "a meaningful step-down in PuraPly revenue," and "total revenue declines" following the expiration of PuraPly's pass-through status.

6. Organogenesis reassured investors that its new products, Affinity and PuraPly XT, and its strategic shift to marketing in physician offices—which were not subject to bundled pricing—would "help absorb" the loss in revenues from the expiration of pass-through. While

analysts were encouraged by these assurances, it remained to be seen whether Organogenesis could execute on its strategy to replace PuraPly's pass-through revenue.

7. During the Class Period, reimbursement for most of Organogenesis's products in physician offices was based on an Average Sales Price ("ASP") formula set by the Centers for Medicaid and Medicare Services ("CMS") using prices published quarterly. However, for most of the Class Period, neither Affinity nor PuraPly XT had an ASP. Therefore, the reimbursement rate for these two products was set at the discretion of regional MACs until an ASP was established. Significantly, Organogenesis had previously marketed Affinity prior to 2019, but withdrew it from the market in 1Q2019 just before an ASP was established, claiming that this was due to purported production issues. When Organogenesis reintroduced Affinity at the end of 1Q2020, it lacked an ASP, allowing the Company to take advantage of higher reimbursement rates paid by certain MACs.

8. On August 10, 2020, the first day of the Class Period, Organogenesis appeared to deliver on its promises to offset the loss of PuraPly revenue, reporting a revenue beat in 2Q2020 despite the onset of the COVID-19 pandemic. During the earnings call on this date, Defendant Gary S. Gillheeney, Sr. specifically attributed the Company's sales growth to increased demand for Affinity and PuraPly XT in the physician office channel, stating that "***we launched PuraPly XT and Affinity in the midst of a crisis and both have exceeded our expectations***," that Affinity was "***selling extremely well***," and that "***the office space business grew even faster than we thought***."

9. Over the next four quarters, Organogenesis consistently exceeded analysts' expectations. The Company reported steadily increasing revenues for both its PuraPly products (which include PuraPly XT) and non-PuraPly products (which include Affinity), and raised its

revenue guidance on ***three separate occasions*** in 3Q2020, 1Q2021, and 2Q2021. Throughout this period, Defendants attributed Organogenesis's sales growth to increased demand in the physician office channel, which they claimed was due to the clinical benefits of Affinity and PuraPly XT and the Company's investments in its sales force.

10. During the 3Q2020 earnings call on November 9, 2020, Gillheeney stated that Affinity sales were "***driven by the differentiated features of the product that our clinical customers value***." With respect to the increase in PuraPly sales, Gillheeney stated that "***[c]linicians continue to value the product's clinical value, and we continue to see growth in the number of accounts that are utilizing PuraPly, aided in part by the introduction of new sizes and the introduction of our XT line extension, which is selling extremely well***." Defendants made similar claims on each of the Company's earnings calls during the Class Period. For example, during the 4Q2020 earnings call on March 16, 2021, Gillheeney stated that "***[o]ur product, Affinity, is the only living amnion in the space, so it's a bit unique***. . . . ***And the efficacy that we're hearing from the field is very strong for the product as well***."

11. Defendants also touted the success of their "***office strategy***" as a means to offset the loss of revenue from the expiration of PuraPly's pass-through reimbursement. For example, on May 10, 2021, Gillheeney touted "***the strong execution of the strategy to navigate the loss of PuraPly pass-through status and the corresponding headwinds related to this change in reimbursement***," stating that "***[w]e have been working on penetrating the office market***," and "***continue to expand the number of customers in the office channel***."

12. Market analysts described Organogenesis's performance during the Class Period as "***astounding***," and Organogenesis's stock price skyrocketed ***over 400%***. While the Company's stock price was inflated by Defendants' statements, Gillheeney began a frenzy of insider selling,

unloading ***$16.8 million*** of Organogenesis stock in a series of suspiciously timed transactions during the Class Period.

13. In reality, Organogenesis's "astounding" revenue growth during the Class Period was the result of a concerted effort by the Company to market Affinity and PuraPly XT to physicians based on a reimbursement spread between what Organogenesis was actually charging physicians for the products and the much higher reimbursement rates that certain MACs were paying to physicians. Defendants' scheme allowed physicians to reap thousands of dollars in illicit profits for each application of Affinity and PuraPly XT—a fact that Defendants encouraged the Company's sales force to market aggressively.

14. As revealed by reimbursement data obtained from these MACs, as well as information obtained through Lead Counsel's investigation, certain MACs reimbursed physicians for Affinity and PuraPly XT at rates that far exceeded what the Company charged for these products. This difference between the cost of the products and the amount physicians were reimbursed was known at the Company as the reimbursement "spread."

15. Moreover, many MACs did not require physicians to submit a physical invoice documenting how much they had actually been charged by Organogenesis. Organogenesis knew this and encouraged physicians to submit claims for invoice amounts higher than the actual sales price for the products. In effect, Organogenesis systematically targeted MACs with the least demanding reimbursement processes. This situation created a perfect storm for Medicare fraud, which Organogenesis capitalized on by marketing the reimbursement spread for Affinity and PuraPly XT to induce physicians to select these products over competing products and thereby inflate the Company's revenues.

16. As detailed in accounts by numerous former Organogenesis employees with direct knowledge of the Company's marketing practices, Organogenesis's sales force marketed the reimbursement spread for Affinity and PuraPly XT using Company-supplied marketing materials, including iPad applications, spreadsheets, and PowerPoint presentations that calculated the profits available to physicians for these products based on the prevailing MAC reimbursement rates. The Company's sales managers also encouraged Organogenesis's sales representatives to market the reimbursement spread during sales meetings. Sales representatives who refused to comply with this directive or who reported their concerns to the Company's management or compliance department were retaliated against and silenced.

17. Defendants also knew that the inflated demand for Affinity and PuraPly XT created by Organogenesis's marketing of the reimbursement spread was temporary. That is, Defendants knew their scheme would end as soon as these products received an ASP, ending the MACs' discretion to reimburse physicians at "invoice" cost, and in turn, removing the profit incentive for physicians to choose Organogenesis's products over competing products. Indeed, as several FEs confirmed, the anticipated decline in revenues for Affinity and PuraPly XT was widely discussed within the Company, prompting managers to direct sales representatives to sell as much of these products as possible while they lacked an ASP.

18. Defendants' fraud began to unravel in July 2021, when CMS set an ASP for Affinity that was nearly half the reimbursement rate previously paid by certain MACs. Predictably, sales of Affinity immediately declined as the inflated demand for the product evaporated—but not before Defendant Gillheeney profited by selling ***$4.3 million*** of Organogenesis common stock to unsuspecting investors in July 2021.

19. On October 12, 2021, a report was published alleging that Organogenesis was "***[m]arketing the spread***" for Affinity and PuraPly XT and predicting that the Company's sales would plummet once the products were reimbursed based on the ASP formula. The report also cited the fact that CMS had not included Affinity in its quarterly pricing file in October 2021 as evidence that CMS had caught on to Defendants' scheme. In response to this report, Organogenesis's stock price declined ***over 14%***.

20. On November 9, 2021, Organogenesis reported a 5% decline in non-PuraPly product revenues in 3Q2021, reflecting the impact of Affinity's ASP, but touted the continued strength of PuraPly products, which were continuing to benefit from the lack of an ASP for PuraPly XT. Gillheeney attributed the decline in Affinity sales to a "***tougher operating environment in the third quarter***" and reassured investors that the fact that CMS did not list an ASP for Affinity in its fourth quarter pricing file was due to a "filing error." Analysts were reassured by Gillheeney's statements and predicted a return to growth in Affinity sales after CMS reinstated an ASP for Affinity in January 2022.

21. In January 2022, CMS reinstated the ASP for Affinity. When Organogenesis reported its 4Q2021 earnings on March 1, 2022, sales of Affinity appeared to rebound, which Gillheeney claimed reflected a return to "***grow[th] as expected and actually better than expected***." In light of these results, analysts concluded that Organogenesis's "**reimbursement noise [is] seemingly behind us**" and projected that the Company would return "**to a sustainable double-digit sales growth trajectory**." (Emphases in original).

22. However, unbeknownst to investors, the modest growth in Affinity sales during 4Q2021 was the result of the temporary lapse in Affinity's ASP. When CMS reinstated the ASP in January 2022, Affinity sales continued to decline since the Company could no longer market

the reimbursement spread to physicians. In fact, internal marketing spreadsheets obtained through Lead Counsel's investigation reveal that some providers who were reimbursed in 1Q2022 based on the published ASP rate stood to ***lose*** money when using Affinity.

23. When Organogenesis reported its 1Q2022 earnings on May 10, 2022, Defendants disclosed that sales of non-PuraPly products had declined ***32%*** year-over-year. However, Gillheeney claimed that this decline reflected "***the impact of Omicron on our national launch of Affinity***" and falsely assured investors that "***[t]he trends that we're seeing now are very positive***" and that "***the sales trends over the last 4 to 5 weeks have actually been quite strong***." Immediately after issuing these statements, Gillheeney sold an additional ***$7.2 million*** of Organogenesis common stock in a series of transactions between May 13, 2022 and June 3, 2022.

24. Finally, on August 9, 2022, Defendants were forced to admit the truth. On this date, when Organogenesis reported its 2Q2022 earnings, Defendants revealed that sales of amniotic products had declined ***46%*** year-over-year, signaling that Affinity's ASP had put an end to its rapid sales growth. Indeed, Gillheeney acknowledged that Affinity sales had suffered from competition from products "***with no published ASPs . . . particularly in the office***." In other words, after years of touting the "***differentiated features***" and clinical benefits of Affinity, Defendants admitted that the reduced ASP-based reimbursement for Affinity meant that it could no longer compete.

25. Upon this news, Organogenesis's stock price declined ***20%***. Significantly, after Defendants' fraud was revealed at the end of the Class Period, Organogenesis's stock price returned to its price at the start of the Class Period, illustrating the unsustainable nature of Defendants' fraudulent scheme.

II. JURISDICTION AND VENUE

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

27. 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.

28. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), because Defendant Organogenesis conducts business in this District through its direct sales representatives. Defendants have also appeared in this Action and represented their consent to venue in this District.

29. 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 mails, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

A. Plaintiffs

30. Lead Plaintiff Donald Martin Meyer is a resident of New Jersey. As stated in his certification attached to this Complaint as Exhibit A, he acquired shares of Organogenesis's common stock at artificially inflated prices during the Class Period, and was damaged by the revelation of the Company's false or misleading statements and omissions of material fact.

31. Named Plaintiff Manishkumar H. Bhagat is a resident of North Carolina. As stated in his certification attached to this Complaint as Exhibit B, he acquired shares of Organogenesis's

common stock at artificially inflated prices during the Class Period, and was damaged by the revelation of the Company's false or misleading statements and omissions of material fact.

32. Named Plaintiff Dustin L. Lineweber is a resident of Nebraska. As stated in his certification attached to this Complaint as Exhibit C, he acquired shares of Organogenesis's common stock at artificially inflated prices during the Class Period, and was damaged by the revelation of the Company's false or misleading statements and omissions of material fact.

B. Defendants

33. Defendant Organogenesis, a Delaware corporation headquartered in Canton, Massachusetts, is a regenerative medicine company engaged primarily in the development, manufacture, and commercialization of solutions for two key markets: (i) Advanced Wound Care ("AWC"), which focuses on "wound care products for the treatment of chronic and acute wounds in various treatment settings"; and (ii) Surgical & Sports Medicine ("SSM"), which focuses on "products that support the healing of musculoskeletal injuries." SSM has historically generated approximately 9-15% of Organogenesis's net revenue. As of December 31, 2021, Organogenesis had 950 full-time employees including a direct sales force of approximately 340 sales representatives. The direct sales force is also supplemented by independent contractors. Organogenesis's common stock trades on the NASDAQ Capital Market under the ticker symbol "ORGO." For fiscal year ("FY") 2021, Organogenesis reported net revenue of $468.1 million and net income of $94.9 million.

34. Defendant Gary S. Gillheeney, Sr. ("Gillheeney") is an Organogenesis Director and the Company's President and Chief Executive Officer ("CEO"). Gillheeney has served as President and CEO since 2014. During the Class Period, Gillheeney made false or misleading statements or omitted material facts in Organogenesis's press releases, earnings calls, and during

promotional interviews. Gillheeney, along with Defendant David C. Francisco, was a signatory to the Company's SEC filings during the Class Period.

35. Defendant David C. Francisco ("Francisco") is Organogenesis's Chief Financial Officer ("CFO") and has served in that capacity since February 2021. Francisco took over for Henry Hagopian, who had served as the Company's interim CFO after Organogenesis's former CFO, Timothy M. Cunningham, resigned on August 18, 2020. During the Class Period, Francisco made false or misleading statements or omitted material facts in Organogenesis's press releases, earnings calls, and during promotional interviews.[2]

36. As alleged in this Complaint, Defendants Gillheeney and Francisco each personally made or directed the making of false or misleading statements or omissions of material fact in violation of SEC Rule 10b-5(b), or acted in a scheme to disseminate false or misleading statements in violation of SEC Rules 10b-5(a) and (c).

C. Relevant Non-Parties

37. Organogenesis employs approximately 340 direct sales representatives known as Tissue Regeneration Specialists and Tissue Regeneration Associates to sell its AWC and SSM products to physicians' offices, wound care centers, government facilities, ASCs, and hospitals. Organogenesis's sales force receives approximately five to six weeks of training including lectures and daily tests on its products, including Affinity and PuraPly XT. Sales representatives also participate in regular sales meetings with the sales team in their area as well as annual regional and national sales meetings.

[2] As used in this Complaint, prior to February 2021, "Defendants" refers to Defendant Organogenesis and Defendant Gillheeney. After February 2021, "Defendants" includes Defendant Francisco.

38. FE-1 worked as a Tissue Regeneration Specialist for Organogenesis prior to the start of the Class Period through the beginning of 2Q2021. FE-1's geographical sales territory included the Oregon and Washington state areas. FE-1 was part of a Regional sales team with a territory that included all of Oregon, Washington, and Alaska.

39. FE-2 was employed by Organogenesis as a Tissue Regeneration Specialist prior to the start of the Class Period through 2Q2021. FE-2 reported up through Area Director, Christopher Williams. FE-2's sales territory was in the Midwestern U.S.

40. FE-3 was employed by Organogenesis as a Tissue Regeneration Associate from 1Q2021 through 3Q2021. FE-3 reported up through Area Director of Sales, Dana Rogers. FE-3's sales territory was in the Western U.S.

41. FE-4 was employed by Organogenesis as a Regional Sales Manager prior to the start of the Class Period through 3Q2021. As a Regional Sales Manager, FE-4 managed approximately seven other Organogenesis sales representatives throughout the Western U.S.

42. FE-5 was employed by Organogenesis as a Tissue Regeneration Specialist prior to the start of the Class Period through 3Q2021. FE-5 reported up through Area Director of Sales, Ed Jackson. FE-5's sales territory included the West Virginia region.

43. FE-6 was employed by Organogenesis as a Regional Sales Manager from the end 1Q2021 through the beginning of 3Q2022.

44. FE-7 was employed by Organogenesis as a Tissue Regeneration Associate prior to the start of the Class Period through 2Q2022. FE-7's sales territory was in the Midwestern U.S.

45. FE-8 was employed by Organogenesis a Tissue Regeneration Specialist prior to the start of the Class Period through the beginning of 4Q2021. FE-8's sales territory included parts of West Virginia, Ohio, and Kentucky.

46. FE-9 was employed by Organogenesis as a marketing executive prior to the start of the Class Period through the beginning of 1Q2021. As a senior executive of Organogenesis's marketing team, FE-9 was directly involved in the Company's brand strategy and growth strategy. FE-9 participated in cross-functional meetings with other areas of the Company, including Finance, regarding Organogenesis's revenue and drivers of revenue.

47. FE-10 was employed by Organogenesis as a Tissue Regeneration Sales Associate from 3Q2021 through 2Q2022. FE-10's sales territory was in the Southwestern U.S.

48. FE-11 was employed by Organogenesis as a Tissue Regeneration Sales Specialist throughout the Class Period.

49. FE-12 was employed by Organogenesis as a Tissue Regeneration Sales Assistant prior to the start of the Class Period through 1Q2021. FE-12 supported several Tissue Regeneration Specialists, all of whom reported through a Regional Sales Manager, in the Northeastern U.S.

50. FE-13 was employed by Organogenesis as a Tissue Regeneration Sales Associate from the end of 1Q2021 through prior to the Class Period through mid-2021. FE-13's sales territory was in the Midwestern U.S.

IV. FACTUAL ALLEGATIONS

A. Organogenesis's Corporate History Prior To The Class Period

1. Early Growth And Introduction Of PuraPly

51. Organogenesis Inc. was founded in 1985, and was born out of technology developed at the Massachusetts Institute of Technology.[3] According to the Company, it pioneered the commercialization of tissue engineering. One of Organogenesis Inc.'s early products was a living skin equivalent, known as Graftskin, used for the treatment of skin wounds.

[3] As discussed below, the Company's current form is the product of a 2018 merger. Organogenesis Inc. refers to the pre-merger entity.

52. In 1998, Organogenesis Inc. introduced Apligraf, a product containing living human cells. Organogenesis Inc. entered into an agreement with Novartis Pharma AG ("Novartis") giving Novartis the exclusive global marketing rights to market and sell Apligraf. On September 25, 2002, following a breakdown of the relationship between the two companies, Organogenesis Inc. filed a voluntary petition for relief under Chapter 11 of the U.S. Bankruptcy Code.

53. Organogenesis Inc. emerged from Chapter 11 protection in 2003 and proceeded to spend the next fifteen years developing its commercialized product pipeline as a privately held company.

54. Organogenesis Inc.'s first major product development came in 2015, when it launched PuraPly and PuraPly Antimicrobial ("PuraPly AM"), two advanced wound care products whose application includes a variety of wounds. PuraPly AM, an antimicrobial version of PuraPly, is a "purified native collagen matrix with broad-spectrum antimicrobial agent, designed to address challenges posed by bioburden and excessive inflammation in the wound." When launched, both products were approved by the Food and Drug Administration ("FDA") as 510(k) Class II medical devices.

2. NuTech Acquisition And Expanded Product Portfolio

55. In April 2017, one year after an infusion of $30 million in capital raised from existing investors, the Company obtained a $25 million revolving line of credit agreement with Silicon Valley Bank. Around the same time, Organogenesis Inc. completed its acquisition of NuTech Medical ("NuTech"), a company focused on the development of amniotic products. NuTech's portfolio of amnions expanded Organogenesis Inc.'s market share in the AWC market and into the SSM market. In total, Organogenesis Inc. acquired four products through the NuTech acquisition: Affinity, NuShield, NuCel, and ReNu.

56. Affinity, which was originally introduced by NuTech in 2014, became Organogenesis Inc.'s fastest growing product by 2018. Affinity is a fresh, amniotic membrane intended for use in both the AWC and SSM markets. Organogenesis describes the product as "one of only a few placental tissue products containing viable amniotic cells," distinguishable from competing products because it undergoes a "proprietary AlloFresh process that hypothermically stores the products in their fresh state, never dried or frozen, which retains their native benefits and structure." Affinity is regulated as a human cells, tissues, and cellular and tissue-based product ("HCT/P"), under Section 361 of the Public Health Service Act. In the SSM context, Affinity is implanted in spine, orthopedic, and sports medicine surgeries to support soft tissue repair. In the AWC context, Affinity is applied to chronic and acute wounds, tendon, ligament, or other soft tissue injuries to support wound and soft tissue repair. Affinity is sold in multiple sizes designed to fit different wound sizes.

57. Like Affinity, NuShield, ReNu, and NuCel are also regulated as Section 361 HCT/Ps. Organogenesis describes NuShield as a "dehydrated placental tissue graft preserved to retain all layers of the native tissue" with applications in both the AWC and SSM markets. ReNu and NuCel are amnions exclusively used in SSM with limited clinical applications.

58. Despite its expanded product portfolio in 2017, Organogenesis Inc. reported a net loss of approximately $7.53 million.

3. Avista Merger

59. In August 2018, Avista Healthcare Public Acquisition Corp. ("AHPAC"), a publicly traded special purpose acquisition company formed by the healthcare-focused private equity firm, Avista Capital Partners, set its sights on Organogenesis Inc. The acquisition was a lifeline for Organogenesis. Despite a recent, unexpected extension of PuraPly and PuraPly AM's

pass-through status, discussed *infra*, Organogenesis Inc. was in serious need of capital due to net losses for the prior three years.

60. On August 17, 2018, Organogenesis Inc. and AHPAC entered into a joint agreement to merge Organogenesis Inc. and AHPAC's merger subsidiary, Avista Healthcare Merger Sub, Inc. (the "Merger Agreement"). The merger was completed on December 10, 2018. The company surviving the merger, Organogenesis Inc., became a wholly-owned subsidiary of AHPAC and changed its name to Organogenesis Holdings Inc. On January 8, 2019, Organogenesis began trading under the NASDAQ ticker "ORGO." In connection with the Merger Agreement, AHPAC agreed to invest a much-needed $92 million into the Company.

B. The Market For Skin Substitutes During The Class Period

61. The global market for skin substitute products is rapidly growing and highly competitive. Estimates of the total market size vary, but most forecasts agree that the industry will continue to experience exponential growth. Indeed, in its annual report on Form 10-K for the year ended December 31, 2021 ("2021 10-K"), Organogenesis predicts that the market for its products will continue to experience "accelerated growth given favorable global demographics that include an aging population and a greater incidence of comorbidities such as diabetes, obesity, cardiovascular and peripheral vascular disease and smoking" as well as the "growing adoption of regenerative medicine products by the physician community."

62. During the Class Period, Organogenesis was subject to intense competition from a wide range of skin substitute and wound care manufacturers. In the 2021 10-K, Organogenesis acknowledged that it "operate[s] in highly competitive markets that are subject to rapid technological change" and that it "expect[s] competition to remain intense." According to Organogenesis, the Company's products primarily compete with other "skin substitute products, placental-based technology products, orthobiologics products, other advanced wound care and

traditional wound care products." Specific competitors identified by Organogenesis include 3M, Inc., Amniox Medical, Inc. ("Amniox"), Arthrex, Inc., Integra LifeSciences Holdings Corp., MiMedx Group, Inc. ("MiMedx"), Smith & Nephew plc, Bioeventus Inc., and Vivex Biologics ("Vivex"). Given the high degree of competition, Organogenesis stated that its success depended on its ability to market products that are "cost effective and are safe and effective" and that "receive adequate coverage and reimbursement."

63. Organogenesis marketed Affinity, which consists of a tissue graft made from human amniotic cells, as being "one of only a few placental tissue products containing viable amniotic cells." Organogenesis claimed that Affinity was "unique in that [the amniotic cells] undergo our proprietary AlloFresh process that hypothermically stores the products in their fresh state, never dried or frozen which retains their native benefits and structure." Affinity's direct competition includes, among others, the following products: Amniox's Clarix FLO, MiMedx's Amniofix, Human Regenerative Technologies's PX50, Amnio Technology's PalinGen Flow/ SportFlow, Vivex's Allogen, and Applied Biologics's FloGraft. Each of these products contains either amniotic tissue, amnion membrane, or amniotic fluids.

64. PuraPly XT consists of a porcine collagen (derived from pig tissue) sheet coated with polyhexamethylene biguanide ("PHMB"), an antimicrobial agent. Organogenesis marketed PuraPly XT as a line extension of PuraPly AM containing "additional layers of collagen matrix and a higher level of PHMB." According to the Company's 10-K for the year ended December 31, 2020 ("2020 10-K"), PuraPly XT is similar to PuraPly AM, but PuraPly XT has an "enhanced thickness and PHMB content that allows for sustained presence of the antimicrobial barrier in the wound." Like its sister-product, PuraPly AM, PuraPly XT is regulated by the FDA as a 510(k) Class II medical device and is intended for use in both the AWC and SSM markets.

65. Numerous wound care products containing PHMB were available during the Class Period, including many over-the-counter wound dressings. Collagen-based wound care products were also widely available during the Class Period from a variety of manufacturers, including, among others, Harbor MedTech, Inc., MLM Biologics, Inc., Collamatrix Co., Ltd., Hollister Wound Care, and Mölnlycke Health Care.

66. In a 2020 systematic review of the published medical literature on skin substitutes, researchers at the Agency for Healthcare Research and Quality identified "76 commercially available skin substitutes," including PuraPly AM and Affinity. The majority of these products are "acellular dermal substitutes" mostly derived from human placental membranes and animal tissue sources. The study identified dozens of different skin substitute products derived from human amniotic tissue, fluid or membranes, including Affinity. The study also identified dozens of different products derived from animal collagen, including PuraPly AM. Notably, however, the study could not reach any conclusions with respect to the comparative efficacy of the different skin substitutes available on the market due to "[t]he lack of studies examining the efficacy of most skin substitute products and the need for better-designed and -reported studies providing more clinically relevant data in this field."

67. Third-party insurers have likewise cited the lack of clinical data supporting the efficacy of many skin substitute products, including Affinity and PuraPly XT, in refusing to provide coverage for such products. For example, an October 1, 2022 report by United Healthcare's Commercial Medical Policy group found that Affinity and PuraPly XT are "unproven and not medically necessary for any indication due to insufficient evidence of efficacy." With respect to Affinity in particular, the report found that "[t]here are few published studies addressing the use of [A]ffinity. Therefore, it is not possible to conclude whether Affinity has a beneficial

effect on health outcomes." The report also found that "it is not possible to conclude whether PuraPly, PuraPly AM . . . or PuraPly XT . . . has a beneficial effect on health outcomes" due to the limitations of existing studies. Similarly, as of September 15, 2022, Aetna's Medical Clinical Policy group also deemed the use of Affinity and PuraPly XT for wound care "experimental and investigational because there is inadequate evidence in the peer-reviewed medical literature to support their clinical effectiveness."

68. As discussed below, despite the lack of clinical data supporting Affinity and PuraPly XT's effectiveness, or their superiority over other available treatments, during the Class Period, Medicare covered reimbursement for both products for certain uses.

C. Medicare Reimbursement Was Essential To The Success of Affinity And PuraPly XT During The Class Period

69. As a medical device manufacturer, Organogenesis's growth and profitability depends on its ability to obtain reimbursement for its products by Medicare and private insurers. According to the 2020 10-K, Organogenesis's "customers primarily consist of hospitals, wound care centers, government facilities, ASCs [Ambulatory Surgery Centers] and physician offices, all of whom rely on coverage and reimbursement for [Organogenesis's] products by Medicare, Medicaid and other third-party payers." The 2020 10-K acknowledged that the Company's "success will depend in part on the extent to which coverage and adequate reimbursement for the costs of our products and related treatments will be available from government health administration authorities, private health insurers and other third-party payers." The 2020 10-K further stated that Organogenesis's "ability to compete successfully will depend on our ability to develop proprietary products that . . . receive adequate coverage and reimbursement."

70. Prior to and during the Class Period, most private insurers only covered the Company's legacy products, Apligraf and Dermagraft. As stated by the Company in its 10-K for

the year ended December 31, 2019 ("2019 10-K") and 2020 10-K, "[w]hile most private payers currently cover Apligraf and Dermagraft, most of those payers do not cover many of our other products, such as PuraPly, PuraPly AM, NuShield, and Affinity." In the 2021 10-K, Organogenesis stated that "[w]hile most private payers currently cover Apligraf and Dermagraft, *and some cover Affinity*, most of those payers do not cover many of our other products, such as PuraPly, PuraPly AM, and NuShield."

71. Therefore, during the Class Period, Medicare was the primary, if not exclusive source of reimbursement for Organogenesis's newest and most profitable products, including Affinity and PuraPly XT. As such, Organogenesis's sales strategy with respect to these products was focused on providers who treated patients covered by Medicare.

72. The reimbursement for Organogenesis's products depends on the treatment setting where the product is used. As explained in the Company's 2020 10-K, "[i]n the outpatient hospital and ASC settings, Medicare payment for all our products . . . is bundled into the payment for the application procedure," whereas "Medicare makes a separate payment for our products when used in the physician office at a payment rate of average sales price (ASP) plus 6% (less the statutory sequestration rate of 2% of the government portion for a final payment rate of ASP+4.3%)."

73. In the hospital outpatient and ASC settings, because Medicare reimbursement for Organogenesis's products is "bundled" with the payment for the procedure, the payment rate for these procedures does not vary based on which device is used, and so higher-cost products like Affinity or PuraPly may be reimbursed at less than their cost. This encourages hospitals to provide more cost-effective care. However, in certain instances, a product may be granted pass-through reimbursement status ("pass-through status") by CMS. CMS pass-through status is reserved for certain new, high-cost drugs, biologics, and devices. If pass-through status is granted,

reimbursement for the product is similar to the outpatient setting, and is equal to the ASP plus six percent for two to three years until the grace period ends.

74. Organogenesis's SSM products administered in the inpatient hospital setting had a similar reimbursement structure to those products administered in the hospital outpatient and ASC settings. According to the Company's 2020 10-K, reimbursement for Organogenesis's SSM products were "reimbursed by Medicare as part of a bundled payment based on the Medicare Severity Diagnosis Related Group, or MS-DRG, to which a patient is assigned upon discharge from the hospital. . . . The MS-DRG payment rate is a consolidated prospective payment for all services provided by the hospital during the patient's hospitalization, based on the average cost of care calculated from Medicare claims data."

75. During the Class Period, Affinity and PuraPly XT did not have pass-through reimbursement status. Due to these products' high cost and inclusion in Medicare's bundled reimbursement structure, it was extremely difficult for Organogenesis's sales representatives to sell Affinity or PuraPly XT in outpatient hospital and ASC settings, where providers could lose money if they chose to use these products. Therefore, the success of these products—and by extension, the Company's strategy of expanding into the physician office channel—depended on the ability of the Organogenesis's sales force to generate sales in physician offices.

76. In the physician office setting, reimbursement for Organogenesis's products is not bundled, and so providers are reimbursed directly for using the Company's products. The Company's 2020 10-K explained the typical Medicare reimbursement in this setting as follows:

> In the physician office setting, payment for skin substitutes is not bundled into the payment for the administration of the product. Skin substitutes are paid separately from the application procedure and the Medicare payment rate for all skin substitutes (including ours) is calculated based on the manufacturer's ASP on a per square centimeter basis with the total payment for the product being the per square centimeter ASP-based payment rate multiplied by the total number of centimeters. In the physician office setting

> the Medicare payment rates for all skin substitutes (including ours) are updated quarterly based on manufacturer reported ASP and are not geographically adjusted. The actual payment rate for skin substitutes is ASP plus 6%, which is adjusted for the statutorily mandated sequestration resulting in an actual payment of ASP plus 4.3%. This payment methodology applies only to physician offices.

77. Significantly, the ASP-based reimbursement system in the physician office setting described above does not apply in all circumstances. Generally speaking, in the physician office setting, reimbursement for skin substitutes such as those sold by Organogenesis are reimbursed by Medicare using an ASP plus 6% formula, with the ASP updated quarterly based on data reported by the manufacturer and published in the CMS quarterly ASP Drug Pricing File. However, during the Class Period (which runs from the reporting of Organogenesis's 2Q2020 results on August 10, 2020 through the release of its 2Q2022 results on August 9, 2022) PuraPly XT did not have an ASP, while Affinity only had an ASP for 3Q2021 and then again for 1Q2022 and 2Q2022. The below table summarizes the Class Period data from the ASP Drug Pricing File for Affinity and PuraPly XT:

Affinity (Class Period in Bold)[4]			
1Q2019	2Q2019	3Q2019	4Q2019
No ASP	$176.067 per square centimeter	$175.454 per square centimeter	$644.480 per square centimeter
1Q2020	2Q2020	**3Q2020**	**4Q2020**
$644.480 per square centimeter	No ASP	No ASP	No ASP
1Q2021	**2Q2021**	**3Q2021**	**4Q2021**
No ASP	No ASP	$583.667 per square centimeter	No ASP
1Q2022	**2Q2022**		
$535.602 per square centimeter	$534.888 per square centimeter		

[4] The Medicare ASP pricing files list an ASP for Affinity between 2Q2019 and 1Q2020. However, according to Organogenesis, Affinity was not sold during those quarters, and was relaunched at the end of 1Q2020.

PuraPly XT (Class Period in Bold)			
	2Q2020	**3Q2020**	**4Q2020**
	No ASP	No ASP	No ASP
1Q2021	**2Q2021**	**3Q2021**	**4Q2021**
No ASP	No ASP	No ASP	No ASP
1Q2022	**2Q2022**		
No ASP	No ASP		

78. In the absence of an ASP, the reimbursement amount for these products sold in the physician office setting was determined by the regional MACs, which often reimbursed physicians in amounts far in excess of the cost charged by Organogenesis to the treating physician. As extensively described by numerous FEs, the temporary reimbursement rate by certain MACs for Affinity and PuraPly XT gave prescribing physicians a powerful economic incentive to choose Organogenesis's products over those of its competitors. During the Class Period, the Company's sales team aggressively marketed (and as set forth below, illegally marketed) this difference, or "spread" between the amount reimbursed by the MACs and the amount charged by Organogenesis. This, in turn, allowed Organogenesis to temporarily inflate its sales and gave investors a false impression of the Company's business.

D. Organogenesis Is Subject To Extensive Healthcare Laws And Regulations With Respect To The Marketing Of Its Skin Substitute Products

79. At all times during the Class Period, Organogenesis was required to comply with healthcare fraud, waste, and abuse laws with respect to the sales and marketing of its products that received reimbursement under Medicare. As Organogenesis explained in its 2020 10-K:

> [A]ctivities and arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, waste and other abusive practices. These laws and regulations may restrict or prohibit a wide range of activities or other arrangements related to the development, marketing or promotion of products, including pricing and discounting of products, provision of customer incentives, provision of reimbursement support, other customer support services, provision of sales commissions or other incentives to employees and independent contractors and other interactions with healthcare practitioners, other healthcare providers and patients.

80. The 2020 10-K acknowledged that "[a]ny non-compliance could result in regulatory sanctions, criminal or civil liability and serious harm to our reputation."

81. Among the "extensive laws and regulations intended to prevent fraud, waste and other abusive practices," the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, protects the government from overpaying for physician services by making it illegal for physicians to submit reimbursement claims that are false or fraudulent, and prohibits other parties from causing false or fraudulent claims to be presented for payment. In relevant part, the FCA provides:

> (a)(1) Any person who—(A) knowingly presents, ***or causes to be present presented, a false or fraudulent claim for payment or approval***; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or] (C) conspires to commit a violation of subparagraph (A), (B) . . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410), ***plus 3 times the amount of damages which the Government sustains because of the act of that person***.
>
> (b)(1) For purposes of this section—the terms "knowing" and "knowingly"—(A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) ***require no proof of specific intent to defraud*** . . . .

82. The criminal FCA, 18 U.S.C. § 287, imposes additional penalties for submitting knowingly false or fraudulent claims to any department or agency of the United States government.

83. The Federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), also imposes criminal penalties for certain acts involving products reimbursed under Federal healthcare programs. In relevant part, the AKS provides:

> (b) Illegal remuneration
>
> * * *
>
> (2) Whoever knowingly and willfully ***offers or pays any remuneration (including any kickback, bribe, or rebate)*** directly or indirectly, overtly or covertly, ***in cash or in kind*** to any person to induce such person—

> (A) ***to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program***, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

84. As explained by the U.S. Department of Health and Human Services Office of Inspector General ("HHS-OIG"), the AKS prohibits remuneration to induce "the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare [patients])."

85. Schemes by pharmaceutical and medical device companies to market and sell products based on false or inflated prices have caused the government to pay billions of dollars in excess payments to physicians. As a result, the U.S. Department of Justice ("DOJ") has brought numerous enforcement actions against companies who violate the FCA, including based on schemes to market a "spread" between the price paid by the government and the actual price paid by healthcare providers. For example, on December 7, 2010, the DOJ announced a $421.2 million settlement with three drug companies to "resolve claims by the United States that the defendants engaged in a scheme to report false and inflated prices for numerous pharmaceutical products knowing that federal healthcare programs relied on those reported prices to set payment rates" and where "[t]he actual sales prices for the products were far less than what defendants reported." The DOJ explained the scheme as follows:

> The difference between the resulting inflated government payments and the actual price paid by healthcare providers for a drug is referred to as the "spread." The larger the spread on a drug, the larger the profit for the health care provider or pharmacist who gets reimbursed by the government. The government alleges that [defendants] created artificially inflated spreads to market, promote and sell the drugs to existing and potential customers. Because payment from the Medicare and Medicaid programs was based on

> the false inflated prices, the government alleged that the defendants caused false claims to be submitted to federal healthcare programs, and as a result, the government paid millions of claims for far greater amounts than it would have if [defendants] had reported truthful prices.

86. The DOJ's December 7, 2010 press release quoted an Assistant Attorney General for the DOJ's Civil Division as stating:

> By offering their customers one price and then falsely reporting a greatly inflated price to the lists the government uses when determining how much to pay for the drugs, we believe pharmaceutical companies created an incentive for the purchase of their drugs, since buyers could obtain government payment at the inflated price and pocket the difference. . . . Taxpayer-funded kickback schemes like this not only cost federal healthcare programs millions of dollars, they threaten to undermine the integrity of the choices health care providers make for their patients.

87. Other enforcement actions have resulted in the payment of substantial fines and penalties based on similar allegations. For example, a DOJ Fact Sheet summarizing significant FCA settlements and judgments in fiscal years 2009-2016 identifies $900 million recovered from eight companies, including the $421.2 million settlement referenced above, to resolve allegations that they "knowingly reported inflated drug prices that caused providers to submit inflated claims to the Medicaid and Medicare programs." The DOJ Fact Sheet states that each case involved allegations that the company "'marketed the spread' between the actual prices they charged their customers and the amount the government later reimbursed the customer to induce higher sales."

88. The DOJ has also pursued enforcement actions based on the provision of kickbacks in the form guaranteed payments to patients or providers in the event Medicare denies coverage. For example, on August 2, 2021, the DOJ announced a $160 million settlement with a mail-order diabetic testing supplier based on allegations that the company "paid kickbacks to Medicare beneficiaries by providing them 'free' or 'no cost' glucometers," including by offering "Medicare beneficiaries a 'no cost guarantee,' under which [the company] would provide the meters at 'no cost' if Medicare denied payment."

89. As these enforcement actions demonstrate, it is a violation of the FCA for companies to knowingly or recklessly charge providers less than the amount the providers submit in claims for reimbursement to Medicare. It is also unlawful for companies to induce providers to use their products based on a "spread" between the reimbursement amount and the actual price charged to the providers. Furthermore, it is unlawful for a company to induce a provider to use a product by providing a kickback in the form of a guaranteed payment amount in the event Medicare denies a claim. As discussed below, during the Class Period, Organogenesis engaged in each of these practices with respect to its sales and marketing of Affinity and PuraPly XT.

E. Prior To The Class Period, Organogenesis Relied On PuraPly's Temporary Pass-Through Status As One Of The Primary Drivers Of Its Sales

90. In 2015, CMS approved both PuraPly and PuraPly AM for pass-through status for the hospital outpatient and ASC settings. As explained above, this temporary status meant that Medicare reimbursement for these products was not bundled with the reimbursement for the procedure. This provided an incentive for outpatient hospitals and ASCs to use PuraPly and PuraPly AM, since they would be reimbursed at a rate of ASP plus six percent, and provided Organogenesis Inc. with a competitive edge over manufacturers of similar wound care products. Organogenesis Inc. maintained this advantageous pass-through status for both PuraPly and PuraPly AM for approximately two years, until it expired on December 31, 2017.

91. During this period, from 2015 to 2017, PuraPly and PuraPly AM's favorable pass-through reimbursement status more than doubled Organogenesis Inc.'s net revenue, from $98.9 million in 2015 to $198.5 million in 2017. However, despite this extraordinary year-over-year growth in net revenue, Organogenesis Inc. operated at a net loss for 2015, 2016, and 2017.

92. The boost to Organogenesis Inc.'s sales from PuraPly and PuraPly AM's pass-through status was short-lived. As soon as these products lost pass-through status, Organogenesis

Inc.'s reported net losses increased dramatically. For the first six months of 2018, Organogenesis Inc. reported a net loss of approximately $42.5 million. By the end of 2018, that number grew to a total reported net loss of approximately $64.8 million. Indeed, just one year into the loss of pass-through status for PuraPly and PuraPly AM, the Company's net losses for FY 2018 ballooned nearly 800% year-over-year. One market analyst described the "cascade[] downward" caused by the loss of PuraPly pass-through as follows:

> PuraPly came off pass-through status on December 31, 2017. This resulted in a revenue decline for PuraPly during the first three quarters of 2018. ORGO's total sales declined approximately 11% year-over-year during the first three quarters of 2018 and PuraPly sales fell 49% y/y. Qualitatively, these factors cascaded downward for PuraPly: 1) Lower reimbursement dynamic negatively affected customer demand for PuraPly products, resulting in decreased product volumes; 2) A lower relative reimbursement for larger, higher-priced SKUs resulted in a shift towards smaller and cheaper-priced SKUs; and 3) Organogenesis reduced its sales force focus on PuraPly in comparison to other products within the portfolio.

93. On March, 23, 2018, Congress gave Organogenesis Inc. a temporary reprieve, enacting the 2018 Consolidated Appropriations Act, H.R. 1625 ("2018 Appropriations Act"), which included a provision restoring pass-through status for certain drugs and biologicals effective October 1, 2018. The provision, which applied to just four product codes, reinstated pass-through status for both PuraPly and PuraPly AM through September 30, 2020.

94. With pass-through status restored, Organogenesis's dismal financial results improved, and in 1Q2019, Organogenesis reported a 60% year-over-year increase in net revenue and a 139% year-over-year increase for PuraPly net revenue. In a May 10, 2019 press release, Organogenesis stated that "2019 [was] off to a strong start," and the Company increased its fiscal year 2019 revenue guidance from a range of $248-$259 million to a range of $249-$262 million.

95. Organogenesis's ability to leverage PuraPly and PuraPly AM's pass-through status throughout 2019 was particularly advantageous because it allowed the Company to suspend sales of Affinity, its key amniotic product, without sacrificing Organogenesis's ability to deliver on its

guidance. In 1Q2019, the Company announced that it was suspending sales of Affinity due to purported "production issues." As discussed below, Lead Counsel's investigation revealed that the decision to suspend Affinity sales was, in truth, an effort to game Medicare reimbursement by extending the time Organogenesis could rely on favorable invoice-based reimbursement from the MACs, and also ultimately inflate the published ASP for Affinity. According to FE-2, the real reason the Company pulled Affinity from the market was because of its low price point. Indeed, Organogenesis pulled Affinity from the market in 1Q2019 just before Affinity's ASP of $176 was set to take effect on April 1, 2019.

96. Despite the Company's withdrawal of Affinity from the market, with PuraPly and PuraPly AM's pass-through status restored, Organogenesis delivered on its increased guidance for 2019, reporting a 35% increase in net revenue year-over-year. Defendants touted this feat to investors. For example, in a March 9, 2020 press release, Gillheeney stated that Organogenesis's "2019 revenue growth performance [was] even more impressive given the amniotic supply constraints throughout the year."

F. With The Expiration Of PuraPly's Pass-Through Status Looming, Organogenesis Pivots To The Physician Office Channel And To Its Products, Affinity And PuraPly XT, To Generate Sales Growth

97. Notwithstanding the Company's reported success in 2019, the market was well aware of the impending expiration of PuraPly and PuraPly AM's pass-through status, and was bracing for the potential negative impact this would have on the Company's sales. On April 11, 2019, analysts at SunTrust Robinson Humphrey described a bear case scenario that assumed "a worse than expected decline in PuraPly sales once these products lose pass-through status at the end of 3Q20." On April 12, 2019, BTIG analysts similarly warned of "reimbursement headwinds," explaining that "PuraPly, ORGO's largest product in sales, is expected to lose 'pass-through' status in late FY20," and that these "reimbursement dynamics will likely hamper revenue growth related

to PuraPly beginning in late FY20 and continuing through part of FY21." Likewise, on April 16, 2019, Oppenheimer analysts reported that they "expect[ed] a meaningful step-down in Puraply revenue and assume[d] total revenue declines slightly in 2021 as a result."

98. The market's concerns about the loss of PuraPly's pass-through status continued throughout 2019. For example, on December 18, 2019, Oppenheimer reported that "[i]n the medium term, ORGO will have to navigate reimbursement swings of key product PuraPly (reimbursement pass-through ends 9/30/20)." On December 20, 2019, BTIG warned that "some investors may be tempted to stay on the sidelines until after the PuraPly pass-through status comes off in September 2020."

99. Defendants sought to assuage investors' concerns by highlighting the Company's shift in focus to the physician office channel—which was not subject to bundled pricing—and by touting the launch of PuraPly XT and re-launch of Affinity. In February 2020, Organogenesis launched PuraPly XT, which was billed as a "line extension" of PuraPly AM. In late 1Q2020, Organogenesis relaunched Affinity after an approximately one year hiatus due to purported "production issues," and began rolling the product out to physician offices.

100. In a March 9, 2020 press release, Defendant Gillheeney assured the market that "we remain confident in our ability to drive solid growth over a multi-year period, despite the transition of PuraPly products to the high cost bundle in the outpatient setting beginning October 1, 2020." Gillheeney added that "[o]ur growth expectations are supported by targeted investments in commercial infrastructure, new products, line extensions, and clinical evidence." In other words, Gillheeney assured the market that once PuraPly products lost their pass-through status in hospital outpatient settings (i.e., reimbursement for the products would be bundled with the overall cost of

the procedure, resulting in lower reimbursement), Organogenesis still expected overall growth in PuraPly revenue as a result of increased sales in other channels.

101. During the Company's 4Q2019 earnings call on March 9, 2020, a Credit Suisse analyst asked about Organogenesis's PuraPly line extension strategy "and how [Gillheeney] see[s] that effectively helping to soften the blow of pass-through change in the back half of the year." Gillheeney responded:

> Reimbursement in the office-based setting will be improved when we come off pass-through this time than last time, and we do have those line extensions, PuraPly XT. We also have Affinity coming back online, which is a major component of our amnion strategy, which will help absorb some of the PuraPly ASP decline. . . .
>
> * * *
>
> [W]hat's also helpful is in the office-based setting where pass-through is not impacted, that's ASP plus 6 [%].

102. Market analysts were encouraged by Gillheeney's statements that the Company anticipated different results when PuraPly's pass-through status expired compared to its experience in 2018. In a March 10, 2020 report, BTIG stated that "[t]here are a lot of moving parts in the initial FY20 guidance, but broadly it is encouraging" and "importantly calls for Y/Y growth in spite of the loss of pass-through status for PuraPly." In a March 10, 2020 report, SVB Leerink analysts also expressed increased confidence "**that ORGO's underlying business can grow solidly in the double-digits (and accelerate) even as PuraPly rolls off pass-through reimbursement status in 4Q20**." (Emphasis in original). Similarly, on March 10, 2020, Oppenheimer analysts commented that "ORGO believes its pull-through of non-PuraPly products, PuraPly products/line extensions—at prices below the high-cost bundle—coupled with new products/extensions through 1Q20-3Q20 will aide in offsetting post pass-through during 4Q20."

103. Analysts closely monitored the roll-out of Affinity and PuraPly XT given Defendants' claims that these products would mitigate the loss of PuraPly's pass-through status.

During the 1Q2020 earnings call on May 11, 2020, a Credit Suisse analyst asked Gillheeney how the Company expected the COVID-19 pandemic to "play out in terms of progression of new products or steps that you're taking in preparation for the expiration of the pass-through?" Gillheeney responded that the COVID-19 pandemic was accelerating the Company's strategy to pivot to the physician office channel:

> [I]f you recall, part of our strategy with PuraPly post pass-through was to have a much larger office presence, having more sizes, so we can treat more wounds. Many of those wounds, we didn't have sizes for the first time we came out of pass-through. We have a higher reimbursement in the office. We expected that. We've achieved that. So -- actually, the pandemic has pushed procedures from the outpatient setting into the office. So we've seen a significant increase in that move from the outpatient center to the office happening. That's consistent to where we're going. It just seems to now be happening faster.

104. Market analysts were encouraged by Gillheeney's remarks. For example, on May 12, 2020, Oppenheimer analysts stated that "[o]verall, mgmt remains positive on ORGO's business outlook, with new products, line extensions (including re-launch of Affinity), and growing clinical data cited as drivers." The report noted that "Affinity was re-launched in late 1Q20; with a focus on previous Affinity users, and is an anticipated solid offset to PuraPly pass-through (4Q20-expiration)." Credit Suisse analysts similarly reported on the same day that Organogenesis was faring better than most in the first quarter of the COVID-19 pandemic, stating that "[a]s regional centers begin to open up, mgmt is seeing increased traction and demand in the doctors' office setting, where the company enjoys favorable Medicare ASP+6% reimbursement for PurAply [sic] and the recently re-launched Affinity fresh amnion product."

105. In a July 15, 2020 press release, Organogenesis preliminarily announced total net revenue of $68-68.6 million for 2Q2020, an increase of 5-6% year-over-year. Organogenesis also reported expected net revenue from the sale of its PuraPly products of $27.7-28.1 million, down 5-7% year-over-year for 2Q2020. Notably, Organogenesis's 2Q2020 preliminary revenue results did not disclose expected revenues from Affinity or its other non-PuraPly products. Nonetheless,

analysts were encouraged by the Company's apparent success in largely offsetting the decline in revenues associated with the loss of pass-through status for PuraPly.

106. In a report on July 15, 2020, SVB Leerink described the revenue beat as "***[h]uge***," and despite the lack of commentary regarding Affinity, "believe[d] this outperformance is likely attributed to the amniotic portfolio (specifically Affinity) continuing to accelerate growth." (Emphasis in original). SVB Leerink stated that Organogenesis's "**[o]utperformance in [non]-PuraPly products is particularly important as this will be a key growth acceleration engine to sustain DD [double digit] growth on the other side of PuraPly pass-through**. Recall, PuraPly will face a tough comp and create a negative total company growth optic when pass-through status expires starting in 4Q20." (Emphasis in original). Similarly, in a July 15, 2020 report, Credit Suisse analysts stated that the "[u]pside in preliminary Q2 numbers is likely due in part to the company's strong product cycles, strength of ORGO's amnion franchise, additional product sizes and further penetration in the doctor office site of care (particularly with Affinity)." The report commented that "[t]oday's better than expected results should help improve investor confidence in the company's ability to execute at or above expectations." BTIG analysts were also encouraged by the preliminary net revenue beat despite the declining PuraPly sales, stating on July 15, 2020, that "we believe one of the central investor concerns is the forthcoming loss of pass-through status for PuraPly in 3Q20" but that "this quarter is a good reflection of how ORGO may fare once PuraPly's pass-through status is removed."

G. During The Class Period, Defendants Engaged In An Unsustainable Reimbursement Marketing Scheme Involving Affinity And PuraPly XT While Falsely Attributing Sales Increases To Factors Such As Efficacy And Commercial Investments

107. As more fully set forth below, during the Class Period, Defendants told investors that Organogenesis had successfully offset the revenue it lost from the expiration of PuraPly's

pass-through reimbursement status through its expansion in the physician office channel, investments in the Company's sales force, and educating physicians on the clinical benefits of the Company's products over those of its competitors. These trends, according to Defendants, were driving the unprecedented revenue growth achieved by Organogenesis during the Class Period. The truth, however, was that Organogenesis's revenue growth was the product of a reimbursement marketing scheme perpetrated by the Company's sales force—under the direction of senior management—with respect to two key AWC products: Affinity and PuraPly XT.

108. This scheme was possible for two reasons. *First*, during most of the Class Period, Affinity and PuraPly XT did not have an ASP set by CMS. Therefore, reimbursement for these products when used in the physician office setting was determined by the regional MACs, which had discretion to set reimbursement amounts different from, any in many cases, much higher than the later-established ASP set by CMS. Several of these MACs regularly reimbursed physicians for Affinity and PuraPly XT far in excess of the cost invoiced by Organogenesis. Significantly, Organogenesis did not publicly report its product costs during the Class Period, and reimbursement data from the MACs was not readily available publicly. *Second*, these MACs did not require the physician to submit an actual, physical invoice from Organogenesis in order to be reimbursed for using the Company's products. Accordingly, the MACs did not have any independent record to ferret out inflated claims.

109. Accounts by FE-1, FE-2, FE-3, FE-4, FE-6, FE-7, FE-8, FE-12, FE-13, each of whom actively marketed Affinity or PuraPly XT, or witnessed the Company's marketing practices with respect to these products during the Class Period, reveal that Organogenesis encouraged physicians to submit claims for invoice amounts equal to, or higher than the regional MAC reimbursement rates, while at the same time, Organogenesis set the non-public cost of these

products substantially less than the amount reimbursed by the MACs. This practice served to inflate revenues for Affinity and PuraPly XT by engineering a sizeable profit for the physicians who purchased the products.

110. These accounts are corroborated by marketing materials obtained from several witnesses and reimbursement data obtained from the MACs. These records show that the "product cost" for Affinity and PuraPly XT—the amount charged by the Company—was significantly lower than the amount physicians were reimbursed, yielding an "over cost" amount, or spread, that was pocketed by physicians—in some cases thousands of dollars per application.

111. Moreover, FE-1, FE-2, FE-3, FE-4, FE-6, FE-7, FE-8, and FE-13, described conduct which shows that Organogenesis marketed the spread for Affinity and PuraPly XT. For example, Organogenesis sales representatives were trained and encouraged to market Affinity and PuraPly XT in the physician office channel based on the reimbursement for these products, and were supplied with marketing materials for this purpose, including iPads and PowerPoint presentations showing the difference between the product cost and reimbursement amount, and spreadsheets that illustrated the favorable reimbursement to physicians based on inflated claims submitted to the MACs. In some cases, Organogenesis even guaranteed reimbursement in the event Medicare denied coverage in order to convince physicians to purchase the Company's products.

112. Defendants' aggressive campaign to market the temporary reimbursement spread for Affinity and PuraPly XT had its intended effect, which was to artificially inflate the Company's reported revenues throughout the Class Period. Indeed, rather than experience a ***decline*** in net revenues following the expiration of PuraPly's pass-through status—as investors expected—net revenues for both PuraPly and non-PuraPly products ***increased substantially***, sending the Company's stock price soaring and allowing Organogenesis to continually "beat and raise" Wall

Street expectations. In truth, Defendants' apparently successful pivot to the physician office channel was only made possible by the Company's undisclosed marketing of the reimbursement spread for Affinity and PuraPly XT.

113. Defendants' scheme could only prop up the Company's sales temporarily, however. Once CMS set an ASP for Affinity in 3Q2021 (and then again in 1Q2022), Organogenesis lost its competitive edge because the Company's sales representatives could no longer induce physicians to purchase Affinity based on the reimbursement spread. As discussed below, by the end of the Class Period, this led to dramatic declines in Organogenesis's AWC sales growth—but only after Defendant Gillheeney capitalized on the temporary inflation in the Company's share price through his insider stock sales.

1. Defendants Tout The Successful Launch Of Affinity And PuraPly XT, And Organogenesis Reinstates Its Pre-COVID-19 Guidance

114. On August 10, 2020, the first day of the Class Period, Organogenesis announced its actual 2Q2020 net revenue results, which Defendants described as "well ahead of expectations." Organogenesis reported total net revenue of $69.0 million for the quarter, including net revenues from the sale of non-PuraPly products of $40.4 million, an increase of 15% year-over-year. In a press release on this date, Gillheeney explained that based on the Company's 2Q2020 results, Organogenesis was reinstating the Company's pre-COVID-19 pandemic guidance:

> [W]e are reinstating formal financial guidance reflecting our expectations for total revenue growth of 5% to 6% in 2020. Notably, this total revenue guidance is consistent with the projections we made during our fourth quarter earnings report in early March, before the COVID-19 pandemic. We are proud of Organogenesis' resilience in the face of unprecedented challenges, and believe it is a direct result of our team's hard work and commitment to delivering on our mission to provide integrated healing solutions that substantially improve medical outcomes while lowering the overall cost of care.

115. During the 2Q2020 earnings call on August 10, 2020, Gillheeney stated that "we launched PuraPly XT and Affinity in the midst of a crisis and both have exceeded our

expectations." Gillheeney specifically attributed Organogenesis's ability to exceed expectations despite the COVID-19 pandemic to the "***strong demand***" for these products in the physician office channel:

> Our second quarter results reflect the dedication of our employees to the patients we serve and strong execution against our commercial strategy while adapting to the challenges of the pandemic. ***During the second quarter, we grew our customer base, drove customer and clinician adoption deeper into existing accounts and leveraged the strong demand for our PuraPly and amnion products, particularly in the office channel***.

116. In particular, Gillheeney emphasized the successful relaunch of Affinity, stating that the product "***certainly had a significant impact on the quarter, the product is selling extremely well***" and that "***Affinity is already beyond the run rate that we exited in 2018 in a very short period of time***."

117. Citing the apparent success of the Company's strategy to market Affinity and PuraPly XT in physician offices, Gillheeney stated that Organogenesis was expanding its sales force, and planned to increase the number of sales representatives to over 300 by the end of the 2020. Gillheeney also dismissed an analyst question about the "competitive landscape," stating that "***Affinity is the only fresh amniotic product in the space***" and that "***PuraPly is still a very strong product, particularly in the office, in outpatient setting***," and so the Company was "***confident that our portfolio will withstand anything that we see in the competitive environment today***."

118. Gillheeney's statements had their intended effect, which was to reassure the market that Organogenesis could continue to generate sales growth despite PuraPly's pass-through status expiration, then less than two months away. For example, on August 10, 2020, BTIG analysts reiterated their "Buy" rating and stated that "[i]nvestors' concerns around the loss of pass-through status for PuraPly appear overblown in the face of expected growth in amnions, sales force expansion, and incremental PuraPly line extensions." Oppenheimer, Credit Suisse, and SVB

Leerink all reiterated their "Outperform" ratings for the Company, with Oppenheimer's analysts stating on August 11, 2020:

> While not surprisingly, 4Q is expected to see a large drop-off in PuraPly sales as reimbursement pass-through ends, sales of ORGO's other products, particularly Affinity, are accelerating; salesforce investments are paying off; and the physician-office strategy is expanding its market opportunities. . . . ORGO has several offsets including expansion efforts into physician offices where PuraPly is reimbursed at cost-plus; the newly relaunched Affinity is having significant success.

119. These views were echoed in SVB Leerink's August 11, 2020 report, which stated that "amnion sales momentum in 2Q—particularly the affinity re-launch . . . reinforces our thesis that ex-PuraPly products can support growth accelerating and sustainable DD [double-digit] growth even as PuraPly comes off pass-through reimbursement status."

120. On September 16, 2020, Morgan Stanley hosted Gillheeney and then-interim CFO, Henry Hagopian at the virtual Morgan Stanley Global Healthcare Conference. In response to a question about the expected impact of the loss of PuraPly's pass-through status, Gillheeney stated that the Company's strategy of selling Affinity and PuraPly XT in physician offices would fully offset any lost PuraPly revenue: "***So PuraPly itself will do pretty well with the offsets that I mentioned in the office and XT. And then our other product portfolio, including Affinity and the rest of our portfolio, will absorb any ASP decline in Q4***."

2. Organogenesis Announces An "Astounding Beat" Driven By Purportedly Strong Demand For Affinity And PuraPly XT, And Raises Its Guidance

121. On October 14, 2020, Organogenesis preliminarily announced its 3Q2020 results, including expected total net revenue of $99-100 million, reflecting an increase of 54-56% year-over-year. Based on these expected results, Organogenesis updated its FY 2020 guidance, increasing expected total net revenue from a range of $273-275 million to a range of $311-314 million. Importantly, the Company announced that it expected positive Generally Accepted

Accounting Principles ("GAAP") net income for 3Q2020, 4Q2020, and FY 2020, signaling that the Company had turned a corner from the net losses reported the prior three years.

122. The Company's preliminary revenue announcement and revised guidance stunned the market. In an October 14, 2020 report, BTIG analysts described the results as "***an astounding beat that surpassed expectations by almost ~40% combined with a with a substantial guidance raise for FY20***." The results also appeared to confirm Defendants' claims that Affinity and PuraPly XT would fully offset the lost revenue from the expiration of PuraPly's pass-through status. For example, in the October 14, 2020 report, BTIG analysts stated that they "suspect[ed] amniotics were the driving force behind the growth and in-line with mgmt. commentary . . . that ORGO was 'selling every amniotic unit it could make.'"

123. Immediately following the release of Organogenesis's preliminary 3Q2020 results, the Company's stock increased $0.80 from a closing price of $3.78 on October 14, 2020 to a closing price of $4.58 on October 15, 2020, on extremely heavy trading volumes—a one-day increase of ***over 20%***.

124. On November 9, 2020, Organogenesis officially announced its 3Q2020 results, reporting total net revenue of $100.8 million—an increase of 57% year-over-year. The Company reported net revenue from the sale of non-PuraPly products of $59.9 million, an increase of 84% year-over-year, and net revenue from the sale of PuraPly products of $40.9 million, an increase of 29% year-over-year. The November 9, 2020 press release quoted Gillheeney as stating:

> ***During the third quarter, we grew our customer base, drove customer and clinician adoption deeper into existing accounts and leveraged the strong demand for our PuraPly and amniotic products, particularly in the office channel***. The strong execution against our commercial strategy during the third quarter drove not only strong revenue growth, but also, significant improvement in our profitability as well.

125. During the November 9, 2020 3Q2020 earnings call, Gillheeney touted the Company's net revenue growth, which he attributed primarily to Affinity, stating that the product

was "***the largest contributor to growth again in Q3, driven by the differentiated features of the product that our clinical customers value and positive reimbursement in the office channel***." Gillheeney also represented that the Company was continuing to see growth in the number of accounts utilizing PuraPly, specifically "***aided in part by the introduction of new sizes and the introduction of our XT line extension, which is selling extremely well***."

126. During the Q&A portion of the earnings call, analysts asked about the trends that the Company had observed since the expiration of PuraPly's pass-through status on October 1, 2020. Gillheeney stated that it was "still a little early to tell," but assured investors that the Company was seeing "***positive trends***" related to the "***office strategy sales of PuraPly doing well [sic]***" and reiterated that the "***[PuraPly] XT line extension in the office is doing extremely well***."

127. Analysts relied on Gillheeney's representations that demand for Affinity and PuraPly XT were the primary drivers of Organogenesis's 3Q2020 earnings beat, and that the Company had managed to replace the lost revenue from the expiration of PuraPly's pass-through status. For example, on November 9, 2020, BTIG reported that the Company was "Positioned Well to Navigate the Loss of Pass-Through on PuraPly as Amniotic Products Grow Over 100%." Similarly, on November 10, 2020, Credit Suisse reported that "ORGO's strategy to expand its presence and product offering to the physician office site of care is paying dividends in a significant way. While the company is navigating the expiration of add-on reimbursement for PuraPly in the outpatient setting, strength in PuraPly XL [sic] and amniotic tissue products in the physician office are now on track to help offset the widely expected pricing pressure in Q4 and 2021."

3. Capitalizing On The Apparent Success Of Affinity And PuraPly XT, Organogenesis Raises $59 Million In A Secondary Public Offering

128. Following Organogenesis's release of its preliminary 3Q2020 financial results, on October 16, 2020, Organogenesis filed a Form S-1 Registration Statement for a secondary public

offering "(SPO") of its Class A common stock. The S-1 was amended on November 10, 2020, the day after the release of Organogenesis's 3Q2020 results, to register 17,500,000 new shares. The Registration Statement was declared effective by the SEC on November 12, 2020, and on this date, Organogenesis filed a Rule 424(b)(4) prospectus ("SPO Prospectus"), which stated that the Company expected to raise an estimated $56.875 million in gross proceeds before underwriting fees and expenses.

129. The SPO Prospectus touted Organogenesis's "Competitive Strengths," including its "experienced wound care sales force [that] is highly trained to assist clinicians to effectively deploy the full complement of our wound care products," the "deep body of scientific, clinical and real-world outcomes data" supporting the use of the Company's products, and "extensive in-house customer support capabilities," including "in-house third-party reimbursement" support. The SPO Prospectus also touted Organogenesis's "Business Strategy," including its "access to the rapidly growing amniotic category of the wound care market," "the ability of our sales representatives to reach and penetrate customer accounts," and "invest[ments] to support physician and payer education" about the Company's products.

130. The SPO closed on November 17, 2020, and was oversubscribed. Organogenesis sold a total of 19,916,708 shares of its common stock in the SPO, reflecting the underwriters' partial exercise of an option to sell an additional 2,625,000 shares. In total, the Company raised gross proceeds of $64.7 million, and net proceeds of $59 million after deducting underwriter discounts, fees, and expenses.

4. Organogenesis Delivers Another "Blowout" Quarter, Which Defendants Again Attribute To Increased Demand For Affinity And PuraPly XT

131. On January 13, 2021, Organogenesis announced preliminary 4Q2020 and FY 2020 financial results. Organogenesis reported anticipated 4Q2020 total net revenue of $104.6-106

million, an increase of approximately 40-42% over the prior year, and FY 2020 total net revenue of $336.1-337.5 million, an increase of approximately 29% as compared to FY 2019.

132. Organogenesis's preliminary results appeared to confirm the success of the Company's strategy of pivoting to sales of Affinity and PuraPly XT in the office channel, and dispelled any concern among analysts about the negative impact the loss of PuraPly pass-through revenue would have on Organogenesis's revenue growth. On January 15, 2021, Oppenheimer analysts reported that they were "Raising Price Target Following Blowout 4Q," stating that "[i]n the first quarter after ORGO's PuraPly had reimbursement pass-through status sunset, ORGO not only avoided feared declines in the product, but generated a big sales beat and saw sequentially *better* performance as the many pass-through offsets management has put in place continued to build." (Emphasis in original). SVB Leerink analysts similarly commented on January 13, 2021 that the preliminary results "should help alleviate investor concerns over Street forecast achievability in 2021 during a much anticipated PuraPly reimbursement transition. . . ."

133. Following the announcement of Organogenesis's preliminary 4Q2020 results, the Company's stock price increased $2.15, from a closing price of $7.34 on January 13, 2021 to a closing price of $9.49 on January 14, 2021—an increase of ***29%***.

5. On The Heels Of Organogenesis's Revenue Beats And Guidance Raises, Gillheeney Begins To Unload Shares Of Organogenesis Stock

134. In February 2021, immediately after Organogenesis reported a second consecutive quarter of revenue results that exceeded market expectations, Gillheeney sold ***397,900 shares*** of Organogenesis common stock for total proceeds of approximately ***$5.3 million***. Gillheeney's February 2021 sales were the first time he sold Organogenesis common stock since the Avista merger in 2018, and represented between ***43%*** and ***60%*** of the shares he held as of the dates of the transactions. As discussed below in Section VII.A.1, Gillheeney's February 2021 insider sales

were suspicious notwithstanding the fact that these sales were made pursuant to a Rule 10b5-1 trading plan. This plan was entered into in August 2020, at the start of the Class Period. At this time, Gillheeney knew that the Company's sales force was inflating sales of Affinity and PuraPly XT by marketing the temporary reimbursement spread for these products, and also knew that this scheme was unsustainable.

6. Defendants Continue To Tout The Strength Of Affinity And PuraPly XT Sales And Organogenesis Raises Its Guidance A Second Time

135. On March 16, 2021, Organogenesis released its official 4Q2020 financial results, which appeared even better than the preliminary results reported on January 13, 2021. The Company reported total net revenue for the quarter of $106.8 million—a 43% increase over the prior year—and full-year net revenue of $338.3 million, up 30% year-over-year. Significantly, Organogenesis reported year-over-year increases in both PuraPly and non-PuraPly product revenues, seeming to confirming that the Company's PuraPly reimbursement woes were a thing of the past. With respect to non-PuraPly product revenues, which include Affinity sales, Organogenesis reported $61.5 million in 4Q20202 revenue, an increase of 77% year-over-year. Organogenesis also reported that sales of its AWC products, which include physician office sales of Affinity and PuraPly XT, increased 48% year-over-year and accounted for nearly 88% of total 4Q2020 net revenue. Organogenesis attributed this increase in AWC sales "***primarily . . . to the expanded sales force, increased sales to existing and new customers, and increased adoption of our amniotic product portfolio, including our Affinity product***."

136. During the 4Q2020 earnings call on March 16, 2021, Defendant Gillheeney attributed Organogenesis's purportedly strong performance in the quarter to, *inter alia*, investments in the Company's sales force, its focus on marketing its products in the physician office setting, the clinical benefits of the Company's products, and expanded sales of Affinity and

PuraPly XT. With respect Affinity sales, which Gillheeney described as an "***area of notable strength in Q4***," Gillheeney stated that "***sales of amniotic products were the largest contributor to the company's growth again in Q4***."

137. With respect to the outperformance of PuraPly revenues, Gillheeney claimed that the Company was able to increase PuraPly revenues despite "anticipated pricing headwinds" because "***[w]e've positioned the product differently this time coming off of pass-through***" and "***launched 5 new PuraPly product and line extensions in 2020***," which "***contributed to our ability to drive strong sales performance in the fourth quarter***." Gillheeney stated that this strategy allowed the Company to report a ***13% increase*** in PuraPly revenues even though the Company's guidance had projected PuraPly "sales to ***decline approximately 50% year-over-year***." Gillheeney further attributed the strength of PuraPly revenues to PuraPly XT's purported clinical benefits, stating that "***[c]linicians continue to value this product's differentiation, and we continue to see growth in the number of accounts utilizing PuraPly, aided in part by the strong sales of the 5 new product and line extensions introduced in 2020***. . . ."

138. Alongside the release of the Company's 4Q2020 results, on March 16, 2021, Organogenesis filed its 2020 10-K with the SEC, which was signed by Defendants Gillheeney and Francisco. The 2020 10-K reaffirmed the Company's FY 2020 reported net revenue and AWC net revenue as reported in the 4Q2020 press release, and attributed those results to the same factors identified in the 4Q2020 press release and discussed by Gillheeney during the 4Q2020 earnings call. For example, the 2020 10-K attributed the Company's sales growth in the AWC segment to its "***expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product***."

139. Analysts at BTIG, SVB Leerink, and Credit Suisse praised Organogenesis's 4Q2020 and FY2020 performance as "stellar" and "impressive," and echoed Gillheeney's statements regarding the purported strength of the Company's amniotic portfolio. For example, SVB Leerink analysts commented on March 17, 2021 that "[t]he Amnion portfolio was a key growth driver in 4Q driven by increasing uptake of Affinity, where demand continues to outstrip supply. But capacity will increase during 2021 and the Amniotic portfolio (led by Affinity) should still be the largest contributor to revenue growth." In a March 17, 2021 report, Oppenheimer similarly noted the "increasing momentum in the office channel" and projected further sales increases "on continued amnion strength."

140. Organogenesis's stock price rose dramatically as a result of Defendants' statements regarding the strength of Affinity and PuraPly XT sales during the preceding three quarters. In fact, between the first day of the Class Period on August 20, 2020, when Organogenesis reported 2Q2020 results—the first quarter that included sales from the relaunch of Affinity and launch of PuraPly XT—and the 4Q2020 earnings release on March 16, 2021, the Company's stock price increased ***over 270%***, from $4.58 to $17.06. Buoyed by Defendants' statements about the Company's apparent outperformance despite the loss of PuraPly's pass-through status, the Company's stock price continued to rise following the 4Q2020 earnings release, reaching a Class Period high of $23.99 on May 3, 2021—a ***423%*** increase from the start of the Class Period. As discussed below, however, following several additional quarters of apparent success, the Company's stock price would soon give up nearly all of these short-lived gains as Defendants' fraud was gradually revealed to investors.

141. On May 10, 2021, Organogenesis announced its 1Q2021 financial results, which appeared to reflect a continuation of the trends reported in 2020. The Company reported net

revenue of $102.6 million for the quarter, up 66% year-over-year, and AWC net revenue of $90.7 million, an increase of 77% year-over-year. Net revenues of PuraPly products increased 27% year-over-year, while non-PuraPly products increased 109% year-over-year. The press release announcing the results quoted Defendant Gillheeney as stating that the Company's "significant year-over-year revenue growth across both our Advanced Wound Care and Surgical and Sports Medicine portfolios [was] ***driven by strong sales of our amniotic and PuraPly products***."

142. In connection with the 1Q2021 earnings announcement, Organogenesis increased its FY 2021 net revenue guidance from a range of $390-405 million to a range of $438-454 million. The majority of this increase was attributable to the Company's projected AWC net revenue, which was increased from a range of $362-375 million to a range of $409-422 million.

143. During the 1Q2021 earnings call on May 10, 2021, analysts asked Defendants to clarify the rationale for the Company's increased revenue guidance—the second such increase in three quarters—questioning how, in the first quarter of Organogenesis's fiscal year, Defendants could have such confidence in the Company's continued outperformance throughout 2021. Defendants Gillheeney and Francisco both responded that continued strength in the Company's Affinity and PuraPly XT sales supported the Company's increased guidance. Specifically, a Credit Suisse analyst asked: "I think the raise comes in as impressive and welcome, of course, more than the beat. But the ability to raise, I guess, this much . . . what gives you the confidence to deliver that sort of update to your full year guidance at this point." Defendant Francisco responded that "***it's just the strength in PuraPly over the last 2 quarters really gives us the confidence to increase that by quite a bit and strength of the amnions as well***."

144. During the 1Q2021 earnings call, Gillheeney also claimed that Organogenesis's sales growth reflected the Company's outperformance relative to its competitors, stating:

> And I think when we see the number of patients that we're treating and the number of accounts that we're acquiring as customers, ***we definitely feel that there's a margin -- a market shift in our favor***. So we definitely see that happening in the market. And some of the other dynamics from some of the other competitors seems to reflect that.
>
> ***We also think with our expansion in the office channel, we really are expanding the market***. There's a lot of offices that have dabbled in wound care and are now starting to participate with Advanced Wound Care products and starting to get educated in Advanced Wound Care products, starting to treat more patients and more types of wounds in the office. And that is something that we think will continue to grow.
>
> ***So it's a combination of market share shift and just expanding the market with multiple channels***. And again, the physician specialties that we talk about often that we now serve -- we never had sold in some of those markets before and for indications that we've never sold to before. ***So it's a combination of all of that, that is really helping to drive the revenue***.

145. In response to Defendants' statements touting the growing strength of Affinity and PuraPly XT sales, multiple analysts increased their price targets. For example, on May 10, 2021, Oppenheimer increased their price target from $25 to $28, citing management commentary regarding "continued strong demand for amniotic products," a "notable tailwind from [the Company's] strategy to target the office-based market," and statements that "PuraPly continues to grow, driven in part by strong sales of give new products and line extensions introduced in '20."

146. On May 11, 2021, Credit Suisse analysts raised their price target from $21 to $24, stating that "Organogenesis is now executing consistently across an array of key growth opportunities, including: 1) Sales growth and capacity expansion supporting Affinity and NuShield in the high-margin amniotic tissue segment; 2) New products and line extensions for PuraPly, four of which were launched in Q4, and; 3) Expansion of its target market into the physicians' office site of care, where the company sees robust demand and continues to open new accounts." BTIG raised their price target from $24 to $27 on May 10, 2021, stating that "ORGO's top-line continues

to perform across all product categories with PuraPly (27% Y/Y) and Amniotics (100%+) posting another strong result even as ORGO laps pass-through status headwinds." SVB Leerink likewise raised their price target from $26 to $27 on May 11, 2021, citing the Company's "beat & raise momentum" and management's "bullish outlook for PuraPly and the amniotic portfolio."

7. With Organogenesis's Share Price At An All-Time High, Defendant Gillheeney Sells An Additional $4.3 Million Of Organogenesis Stock

147. Immediately following the release of Organogenesis's 1Q2021 earnings and Defendants' statements touting the "***strong sales of our amniotic and PuraPly products***," in June 2021, Defendant Gillheeney entered into a Rule 10b5-1 trading plan. Pursuant to this plan, in July 2021, Gillheeney sold ***300,000 shares*** of Organogenesis common stock for total proceeds of ***$4.3 million***.

148. As discussed below, at the time Gillheeney entered into this trading plan and at the time of these sales, Defendant Gillheeney knew that a decline in Affinity revenues was imminent because CMS set an ASP for Affinity effective July 1, 2021, which would dramatically curtail Defendants' ability to market Affinity based on the much higher reimbursement from the regional MACs. Significantly, Gillheeney's July 2021 sales involved the exercise of stock options that were not set to expire until July 25, 2023 at the earliest, with approximately one-third of the options set to expire on April 22, 2030.

8. Citing Continued "Strong Demand" For Affinity And PuraPly XT, Organogenesis Raises Its Guidance For A Third Time

149. On August 9, 2021, Organogenesis reported its 2Q2021 financial results, including total net revenue of $123.2 million, an increase 79% year-over-year. Organogenesis reported AWC net revenue of $111.4 million, an increase of 87%; net revenue from non-PuraPly products of $85.6 million, an increase of ***112%***; and net revenue from PuraPly products of $37.6 million, an increase of 32% year-over-year.

150. In the 2Q2021 press release, Organogenesis raised its FY 2021 Guidance for the second quarter in a row, increasing its net revenue guidance to a range of $456-472 million. As with its guidance increase in the prior quarter, the majority of the guidance increase in 2Q2021 was attributable to Organogenesis's AWC net revenues, which the Company increased from a range of $409-422 million to a range of $423-436 million.

151. During the 2Q2021 earnings call on August 9, 2021, Gillheeney specifically attributed the "***strong demand***" for Affinity and PuraPly to the clinical benefits of these products. For example, Gillheeney stated that "sales of our amniotic products were once again the largest contributor to our year-over-year growth in the second quarter. ***And as mentioned previously, we're pleased with the strong demand for these products given the amniotic portfolio's high degree of efficacy that clinicians and their patients truly value in the market***." With respect to PuraPly, Gillheeney stated that "sales of our PuraPly products increased 32% in the period, ***representing the third consecutive quarter of double-digit growth after coming off pass-through status in the fourth quarter of last year***. ***This strong growth further validates the clinical utility of our brand and our strategic positioning of the product family with new SKUs as well as additional clinical data, sites of care and physician specialties***." Gillheeney further touted "the unique customer value proposition our portfolio offers through the combination of our PuraPly brand, which is the only skin substitute with a broad-spectrum antimicrobial agent" and "our amniotic portfolio with the only fresh amniotic membrane on the market." Gillheeney claimed that based on these product features, "***[o]ur highly differentiated competitive advantage has allowed us to continue to gain share in the market and deliver another strong quarter***."

152. Following the Company's 2Q2021 earnings release and guidance raise, analysts reiterated their "buy" or "outperform" ratings and maintained or increased their price targets. For

example, on August 9, 2021, BTIG reiterated its $27 price target and "remind[ed] investors that ORGO is a BTIG top-pick for us in FY21." In support of its recommendation, BTIG cited the fact that "[a]mniotics [were] leading growth higher," "ORGO is expanding its sales force," and "seeing increasing utilization from an increasing number of MD specialties." On August 9, 2021, Credit Suisse increased its price target from $24 to $25, citing "continued strong growth in the physicians' office channel." On August 10, 2021, Oppenheimer reiterated its outperform rating and increased its price target from $28 to $29, stating: "PuraPly trends remain strong as physician-office/specialties continue to expand. ORGO remains well positioned led by ongoing momentum in amniotics . . . benefits of ongoing sales force investments, solid balance sheet and expanding market opportunities from the company's physician-office strategy."

H. Contrary To Defendants' Public Statements, Organogenesis's Sales Growth During The Class Period Was Driven By Aggressive Marketing Of The Reimbursement "Spread" For Affinity and PuraPly XT

1. During The Class Period, Certain MACs Reimbursed Physicians For Affinity And PuraPly XT Far In Excess Of The Cost Charged By Organogenesis

153. The primary selling point for Affinity and PuraPly XT during the Class Period had nothing to do with the clinical benefits of the products or their superiority over competing products. Rather, the appeal of these products was purely economic: physicians were reimbursed for using Affinity and PuraPly XT in amounts far more than the cost charged by Organogenesis. This was by design. FE-9 stated that the pricing for Affinity and PuraPly XT was set by the Pricing Committee, which included Defendant Gillheeney, Chief Commercial Officer Brian Grow, Vice President Robert Cavorsi, and Vice President Antonio Montecalvo. According to FE-1, Organogenesis senior management also "knew exactly what the reimbursement rates were." As discussed below, based on reimbursement data obtained from the regional MACs and pricing data reflected in Organogenesis marketing materials, these two figures—the prices set by the Pricing

Committee for Affinity and PuraPly XT, and the amount MACs reimbursed for these products—created what was referred to internally at the Company as the "spread," the "estimated reimbursement over cost," or "allowable over cost."

154. During the Class Period, the reimbursement amount paid by certain MACs allowed physicians to make as much as ***$3,800*** with a single application of Affinity, and as much as ***$5,410*** for a single application of PuraPly XT. Since these products often required as many as ten applications for a single patient, physicians were often able to generate ***tens of thousands of dollars in profits from a single patient***—a powerful economic incentive to choose Organogenesis's products over those of its competitors.

a. The Reimbursement Spread For Affinity

155. The reimbursement spread available to physicians prescribing Affinity was confirmed by multiple FEs working in regions covered by different MACs. FE-5 explained that the standard size of an Affinity application was 2.5 x 2.5 centimeters (6.25 square centimeters total), which Medicare rounded up to 7 one-square-centimeter "units." Each 6.25 square centimeter application cost a physician approximately $3,200 to purchase. However, FE-5 recalled that physicians were reimbursed by the regional MAC at a rate close to $1,000 per square centimeter during the Class Period. As such, a claim for just one application of Affinity yielded a total possible reimbursement of approximately $7,000, and a corresponding profit up to ***$3,800*** for the physician. The regional MAC in FE-5's area was Palmetto GBA, the MAC servicing West Virginia, Virginia, North Carolina, and South Carolina. In response to a FOIA request, Palmetto GBA confirmed that it received thousands of claims for Affinity during the Class Period and reimbursed at the "invoice" price when Affinity did not have an established ASP.

156. The excessive MAC reimbursement rates for Affinity extended beyond FE-5's territory. FE-4, who managed approximately seven to eight Tissue Regeneration Specialists whose

territories were covered by the MACs Novitas Solutions ("Novitas") and Noridian Healthcare Solutions, LLC ("Noridian"),[5] recalled nearly identical MAC reimbursement and Organogenesis product cost amounts. Specifically, FE-4 recalled that during the Class Period, physicians were reimbursed around $7,000 per application of a 2.5 x 2.5 centimeter piece of Affinity, meaning the physicians could earn up to ***$3,800*** per application in FE-4's region. In response to a FOIA request, the MAC for FE-4's region, Noridian, confirmed that it received thousands of claims for Affinity during the Class Period and reimbursed for Affinity "using invoice pricing" when Affinity did not have an established ASP.

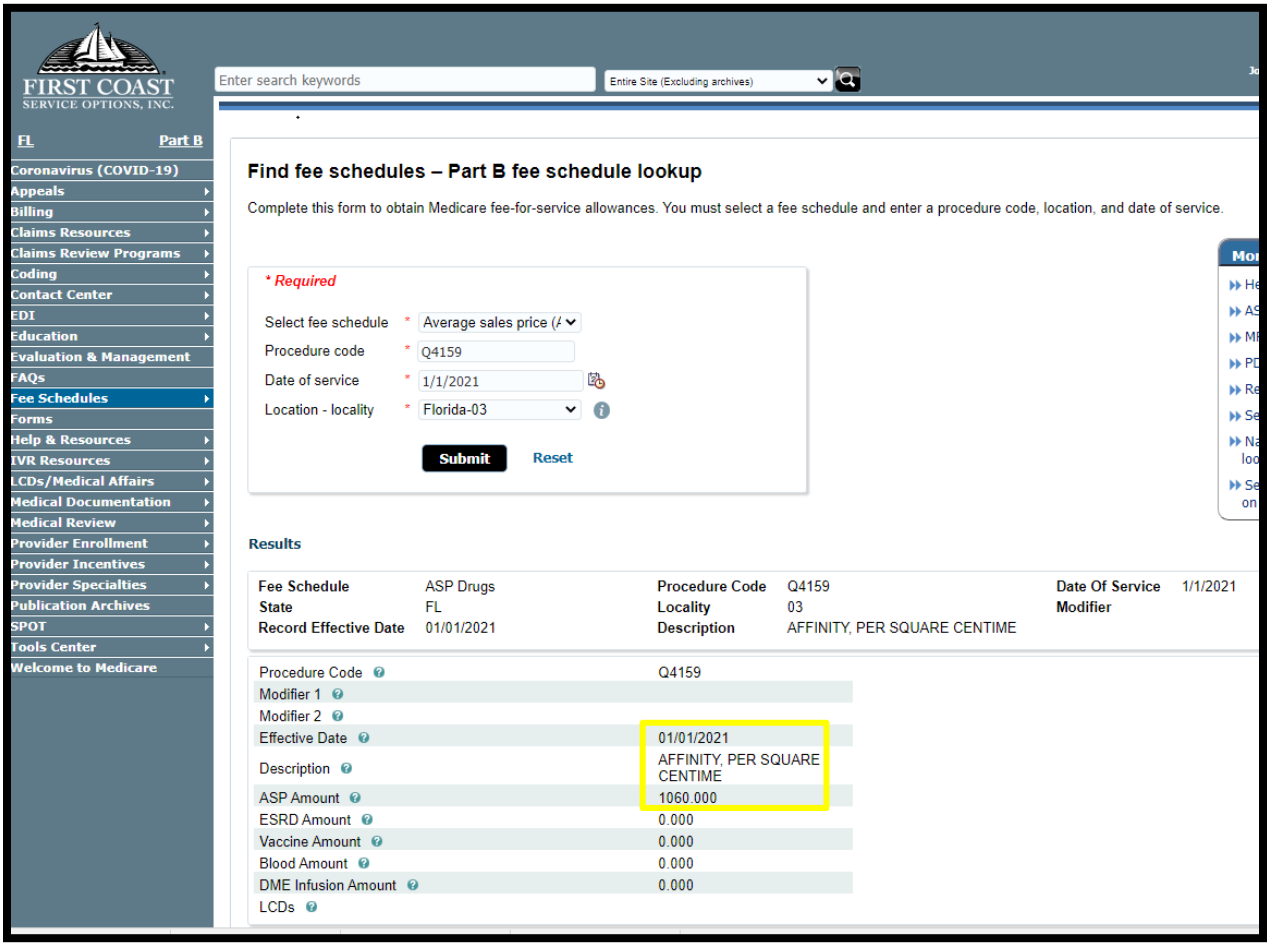
157. Another former Tissue Regeneration Associate, FE-12, recalled that at the time of Affinity's reintroduction to the market in 1Q2020, the cost to physicians for Affinity was approximately $2,450 per application, whereas the Medicare reimbursement in FE-12's region was between $7,000 and $8,000 per application. As FE-12 explained, the physicians would pocket the difference between the invoice cost and the Medicare reimbursement amount. The MAC in FE-12's region, Novitas, explains on its website that when "the invoice information is entered in the narrative field on a claim for any of the HCPCS codes listed below [including Affinity and PuraPly XT], ***it is not necessary to provide the actual paper invoice for these services***."

158. FE-2 similarly recalled that during the period in which there was no ASP for Affinity, physicians would be reimbursed a certain amount by the MACs and Organogenesis would charge the physicians a lower amount. FE-2 recalled that physicians would be reimbursed

[5] Novitas is responsible for Pennsylvania, New Jersey, Delaware, Maryland, Texas, Louisiana, Mississippi, Arkansas, Oklahoma, New Mexico, Colorado, and the District of Columbia. Noridian covers California, Nevada, Hawaii, Washington, Oregon, Idaho, Montana, North Dakota, South Dakota, Wyoming, Utah, Alaska, and Arizona.

up to $1,000 per square centimeter but that Organogenesis charged them approximately 1/6 of that amount.

159. These FE accounts concerning the reimbursement spread for Affinity based on the reimbursement amount by different MACs are corroborated by data obtained from First Coast Service Options ("FCSO"), the MAC servicing the State of Florida. Specifically, throughout the Class Period, FCSO reimbursed for Affinity at a rate of $1,060 per square centimeter for the quarters in which Affinity did not have a CMS-established ASP. This amount can be seen in the figure below under "ASP Amount."[6]



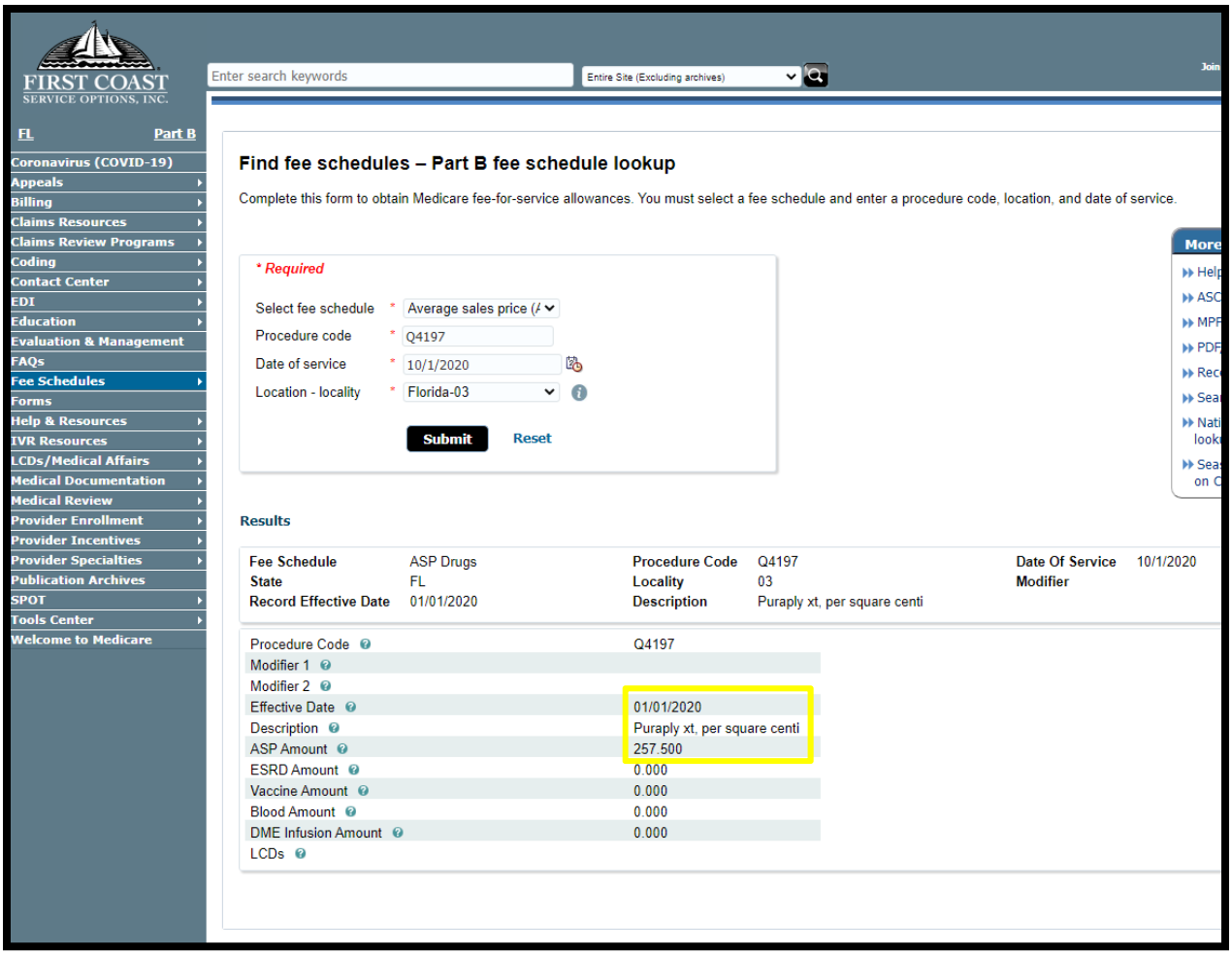
[6] The FCSO data refers to the reimbursement amount for Affinity as the "ASP Amount." However, as confirmed by CMS quarterly ASP pricing data during the Class Period, Affinity did not have an ASP prior to 3Q2021.

160. The reimbursement data from FCSO reproduced above is consistent with the amounts reported by FE-4, FE-5, and FE-12, all of whom recalled that the MACs in their regions—which were not FCSO—reimbursed physicians at a rate of approximately $1,000 per square centimeter. FE-4 and FE-5 both agreed that the spread between the product cost charged by Organogenesis and the MAC reimbursement amount was a selling point for Affinity and led to higher sales for Affinity during the Class Period.

b. The Reimbursement Spread For PuraPly XT

161. The excessive reimbursement available to physicians from certain MACs extended to PuraPly XT, which was also reimbursed by the MACs in amounts far in excess of the cost Organogenesis charged physicians. Moreover, unlike Affinity, which initially received an ASP in 3Q2021, PuraPly XT did not have an ASP at any point during the Class Period. In response to a FOIA request, Palmetto GBA confirmed that during the Class Period, it reimbursed at a rate of $265 per square centimeter for PuraPly XT. As reflected in the below figures, FCSO also reimbursed physicians between $257.50 and $265 for PuraPly XT during the Class Period.[7]

[7] The FCSO data refers to the reimbursement amount for PuraPly XT as the "ASP Amount." However, as confirmed by the CMS quarterly pricing data, PuraPly XT did not have an ASP at any point during the Class Period.


FIRST COAST
SERVICE OPTIONS, INC.
Enter search keywords
Entire Site (Excluding archives)
FL
Part B
Coronavirus (COVID-19)
Appeals
Billing
Claims Resources
Claims Review Programs
Coding
Contact Center
EDI
Education
Evaluation & Management
FAQs
Fee Schedules
Forms
Help & Resources
IVR Resources
LCDs/Medical Affairs
Medical Documentation
Medical Review
Provider Enrollment
Provider Incentives
Provider Specialties
Publication Archives
SPOT
Tools Center
Welcome to Medicare
Find fee schedules – Part B fee schedule lookup
Complete this form to obtain Medicare fee-for-service allowances. You must select a fee schedule and enter a procedure code, location, and date of service.
* Required
Select fee schedule
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Modifier
Record Effective Date
01/01/2020
Description
Puraply xt, per square centi
Procedure Code
Q4197
Modifier 1
Modifier 2
Effective Date
01/01/2020
Description
Puraply xt, per square centi
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Blood Amount
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DME Infusion Amount
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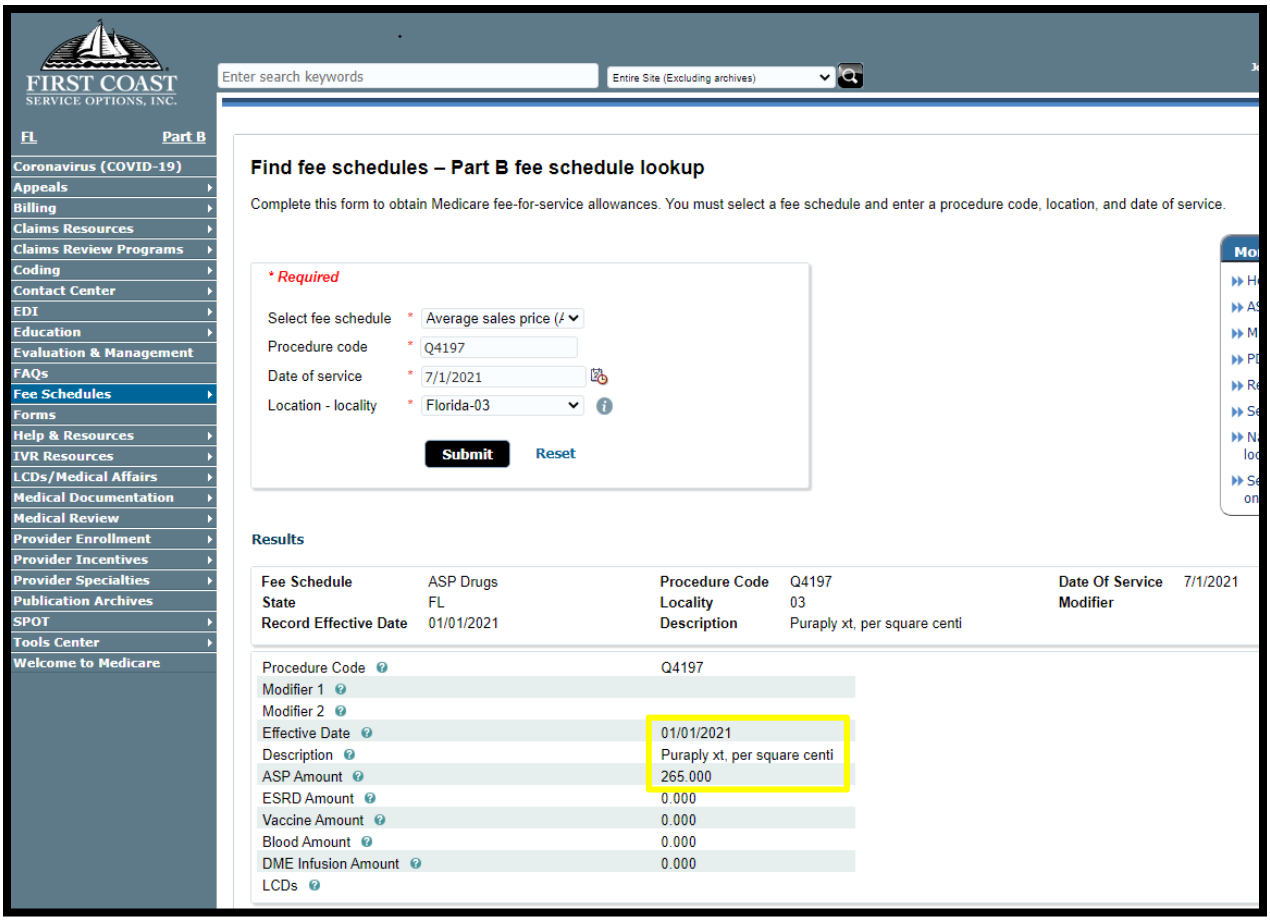


162. Another MAC, Noridian, did not provide the exact reimbursement amount for PuraPly XT, but confirmed in response to a FOIA request that PuraPly XT was reimbursed during the Class Period based on "invoice pricing."

163. The $265 per square centimeter reimbursement amount reflected in data obtained from Palmetto GBA and FCSO is consistent with marketing materials produced by FEs who sold PuraPly XT during the Class Period. For example, a marketing spreadsheet titled "Office Setting Payment Q3 2021 – Non GPO [Group Purchasing Organization] Volume" produced by FE-10, shows that the MAC reimbursement in FE-10's region was $265 per square centimeter in 3Q2021. The spreadsheet, reproduced below, lists: (i) each of Organogenesis's products by HCPCS code (including Affinity-Q4159, and PuraPly XT-Q4197); (ii) their corresponding per-square-centimeter reimbursement amounts; (iii) the non-public "Product Cost" charged by Organogenesis

for each product depending on the application size; (iv) the "Product Payment" reflecting the total amount reimbursed by Medicare; and (v) the "After Cost" profit available to the physician after reimbursement, i.e., the reimbursement spread.[8]

Office Setting Payment Q3 2021 - NON GPO Volume							
	Products	Size	Unit Size	Rate Per Cm2	~Product Payment	Office MUE	
Q4101	Apligraf	44	44	30.427	$1,338.79	88	
Q4106	Dermagraft	38	38	32.026	$1,216.99	76	
Q4160	NuShield	3.2x3.2	11	96.264	$1,058.90	36	
		4x4	16	96.264	$1,540.22	36	
		4x6	24	96.264	$2,310.34	36	
		6x6	36	96.264	$3,465.50	36	
Q4196	Puraply AM	3.02X3.02	10	108.285	$1,082.85	54	
		3.76x3.76	15	108.285	$1,624.28	54	
Q4197	PuraPly XT	4.91x4.91	25	265.000	$6,625.00	54	** Unpublished. Use on Medicare Only
		6x9	54	265.000	$14,310.00	54	
Q4159	Affinity	2.5x2.5	7	583.667	$4,085.67	28	** Unpublished.
CPT 15275 Face, Scalp, Feet			$150.00				
	Products	Size	Product Cost	~Product Payment	~After Cost @100%	~After Cost @80%	
Q4101	Apligraf	44	$1,295.00	$1,338.79	$43.79	($223.97)	
Q4106	Dermagraft	38	$1,050.00	$1,216.99	$166.99	($76.41)	
Q4160	NuShield	3.2x3.2 volume	$720.00	$1,058.90	$338.90	$127.12	
		4x4 volume	$1,275.00	$1,540.22	$265.22	($42.82)	
		4x6 volume	$1,800.00	$2,310.34	$510.34	$48.27	
		6x6 volume	$2,700.00	$3,465.50	$765.50	$72.40	
Q4196	Puraply AM	3.02X3.02 volume	$800.00	$1,082.85	$282.85	$66.28	
		3.76x3.76 volume	$1,200.00	$1,624.28	$424.28	$99.42	
Q4197	PuraPly XT	4.91x4.91	$4,250.00	$6,625.00	$2,375.00	$1,050.00	
		6x9	$8,900.00	$14,310.00	$5,410.00	$2,548.00	
Q4159	Affinity	2.5x2.5	$3,150.00	$4,085.67	$935.67	$118.54	

164. As reflected in the spreadsheet reproduced above, the MAC reimbursement rate of $265 per square centimeter for PuraPly XT was far greater than the product cost charged by Organogenesis. For example, in 3Q2021, physicians in an office setting were charged ***$8,900*** by Organogenesis for one 6 x 9 centimeter application of PuraPly XT (consisting of 54 one-square-centimeter units). However, physicians were reimbursed ***$14,310*** by the MAC (reflecting a rate of

[8] The "After Cost" columns inform physicians of their total profit for the products at both 100% and 80%, to account for the fact that Medicare typically pays 80% of the allowable amount and a patient must either pay the remaining 20% or bill the remaining 20% to a supplemental insurance policy.

$265 per square centimeter multiplied by 54 units). This meant that physicians using PuraPly XT could profit as much as ***$5,410 per application***.

165. FE-10 produced a similar spreadsheet reflecting data as of 1Q2022. As shown in the spreadsheet reproduced below, physicians in 1Q2022 were still profiting up to ***$5,410*** for each 6 x 9 centimeter application of PuraPly XT.

Office Setting Payment Q1 2022 - NON GPO Volume							
	Products	**Size**	**Unit Size**	**Rate Per Cm2**	**~Product Payment**	**Office MUE**	
Q4101	**Apligraf**	*44*	44	30.442	**$1,339.45**	88	
Q4106	**Dermagraft**	*38*	38	31.971	**$1,214.90**	76	
Q4160	**NuShield**	*3.2x3.2*	11	95.943	**$1,055.37**	36	
		4x4	16	95.943	**$1,535.09**	36	
		4x6	24	95.943	**$2,302.63**	36	
		6x6	36	95.943	**$3,453.95**	36	
Q4196	**Puraply AM**	*3.02X3.02*	10	110.645	**$1,106.45**	54	
		3.76x3.76	15	110.645	**$1,659.68**	54	
Q4197	**PuraPly XT**	*4.91x4.91*	25	265.000	**$6,625.00**	54	** Unpublished. Use on Medicare Only
		6x9	54	265.000	**$14,310.00**	54	
Q4159	**Affinity**	*2.5x2.5*	7	535.602	**$3,749.21**	28	
Q4194	NovaChor	*1.5x2.75*	5	1060.000	**$5,300.00**	28	**Unpublished. Use on Medicare Only
CPT 15275 Face, Scalp, Feet			**$150.00**				
	Products	**Size**	**Product Cost**	**~Product Payment**	**~After Cost @100%**	**~After Cost @80%**	
Q4101	**Apligraf**	*44*	$1,295.00	$1,339.45	**$44.45**	($223.44)	
Q4106	**Dermagraft**	*38*	$900.00	$1,214.90	**$314.90**	$71.92	
Q4160	**NuShield**	*3.2x3.2 volume*	$720.00	$1,055.37	**$335.37**	**$124.30**	
		4x4 volume	$1,275.00	$1,535.09	**$260.09**	($46.93)	
		4x6 volume	$1,800.00	$2,302.63	**$502.63**	$42.11	
		6x6 volume	$2,700.00	$3,453.95	**$753.95**	$63.16	
Q4196	**Puraply AM**	*3.02X3.02 volume*	$800.00	$1,106.45	**$306.45**	**$85.16**	
		3.76x3.76 volume	$1,200.00	$1,659.68	**$459.68**	**$127.74**	
Q4197	**PuraPly XT**	*4.91x4.91*	$4,250.00	$6,625.00	**$2,375.00**	**$1,050.00**	
		6x9	$8,900.00	$14,310.00	**$5,410.00**	**$2,548.00**	
Q4159	**Affinity**	*2.5x2.5*	$3,150.00	$3,749.21	**$599.21**	**($150.63)**	
Q4194	NovaChor	1.5x2.75	$3,800.00	$5,300.00	$1,500.00	**$440.00**	**Unpublished. Use on MEDICARE ONLY.

2. Organogenesis Marketed Affinity And PuraPly XT Based On The Reimbursement Spread

166. Based on the accounts of FE-1, FE-2, FE-6, and FE-7, throughout the Class Period, the Company's sales team, under the direction of Organogenesis's management, marketed the temporary reimbursement spread for Affinity and PuraPly XT to generate sales, thereby inflating the Company's revenues to unsustainable levels. This reveals that without the reimbursement spread, physicians would not have otherwise purchased Affinity or PuraPly XT.

167. For example, FE-7 explained that podiatrists would not use Affinity or PuraPly XT unless they stood to earn a profit. FE-3 likewise stated that physicians were not purchasing Affinity and PuraPly XT based on efficacy, but were choosing these products over competing products because of the profit they stood to make. FE-5 also stated that while there were similar products on the market, the reimbursement for Affinity was higher by comparison, providing an incentive for physicians to select Affinity over competing products. FE-13 stated that physicians were highly unlikely to purchase either Affinity or PuraPly XT for non-Medicare patients because the products were too costly without Medicare reimbursement.

168. FE-6 stated that sales representatives never discussed efficacy, and that their sales pitches focused on the "robust reimbursement" for Affinity and PuraPly XT. As an example of this practice, FE-6 described witnessing a sales representative go to the front desk at a physician's office and state that he needed to speak with the physician because the physician was using a competing product, but if the physician used Affinity, the physician could make $500 more. The sales representative said: "Let me take the doctor to lunch and tell him how to do it." FE-6 also estimated that 90% of the Company's sales representatives were marketing Affinity and PuraPly XT based on the products' reimbursement. FE-6 said it was "systemic," and not just random sales representatives. For example, FE-6 recalled attending a compliance training, after which sales representatives were laughing because "they couldn't sell anything if they couldn't sell on the margin." These accounts are confirmed by the marketing spreadsheets produced by FE-10, which state that PuraPly XT should be "***Use[d] on Medicare Only***." In other words, the selling point for these products was their reimbursement, and not their clinical benefits. Confirming this, FE-2 stated that Organogenesis provided "zero clinical information" for sales representatives to sell

PuraPly XT. FE-2 was just told to explain to physicians that PuraPly XT was thicker and therefore better in order to justify the price point.

169. FE-9 stated that Organogenesis understood that physicians did not want to pay out of pocket for the Company's products and so it was not possible to "decouple efficacy from reimbursement." In practice, according to FE-5, physicians wanted to know the reimbursement amount regardless of any claimed clinical benefits of the products. FE-5 stated that "it's one of the first questions they ask you" and that physicians would "perk up" when they heard the reimbursement amount for Affinity. FE-4 recalled similar conversation with physicians regarding reimbursement. FE-4 stated that the Company's sales representatives were not technically supposed to speak about "profit" with physicians, so instead they framed by the conversation by saying, "this is what you're going to pay, this is the dollar amount you should receive back from Medicare, and here is your 'allowable over cost.'"

170. FE-13 stated that the strategy to target Medicare providers was instilled in Organogenesis's sales force by the Company's sales trainers, who emphasized how important it was to first verify that a patient was covered by Medicare before a provider applied PuraPly XT. FE-5 similarly recalled that Organogenesis contacted Medicare to verify coverage and reimbursement prior to a physician using Affinity. FE-12 likewise recalled that physicians would determine whether Affinity or PuraPly XT was covered by Medicare and/or a supplemental insurance program before purchasing the products.

171. To assist Organogenesis's sales representatives with marketing based on reimbursement, according to FE-8, Organogenesis provided each sales representative with an iPad with a pre-installed, Organogenesis-branded application for use in sales calls. This application demonstrated the potential profit to the physician for purchasing each of the Company's products.

FE-8 stated that each sales representative received an iPad during their initial training, and the application, called "mTrain," would show physicians the Medicare reimbursement rate for the products in their specific region.

172. The accounts of FE-1, FE-2, FE-4, FE-7, and FE-11, described similar Organogenesis-supplied marketing materials. FE-1 recalled that sales representatives were given iPads with a proprietary application installed in order to make sales presentations to treating physicians. According to FE-1, the application showed the physician's cost for each product and the spread, or profit, potentially available based on the prevailing reimbursement amount in that physician's region. FE-1 stated that the application had a reimbursement "calculator" which factored in several variables, such as the wound size, the size of the application, and the location of the clinic or hospital where the treatment was given, to arrive at an estimated cost of the product, reimbursement cost, and profit margin for the physician. Similarly, both FE-4 and FE-7 recalled that each of the Company's sales representatives were given an iPad by Organogenesis with an application that showed the spread, which FE-4 characterized as the "allowable over cost," and FE-7 described as the physician's "estimated reimbursement over cost." FE-2 and FE-11 also confirmed that Organogenesis provided sales representatives with iPads that showed reimbursement amounts for the Company's products, and FE-2 stated that sales representatives used the iPad to show reimbursement amounts to physicians.

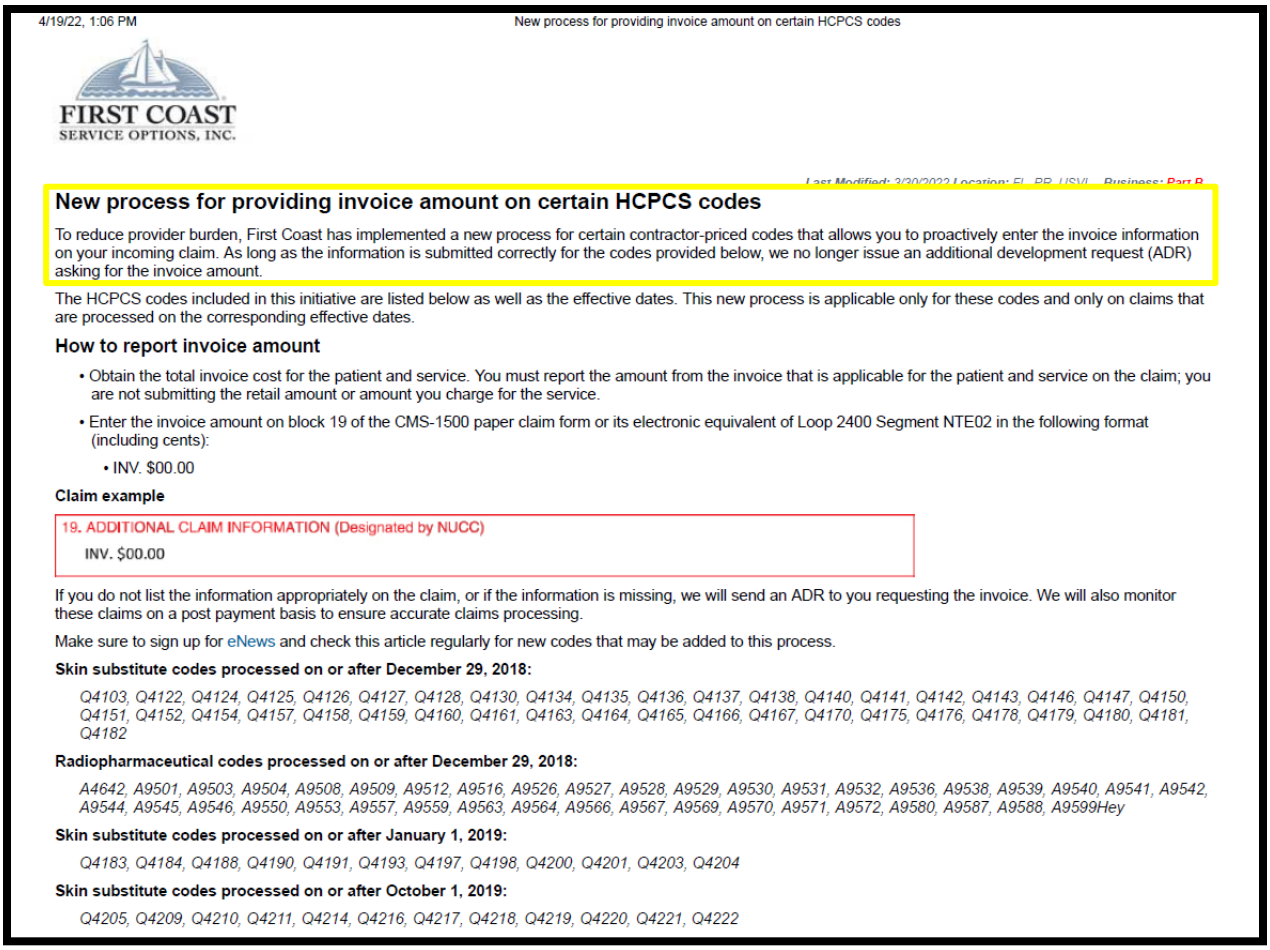
173. FE-1 believed that Organogenesis's Reimbursement Team was responsible for regularly updating the product reimbursement rates and costs in the iPad application, and would send emails to the sales force when changes in reimbursement rates were uploaded to the iPads. FE-11 similarly recalled that there was a quarterly e-mail for all products which detailed reimbursement rates and whether an ASP had been set.

174. As FE-1 explained, the reimbursement information provided by the Company in its marketing materials was relied upon by physicians in determining the amount to submit to Medicare as part of their reimbursement claims. In FE-1's region, the claim form that was submitted to Medicare had a place in which physicians could simply write in an invoice "cost per unit" for the product, and physicians could write in any number they wanted. The MAC for FE-1's region, Noridian, confirmed in response to a FOIA request that it reimbursed "using invoice pricing" when there was no ASP established for Affinity and PuraPly XT during the Class Period. Regarding a copy of the actual invoice from Organogenesis, Noridian's procedure directs physicians to enter the total invoice price on the claim. This is consistent with the fact that during the Class Period, several other MACs, including Palmetto GBA and Novitas, as detailed above, as well as FCSO and CGS Administrators, LLC ("CGS"),[9] did not require a copy of a physical invoice when processing reimbursement claims for either Affinity or PuraPly XT.

175. In response to a FOIA request, CGS confirmed that Affinity and PuraPly XT were reimbursed "based on invoice" during the Class Period for the quarters in which there was no established ASP. CGS further confirmed that a physician has the option to either submit the actual invoice or "***submit invoice information on the claim line***."

176. FCSO previously detailed its reimbursement requirements for Affinity and PuraPly XT on the FCSO website. A screenshot of a FCSO webpage taken on April 19, 2022 explains that to "reduce provider burden" physicians are allowed to "***proactively enter***" the invoice amount on the claim form. FCSO further explains that "***[a]s long as the information is submitted correctly***," FCSO will not issue an additional development request, or ADR, requesting the invoice.

[9] CGS administers Medicare Part B in Ohio and Kentucky.



4/19/22, 1:06 PM New process for providing invoice amount on certain HCPCS codes

FIRST COAST SERVICE OPTIONS, INC.

Last Modified: 3/30/2022 Location: FL, PR, USVI Business: Part B

New process for providing invoice amount on certain HCPCS codes

To reduce provider burden, First Coast has implemented a new process for certain contractor-priced codes that allows you to proactively enter the invoice information on your incoming claim. As long as the information is submitted correctly for the codes provided below, we no longer issue an additional development request (ADR) asking for the invoice amount.

The HCPCS codes included in this initiative are listed below as well as the effective dates. This new process is applicable only for these codes and only on claims that are processed on the corresponding effective dates.

How to report invoice amount

- Obtain the total invoice cost for the patient and service. You must report the amount from the invoice that is applicable for the patient and service on the claim; you are not submitting the retail amount or amount you charge for the service.
- Enter the invoice amount on block 19 of the CMS-1500 paper claim form or its electronic equivalent of Loop 2400 Segment NTE02 in the following format (including cents):
  - INV. $00.00

Claim example

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
INV. $00.00

If you do not list the information appropriately on the claim, or if the information is missing, we will send an ADR to you requesting the invoice. We will also monitor these claims on a post payment basis to ensure accurate claims processing.

Make sure to sign up for eNews and check this article regularly for new codes that may be added to this process.

Skin substitute codes processed on or after December 29, 2018:

Q4103, Q4122, Q4124, Q4125, Q4126, Q4127, Q4128, Q4130, Q4134, Q4135, Q4136, Q4137, Q4138, Q4140, Q4141, Q4142, Q4143, Q4146, Q4147, Q4150, Q4151, Q4152, Q4154, Q4157, Q4158, Q4159, Q4160, Q4161, Q4163, Q4164, Q4165, Q4166, Q4167, Q4170, Q4175, Q4176, Q4178, Q4179, Q4180, Q4181, Q4182

Radiopharmaceutical codes processed on or after December 29, 2018:

A4642, A9501, A9503, A9504, A9508, A9509, A9512, A9516, A9526, A9527, A9528, A9529, A9530, A9531, A9532, A9536, A9538, A9539, A9540, A9541, A9542, A9544, A9545, A9546, A9550, A9553, A9557, A9559, A9563, A9564, A9566, A9567, A9569, A9570, A9571, A9572, A9580, A9587, A9588, A9599Hey

Skin substitute codes processed on or after January 1, 2019:

Q4183, Q4184, Q4188, Q4190, Q4191, Q4193, Q4197, Q4198, Q4200, Q4201, Q4203, Q4204

Skin substitute codes processed on or after October 1, 2019:

Q4205, Q4209, Q4210, Q4211, Q4214, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222

177. FE-1 stated that physicians would add in a profit margin above the product cost charged by Organogenesis, relying on the reimbursement and product cost calculations generated by the Company's iPad application. FE-1 stated that each claim could include a 15% to 20% "add-on margin" for the physician, and that the Organogenesis application would assist physicians in determining this "add-on margin" estimate. FE-1 stated that Organogenesis did not discourage physicians from adding such margins to their claims, and that this practice of adding margin to Medicare claim forms was a "topic of conversation" among Organogenesis sales representatives. Indeed, according to FE-1, all of the sales representatives in FE-1's region participated in the same practice whereby physicians added margin above the product cost amount charged by Organogenesis. Moreover, FE-1 stated some physicians would file claims for more than

Organogenesis's estimate of what Medicare would reimburse for the claim. As an example, FE-1 stated that for a 2.5 x 2.5 centimeter application of Affinity, a physician could earn as much as $1,500 in "add-on margin."

178. FE-2 similarly stated that the sales representatives in FE-2's region would tell physicians that they should claim enough in their reimbursement claims to Medicare so that they would be reimbursed the maximum amount from the MACs. FE-2 stated that this amount was higher than the amount charged by Organogenesis for the products, and that physicians knew what they were being charged by Organogenesis because Organogenesis emailed the physicians the details of what they were being charged. FE-2 stated that the doctors would not submit the amount they were being charged by Organogenesis for the product to Medicare, and that Medicare would only receive this information if Medicare asked for it.

179. In addition to the reimbursement application supplied by the Company, FE-3, FE-4, FE-5, and FE-6 reported that sales representatives and their managers generated additional materials to market the reimbursement spread for Affinity and PuraPly XT. FE-5 recalled using a document that listed product name and sizes, whether there was an ASP, the cost of the product, and the reimbursement amount. FE-5 used this document, which was made by either FE-5's Regional Sales Manager or another sales representative, to discuss the reimbursement with physicians. FE-4 similarly received a spreadsheet from a fellow employee on a monthly basis that illustrated the "pricing dynamics" available to physicians. FE-4 described the spreadsheet as a "calculator for the products," which listed each product and the corresponding reimbursement amount from Medicare at 100% and 80%, respectively. Significantly, FE-4's description of this document matches the spreadsheets produced by FE-10 and discussed in ¶¶ 163-65 above.

180. FE-3 also received a pricing spreadsheet from a sales representative colleague to assist with Affinity sales to doctors. FE-3 explained that this spreadsheet made it easier for doctors to visualize reimbursement numbers and the profit they would receive by purchasing Affinity. According to FE-3, the spreadsheet showed the price of the product, the reimbursement rate, and the difference between the two numbers. Likewise, FE-5 believed that sales representatives in other regions utilized similar sales spreadsheets because physicians were likely to ask: "What am I making on this?"

181. FE-2 and FE-7 both confirmed the use of spreadsheets detailing the reimbursement spread and recalled that these spreadsheets were provided by sales managers. FE-7 recalled that a manager explained the spreadsheet to FE-7. FE-7 stated that in FE-7's region, sales representatives used the marketing spreadsheets to detail product pricing and reimbursement to physicians.

182. FE-6 stated that Organogenesis management also distributed a PowerPoint presentation titled "Business of Wound Care" and directed sales representatives to use the presentation during meetings with physicians. The presentation, which was approximately six pages in length, was formatted such that it could be updated to reflect the reimbursement spread in a specific territory. According to FE-6, the "Business of Wound Care" slides contained tables highlighting certain products in green to indicate that the physician would make money using the product due to the favorable reimbursement spread created by Organogenesis. Conversely, the products that would result in a loss to the physician were highlighted in red.

3. Organogenesis's Management Knew The Reimbursement Spread For Affinity And PuraPly XT Was Temporary And Pushed Sales Representatives To Market The Spread While These Products Lacked An ASP

183. Organogenesis management sanctioned sales representatives' marketing of the reimbursement spread for Affinity and PuraPly XT and pushed the Company's sales force to sell

these products while they lacked an ASP. As discussed above, this encouragement included supplying sales representatives with marketing materials, including Company-supplied iPads, spreadsheets, and PowerPoint presentations calculating the profits to physicians for these products based on the prevailing MAC reimbursement rates and the Company's non-public product costs. In addition, the conduct described by FE-1, FE-2, FE-4, and FE-6 reveals that sales managers emphasized Affinity and PuraPly XT's reimbursement as a selling point during sales meetings and stressed the need to drive sales while the profitable reimbursement existed. During these meetings, Organogenesis's management acknowledged that the favorable reimbursement for these products was temporary and that the Company's ability to boost sales of Affinity and PuraPly XT by marketing the spread would come to an end once an ASP was established. Organogenesis also directed its sales force to market Affinity and PuraPly XT in those regions where the MAC reimbursement was higher.

184. FE-2 stated that Organogenesis management "absolutely" wanted sales representatives to sell Affinity and PuraPly XT based on their reimbursement. FE-2 stated that managers directed sales representatives to sell Affinity and PuraPly XT in physician offices based on the "robust reimbursement" for these products, and told sales representatives that as part of their sales pitches, representatives should discuss reimbursement and how much money the physicians would be making when using the products. FE-2 participated in weekly sales calls that included the seven representatives in FE-2's area and their direct managers, and stated that these calls often included Regional Sales Manager, Chris Williams, and members of more senior management, including Brian Grow, Organogenesis's Chief Commercial Officer, Lowell Berg,

former Senior Director of Sales and now Vice President of Commercial Development, and the Head of Reimbursement, whose name FE-2 did not recall.[10]

185. During these calls, FE-2 stated that the sales managers would go over "talk tracks" which detailed how sales representatives should discuss reimbursement with physicians during sales calls. FE-2 described the talk tracks as product pitches that the sales representatives were supposed to use when they went into physician offices. For example, the managers would take a representative who was doing well with Affinity or PuraPly XT sales and ask the sales representative to talk about the conversations they had with physicians in order to sell the products. The talk tracks would demonstrate for the sales representatives that they should tell the physicians the price Organogenesis was charging, the amount that Medicare would reimburse for the product, and how much in spread the physician would be making.

186. Organogenesis management not only accepted that sales representatives would sell Affinity and PuraPly XT based on the reimbursement spread, but, according to FE-6, Organogenesis management actually directed sales representatives to do so. FE-6 stated that management trained its sales representatives on how not to get caught selling on the spread, and told sales representatives not to leave any of the so-called marketing materials behind at physicians' offices. FE-6 also stated that senior management would try to "bury" anyone who attempted to turn in managers for the Company's illegal practice of marketing Affinity and PuraPly XT based on the reimbursement spread. FE-6 stated that when Organogenesis's Compliance department was informed of the push to market the spread of Affinity and PuraPly XT, the Company retaliated against the sales representatives who reported the illegal conduct. FE-6 personally sent numerous communications to the head of Compliance to inform the head of

[10] Brian Grow and Lowell Berg's titles have been identified based on public sources.

Compliance what was going on. FE-6 also met with Compliance and made it clear that the Company's marketing practices were improper. Moreover, FE-6 stated that in 2022, FE-6 sent copies of marketing materials to Compliance which provided evidence of the Company's sales practices. FE-6 stated that the head of Compliance did not do anything about it and covered it up, and FE-6 was retaliated against and threatened by members of senior management, including Senior Director of Sales, Darren McBee. Moreover, FE-6 stated that a letter addressed to Gillheeney detailing concerns about the Company's marketing practices went unanswered.

187. FE-8 stated that, officially, Organogenesis sales representatives were not supposed to market products based on the reimbursement spread, but in practice, it was "pretty clear what the goal was." FE-2 recalled that when the clinical benefits of Affinity and PuraPly XT were raised during weekly calls with the sales team, the sales managers stated: "Yeah, yeah, sell clinically but if the doctors asked, talk about the reimbursement." That is, despite any statements to the contrary, Organogenesis's management provided the Company's sales representatives with the exact tools that they needed to market Affinity and PuraPly XT based on reimbursement. As a result, the Company's practice of marketing Affinity and PuraPly XT based on the economic, rather than clinical benefits of the products was widespread.

188. FE-4 recalled that sales representatives received under the radar direction from Organogenesis management that they should sell Affinity and PuraPly XT on the spread while there was no ASP. FE-4 stated that physicians could not profit as much from purchasing PuraPly AM, which had a published ASP during the Class Period, so there was a push to sell PuraPly XT over given PuraPly XT's more favorable reimbursement due to its lack of an ASP. FE-4's account is confirmed by the marketing spreadsheets produced by FE-10, which show reimbursement

amounts ranging from $66.28 to $424.28 per application of PuraPly AM in the physician office setting, compared to $1,050 to $5,410 for PuraPly XT.

189. FE-9 also reported that senior management, including Gillheeney and Francisco, had full access to the Company's Microsoft Power BI system that reported sales and revenue geographically by region. FE-1 recalled attending two national sales meetings during which Organogenesis senior management discussed the reimbursement rates for Affinity and PuraPly XT. FE-1 also recalled that Organogenesis management urged all sales representatives to "drive to sell" as much Affinity and PuraPly XT as possible while the products had favorable reimbursement given the lack of an ASP. According to FE-1, Organogenesis management constantly talked about the fact that Affinity and the PuraPly products were responsible for a large amount of the company's growth and that management was always "driving sales" in these products because the favorable reimbursement rates made them big sellers. For example, FE-1 recalled that management provided incentives tied to the amount of PuraPly XT sold. Consistent with FE-1's account, FE-3 stated that there was a huge emphasis placed on the importance of selling Affinity and PuraPly XT during FE-3's weekly regional sales meetings, and FE-2 similarly recalled discussions during FE-2's weekly sales meetings about the need to market Affinity and PuraPly XT exclusively in physicians' offices because of the higher reimbursement.

190. FE-9, an Organogenesis marketing executive, confirmed that Organogenesis's sales strategy was to focus on MACs that reimbursed for products without an ASP. FE-9 knew of this strategy through conversations with Organogenesis's Chief Commercial Officer, Brian Grow, and confirmed that senior management from Gillheeney "on down" knew of this strategy. FE-4 confirmed this, stating that there were certain MACs that would not reimburse physicians for

Affinity, and therefore little to no Affinity was sold in those regions during those times. FE-8 similarly stated that sales of Affinity grew in regions where the MACs reimbursed for the product.

191. FE-1 stated that it was known that sales would decline once Affinity and PuraPly XT were eventually reimbursed at an ASP-based rate. Sales representatives were "terrified" by this dynamic, as recalled by FE-4. FE-4 stated that the sales representatives were concerned that physicians would move to a different product once Affinity received its ASP. FE-4 explained that Organogenesis had experienced such a decline in sales for one of the Company's other products, NuShield, when NuShield received an ASP and physicians could no longer profit by using the product. FE-4's account of NuShield's unprofitable reimbursement after it received an ASP is corroborated by the spreadsheets produced by FE-10. As seen above in ¶ 163, by 3Q2021, NuShield had negative reimbursement for certain sized applications, meaning physicians would lose money when using this product, and for those sizes with positive reimbursement, the reimbursement spread was often less than $100 at 80% reimbursement. As reflected in the spreadsheets produced by FE-10, several of the Company's other products, including Apligraf and Dermagraft, also had negative reimbursement when used in the physician office setting.

192. Indeed, as discussed below, sales representatives in regions wherein the MACs were reimbursing based on the invoice price for Affinity felt the negative effects almost immediately in 3Q2021—the first quarter that Affinity received an ASP during the Class Period. According to FE-3, physicians in Colorado who were reimbursed by the MAC Novitas made significant profits from using Affinity while it did not have an ASP. But, as FE-3 recalled, once Affinity received an ASP in 3Q2021, sales representatives in the Colorado region were negatively affected because they lost Affinity sales due to the lower reimbursement rate. The dramatically reduced reimbursement rate for Affinity after it received an ASP is confirmed by the marketing

spreadsheets produced by FE-10. As seen below, in 3Q2021, the after cost reimbursement amount for Affinity using the ASP of $583.667 dropped as low as $118.54 per application—down from the $3,800 that physicians stood to profit prior to Affinity receiving an ASP.

Office Setting Payment Q3 2021 - NON GPO Volume							
	Products	Size	Unit Size	Rate Per Cm2	~Product Payment	Office MUE	
Q4101	Apligraf	44	44	30.427	$1,338.79	88	
Q4106	Dermagraft	38	38	32.026	$1,216.99	76	
Q4160	NuShield	3.2x3.2	11	96.264	$1,058.90	36	
		4x4	16	96.264	$1,540.22	36	
		4x6	24	96.264	$2,310.34	36	
		6x6	36	96.264	$3,465.50	36	
Q4196	Puraply AM	3.02X3.02	10	108.285	$1,082.85	54	
		3.76x3.76	15	108.285	$1,624.28	54	
Q4197	PuraPly XT	4.91x4.91	25	265.000	$6,625.00	54	** Unpublished. Use on Medicare Only
		6x9	54	265.000	$14,310.00	54	
Q4159	Affinity	2.5x2.5	7	583.667	$4,085.67	28	** Unpublished.
CPT 15275 Face, Scalp, Feet			$150.00				
	Products	Size	Product Cost	~Product Payment	~After Cost @100%	~After Cost @80%	
Q4101	Apligraf	44	$1,295.00	$1,338.79	$43.79	($223.97)	
Q4106	Dermagraft	38	$1,050.00	$1,216.99	$166.99	($76.41)	
Q4160	NuShield	3.2x3.2 volume	$720.00	$1,058.90	$338.90	$127.12	
		4x4 volume	$1,275.00	$1,540.22	$265.22	($42.82)	
		4x6 volume	$1,800.00	$2,310.34	$510.34	$48.27	
		6x6 volume	$2,700.00	$3,465.50	$765.50	$72.40	
Q4196	Puraply AM	3.02X3.02 volume	$800.00	$1,082.85	$282.85	$66.28	
		3.76x3.76 volume	$1,200.00	$1,624.28	$424.28	$99.42	
Q4197	PuraPly XT	4.91x4.91	$4,250.00	$6,625.00	$2,375.00	$1,050.00	
		6x9	$8,900.00	$14,310.00	$5,410.00	$2,548.00	
Q4159	Affinity	2.5x2.5	$3,150.00	$4,085.67	$935.67	$118.54	

193. The Company's knowledge that Affinity revenue would decline after the product received an ASP was confirmed by FE-6. FE-6 stated that the Company knew it would lose business once Affinity's ASP was published because of how expensive the product was, and that the decline in sales was expected by every Organogenesis manager. FE-6 explained that after the ASP, physicians no longer had the financial motivation to use Affinity because they went from making thousands from each application to potentially only breaking even.

4. During The Class Period, Organogenesis Engaged In Other Unsustainable Practices To Inflate Sales Of Affinity And PuraPly XT

a. Organogenesis Manipulated Medicare Reimbursement Through "Odd-Even Pricing"

194. In addition to Organogenesis's strategy of marketing the reimbursement spread for Affinity and PuraPly XT to inflate sales of these products, Organogenesis engaged in other manipulations designed to maximize sales and reimbursement for these products. One such strategy involved "odd-even pricing." Odd-even pricing is a strategy that seeks to capitalize on the fact that Medicare round ups to the next highest square centimeter when reimbursing products sold in square centimeter units. For example, Affinity's standard application size is 2.5 x 2.5 centimeters, totaling 6.25 square centimeters. Since the Medicare reimbursement rate is calculated based on square centimeter units, by setting the Affinity size to 6.25 square centimeters, Organogenesis provided physicians an additional profit because the physicians could submit claims to Medicare for 7 square centimeter units for each 6.25 square centimeter application of Affinity sold by the Company.

195. According to FE-9, Organogenesis knew that Medicare reimbursed based on whole numbers and discussed adjusting product sizes to allow for added reimbursement based on odd-even pricing. FE-9 recalled conversations regarding Organogenesis's odd-even pricing strategy that were held across the Company, and believed that Gillheeney and Brian Grow had discussions regarding this strategy.

196. FE-11 stated that Organogenesis's sizing gave extra billable units to physicians and increased the reimbursement physicians would receive. For example, FE-11 stated for an Affinity application in a 2.5 x 2.5 centimeter wound, or 6.25 square centimeters, physicians would round up to 7 units of Affinity. If the wound was larger and required two pieces of Affinity, the providers would bill for 14 units, even though the total amount of Affinity used was only 12.5 square

centimeters. FE-11 was told that more recently in 2022, Medicare began pulling back money and stating that Organogenesis should be billing for only 13 units in such a situation, not 14 units. FE-5 and FE-7 confirmed that physicians took advantage of Organogenesis's odd-even pricing and would round up to the next whole number when submitting claims to Medicare.

197. These accounts are confirmed by the marketing spreadsheets produced by FE-10, which show a whole number "Unit Size" for each size of PuraPly XT and Affinity sold by the Company. For example, as reflected in ¶¶ 163, 167 above, the Unit Size for Affinity is 7, even though the total size of each application was 6.25 square centimeters; for PuraPly XT, the Unit Size for a 4.91 x 4.91 centimeter application, totaling 24.10 square centimeters, was 25 square centimeter units.

b. Organogenesis Guaranteed Reimbursement To Physicians

198. As a further inducement to get physicians to purchase Affinity and PuraPly XT, Organogenesis developed an "Assurance Program" which acted as a reimbursement guarantee for physicians. As FE-5 explained, if a physician worked with Organogenesis's in-house reimbursement department to confirm that the wound and product combination would be reimbursed by Medicare, reimbursement was guaranteed, even if Medicare denied the physician's claim. That is, if Medicare reimbursed for a lesser amount or the reimbursement was rejected entirely, Organogenesis would reimburse the physician. According to FE-5, Organogenesis also contacted Medicare on behalf of physicians in order to confirm reimbursement. Additionally, as recalled by FE-3, the Organogenesis Customer Care Team would walk physicians through the process of filling out Affinity order forms and Medicare reimbursement paperwork.

199. FE-7 stated that Organogenesis's in-house benefit verification team would assist physicians in determining whether products were covered by Medicare and would check submissions to Medicare to ensure that the product would be approved and covered by Medicare.

FE-7 also stated that Organogenesis's customer relationship management system showed when benefit verifications were submitted by physicians allowing Organogenesis to track how many patients were covered and determine if others would be approved. Further, FE-7 stated that Organogenesis told sales representatives to average a certain number of benefit verifications per day and required sales representatives to submit more benefit verifications than the daily goal because some may not be approved.

c. Organogenesis "Gamed the System" For ASPs

200. According to FE-2, Organogenesis also "gamed the system" for ASPs. FE-2 recalled sales managers stating that they "all have to play an ASP game." FE-2 explained that Affinity was pulled from the market to avoid having a low ASP set for the product. Indeed, just after Organogenesis took Affinity off the market at the end of 1Q2019, Affinity's ASP was set at around $176 per square centimeter effective April 1, 2019. FE-2 stated that the decision to withdraw Affinity from the market was part of Organogenesis's efforts to game Medicare reimbursement. FE-2 recalled that at the time Affinity was withdrawn from the market, the direction from senior management was to explain that there were difficulties with the Company's manufacturer and that Organogenesis was looking to bring the manufacturing in-house. However, when Affinity was put back on the market, FE-2 stated that the Company used the same manufacturer as before it went off the market. FE-2 further stated that Affinity was put back on the market at a higher price point.

201. FE-7 also recalled that Organogenesis "plays games" with ASPs. FE-7 stated that Organogenesis had pulled Affinity from the market at one point and FE-7 was told to explain to customers that it was due to a production problem. In reality, FE-7 heard that Affinity was pulled from the market for reimbursement reasons. FE-7 recalled that another sales representative's

manager explained that if Affinity was not available for part of the year, the ASP would be better later on and Organogenesis would make more money.

202. FE-2 provided other examples describing Organogenesis's efforts to inflate the ASP that would eventually be set for Affinity and PuraPly XT. FE-2 stated that during weekly sales calls, which often included members of senior management, including Brian Grow and Lowell Berg, Organogenesis sales managers discussed Organogenesis's strategy of marketing Affinity and PuraPly XT exclusively in physicians' offices because of the higher reimbursement available in this treatment setting. During these weekly calls, sales managers told sales representatives not to sell Affinity or PuraPly XT in the wound care setting, where reimbursement for the products was bundled, because they did not want such sales to lower the ASP that would be set for the products.

I. Investors Gradually Learn That Organogenesis's Reimbursement-Fueled Growth During The Class Period Is Unsustainable

1. October 12, 2021 Value Investors Club Report

203. On October 12, 2021, a report on Organogenesis was published on the Value Investors Club website, an online forum where investors share investment ideas (the "VIC Report"). The VIC Report alleged, among other things, that the Company was inflating its revenue growth by "[m]arketing the spread" to physicians, including "often ethically questionable podiatrists," and estimated that physicians were making between $500 and $2,000 per application of Affinity through reimbursement claims submitted to Medicare. The VIC Report alleged that "Affinity was very profitable for doctors to use and Affinity drove almost all of Organogenesis growth." Therefore, "[t]he Company decided to exploit the same loophole with its new PuraPly XT product" and "[i]nstead of PuraPly declining 50% as guided, PuraPly grew 30%."

204. However, as the VIC Report alleged, "ORGO's Affinity game ended on 7/1/21 when CMS set a price of $584/sq cm. This means that instead of collecting a large spread and making thousands in profit per use, Doctors will only be reimbursed for the cost of the product plus 6%, which is the industry standard." In short, the VIC Report alleged that by setting an ASP in July 2021, Medicare removed the profit incentive for physicians to use Affinity.

205. The VIC Report also alleged additional details regarding the uncertainty surrounding Affinity's future reimbursement. According to the VIC Report, "**AFFINITY WAS DROPPED FROM MEDICARE ASP COVERAGE ON OCTOBER 1st**." (Emphasis in original). Based on an investigation that included contacting the MACs directly, the VIC Report stated that one MAC indicated that "Affinity was not added back to the invoice list, where it needs to be listed to be invoiced." Further, the VIC Report stated that "[m]ost others" stated that "they do not have an invoice list and the product needs to be invoiced for reimbursement. And CMS will reimburse at its discretion." In other words, the VIC Report raised the possibility that without an ASP, the MACs would no longer reimburse physicians for Affinity based on invoice pricing. The VIC Reported stated: "That's a lot of uncertainty for an expensive product where reimbursement will collapse to product cost plus 6%, at best. An industry contact described this coverage drop for Affinity as a killer."

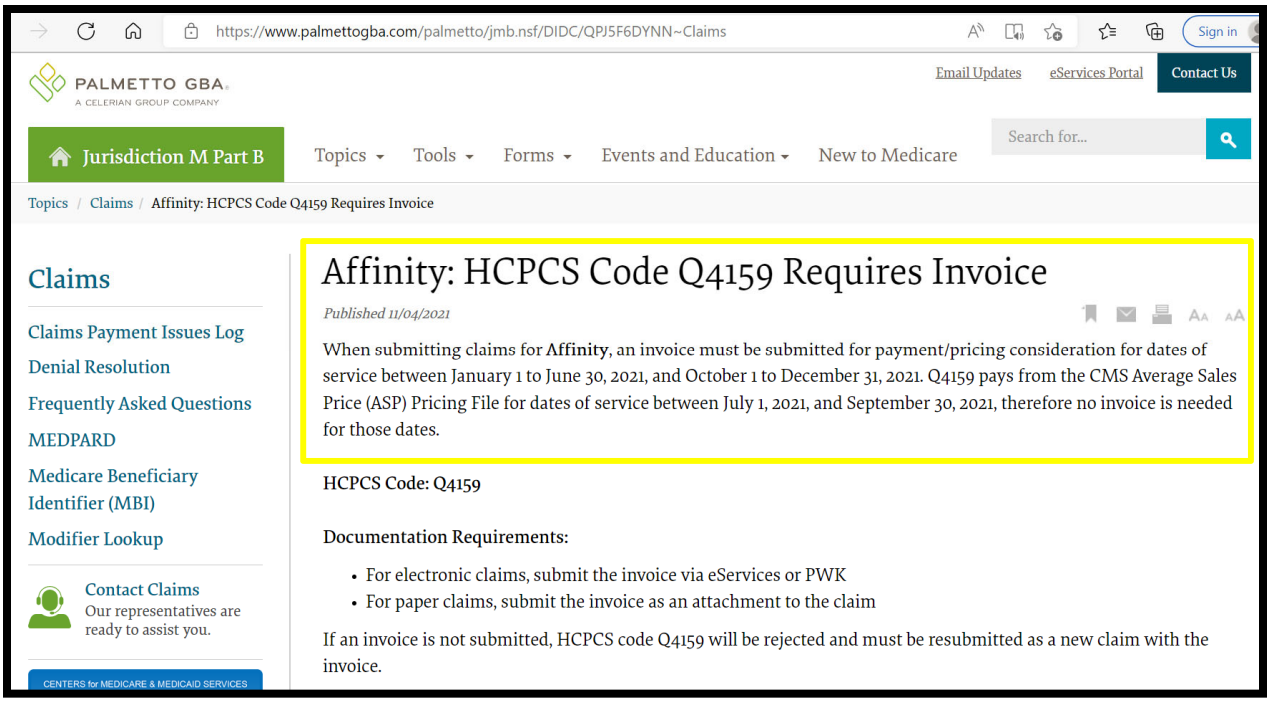
206. Following the release of the VIC Report, Organogenesis's stock price declined $1.70 per share, or ***14.11%***, from a closing price of $12.05 per share on October 11, 2021, to a closing price of $10.35 per share on October 12, 2021, on heavy trading volume.

207. A report published on October 12, 2021 by *Seeking Alpha* attributed the decline in Organogenesis's stock price to the release of the VIC Report. The report stated that: "Shares of

Organogenesis (ORGO -18.4%) are down after a[n] anonymous short report published in Value Investors Club accuses the company of 'ripping off' the federal government with reimbursement."

208. On October 14, 2021, BTIG analysts also attributed the decline in Organogenesis's stock price on October 12, 2021 to the release of the VIC Report. BTIG summarized the allegations in the VIC Report as follows: "The concerns around ORGO boil down to the notion that Affinity . . . has been overused based on a reimbursement structure which rewarded physicians for usage and that ORGO would see a significant drop in usage going forward as CMS appears to have left Affinity off its latest ASP Drug Pricing file for 4Q21." However, BTIG analysts disagreed with the VIC Report's conclusions regarding Affinity's future growth prospects, stating that "shares are attractive following the sell-off." BTIG also attributed the lack of an ASP to a "clerical error," stating, "we continue to think CMS made a clerical error around Affinity and could publish its next quarterly file for 1Q21 in the coming weeks and, if Affinity is included, a lot of the questions raised go away."

209. Notwithstanding some analysts' skepticism regarding the VIC Report, on November 4, 2021, Palmetto GBA, the MAC for several southeastern states, posted an alert on its website that "Affinity: HCPCS Code Q4159 Requires Invoice." The alert notified providers of its new policy that "***[w]hen submitting claims for Affinity, an invoice must be submitted for payment/pricing consideration for dates of service between January 1 to June 30, 2021, and October 1 to December 31, 2021***." The introduction of this policy meant that physicians could no longer inflate reimbursement claims for Affinity above the product cost charged by Organogenesis, thus removing the primary incentive for physicians reimbursed by Palmetto GBA to use Affinity over competing products.



2. Defendants Reassure Investors About The Reimbursement Status Of Affinity And Tout The Continued Strong Demand For PuraPly XT

210. On November 9, 2021, Organogenesis announced its 3Q2021 financial results, reporting total net revenue of $113.8 million, representing an increase of 20% on an adjusted basis year-over-year. Notably, however, the Company reported net revenue from the sale of non-PuraPly products—the category which includes Affinity—of $56.8 million, which represented a ***decrease*** of 5% from the third quarter of 2020.

211. During the 3Q2021 earnings call on November 9, 2021, Defendants downplayed the reported decline in non-PuraPly net revenues and dismissed the allegations in the VIC Report. Specifically, Gillheeney stated that the Company's 3Q2021 performance "***continue[d] to reflect our strong execution against our key pillars of our growth strategy, which includes leveraging our comprehensive and differentiated portfolio of products, diversifying our revenue sources across multiple sites of care and physician specialties, and leveraging our broad commercial reach***." Gillheeney also touted the performance of PuraPly, stating that the "***sale of PuraPly***

products increased 39% in the quarter . . . driven by strong utilization from existing customers and a contribution from new customers."

212. With respect to the reimbursement status of Affinity, Gillheeney claimed that the lack of an ASP for Affinity in 4Q2021 was due to a "filing error" and that "[a]s part of our strategy to grow the brand nationwide, in Q1 of this year, we voluntarily reported our ASP for Affinity, and ***we're very pleased to receive a published ASP for Q3***." Gillheeney assured the market that "we are confident that the national published rate will be reinstated on January 1, 2022, and contrary to some speculation in the market, Affinity continues to be covered and reimbursed by [all MACs] in the fourth quarter."

213. Analysts credited Gillheeney's reassurances about Affinity and took comfort in the continued strength of PuraPly sales. In a report on November 9, 2021, BTIG analysts noted that "PuraPly continued to outperform" in 3Q2021. BTIG also dismissed concerns about "slower Amniotic growth" and described the changes in Affinity's reimbursement as "blips":

> All told, while ORGO expects some blips on Affinity sales in 4Q (as MACs await benefit verification in early 4Q following the CMS omission), it does not appear to be as impactful as investors may fear. Bears will point to the slower Amniotic growth as indicative for slowing utilization in the face of the CMS-related issues, but we think this conflates what has been a tougher macro environment with a completely separate dynamic.

214. In a report on November 10, 2021, Oppenheimer analysts attributed Affinity's lower sales in 3Q2021 to "the tougher macro environment in 3Q owing to both COVID case increases and staffing shortages." On November 10, 2021, Credit Suisse analysts echoed a similarly optimistic outlook for Organogenesis, reporting that:

> Upside in the quarter was led by PuraPly (+$14MM), offset by a shortfall in Affinity related to a filing error related to the shift of reimbursement from a local to national coverage model during Q3. Importantly, after several weeks of questions and confusion about the addition and subsequent removal of Affinity from the Medicare price list, mgmt expects the product to be returned to the list as of Jan 1. Once the price is reestablished, the company will return to its efforts to expand the adoption and penetration of the

product nationwide. In the meantime, Affinity remains reimbursed on a local level, and is expected to grow both sequentially and Y/Y in Q4.

3. Sales of Affinity Appear To Rebound, And Defendants Tout The Continued Success Of The Company's Growth Strategy

215. On March 1, 2022, Organogenesis reported its 4Q2021 and FY 2021 financial results. Organogenesis reported total net revenue of $128.6 million for 4Q2021 and total net revenue of $468.1 million for the year ended December 31, 2021, representing year-over-year increases of 38% and 45% on an adjusted basis, respectively. Additionally, Organogenesis reported net revenue from the sale of PuraPly products of $62.6 million for 4Q2021, an increase of 38% year-over-year, and net revenue from the sale of non-PuraPly products of $66.0 million, an increase of 7% year-over year.

216. During the 4Q2021 earnings call on March 1, 2022, Gillheeney stated that the Company's performance in 4Q2021 and FY 2021 "***reflect[ed] the continuation of the key drivers of our growth strategy and competitive advantages***," and touted the Company's "significant investments to grow our team of direct sales representatives" and "***comprehensive portfolio of products***" as being responsible for the Company's "***impressive growth in recent years***." Gillheeney also claimed that PuraPly XT was experiencing "strong demand" and that Affinity had "strong net revenue growth":

> ***PuraPly is back with proven clinical outcomes is highly efficacious in the early stages of wound healing and therefore, remains a key component to the healing algorithm from our clinicians and patients***.
>
> We've strategically expanded the [PuraPly] brand since we launched the product in 2015, bringing new products and line extensions to address varying wound attributes across size, depth and complexity. ***These new products and line extensions have enabled access to multiple sites of care and physician specialties and continue to drive strong demand for the brand. Our portfolio of highly differentiated amniotic products continues to experience strong net revenue growth with sales increasing 15% year over year in Q4 and up 38% on an adjusted basis, which exceeded our expectations***.

217. In response to a question about the performance of Organogenesis's amniotic products, Gillheeney stated:

> On the amniotic side, they did do well. They performed -- exceeded our expectations. ***We did see a slight decline as expected in the first month and then started to grow as expected and actually better than expected***. ***So we put a lot of time and focus on the amniotic portfolio in Q4, and it helped in exceeding our expectations***.

218. Defendants' statements assuaged investor concerns about changes in the reimbursement for Affinity and slowing growth in Affinity sales. Following Defendants' statements during the Company's 4Q2021 earnings call, Organogenesis's stock price increased ***21%***, from a closing price of $7.24 on March 1, 2022 to a closing price of $8.79 on March 2, 2022.

219. Analysts also credited Defendants' statements, agreeing that concerns regarding Affinity's reimbursement were misplaced and projecting a return to double-digit sales growth for Affinity. SVB Leerink reported on March 1, 2022 that Organogenesis's "**reimbursement noise [is] seemingly behind us** . . . **we hope that investors will increasingly shift focus to the positive underlying growth drivers of the business, which we believe will return the company to a sustainable double-digit sales growth trajectory**. . . . **These growth drivers include the amnion portfolio (i.e., Affinity)** . . . **which widen[s] ORGO'S competitive moat and successfully position[s] the company for sustained above-market growth**." (Emphasis in original). On March 2, 2022, Credit Suisse similarly stated that "concerns over Affinity reimbursement [are] fading as the product was returned to the Medicare price list." Credit Suisse expected "more normalized growth and [sic] in Q2 and beyond . . . we believe the differentiated product is positioned to be a significant growth driver in 2H22 and 2023."

220. On March 2, 2022, Oppenheimer analysts stated that they, too, expected Organogenesis's amniotic sales to ramp with the "[f]ull launch of Affinity initiated in 1Q now with the product back on CMS's ASP list." Similarly, on March 1, 2022, BTIG reported that

"[f]ollowing CMS' updated January-quarter pricing which included Affinity . . . Affinity has retained its premium relative to peers and we think that the publication assuages concerns around Affinity reimbursement LT. Amniotics grew 15% Y/Y or grew an adj. 38% Y/Y, and mgmt. sees Affinity as a LT growth opportunity with CMS pricing in place now."

4. The ASP For Affinity Put An End To Affinity's Rapid Sales Growth

221. Unbeknownst to investors, Affinity's return to Medicare's ASP list would not lead to sustained revenue growth, let alone "double-digit sales growth." As Defendants knew, the favorable reimbursement that had driven Affinity's growth since 2020 had come to an end. As reflected in the 1Q2022 marketing spreadsheet produced by FE-10, Affinity's ASP price of $535.602 per square centimeter for 1Q2022 meant that physicians stood to ***lose*** $150.63 per application of Affinity:

Office Setting Payment Q1 2022 - NON GPO Volume							
	Products	Size	Unit Size	Rate Per Cm2	~Product Payment	Office MUE	
Q4101	Apligraf	44	44	30.442	$1,339.45	88	
Q4106	Dermagraft	38	38	31.971	$1,214.90	76	
Q4160	NuShield	3.2x3.2	11	95.943	$1,055.37	36	
		4x4	16	95.943	$1,535.09	36	
		4x6	24	95.943	$2,302.63	36	
		6x6	36	95.943	$3,453.95	36	
Q4196	Puraply AM	3.02X3.02	10	110.645	$1,106.45	54	
		3.76x3.76	15	110.645	$1,659.68	54	
Q4197	PuraPly XT	4.91x4.91	25	265.000	$6,625.00	54	** Unpublished. Use on Medicare Only
		6x9	54	265.000	$14,310.00	54	
Q4159	Affinity	2.5x2.5	7	535.602	$3,749.21	28	
Q4194	NovaChor	1.5x2.75	5	1060.000	$5,300.00	28	**Unpublished. Use on Medicare Only
CPT 15275 Face, Scalp, Feet			$150.00				
	Products	Size	Product Cost	~Product Payment	~After Cost @100%	~After Cost @80%	
Q4101	Apligraf	44	$1,295.00	$1,339.45	$44.45	($223.44)	
Q4106	Dermagraft	38	$900.00	$1,214.90	$314.90	$71.92	
Q4160	NuShield	3.2x3.2 volume	$720.00	$1,055.37	$335.37	$124.30	
		4x4 volume	$1,275.00	$1,535.09	$260.09	($46.93)	
		4x6 volume	$1,800.00	$2,302.63	$502.63	$42.11	
		6x6 volume	$2,700.00	$3,453.95	$753.95	$63.16	
Q4196	Puraply AM	3.02X3.02 volume	$800.00	$1,106.45	$306.45	$85.16	
		3.76x3.76 volume	$1,200.00	$1,659.68	$459.68	$127.74	
Q4197	PuraPly XT	4.91x4.91	$4,250.00	$6,625.00	$2,375.00	$1,050.00	
		6x9	$8,900.00	$14,310.00	$5,410.00	$2,548.00	
Q4159	Affinity	2.5x2.5	$3,150.00	$3,749.21	$599.21	($150.63)	
Q4194	NovaChor	1.5x2.75	$3,800.00	$5,300.00	$1,500.00	$440.00	**Unpublished. Use on MEDICARE ONLY.

222. As shown in the above spreadsheet, the Product Cost for a 2.5 x 2.5 centimeter application of Affinity in 1Q2022 was $3,150. Based on the ASP of $535.602 per square centimeter (rounded up to 7 one-square-centimeter units), Medicare reimbursed physicians only $3,749.21 for each application, yielding an After Cost amount of only $599.21 assuming 100% reimbursement, and ***negative $150.63*** assuming 80% reimbursement. Therefore, unlike in prior quarters—when physicians could make as much as $3,800 per application of Affinity based on the invoice-based reimbursement from certain MACs—Organogenesis was no longer able to market the spread for Affinity. As investors would soon learn, the Company's loss of this unfair competitive edge for Affinity would lead to a dramatic decline in Affinity sales.

223. In fact, Organogenesis was only able to report modest sales growth for non-PuraPly products in 4Q2021 because Affinity was not included on the ASP list for this quarter due to a purported "filing error." As discussed below, as soon as Affinity's ASP was reinstated in 1Q2022, Organogenesis immediately began reporting substantial year-over-year declines in Affinity sales.

224. By contrast, as seen in the 1Q2022 marketing spreadsheet reproduced above, PuraPly XT continued to benefit from the lack of an ASP, with physicians able to profit as much as $5,410 per application. Accordingly, as discussed above, Organogenesis's sales force continued to market the reimbursement spread for PuraPly XT through the end of the Class Period. As a result, the Company's inflated PuraPly revenues partially offset the decline in Affinity revenues, and allowed Defendants to conceal their fraud for an additional quarter.

5. As Affinity Sales Begin To Decline, Defendants Seek To Prop Up The Company's Stock Price

225. On May 10, 2022, Organogenesis reported its financial results for 1Q2022, including total net revenues of $98.1 million, an increase of 1% year-over-year on an adjusted

basis.[11] Organogenesis reported net revenue from AWC products of $91.0 million, an increase of 0.3% year-over-year, and net revenue from PuraPly products of $53.3 million, an increase of 29% year-over-year. Notably, however, Organogenesis reported net revenue from non-PuraPly products of only $44.8 million, a ***decrease of 27%*** year-over-year.

226. Despite the reported decline in non-PuraPly revenue, Defendants did not disclose to investors that the ASP for Affinity prevented the Company from inflating Affinity revenues through its aggressive marketing of the reimbursement spread. Nor did Defendants disclose that the Company's seemingly sustained growth in PuraPly revenues was the result of PuraPly XT continuing to benefit from the lack of an ASP, allowing the Company to continue to market the reimbursement spread for that product. Instead, in the 1Q2022 press release, Gillheeney falsely attributed the Company's declining non-PuraPly revenues to "***near-term operating environment challenges***."

227. During the 1Q2022 earnings call on May 10, 2022, Gillheeney clarified that the reported 27% decline in non-PuraPly revenues was actually a decrease of 32% year-over-year, or a decrease of 22% on an adjusted basis. Gillheeney attributed the decline in sales of Organogenesis's amniotic products to "***the impact of Omicron on our national launch of Affinity***," i.e., the relaunch of Affinity following CMS's setting of an ASP on January 1, 2022. Gillheeney reiterated that the amniotic portfolio was positioned for success in 2022, representing that "[w]e continue to expect our portfolio of highly differentiated amniotic products to be the largest contributor to our company's net revenue growth for fiscal year 2022 and the midpoint of

[11] Organogenesis ceased commercial distribution of ReNu and NuCel on May 31, 2021 due to the end of an FDA enforcement grace period affecting the products. Organogenesis's report revenue for 1Q2022 was adjusted to account for the exclusion of net revenue of ReNu and NuCel.

our full year revenue range continues to assume amniotic growth of approximately 12% year-over-year in 2022."

228. During the Q&A portion of the 1Q2022 earnings call, in response to an analyst question, Gillheeney reiterated that the performance of Organogenesis's amniotic products, in particular Affinity, was "as expected" and that the decline in revenues was the result of disruptions due to the Omicron variant of COVID-19:

> [Analyst:] Congrats on a solid start to the year. Just a quick question on the amniotic product line and Affinity specifically. Came in a little bit below what we were thinking. I guess, number one, maybe we mismodeled it a little bit here. But any incremental color you can give on what you saw exiting the quarter and sort of how that's trended so far in April as it relates to that product line? And then secondarily, what gives you the confidence that that's going to be the primary growth contributor to the 2022 guidance? And then I have one follow-up.
>
> [Gillheeney:] Sure. So this is Gary. ***So Q1 was -- for Affinity was as expected for us with the national launch***. ***We had to relaunch the product again in Q1 so you have a rate change. We also had the issues as we discussed that everybody had with Omicron. So it was a slow start for sure. The trends that we're seeing now are very positive. We're adding new accounts in multiple sites of care for the product and the sales trends over the last 4 to 5 weeks have actually been quite strong***. So we feel that the rest of the year with the national launch and with the second half of the year, the operating environment improving, that we'll be able to continue to expand the usage of the product across the country.

229. Market analysts remained positive after the 1Q2022 earnings call despite the downturn in Affinity net revenue for the quarter. In reiterating their "Outperform" rating on May 11, 2022, Credit Suisse reported that they now "expect concerns over Affinity reimbursement and growth potential fading as the product returns to more normalized growth trends in Q2 and 2H22" and "continue to expect Affinity to remain a significant growth driver in 2H22 and 2023." On May 11, 2022, Oppenheimer analysts also reported that, despite the 32% year-over-year decline in amniotic revenue, which management attributed to "an expected slow start due to COVID-related headwinds," management noted "solid positive recent trends . . . and reiterated '22 amniotic growth guidance of ~12% at the mid-point."

6. Defendant Gillheeney Sells $7.2 Million In Organogenesis Stock Just Before Investors Learn The Truth About Affinity's Declining Sales

230. Immediately after assuring investors that the decline in Affinity sales was the result of COVID-related disruptions, Defendant Gillheeney sold an additional ***$7.2 million*** of Organogenesis common stock. In a series of transactions between May 13, 2022 and June 3, 2022, Gillheeney sold a total of ***1,250,000*** shares for total proceeds of ***$7,214,769 million***. Significantly, Gillheeney's May and June 2022 stock sales were nearly double all of his prior sales of Organogenesis shares, including Gillheeney's February and July 2021 stock sales discussed above. Although Defendant Gillheeney's May and June 2022 transactions were conducted pursuant to a Rule 10b5-1 trading plan, Defendant Gillheeney entered into this plan in March 2022. At this time, Gillheeney knew that the ASP that CMS set for Affinity in January 2022 would soon cause Affinity sales to plummet, since it prevented the Company from marketing the reimbursement spread as it had done for the preceding two years. Once again, to execute his insider sales in May and June 2022, Gillheeney exercised stock options that were at no risk of expiration—the majority were not set to expire until August 21, 2024 and December 8, 2024, with a small minority (14,810 shares) set to expire on July 25, 2023.

7. Defendants Admit That Affinity Sales Have Declined As A Result Of Its Lower ASP-Based Reimbursement

231. On August 9, 2022, Organogenesis reported its financial results for 2Q2022, including total net revenue of $121.4 million, an increase of 3% year-over-year on an adjusted basis, and net revenue from the sale of PuraPly products of $69.4 million, an increase of 84% year-over-year. However, Organogenesis reported a continued decline of net revenues from the sale of non-PuraPly products of ***39%*** year-over-year.

232. During the 2Q2022 earnings call on August 9, 2022, Gillheeney disclosed that the reported decline in non-PuraPly revenue was the result of "softer than expected" amniotic sales

amounting to a ***46% decline*** year-over-year. Gillheeney explained that the performance of the Company's amniotic products in 2Q2022 "reflected the impact of a more challenging environment." As a result of the decline in amniotic product sales, Defendant Francisco announced revised FY 2022 amniotic net revenue guidance that projected a ***15% decline*** year-over-year, a dramatic revision compared to the previously announced 12% growth.

233. During the Q&A portion of the 2Q2022 earnings call, Gillheeney admitted that, contrary to Defendants' prior statements to the market, Organogenesis could not compete based solely on the clinical benefits of its products. Gillheeney acknowledged that, unlike some competing products, Affinity's sales had been limited by the Company's inability to market the product based on invoice-based reimbursement. In response to a question from an analyst regarding the "amniotic competition," Gillheeney stated:

> So what we've seen is more of the smaller players in the space that mostly amniotic products, and those products are competing with our products, competing for share of voice and we just see a lot more of them. ***I think the transient component of it is with no published ASPs, that competition can continue in the -- particularly in the office***. So we think over time, those smaller players will not be as competitive going forward.

234. In other words, Gillheeney acknowledged that Organogenesis's competitors—whose products did not yet have an ASP—were taking market share away from the Company given their ability to market their products based on more favorable reimbursement.

235. On this news, Organogenesis's stock price fell $1.20 per share, or ***20%***, from a closing price of $6.01 per share on August 9, 2022, to a closing price of $4.81 per share on August 10, 2022, on heavy trading volume.

236. Analysts were quick to lower their expectations of Organogenesis's revenue growth in light of the Company's disclosures in its 2Q2022 earnings report. On August 9, 2022, BTIG analysts lowered their price target from $14 to $13. In support of this change, BTIG highlighted the impact of competition from companies whose products did not have an ASP, stating:

> [C]ompetition in the Advanced Wound market is capitalizing on a lack of formalized pricing for its own products which, as a result, provides MDs with an economic incentive (shifting usage away from ORGO). Mgmt. believes this dynamic will be transitory (and unsustainable), which we agree, but nonetheless will pressure ORGO's Amniotic sales in 3Q22 and to a lesser extent in 4Q22.

237. Significantly, as detailed above in Section IV.H, BTIG's description of the "economic incentive" for physicians to choose competing products based on "a lack of formalized pricing" as "***transitory***" and "***unsustainable***," precisely describes Organogenesis's unsustainable revenue growth from Affinity and PuraPly XT during the Class Period.

238. On August 10, 2022, Oppenheimer analysts downgraded Organogenesis stock from "Outperform" to "Perform" and removed their $14 price target, replacing it with "NA." Oppenheimer concluded that while "ORGO did deliver in-line 2Q with PuraPly coming in meaningfully ahead of guidance . . . with ORGO's amniotic portfolio a key piece to our thesis, we step to the sidelines as we look for better visibility on the new competitive dynamics."

239. In the wake of the Company's disclosures in the 2Q2022 earnings release, Organogenesis's stock price has continued its decline, closing below $4 per share on August 26, 2022, and remains below $4 per share as of this writing.

V. DEFENDANTS' MATERIALLY FALSE OR MISLEADING STATEMENTS AND OMISSIONS OF MATERIAL FACT

240. During the Class Period, Defendants made a series of materially false or misleading statements and omissions of material fact in Organogenesis's press releases, earnings calls with investors, and the Company's SEC filings.[12] In connection with Defendants' false or misleading statements and omissions, Defendants misrepresented or omitted material information concerning:

[12] During the Class Period, Organogenesis filed amendments to the 2020 10-K and 2021 10-K because the Company did not file a proxy statement within 120 days of the end of its fiscal year. The amendments did "not amend, update or change any other items or disclosures" in either the 2020 10-K or 2021 10-K.

(i) Organogenesis's practice of marketing the reimbursement spread for Affinity and PuraPly XT and the impact that this unsustainable practice had on the Company's reported revenue; (ii) the factors contributing to the Company's sales growth and apparent ability to offset the loss of revenue from the expiration of PuraPly's pass-through status; (iii) the impact that changes in reimbursement for Affinity had on the Company's ability to generate sustainable sales growth; (iv) the Company's compliance with healthcare laws and regulations intended to prevent fraud, waste, and other abusive practices; and (v) Organogenesis's ability to compete on the basis of the clinical benefits of its products, as opposed to the reimbursement physicians received for using the Company's products.

A. August 10, 2020: 2Q2020 Earnings Report And 10-Q

241. On August 10, 2020, Organogenesis issued a press release reporting the Company's 2Q2020 net revenue results that Defendants described as "well ahead of expectations." The press release quoted Gillheeney as stating:

> Our second quarter results reflect the dedication of our employees to the patients we serve and strong execution against our commercial strategy while adapting to the challenges of the pandemic. ***During the second quarter, we grew our customer base, drove customer and clinician adoption deeper into existing accounts and leveraged the strong demand for our PuraPly and amnion products, particularly in the office channel***.

242. During the August 10, 2020 earnings call, in response to an analyst question, Gillheeney elaborated on the Company's performance in 2Q2020, including the factors that purportedly drove the Company's reported revenue growth:

> [Analyst:] And I'm just curious, beyond Affinity, anything else in the portfolio that surprised you positively or negatively, in particular, during the quarter . . . ?
>
> [Gillheeney:] ***The launching of 2 products, we launched PuraPly XT and Affinity in the midst of a crisis and both have exceeded our expectations. Affinity is already beyond the run rate that we exited in 2018 in a very short period of time***. . . . ***[T]he office space business grew even faster than we thought and launching 2 new products in the middle of all of this went very well***.

243. Gillheeney had the following exchange with an analyst regarding the growth of Affinity and PuraPly XT and the products' performance relative to competing products:

> [Analyst:] One was the sort of the strength in amnion and what you can say maybe about your supply levels, the trajectory of that growth in the quarter and maybe how it differed across sites of care. And I don't want to stress this too much, but there's competitive landscape, if it's changing, if you anticipate it changing. One of your old friends is getting refunded and recapitalized and expect, I guess, to be back out in the market and how we should think about that. . . .
>
> [Gillheeney:] Regarding our amnions, ***I think what's important is we relaunched Affinity, which certainly had a significant impact on the quarter, the product selling extremely well, and also our strategy of diversifying our sites of care and our offerings in those sites of care***. So as we focused on the office, that allowed us to continue to sell not only just our amnions, but also our other products that are designed for that site of care. So we're pretty excited about how our amnions are performing, excited about the relaunch of Affinity. . . . ***On the competitive landscape, we really haven't seen much of a change yet, though other competitors are certainly stepping back in. Affinity is the only fresh amniotic product in the space.*** We're pretty excited about that. ***PuraPly is still a very strong product, particularly in the office, in outpatient setting. So we're pretty excited and pretty confident that our portfolio will withstand anything that we see in the competitive environment today***.

244. In response to an analyst question regarding the revenue impact of PuraPly XT's recent launch and the ability of PuraPly XT sales to offset the revenue loss from the expiration of PuraPly's pass-through status, Gillheeney stated:

> [Analyst:] And I guess just to clarify, Gary, your comment on XT, recently launched. Is that effect, I guess, on the potential growth or decline in PuraPly still sort of uncertain? Or what are your assumptions in terms of the success of that product?
>
> [Gillheeney:] Right now, we're very confident in the product. ***It's selling extremely well. We thoughtfully launched it in only certain regions of the country, and it's performing above our expectations at this point. So we think it will be a strong contributor to help offset any ASP impact on the larger sizes that we have that are impacted by pass-through***.

245. Gillheeney had the following exchange with an analyst regarding Affinity utilization and growth in Affinity sales:

> [Analyst:] And with respect to Affinity accounts and utilization relative to maybe what your expectations would have been for the relaunch of this, who's using it and where and

> is this existing customers? Or what's the mix of the customer base for that product in particular . . . ?
>
> [Gillheeney:] ***It's primarily in the office right now. So we've strategically launched it in certain areas of the country in the office only, and we have historical users of the product. As you know, we -- the product was sold in 2018, but we've been able to add additional customers at a very rapid rate. So the product is selling extremely well. It's exceeded our expectations at this point in time, and we'll continue to expand the office offering as capacity expands.***

246. In response to a question regarding drivers of AWC growth, Gillheeney stated:

> [Analyst:] The May, June growth was very impressive. You mentioned, Gary, that you didn't see the growth being driven by backlog. Looking forward, do you see deferred procedures, say, from that late March and April time frame, therefore being an incremental tailwind still to come and potential upside driver?
>
> [Gillheeney:] We do more on the Surgical & Sports Medicine side, but we do see that as a potential tailwind for us in the end of Q3 and more so in Q4. More -- we don't see a lot of backlog in the Advanced Wound Care side because many of those wounds, I think, moved to the office because we're seeing a significant growth in the office. ***We are clearly taking share in the office***, but I believe a lot of those wounds are wounds that would have been treated in an Advanced Wound Care outpatient center are being treated in the office. So I think we've absorbed some of that. There should be some, but not significant on the Advanced Wound Care side, in my opinion.

247. The statements identified in ¶¶ 241-46 above were materially false or misleading when made. Defendants' statements regarding the successful launch of PuraPly XT and Affinity, including Gillheeney's statements touting "***the strong demand for our PuraPly and amnion products, particularly in the office channel***," falsely attributed the growth in Affinity and PuraPly XT sales to factors other than Defendants' marketing of the reimbursement spread. Defendants failed to disclose that: (i) the demand for Affinity and PuraPly XT was being engineered by a concerted scheme by Defendants to incentivize physicians to purchase Affinity and PuraPly XT based on the spread between the cost Organogenesis charged for these products and the amount physicians were reimbursed by certain regional MACs, who did not require physicians to submit invoices reflecting what Organogenesis actually charged for these products; and (ii) the rapid increase in Affinity and PuraPly XT sales in the physician office channel had been driven by the

Company's marketing of this temporary reimbursement spread using Company-supplied marketing materials ("Medicare Reimbursement Scheme").

248. Gillheeney's statements that Organogenesis had "***thoughtfully launched***" and "***strategically launched***" Affinity and PuraPly XT in certain regions were also materially false or misleading when made because Defendants failed to disclose that Organogenesis focused its illicit marketing efforts for Affinity and PuraPly XT in the physician office channel in areas where the regional MAC reimbursement rates were highest, and where the MACs did not require physicians to submit physical invoices from the Company. For the reasons stated above, Defendants' Medicare Reimbursement Scheme was unsustainable because the invoice-based reimbursement rates by these MACs were temporary and could only persist until a national ASP was set, which would prevent these MACs from reimbursing physicians at inflated reimbursement rates.

249. Gillheeney's statements that the Company had been able to offset the loss of revenue from the expiration of PuraPly's pass-through status through increased sales of Affinity and PuraPly XT were also materially false or misleading when made because the Medicare Reimbursement Scheme driving demand for Affinity and PuraPly XT in the office channel and, in turn, the revenue growth of Affinity and PuraPly XT, was unsustainable. Defendants failed to disclose that once these products had an established ASP, demand for these products would diminish and revenue for these products would decrease or grow at a much slower rate, since physicians would no longer have the lucrative incentive to prescribe Organogenesis's products over its competitors.

250. Gillheeney's statements that the Company was "***clearly taking share in the office***" and could "***withstand anything that we see in the competitive environment today***" were materially false or misleading when made for the additional reason that Defendants failed to disclose that

Organogenesis had a temporary competitive edge that was dependent on its Medicare Reimbursement Scheme. Defendants failed to disclose that once Affinity and PuraPly XT had an established ASP, the products were vulnerable to competition from products without established ASPs or which were available at a lower cost—precisely what Defendants admitted caused the dramatic decline in Affinity sales at the end of the Class Period when Affinity received an ASP.

251. On August 10, 2020, Organogenesis filed a 10-Q. In the Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") section of the 2Q2020 10-Q, Defendants stated:

> ***Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions***.

252. The 2Q2020 10-Q further stated that "***[t]he increase in Advanced Wound Care net revenue [in the six months ended June 30, 2020] was primarily attributable to the expanded sales force and increased sales to existing and new customers***" and "***[t]he increase in PuraPly revenue in the current six-month period was due to the expanded sales forces and increased sales to existing and new customers***."

253. Defendants' discussion of the factors affecting the Company's reported revenue in in the 2Q2020 10-Q and the purported reasons for the reported increases in AWC revenue and PuraPly revenue during the quarter was materially false or misleading for the reasons stated above in ¶¶ 247-50.

B. September 16, 2020 Morgan Stanley Global Healthcare Conference (Virtual)

254. Defendant Gillheeney presented at the September 16, 2020, Morgan Stanley Global Healthcare Conference (Virtual). During Gillheeney's presentation, he stated:

> From a risk perspective, the thing you always worry about is reimbursement. ***So one of the reasons we've moved into the office and really put a major emphasis on the office-***

based setting is it's a different reimbursement model than the outpatient model. So it not only diversifies the revenue risk, it diversifies the reimbursement risk, and it's also a very, very large market. So in this space, it's reimbursement that you typically will focus on and want to make sure that your products are well positioned and well reimbursed.

255. In response to a question regarding reimbursement, and how the Company was offsetting the loss of revenue from the expiration of PuraPly's pass-through status, Gillheeney stated:

> [Morgan Stanley:] Talking about reimbursement, it would probably be helpful for the listeners on the call here to understand what the changes are expected for PuraPly later this year are. Could you briefly describe what impact on revenue you expect the change to have? And what actions the team has taken to minimize this impact . . . ?
>
> [Gillheeney:] Those products [PuraPly] are today priced above the bundle and are reimbursed above the bundle, they will not be reimbursed above the bundle. So those products will have to be priced under the bundle. So you will have some ASP loss related to those products.
>
> ***However, the offsets that we've been working on, as I mentioned, first of all, is the office.*** So we now have a unique PuraPly offering in the office, unique sizes that address the wounds that are actually seen in the office. Reimbursement is strong for the product in the office. ***We have line extensions, the PuraPly XT that I mentioned, which is doing extremely well.*** We'll also have different sizes that will fit under the bundle price that will be scalable to handle the larger wounds, that the bigger pieces that were priced above the bundle addressed, so we won't lose the wounds. ***So we have significant offsets for the ASP loss***. . . .
>
> ***So PuraPly itself will do pretty well with the offsets that I mentioned in the office and XT. And then our other product portfolio, including Affinity and the rest of our portfolio, will absorb any ASP decline in Q4***.

256. With respect to the Company's compliance program, Gillheeney stated:

> ***The other point that I think I would like to just leave everyone with is we are a very compliant company, and we are the gold standard of compliance, and that's not my opinion. That's what I hear back from the financial community when they do diligence on our company and that's just -- that's who we are. We think it's the right way to do business. We think our customers feel that, that's important. And particularly, as some of our competitors have stumbled, we have stood out, and that brand is now paying dividends for us as folks look to us for solving their wound care problems and making sure that we're conducting ourselves and conducting business in their clinics in a very compliant way. It's important in this space***.

257. The statements identified in ¶¶ 254-56 above were materially false or misleading when made. Defendant Gillheeney's statements regarding the Company's "***major emphasis on the office-based setting***," the "***different reimbursement model***" in physician offices, and the Company's "***focus***" that its products were "***well reimbursed***" in physician offices were materially false or misleading for the reasons discussed in ¶¶ 247-48. Defendants failed to disclose that sales of Affinity and PuraPly XT in the physician office channel were being driven by the Company's Medicare Reimbursement Scheme.

258. Gillheeney's statements that one of the reasons they "***put a major emphasis on the office-based setting***" is that it "***diversifies the revenue risk, it diversifies the reimbursement risk, and it's also a very, very large market***," was materially false or misleading when made because of the reasons discussed in ¶¶ 247-48, 250. Additionally, Defendants failed to disclose that the Medicare Reimbursement Scheme, which was at the core of Organogenesis's shift to the office-based setting, actually increased revenue and reimbursement risk and made Organogenesis's revenues susceptible to the risk of material declines once CMS set an ASP.

259. Gillheeney's statements regarding the "***offsets***" to the loss of revenue from the expiration of PuraPly's pass-through status, including that PuraPly XT and Affinity "***will absorb any ASP decline in Q4***" were materially false or misleading for the reasons discussed in ¶¶ 247, 249. In order to offset the loss of PuraPly pass-through status, Organogenesis was relying on inflated revenues from the Company's Medicare Reimbursement Scheme with respect to Affinity and PuraPly XT.

260. Gillheeney's statements that Organogenesis was "***a very compliant company, and we are the gold standard of compliance, and that's not my opinion***," were materially false or misleading for the reasons discussed in ¶ 247. Defendants' statements were additionally false or

misleading because the Company was knowingly violating numerous healthcare laws and regulations through its Medicare Reimbursement Scheme, which included encouraging physicians to submit inflated invoices seeking reimbursement for amounts higher than the cost charged by Organogenesis, providing Organogenesis's sales representatives with Company-supplied marketing materials to sell Affinity and PuraPly XT based on the reimbursement spread, and retaliating against employees who reported concerns about these practices. Defendants also engineered the sizing of the Company's products in order to maximize reimbursement profits for physicians, and provided kickbacks in the form of reimbursement guarantees to induce physicians to use the Company's products.

C. November 9, 2020: 3Q2020 Earnings Report And 10-Q

261. On November 9, 2020, Organogenesis issued a press release reporting a 57% increase year-over-year for its total net revenues for 3Q2020. The press release quoted Gillheeney as stating:

> ***During the third quarter, we grew our customer base, drove customer and clinician adoption deeper into existing accounts and leveraged the strong demand for our PuraPly and amniotic products, particularly in the office channel***. The strong execution against our commercial strategy during the third quarter drove not only strong revenue growth, but also, significant improvement in our profitability as well.

262. During Organogenesis's November 9, 2020 3Q2020 earnings call, Gillheeney stated the following with respect to the Company's growth in 3Q2020:

> ***Our growth in Q3 reflects a continuation of the key drivers of our growth strategy and competitive advantages that we've been talking about on each of our earnings calls this year - the investments we've made to expand our sales force in recent years, the benefits of our comprehensive and differentiated portfolio of products that address patients' needs to treat wounds across all the stages of healing, and strong execution of our commercial strategy focused on leveraging multiple channels, new product introductions and brand loyalty***.
>
> We were pleased to see the overall environment improve during the third quarter, and ***we reported a 66% increase in total Advanced Wound Care sales year-over-year, driven by our strong performance in the office channel. And we've talked about our strategic***

focus in the office channel on prior calls, and the growth we reported in sales in our Advanced Wound Care products this quarter are a direct result of the continued strong execution of our commercial strategy in the office, which started over 18 months ago.

This third quarter Advanced Wound Care sales growth was driven by strong demand not only from our existing customers, but also strong contributions from adding new customers in the office channel during the period.

263. With respect to the purported drivers of Affinity sales, Gillheeney stated:

And while our broad portfolio of products and solutions remain a key differentiator for us, ***the demand for our amniotic products from our Advanced Wound Care customers has been notable throughout 2020***.

Our fresh amniotic membrane product, Affinity, was the largest contributor to growth again in Q3, driven by the differentiated features of the product that our clinical customers value and positive reimbursement in the office channel.

264. Regarding the purported drivers of PuraPly sales, Gillheeney stated:

We were also very encouraged by the performance of our PuraPly franchise, where sales increased 29% year-over-year in the third quarter. ***Clinicians continue to value the product's clinical value, and we continue to see growth in the number of accounts that are utilizing PuraPly, aided in part by the introduction of new sizes and the introduction of our XT line extension, which is selling extremely well.***

265. Gillheeney summarized the drivers of the Company's performance in 3Q2020 as follows:

Simply stated, we believe our operating and financial performance is a direct result of the strong execution of our growth and profitability strategy and the dedication of our employees to our customers and the patients they serve.

266. In response to a question regarding the Company's ability to offset the loss of revenue from PuraPly's pass-through status expiration, Gillheeney stated:

[Analyst:] You spoke about PuraPly trends in the quarter. I was just wondering if you could kind of help us learn what you've seen in the past couple of weeks with the pass-through having expired and how that expiration of pass-through is impacting your larger product sizes thus far. . . .

[Gillheeney:] [W]e didn't see the decline in PuraPly revenue in Q3 that we had seen in the past where, just 6 to 7 weeks prior to the expiration of pass-through, we would see a decline. ***We did not see that decline. So that was important and encouraging. We did introduce some new sizes of PuraPly, and we've also accelerated our office growth***

> ***strategy with PuraPly. So both of those are doing well. The office strategy sales of PuraPly doing well. Our XT line extension in the office is doing extremely well.*** And the new sizes that we're introducing under the bundle to absorb some of those larger wounds are also doing well. ***So those are the positive trends that Henry had alluded to.***

267. In response to a question regarding the market demand for Affinity, Gillheeney stated:

> [Analyst:] Gary, just wanted to touch base on Affinity. Just given the extraordinary growth you're seeing in Advanced Wound Care, and Amnion in particular, any color you can provide on how much of what we're seeing in the near term has been sort of pent-up demand prior to being able to sort of relaunch in the first half of this year versus some of the expansion that you talked about with new customers? And what is that runway like that you see expansion into new customers in the office channel . . . ?
>
> [Gillheeney:] So there was some pent-up demand for the product in Q2 because we did have some existing customers back in 2018, but ***the majority of the growth is from our existing customers that had not used [A]ffinity and the expansion of the customer base.***
>
> ***So one of the advantages of our amniotic technology is we're really expanding the market, and we're doing that with our Amnion.***

268. The statements identified in ¶¶ 261-67 above were materially false or misleading when made. Defendant Gillheeney's statements touting "***the strong demand for our PuraPly and amnion products, particularly in the office channel***" and the Company's reported revenue growth in 3Q2020, and attributing the increased sales of Affinity and PuraPly XT to factors other than Defendants' Medicare Reimbursement Scheme, were materially false or misleading for the reasons discussed in ¶ 247. Contrary to Gillheeney's statements, demand for Affinity was not "***driven by the differentiated features of the product***," nor was demand for PuraPly XT due to "***the product's clinical value***." Rather, sales of these products were being inflated by the Company's Medicare Reimbursement Scheme.

269. Gillheeney's statements touting the success of the Company's "***office strategy***" to offset the loss of PuraPly pass-through revenue, including that Organogenesis had "***accelerated our office growth strategy***" with respect to PuraPly XT and was "***really expanding the market***"

through its sales of Affinity in the office channel, were materially false or misleading for the reasons discussed in ¶¶ 247-48. Defendants failed to disclose that the Company's office strategy depended on its Medicare Reimbursement Scheme to induce physicians to purchase Affinity and PuraPly XT.

270. Organogenesis filed a 10-Q on November 9, 2020. In the MD&A section of the 3Q2020 10-Q, Defendants stated:

> ***Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.***

271. The 3Q2020 10-Q further stated that "***[t]he increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product***" and that "***[t]he increase in PuraPly revenue in the three and nine month periods was due to the expanded sales forces and increased sales to existing and new customers***."

272. The statements identified above in ¶¶ 270-71 were materially false or misleading when made for the reasons discussed above in ¶¶ 247-50.

D. March 16, 2021: 4Q2020 Earnings Report And 2020 10-K

273. On March 16, 2021, Organogenesis issued a press release reporting net revenues "well ahead" of the Company's guidance for 4Q2020. The press release quoted Gillheeney as stating:

> ***Our Q4 results reflect a continuation of the key drivers of our growth strategy including: the investments we have made to expand our sales force in recent years, the benefits of our comprehensive, and differentiated, portfolio of products that address patients' needs to treat wounds across all stages and our commercial strategy focused on leveraging multiple channels, new product introductions, and brand loyalty.***

274. Organogenesis also attributed the 4Q2020 increase in AWC net revenues to "***primarily . . . to the expanded sales force, increased sales to existing and new customers, and increased adoption of our amniotic product portfolio, including our Affinity product***."

275. During Organogenesis's March 16, 2021 4Q2020 earnings call, Gillheeney again discussed the "***key drivers of our growth strategy and competitive advantages***," and explained "***how each of these longer-term drivers of growth contributed to the strong performance in Q4***." Among these "***drivers of growth***," Gillheeney touted the Company's Affinity sales, stating that ***"[s]ales of our amniotic products were the third area of notable strength in Q4. The sales of amniotic products were the largest contributor to the company's growth again in Q4***." Gillheeney also touted the Company's sales in the physician office setting, stating that "***[o]ur growth strategy in the office is our fourth area of notable strength. It's a continuation of what we've discussed on calls throughout 2020***."

276. With respect to the outperformance of PuraPly revenues, Gillheeney explained that the Company was able to increase PuraPly revenues despite "anticipated pricing headwinds" because "***[w]e've positioned the product differently this time coming off of pass-through***" and "***launched 5 new PuraPly product and line extensions in 2020***," which "***contributed to our ability to drive strong sales performance in the fourth quarter***." Gillheeney stated that this strategy allowed the Company to report a 13% increase in PuraPly revenues even though the Company's guidance had projected PuraPly "sales to decline approximately 50% year-over-year." Gillheeney further attributed the strength of PuraPly revenues to PuraPly XT's purported clinical benefits, stating that "***[c]linicians continue to value this product's differentiation, and we continue to see growth in the number of accounts utilizing PuraPly, aided in part by the strong sales of the 5 new product and line extensions introduced in 2020***."

277. In response to an analyst question regarding demand for Affinity, Gillheeney stated:

> [Analyst:] I wanted to ask on the amnion business. The guidance for 2021 speaks for itself. I'm wondering what you are seeing competitively. How you're feeling relative to competitive efforts. And are we seeing just also a significant expansion, again, in the overall use of amnions in the marketplace, given the strong guide that you talked about today.
>
> [Gillheeney:] Well, we certainly see an expansion of amnion technology. It continues to be the largest growth technology in the skin subspace. We even see that same growth in the auto biologics space in our Surgical & Sports Medicine business. So amnions are clearly expanding the market and growing.
>
> ***Our product, Affinity, is the only living amnion in the space, so it's a bit unique. So from a competitive perspective, we don't see any product out there that's really challenging it from a technology perspective. And the efficacy that we're hearing from the field is very strong for the product as well.*** So we feel really good about that.
>
> I think just generally, you're seeing more activity from some of the competitive companies. And I think that will continue to expand the amniotic space as well.

278. The statements identified in ¶¶ 273-77 above were materially false or misleading when made. Defendant Gillheeney's statements touting the Company's reported revenue growth in 4Q2020, and attributing the Company's increased sales to factors other than Defendants' undisclosed Medicare Reimbursement Scheme to market Affinity and PuraPly XT based on the temporary reimbursement spread, were materially false or misleading for the reasons discussed in ¶¶ 247-48, 250. Contrary to Gillheeney's statements, demand for PuraPly XT was not due to "***[c]linicians continu[ing] to value this product's differentiation***." Rather, sales of PuraPly XT were being inflated by the Company's Medicare Reimbursement Scheme.

279. Gillheeney's statements claiming that Organogenesis "***positioned the [PuraPly] product differently this time coming off of pass-through***" and the launch of "***5 new PuraPly product and line extensions in 2020. . . . contributed to our ability to drive strong sales performance in the fourth quarter***" were materially false or misleading for the reasons discussed in ¶¶ 247, 249. Gillheeney failed to disclose that the Company's strategy to offset the loss in

revenue from the expiration of PuraPly's pass-through status depended, at least in part, on its unsustainable Medicare Reimbursement Scheme.

280. Gillheeney's statements that the clinical benefits of Affinity differentiated it from competing products and insulated the Company from competition were materially false or misleading for the reasons discussed in ¶¶ 247, 250. Defendants failed to disclose that Organogenesis had a temporary competitive edge that was dependent on its Medicare Reimbursement Scheme, and that once Affinity and PuraPly XT had an established ASP, the products were vulnerable to competition from products without established ASPs or which were available at a lower cost.

281. Gillheeney's statements touting the Company's "***growth strategy in the office***" were materially false or misleading for the reasons discussed in ¶¶ 247-48. Defendants failed to disclose that the Company's office strategy depended on its Medicare Reimbursement Scheme to market the spread for Affinity and PuraPly XT to physicians in the office channel.

282. On March 16, 2021, Organogenesis filed its 2020 10-K signed by both Gillheeney and Francisco. In the MD&A section of Organogenesis's 2020 10-K, Defendants stated:

> ***Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions***.

283. The 2020 10-K further stated that "***[t]he increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product***" and that "***[t]he continued increase in PuraPly revenue in the year ended December 31, 2020 was due to the expanded sales forces, expanded product offerings, and increased sales to existing and new customers***."

284. The statements identified above in ¶¶ 282-83 were materially false or misleading when made for the reasons discussed above in ¶¶ 247-50.

E. May 10-11, 2021: 1Q2021 Earnings Report And 10-Q

285. On May 10, 2021, Organogenesis issued a press release reporting another quarter of significant year-over-year net revenue growth for 1Q2021. The press release quoted Gillheeney as stating:

> 2021 is off to strong start. ***We delivered significant year-over-year revenue growth across both our Advanced Wound Care and Surgical and Sports Medicine portfolios driven by strong sales of our amniotic and PuraPly products. We are pleased that successful execution of our PuraPly strategy generated PuraPly sales well ahead of our expectations.*** With continued strong execution against our commercial strategy, we also significantly improved our profitability.

286. During Organogenesis's May 10, 2021 1Q2021 earnings call, Gillheeney attributed Organogenesis's performance to the following factors:

> ***Our better-than-expected growth in Q1 reflects a continuation of the key drivers of our growth strategy, including the benefits of our comprehensive portfolio of products, the investments that we've made to broaden our reach by expanding our sales force and the strong execution of our commercial strategy, focusing on leveraging multiple channels, new product introductions and brand loyalty***.

287. Gillheeney then "provide[d] some color on how each of these longer-term drivers of growth contributed to the strong revenue performance in the first quarter." Gillheeney first highlighted Affinity's clinical benefits as the most prominent of these "***drivers of growth***":

> First, the sale of our amniotic portfolio were the largest contributors to our year-over-year growth in Q1. And while our broad portfolio of products and services remains a key differentiator for us, ***the demand for our amniotic products from our Advanced Wound Care customers was notable throughout 2020. And as expected, these strong demand trends continued in the first quarter of 2021***.
>
> ***We are pleased with the growing awareness of our amniotic portfolio's differentiated features that our customers truly value. Additionally, our efforts to increase the body of clinical evidence, demonstrating the benefits of our amniotic portfolio, continues to pay dividends, not only in terms of increasing clinician awareness but also in supporting our discussions with payers as we look to increase our commercial coverage in the coming years***.

288. Gillheeney next touted the Company's PuraPly revenues, which he again attributed to the Company's ability to market PuraPly's clinical benefits and the "***the product's differentiation***":

> ***And consistent with what we've experienced in the last quarter, PuraPly's performance in the first quarter further validates the benefits of these strategic initiatives***.
>
> In the first quarter, PuraPly sales increased 27% year-over-year, well ahead of our expectations, and we are very proud of our Q1 results as ***we believe it reflects the strong execution of the strategy to navigate the loss of PuraPly pass-through status and the corresponding headwinds related to this change in reimbursement***.
>
> ***We have repositioned the product with additional clinical data, additional sites of care and additional physician specialties. Clinicians continue to value the product's differentiation, and we continue to see the number of accounts utilizing PuraPly, aided in part by strong sales of our 5 new products and line extensions introduced in 2020, 4 of which were launched in the fourth quarter***.

289. Third, Gillheeney touted Organogenesis's "office strategy," stating that "***[o]ur office strategy is our third area of notable strength in Q1. We have been working on penetrating the office market primarily with channel-specific product offerings and . . . . as a result, we continue to expand the number of customers in the office channel, and we are seeing increasing utilization of our products from existing customers***."

290. In response to an analyst question regarding Gillheeney's confidence to deliver on the Company's revenue guidance, Gillheeney stated:

> [Analyst:] So in terms of -- if I could ask to -- maybe, Gary, if you could clarify this -- where the raise -- I think the raise comes in as impressive and welcome, of course, more than the beat. But the ability to raise, I guess, this much and also sort of still confirm that you're really not going to be selling any of these 2 products, ReNu and NuCel. Maybe talk -- it's a pretty dramatic change from where you maybe left Q4. Maybe walk us through that again, the math, just one more time. And what gives you the confidence to deliver that sort of upside to your full year guidance at this point. . . .
>
> [Gillheeney:] So I think PuraPly is probably the most important change in our guidance. Obviously, PuraPly performed extremely well in Q1. And we had 4 product launches, as you know, right at the end of Q4. And it was one of the areas that we focused on to see if those products would continue to grow as they did in Q1. ***And all trends right now are***

> ***very positive for all of the 5 products that we put out in 2020***, but 4 of them came out late in the fourth quarter, ***and they're all growing extremely well.***
>
> ***So that gives us a lot of confidence that the brand continues to grow. It continues to expand in multiple sites of care as we've discussed as part of our strategy.*** So that's given us a lot of confidence.
>
> ***Our amnions continue to grow.*** Our capacity, our goal is to have 2.5x the capacity of Affinity this year versus 2020. And we're on our way to seeing that happen. So we're pretty comfortable right now that the amount of Affinity that we're able to produce will be meeting our goal of 2.5x. So I think the combination of those 2. . . . I don't know, Dave . . .
>
> * * *
>
> [Francisco:] No, I think that's -- you're absolutely right. I mean, ***it's just the strength in PuraPly over the last 2 quarters really gives us the confidence to increase that by quite a bit and strength of the amnions as well.***

(Second ellipsis in original).

291. In response to an analyst question regarding the Company's AWC revenue growth, Gillheeney stated:

> [Analyst:] And then the second part of that question that dovetails with it is, if you could talk a little bit about the strength you're seeing, this growth you're seeing here, that we're seeing in the numbers, is this a reflection of share dynamics? Or are you seeing an uptick in market growth broadly in Advanced Wound Care, just because it is pretty astounding.
>
> * * *
>
> [Gillheeney:] And I think when we see the number of patients that we're treating and the number of accounts that we're acquiring as customers, ***we definitely feel that there's a margin -- a market shift in our favor***. So we definitely see that happening in the market. And some of the other dynamics from some of the other competitors seems to reflect that.
>
> ***We also think with our expansion in the office channel, we really are expanding the market.*** There's a lot of offices that have dabbled in wound care and are now starting to participate with Advanced Wound Care products and starting to get educated in Advanced Wound Care products, starting to treat more patients and more types of wounds in the office. And that is something that we think will continue to grow.
>
> ***So it's a combination of market share shift and just expanding the market with multiple channels***. And again, the physician specialties that we talk about often that we now serve -- we never had sold in some of those markets before and for indications that we've never

sold to before. ***So it's a combination of all of that, that is really helping to drive the revenue.***

292. The statements identified in ¶¶ 285-91 above were materially false or misleading when made. During the 1Q2021 earnings call, Defendant Gillheeney touted the Company's reported revenue growth in 1Q2021, identified Affinity and PuraPly XT as "***drivers of growth***," and claimed that "***all trends right now are very positive for all of the 5 products that we put out in 2020***," including Affinity and PuraPly XT. Defendant Francisco stated that Defendants' ability to increase and deliver on its 2021 guidance was due to "***the strength in PuraPly over the last 2 quarters***" and the "***strength of the amnions***." Gillheeney also attributed the increased sales of these products to factors other than Defendants' Medicare Reimbursement Scheme. These statements were materially false or misleading for the reasons discussed in ¶¶ 247, 250. Contrary to Defendants' statements, demand for Affinity was not the result of the "***differentiated features***" of the product or Organogenesis's "***efforts to increase the body of clinical evidence***" supporting the use of the product. Nor was demand for PuraPly XT the result of "***additional clinical data***" or "***the product's differentiation***." Rather, sales of these products were being inflated by the Company's Medicare Reimbursement Scheme.

293. Gillheeney's statements claiming that Organogenesis's PuraPly revenues "***reflect[ed] the strong execution of the [Company's] strategy to navigate the loss of PuraPly pass-through status and the corresponding headwinds related to this change in reimbursement***" were materially false or misleading for the reasons discussed in ¶¶ 247, 249. Defendants failed to disclose that the Company's ability to offset the loss in revenue from the expiration of PuraPly's pass-through status relied, at least in part, on its Medicare Reimbursement Scheme with respect to PuraPly XT.

294. Gillheeney's statements touting the success of the Company's "***office strategy***," including his claims that Organogenesis was "***expanding the market***" and benefiting from a "***market share shift***," were materially false or misleading for the reasons discussed in ¶¶ 247-48, 250. These statements were additionally false or misleading because the Company's office strategy was dependent on its Medicare Reimbursement Scheme for Affinity and PuraPly XT, which was the true reason for these products' expansion in the market and the purported "***market share shift***" in Organogenesis's favor.

295. Organogenesis filed a 10-Q on May 11, 2021 signed by both Gillheeney and Francisco. In the MD&A section of the 1Q2021 10-Q, Defendants stated:

> ***Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.***

296. The 1Q2021 10-Q further stated that "***[t]he increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product***" and that "***[t]he continued increase in PuraPly revenue in the three months ended March 31, 2021 was due to the expanded sales forces, increased sales to existing and new customers, and increased adoption of our recently launched line extensions***."

297. The statements identified above in ¶¶ 295-96 were materially false or misleading when made for the reasons discussed above in ¶¶ 247-50.

F. August 9, 2021: 2Q2021 Earnings Report And 10-Q

298. On August 9, 2021, Organogenesis issued a press released reporting a 79% increase in total net revenues year-over-year for 2Q2021. That same day, during Organogenesis's 2Q2021

earnings call, Gillheeney claimed that the Company's performance in the quarter was attributable to the following factors:

> ***Our better-than-expected performance in Q2 reflected our continuing execution against the pillars of growth and our strategy, which include leveraging our comprehensive portfolio of products, diversifying our revenue sources across multiple sites of care and physician specialties and leveraging our broad and growing commercial reach***.

299. Gillheeney then "provide[d] more color on how each of these long-term drivers of growth contributed to the strong revenue performance in the second quarter." Gillheeney claimed that the "***strong demand***" for the products in the Company's amniotic portfolio, including Affinity, were due to their "***high degree of efficacy***":

> First, regarding the strength of our portfolio, sales of our amniotic products were once again the largest contributor to our year-over-year growth in the second quarter. ***And as mentioned previously, we're pleased with the strong demand for these products given the amniotic portfolio's high degree of efficacy that clinicians and their patients truly value in the market***.

300. Gillheeney next touted the growth in the Company's PuraPly revenues despite the loss of PuraPly's pass-through reimbursement status, which he again attributed to the products' "***clinical utility***":

> Additionally, sales of our PuraPly products increased 32% in the period, ***representing the third consecutive quarter of double-digit growth after coming off pass-through status in the fourth quarter of last year. This strong growth further validates the clinical utility of our brand and our strategic positioning of the product family with new SKUs as well as additional clinical data, sites of care and physician specialties***.

301. Gillheeney further touted "the unique customer value proposition our portfolio offers through the combination of our PuraPly brand, which is the only skin substitute with a broad-spectrum antimicrobial agent" and "our amniotic portfolio with the only fresh amniotic membrane on the market." Gillheeney claimed that based on these product features, "***[o]ur highly differentiated competitive advantage has allowed us to continue to gain share in the market and deliver another strong quarter***."

302. Third, Gillheeney touted Organogenesis's office strategy, stating that "***we have been continuing our efforts to further penetrate the office channel with offerings*** . . . . ***As a result, we continue to expand the number of customer accounts in the office channel, and we are experiencing increased utilization of our products from our existing customers***."

303. The statements identified in ¶¶ 298-302 above were materially false or misleading when made. Defendant Gillheeney's statements attributing the Company's reported revenue growth in 2Q2021 to factors other than the Company's undisclosed reliance on its Medicare Reimbursement Scheme for Affinity and PuraPly XT, and attributing the growth in amniotic and PuraPly revenues to the products' "***high degree of efficacy***," and "***the clinical utility of our brand***," were materially false or misleading for the reasons discussed in ¶ 247. Contrary to Gillheeney's statements, demand for Affinity and PuraPly XT was being inflated by the Company's unsustainable Medicare Reimbursement Scheme for these products.

304. Gillheeney's statements touting the Company's "***highly differentiated competitive advantage***" that allowed Organogenesis "***to continue to gain share in the market and deliver another strong quarter***" were materially false or misleading for the reasons discussed in ¶¶ 247, 250. Defendants failed to disclose that the Company's competitive advantage depended on its unsustainable Medicare Reimbursement Scheme.

305. Gillheeney's statements touting the success of the Company's office strategy, including his claims that Organogenesis had "***continue[d] to expand the number of customer accounts in the office channel***" and was "***experiencing increased utilization***" were materially false or misleading for the reasons discussed in ¶¶ 247-48. Defendants failed to disclose that the Company's office strategy depended on its Medicare Reimbursement Scheme for Affinity and

PuraPly XT, which was the true reason for the increasing utilization of these products in the office channel.

306. Organogenesis filed a 10-Q on August 9, 2021 signed by both Gillheeney and Francisco. In the MD&A section of the 2Q2021 10-Q, Defendants stated:

> ***Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.***

307. The 2Q2021 10-Q further stated that "***[t]he increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product***" and that "***[t]he continued increase in PuraPly revenue in the three and six months ended June 30, 2021 was due to the expanded sales forces, increased sales to existing and new customers, and increased adoption of our recently launched line extensions***."

308. The statements identified above in ¶¶ 306-07 which attributed the growth in the AWC revenues for PuraPly and Affinity to factors other than Defendants' Medicare Reimbursement Scheme for these products were materially false or misleading when made for the reasons discussed above in ¶¶ 247-50.

G. September 20, 2021 Oppenheimer Fall Healthcare Life Sciences & MedTech Summit (Virtual)

309. Defendant Gillheeney presented at the September 20, 2021 Oppenheimer Fall Healthcare Life Sciences & MedTech Summit (Virtual). With respect to Organogenesis's revenue growth drivers, Gillheeney stated:

> ***So in the medium-term, our growth strategy reflects our continued ramp of Affinity which we've launched nationally in Q3. Our execution on the office setting strategy, we continue to penetrate that side of care. And that side of care has allowed us to expand the market, really moving clinicians that traditionally did basic wound care that never did advanced wound care in their office are now starting to do that with our help.***

We've built our commercial infrastructure, our portfolio offerings and some of our services to support that office-based business, and we are seeing the expansion of the market as a result.

310. The statements identified in ¶ 309 above were materially false or misleading when made. Gillheeney's statement that the national launch of Affinity after it received an ASP in 3Q2021 reflected a "***continued ramp of Affinity***" was materially false or misleading because it created the false impression that Affinity's sales were sustainable and based on a growth strategy tied to its efficacy in the office setting. In truth, as stated above in ¶¶ 247-48, Organogenesis had built its office-based revenues on its unsustainable Medicare Reimbursement Scheme tailored to certain regional MACs that had high reimbursement rates and did not require physicians to submit physical invoices. Contrary to Gillheeney's statements, the ASP for Affinity would not result in continued growth in sales, but would result in a steady decline in Affinity sales because physicians could no longer be induced to purchase the product based on its favorable reimbursement by the MACs.

311. Gillheeney's statements touting the Company's "***execution on the office setting strategy***," including his claims that the sales growth in the office channel was due to Organogenesis's "***commercial infrastructure***, ***our portfolio offerings and some of our services to support that office-based business***" were materially false or misleading for the reasons discussed in ¶¶ 247-48. Defendant Gillheeney's statements were false or misleading because the Company's office strategy for Affinity depended, at least in part, on Defendants' unsustainable Medicare Reimbursement Scheme.

H. November 9, 2021: 3Q2021 Earnings Report And 10-Q

312. On November 9, 2021, Organogenesis issued a press release reporting another year-over-year increase in net revenues for 3Q2021. The press release quoted Gillheeney as stating:

> We are proud of what we have accomplished so far this year. ***Our year-to-date performance and progress against our strategic priorities is a direct result of the strength of our organization and the dedication of our employees.*** We remain confident in our ability to continue to deliver both strong operating and financial results as well as provide integrated healing solutions that substantially improve medical outcomes while lowering the overall cost of care.

313. During Organogenesis's November 9, 2021 3Q2021 earnings call, Gillheeney attributed the Company's performance to its purported "***strong execution against our key pillars of our growth strategy***," stating:

> ***Our performance in Q3 continues to reflect our strong execution against our key pillars of our growth strategy, which includes leveraging our comprehensive and differentiated portfolio of products, diversifying our revenue sources across multiple sites of care and physician specialties, and leveraging our broad commercial reach***.

314. Gillheeney then "provide[d] more color on how each of these long-term drivers of growth contributed to our revenue performance despite ***the tougher operating environment in the third quarter***." Downplaying Affinity's "***essentially flat***" sales, which were suffering from a downturn in demand due to the ASP of $583.667 per square centimeter set in 3Q2021, Gillheeney highlighted the continued strength of PuraPly sales, stating:

> ***Our sale of PuraPly products increased 39% in the quarter. This growth was driven by strong utilization from existing customers and a contribution from new customers***. Excluding the expected loss of ReNu and NuCel product lines, ***sale of our amniotic products were essentially flat in the third quarter*** and the sale of our PMA and other products increased 14% year-over-year in Q3.

315. Gillheeney also touted the "***increased utilization of [Organogenesis's] products***" in the office channel and the "***competitive advantage***" offered by the Company's sales force, stating:

> Second, we continue to diversify our revenue by expanding into new physician specialties and multiple sites of care to better position the company for sustained long-term growth. . . . ***And as a result, we continue to expand the number of customers and customer accounts in the office channel, and we're experiencing increased utilization of our products from existing customers***. Lastly, on enhancing our commercial reach, we continue to make significant investments to grow our sales force, and ***we believe our team***

of 330 direct sales representatives represents a key competitive advantage for Organogenesis.

316. Gillheeney then addressed Affinity's ASP status, stating:

> [W]e've had several inquiries regarding Medicare and not having a published rate for [A]ffinity in the fourth quarter. ***As part of our strategy to grow the brand nationwide, in Q1 of this year, we voluntarily reported our ASP for Affinity, and we're very pleased to receive a published ASP for Q3.***
>
> ***Our Q4 ASP submission was impacted by a filing error, which initially resulted in an incorrect rate issued by CMS and ultimately resulted in Affinity not having a published rate for the fourth quarter. However, we are confident that the nationally published rate will be reinstated on January 1, 2022, and contrary to some speculation in the market, Affinity continues to be covered and reimbursed by [all MACs] in the fourth quarter.***

317. Defendant Gillheeney's statements identified above in ¶¶ 312-16 attributing the Company's reported revenue growth in 3Q2021 to factors other than the Company's undisclosed reliance on its continued Medicare Reimbursement Scheme for PuraPly XT were materially false or misleading for the reasons discussed in ¶ 247.

318. Gillheeney's statements identified above in ¶ 314 attributing the "***essentially flat***" sales for the Company's amniotic products to the "***the tougher operating environment in the third quarter***" were materially false or misleading because Defendants failed to disclose that Affinity sales had declined due to the product's published ASP, effective July 1, 2021. That is, Defendants knew that demand for Affinity suffered in 3Q2021 because Defendants could no longer perpetuate their Medicare Reimbursement Scheme for Affinity because physicians were no longer profiting from the excessive reimbursement spread from certain MACs.

319. Gillheeney's statements identified above in ¶ 315 touting the Company's performance in the office channel and attributing this performance to "***increased utilization of our products from existing customers***" were materially false or misleading for the reasons discussed

in ¶¶ 247-48. Defendants failed to disclose that, as of this date, the Company's office strategy depended on its Medicare Reimbursement Scheme for PuraPly XT in the office channel.

320. Gillheeney's statements identified above in ¶ 315 touting the Company's "***330 direct sales representatives***" as "***a key competitive advantage***" were materially false or misleading when made for the for the reasons discussed in ¶¶ 247, 250. Defendants failed to disclose that, as of this time, Organogenesis had a temporary competitive edge for PuraPly XT based on its Medicare Reimbursement Scheme. Defendants failed to disclose that once PuraPly XT had an established ASP, Organogenesis was vulnerable to competition from products without an established ASP or which were priced lower, which was then occurring with respect to Affinity sales.

321. Gillheeney's statements identified above in ¶ 316 regarding Affinity's ASP status were materially false or misleading for the reasons discussed in ¶¶ 247, 318. Defendants failed to disclose that sales of Affinity had previously been driven by Defendants' Medicare Reimbursement Scheme, and that Affinity's ASP prevented Defendants from continuing this scheme, resulting in decreased sales.

322. Organogenesis filed a 10-Q on November 9, 2021 signed by both Gillheeney and Francisco. In the MD&A section of the 3Q2021 10-Q, Defendants stated:

> ***Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.***

323. The 3Q2021 10-Q further stated that "***[t]he increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers, increased adoption of our amniotic product portfolio, including our Affinity product, as well as increased adoption of our PuraPly line extensions launched in the second***

half of 2020" and that "***[t]he continued increase in PuraPly revenue in the three and nine months ended September 30, 2021 was due to the expanded sales forces, increased adoption, by existing and new customers, of our PuraPly line extensions launched in the second half of 2020 as well as expanded sites of care***."

324. The statements identified above in ¶¶ 322-23 in attributing the increases in AWC revenues to factors other than the Medicare Reimbursement Scheme were materially false or misleading when made for the reasons discussed above in ¶¶ 247-50.

I. February 18, 2022: 11th Annual SVB Leerink Global Healthcare Conference 2022

325. On February 18, 2022, Gillheeney and Francisco attended the SVB Leerink Global Healthcare Conference. During the Q&A session, Gillheeney reassured the market that Affinity's reimbursement issues were "***clearly behind us from a company and from a customer perspective***." And, in response to a follow-up question regarding any reimbursement-related risk, Gillheeney stated:

> [Analyst:] Yes. So - - just as a reimbursement writ going forward, is no different than it is for any sort of - - any other product that's out there and has payer coverage, right? I mean there's nothing unique to this market that makes [Affinity] more at risk from a significant downdraft in reimbursement?
>
> [Gillheeney:] ***No, and I think from an individual product perspective, no. I mean we believe Affinity is appropriately priced in the market***.

326. Gillheeney's statements identified above in ¶ 325 that Affinity was not "more at risk from a significant downdraft in reimbursement" and was "***appropriately priced in the market***" were materially false or misleading when made. Gillheeney knew that the ASP for Affinity set on January 1, 2022 had put an end to Defendants' Medicare Reimbursement Scheme with respect to Affinity because physicians could no longer profit from the excessive reimbursement spread from certain MACs. Based on Affinity's pricing as set by the Pricing Company (which included

Gillheeney), the ASP of $535.602 set in January 2022 meant that physicians stood to ***lose*** money when using Affinity, a fact confirmed by marketing spreadsheets distributed by Organogenesis management. For the reasons discussed in ¶¶ 247, 250, Gillheeney's statements were also materially false or misleading when made because they failed to disclose that the ASP for Affinity meant that Affinity could no longer compete against products without established ASPs.

J. March 1, 2022: 4Q2021 Earnings Report And 2021 10-K

327. On March 1, 2022, Organogenesis issued a press release reporting increases year-over-year for both its 4Q2021 net revenues and fiscal year 2021 net revenues. During Organogenesis's 4Q2021 earnings call that same day, Gillheeney stated that the following with respect to factors contributing to the Company's performance in 4Q2021:

> ***Our fourth quarter and fiscal year 2021 net revenue results reflect the continuation of the key drivers of our growth strategy and competitive advantages we have discussed in recent years, including the investments we've made to expand our sales force, the benefits of our comprehensive and differentiated portfolio of products that address patient needs to treat wounds across all stages of the healing process and strong execution of our commercial strategy focused on leveraging multiple channels, new product introductions and brand loyalty***.

328. Gillheeney then provided an "update . . . on the progress of each of these in 2021." Gillheeney stated that the "***net revenue results clearly benefited from the investments we've made to grow our direct commercial team in the recent years***." Gillheeney then highlighted the Company's product portfolio as a "***primary driver***" of growth:

> ***Second, our comprehensive portfolio of products is a key competitive advantage for Organogenesis and continues to be a primary driver of our impressive growth in recent years***.

329. Gillheeney next touted PuraPly's "***clinical outcomes***" as "***continu[ing] to drive strong demand for the brand***":

> ***PuraPly is back with proven clinical outcomes is highly efficacious in the early stages of wound healing and therefore, remains a key component to the healing algorithm from our clinicians and patients***.

> We've strategically expanded the brand since we launched the product in 2015, bringing new products and line extensions to address varying wound attributes across size, depth and complexity. ***These new products and line extensions have enabled access to multiple sites of care and physician specialties and continue to drive strong demand for the brand***.

330. With respect to Affinity, Gillheeney stated that "***[o]ur portfolio of highly differentiated amniotic products continues to experience strong net revenue growth with sales increasing 15% year-over-year in Q4 and up 38% on an adjusted basis, which exceeded our expectations***."

331. In response to an analyst question about the performance of Organogenesis's amniotic products, Gillheeney stated:

> On the amniotic side, they did do well. They performed -- exceeded our expectations. ***We did see a slight decline as expected in the first month and then started to grow as expected and actually better than expected. So we put a lot of time and focus on the amniotic portfolio in Q4, and it helped in exceeding our expectations***.

332. The statements identified in ¶¶ 327-31 above were materially false or misleading when made. Defendant Gillheeney's statements touting the Company's revenue growth in 4Q2021 and attributing the Company's reported growth to factors other than the Company's undisclosed Medicare Reimbursement Scheme for Affinity and PuraPly XT were materially false or misleading for the reasons discussed in ¶ 247. Contrary to Gillheeney's statements, demand for Affinity and PuraPly XT were being inflated by the Company's unsustainable marketing of the temporary reimbursement spread for these products. Gillheeney's statements touting the "***strong net revenue growth***" in the Company's amniotic products were materially false or misleading for the additional reasons that Defendants failed to disclose that the rebound in Affinity sales was due to Affinity not having an ASP for 4Q2021, thereby allowing the Company to resume it marketing of the reimbursement spread.

333. Gillheeney's statements identified above in ¶ 328 stating that the Company's "***comprehensive portfolio of products***" was "***a key competitive advantage for Organogenesis and continues to be a primary driver of our impressive growth in recent years***" were materially false or misleading when made for the for the reasons discussed in ¶¶ 247, 250. Defendants failed to disclose that, as of this time, Organogenesis had a temporary competitive edge for Affinity and PuraPly XT based on its Medicare Reimbursement Scheme. Defendants failed to disclose that once these products had an established ASP, Organogenesis was vulnerable to competition from products without an established ASP or that were priced lower, as would occur when Affinity again received an ASP in 1Q2022.

334. On March 1, 2022, Organogenesis filed its 2021 10-K signed by both Gillheeney and Francisco. In the MD&A section of Organogenesis's 2021 10-K, Defendants stated:

> ***Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.***

335. Defendants stated the following in the 2021 10-K with respect to the reasons for the Company's revenue growth in 2021:

> ***The increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers, increased adoption of our placental-based product portfolio, including our Affinity product, as well as increased adoption of our PuraPly line extensions launched in the second half of 2020***.
>
> * * *
>
> ***The increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our placental-based product portfolio, including our Affinity product***.
>
> * * *
>
> ***PuraPly exited pass-through status on October 1, 2020. The continued increase in PuraPly revenue in the year ended December 31, 2021 was due to the expanded sales forces, increased adoption, by existing and new customers, of our PuraPly line extensions launched in the second half of 2020 as well as expanded sites of care***.

336. The statements identified above in ¶¶ 334-35 attributing the increase in AWC net revenues exclusively to certain factors without mentioning the Medicare reimbursement scheme were materially false or misleading when made for the reasons discussed above in ¶¶ 247-50.

K. May 10, 2022: 1Q2022 Earnings Report And 10-Q

337. On May 10, 2022, Organogenesis issued a press release reporting a decrease in total net revenues for 1Q2022. The press release quoted Gillheeney as stating that "***Organogenesis is well-positioned to manage through the near-term operating environment challenges and achieve strong, long-term growth***."

338. During Organogenesis's May 10, 2022 1Q2022 earnings call, Gillheeney stated the following with respect to Organogenesis's performance in 1Q2022:

> ***Despite the challenging start to the quarter, the team executed well as our growth strategy and competitive advantages continue to yield results for the company. The strength of our expanded sales force, the benefits of our comprehensive and differentiated portfolio of product and leveraging multiple channels, new product introductions and brand loyalty in the market***.

339. Gillheeney highlighted the strength of the PuraPly brand, stating: "***Our strategy to introduce new products and line extensions have enabled access to multiple sites of care and physician specialties and continue to drive strong demand for the PuraPly brand***."

340. Gillheeney provided the following explanation for the performance of the Company's amniotic products in the quarter:

> Sales of our amniotic products declined 32% year-over-year and declined 22% on an adjusted basis, excluding the sales of ReNu and NuCel in the prior year period. ***These results were largely in line with our expectation and reflect the impact of Omicron on our national launch of Affinity***.
>
> We continue to expect that portfolio of highly differentiated amniotic products to be the largest contributor to our company's net revenue growth for fiscal year 2022 and the midpoint of our full year revenue range continues to assume amniotic growth of approximately 12% year-over-year in 2022.

341. In response to an analyst question regarding the cause of Affinity's disappointing performance in 1Q2022, Gillheeney stated:

> [Analyst:] Just a quick question on the amniotic product line and Affinity specifically. Came in a little bit below what we were thinking. I guess, number one, maybe we mismodeled it a little bit here. But any incremental color you can give on what you saw exiting the quarter and sort of how that's trended so far in April as it relates to that product line? And then secondarily, what gives you the confidence that that's going to be the primary growth contributor to the 2022 guidance . . . ?
>
> [Gillheeney:] ***So Q1 was -- for Affinity was as expected for us with the national launch. We had to relaunch the product again in Q1 so you have a rate change. We also had the issues as we discussed that everybody had with Omicron. So it was a slow start for sure. The trends that we're seeing now are very positive.***
>
> ***We're adding new accounts in multiple sites of care for the product and the sales trends over the last 4 to 5 weeks have actually been quite strong***. So we feel that the rest of the year with the national launch and with the second half of the year, the operating environment improving, that we'll be able to continue to expand the use of the product across the country.

342. The statements identified above in ¶¶ 337-41 were materially false or misleading when made. Defendant Gillheeney's statements touting the "***strong demand***" for PuraPly products and attributing the Company's reported revenue growth in 1Q2022 to factors other than the Company's Medicare Reimbursement Scheme for PuraPly XT were materially false or misleading for the reasons discussed in ¶¶ 247, 319.

343. Gillheeney's statements identified above in ¶ 340 explaining the reasons for the poor performance of the Company's amniotic products in 1Q2022, including his statements that the decline in revenue was due to "***the impact of Omicron on our national launch of Affinity***" and explanation that "***Organogenesis is well-positioned to manage through the near-term operating environment challenges***," were materially false or misleading because Defendants failed to disclose that Affinity sales had declined due to the product's published ASP, effective January 1, 2022. That is, Defendants knew that demand for Affinity suffered in 1Q2022 because Defendants could no longer perpetuate their Medicare Reimbursement Scheme for Affinity

because physicians were no longer profiting from the excessive reimbursement spread from certain MACs. Indeed, as discussed in ¶ 326, internal reimbursement spreadsheets distributed by Organogenesis management show that Affinity's ASP removed any profit incentive for physicians to prescribe Affinity. Moreover, Defendants failed to disclose that the ASP for Affinity meant that the product could no longer compete against products without established ASPs. Therefore, Defendants' statements that "***[t]he trends that we're seeing now are very positive***" and "***the sales trends over the last 4 to 5 weeks have actually been quite strong***" were materially false or misleading because they failed to disclose that demand for Affinity had been, and was continuing to be, negatively impacted by the ASP set in 1Q2021, as had occurred when an ASP was set in 3Q2021.

344. Organogenesis filed a 10-Q on May 10, 2022 signed by both Gillheeney and Francisco. In the MD&A section of the 1Q2022 10-Q, Defendants stated:

> ***Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.***

345. Unlike each of the prior quarters in the Class Period, the 1Q2022 10-Q did not provide any explanation of the factors contributing to the Company's AWC revenues in 1Q2022, stating that "[n]et revenue from our Advanced Wound Care products in the three months ended March 31, 2022 was $91.0 million, relatively consistent with the net revenue of $90.7 million in the three months ended March 31, 2021." With respect to PuraPly revenues, the 1Q2022 10-Q stated that "***[t]he continued increase in PuraPly revenue in the three months ended March 31, 2022 was due to our expanded sales force, expanded sites of care, and increased adoption, by existing and new customers, of our PuraPly line extensions***."

346. The statements identified above in ¶¶ 344-45 attributing the increase in PuraPly net revenues exclusively to factors other than Defendants' Medicare Reimbursement Scheme were materially false or misleading when made for the reasons discussed above in ¶¶ 247-50, 319.

VI. DEFENDANTS VIOLATED SEC DISCLOSURE OBLIGATIONS

347. SEC Regulation S–K, 17 C.F.R. § 229.303 ("Item 303"), requires public companies in the MD&A section of a company's annual and quarterly reports filed with the SEC on Forms 10-K and 10-Q to provide discussion that "must focus specifically on material events and uncertainties known to management that are reasonably likely to cause reported financial information not to be necessarily indicative of future operating results or of future financial condition." Item 303(a). With respect to "Results of operations," Item 303(b)(2)(ii) specifically requires that the MD&A "[d]escribe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." A company's failure to disclose information required by Item 303 in its annual and quarterly reports filed with the SEC is actionable under the federal securities laws, including under Section 10(b) of the Exchange Act.

348. The purpose of MD&A disclosures, according to the SEC, is to provide investors with information that enables investors to see the company through management's eyes and to provide information about the quality and potential variability of a company's earnings and cash flow. In a May 18, 1989 interpretive release concerning MD&A disclosure obligations, the SEC stated:

> MD&A is intended to give the investor an opportunity to look at the company through the eyes of management by providing both a short and long-term analysis of the business of the company. . . . It is the responsibility of management to identify and address those key variables and other qualitative and quantitative factors which are peculiar to and necessary for an understanding and evaluation of the individual company.

349. On April 7, 2003, the SEC issued a final rule addressing registrants' disclosure obligations under Item 303 that emphasized that MD&A disclosures are "of paramount importance in increasing the transparency of a company's financial performance and providing investors with the disclosure necessary to evaluate a company and to make informed investment decisions." The SEC stated that MD&A provides "a unique opportunity for management to provide investors with an understanding of its view of the financial performance and condition of the company, ***an appreciation of what the financial statements show and do not show, as well as important trends and risks that have shaped the past or are reasonably likely to shape the future***." The SEC reiterated this guidance in its amendments to Item 303 promulgated in 2021 and emphasized the importance of this disclosure in MD&A. *See* SEC Release No. 33-10890.

350. As alleged above, during the Class Period, Organogenesis's revenues were inflated by an undisclosed Medicare Reimbursement Scheme involving two of the Company's key AWC products, Affinity and PuraPly XT. This scheme, which depended on the lack of an ASP for these products and the fact that certain MACs reimbursed physicians based on invoices that did not reflect the actual costs charged by the Company, could only temporarily inflate Organogenesis's revenue. Indeed, once an ASP was set for Affinity, sales of this product declined dramatically, as reflected in the Company's reported declines in sales of its amniotic products and reported net revenues in non-PuraPly products.

351. Organogenesis's reliance on its Medicare reimbursement scheme was a "known . . . uncertaint[y] . . . reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Item 303(b)(2)(ii). Defendants' failure to disclose this known uncertainty in the sustainability of its revenues driven by its Medicare Reimbursement Scheme for Affinity and PuraPly XT in the Company's 10-Ks and 10-Qs filed

during the Class Period violated Item 303 and Section 10(b) of the Exchange Act. Without this information, investors had no ability to view Organogenesis "through the eyes of management" or know what the Company's financial statements did "not show," including the "material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition" and "important trends and risks that have shaped the past or are reasonably likely to shape the future." Defendants also failed to disclose "[a]ny unusual or infrequent events or transactions," such as the false demand for the Company's products generated by its marketing of the temporary reimbursement spread for Affinity and PuraPly XT.

VII. ADDITIONAL ALLEGATIONS OF SCIENTER

352. In addition to the facts alleged above, the following facts further support a strong inference that Defendants knowingly or recklessly made false or misleading statements to investors during the Class Period.

A. Defendants Were Financially Motivated To Commit Securities Fraud

1. Defendant Gillheeney Made Millions From Suspiciously-Timed Insider Sales During The Class Period

353. Defendant Gillheeney personally profited by selling millions in Organogenesis common stock while the Company's stock price was artificially inflated by his repeated false or misleading statements, supporting an inference that Gillheeney acted with scienter in making these statements to investors. As detailed below, Gillheeney's extensive insider sales during the Class Period were suspicious in both timing and amount.

354. In February 2021, Gillheeney sold ***397,900 shares*** of Organogenesis common stock for total proceeds of approximately ***$5.3 million***. Gillheeney's February 2021 transactions are listed in the below table.

Gillheeney's February 2021 Transactions[13]			
Date of Transaction	**Description of Transaction**	**Number of Shares Owned After Transaction**	**Percentage of Current Holdings Sold**
2/11/2021-2/16/2021	**Sold 291,862 shares for total proceeds of $3,886,852**	**194,219**	**60%**
2/17/2021-2/18/2021	**Sold 106,038 shares for total proceeds of $1,408,617**	**139,807**	**43.1%**
Total Shares Sold: 397,900 Total Proceeds: $5,295,469			

355. The timing of Gillheeney's stock sales in February 2021 were highly suspicious in that they occurred immediately after Organogenesis reported a second consecutive quarter of revenue results that exceeded market expectations, driven by purportedly strong demand for Affinity and PuraPly XT. On October 14, 2020, Organogenesis preliminarily reported an

[13] The table does not include grants of stock options, grants of restricted stock units ("RSUs") under Organogenesis's 2018 Equity Incentive Plan, or forfeitures for tax withholding purposes.

"astounding beat" relative to analyst expectations for 3Q2020, and raised its FY2020 guidance. On November 9, 2020, Gillheeney touted the "***demand for our amniotic products***," stating that Affinity sales were "***the largest contributor to growth again in Q3***." Gillheeney also touted "***the introduction of our XT line extension, which is selling extremely well***." Then, on January 13, 2021, Organogenesis preliminarily reported another "[b]lowout" quarter, sending the Company's stock price soaring 29%. Weeks later, Gillheeney sold nearly ***$5.3 million*** of Organogenesis common stock. Significantly, Gillheeney's February 2021 sales were the first time he sold Organogenesis common stock since the Avista merger in 2018, and represented ***60%*** and ***43.1%*** of the shares he held as of the dates of the transactions, respectively.

356. While Gillheeney's February 2021 insider sales were made pursuant to a Rule 10b5-1 trading plan entered into in August 2020, the start of the Class Period, the existence of this trading plan does not diminish the suspiciousness of these transactions. As alleged throughout this Complaint, at the time Gillheeney entered into this trading plan, Gillheeney knew that the Company's sales force was inflating sales of Affinity and PuraPly XT by marketing the temporary reimbursement spread for these products, and also knew that this scheme was unsustainable. Therefore, Gillheeney ***possessed material, non-public information*** regarding the Company's Affinity and PuraPly revenues at the time he entered into this trading plan. The timing of Gillheeney's adoption of the Rule 10b5-1 trading plan, the short time period between Defendants' reported revenue growth and guidance increases related to Affinity and PuraPly XT sales and the execution of these trades, and the size and amount of Gillheeney's transactions all strongly suggest

that Gillheeney used this trading plan to opportunistically capitalize on Organogenesis's inflated stock price during the Class Period.[14]

357. In July 2021, Defendant Gillheeney sold an additional ***300,000 shares*** of Organogenesis common stock for total proceeds of ***$4.3 million***. Gillheeney's July 2021 transactions are listed in the below table.

Gillheeney's July 2021 Transactions[15]			
Date of Transaction	**Description of Transaction**	**Number of Shares Owned After Transaction**	**Percentage of Current Holdings Sold**
7/16/2021	Exercised options to purchase 24,313 shares at $0.99 and 115,450 shares at $4.04	271,680	N/A
7/16/2021	**Sold 139,763 shares for total proceeds of $2,059,820**	131,917	**51.4%**
7/19/2021	Exercised an option to purchase 160,237 shares at $0.99	292,154	N/A
7/19/2021	**Sold 160,237 shares for total proceeds of $2,246,522**	131,917	**54.8%**
Total Shares Sold: 300,000 Total Proceeds: $4,306,342			

358. Gillheeney's July 2021 sales were also suspiciously timed because, over the preceding four quarters, Organogenesis had reported rapidly increasing sales following the launch of Affinity and PuraPly XT, and had raised its guidance on two occasions, in 3Q2020 and 1Q2021. Throughout this period, Gillheeney touted the purportedly "***strong demand***" and "***strong sales of [Organogenesis's] amniotic and PuraPly products***" in the physician office channel, and claimed that demand for Affinity and PuraPly XT had allowed the Company to offset the loss of revenue

[14] *See* David F. Larcker, Bradford Lynch, Phillip Quinn, Brian Tayan & Daniel J. Taylor, *Gaming the System: Three "Red Flags" of Potential 10b5-1 Abuse*, Stanford Closer Look Series, 2021 (explaining that the shorter the interval of time between a 10b5-1 plan adoption and the first trade, the more likely that the plan is being used opportunistically by an executive in possession of material, non-public information).

[15] The table does not include grants of stock options, grants of RSUs under Organogenesis's 2018 Equity Incentive Plan, or forfeitures for tax withholding purposes.

from the expiration of PuraPly's pass-through status, which investors had feared would lead to a significant decline in revenue. In fact, just two months prior to Gillheeney's sales, on May 10, 2021, while the Company's stock price was at an all-time high, Defendants further inflated market expectations again by increasing the Company's FY 2021 net revenue guidance.

359. Shortly after Gillheeney's statements touting the Company's Affinity and PuraPly XT sales and Organogenesis's second guidance increase, in June 2021, Gillheeney entered into a Rule 10b5-1 trading plan. At the time Gillheeney entered into this trading plan, Gillheeney knew that a decline in the Company's amniotic products revenue was imminent because CMS had set an ASP for Affinity effective July 1, 2021, thereby preventing the Company from marketing the reimbursement spread for this product. Gillheeney then used this Rule 10b5-1 trading plan to effectuate his sales in July 2021—***while in possession of material, non-public information*** regarding the Company's amniotic product revenues. The short time period between Gillheeney's statements, adoption of the Rule 10b5-1 trading plan, and execution of these trades provides "red flag[]" evidence that the plan was being used to opportunistically capitalize on Organogenesis's inflated stock price during the Class Period.[16]

360. Notably, to sell his 300,000 shares in July 2021, Gillheeney exercised stock options that were at no risk of expiration—approximately one-third of the options were set to expire on April 22, 2030, and approximately two-thirds of the options were to expire on July 25, 2023.

361. Beginning in May 2022, Defendant Gillheeney engaged in another series of suspicious transactions. In total, between May 13, 2022 and June 3, 2022, Gillheeney sold

[16] David F. Larcker, Bradford Lynch, Phillip Quinn, Brian Tayan & Daniel J. Taylor, *Gaming the System: Three "Red Flags" of Potential 10b5-1 Abuse*, Stanford Closer Look Series, 2021.

1,250,000 shares for total proceeds of more than ***$7.2 million.*** Gillheeney's May and June 2022 transactions are listed in the below table.

Gillheeney's May and June 2022 Transactions[17]			
Date of Transaction	**Description of Transaction**	**Number of Shares Owned After Transaction**	**Percentage of Current Holdings Sold**
5/13/2022	Exercised an option to purchase 136,390 shares at $0.99	534,632	N/A
5/13/2022	**Sold 136,390 shares for total proceeds of $841,113**	398,242	**25.5%**
5/16/2022	Exercised an option to purchase 80,369 shares at $0.99	478,611	N/A
5/16/2022	**Sold 80,369 shares for total proceeds of $475,784**	398,242	**16.7%**
5/17/2022	Exercised an option to purchase 98,078 shares at $0.99	496,320	N/A
5/17/2022	**Sold 98,078 shares for total proceeds of $578,660**	398,242	**19.7%**
5/18/2022	Exercised an option to purchase 86,531 shares at $0.99	484,773	N/A
5/18/2022	**Sold 86,531 shares for total proceeds of $472,459**	398,242	**17.8%**
5/19/2022	Exercised an option to purchase 118,504 shares at $0.99	516,746	N/A
5/19/2022	**Sold 118,504 shares for total proceeds of $703,913**	398,242	**22.9%**
5/20/2022	Exercised an option to purchase 58,654 shares at $0.99	456,896	N/A
5/20/2022	**Sold 58,654 shares for total proceeds of $345,472**	398,242	**12.8%**
5/23/2022	Exercised options to purchase 60,350 shares at $0.99	458,592	N/A
5/23/2022	**Sold 60,350 shares for total proceeds of $350,296**	398,242	**13.1%**
5/24/2022	Exercised an option to purchase 52,312 shares at $0.99	450,554	N/A
5/24/2022	**Sold 52,312 shares for total proceeds of $296,085**	398,242	**11.6%**
5/25/2022	Exercised an option to purchase 84,674 shares at $0.99	482,916	N/A

[17] The table does not include grants of stock options, grants of RSUs under Organogenesis's 2018 Equity Incentive Plan, or forfeitures for tax withholding purposes.

5/25/2022	**Sold 84,674 shares for total proceeds of $474,174**	398,242	**17.5%**
5/26/2022	Exercised an option to purchase 61,202 shares at $0.99	459,444	N/A
5/26/2022	**Sold 61,202 shares for total proceeds of $349,463**	398,242	**13.3%**
5/27/2022	Exercised an option to purchase 56,362 shares at $0.99	454,604	N/A
5/27/2022	**Sold 56,362 shares for total proceeds of $334,226**	398,242	**12.3%**
5/31/2022	Exercised an option to purchase 109,240 shares at $0.99	507,482	N/A
5/31/2022	**Sold 109,240 shares for total proceeds of $620,483**	398,242	**21.5%**
6/1/2022	Exercised an option to purchase 94,487 shares at $0.99	492,729	N/A
6/1/2022	**Sold 94,487 shares for total proceeds of $521,568**	398,242	**19.1%**
6/2/2022	Exercised an option to purchase 116,608 shares at $0.99	514,850	N/A
6/2/2022	**Sold 116,608 shares for total proceeds of $650,672**	398,242	**22.6%**
6/3/2022	Exercised an option to purchase 36,239 shares at $0.99	434,481	N/A
6/3/2022	**Sold 36,239 shares for total proceeds of $200,401**	398,242	**8.34%**
Total Shares Sold: 1,250,000		**Total Proceeds: $7,214,769**	

362. These sales were also suspicious in amount because—even including Gillheeney's February 2021 and July 2021 stock sales—his May through June 2022 transactions were dramatically out of line with his prior sales during the Class Period, representing ***nearly double*** his total prior sales.

363. The timing of Gillheeney's May and June 2022 sales was likewise suspicious, notwithstanding the fact that these sales were made pursuant to a Rule 10b5-1 trading plan entered into in March 2022. Gillheeney knew that as of January 1, 2022, Affinity's reimbursement rate had plummeted and would no longer drive the Company's revenues as it had for the prior two years. Then in March 2022, ***while in possession of this material, non-public information***,

Gillheeney entered into a Rule 10b5-1 trading plan. Just two months later, Gillheeney executed ***$7.2 million*** in sales pursuant to this trading plan. The short time period between Affinity receiving an ASP in January 2022 and Gillheeney's adoption of the Rule 10b5-1 trading plan in March 2022 provides "red flag[]" evidence that the plan was being used capitalize on Organogenesis's inflated stock price before investors learned the truth about the declines in Affinity sales. Further, the timing of Gillheeney's transactions is particularly suspicious given that he executed these sales after making material misstatements and omissions that maintained or increased the artificial inflation in Organogenesis's stock price. On May 10, 2022, Gillheeney falsely attributed the Company's reported 32% year-over-year decline in amniotic product revenues to the impact of the Omicron COVID-19 variant. In truth, as would be revealed on August 9, 2022, the Company's amniotic sales were declining due to its inability to market the reimbursement spread for Affinity and inability to compete with companies whose products lacked an ASP.

364. Notably, to sell the large amounts of common stock in May and June 2022, Gillheeney exercised stock options that were at no risk of expiration—the majority of these options were not set to expire until August 21, 2024 and December 8, 2024, with a small minority (14,810 shares) set to expire on July 25, 2023.

2. Organogenesis Raised $59 Million In A Secondary Offering While Its Stock Price Was Inflated By Defendants' Fraud

365. Organogenesis also profited from the Company's misstatements and omissions. Soon after releasing its "astounding" preliminary 3Q2020 financial results on October 14, 2020, and immediately following Gillheeney's statements touting the strong demand for Affinity and PuraPly XT during the November 9, 2020 3Q2020 earnings call, Organogenesis sold a total of 19,916,708 shares of its common stock in the SPO, raising gross proceeds of $64.7 million, and net proceeds of $59 million. The SPO occurred while Organogenesis's stock price was inflated by

Defendants' false or misleading statements and omissions of material fact, and while the Company's sales force, under the direction of Organogenesis's management, was engaged in a fraudulent scheme to market the reimbursement spread for Affinity and PuraPly XT in order to inflate the Company's reported revenue. This fact supports an inference of Organogenesis's corporate scienter.

B. Defendants Knew Or Had Access To Information Contradicting Their Public Statements

366. Numerous additional facts support a strong inference that Defendants acted with scienter because they knew or recklessly disregarded that their public statements during the Class Period were materially false or misleading.

1. Defendants' Statements Establish Their Knowledge Of The Company's Marketing Practices With Respect To Affinity And PuraPly XT

367. Defendants Gillheeney and Francisco—Organogenesis's senior-most executives—regularly spoke to investors about Affinity and PuraPly XT and the purported reasons for the growth in sales of these products during the Class Period. Indeed, the vast majority of Defendants' false or misleading statements and omissions of material fact explicitly or implicitly pertain to the drivers of Organogenesis's revenues, and the contributions of Affinity and PuraPly XT to those revenues, and could not have been made with any reasonable basis in fact. For example, Gillheeney made the following statements, in which he purported to have direct knowledge of the drivers of the Company's Affinity and PuraPly XT sales during the Class Period:

a. August 10, 2020: "***It's [PuraPly XT] selling extremely well. We thoughtfully launched it in only certain regions of the country, and it's performing above our expectations at this point***."

b. August 10, 2020: "***It's [Affinity] primarily in the office right now. So we've strategically launched it in certain areas of the country in the office only, and we have historical users of the product. As you know, we -- the product was sold in 2018, but we've been able to add additional customers at a very rapid rate. So the***

product is selling extremely well. It's exceeded our expectations at this point in time, and we'll continue to expand the office offering as capacity expands."

c. September 16, 2020: "***So one of the reasons we've moved into the office and really put a major emphasis on the office-based setting is it's a different reimbursement model than the outpatient model. So it not only diversifies the revenue risk, it diversifies the reimbursement risk, and it's also a very, very large market. So in this space, it's reimbursement that you typically will focus on and want to make sure that your products are well positioned and well reimbursed***."

d. November 9, 2020: "***Our fresh amniotic membrane product, Affinity, was the largest contributor to growth again in Q3, driven by the differentiated features of the product that our clinical customers value and positive reimbursement in the office channel***."

e. November 9, 2020: "***Clinicians continue to value the product's clinical value, and we continue to see growth in the number of accounts that are utilizing PuraPly, aided in part by the introduction of new sizes and the introduction of our XT line extension, which is selling extremely well***."

f. May 10, 2021: "***And consistent with what we've experienced in the last quarter, PuraPly's performance in the first quarter further validates the benefits of these strategic initiatives. . . . Clinicians continue to value the product's differentiation, and we continue to see the number of accounts utilizing PuraPly, aided in part by strong sales of our 5 new products and line extensions introduced in 2020***[.]"

g. September 20, 2021: "***So in the medium-term, our growth strategy reflects our continued ramp of Affinity which we've launched nationally in Q3. Our execution on the office setting strategy, we continue to penetrate that side of care***."

368. That Defendants made many of these public statements in response to direct questions from investment analysts about revenue drivers and product reimbursement further supports a strong inference of scienter. Significantly, Gillheeney's statements also specifically addressed the impact of reimbursement in "***certain regions***" and "***certain areas***" of the country while these products lacked an ASP.

369. Gillheeney also claimed to have knowledge of the reasons why Affinity sales declined at the end of the Class Period after Affinity received an ASP, and acknowledged during

the August 9, 2022 earnings call that Affinity sales had declined because the product could not compete against products without a published ASP:

a. May 10, 2022: "So Q1 was -- for Affinity was as expected for us with the national launch. We had to relaunch the product again in Q1. So you have a rate change. We also had the issues as we discussed that everybody had with Omicron. So it was a slow start for sure. ***The trends that we're seeing now are very positive. We're adding new accounts in multiple sites of care for the product and the sales trends over the last 4 to 5 weeks have actually been quite strong***."

b. August 9, 2022: "So what we've seen is more of the smaller players in the space that mostly amniotic products, and those products are competing with our products, competing for share of voice and we just see a lot more of them. ***I think the transient component of it is with no published ASPs, that competition can continue in the -- particularly in the office***. So we think over time, those smaller players will not be as competitive going forward."

370. Gillheeney also made statements claiming to have direct knowledge of the Company's compliance with laws and regulations governing its marketing practices, stating on September 16, 2020:

> ***[W]e are a very compliant company, and we are the gold standard of compliance, and that's not my opinion. That's what I hear back from the financial community when they do diligence on our company and that's just -- that's who we are. We think it's the right way to do business. We think our customers feel that, that's important. And particularly, as some of our competitors have stumbled, we have stood out, and that brand is now paying dividends for us as folks look to us for solving their wound care problems and making sure that we're conducting ourselves and conducting business in their clinics in a very compliant way. It's important in this space.***

371. Moreover, as the Company's top executives, Gillheeney and Francisco—the CEO and CFO, respectively—controlled the Company's daily operations and were informed of and monitored the true drivers of Organogenesis's sales, the pricing and reimbursement rates for the Company's products, the Company's marketing practices, and the Company's compliance with healthcare laws and regulations. Organogenesis's 2021 10-K stated that "[w]e are highly dependent on our executive officers, the loss of whose services may adversely impact the achievement of our objectives" and explained that "[i]n particular, we depend on Gary Gillheeney,

our President and Chief Executive Officer." In addition to being its senior-most executive officer, Gillheeney is also a member of the Company's Board of Directors and certified the Company's financial reporting filed with the SEC.

372. As Organogenesis's CFO, Defendant Francisco oversaw the Company's financial and accounting functions, and had access to, and knowledge of, aspects of Organogenesis's financial status that were unavailable to the investing public. Additionally, Francisco certified the Company's financial reporting filed with the SEC.

373. Defendants' statements and roles at the Company strongly suggest that each had detailed knowledge of or access to information concerning the Company's Medicare Reimbursement Scheme. If Defendants issued their statements without such knowledge, Defendants were reckless in failing to investigate the subject matter of their statements.

2. Defendants Knew Or Had Access To Information That The Company's Sales Force Marketed The Reimbursement Spread For Affinity And PuraPly XT

374. Contrary to Defendants' public statements throughout the Class Period purporting to describe the factors contributing to Affinity and PuraPly XT sales, Defendants knew or recklessly disregarded that Organogenesis's sales force was engaged in an unsustainable scheme to maximize revenue for Affinity and PuraPly XT by marketing the reimbursement spread for these products based on temporary reimbursement rates by certain MACs. As numerous FEs explained, these marketing practices were encouraged by the Company's management and discussed at the highest levels of the Company.

375. As alleged above, FE-9 stated that the Organogenesis Pricing Committee, comprised of Organogenesis senior management including Defendant Gillheeney, formulated and oversaw the Company's pricing strategy. The Pricing Committee was responsible for setting the cost to physicians for Affinity and PuraPly XT. Information obtained from the MACs and

corroborated by accounts of the FEs, including marketing spreadsheets produced by FE-10, shows that the Pricing Committee set the cost of Affinity and PuraPly XT significantly lower than the amount physicians were reimbursed by the MACs for these products. Organogenesis also employed odd-even pricing to intentionally allow physicians to round up the amount of product used for to further maximize reimbursement profits for physicians.

376. The accounts of FE-1, FE-2, FE-4, FE-6, FE-7, and FE-8, describe conduct which shows that to effectuate the Medicare Reimbursement Scheme, Organogenesis management oversaw and encouraged the Company's sales representatives to market the spread of Affinity and PuraPly XT by supplying iPads with an application that calculated physicians' reimbursement profits and by training its sales representatives on the application. Moreover, the Organogenesis Reimbursement Team calculated the reimbursement amounts and updated this information to the iPad application used by the Company's sales representatives during sales meetings with physicians. The Reimbursement Team also notified the sales representatives when the reimbursement amounts were updated in the iPad application.

377. Both FE-1 and FE-2 stated that Organogenesis management also participated in discussions regarding the reimbursement for Affinity and PuraPly XT during national and regional sales meetings, and urged its sales representatives to sell the products before an ASP was established. FE-2 explained that certain members of Organogenesis senior management, including Brian Grow and Lowell Berg, participated in weekly sales team calls in which sales managers reviewed "talk tracks" that demonstrated how to market Affinity and PuraPly XT based on the reimbursement spread.

378. Furthermore, FE-9 explained that Organogenesis senior management, including Defendants Gillheeney and Francisco, had full access to Power BI which showed sales and revenue

data by geographic region. This internal reporting system provided Organogenesis management with the ability to track the effectiveness of the Company's Reimbursement Scheme.

379. The accounts of FE-1, FE-3, FE-4, and FE-6, also reveal that Organogenesis management acknowledged and communicated internally to its sales representatives that Organogenesis could no longer market the reimbursement spread once Affinity and PuraPly XT received an ASP, which would put an end to their favorable reimbursement. This had become a reality by 3Q2021, as reflected in the spreadsheet produced by FE-10, and was likely reflected in the spreadsheets described in the accounts of FE-2, FE-3, FE-4, FE-5, and FE-7 as well. These documents show that based on the product cost for Affinity and the ASP set by CMS, physicians could lose money when using the product depending on the amount of reimbursement received from Medicare. That is, Defendants had already internally acknowledged on a reimbursement spreadsheet distributed to the Company's sales representatives that Affinity's reimbursement-fueled growth had come to an end.

3. Defendants Retaliated Against Employees Who Did Not Comply With Their Reimbursement Scheme

380. Organogenesis management knew that marketing the reimbursement spread for Affinity and PuraPly XT was illegal, as evidenced by the fact that Organogenesis trained its sales representatives on how not to get caught marketing the spread, and told the sales force "don't get caught doing it," as recalled by FE-6. Nonetheless, Organogenesis management provided a top-down directive to its sales representatives to sell on the spread, as detailed above in Section IV.H.

381. When sales representatives refused to comply with this directive, or reported their concerns to the Company's management and compliance department, they were retaliated against and silenced. FE-6 recalled that in one case, senior management attempted to "bury" a sales representative who turned in their manager for pressuring them to sell PuraPly XT on the spread.

This was not an isolated incident, as FE-6 recalled that as many as 15 sales representatives were retaliated against for reporting their managers' illegal conduct with respect to the Company's marketing practices. The same occurred to FE-6 when FE-6 reported this illegal conduct to the Director of Compliance. Notably, according to Organogenesis's website, "[t]he Compliance Officer is also charged with reporting compliance-related issues directly to the organization's senior management." However, even though FE-6 sent copies of marketing materials to Compliance demonstrating the Company's illegal marketing practices, and also met with Compliance and made it clear that the Company's marketing practices were improper, Organogenesis failed to take any action to address its marketing practices. Rather, Organogenesis's management retaliated against FE-6 in response to these complaints. FE-6 also wrote a letter to Gillheeney and explained that Gillheeney was placing too much pressure on the sales force to grow sales, and that this pressure had led the sales representatives to engage in misconduct. However, FE-6's letter went unanswered.

382. FE-6 specifically recalled attending a compliance training in Denver, Colorado in 2022. FE-6 stated that after the training session, FE-6 confronted Senior Director of Sales Darren McBee regarding Organogenesis's practice of marketing the spread. FE-6 was told by McBee that "[FE-6] better shut [FE-6]'s mouth before somebody shuts it for [them]."

383. Defendants' systematic silencing of employees who reported the Company's illegal marketing activities supports an inference that Defendants knew or recklessly disregarded that Organogenesis's sales force was engaged in the Medicare Reimbursement Scheme. This is confirmed by the fact that senior sales managers directed and encouraged sales representatives to market the spread for Affinity and PuraPly XT while the temporary reimbursement rates existed.

4. Defendants' Scheme To Pull Affinity From The Market In 2019 And Reintroduce The Product In 2020 Supports A Strong Inference Of Defendants' Scienter

384. As alleged in this Complaint, Defendants' Medicare Reimbursement Scheme was a coordinated and deliberate strategy hatched in 2019 when Affinity was slated to receive a low ASP. On May 10, 2019, during the 1Q2019 earnings call, Gillheeney told market analysts that Affinity was being withdrawn from the market until the Company could contract with another manufacturer and bring Affinity production to commercial scale—likely 1Q2020.

385. Unbeknownst to the market, however, the true reason for suspending Affinity's sales was that Affinity was going to receive a low ASP. The CMS ASP pricing files for 2019 confirm that Affinity received an ASP of ***just $176.07 per square centimeter*** effective April 1, 2019. FE-2 stated that the decision to withdraw Affinity from the market was part of Organogenesis's efforts to game Medicare reimbursement. FE-2 recalled that at the time Affinity was withdrawn from the market, the direction from senior management was to explain that there were difficulties with the Company's manufacturer and that Organogenesis was looking to bring the manufacturing in-house. However, when Affinity was put back on the market, FE-2 stated that the Company used the same manufacturer.

386. The fact that Gillheeney misstated the true reasons for Affinity being suspended from the market supports a strong inference of Defendants' scienter to perpetuate their scheme.

387. The 2020 10-K, signed by both Gillheeney, and filed with the SEC on March 16, 2021, repeated this falsehood, claiming that:

> ***In the first quarter of 2019, however, we suspended production of our product Affinity due to production issues at one of our suppliers. As this was our sole supplier of Affinity, it resulted in a disruption of our production capabilities. We identified an alternate supplier and were able to resume commercial-scale production in the second quarter of 2020.***

388. When Affinity was eventually reintroduced in late 1Q2020, as alleged in this Complaint, it no longer had an ASP, and the Company targeted its marketing efforts in regions where MACs were reimbursing at ***over $1,000 dollars per square centimeter***, without physical invoices from physicians.

C. The Knowledge Of Organogenesis Employees Concerning The Company's Reimbursement Marketing Practices Is Imputed To Organogenesis

389. By virtue of their high-level positions as the most senior officers of the Company, participation in and awareness of Organogenesis's day-to-day operations, and control over the issuance of the false or misleading statements alleged above in Section V, the knowledge or recklessness of Defendants Gillheeney and Francisco concerning Defendants' false or misleading statements is imputed to Organogenesis.

390. In addition, the knowledge or recklessness of other senior employees and managers concerning the Company's unsustainable Medicare Reimbursement Scheme with respect to Affinity and PuraPly XT is also imputed to Organogenesis. As alleged above in Section IV.H, Organogenesis management openly discussed the Company's strategy of marketing the spread for Affinity and PuraPly XT while the products lacked an ASP, directed the Company's sales force to market Affinity and PuraPly XT based on the reimbursement spread, encouraged its sales force to use illegal marketing materials in the process, and instructed sales representatives to conceal evidence of these marketing materials. The widespread nature of the marketing misconduct is further evidence by Organogenesis's "Assurance Program"—a cross-functional program that engages employees from across the Company for the purpose of ensuring that a certain wound will be reimbursed by Medicare. Each of these facts supports an inference that Organogenesis knew or recklessly disregarded that its sales force was engaged in the unsustainable Reimbursement Marketing Scheme.

D. Affinity and PuraPly XT Sales Were Core Operations Of The Company

391. The sale of Affinity and PuraPly XT were part of Organogenesis's core operations during the Class Period, supporting an inference that Defendants knew or recklessly disregarded information concerning the true reasons for the dramatic increase in sales of these products, and the subsequent decline in Affinity sales after Affinity received an ASP. Defendants' statements repeatedly attributed the Company's AWC net revenue growth to the sale of Affinity and PuraPly XT. The importance of revenue generated from the sale of Affinity and PuraPly XT is also underscored by Organogenesis's reliance on this revenue to offset the loss of revenue from the expiration of PuraPly and PuraPly AM's pass-through status.

392. For example, when reporting the Company's 66% year-over-year AWC revenue growth for 3Q2020, Gillheeney stated that Affinity "***was the largest contributor to growth again in Q3***." Similarly, when reporting the Company's 43% year-over-year revenue growth for 4Q2020, Gillheeney stated that "***sales of amniotic products were the largest contributor to the company's growth again in Q4***" and that PuraPly XT "***contributed to our ability to drive strong sales performance in the fourth quarter***." Indeed, for every quarter of the Class Period, AWC net revenue—driven by Affinity and PuraPly XT—was responsible for ***88%-94%*** of Organogenesis's total net revenues.

393. In May 2021, Defendants also raised the Company's financial guidance for FY 2021 by approximately $48 million in light of Affinity and PuraPly XT's sales performance. Indeed, both Defendant Gillheeney and Defendant Francisco explained that they were confident in the guidance increase because Affinity sales "***continue to grow***" and "***the strength in PuraPly over the last 2 quarters really gives up the confidence to increase that by quite a bit and strength of the amnions as well***." The clear importance of Affinity to Organogenesis's financial

performance is further confirmed by the drastic cut to Organogenesis's 2022 amniotic revenue guidance after an ASP was re-established in 1Q2022, as well as the related downward revision to the Company's total net revenue guidance for fiscal year 2022.

394. The critical importance of Affinity and PuraPly XT sales is further illustrated by the fact that Defendants attempted to assuage investors' concerns regarding the loss of PuraPly pass-through reimbursement status by telling the market that any loss in revenue would be offset by revenue from Affinity and PuraPly XT sales. For example, prior to the Class Period, in March 2020, Gillheeney told the market that Affinity and PuraPly XT would "***help absorb some of the PuraPly ASP decline***." On September 16, 2020, just two weeks before PuraPly's pass-through status expiration, Gillheeney stated that "***PuraPly itself will do pretty well with the offsets that I mentioned in the office and XT. And then our other product portfolio, including Affinity and the rest of our portfolio, will absorb any ASP decline in Q4***."

395. Defendants also continually touted the Company's "***office strategy***" as an offset to the loss of PuraPly pass-through revenue throughout the Class Period. On November 9, 2020, Gillheeney told the market that Organogenesis did not see a decline in PuraPly revenues because the "***[PuraPly] XT line extension in the office is doing extremely well***." On March 16, 2021 Gillheeney stated that the Company's "***growth strategy in the office is our fourth area of notable strength***." And on August 9, 2021, Gillheeney stated that Organogenesis was "***continuing our efforts to further penetrate the office channel with offerings***."

396. Defendants' statements highlighting the importance of Affinity and PuraPly XT to the Company's revenue growth, and to its strategy to increase sales in the office channel as a means of offsetting the loss of PuraPly pass-through revenue, support an inference that they knew or recklessly disregarded information concerning the Company's Medicare Reimbursement Scheme,

which they failed to disclose was one of the primary drivers of these products' sales during the Class Period.

VIII. LOSS CAUSATION

397. Plaintiffs and Class members were damaged as a result of Defendants' fraudulent conduct as alleged in this Complaint. During the Class Period, Defendants engaged in a scheme to deceive investors by issuing a series of material misrepresentations and omissions of material facts, trends, events, and uncertainties required to be disclosed, relating to, among other things: (i) Organogenesis's practice of marketing the reimbursement spread for Affinity and PuraPly XT and the impact that this unsustainable practice had on the Company's reported revenue; (ii) the factors contributing to the Company's sales growth and apparent ability to offset the loss of revenue from the expiration of PuraPly's pass-through status; (iii) the impact that changes in reimbursement for Affinity had on the Company's ability to generate sustainable sales growth; (iv) the Company's compliance with healthcare laws and regulations intended to prevent fraud, waste, and other abusive practices; and (v) Organogenesis's ability to compete on the basis of the clinical benefits of its products, as opposed to the reimbursement physicians received for using the Company's products.

398. Defendants' material misstatements and omissions artificially inflated and/or maintained the artificial inflation in the market price of Organogenesis's publicly traded common stock. The artificial inflation in Organogenesis's common stock price was removed when the facts and risks misstated, omitted, and/or concealed by Defendants were revealed to the market. Such corrective information was disseminated through public disclosures on October 12, 2021 and August 9, 2022. Each of these disclosures partially revealed relevant facts or concealed risks regarding the false or misleading nature of Defendants' material misstatements and omissions,

thereby removing artificial inflation in the price of Organogenesis's publicly traded stock, causing economic injury to Plaintiffs and other members of the Class.

399. Unknowingly and in reliance upon Defendants' materially false or misleading statements and omissions, Class Members purchased Organogenesis common stock at artificially inflated prices on the NASDAQ exchange. But for Defendants' misrepresentations, omissions, and fraudulent scheme, Plaintiffs and other Class members would not have purchased or otherwise acquired Organogenesis common stock at the artificially inflated prices at which the stock traded during the Class Period.

400. The relevant truth regarding Defendants' fraud was revealed beginning on October 12, 2021. On this date, the VIC Report alleged, among other things, that the Company was inflating its revenue growth by "[m]arketing the spread" for Affinity and PuraPly XT to physicians, that this reimbursement scheme "drove almost all of Organogenesis growth," and had allowed the Company to offset the loss of revenue from the expiration of PuraPly's pass-through status. Further, the VIC Report alleged that "ORGO's Affinity game ended on 7/1/21 when CMS set a price of $584/sq cm. This means that instead of collecting a large spread and making thousands in profit per use, Doctors will only be reimbursed for the cost of the product plus 6%, which is the industry standard." The VIC Report alleged that Affinity's removal from the ASP price list in 4Q2021 meant there was uncertainty regarding its future reimbursement and whether the Company would be able to continue marketing the reimbursement spread based on higher reimbursement rates by the MACs.

401. In response to the VIC Report, Organogenesis's stock price declined $1.70 per share, or ***14.11%***, from a closing price of $12.05 per share on October 11, 2021, to a closing price of $10.35 per share on October 12, 2021, on heavy trading volume. Analysts and market

commentators attributed the decline in the Company's stock price to the information disclosed in the VIC Report. However, analysts did not fully credit the VIC Report's allegations. For example, BTIG stated on October 14, 2021 that Organogenesis's "shares are attractive following the sell-off." BTIG also attributed the lack of an ASP in 4Q2021 to a "clerical error," stating that "we continue to think CMS made a clerical error around Affinity and could publish its next quarterly file for 1Q21 in the coming weeks and, if Affinity is included, a lot of the questions raised go away."

402. During the Company's earnings calls on November 9, 2021, March 1, 2022, and May 10, 2022, Defendants continued to falsely attribute the performance of the Company's AWC segment to factors other than Organogenesis's marketing of the reimbursement spread for Affinity and PuraPly XT, and falsely attributed the declines in Affinity revenues to factors unrelated to Defendants' fraud. Analysts accepted Defendants' explanations. For example, on March 1, 2022, SVB Leerink analysts stated that Organogenesis's:

> **[R]eimbursement noise [is] seemingly behind us . . . we hope that investors will increasingly shift focus to the positive underlying growth drivers of the business, which we believe will return the company to a sustainable double-digit sales growth trajectory . . . . These growth drivers include the amnion portfolio (i.e., Affinity) . . . which widen[s] ORGO's competitive moat and successfully position[s] the company for sustained above-market growth**.

(Emphasis in original).

403. On August 9, 2022, Organogenesis reported a ***39%*** year-over-year decline in net revenues from the sale of non-PuraPly products. During the 2Q2022 earnings call on August 9, 2022, Gillheeney disclosed that the reported decline in non-PuraPly revenue was the result of a ***46% decline*** year-over-year in revenue from amniotic products. Defendant Francisco announced revised FY 2022 amniotic net revenue guidance that projected a ***15% decline*** year-over-year, a dramatic revision compared to the previously announced 12% growth. During the Q&A portion of

the 2Q2022 earnings call, Gillheeney admitted that Organogenesis could not compete based solely on the clinical benefits of its products, stating that "what we've seen is more of the smaller players in the space that mostly amniotic products, and those products are competing with our products, competing for share of voice and we just see a lot more of them. ***I think the transient component of it is with no published ASPs, that competition can continue in the -- particularly in the office***."

404. In response to the Company's disclosures on August 9, 2022, Organogenesis's stock price fell $1.20 per share, or ***20%***, from a closing price of $6.01 per share on August 9, 2022, to a closing price of $4.81 per share on August 10, 2022, on heavy trading volume. Multiple analysts downgraded Organogenesis's stock price or lowered their price targets in response to the information disclosed by the Company on August 9, 2022.

405. The declines in Organogenesis's common stock price on October 12, 2021 and August 10, 2022 are directly attributable to the market absorbing information that corrected, or reflected the materialization of risks concealed by, Defendants' material misrepresentations or omissions. Plaintiffs and other Class members suffered economic losses as Organogenesis's common stock price fell in response to the disclosure of new information concealed by the Defendants' misstatements and omissions on these dates. These price declines were a direct result of the materially false or misleading statements and omissions alleged in this Complaint. It was entirely foreseeable that Defendants' materially false or misleading statements and omissions would artificially inflate and/or maintain the price of Organogenesis's common stock. It was also foreseeable to Defendants that the revelation of the truth would cause the price of the Company's common stock to fall when the artificial inflation caused or maintained by Defendants' misstatements and omissions was removed. Thus, the stock price decline described above was

directly and proximately caused by Defendants' materially false or misleading statements and omissions.

IX. CLASS ACTION ALLEGATIONS

406. Plaintiffs bring this action on their 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 Organogenesis from August 10, 2020 through August 9, 2022, inclusive, and were damaged thereby. Excluded from the Class are: (i) Defendants; (ii) present or former executive officers of Organogenesis or any of Organogenesis's subsidiaries or affiliates, members of Organogenesis's Board of Directors, and members of the immediate families of each of the foregoing (as defined in 17 C.F.R. § 229.404, Instructions (1)(a)(iii) & (1)(b)(ii)); (iii) any of the foregoing individuals' and entities' legal representatives, heirs, successors, or assigns; and (iv) any entity in which any Defendant has a controlling interest.

407. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Organogenesis had more than 130 million shares of common stock outstanding and actively trading on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery and procedure, Plaintiffs believe 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.

408. Plaintiffs' 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 alleged in this Complaint. Plaintiffs have no interests that are adverse or antagonistic to the interests of other Class members.

409. Plaintiffs will fairly and adequately protect the interests of the members of the Class. Plaintiffs have retained counsel that is competent and experienced in class and securities litigation.

410. 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:

a. whether Defendants violated the federal securities laws by their acts and omissions as alleged in this Complaint;

b. whether Defendants' statements to the investing public during the Class Period misrepresented and/or omitted material facts;

c. whether and to what extent the market price of Organogenesis's common stock was artificially inflated during the Class Period due to the misrepresentations and/or omissions alleged in this Complaint;

d. whether Defendants named under Section 10(b) of the Exchange Act acted with the requisite level of scienter;

e. whether reliance may be presumed pursuant to the fraud-on-the-market doctrine (*see infra* Section X) and/or the *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972) presumption;

f. whether the members of the Class have sustained damages as a result of the conduct complained of in this Complaint and, if so, the proper measure of damages; and

g. whether Defendants Gillheeney and Francisco were controlling persons of the Company.

411. 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.

X. THE FRAUD ON THE MARKET PRESUMPTION OF RELIANCE APPLIES

412. At all relevant times, the market for Organogenesis's common stock was efficient for the following reasons, among others: it was listed and actively traded on the NASDAQ, a highly efficient and automated market; as a regulated issuer, Organogenesis filed periodic public reports with the SEC, in addition to the Company's frequent voluntary public dissemination of information; Organogenesis regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of newswire services, and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and Organogenesis was followed by numerous securities analysts employed by major brokerage firms who wrote reports that were distributed to those brokerage firms' sales forces and certain customers, and which were publicly available and entered the public marketplace.

413. As a result of the foregoing, the market for Organogenesis's common stock promptly digested current information regarding Organogenesis from all publicly available sources and reflected such information in the price of Organogenesis's common stock. Under these circumstances, all purchasers of Organogenesis's common stock during the Class Period suffered

similar injury through their purchase of Organogenesis's common stock at artificially inflated prices, and a presumption of reliance applies.

414. Further, at all relevant times, Plaintiffs 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. Plaintiffs and the other members of the Class would not have purchased or otherwise acquired Organogenesis's 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, Plaintiffs and other members of the Class are entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972).

XI. THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE ARE INAPPLICABLE

415. The Private Securities Litigation Reform Act of 1995'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 in this Complaint.

416. None of the statements complained of in this Complaint was a forward-looking statement. Each was a historical statement or a statement of purportedly current facts and conditions at the time the statement was made.

417. To the extent that any materially false or misleading statement alleged in this Complaint, 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.

418. To the extent that any materially false or misleading statement alleged in this Complaint, 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.

419. To the extent that the statutory safe harbor may apply to any materially false or misleading statement alleged in this Complaint, 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 Organogenesis who knew that such statement was false or misleading.

XII. CAUSES OF ACTION

COUNT I

Violations Of Section 10(b) Of The Exchange Act And SEC Rule 10b-5 Promulgated Thereunder Against All Defendants

420. Plaintiffs incorporate ¶¶ 1-419 by reference. During the Class Period, Defendants disseminated or approved the false or misleading statements and omissions of material fact specified above, which they knew or recklessly disregarded were misleading in that the statements contained misrepresentations and failed to disclose material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading, thereby violating Section 10(b) of the Exchange Act and SEC Rule 10b-5. Defendants also violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 in that they employed devices, schemes, and artifices to defraud and carried out a plan, scheme, and course of conduct which operated as a fraud and deceit

upon those who purchased or otherwise acquired the Company's common stock during the Class Period.

421. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Organogenesis's common stock. Plaintiffs and the Class would not have purchased Organogenesis's common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by the Defendants' false or misleading statements and omissions of material fact. Plaintiffs and other Class members suffered actual economic loss and were damaged when the trading price of Organogenesis's common stock declined upon the public disclosure of new information correcting Defendants' false or misleading statements and omissions regarding: (i) Organogenesis's practice of marketing the reimbursement spread for Affinity and PuraPly XT and the impact that this unsustainable practice had on the Company's reported revenue; (ii) the factors contributing to the Company's sales growth and apparent ability to offset the loss of revenue from the expiration of PuraPly's pass-through status; (iii) the impact that changes in reimbursement for Affinity had on the Company's ability to generate sustainable sales growth; (iv) the Company's compliance with healthcare laws and regulations intended to prevent fraud, waste, and other abusive practices; and (v) Organogenesis's ability to compete on the basis of the clinical benefits of its products, as opposed to the reimbursement physicians received for using the Company's products.

422. This claim is brought within the applicable statute of limitations.

COUNT II

Violations Of Section 20(a) Of The Exchange Act Against Defendants Gillheeney And Francisco

423. Plaintiffs incorporate ¶¶ 1-422 by reference. During their tenures as officers of Organogenesis, Defendants Gillheeney and Francisco were controlling persons of Organogenesis

within the meaning of Section 20(a) of the Exchange Act. By reason of their positions of control and authority as officers of Organogenesis, Defendants Gillheeney and Francisco had the power and authority to cause Organogenesis to engage in the conduct complained of in this Complaint. Defendants Gillheeney and Francisco were able to, and did, control, directly and indirectly, the decision-making of Organogenesis, including the content and dissemination of Organogenesis's public statements and filings described in this Complaint, and they caused the dissemination of the materially false or misleading statements and omissions as alleged in this Complaint.

424. In their capacities as senior corporate officers of Organogenesis, and as more fully described above, Defendants Gillheeney and Francisco participated in the misstatements and omissions alleged above. Indeed, Defendants Gillheeney and Francisco had direct and supervisory involvement in the day-to-day operations of the Company, and had access to non-public information regarding Organogenesis's sales and marketing practices, the cost of its products and rate at which its products were reimbursed by Medicare, the reasons for growth and declines in the sales of its products, and the Company's compliance with relevant healthcare fraud, waste and abuse laws with respect to the sales and marketing of its products. Defendants Gillheeney and Francisco also had the ability to influence and direct and did influence and direct the activities of the Company and its employees in their violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5. As a result, Defendants Gillheeney and Francisco were control persons within the meaning of Section 20(a) of the Exchange Act.

425. As alleged above, Organogenesis violated Section 10(b) of the Exchange Act. By virtue of their positions as controlling persons, Defendants Gillheeney and Francisco are liable under Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as Organogenesis is liable to Plaintiffs and the other members of the Class.

426. This claim is brought within the applicable statute of limitations.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

a. determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined in this Complaint, and a certification of Plaintiffs as class representatives pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiffs' counsel as Lead Counsel;

b. awarding compensatory damages in favor of Plaintiffs and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon;

c. awarding Plaintiffs and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

d. awarding Plaintiffs and the other Class members such other relief as this Court may deem just and proper.

XIV. JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury.

DATED: October 24, 2022

Respectfully submitted,

KESSLER TOPAZ MELTZER & CHECK, LLP

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CERTIFICATE OF SERVICE

I, Sharan Nirmul, hereby certify that on October 24, 2022, I authorized a true and correct copy of the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF System, which will send notification of such public filing to all counsel registered to receive such notice.

/s/ Sharan Nirmul
Sharan Nirmul