UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

CARL JOHAN DROTT, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. SANA BIOTECHNOLOGY, INC., STEVEN D. HARR, and NATHAN HARDY, Defendants.	Case No. 2:25-cv-512 CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff Carl Johan Drott ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Sana Biotechnology, Inc. ("Sana" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet.

Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Sana securities between March 17, 2023 and November 4, 2024, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against Sana and certain of its top officials.

2. Sana is a biotechnology company that develops *ex vivo* and *in vivo* cell engineering programs to purportedly revolutionize treatment across a broad array of therapeutic areas with unmet treatment needs, including, *inter alia*, oncology, diabetes, central nervous system ("CNS") disorders, and B-cell-mediated autoimmune diseases. The Company's product candidates include, among others, SC291 for the treatment of, *inter alia*, B-cell malignancies; SC379 for the treatment of certain CNS disorders; and SG299, which is part of the Company's fusogen platform for *in vivo* gene delivery for the treatment of hematologic malignancies.

3. Despite the attendant financial burden of developing numerous product candidates for a wide array of therapeutic areas, throughout the Class Period, Defendants repeatedly touted Sana's financial wherewithal to maintain its current operations and advance its existing product candidates. Simultaneously, Defendants consistently represented to investors that they were committed to financing and advancing SC291 (in oncology), SC379, and SG299. For example, throughout the Class Period, Defendants repeatedly touted those product candidates' purportedly promising preclinical and/or clinical results, upcoming data readouts, and regulatory events and

timelines, including, *inter alia*, the preparation, submission, and/or approval of multiple investigational new drug applications ("INDs") with the U.S. Food and Drug Administration ("FDA").

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding Sana's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Sana was at significant risk of having insufficient funds to maintain its current operations and advance one or more of its product candidates; (ii) SC291 in oncology, SC379, and SG299 were less promising than Defendants had led investors to believe; (iii) in order to preserve cash and advance its more promising product candidates, Sana was likely to decrease funding for and/or discontinue SC291 in oncology, SC379, and SG299, as well as significantly reduce its headcount; (iv) accordingly, Defendants overstated Sana's financial capacity to maintain its current operations and advance its existing product candidates; and (v) as a result, Defendants' public statements were materially false and/or misleading at all relevant times.

5. On October 10, 2023, during after-market hours, Sana issued a press release announcing that it "will reduce near-term spend on its fusogen platform for *in vivo* gene delivery" and instead "[i]ncreas[e its] focus on [its] *ex vivo* cell therapy platform[,]" thereby "postpon[ing] the planned SG299 IND" while "decreas[ing] its expected forward operating burn." Sana further disclosed a "29% headcount reduction" that, in tandem with the "decreased expenses related to the fusogen platform[,]" would keep its "2024 operating cash burn . . . below $200 million[,]" thereby "allowing [its] current cash position to extend further into 2025." The same press release also quoted Defendant Steven D. Harr ("Harr"), Sana's President and Chief Executive Officer ("CEO"), as stating that "[w]e need to ensure that we have a financeable cost structure with . . .

emerging opportunities factored in," and that "this strategic re-positioning enables us to deliver significant clinical data across multiple drug candidates with the current balance sheet."

6. On this news, Sana's stock price fell $0.34 per share, or 8.95%, to close at $3.46 per share on October 11, 2023.

7. Then, on November 4, 2024, during after-market hours, Sana issued a press release announcing that it "will suspend development of both SC291 in oncology and of SC379 . . . as it seeks partnerships for these programs" and instead "increase its investment in its type 1 diabetes program with the cash savings from these changes[,]" thereby "extend[ing] its expected cash runway into 2026." The same press release also quoted Defendant Harr as stating that "we need to ensure that we are directing our investments into the areas where we believe we can have the greatest impact for patients" and that "[t]his modified strategy will also help us reduce our cash burn but comes with the necessity of parting with some talented and valued colleagues."

8. On this news, Sana's stock price fell $0.37 per share, or 9.84%, to close at $3.39 per share on November 5, 2024.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

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

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

12. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Sana is headquartered in this District, Defendants conduct business in this District, and a significant portion of Defendants' activities took place within this District.

13. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

14. Plaintiff, as set forth in the attached Certification, acquired Sana securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

15. Defendant Sana is a Delaware corporation with principal executive offices located at 188 East Blaine Street, Suite 400, Seattle, Washington 98102. Sana's common stock trades in an efficient market on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "SANA."

16. Defendant Harr has served as Sana's President and CEO at all relevant times.

17. Defendant Nathan Hardy ("Hardy") served as Sana's Chief Financial Officer at all relevant times until October 4, 2024.

18. Defendants Harr and Hardy are collectively referred to herein as the "Individual Defendants."

19. The Individual Defendants possessed the power and authority to control the contents of Sana's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Sana's SEC filings and press releases alleged herein to

be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Sana, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

20. Sana and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

21. Sana is a biotechnology company that develops *ex vivo* and *in vivo* cell engineering programs to purportedly revolutionize treatment across a broad array of therapeutic areas with unmet treatment needs, including, *inter alia*, oncology, diabetes, CNS disorders, and B-cell-mediated autoimmune diseases. The Company's product candidates include, among others, SC291, a hypoimmune-modified CD19 targeted allogeneic chimeric antigen receptor ("CAR") T ("CAR-T") therapy for, *inter alia*, B-cell malignancies, including non-Hodgkin's lymphoma ("NHL") and chronic lymphoblastic leukemia ("CLL"); SC379, a pluripotent stem cell-derived glial progenitor cell ("GPC") therapy to deliver healthy allogeneic GPCs to patients with certain CNS disorders; and SG299, a CD8-targeted fusosome that delivers a CD19 CAR to target CD19+ cancer cells for the treatment of hematologic malignancies.

22. Despite the attendant financial burden of developing numerous product candidates for a wide array of therapeutic areas, throughout the Class Period, Defendants repeatedly touted

Sana's financial wherewithal to maintain its current operations and advance its existing product candidates. Simultaneously, Defendants consistently represented to investors that they were committed to financing and advancing SC291 (in oncology), SC379, and SG299. For example, throughout the Class Period, Defendants repeatedly touted those product candidates' purportedly promising preclinical and/or clinical results, upcoming data readouts, and regulatory events and timelines, including, *inter alia*, the preparation, submission, and/or approval of multiple INDs with the FDA.

Materially False and Misleading Statements Issued During the Class Period

23. The Class Period begins on March 17, 2023. On March 16, 2023, during after-market hours, Sana issued a press release announcing its fourth quarter and full year 2022 financial results and business updates (the "4Q/FY22 Earnings Release"). Therein, Sana stated, *inter alia*, that its "[c]urrent cash position [of $434 million] enables for runway into 2025[.]"

24. In addition, the 4Q/FY22 Earnings Release quoted Defendant Harr as stating, in relevant part:

> The recent clearance of our first IND – for SC291, a hypoimmune-modified, CD19-targeted allogeneic CAR T therapy for patients with B-cell malignancies – offers the first of several near-term opportunities to understand our hypoimmune technology in patients and its potential to move forward important medicines . . . . We also expect to file INDs in oncology for an additional allogeneic CAR T program and our first *in vivo* fusogen program targeting T cells. Our balance sheet gives us the financial strength to build on our execution in 2022 and push our R&D portfolio forward.

25. With respect to Sana's development of SC291 in oncology, the 4Q/FY22 Earnings Release stated, in relevant part, that "[t]he SC291 IND has been cleared," and that its "[s]uccess unlocks potential value of a broader hypoimmune-modified allogeneic CAR T platform[.]"

26. With respect to SC379, the 4Q/FY22 Earnings Release stated, in relevant part, that Sana set "a goal [for] a 2024 IND."

27. With respect to SG299, the 4Q/FY22 Earnings Release stated, in relevant part, that Sana's "goal is to file an IND this year to study this drug candidate in patients with B cell malignancies"; and that "SG299 has at least a 50X improvement in product potency, which Sana believes has the potential to translate into better efficacy, safety, and long-term manufacturability."

28. Also on March 16, 2023, during after-market hours, Sana filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2022 (the "2022 10-K"). With respect to Sana's purported financial wherewithal to maintain its current operations and advance its existing product candidates, the 2022 10-K stated, in relevant part, that "[b]ased on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months"; and that "[b]ased on our current timelines for our lead programs, we believe our cash runway will enable multiple data readouts across our platforms."

29. With respect to SC379, the 2022 10-K stated, *inter alia*:

> [SC379] has the potential to treat myelin- and glial-based disorders, which represent a broad group of debilitating neurological disorders, such as multiple sclerosis (MS) and a number of neurodegenerative disorders, none of which have effective treatment alternatives. We intend to develop our stem cell-derived GPC therapy for secondary progressive MS, Pelizaeus-Merzbacher disease (PMD) other disorders of myelin, Huntington's disease, and other astrocytic diseases. Our goal is to submit three INDs for SC379 as early as 2024.

30. With respect to SG299, the 2022 10-K stated, *inter alia*:

> Our most advanced CAR T cell fusosome product candidate is SG299 . . . . This program is an opportunity to develop potential product candidates that can expand access to CAR T cell therapy to patients in need . . . . . Our goal is to submit an IND for SG299 in 2023. Initial clinical success would unlock meaningful standalone value in the development of SG299 in NHL, CLL, and ALL, support and validate the expansion of our *in vivo* CAR T efforts, and support the validation of

> our fusogen platform overall, which we are pursuing in therapeutic areas beyond oncology with the goal of targeted delivery of DNA and gene editing machinery to specific cells *in vivo.*

31. Appended as exhibits to the 2022 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein the Individual Defendants certified that the 2022 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report"; and that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the [Company] as of, and for, the periods presented in this report[.]"

32. On May 8, 2023, Sana issued a press release announcing its first quarter 2023 financial results and business updates (the "1Q23 Earnings Release"). Therein, Sana stated, *inter alia*, that its "[c]ash position of $355 million [is] expected to support activities through multiple data readouts and last into 2025[.]"

33. In addition, the 1Q23 Earnings Release quoted Defendant Harr as stating, in relevant part:

> Our initial human studies using Sana's hypoimmune technology remain on track, as we have begun enrolling patients in our SC291 trial and expect to deliver data from two clinical studies in 2023 . . . . We are also making progress in our earlier-stage pipeline and are on pace to file two additional INDs later this year and potentially three more in 2024 . . . . Our capital position and people give us the resources for multiple data read-outs with our current balance sheet[.]

34. With respect to Sana's development of SC291 in oncology, the 1Q23 Earnings Release stated, in relevant part, that Sana "[r]eceived clearance from the [FDA] to initiate a first-in-human Phase 1 study of SC291 in patients with B-cell malignancies (ARDENT)"; "[b]egan enrollment in the ARDENT Phase 1 study"; and was "[g]ranted Fast Track Designation for SC291

by the FDA for the treatment of relapsed/refractory (r/r) large B-cell lymphoma and r/r chronic lymphocytic leukemia"; while touting that "SC291 has the potential to serve as clinical proof-of-platform for other hypoimmune-modified CAR T cell candidates[.]"

35. With respect to SG299, the 1Q23 Earnings Release stated, *inter alia*, that Sana's "[g]oal [is] to submit [an] IND[] this year[.]"

36. Also on May 8, 2023, Sana filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2023 (the "1Q23 10-Q"). The 1Q23 10-Q contained the same statements as referenced in ¶ 28, *supra*, regarding Sana's purported financial wherewithal to maintain its current operations and advance its existing product candidates.

37. With respect to Sana's development of SC291 in oncology, the 1Q23 10-Q stated, in relevant part:

> We began enrolling patients in our Phase 1 clinical trial evaluating SC291 in B-cell malignancies, which we refer to as our ARDENT trial, and expect initial clinical data for this program in 2023. In addition, SC291 was granted Fast Track Designation by the FDA for the treatment of relapsed/refractory (r/r) large B-cell lymphoma and r/r chronic lymphocytic leukemia.

38. With respect to SG299, the 1Q23 10-Q stated, in relevant part:

> Our *in vivo* CAR T with CD8-targeted fusogen delivery of a CD19-targeted CAR (SG299) has the potential to generate CAR T cells *in vivo*, which would potentially reduce or eliminate the need for conditioning chemotherapy and complex CAR T cell manufacturing . . . . Recently, our scientists have made progress in a second-generation manufacturing process that results in at least a 50X improvement in product potency, which we believe has the potential to translate into better efficacy, safety, and long-term manufacturability. In the fourth quarter of 2022, we decided to bring this second-generation process forward for our first-in-human studies in patients with B-cell malignancies. We plan to file an IND for SG299 in 2023.

39. Appended as exhibits to the 1Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 31, *supra*, signed by the Individual Defendants.

40. On August 3, 2023, Sana issued a press release announcing its second quarter 2023 financial results and business updates (the "2Q23 Earnings Release"). Therein, Sana stated, *inter alia*, that its "[c]ash position of $325.9 million [is] expected to support activities through multiple data readouts and last into 2025[.]"

41. In addition, the 2Q23 Earnings Release quoted Defendant Harr as stating, in relevant part, that "[w]e are on track to advance our emerging clinical pipeline and file multiple additional INDs this year, and we have the balance sheet to enable multiple clinical data readouts from our pipeline."

42. With respect to Sana's development of SC291 in oncology, the 2Q23 Earnings Release stated, in relevant part, that the Company is "[e]nrolling patients in ARDENT, the SC291 Phase 1 clinical trial in B-cell malignancies, with initial data expected this year[.]"

43. With respect to SG299, the 2Q23 Earnings Release continued to assert that the Company's "[g]oal [is] to submit [an] IND[] this year[.]"

44. Also on August 3, 2023, Sana filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2023 (the "2Q23 10-Q"). The 2Q23 10-Q contained the same statements as referenced in ¶¶ 28 and 37-38, *supra*, regarding Sana's purported financial wherewithal to maintain its current operations and advance its existing product candidates; and its development of SC291 in oncology and SG299.

45. Appended as exhibits to the 2Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 31, *supra*, signed by the Individual Defendants.

46. The statements referenced in ¶¶ 23-45 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about Sana's business, operations, and prospects. Specifically, Defendants made

false and/or misleading statements and/or failed to disclose that: (i) Sana was at significant risk of having insufficient funds to maintain its current operations and advance one or more of its product candidates; (ii) SC291 in oncology, SC379, and SG299 were less promising than Defendants had led investors to believe; (iii) in order to preserve cash and advance its more promising product candidates, Sana was likely to decrease funding for and/or discontinue SC291 in oncology, SC379, and SG299, as well as significantly reduce its headcount; (iv) accordingly, Defendants overstated Sana's financial capacity to maintain its current operations and advance its existing product candidates; and (v) as a result, Defendants' public statements were materially false and/or misleading at all relevant times.

The Truth Begins to Emerge

47. On October 10, 2023, during after-market hours, Sana issued a press release (the "October 2023 Press Release") announcing that it would reduce funding for its fusogen platform for *in vivo* gene delivery, thereby postponing the planned SG299 IND, as well as reduce its headcount by 29%, stating, in relevant part:

> *Reducing near-term investment on fusogen in vivo delivery platform clinical and preclinical programs, including delaying SG299 IND (in vivo CD19 CAR T)*
>
> *2024 operating cash burn expected below $200 million following 29% headcount reduction and decreased expenses related to the fusogen platform*
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> * * *
>
> Sana . . . announce[s] a portfolio update, including both increased focus on its *ex vivo* cell therapy product candidates and an IND submission for SC291 in autoimmune diseases . . . . The company will reduce near-term spend on its fusogen platform for *in vivo* gene delivery, which postpones the planned SG299 IND and decreases its expected forward operating burn.
>
> * * *
>
> Sana expects 2024 operating cash burn to be below $200 million, allowing the current cash position to extend further into 2025. The strategic re-positioning will

> reduce headcount by 29% while allowing the company to invest in clinical capabilities across multiple indications in oncology, autoimmune diseases, type 1 diabetes, and [CNS] disorders.

(Emphases in original.)

48. In addition, the October 2023 Press Release quoted Defendant Harr as stating, in relevant part:

> We need to ensure that we have a financeable cost structure with . . . emerging opportunities factored in, and this strategic re-positioning enables us to deliver significant clinical data across multiple drug candidates with the current balance sheet. These changes unfortunately mean that many talented and valued colleagues will depart the company[.]

49. On this news, Sana's stock price fell $0.34 per share, or 8.95%, to close at $3.46 per share on October 11, 2023. Despite this decline in Sana's stock price, the Company's securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding, *inter alia*, Sana's financial wherewithal to maintain its current operations and advance its existing product candidates, as well as its commitment to advance SC291 in oncology and SC379.

50. For example, on November 8, 2023, Sana issued a press release announcing its third quarter 2023 financial results and business updates (the "3Q23 Earnings Release"). Therein, Sana stated, *inter alia*, that its "[c]ash position of $268.6 million [is] expected to last into 2025; supporting activities through multiple data readouts[.]"

51. In addition, the 3Q23 Earnings Release quoted Defendant Harr as stating, in relevant part, that "[w]ith our recent strategic repositioning, we expect 2024 operating cash burn to be below $200 million, enabling multiple clinical data readouts with our current balance sheet and a cash runway into 2025."

52. With respect to Sana's development of SC291 in oncology, the 2Q23 Earnings Release stated, in relevant part, that the Company continued "[e]nrolling [patients in the] Phase 1 ARDENT trial investigating SC291 in patients with refractory B-cell malignancies with initial data expected in 2023 and more robust data in 2024[.]"

53. Also on November 8, 2023, Sana filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2023 (the "3Q23 10-Q). The 3Q23 10-Q contained substantively the same statements as referenced in ¶ 28, *supra*, regarding Sana's purported financial wherewithal to maintain its current operations and advance its existing product candidates.

54. Likewise, the 3Q23 10-Q assured investors, *inter alia*, that "[b]ased on our current timelines for our lead programs, we believe our cash runway will enable multiple data readouts across our programs."

55. With respect to Sana's development of SC291 in oncology, the 3Q23 10-Q stated, in relevant part:

> We are enrolling and have commenced dosing patients in our Phase 1 clinical trial evaluating SC291 in B-cell malignancies, which we refer to as the ARDENT trial. We expect to present initial clinical data for this program in 2023 and more robust clinical data from multiple patients in 2024. In addition, SC291 was granted Fast Track Designation by the FDA for the treatment of relapsed/refractory (r/r) large B-cell lymphoma and r/r chronic lymphocytic leukemia.

56. Appended as exhibits to the 3Q23 10-Q were substantively the same SOX certifications as referenced in ¶ 31, *supra*, signed by the Individual Defendants.

57. On February 29, 2024, Sana issued a press release announcing its fourth quarter and full year 2023 financial results and business updates (the "4Q/FY23 Earnings Release"). Therein, Sana touted its "Q4 2023 cash position of $205.2 million and expected 2024 operating cash burn below $200 million"; while assuring investors that its "[r]ecent financing of $189.8

million in gross proceed combined with [its] existing cash position supports activities through multiple data readouts[.]"

58. In addition, the 4Q/FY23 Earnings Release quoted Defendant Harr as stating, in relevant part, that "[w]ith the ongoing trials in [*inter alia*] . . . ARDENT . . . we expect to treat 40-60 patients across multiple indications in 2024 and report data from each study"; and that "[w]ith the recent financing, we were able to strengthen the balance sheet, allowing us to continue to invest appropriately in moving our clinical pipeline forward."

59. With respect to Sana's development of SC291 in oncology, the 4Q/FY23 Earnings Release stated, in relevant part, that "[e]arly SC291 data from ongoing ARDENT trial in relapsed/refractory NHL and CLL suggest [its] ability to dose safely, demonstrate the desired immune evasion profile, and early clinical efficacy using hypoimmune technology"; and that "Sana expects to share more data in 2024."

60. Also on February 29, 2024, Sana filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2023 (the "2023 10-K"). The 2023 10-K contained substantively the same statements as referenced in ¶ 28, *supra*, regarding Sana's purported financial wherewithal to maintain its current operations and advance its existing product candidates.

61. With respect to Sana's development of SC291 in oncology, the 2023 10-K stated, in relevant part:

> As of January 5, 2024, the cut-off date for our early interim analysis [in the ARDENT trial], six patients had been dosed with SC291 and four patients were evaluable . . . . With respect to the four evaluable patients at these two dose levels, we observed no dose limiting toxicities, no SC291-related serious adverse events, and no incidences of graft versus host disease (GvHD). We also observed no cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) of any grade or any infections of Grade 3 or higher. Additionally, we observed at least a partial response in three of the patients,

> including ongoing complete responses in one patient from Dose Level 1 after three months and the patient from Dose Level 2 after two months.
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> * * *
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> We believe the initial ARDENT safety and clinical data described above support continued dose escalation and expansion within the trial to treat additional patients and monitor outcomes over longer periods of time. We expect to share additional data from the ARDENT trial in 2024.

62. With respect to Sana's development of SC379, the 2023 10-K stated, *inter alia*:

> We plan to submit an IND for SC379 following completion of safety and toxicology studies. We also plan to conduct definitive preclinical efficacy studies using the anticipated clinical product, which we believe will replicate studies that we have published . . . . We anticipate beginning human testing for SC379 in at least one indication as early as 2025.

63. Appended as exhibits to the 2023 10-K were substantively the same SOX certifications as referenced in ¶ 31, *supra*, signed by the Individual Defendants.

64. On May 8, 2024, Sana issued a press release announcing its first quarter 2024 financial results and business updates (the "1Q24 Earnings Release"). Therein, Sana touted its "[c]ompleted financing of $189.8 million in gross proceeds to support activities through multiple data readouts"; as well as its "[c]ash position of $311.1 million and expected 2024 operating cash burn below $200 million[.]"

65. In addition, the 1Q24 Earnings Release quoted Defendant Harr as stating, in relevant part, that "[w]e have four ongoing clinical trials in seven indications, and we remain on track to share initial data from each of these studies in 2024"; and that "[w]e strengthened our capital position with the financing in the first quarter, enabling us to share readouts from multiple clinical studies with our current balance sheet."

66. With respect to Sana's development of SC291 in oncology, the 1Q24 Earnings Release stated, in relevant part, that the Company's "[o]ngoing ARDENT trial for SC291

continues in B-cell malignancies"; that "[e]arly SC291 data from the ongoing ARDENT trial suggest the ability to dose safely, the desired immune evasion profile, and early clinical efficacy"; and that "[e]nrollment in this study continues, and Sana expects to share more data in 2024."

67. Also on May 8, 2024, Sana filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2024 (the "1Q24 10-Q"). The 1Q24 10-Q contained substantively the same statements as referenced in ¶ 28, *supra*, regarding Sana's purported financial wherewithal to maintain its current operations and advance its existing product candidates.

68. Appended as exhibits to the 1Q24 10-Q were substantively the same SOX certifications as referenced in ¶ 31, *supra*, signed by the Individual Defendants.

69. On August 8, 2024, Sana issued a press release announcing its second quarter 2024 financial results and business updates (the "2Q24 Earnings Release"). Therein, Sana touted its "[c]ash position of $251.6 million and expected 2024 operating cash burn below $200 million[.]"

70. With respect to Sana's development of SC291 in oncology, the 2Q24 Earnings Release stated, in relevant part, that "[e]arly SC291 data from the ongoing ARDENT trial suggest the ability to dose safely, the desired immune evasion profile, and early clinical efficacy"; and that "Sana is enrolling patients in [the] stud[y] and expects to share data in 2024."

71. With respect to SC379, the 2Q24 Earnings Release stated, in relevant part, that the Company "[p]ublished preclinical data in Nature Biotechnology showing that healthy transplanted human [GPC]s replaced diseased glial cell population in a preclinical model"; and that "[t]hese data establish additional proof-of-concept for the development of SC379 . . . as a potential therapy to deliver healthy allogeneic GPCs to patients with certain [CNS] disorders."

72. Also on August 8, 2024, Sana filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2024 (the "2Q24 10-Q"). The 2Q24 10-Q contained substantively the same statements as referenced in ¶ 28, *supra*, regarding Sana's purported financial wherewithal to maintain its current operations and advance its existing product candidates.

73. Appended as exhibits to the 2Q24 10-Q were substantively the same SOX certifications as referenced in ¶ 31, *supra*, signed by the Individual Defendants.

74. The statements referenced in ¶¶ 50-73 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about Sana's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Sana was at significant risk of having insufficient funds to maintain its current operations and advance one or more of its product candidates; (ii) SC291 in oncology and SC379 were less promising than Defendants had led investors to believe; (iii) in order to preserve cash and advance its more promising product candidates, Sana was likely to discontinue SC291 in oncology and SC379, as well as significantly reduce its headcount; (iv) accordingly, Defendants overstated Sana's financial capacity to maintain its current operations and advance its existing product candidates; and (v) as a result, Defendants' public statements were materially false and/or misleading at all relevant times.

The Truth Fully Emerges

75. On November 4, 2024, during after-market hours, Sana issued a press release (the "November 2024 Press Release") announcing that it would suspend development of SC291 in oncology and SC379 while seeking partnerships for these programs, stating, in relevant part:

> Sana . . . will prioritize future development activity for SC291 . . . in B-cell mediated autoimmune diseases (AID). The company will suspend development of both

> SC291 in oncology and of SC379 . . . as it seeks partnerships for these programs. Sana will increase its investment in its type 1 diabetes program with the cash savings from these changes.
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> With these changes, Sana extends its expected cash runway into 2026. Payments related to ongoing activities combined with the reduction in force may increase the 2024 operating cash burn above prior guidance of less than $200 million.

76. The November 2024 Press Release also quoted Defendant Harr as stating, in relevant part:

> [W]e need to ensure that we are directing our investments into the areas where we believe we can have the greatest impact for patients . . . . Greater focus on type 1 diabetes, SC291 in AID, and SC262 in refractory blood cancers will enhance our ability to present robust clinical data over the next twelve to eighteen months. This modified strategy will also help us reduce our cash burn but comes with the necessity of parting with some talented and valued colleagues.

77. On this news, Sana's stock price fell $0.37 per share, or 9.84%, to close at $3.39 per share on November 5, 2024.

78. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

Regulation S-K Items 105 and 303

79. Throughout the Class Period, Sana's periodic financial filings were required to disclose the adverse facts and circumstances detailed above under applicable SEC rules and regulations. Specifically, Item 105 of SEC Regulation S-K, 17 CFR § 229.105 ("Item 105"), required Sana to "provide under the caption 'Risk Factors' a discussion of the material factors that make an investment in the [Company] or offering speculative or risky" and "[c]oncisely explain how each risk affects the [Company] or the securities being offered." Defendants failed to disclose, *inter alia*, that SC291 in oncology, SC379, and SG299 were less promising than

Defendants had led investors to believe and that, in order to preserve cash and advance its more promising product candidates, Sana was likely to decrease funding for and/or discontinue SC291 in oncology, SC379, and SG299, as well as significantly reduce its headcount. Defendants' failure to disclose the foregoing issues violated Item 105 because these issues represented material factors that made an investment in the Company speculative or risky.

80. For similar reasons, Defendants violated Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii) ("Item 303"), which required the Company to "[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." Defendants' failure to disclose, *inter alia*, the issues described *supra* at ¶ 79 violated Item 303 because these issues represented known trends and uncertainties that were likely to have a material unfavorable impact on the Company's business and financial results.

SCIENTER ALLEGATIONS

81. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

82. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Sana securities during the Class Period (the "Class"); and were damaged upon the

revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

83. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sana securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Sana or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

84. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

85. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

86. 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. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Sana;
- whether the Individual Defendants caused Sana to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Sana securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

87. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as 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.

88. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Sana securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Sana securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

89. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

90. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

91. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

92. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

93. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud

in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Sana securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Sana securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

94. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Sana securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Sana's finances and business prospects.

95. By virtue of their positions at Sana, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

96. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Sana, the Individual Defendants had knowledge of the details of Sana's internal affairs.

97. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Sana. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Sana's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Sana securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Sana's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Sana securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

98. During the Class Period, Sana securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Sana securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated

prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Sana securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Sana securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

99. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

100. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

101. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

102. During the Class Period, the Individual Defendants participated in the operation and management of Sana, and conducted and participated, directly and indirectly, in the conduct of Sana's business affairs. Because of their senior positions, they knew the adverse non-public information about Sana's misstatement of income and expenses and false financial statements.

103. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Sana's

financial condition and results of operations, and to correct promptly any public statements issued by Sana which had become materially false or misleading.

104. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Sana disseminated in the marketplace during the Class Period concerning Sana's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Sana to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Sana within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Sana securities.

105. Each of the Individual Defendants, therefore, acted as a controlling person of Sana. By reason of their senior management positions and/or being directors of Sana, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Sana to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Sana and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

106. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Sana.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: