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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

IN RE IMMUNITYBIO, INC. SECURITIES LITIGATION	No. 3:23-cv-01216-GPC-DEB CLASS ACTION AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL
THIS DOCUMENT RELATES TO: ALL ACTIONS	

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Court-appointed lead plaintiff Dipak Patel ("**Lead Plaintiff**"), individually and on behalf of all others similarly situated, by and through his undersigned counsel, as for his Amended Class Action Complaint against Defendants ImmunityBio, Inc. ("**ImmunityBio**" or the "**Company**"), Richard Adcock, David C. Sachs, and Patrick Soon-Shiong (collectively, with ImmunityBio, "**Defendants**"), alleges the following based on personal knowledge as to Lead Plaintiff's own acts and on information and belief as to all other matters based upon the investigation conducted by Lead Plaintiff's counsel, which has included, among other things a review and analysis of regulatory filings made with the U.S. Securities and Exchange Commission ("**SEC**"), securities analyst research reports, press releases, media reports, and other publicly available information issued by or about ImmunityBio, interviews with former employees of ImmunityBio and/or its business partners, and consultations with experts. Lead 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 against ImmunityBio and certain of its top officials for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "**Exchange Act**"), codified at 15 U.S.C. §§ 78j(b) & 78t(a), and SEC Rule 10b-5 promulgated thereunder, codified at 17 C.F.R. § 240.10b-5, on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired ImmunityBio securities between March 10, 2021 and May 10, 2023, both dates inclusive (the "**Class Period**"), and were damaged thereby (the "**Class**").

2. ImmunityBio, as it now stands, was formed in connection with a merger between two clinical-stage biopharmaceutical companies controlled by Defendant Soon-Shiong on March 9, 2021. The combined Company owned a broad portfolio of at least 17 product candidates at various stages of clinical development, including several in late-stage clinical trials.

3. Throughout the Class Period, ImmunityBio's "lead" product candidate was a cell fusion protein for the treatment of bladder cancer known as Anktiva. By the start of the Class Period, Anktiva yielded impressive results in one of its Phase 3 trials and the Individual Defendants actively planned to file an application to seek marketing approval from the FDA, the first for any product in its development pipeline. As such, ImmunityBio did not generate any meaningful revenues from the commercial sale of any other products, and did not expect to generate any meaningful revenue from the commercial sale of any products unless Anktiva received marketing approval.

4. As seasoned biotech executives, the Individual Defendants were fully aware that their plan for Anktiva meant that ImmunityBio would need to demonstrate in its forthcoming application that the facility which produced Anktiva fully complied with the FDA's minimum standards for drug manufacturing known as current good manufacturing practices ("**cGMP**"), and, later, submit to a mid-review inspection by a team of FDA field specialists to observe the facility in use and verify its cGMP status.

5. The FDA's cGMP requirements are especially important for drugs derived from living materials, like Anktiva. Unlike chemically synthesized drugs, "biologics," as they are called, often have a complex structure and manufacturing such drugs at scale requires a series of highly-technical steps, each of which must be carefully controlled to ensure a consistent end product free from impurities. Even a small deviation from protocol can have a devastating impact on the composition of the drug and, thus, its safety. For this reason, the FDA is not authorized to approve an application for a new biologic unless it is satisfied from all evidence that it receives, including the findings from the facility inspection, that it is manufactured in accordance with cGMP.

6. In contrast to ImmunityBio's other "home grown" product candidates that are manufactured in house, Anktiva was acquired from another company that relied on a third-party contract manufacturing organization ("**CMO**") to produce the active pharmaceutical ingredient in Anktiva, which ImmunityBio continued to use. However, the Individual Defendants repeatedly assured investors that the Company's

manufacturing resources complied with cGMP and even represented that the CMO it used to manufacture Anktiva had robust cGMP standards in place.

7. On or around May 23, 2022, the Company submitted a marketing application for Anktiva to the FDA, and continued to represent that its manufacturing resources, including the CMO that it used to make Anktiva, complied with cGMP. Because new data from the Phase 3 study continued to show a durable treatment effect, the market, including analysts that followed the Company, were led to believe that there were no major impediments to approval—certainly no cGMP issues.

8. Unbeknownst to investors, the facility used by ImmunityBio's CMO to manufacture Anktiva was plagued by myriad cGMP issues throughout the Class Period. In March and July 2021, the FDA issued a Form 483—an official document that memorializes any serious departures from cGMP—to the site's management following on-site inspections. Even after that episode, issues continued at the most basic level. The CMO was unable to release manufacturing batch records or close out investigations into critical deviations from established protocols on schedule. It regularly failed to conduct stability tests designed to show that the active ingredient produced there did not undergo unacceptable deterioration over time while in storage. It ran out of "reference material" used as the control against which batch samples were tested. And numerous batches of Anktiva failed for a variety of reasons.

9. With the application for their inaugural product on the line, the Individual Defendants were keenly aware of these recurring issues. Defendant Richard Adcock, ImmunityBio's Chief Executive Officer, and Leonard Sender, ImmunityBio's Chief Operating Officer, were meeting with AGC officials on a monthly or bi-monthly basis throughout the Class Period to discuss AGC's continued delays.

10. In November 2022, the FDA notified the CMO that it would conduct a two week inspection with six inspectors, signaling that the inspection would be more intensive than usual. After learning this, ImmunityBio leadership became very concerned given the history of deficiencies at the plant and asked to hold a mock

inspection. Adcock and Sender were intimately involved in all aspects of the mock inspection, which revealed that the facility continued to suffer from rampant cGMP lapses. Because the mock inspection was just weeks before the FDA's visit, not nearly all of the issues identified could be remediated in time.

11. The FDA inspection, which took place in February 2023, was catastrophic. After the FDA observed numerous violations on the first day of the visit, Defendant Soon-Shiong demanded real-time updates and executive-to-executive calls at the end of each inspection day. Adcock flew overnight to the site to participate in the rest of the inspection. Ultimately, the FDA issued a scathing 15-page Form 483 cataloging a litany of cGMP failings that it both observed while the facility was in operation and that it confirmed by reviewing historic records at the site. The violations were so severe that the FDA ultimately classified the inspection as "Official Action Indicated," meaning it recommended administrative or enforcement action to remedy the violations.

12. The serious nature of the cGMP violations uncovered by the FDA in connection with its pre-approval inspection and the threat that they posed to patients if not rectified would have been apparent to anyone with experience in world of biotechnology development. They would certainly be obvious to the Individual Defendants, especially industry veteran Soon-Shiong who has a background in medicine and stewarded numerous drugs through the FDA approval process. This Complaint includes the interlocking analysis of a highly qualified expert in the field of FDA compliance, who explains the serious gravity of the cGMP violations throughout the Class Period and concludes that the findings by the FDA during its pre-approval inspection would, at a minimum, result in a recommendation to withhold rather than approve the pending application for Anktiva.

13. Investors, however, were kept in the dark. Shockingly, ImmunityBio continued to represent that its manufacturing resources, including the CMO that it used to make Anktiva, complied with cGMP, even after the FDA's February 2023 inspection.

14. It was not until May 2023 that investors began to learn the true extent of the manufacturing issues. On the morning of May 11, 2023, ImmunityBio announced that the FDA rejected its application for Anktiva not because of its risk benefit profile or concerns with the clinical studies but, rather, because of deficiencies arising from the pre-approval inspection at its CMO. The stock crashed, shedding ***over 55%*** of its market value in a single day.

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

JURISDICTION AND VENUE

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27(a) of the Exchange Act, codified at 15 U.S.C. § 78aa(a). The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, codified at 15 U.S.C. §§ 78j(b), 78t(a), and pursuant to the rules and regulations duly promulgated thereunder, including SEC Rule 10b-5, codified at 17 C.F.R. § 240.10b-5.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and Section 27(a) of the Exchange Act, codified at 15 U.S.C. § 78aa(a). ImmunityBio's principal executive offices are located in this judicial district, Defendants transact business in this judicial district, and a substantial part of the events or omissions giving rise to the claims asserted herein, including the dissemination of materially false or misleading statements to the public, occurred in this judicial district.

18. In connection with the acts and omissions alleged herein, Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, the facilities of a national securities market, and interstate telephonic and digital communications systems.

PARTIES

19. Lead Plaintiff, Dipak Patel purchased or otherwise acquired ImmunityBio securities at artificially inflated prices during the Class Period, as set forth in the amended certification attached hereto, and was damaged thereby, as set forth herein.

20. ImmunityBio is a biopharmaceutical company incorporated in Delaware with its principal executive offices located at 3530 John Hopkins Court in San Diego, California. The Company's securities trade on the NASDAQ Global Select Market under the ticker symbol IBRX.

21. Defendant Patrick Soon-Shiong ("**Soon-Shiong**") is the founder and CEO of one of the companies involved in the formation of what is now known as ImmunityBio. He has held the role of Executive Chairman of ImmunityBio's Board of Directors (the "**Board**") since October 2020, and served as ImmunityBio's Global Chief Scientific and Medical Officer since the position was created for him in August 2021. He previously served as Chairman of the Board and CEO of the predecessor to ImmunityBio from March 2015 to October 2020. The release announcing Soon-Shiong's appointment as Executive Chairman stated that he will "continue to play a key, active role in [ImmunityBio]'s business and in the development of the company's long-term business strategy."

22. Defendant Richard Adcock ("**Adcock**") has served as ImmunityBio's CEO since Soon-Shiong stepped down from that position in October 2020 and as a member of its Board since March 2021. In the release announcing Adcock's appointment as CEO, Soon-Shiong stated that he had "worked with him [Adcock] for several years" in previous capacities and that "I intend to work closely with him" moving forward.

23. Defendant David Sachs ("**Sachs**") has served as ImmunityBio's CFO since its inception in March 2021. He previously held different executive positions at various companies controlled by Soon-Shiong and/or their subsidiaries since 2011.

24. For ease of reference, Defendants Soon-Shiong, Adcock, and Sachs are referred to herein as the "**Individual Defendants**."

THE CONFIDENTIAL WITNESSES

25. Confidential Witness 1 ("**CW1**") worked for the Company since January 2021. CW1 initially worked at NantKwest as a Senior Specialist, Quality Control Analytics from January 2021 to January 2022. CW1 was promoted to Supervisor for the QCA Molecular Bio/Cell Assay Lab and worked primarily in the Company's Culver City facility, but also spent time at ImmunityBio's El Segundo facility. In this position, CW1 reported to Senior Director of Quality Control, Scott Yuen. CW1 was responsible for setting up a quality control testing lab and working within the Company's labs on quality control testing for research and development of products. CW1 learned of issues occurring at the CMO where Anktiva was manufactured from discussions within the quality department, via supervisors, colleagues, and attending department meetings.

26. Confidential Witness 2 ("**CW2**") worked at ImmunityBio from January of 2022 to November of 2022 as Associate Director, External Manufacturing and Tech Transfer. CW2 reported to CW4, until such time as CW4 left the Company. Thereafter, CW2 reported to Chief Operating Officer, Leonard Sender, who in turn reported to Defendant Adcock. In the role of Associate Director, External Manufacturing and Tech Transfer, CW2 was responsible for overseeing the "fill" step in the manufacturing process for Anktiva, where the drug substance is placed into sterile medical vials with other solutions in its final drug product form. CW2 oversaw a CMO that performed the fill operation after receiving the drug substance from the CMO that manufactured it.

27. Confidential Witness 3 ("**CW3**") worked for AGC Biologics from August 2021 to March 2023 as Senior Vice President and General Manager of AGC Biologics' Bothell, Washington facility, where Anktiva was manufactured. CW3 reported to Paul Tsang, Executive VP of U.S. Operations at AGC Biologics. Paul Tsang in turn reported to AGC Biologics' CEO, Patricio Massera. As Senior Vice President and General Manager, CW3 had oversight of all aspects of the facility's manufacturing operations, including safety, delivery to clients, financial, and cGMP.

28. Confidential Witness 4 ("**CW4**") worked for the Company from January 2018 to May 2022. From March 2021, CW4 served as VP of Manufacturing. While at ImmunityBio, CW4 reported to Chief Operating Officer, Leonard Sender. Until the later part of CW4's tenure, CW4 worked directly on the Anktiva program and aspects of the manufacturing process.

SUBSTANTIVE ALLEGATIONS

A. Relevant Background

1. ImmunityBio and Its Business

29. ImmunityBio purports to be a clinical-stage biotechnology company focused on the development of immunotherapies to treat cancer and other infectious diseases. Immunotherapies refer to a broad class of drugs that complement or stimulate the body's immune system to fight disease, like cancer, and have become increasingly common in the field of oncology in recent years, particularly in combination with standard cancer therapies. ImmunityBio's lead product candidate is a compound known as N-803 marketed under the trade name Anktiva.

30. As it currently exists, ImmunityBio was formed in connection with a business combination between a separate entity by the name of ImmunityBio, Inc. ("**Legacy ImmunityBio**") and NantKwest, Inc. ("**NantKwest**") in March 2021. At the time of this business combination, both companies were majority owned by entities controlled by Defendant Soon-Shiong and was, effectively, a merger between two of the many businesses within his family of companies.

31. Defendant Soon-Shiong is a former surgeon, scientist, biotech mogul, and media tycoon known for his ownership of the *Los Angeles Times* and his interest in the Los Angeles Lakers. He achieved fantastic success approximately twenty years ago inventing and bringing to market a novel cancer treatment known as Abraxane. In 1998, his start-up, American Pharmaceutical Partners, Inc. ("**APP**"), acquired Fujisawa USA and used its ties to hospital buyer groups to generate revenues from Fujisawa's money-losing portfolio of injectable generic drugs, which, in turn, APP used to develop

Abraxane. APP went public in 2001. In 2005, the FDA approved Abraxane for metastatic breast cancer. Following a merger with American BioScience, Inc., Soon-Shiong split the company into Abraxis BioScience, Inc. ("**Abraxis BioScience**"), which focused on Abraxane and other proprietary products, and APP Pharmaceuticals, Inc. ("**APP Pharmaceuticals**"), which focused on the injectables business. In 2008, he sold APP Pharmaceuticals to Fresenius SE for approximately $5.6 billion. In 2010, he sold Abraxis BioScience to Celgene for approximately $3.6 billion. Subsequently, the FDA approved Abraxane for the treatment of several other forms of cancer. By 2019, Abraxane was generating over $1 billion in annual sales.

32. In 2011, Soon-Shiong was free to pursue his other interests and formed NantWorks LLC ("**NantWorks**"), among other ventures, to do so. It now serves as a holding company for a collection of healthcare, technology, and finance companies.

33. In November 2014, Soon-Shiong formed Legacy ImmunityBio as a NantWorks subsidiary under the name NantBioCell, LLC to focus on next generation cancer immunotherapies. It later changed its name to Legacy ImmunityBio in May 2019. For ease of reference, all predecessors to Legacy ImmunityBio will be referred to herein as Legacy ImmunityBio.

34. Soon-Shiong's interest in NantKwest began around the same time that he formed Legacy ImmunityBio. In December 2014, a clinical-stage immunotherapy company by the name ConKwest, Inc. ("**ConKwest**") announced that Soon-Shiong made a $48 million investment in its business. At the time, ConKwest was developing a proprietary line of enhanced natural killer cells for off-the-shelf commercialization. Soon-Shiong quietly assumed the title of Chief Medical Officer and CEO between January and March 2015. He made another $71 million investment in June 2015. In July 2015, ConKwest changed its name to NantKwest and commenced an IPO at a market valuation of $2.6 billion. Upon completing the IPO, Soon-Shiong and/or entities his affiliates owned over 60% of NantKwest.

35. Soon after NantKwest went public, Soon-Shiong began to court Altor BioScience Corporation ("**Altor**") after learning that it was developing several compounds that act on cytokines which help regulate the immune system, including a cytokine fusion protein known as ALT-803. Throughout early 2016, Soon-Shiong worked closely with Altor to bring their products into a cancer research coalition he created. In April 2016, he was named Chairman of Altor's Board of Directors. By the end of 2016, entities controlled by Soon-Shiong had acquired over 50% of the equity in Altor.

36. At the time Soon-Shiong took majority control of Altor, ALT-803 was being evaluated in several late-stage Phase 2 trials for various forms of cancer, including non-muscle invasive bladder cancer ("**NMIBC**"). In May 2017, ALT-803 received Fast Track designation from the FDA for the treatment of NMIBC in combination with a standard cancer vaccine, baccilus Calmette-Guérin ("**BCG**"), based on the data generated in Phase 1 clinical trials. The FDA's Fast Track program is designed to expedite the development and review of drugs that treat serious conditions, like cancer, and fill unmet medical needs.

37. In or around July 2017, Legacy ImmunityBio acquired Altor, including its lead cytokine-based therapeutic compound, ALT-803, and continued to develop it under the name N-803. At the time, a Phase 3 clinical trial for N-803 with BCG had just begun in BCG unresponsive patients with in situ and papillary forms of NMIBC. In December 2019, N-803 in combination with BCG received Breakthrough Therapy designation from the FDA for the treatment of NMIBC in patients who were unresponsive to BCG based on interim data indicating that the primary endpoint of the Phase 2 trial was already met mid-study. Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat serious conditions and preliminary clinical evidence shows a substantial improvement over available therapy. By August 2020, N-803 was known internally as Anktiva.

38. Since its IPO in 2015, NantKwest experienced a number of setbacks and had not materially progressed its proprietary line of natural killer cell therapies. With Anktiva moving much faster through the clinical development and regulatory process, Soon-Shiong decided to use NantKwest as the vehicle to take Legacy ImmunityBio and its product portfolio public. On December 21, 2020, the two companies issued a joint press release announcing that they agreed to merge in a stock-for-stock merger. That same day, Legacy ImmunityBio announced that preliminary data from the Phase 3 trial of Anktiva with BCG showed that the study already achieved its primary endpoint for patients with in situ forms of NMIBC.

39. The Legacy ImmunityBio-NanktKwest merger closed on March 9, 2021. In connection with the transaction, a subsidiary of NanktKwest merged with and into Legacy ImmunityBio, and NanktKwest changed its name to ImmunityBio. It assumed the assets of Legacy ImmunityBio, including Anktiva, and its publicly traded shares continued to be listed on the NASDAQ under the symbol IBRX as of March 10, 2021. Immediately following the closing of the transaction, Defendant Soon-Shiong or affiliates controlled by him beneficially owned approximately 82% of the Company's outstanding common stock.

2. The FDA Approval Process

40. Before a new drug can be introduced into interstate commerce for commercial purposes, it must be approved by the FDA. The FDA's rules and regulations distinguish between chemically-synthesized drugs, known as "small molecule" drugs, and therapies derived from living material, known as "biologics." In contrast to small molecule drugs, the means used to request FDA approval for a biologic, like Anktiva, is a biologic license application ("**BLA**").

41. The contents of a BLA must conform to strict guidelines outlined in FDA rules and associated guidance. *See* 21 C.F.R. §§ 601.2(a), 601.29. Generally speaking, a BLA includes data and supporting materials collected in clinical trials, along with other information needed for the FDA to determine that the product meets prescribed

standards for approval, including information on the manner in which the product is manufactured. In practice, a new BLA is a voluminous compendium of materials, and usually includes raw study data, historic records, written summaries, and academic literature, among other things, organized using a specific format adopted by the FDA.

42. The section of the BLA that describes the manufacturing process and integrity of the drug is known as the Chemistry, Manufacturing, and Controls ("**CMC**") section of the BLA. Unlike small molecule drugs, biologics are structurally complex materials that are not clearly defined or characterized. The process used to manufacture these materials at scale involves an array of highly technical steps, each of which must be carefully controlled to ensure a consistent final product free from impurities. Accordingly, the CMC section contains extensive information on the overall process, including, among other things, a full description of the manufacturing processes from start to finish, in-process controls used at each step, analytical methods used to test the product for release at various stages, and stability testing to show that the product remains true to form at regular intervals following final release, along with supporting documentation for each. *See* FDA, Guidance for Industry: For the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for *In Vivo* Use (1996).

43. The CMC section of the BLA not only describes the proposed process and protocols for manufacturing at scale, but also must include data generated in connection with previously-produced process performance qualification ("**PPQ**") batches using the stated manufacturing processes and equipment. *See* FDA, Guidance for Industry: Process Validation: General Principles and Practices (2011). The purpose of such a qualification study is to validate that the proposed manufacturing process is capable of reproducing results within predetermined specifications at commercial scale. *Id.*

44. Importantly, the FDA is not authorized to approve a BLA unless it can determine from the materials submitted that the manufacturing process complies with cGMP. *See* 21 C.F.R. §§ 601.2(d), 601.4. cGMP refers to the collection of minimum

procedures and practices set forth in FDA regulations, codified primarily at 21 C.F.R. §§ 210-11, that companies must follow to ensure that the manufacture, processing, packaging and holding of drugs is well-controlled. The FDA has stated that these standards and practices assure the "identity, strength, quality, and purity" of drugs and prevent "contamination, mix-ups, deviations, failures, and errors." Any drug manufactured using systems that fail to comply with these well-known and long-standing cGMP regulations are deemed "adulterated," subjecting the party who is responsible for the failure to adverse regulatory action. *See* 21 C.F.R. § 210.1(b).

45. Once submitted, the time for the FDA to act on the BLA is governed by various rules. In the first instance, the FDA will decide within 60 days if the BLA is sufficiently complete to "file" it for substantive review. *See* 21 C.F.R. § 314.101(a). If the FDA decides to file a BLA, the deadline for the FDA to act on it is determined by the goal dates set forth in the Prescription Drug User Fee Act of 1992, as amended ("**PDUFA**"). The version of PDUFA in effect at the time of the Anktiva BLA (PDUFA VI) directed the FDA to act on 90% of new BLA submissions within 10 months of the 60-day "filing" date, unless the BLA is designated as a "priority" submission which truncates the timeline to 6 months from the 60-day "filing" date. Development programs that receive Fast Track or Breakthrough Therapy designations are ordinarily eligible for, although not automatically entitled to, priority review under PDUFA.

46. As part of the review process, the FDA will also conduct a "pre-license inspection" of each facility used to manufacture the drug at a prescheduled time during the review period. *See* 21 C.F.R. § 601.20(d). The purpose of this inspection is to ensure that the facilities comply with applicable regulations, including cGMP. *Id.* Any cGMP failures identified during the inspection can prevent the issuance of a license for the product. *Id.*

47. Pre-license inspections follow a standard protocol. *See, e.g.*, FDA, Compliance Program Manual ("**CPM**") § 7356.002M (2021). Staff carry out their responsibilities not only by observing the site in operation but also by reviewing

appropriate records at the facility reflecting past activities. *Id.* Given the significance of this visit, many manufacturers hold mock inspections, perform cGMP audits, or otherwise shore up compliance gaps in advance of the FDA review period to minimize the risk for any adverse observations.

48. After completing its review, the FDA will either approve the BLA or send the sponsor a complete response letter ("**CRL**"). A CRL outlines any issues identified by the FDA during the review that prevent approval of the BLA in its current form and, where possible, recommend actions that a sponsor may take to remedy the issues or otherwise position the application for approval. *See* 21 C.F.R. § 601.3(a).

49. Upon receipt of a CRL, the applicant may resubmit the BLA with amendments to address the stated deficiencies or withdraw it. *See* 21 C.F.R. § 601.3(b).

B. Class Period Plans for Anktiva

1. ImmunityBio Actively Planned to File a BLA for Anktiva by No Later Than the Start of the Class Period

50. As noted above, ImmunityBio acquired the rights to Anktiva in July 2017 upon completing its acquisition of Altor. At the time of that acquisition, Altor had recently initiated a Phase 3 clinical trial for N-803 with BCG in BCG unresponsive patients with in situ and papillary forms of NMIBC.

51. By early December 2020, ImmunityBio learned from interim data that the Phase 3 trial of Anktiva with BCG already achieved its primary endpoint for patients with in situ forms of NMIBC with no treatment-related adverse events.

52. Thus, by no later than December 2020, ImmunityBio knew that it was reasonably likely that the Company would file a BLA for Anktiva upon final completion of the study. Indeed, in the release announcing the initial results on December 21, 2020, Soon-Shiong stated "[w]e expect to file a Biologics License Application following a meeting with the FDA in 2021," likely a reference to a "pre-BLA" meeting during which ImmunityBio can gain input from the FDA on the content and format of an

anticipated BLA. *See* 21 C.F.R. § 312.47(b)(2). In fact, the release included the following headline: "Biologics License Application anticipated in second half of 2021."

53. This precipitated a flurry of activity in 2021. On or around August 11, 2021, ImmunityBio appointed Soon-Shiong to the newly-created position of Global Scientific and Medical Officer. In this new role, Soon-Shiong assumed responsibility for clinical development. On September 13, 2021, ImmunityBio issued a press release disclosing that updated data from the Phase 3 study of Anktiva with BCG continued to show favorable data with no treatment-related adverse events in the in situ cohort. Then, at the end of November 2021, ImmunityBio submitted a briefing document to the FDA with updated data from that study. Such briefing material must be submitted to the FDA at least one month before a pre-BLA meeting. *See* 21 C.F.R. § 312.47(b)(2). ImmunityBio subsequently had discussions with the FDA about its forthcoming BLA.

54. On December 17, 2021, NantCapital, LLC, a Soon-Shiong investment vehicle, provided $300 million in financing to ImmunityBio. The release announcing this stated that the financing came directly "from ImmunityBio's founder . . . Dr. Patrick Soon-Shiong." In addition, the release stated that the Company "anticipates a BLA filing . . . in Q1, 2022" and noted that recent financing would be used to "expand our commercial operations in anticipation of our bladder cancer BLA filing in Q1, 2022."

55. On May 23, 2022, ImmunityBio announced that it submitted a BLA to the FDA for Anktiva in combination with BCG for the treatment of BCG-unresponsive patients with the in situ form of NMIBC. The BLA included the results of previous clinical studies in that population, including the recently completed Phase 3 study, as well as at least three previously-completed PPQ runs for Anktiva at the facility where Anktiva was made. ImmunityBio requested priority review of the BLA. The FDA accepted the BLA for filing in late July 2022, and assigned it a target PDUFA date of May 23, 2023. In other words, the FDA put the BLA on a standard 10 month review.

2. The Individual Defendants Were Well-Aware of the Critical Role That cGMP Compliance Played in Securing BLA Approval

56. Like most anyone with a working knowledge of the FDA approval process, much less seasoned biotech executives, the Individual Defendants were well-aware of the FDA's cGMP regulations at all relevant times. On January 29, 2021, Defendants Soon-Shiong and Adcock acknowledged in regulatory filings made with the SEC that any manufacturing facility for products that it develops are subject to "all applicable FDA and foreign regulatory authority requirements, including cGMP," and specified that "cGMP requirements include quality control, quality assurance and the maintenance of records and documentation." The Individual Defendants, including Defendant Sachs, continued to make the same, or substantially similar, statements in each annual report on Form 10-K filed on behalf of ImmunityBio during the Class Period.

57. Throughout the Class Period, the Individual Defendants also knew demonstrating compliance with cGMP was mission critical to securing approval from the FDA for a new biologic product, like Anktiva. In the same regulatory filings referenced above, the Individual Defendants admitted that "[t]he FDA will not approve an application [BLA] unless it determines that the manufacturing process and facilities comply with cGMP requirements."

58. In this regard, the Individual Defendants were privy to the fact that the FDA makes its cGMP assessment based not only on the manufacturing data that must be included in a BLA but also on the results of an in-person inspection of the facility while in use during the review period. In the same regulatory filings referenced above, the Individual Defendants advised that a "BLA/NDA must include . . . detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling," including "quality control documentation" generated by the facility that manufactures the product and that "[m]anufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including our BLAs" to demonstrate that they are compliant with cGMP. Indeed, they specified that the purpose of such inspections was to "assess compliance

with cGMP and to assure that the facilities, methods and controls are adequate to preserve the product candidates' continued safety, quality, purity and potency."

C. ImmunityBio's Reliance on CMOs to Manufacture Anktiva

59. At the time ImmunityBio acquired the rights to Anktiva from Altor, its production was outsourced to a predecessor of AGC Biologics, Inc. ("**AGC**"), a third-party CMO that provided manufacturing services for protein therapies which was recently acquired by Asahi Glass Company. Indeed, just two months earlier, in April 2017, Altor entered into a manufacturing agreement with that CMO to manufacture Anktiva for use in upcoming Phase 3 trials. At the time, Defendant Soon-Shiong was Chairman of Altor's Board of Directors. Following a corporate reorganization in January 2018, that CMO was renamed AGC.

60. Upon acquiring Altor, ImmunityBio continued to rely on AGC to manufacture Anktiva. As CW1 explained, AGC "originated" the technology for producing the active ingredient in Anktiva and, thus, it would be exceedingly expensive and risky to transfer that technology in-house, particularly with Phase 3 clinical trials recently started. This was echoed by CW2, who observed it would be "extremely difficult, time-consuming, and expensive to switch to another manufacturer at that point."

61. By the start of the Class Period in March 2021, AGC manufactured the bulk drug substance for Anktiva. In contrast to a final drug product, which includes both the active pharmaceutical ingredient and other materials used for delivery, appearance, or taste, *e.g.*, tablet coating, saline solution, *etc.*, drug substance refers strictly to the active pharmaceutical ingredient. According to CW2, once released by AGC quality personnel, drug substance for Anktiva was shipped by AGC in large containers to be filled in vials in its final dosage form at another CMO elsewhere. This was confirmed by CW3, who explained that drug substance made at AGC was sent to a fill site operated by another CMO in California.

62. Notably, the building at these CMOs where Anktiva was produced were "multi-product facilities," meaning they were used not only to produce Anktiva but other drugs as well. Indeed, during the Class Period, there were up to *ten* other active pharmaceutical ingredients produced by AGC in the same building, and AGC's internal policies even allowed for the ***simultaneous*** production of two or more products in certain production suites within the building. This configuration poses a heightened risk for cross-contamination and creates other significant control challenges.

D. The Pervasive Undisclosed cGMP Failures at the Facility ImmunityBio Used to Manufacture Anktiva Known to Defendants

1. AGC Was Inundated By Constant cGMP Failures Before the FDA's Pre-License Inspection

63. All facilities that manufacture drugs for the U.S. market must register with the FDA, even if they are not the license holder, including CMOs. *See* 21 C.F.R. § 207. In doing so, they become subject to routine cGMP surveillance inspections. Historically, over 90-95% of drug manufacturers are found to be compliant with cGMP upon inspection.

64. From March 11, 2021, to March 19, 2021, the FDA conducted a non-routine inspection at the same AGC building where Anktiva was manufactured. The inspection resulted in the issuance of a Form 483 by the FDA. A Form 483 is a document issued at the conclusion of an inspection to memorialize significant deficiencies observed during the inspection that, in the judgment of the inspectors, constitute violations of FDA regulations, including cGMP. FDA investigators are trained to ensure that each observation in a Form 483 is clear, specific, and significant. The Form 483 is presented to, and discussed with, the company's senior management at the conclusion of an inspection. This procedure is designed to ensure that firm management understands each observation and what they mean.

65. The Form 483 issued by the FDA in connection with the March 2021 inspection included a staggering ***sixteen item*** list of objectionable observations, replete with numerous examples supporting each item. These included, most notably, failure

on the part of AGC's quality unit to adequately investigate deviations, inadequate oversight of manufacturing procedures on the part of the quality unit, lack of adequate documentation for quality control testing, poorly qualified and validated manufacturing processes, and gaps in record keeping such that inspectors could not determine whether manufacturing was operating in a state of control. Among other things, AGC committed to implement a CAPA that required it to complete a data integrity risk assessment for its computerized systems.

66. Just four months later, from July 12, 2021, to July 23, 2021, the FDA conducted a routine cGMP inspection of the same building. This inspection resulted in the issuance of a three-item Form 483. Among other things, the July 2021 inspection found problems that would repeat themselves in the FDA's February 2023 pre-license inspection. For example, the firm either had deficient procedures or failed to follow existing procedures for sanitation, cleaning, and maintenance. In addition, the FDA also condemned AGC's failure to document conclusions or follow up actions in response to deviations.

67. Despite the FDA identifying these glaring quality lapses, this AGC facility continued to suffer from myriad quality and control issues in the lead up to the Anktiva BLA filing and the ensuing pre-license inspection by the FDA.

68. For example, AGC regularly failed to release batches, and thus delayed the release of corresponding manufacturing batch records to ImmunityBio, on schedule. As CW3 explained, batch records contain extensive detail about all parameters at the plant at each step in the production process, as well as test results at certain stages of production to ensure there are no deviations from the established production process. As is standard, AGC was required to target final batch disposition within a set number of days after completing its production process. But it routinely failed to do so. For example, numerous batches of drug substance produced at AGC were not released until well after the target disposition date by as much as ***three to four months***. CW3 confirmed that AGC "frequently" missed batch disposition timelines between August

2021 and February 2023. This is corroborated by CW2, who observed that ImmunityBio had difficulty obtaining manufacturing batch records from AGC even though they were needed for the Anktiva BLA. In particular, CW2 explained that ImmunityBio did not receive the batch records for the PPQs needed for the Anktiva BLA "for a long time" because AGC was "keeping" them long past the deadline.

69. There were also significant delays initiating and closing deviations throughout the Class Period. A deviation is any departure from the written procedures governing the manufacturing process. Adherence to the stated protocol is of paramount importance for biologics. Due to their complex structure, even minor deviations from normal manufacturing processes can result in significant changes in product composition. cGMP requires manufacturers to document, investigate, and justify the deviation for the batch to remain viable. *See* § 211.100. Prompt record management ensures that immediate action can be taken in response to the root cause. AGC maintained deviation management policies which required deviations to be opened within a set number of days after detection and close out the investigation within a set window of time as well. From 2021 through February 2023, AGC regularly failed to initiate a deviation record and/or close out the investigation on schedule. For example, several deviations during this time were opened ***a full year*** after the incident occurred, and numerous deviations opened in ***2021*** still remained open as of February 2023.

70. Similarly, AGC closed critical deviations without implementing a corrective and preventative action ("**CAPA**"). As the name suggests, maintaining a CAPA is a critical component of a control environment because it can help prevent a significant or recurring issue from arising again. cGMP requires all manufacturers to establish written CAPA policies. *See* 21 C.F.R. § 820.100. AGC's deviation management policies required it to perform a root cause analysis and craft appropriate CAPAs for any critical deviations. But in many instances throughout the Class Period, AGC closed critical deviations without implementing a CAPA.

71. Several CWs also reported that AGC regularly failed to conduct required stability tests on Anktiva. A stability test is study performed on a batch sample at periodic intervals after completing the production process to ensure that it does not undergo unacceptable deterioration over time. Such studies are mandated by cGMP because they ensure that product held for future commercial use remains pure and safe to use when stored as planned. *See* 21 C.F.R. § 211.166. AGC was required to conduct such stability testing at regular intervals, including upon completing the production process, 3 months thereafter, 6 months thereafter, and 12 months thereafter. According to CW1, AGC "regularly missed" required test windows since at least January 2021. CW2 was also aware that AGC failed at times to conduct required stability tests prior to the Anktiva BLA. For example, testing on a single lot of Anktiva produced at AGC missed the 3 month window by ***158 days***, missed the 6 month window by ***21 days***, and the 12 month window by ***60 days***.

72. CW1 also recalled that AGC ran out of "reference material" for Anktiva in approximately April 2022. Reference material, also known as reference standard material, is a specific drug batch of well-known composition and purity used as a benchmark against which samples of unknown composition and purity are compared. The lack of such reference material was a "major concern," said CW1, given that it is used to test drug substance for release during the final quality control review and for stability tests thereafter. CW1 recounted that this lasted for "months." This is consistent with the account of CW2, who recalled that, in May 2022, AGC refused to provide a "firm" date for when the next batch of Anktiva would be released to go to the CMO who ran the fill site. CW2 explained that the delays became so extensive that ImmunityBio was ultimately forced to pay a "postponement fee" to the fill site amounting to hundreds of thousands of dollars.

73. CW3, who headed the AGC facility where Anktiva was made, also confirmed that there were "a number of batches that were not successful" at the facility, meaning ***the entire batch was discarded*** because of critical deviations from the

established manufacturing process, several of which involved Anktiva. In fact, CW3 advised that AGC performed six PPQ runs as part of its PPQ campaign because three failed. CW3 explained that this was unusual because, typically, manufacturers present three successful runs in a row to show that the process is repeatable, and usually only involves one bad run. That there were "six attempts" to get three good runs raised "questions," and CW3 added "they were pretty messy."

74. Plaintiff has retained Mr. Todd D. Clark, the current President of Value of Insight Consulting, Inc. who has decades of experience in FDA compliance, among other topics, and has frequently testified as an expert witness in pharmaceutical litigation. Mr. Clark has a Master of Science in drug development and regulation from John Hopkins University and a Master of Business Administration from the Kellogg Graduate School of Management at Northwestern University.

75. In Mr. Clark's opinion, the actions described above are not merely technical or academic matters but, rather, represent serious substantive violations of cGMP with the potential to directly affect the potency, purity, and composition of active pharmaceutical ingredients of drugs, posing a threat to cancer patients whose health status is already severely weakened. Mr. Clark further explains as follows:

> AGC's lack of effective batch and deviation management is indicative of a manufacturing facility that is out of control. Significantly, the failure to adhere to appropriate quality review timelines—one of the most basic functions of the quality unit—was not limited to one or two isolated incidents, but endemic during the relevant time period across different functions. In addition, the importance of an established reference standard to serve as the basis of comparison cannot be overstated. In the absence of a reference standard, pharmaceutical manufacturers sometimes have to shut down production, even to the point of withdrawing a drug from the market, because it may not be possible to determine whether future batches possess the appropriate characteristics. Stability testing is also critical, arguably more so for biological than for chemical drugs given their increased complexity and specialized storage needs. It is hard to understand why any biopharmaceutical manufacturer would repeatedly fail to conduct required stability tests within the specified timeframe, especially in advance of a BLA submission.

76. Finally, Mr. Clark underscores that, from the sponsor's perspective, even if the cGMP problems were not present, the fact that multiple batches had to be discarded at such a late stage in the development process indicates a poorly controlled (hence, unreliable) process that was not ready for BLA submission, much less FDA approval.

2. The FDA Observed Numerous cGMP Violations During Its Pre-License Inspection for Anktiva at AGC

77. On November 1, 2022, the FDA provided notice to Paul Tsang, Executive Vice President of Global Quality for AGC that it would conduct a pre-license inspection at the facility used to manufacture drug substance for Anktiva in February 2023 in connection with the pending BLA for Anktiva.

78. A group of six cross-functional FDA specialists conducted the pre-license inspection of the AGC facility that manufactured Anktiva from February 2, 2023 to February 10, 2023. As provided in the FDA's CGM, the pre-license inspection covered the firm's quality, production, materials, facilities and equipment, laboratory controls, packaging and labelling systems. *See* FDA, CGM § 7356.002M. The inspection ended with a "closeout" meeting on February 10, 2023, attended by FDA inspectors and AGC senior management, including CW3; Wendy Laderach, Vice President, Corporate Quality; Martin Shawala, Vice President, Quality; and Mike Barlow, Vice President, Manufacturing.

79. At the close-out meeting on February 10, 2023, the FDA issued a scathing five item, 15-page Form 483 to CW3 that detailed a litany of regulatory violations at the site for each item. The objectionable conditions were organized into five categories consistent with FDA standard practice but supported by extensive examples supporting the observations.

80. Inspectors cited multiple instances of inadequate deviation management from as far back as January 2021. At the very core of cGMP is the principle that deviations be timely and reliably traced back to their root cause and, if identified,

addressed with CAPA to avoid repeating the deviation. In its February 2023 inspection, the FDA found overlapping violations of this principle again and again. For example:

- The FDA found that "significant" time passed between an event and its classification as a deviation, citing several examples of a full year passing between the time of the incident and the classification. Unsurprisingly, AGC's failure to create deviation records in a timely manner also prevented appropriate resolutions from being implemented.
- AGC failed to conduct timely investigations, as demonstrated both by the fact that less than 40% of all deviations since ***July 2021*** were closed on schedule and 80 investigations remained open at the time of the inspection, including several that were open for two years. Among other things, AGC's dilatory approach caused market-ready batches to be left in limbo awaiting resolution of open deviations for more than five months.
- The FDA also found that deviation investigations were closed without documenting an appropriate conclusion or implementing ***any*** CAPA.

81. Inspectors found deficiencies in data integrity, missing validation for computer systems, and lack of reliability of audit trails by, among other things, the fact that computerized date and time settings were susceptible to improper changes. Among the production components affected by the lack of proper data procedures were a "critical sterilization process control." Worst still, AGC had still not completed the data integrity risk assessment that it committed to perform following the March 2021 inspection for "most of the computerized systems in use at the site."

82. The site also failed in critical sanitation and contamination-management practices. FDA inspectors cited an absence or lack of adherence to established cleaning and sanitation programs to prevent introduction of microbial contaminants in controlled environments and numerous potential cross-contamination hazards and cleaning failures. A simple walk-through tour found violations in pest control in the warehouse area, deficient filtration in a clean corridor, and a pool of standing liquid on the solution prep room floor. The presence of clean and dirty components in the same room also posed cross-contamination risks and the inspectors noted that AGC transported clean and dirty components between buildings in the same vehicles for intra-site movement.

Notably, inadequate equipment-cleaning procedures had been identified in the March 2021 investigation. AGC revised its policies in response, but failed to conduct a study to validate the revised process. AGC also created a CAPA to control the risk of contamination by personnel, but failed for over two years to implement that program.

83. Inspectors found that AGC did not follow its own standard operating procedures and written instructions. Most notably, the performance of stability tests occurred outside planned test windows "by a significant number of days" including, in one case, approximately five months. Other problems with standard procedures included an operator's nonadherence during a bulk-fill operation in a clean room environment as well as inadequate procedures to ensure that materials were not kept at ambient conditions in an uncontrolled or unacceptable manner.

84. Finally, and most critically of all, the FDA found, at a general level, that AGC's quality unit failed to adequately oversee manufacturing operations and, thus, appropriately exercise its authority and responsibilities. In this regard, FDA inspectors cited a lack of security to prevent unauthorized access to the site, inadequate cleanliness and maintenance, failure to ensure that equipment used for testing was properly qualified, the ad hoc use of a new reference standard different from the one set forth in the BLA (with no assurance that the affected lots would not be released into commerce), and extensive delays in reviewing batch records. As but one example of systemic failure of the quality unit's function, the FDA observed during the inspection a product in cold storage with a printed product label and status tag which carried different lot (*i.e.*, batch) numbers. The FDA inspection team indicated that for "such a critical deviation to occur, quality oversight failed at multiple steps in the process."

85. During the closeout meeting, FDA personnel reviewed each observation with senior management present from AGC, including each of those summarized above. In response, AGC management told the FDA officials that they "understood" each observation and had no other comments. One of the FDA inspectors expressed concern that the GMP deficiencies found by the FDA inspection team indicate that the firm's

quality unit had not been effectively exercising its authority and/or responsibilities and, of considerable importance for Anktiva's FDA review cycle, noted that an independent assessment of the firm's quality management systems might be required to systematically identify and address needed improvements in GMP practices.

86. Significantly, the pre-license inspection at AGC was classified by the FDA as Official Action Indicated ("**OAI**"). Pursuant to its internal guidelines, the FDA will assign one of three classifications to an inspection based on the severity of the infractions observed (or lack thereof). No Action Indicated means there were no objectionable conditions observed. Voluntary Action Indicated means objectionable conditions were found but the FDA is not prepared to recommend administrative or regulatory action. OAI is the most severe and means that regulatory and/or administrative actions are recommended to remedy the objectionable conditions. As set forth in the FDA's internal CPM guidelines for pre-license inspections, an OAI classification will issue if there is a finding that "one or more manufacturing systems is ***out of control.***" FDA, CPM § 7356.002M. Critically, the same guidelines that the FDA used to conduct the pre-license inspection at AGC provide that an OAI classification will result in a "withhold" recommendation on any pending BLA, which "ensures the product cannot be marketed in the United States until a follow-up inspection verifies implementation." FDA CPM § 7346.832. In practice, this means that any pending applications with the FDA will result in a CRL.

87. Given the serious nature of the underlying violations, OAI classifications are exceedingly rare. During the FDA's past ten full fiscal years before the pre-license inspection, *i.e.*, fiscal years 2012 to 2022, only ***nine percent*** of all inspections at drug manufacturing facilities were classified as OAI.

88. Mr. Clark stresses that, wholly apart from the classification assigned to the investigation by the FDA, the nature and extent of the violations cataloged by the FDA inspection team are extremely serious. Mr. Clark explained that the departures from

cGMP were so numerous and pervasive that they called into question whether the quality unit was carrying out its basic functions.

89. In addition, Mr. Clark believes that the findings from the FDA inspection would, at a minimum, lead to a recommendation to withhold rather than approve the Anktiva BLA by the FDA. His assessment is based on the enormous number of unresolved or behind-schedule batch dispositions and deviation investigations, inadequate protections for computer systems and the facility itself, numerous contamination risks, mismatched lot numbers, the possibility that inappropriate batches might be introduced into commerce, multiple other cGMP violations, including several "critical" violations, and a general lack of appropriate oversight by AGC's quality unit.

90. Mr. Clark points out that, in the FDA's view, a pattern of failure to conduct investigations and resolve deviations is, on its own, sufficient cause for an OAI finding. Other reasons for the FDA to issue an OAI finding that were present at the AGC site include a reasonable potential for contamination, failure to qualify computers and other equipment, absent or not-adhered-to standard operating procedures, and failure to follow stability testing protocols.

91. At the end of the inspection, the FDA team raised the possibility that AGC's quality management systems could require an extensive independent assessment to systematically identify and address needed improvements in cGMP practices. Mr. Clark advised that, even if that could somehow be avoided, it would be unreasonable to expect problems of this scale to be resolved to the FDA's satisfaction (including another inspection) within the few months remaining before Anktiva's PDUFA date; meaning, in other words, that a CRL was the only practical outcome.

3. The FDA Observed Several Objectionable Conditions At the CMO That Filled Anktiva Into Vials

92. Making matters worse, the FDA also observed several objectionable conditions at the CMO that ImmunityBio used to fill drug substance received from AGC into vials in connection with its pre-license inspection of that facility.

93. From January 11, 2023 to January 16, 2023, three FDA specialists conducted the pre-license inspect of the facility used by the CMO that operated the fill site for Anktiva. At end of the inspection, the FDA issued a five item Form 483 to facility management which detailed several objectionable conditions at the site, including that (1) the site used equipment and conditions which were not properly validated through qualification studies; and (2) there was inadequate equipment maintenance. For example, a sensor used on a piece of equipment was due for service in December 2020 but still in use at the time of the inspection.

MATERIALLY FALSE AND MISLEADING STATEMENTS

94. Despite the steady stream of significant cGMP failings at AGC known by ImmunityBio, Defendants made numerous false and misleading statements during the Class Period about its manufacturing strategies and capabilities. Lead Plaintiff asserts that all statements set forth below that are bolded and italicized are materially false and misleading for the reasons set forth therein. Statements that are not bolded and italicized are included for context.

95. The Class Period begins on March 10, 2021, when ImmunityBio securities began publicly trading on the NASDAQ and the Company filed a current report on Form 8-K with the SEC signed by Defendant Adcock (the "**March 10, 2021 Form 8-K**"). Among other things, the March 10, 2021 Form 8-K disclosed that the Company updated its previous disclosures regarding its business and risk factors as a result of the Legacy ImmunityBio-NantKwest merger, copies of which were attached as Exhibits 99.2 and 99.3 thereto. Exhibit 99.2 to the March 10, 2021 Form 8-K touted that cGMP manufacturing was one of its core competencies, stating in relevant part:

> ImmunityBio, together with its merger with NantKwest, has now progressed into a leading late-stage clinical company with a broad immunotherapy clinical-stage pipeline of over 40 clinical trials in Phase I, II and III development (company sponsored and investigator initiated) across 19 indications in solid and liquid cancers and infectious diseases. . . . The expansive clinical-stage pipeline and intellectual property portfolio with 17 first in human antibody cytokine fusion proteins, chemo immuno-

> modulators, vaccine vectors and cell therapies in clinical trials, including 25 in Phase II to III clinical trials, as well as a strong global intellectual property portfolio of issued and pending worldwide patent applications with patent life extending to 2035 and beyond, places ImmunityBio in a leading position to transform immunotherapy care beyond current standards of care. ***In addition, the company has adopted the strategy of establishing GMP manufacturing capacity at scale*** and to date, the company has cutting-edge cell manufacturing expertise, ready-to-scale facilities, with extensive and seasoned R&D, clinical trial, and regulatory operations and development teams, which together will occupy over 400,000 square feet of manufacturing and R&D facilities.

96. Exhibit 99.2 also represented that one of the key elements of its current business strategy included investment in manufacturing capabilities for antibody cytokine fusion proteins, such as Anktiva:

> We seek to become the leading global immunological discovery and therapeutics company by creating the next generation of immunotherapies to address serious unmet needs within oncology and infectious diseases. To achieve this goal, **the key elements of our strategy include**:
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> . . .
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> - ***Optimizing investment in our*** discovery, development and ***manufacturing capabilities for our next generation targeted antibody cytokine fusion proteins*** and vaccine candidates, as well as for cell therapies including utilizing our just-in-time, decentralized advanced cell therapy GMP-in-a-box manufacturing technologies.

97. Exhibit 99.3 to the March 10, 2021 Form 8-K outlined certain risks which could adversely impact ImmunityBio's business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
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> . . .

> Currently we manufacture our product candidates or use CMOs.
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> In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including our BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary chemistry, manufacturing and quality control documentation in support of a BLA or NDA on a timely basis. ***There is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.***
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> Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

98. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed

to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

99. On March 10, 2021, ImmunityBio issued a press release announcing that the Company's common stock began trading on the NASDAQ following the completion of the Legacy ImmunityBio-NantKwest merger, which represented as follows:

> ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise, ready-to-scale facilities, extensive and seasoned R&D, clinical trial, and regulatory operations and development teams.

100. The statement identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statement not misleading, because, as more fully described above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

101. On April 30, 2021, ImmunityBio filed an automatic shelf registration statement on Form S-3 with the SEC to place an unspecified number of debt and equity securities on the "shelf," which contained a prospectus relating thereto (as supplemented, the "**April 2021 Shelf Registration Statement**"). The April 2021 Shelf Registration Statement was signed by the Individual Defendants. On May 3, 2023, ImmunityBio filed a prospectus supplement to the April 2021 Shelf Registration Statement with the SEC pursuant to Rule 424(b)(5) (the "**April 2021 Prospectus Supplement**"), to facilitate an open market, or "at-the-market," sales agreement the Company entered into with Jeffries LLC for up to a maximum aggregate amount of

$500 million of its common stock. As supplemented by the April 2021 Prospectus Supplement, the April 2021 Shelf Registration Statement expressly incorporated by reference the March 10, 2021 Form 8-K, including the materially false and misleading statements set forth in ¶¶ 95-97.

102. In addition, the April 2021 Shelf Registration Statement expressly incorporated certain information from the Definitive Proxy Statement on Schedule 14A that ImmunityBio previously filed with the SEC on February 2, 2021 (the "**Merger Proxy Statement**"), including all information under the heading "Business of ImmunityBio—Manufacturing." In that section of the Merger Proxy Statement, the Company boasted that the third-party it used to manufacture Anktiva had robust manufacturing standards:

> ***For our Anktiva product candidate, we have contracted with a multi-national biologics manufacturer with multiple cGMP-compliant facilities*** in the United States, Europe and Asia for our current clinical trials and future commercial sales, if approved. ***The facilities have robust process development and validation and quality oversight*** with high-capacity production suites operating multiple 2,000-20,000L production bioreactors.

103. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

104. On May 14, 2021, ImmunityBio filed with the SEC a quarterly report on Form 10-Q for the quarter ended March 31, 2021 (the "**1Q 2021 Form 10-Q**"), which was signed by Defendants Adcock and Sachs. The 1Q 2021 Form 10-Q outlined certain

risks which "could" have a significant adverse impact on ImmunityBio's business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
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> Currently we manufacture our product candidates or use CMOs.
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> In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including our BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary chemistry, manufacturing and quality control documentation in support of a BLA or NDA on a timely basis. ***There is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.***
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> . . .
>
> ***Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements.*** Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that

> may not be detectable in final product testing. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

105. The statements identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

106. On August 12, 2021, ImmunityBio filed with the SEC a quarterly report on Form 10-Q for the quarter ended June 30, 2021 (the "**2Q 2021 Form 10-Q**"), which was signed by Defendants Adcock and Sachs. The 2Q 2021 Form 10-Q outlined certain risks which "could" have a significant adverse impact on ImmunityBio's business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
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> Currently we manufacture our product candidates or we may use third-party CMOs or some of our related parties to manufacture our product candidates.

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> In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including our BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary chemistry, manufacturing and quality control documentation in support of a BLA or NDA on a timely basis. ***Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.***
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> Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. If microbial, viral, environmental or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay clinical trials and adversely harm our business. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

107. The statements identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture

Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

108. On September 1, 2021, ImmunityBio issued a press release announcing that the oral presentation of new clinical trial results from the Phase 3 trial of Anktiva in patients with BCG-unresponsive bladder cancer at the American Urological Association's Annual Meeting on September 1, 2021, which represented as follows:

> ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams.

109. The statement identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statement not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue.

110. On September 13, 2021, ImmunityBio issued a press release announcing the results of the Phase 3 trial of Anktiva in patients with BCG-unresponsive bladder cancer, filed with the SEC as Exhibit 99.1 to the current report on Form 8-K, dated September 13, 2021 signed by Defendant Sachs, which represented as follows:

> ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams.

111. The statement identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statement not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue.

112. On October 19, 2021, ImmunityBio issued a press release to announce the results of the Phase 3 study of Anktiva in patients with the papillary form of bladder cancer, which represented as follows:

> The company's platforms are based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells. ImmunityBio is currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform. ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams.

113. The statement identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statement not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue.

114. On November 12, 2021, ImmunityBio filed with the SEC a quarterly report on Form 10-Q for the quarter ended September 30, 2021 (the "**3Q 2021 Form 10-Q**"), which was signed by Defendants Adcock and Sachs. The 2Q 2021 Form 10-Q outlined certain risks which "could" have a significant adverse impact on ImmunityBio's

business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
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> Currently we manufacture our product candidates or we may use third-party CMOs or some of our related parties to manufacture our product candidates.
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> In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including our BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary chemistry, manufacturing and quality control documentation in support of a BLA or NDA on a timely basis. ***Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.***
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> Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. If microbial, viral, environmental or other

> contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay clinical trials and adversely harm our business. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

115. The statements identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

116. On December 20, 2021, ImmunityBio issued a press release announcing recent financing activities as well as its ongoing business initiatives, including the planned BLA submission for Anktiva, filed with the SEC as Exhibit 99.1 to the current report on Form 8-K, dated December 20, 2021 signed by Defendant Sachs, which represented as follows:

> The company's platforms are based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells. ImmunityBio is currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform. ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams.

117. The statement identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statement not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue.

118. On March 1, 2022, ImmunityBio filed a post-effective amendment to the Shelf Registration Statement (as amended, the "**Shelf Registration Statement Amendment No. 1**"), which was signed by the Individual Defendants. The Shelf Registration Statement Amendment No. 1 expressly incorporated by reference the March 10, 2021 Form 8-K, including the materially false and misleading statements set forth in ¶¶ 95-97.

119. The statements identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

120. On March 1, 2022, ImmunityBio filed an annual report with the SEC on Form 10-K for the year ended December 31, 2021 (the "**2021 Form 10-K**"), which was signed by the Individual Defendants. The 2021 Form 10-K touted that the Company maintained cGMP manufacturing resources, stating in relevant part:

> ***We have established Good Manufacturing Practice (GMP) manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned

> research and development (R&D), clinical trial, and regulatory operations and development teams.

121. The 2021 Form 10-K also assured investors that ImmunityBio develops its products in accordance with cGMP:

> ***ImmunityBio has adopted a strategic position to*** be vertically integrated and ***develop its products according to the FDA's GMP standards for large-scale manufacturing***, even during Phase 2 clinical trial development. Biological upstream and downstream manufacturing capabilities, with its attendant know-how and regulatory compliance for approval, have long lead times. We have adopted an approach for preparedness to provide our vaccine, immunotherapy and cell therapy products at a global scale. As such, we have established our own plants and have access to facilities on a global basis.

122. In the 2021 Form 10-K, the Company boasted that the third-party it used to manufacture Anktiva, specifically, had robust manufacturing standards:

> ***For our Anktiva product candidate, we have contracted with a multi-national biologics manufacturer with multiple cGMP-compliant facilities*** in the U.S., Europe and Asia for our current clinical trials and future commercial sales, if approved. ***The facilities have robust process development and validation and quality oversight*** with high-capacity production suites operating multiple 2,000-20,000L production bioreactors.

123. The 2021 Form 10-K also outlined certain risks which "could" have a significant adverse impact on ImmunityBio's business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
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> Currently we manufacture our product candidates or we may use third-party CMOs or some of our related parties to manufacture our product candidates.
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> In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including our BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary chemistry, manufacturing and quality control documentation in support of a BLA or NDA on a timely basis. ***Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.***
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> Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. If microbial, viral, environmental or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay clinical trials and adversely harm our business. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

124. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts

necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

125. On May 10, 2022, ImmunityBio filed with the SEC a quarterly report on Form 10-Q for the quarter ended March 31, 2022 (the "**1Q 2022 Form 10-Q**"), which was signed by Defendants Adcock and Sachs. The 1Q 2022 Form 10-Q touted that the Company maintained cGMP manufacturing resources, stating in relevant part:

> ***We have established Good Manufacturing Practice (GMP) manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned research and development (R&D), clinical trial, and regulatory operations and development teams.

126. In addition, the 1Q 2022 Form 10-Q outlined certain risks which "could" have a significant adverse impact on ImmunityBio's business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
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> Currently we manufacture our product candidates or we may use third-party CMOs or some of our related parties to manufacture our product candidates.
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> In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary chemistry, manufacturing and quality control documentation in support of a BLA or NDA on a timely basis. ***Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.***
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> Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. If microbial, viral, environmental or other contaminants are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay clinical trials and adversely harm our business. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

127. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed

to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate, were not merely hypothetical.

128. On May 23, 2022, ImmunityBio issued a press release announcing the submission of the Anktiva BLA to the FDA, which represented as follows:

> ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations, and development teams.

129. The statement identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statement not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue.

130. On June 6, 2022, ImmunityBio issued a press release announcing new data from the Phase 3 trial of Anktiva in BCG-unresponsive patients with the CIS form of NMIBC, in which Defendant Soon-Shiong represented that the Company has built cGMP manufacturing capacity: "***We have, at risk, made the investments to build GMP commercial-scale manufacturing for our platforms*** and are now positioned to launch QUILT trials in earlier first-line, neoadjuvant and even preventative settings."

131. The same press release represented as follows:

> ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations, and development teams.

132. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully

above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue.

133. On July 28, 2022, ImmunityBio issued a press release announcing that the FDA filed the Anktiva BLA for review, in which Defendant Adcock represented that the Company was prepared to quickly move ahead with commercial manufacturing:

> "We are pleased the FDA has begun its review, and ***ImmunityBio is prepared to move rapidly to manufacturing*** and marketing should the Agency approve our therapeutic for this indication," said Richard Adcock, President and CEO of ImmunityBio.

134. The same press release represented as follows:

> ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations, and development teams.

135. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue.

136. On August 8, 2022, ImmunityBio filed with the SEC a quarterly report on Form 10-Q for the quarter ended June 30, 2022 (the "**2Q 2022 Form 10-Q**"), which was signed by Defendants Adcock and Sachs. The 2Q 2022 Form 10-Q touted that the Company maintained cGMP manufacturing resources, stating in relevant part:

> ***We have established Good Manufacturing Practice (GMP) manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned

research and development (R&D), clinical trial, and regulatory operations and development teams.

137. In addition, the 2Q 2022 Form 10-Q outlined certain risks which "could" have a significant adverse impact on ImmunityBio's business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
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> Currently we manufacture our product candidates or we may use third-party CMOs or some of our related parties to manufacture our product candidates.
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> In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary Chemistry, Manufacturing and Controls (CMC) documentation in support of a BLA or NDA on a timely basis. ***Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.***

> Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. If microbial, viral, environmental or other contaminants are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay clinical trials and adversely harm our business. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

138. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate under review by the FDA, were not merely hypothetical.

139. On November 9, 2022, ImmunityBio filed with the SEC a quarterly report on Form 10-Q for the quarter ended September 30, 2022 (the "**3Q 2022 Form 10-Q**"), which was signed by Defendants Adcock and Sachs. The 3Q 2022 Form 10-Q touted that the Company maintained cGMP manufacturing resources, stating in relevant part:

> ***We have established Good Manufacturing Practice (GMP) manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned research and development (R&D), clinical trial, and regulatory operations and development teams.

140. In addition, the 3Q 2022 Form 10-Q outlined certain risks which "could" have a significant adverse impact on ImmunityBio's business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
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> final product testing. If microbial, viral, environmental or other contaminants are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay clinical trials and adversely harm our business. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

141. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; and, accordingly, (iii) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate under review by the FDA, were not merely hypothetical.

142. On November 10, 2022, ImmunityBio issued a press release announcing the publication of the full results of the Phase 3 trial of Anktiva with BCG in BCG-unresponsive patients with the CIS form of NMIBC, which represented as follows:

> ***The company has established GMP manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations, and development teams.

143. The statement identified in bold and italicized text in the paragraph above were materially false and misleading when made, or omitted to state material facts necessary to make the statement not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a

facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue.

144. On February 7, 2023, ImmunityBio filed with the SEC a shelf registration statement on Form S-3 to place an unspecified number of debt and equity securities not to exceed a total aggregate price of $750 million on the "shelf," which contained a prospectus relating thereto (as supplemented, the "**February 2023 Shelf Registration Statement**"). The February 2023 Shelf Registration Statement was signed by the Individual Defendants. The SEC declared the February 2023 Shelf Registration Statement effective on February 9, 2023. On February 16, 2023, ImmunityBio filed a final prospectus supplement to the February 2023 Shelf Registration Statement with the SEC pursuant to Rule 424(b)(5) (the "**February 2023 Prospectus Supplement**"), to facilitate a registered direct offering of approximately $50 million in ImmunityBio common stock and warrants to purchase up to a total of $60 million in ImmunityBio common stock. As supplemented by the February 2023 Prospectus Supplement, the February 2023 Shelf Registration Statement declared that it was "unclear" when, or if, the FDA would approve the pending Anktiva BLA:

> In May 2022, we announced the submission of a Biologics License Application (BLA) to the FDA for our product candidate, Anktiva in combination with BCG for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without Ta or T1 disease. In July 2022, we announced the FDA has accepted our BLA for review and set a target Prescription Drug User Fee Act (PDUFA) action date of May 23, 2023. ***It is unclear when the FDA will approve our BLA, if at all.***

145. The February 2023 Shelf Registration Statement also represented as follows:

> ***We have established Good Manufacturing Practice (GMP) manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned research and development (R&D), clinical trial, and regulatory operations and development teams.

146. In addition, the February 2023 Shelf Registration Statement expressly incorporated by reference the 2021 Form 10-K, the 1Q 2022 Form 10-Q, the 2Q 2022 Form 10-Q, and the 3Q 2022 Form 10-Q, including the materially false and misleading statements set forth in ¶¶ 120-123, 125-126, 136-137, and 139-140.

147. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; (iii) the FDA observed an array of significant cGMP violations at the aforementioned facility during the pre-license inspection for Anktiva which indicated that the firm's quality unit was not effectively exercising its authority and/or responsibilities; and, accordingly, (iv) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate under review by the FDA, were not merely hypothetical; and (v) far from being "uncertain" if the FDA would approve the Anktiva BLA, any such approval was no longer viable.

148. On March 1, 2023, ImmunityBio filed an annual report with the SEC on Form 10-K for the year ended December 31, 2022 (the "**2022 Form 10-K**"), which was signed by the Individual Defendants. The 2022 Form 10-K touted that the Company maintained cGMP manufacturing resources, stating in relevant part:

> ***We have established Good Manufacturing Practice (GMP) manufacturing capacity at scale*** with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned research and development (R&D), clinical trial, and regulatory operations and development teams.

149. The 2022 Form 10-K also assured investors that ImmunityBio develops its products in accordance with cGMP:

> ***ImmunityBio has adopted a strategic position to*** be vertically integrated and ***develop its products according to the FDA's GMP standards for large-scale manufacturing***, even during Phase 2 clinical trial development. Biological upstream and downstream manufacturing capabilities, with its attendant know-how and regulatory compliance for approval, have long lead times. We have adopted an approach for preparedness to provide our vaccine, immunotherapy and cell therapy products at a global scale. As such, we have established our own plants and have access to facilities on a global basis.

150. In the 2022 Form 10-K, the Company boasted that the third-party it used to manufacture Anktiva, specifically, had robust manufacturing standards:

> ***For our N-803 product candidate, we have contracted with a multi-national biologics manufacturer with multiple cGMP-compliant facilities*** in the U.S., Europe and Asia for our current clinical trials and future commercial sales, if approved. ***The facilities have robust process development and validation and quality oversight*** with high-capacity production suites operating multiple 2,000-20,000L production bioreactors.

151. The 2022 Form 10-K also outlined certain risks which "could" have a significant adverse impact on ImmunityBio's business, financial condition, results of operations, or prospects if they came to pass, including the following:

> ***The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***
>
> . . .
>
> Currently we manufacture our product candidates or we may use third-party CMOs or some of our related parties to manufacture our product candidates.
>
> . . .
>
> In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable

> FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary Chemistry, Manufacturing and Controls (CMC) documentation in support of a BLA or NDA on a timely basis. ***Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.***
>
> Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. If microbial, viral, environmental or other contaminants are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay clinical trials and adversely harm our business. ***If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.***

152. Finally, the 2022 Form 10-K declared that it was "unclear" when, or if, the FDA would approve the pending Anktiva BLA:

> In May 2022, we announced the submission of a Biologics License Application (BLA) to the FDA for our product candidate, Anktiva in combination with BCG for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without Ta or T1 disease. In July 2022, we announced that the FDA had accepted our BLA for review and set a target Prescription Drug User Fee Act (PDUFA) action date of May 23, 2023. ***It is unclear when the FDA will approve our BLA, if at all.***

153. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; (iii) the FDA observed an array of significant cGMP violations at the aforementioned facility during the pre-license inspection for Anktiva which indicated that the firm's quality unit was not effectively exercising its authority and/or responsibilities; and, accordingly, (iv) the risks posed by a failure to comply with cGMP at a CMO that manufactured a product for ImmunityBio, particularly the active ingredient in its "lead" product candidate under review by the FDA, were not merely hypothetical; and (v) far from being "uncertain" if the FDA would approve the Anktiva BLA, any such approval was no longer viable.

154. On March 20, 2023, ImmunityBio filed a current report on Form 8-K with the SEC (the "**March 20, 2023 Form 8-K**") to announce various ongoing business initiatives and updates, which was signed by Defendant Sachs. Among other things, the March 20, 2023 Form 8-K declared that it was "unclear" when, or if, the FDA would approve the pending Anktiva BLA:

> As previously disclosed, in May 2022 ImmunityBio, Inc. (the "Company") announced the submission of a Biologics License Application ("BLA") to the United States Food and Drug Administration ("FDA") for N-803 in combination with bacillus Calmette-Guérin ("BCG") for the treatment of patients with BCG-unresponsive NMIBC with carcinoma in situ ("CIS") with or without Ta or T1 disease. In July 2022, we announced that the FDA had accepted our BLA for review and set a target Prescription Drug User Fee Act ("PDUFA") action date of May 23, 2023. The Company continues to engage in ongoing discussions and dialogue with the FDA, including the proposed label for the product candidate under review in the BLA. ***It remains unclear if the FDA will approve our BLA on the PDUFA action date, if at all.***

155. The March 20, 2023 Form 8-K also informed investors that the Company was focused on preparing for the approval of the Anktiva BLA:

> As ***the Company remains focused on preparing for the potential approval of the BLA by the FDA as described above,*** it intends to continue to explore opportunities to engage in incremental financing transactions to raise the working capital needed to fund the Company's ongoing operations through the anticipated May 23, 2023 PDUFA date and execute the Company's business strategy and initiatives.

156. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as described more fully above, ImmunityBio failed to disclose that (i) it relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue; (iii) the FDA observed an array of significant cGMP violations at the aforementioned facility during the pre-license inspection for Anktiva which indicated that the firm's quality unit was not effectively exercising its authority and/or responsibilities; and, accordingly, (iv) far from being "uncertain" if the FDA would approve the Anktiva BLA, any such approval was no longer viable.

THE TRUTH EMERGES

157. During the Class Period, before the truth of Defendants' fraud was revealed, the market as a whole remained in the dark as to the extensive and rampant cGMP failures at the CMO used by ImmunityBio to manufacture Anktiva. The market, including analysts who follow ImmunityBio, did not expect manufacturing issues to pose a threat to the approvability of the Anktiva BLA. For example, Piper Sandler analyst Joseph Catanzaro, Ph. D., said in a note on September 29, 2022 that, "overall we continue to see a high likelihood of approval" for the pending Anktiva BLA. The note acknowledged that there were "a few questions" that could pose obstacles to approval, but manufacturing issues was not one of them.

158. Thus, the market was shocked on May 11, 2023, when ImmunityBio, during pre-market hours, filed a current report with the SEC on Form 8-K (the "May 11, 2023 Form 8-K") which disclosed that, on May 9, 2023, the FDA delivered a CRL to the Company in response to the Anktiva BLA arising from deficiencies observed during the FDA's pre-license inspection of its CMOs. Specifically, the May 11, 2023 Form 8-K disclosed, in relevant part:

> ImmunityBio, Inc. (the "Company") announces that it has received a complete response letter from the U.S. Food and Drug Administration ("FDA") on May 9, 2023 regarding its Biologics License Application ("BLA") for its product candidate, Anktiva™ (N-803) in combination with Bacillus Calmette-Guérin ("BCG") for the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer ("NMIBC") with carcinoma in situ ("CIS") with or without Ta or T1 disease. ***The letter indicates that the FDA has determined that it cannot approve the BLA in its present form***, and the FDA has made recommendations to address the issues raised.
>
> ***The deficiencies relate to the FDA's pre-license inspection of the Company's third-party contract manufacturing organizations***. ***Satisfactory resolution of the observations noted at the pre-license inspection is required before the BLA may be approved***. The FDA further provided recommendations specific to additional Chemistry, Manufacturing and Controls ("CMC") issues and assays to be resolved.

159. On this news, ImmunityBio common stock fell $3.43 per share, or 55.14%, on heavy volume to close at $2.79 on May 11, 2023.

160. ImmunityBio's receipt of the CRL received widespread coverage in the press. Many stories linked the stock drop specifically to the CRL. For example, industry publication *BioSpace* reported on May 11, 2023, that "ImmunityBio took a hit on Thursday as the FDA rejected its bladder cancer treatment due to deficiencies with the company's third-party contract manufacturer," noting the stock was "down nearly 60% in premarket trading." Similarly, *Seeking Alpha* issued a story that day with the headline "ImmunityBio crashes 57% after FDA snub for cancer therapy." A report by *Yahoo Finance* on May 12, 2023, also highlighted that "[s]hares of ImmunityBio IBRX

were down 55.1% on Thursday after management announced that FDA issued a complete response letter ('CRL') to its biologics license application ('BLA') seeking approval for combination use of its lead pipeline candidate, Anktiva (N-803) . . . ."

ADDITIONAL FACTS PROBATIVE OF SCIENTER

161. The Individual Defendants acted with scienter because at the time they issued public documents and other statements in ImmunityBio's name, they knew, or with extreme recklessness disregarded the fact that such statements were materially false and misleading or omitted material facts. The Individual Defendants knew such documents and statements would be issued or disseminated to the investing public, knew that persons were likely to rely upon those misrepresentations and omissions, and knowingly and recklessly participated in the issuance and dissemination of such statements and documents as primary violators of the federal securities laws.

162. A holistic examination of the facts and circumstances, including those set forth below, collectively supports a strong inference that throughout the Class Period, Defendants knew or, at a minimum, recklessly disregarded, that their statements were materially false and misleading.

A. Defendants Had A Known Duty to Ensure That the Their Manufacturing CMOs Complied with cGMP

163. The FDA's cGMP regulations recognize that sponsors commonly use CMOs to perform some or all manufacturing activities. *See* 21 C.F.R. § 200.10(b). These regulations specify that the sponsor remains legally responsible for approving or rejecting drug products that are manufactured by a CMO. *See* 21 C.F.R. § 211.22(a).

164. Importantly, the FDA has emphasized that this duty is non-transferrable and non-delegable in a CMO arrangement. Accordingly, the FDA has advised that "if the license manufacturer enters into an agreement with a [CMO], the license manufacturer ***must*** ensure that the facility complies with the applicable standards," including, specifically, cGMP. FDA, Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics (2008).

165. Consistent with the guidelines outlined above, the Individual Defendants knew that ImmunityBio was ultimately responsible for AGC's compliance with applicable FDA rules and regulations, including cGMP, since before the start of the Class Period. In the same SEC filing on January 29, 2021 discussed above, Defendants Soon-Shiong and Adcock recognized that "our CMOs will need to meet all applicable FDA . . . requirements, including cGMP, on an ongoing basis," but admitted, "to the extent we use CMOs, we are ultimately responsible for the manufacture of our products." The Individual Defendants, including Defendant Sachs, made these same statements in ImmunityBio's periodic reports filed during the Class Period.

B. AGC Was Required to Share Manufacturing Information with ImmunityBio, Including Significant cGMP Issues

166. Because the obligation to comply with cGMP is non-transferable, the FDA has advised for years that "[t]he license manufacturer ***must*** have a procedure in place for receiving information from a contract facility on all deviations, complaints, and adverse events" that arise during manufacturing. FDA, Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics (2008). The FDA also suggested that CMO agreements should include "procedures to regularly assess the [CMO]'s compliance" including, but not limited to, "review of records and manufacturing deviations and defects, and periodic audits" as well as "assurance from the [CMO] that any FDA list of inspectional observations will be shared with the license manufacturer." *Id.*

167. In 2016, the FDA released new guidance which specified that "[t]here should be a written and approved contract or formal agreement between a company and its [CMOs] that defines in detail the GMP responsibilities, including quality measures, of each party." ICH, Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (2016). That FDA also specified that any "[c]hanges in the process, equipment, test methods, specifications, or other contractual requirements should not be made unless the contract giver is informed and approves of the change."

Id. Later that year, the FDA adopted further guidance which recommended that parties enter into "quality agreements" to do so. FDA, Contract Manufacturing Arrangements for Drugs: Quality Agreements, Guidance for Industry (2016). Consistent with its previous guidance, the FDA advised that such agreements should contain provisions for reporting, among other things, deviations, FDA inspection observations, proposed process changes, and all laboratory test results conducted by the CMO, including, in particular, any that generate results which are out of specification. *Id.*

168. ImmunityBio maintained at least one such quality agreement with AGC during the Class Period (the "**Quality Agreement**"). As CW4 explained, the Quality Agreement that ImmunityBio had with AGC was "standard" and required AGC to provide typical information, including any deviations, out of specification tests and any FDA inspection observations. This was echoed by CW3, who indicated that the Quality Agreement required AGC to provide findings of any inspection by a government agency, batch records, batch disposition reports, certain deviation notices, and reports for any deviation investigations. As detailed by CW3, the extensive information contained in the batch records (¶ 68) were used by AGC to decide whether the batch was successful, in which case it signs off on a batch disposition and provides the same records to ImmunityBio so it could perform the same analysis. According to CW3, ImmunityBio was "100 percent" aware of each instance when AGC missed a target date for batch disposition through this reporting mechanism.

169. As is standard, the Quality Agreement during the start of CW3 tenure only required AGC to notify ImmunityBio about certain types of deviations from the established manufacturing process, including, for example, those deemed "critical." But CW3 reported that between August 2021 and November 2022, there was "a verbal or written agreement for all deviations." According to CW3, this change was made because "they [ImmunityBio] wanted to see all of them," even those classified as minor. Thereafter, said CW3, "they [ImmunityBio] had direct awareness of all the deviations and problems that arose with each of the batches from a quality perspective."

170. In addition, AGC maintained a variety of internal policies that required it to either notify ImmunityBio or obtain its approval for certain matters. For example, AGC's internal policy for stability testing required it to confirm with ImmunityBio, in the event testing must be performed outside the test window, that samples can be returned to the long-term storage location until testing can be performed.

171. Consistent with these reporting mechanisms, as described above, it was common knowledge in ImmunityBio's manufacturing and quality departments from approximately mid-2021 through February 2023 that AGC suffered from myriad cGMP problems, including a recurring inability to timely release batch records, close deviations, conduct stability testing, and running out of critical reference material needed for testing. Indeed, CW1 pointed out that ImmunityBio began to "remind" AGC at each test window to perform the testing because of the known buildup of misses before the Anktiva BLA.

C. The Individual Defendants Were Intimately Aware of the Significant cGMP Failings at AGC Throughout the Class Period

172. As provided above (¶¶ 68-71), AGC was consistently unable to provide batch records, deviation reports, and stability tests on schedule throughout the Class Period. CW3 explained that timely batch disposition was especially "important" to ImmunityBio leadership in 2021 because the results were needed for the Anktiva BLA.

173. Numerous CWs confirm that Defendant Adcock regularly met with AGC executives during the Class Period to discuss the firm's continued delays. CW3 attended monthly meetings with Adcock and ImmunityBio's Chief Operating Officer, Leonard Sender, beginning in August 2021, during which they discussed missed target dates for batch dispositions and deviation close outs. CW3 said these meetings became more frequent in the lead up to the FDA inspection. CW1 was personally aware of approximately 10 such meetings between mid-2021 and 2022 attended by Adcock and Sender as well as ImmunityBio's Senior Director of Quality Control, Scott Yuen. This is consistent with the account of CW4, who recalled that Adcock and Sender were

meeting with AGC's senior executives "every other week" during this time. CW4 emphasized that Adcock and Sender were meeting with AGC so often because AGC was extremely late submitting batch records for ImmunityBio to review for final release.

174. CW3 also confirmed that Adcock and Sender discussed the PPQ runs during the routine meetings they held with AGC.

175. According to CW1, in 2022, ImmunityBio placed contract workers in the AGC facility to assist with the growing backlog because AGC was unable to fix the problem on its own. CW1 heard from colleagues that the contract workers were a significant cost and would have, at the very least, required Defendant Sachs approval. Unfortunately, even after this, AGC was still unable to stay on schedule, said CW1.

176. Notably, CW2 said that Defendant Soon-Shiong "personally reviewed" and "approved" the Anktiva BLA before it was filed. CW2 became aware of this from a colleague who explained that the Company was waiting for Soon-Shiong to sign off before formally submitting the BLA. This is notable because the BLA would need to address, among other things, the significant number of missed stability checks as well as the failed batch runs of Anktiva that took place before then.

177. Between the BLA filing and the FDA's pre-license inspection, ImmunityBio continued to work with AGC to shore up its cGMP deficiencies. For example, CW2 advised that, before departing the Company in November 2022, ImmunityBio maintained a spreadsheet internally known as the "pre-approval inspection tracker" which cataloged, in detail, all of the potential cGMP issues at each manufacturing location, including AGC. CW2 commented that "there were a lot of eyes on that," and confirmed that ImmunityBio leadership reviewed it.

178. As provided above (¶ 77), the FDA notified AGC on November 1, 2022, that it planned to hold a pre-license inspection at the facility it used to manufacture Anktiva in February 2023. In connection therewith, the FDA informed AGC that the inspection would span two weeks and involve six inspectors. CW3 noted that this is "on the far side of the high intensity spectrum," explaining that pre-approval inspections

of this type are typically conducted by one or two inspectors over several days. CW3 confirmed that AGC shared this information with ImmunityBio and recalled that, upon learning about the scope of the inspection, "everybody was nervous" at ImmunityBio, including Defendants Soon-Shiong and Adcock. In fact, CW3 said "they were very concerned" after learning this.

179. CW3 said that this prompted ImmunityBio to hold a "mock" inspection for several days in January 2023 in which its representatives had full access to its documentation and facilities. As CW3 explained, "they [ImmunityBio] wouldn't have asked for a pre-audit if they weren't concerned." CW3 emphasized that Defendant Adcock and Leonard Sender were "intricately involved" in the mock inspection, including "the planning of it, the execution of it, the results of it—all aspects." Neither attended the audit itself, but CW3 indicated that they were updated along the way. CW1 also recalled that ImmunityBio conducted its own inspection at AGC in or around January 2023 and confirmed that Scott Yuen attended the mock inspection from ImmunityBio.

180. Both CW3 and CW1 recalled that the mock inspection uncovered a host of objectionable conditions that required remediation by AGC before the FDA's official inspection in February 2023. Among other things, CW3 recalled that one of ImmunityBio's specialists identified gaps and weaknesses in AGC's data integrity system. CW1 learned from Scott Yuen, who attended the mock inspection, that the observations noted deficiencies in cGMP compliance, including general concerns about AGC's repeated testing delays. CW3 confirmed that ImmunityBio's top leadership was made fully aware of the findings of the mock inspection at the time it concluded. Indeed, CW3 personally presented the findings of the mock inspection to Defendant Adcock and Leonard Sender.

181. Based on the findings from the mock inspection, CW3 said that ImmunityBio leadership became engaged "on a very technical level" with prep for the FDA inspection because they "knew this could be a risk." Among other things,

ImmunityBio assembled a list of all "gaps" that needed to be closed before the FDA inspection. But CW3 reported that the team was unable to close all gaps before the FDA inspection. As CW3 explained, "there wasn't enough time between the pre-audit and the actual audit to completely cover everything."

182. The FDA's pre-license inspection at AGC took place between February 2, 2023, and February 10, 2023. CW3 confirmed that ImmunityBio sent at least six representatives to attend the inspection, and there was a plan in place on how to update ImmunityBio on the progress of the inspection.

183. However, as CW3 highlighted, the plan changed after the FDA observed a number of deficiencies on the first day of the inspection. Leonard Sender got "nervous" after hearing this from AGC and, soon thereafter, Defendant Soon-Shiong demanded that he wanted a personal call at the end of each day to discuss how the inspection went that day between ImmunityBio's top leadership and AGC's top leadership, including CW3. In addition, Defendant Adcock flew up to Washington overnight to be present for the next several days of the inspection.

184. As the inspection progressed, the ImmunityBio management team became increasingly anxious. At first, Soon-Shiong demanded that CW3 allow ImmunityBio employees to be "in the room" with the inspectors. CW3 refused because it would be improper, which sent Soon-Shiong into "yelling." Eventually CW3 agreed to have an AGC employee frequently feed information back to ImmunityBio leadership about what was happening, for example, "here are the discussions going on, here are the questions the FDA is asking, here's how we intend to answer." CW3 commented "[i]t was as real time as possible." In addition, CW3 verified that the daily leadership call demanded by Soon-Shiong took place as scheduled every day after the end of the inspection. CW3 participated on the calls and added that they were attended on the ImmunityBio side by Defendants Soon-Shiong and Adcock as well as Leonard Sender. The Individual Defendants were fully informed about the results of the FDA's pre-license inspection.

D. The Fact That ImmunityBio Initiated Plans to Manufacture Anktiva In-House Supports an Inference of Scienter

185. The inference that Defendants were aware of the subpar manufacturing standards and cGMP failures at AGC, and thus the inference of scienter, is further supported by the fact that ImmunityBio initiated plans to manufacture Anktiva in-house midway through the Class Period. Specifically, by no later than March 1, 2022, ImmunityBio initiated plans to establish a cGMP-compliant facility in California, which included a large space for the production of antibodies and fusion proteins, including, specifically, Anktiva.

186. The process of building a cGMP-compliant facility, either from an existing space or from scratch, is very time-consuming and expensive. Similarly, the process of "transferring" the manufacturing technology from one facility to another consistent with the specifications for the product is also very time-consuming and expensive. These activities independently and in combination would require new FDA approvals.

187. At the very least, ImmunityBio would not take on the significant cost and time required to build, qualify, and receive approval for such a facility if it was satisfied with the services provided to it by AGC.

E. FDA Approval of Anktiva Was Critical to ImmunityBio's Financial Success

188. It is reasonable to infer that Defendants were aware of the manufacturing issues that AGC reported or otherwise communicated to ImmunityBio, including the inspection observations made by the FDA in March 2021 and July 2021, given the critical importance of the Anktiva BLA to ImmunityBio's continued success. As of the start of the Class Period, ImmunityBio was a clinical-stage company with no approved drugs and, thus, no source of meaningful revenues. At the time its "lead" product candidate, and by far the most developed in its product portfolio, was Anktiva. As such, on January 29, 2021, Defendants Soon-Shiong and Adcock stated in SEC filings made in connection with the Legacy ImmunityBio-NantKwest merger that "[t]he combined company's business ***depends entirely*** on the successful development, regulatory

approval and commercialization" of its three main product candidates, including Anktiva. Adcock made this same statement in an SEC filing on March 10, 2021.

F. Soon-Shiong Was a Controlling Hands-On Manager

189. According to CW3, Defendant Soon-Shiong was an "extreme control freak." As CW3 explained, it was not uncommon for Soon-Shiong to yell at people during business meetings. CW3 also witnessed meetings where Soon-Shiong was "telling everybody what to do." It appeared to CW3 that Soon-Shiong was the one calling the shots at ImmunityBio, often issuing orders to Defendant Adcock, CEO of ImmunityBio.

G. Respondeat Superior and Agency Principles Apply

190. ImmunityBio is liable for the acts of the Individual Defendants and other Company officers, directors, employees, and agents under the doctrine of *respondeat superior* and common law principles of agency as all wrongful acts alleged herein were carried out within the scope of their employment or agency with the authority or apparent authority to do so. The scienter of the Individual Defendants and other Company officers, employees , and agents is therefore imputable to ImmunityBio.

LOSS CAUSATION

191. At all relevant times, ImmunityBio common stock traded in an open, well-developed, and efficient market which promptly digested new information regarding the Company from all reasonably accessible public sources and reflected such information in the price of ImmunityBio's common stock.

192. As described above, throughout the Class Period, Defendants made false and misleading statements which misrepresented and/or failed to disclose the adverse facts detailed herein. Defendants' false and misleading statements caused ImmunityBio securities to trade at artificially inflated prices throughout the Class Period and, thus, operated as a fraud or deceit on Lead Plaintiff and other members of the Class who purchased or otherwise acquired such securities before such the inflation was removed.

193. As detailed herein, the price of ImmunityBio common stock fell precipitously on high volume in response to disclosures made by the Company on May 11, 2023. The price of ImmunityBio common stock fell in response to each such disclosure by revealing information that removed part of the inflation introduced by Defendants' previous misstatements and omissions, causing real economic loss to Lead Plaintiff and other members of the Class who purchased ImmunityBio common stock during the Class Period at inflated prices.

194. Each decline in the price of ImmunityBio common stock referenced above was a direct and proximate result of Defendants' misstatements or omissions being revealed to the market and/or the materialization of risks concealed by the fraud. The timing and magnitude of each such price decline negates any inference that the losses suffered by Lead Plaintiff and other members of the Class were caused by changed market conditions, macroeconomic factors, or Company-specific facts unrelated to the fraud alleged herein.

195. Accordingly, Defendants' wrongful conduct directly and proximately caused Lead Plaintiff and other members of the Class to suffer economic losses, *i.e.*, damages under the federal securities laws.

PRESUMPTION OF RELIANCE

196. Lead Plaintiff and the Class is entitled to a presumption of reliance under the fraud-on-the-market doctrine adopted by the Supreme Court in *Basic v. Levinson*, 485 U.S. 224 (1998). Such a presumption is appropriate because, among other things:

(a) during the Class Period, Defendants made public misrepresentations or failed to disclose material facts necessary to make the public statements that were made not misleading;

(b) such misrepresentations and/or omissions were material;

(c) the Company's common stock traded in an efficient market;

(d) the misrepresentations and/or omissions would tend to induce a reasonable investor to misjudge the value of ImmunityBio's common stock; and

(e) Lead Plaintiff and other members of the Class purchased ImmunityBio common stock between the time Defendants misrepresented or failed to disclose material facts necessary to make the statements that were made not misleading and the time the true facts were disclosed, without knowledge of the true and/or omitted facts.

197. At all relevant times, the market for ImmunityBio's common stock was efficient for the following reasons, among others:

(a) ImmunityBio's common stock met the requirements for listing, and were listed, on the NASDAQ, a highly efficient and automated market;

(b) as a regulated issuer, ImmunityBio filed periodic public reports with the SEC;

(c) throughout the Class Period, ImmunityBio's common stock was highly liquid, with an average daily trading volume of 1.9 million shares;

(d) ImmunityBio regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(e) ImmunityBio was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales forces and certain customers of their respective brokerage firms, and, thus, entered the public marketplace; and

(f) unexpected company-specific news was reflected and incorporated into the stock price for ImmunityBio's common stock.

198. As a result of the foregoing, the market for ImmunityBio's common stock promptly digested new information regarding the Company from all reasonably accessible public sources and reflected such information in the price of ImmunityBio's common stock. Under these circumstances, all purchasers of ImmunityBio common

stock during the Class Period suffered similar injury through their purchase of such securities at artificially inflated prices, and a presumption of reliance applies.

199. A Class-wide presumption of reliance is also appropriate under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims center, in large part, upon Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated by law to disclose—positive proof of reliance is not a prerequisite to recovery.

NO SAFE HARBOR

200. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the statements alleged to be false or misleading herein.

201. None of the statements alleged herein to be false or misleading are forward-looking statements. Such statements address facts and conditions existing at the time the statements were made. Furthermore, none of the historic or present-tense statements alleged herein to be false or misleading were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such an assumption when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

202. To the extent certain of the statements alleged herein to be false or misleading may be characterized as forward-looking, they were not identified as "forward-looking statements" when made, and they were not accompanied by any meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Any purported cautionary language warned only of theoretical future risks at times when the risks were not merely hypothetical Moreover, the purported cautionary

language failed to adjust over time, using the same theoretical tone even after concrete changes of circumstance. In the alternative, Defendants are liable for those forward-looking statements because at the time each such statement was made, the speaker had actual knowledge, or recklessly disregarded the risk, that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of ImmunityBio who knew, or recklessly disregarded the risk, that the statement was false when made.

CLASS ACTION ALLEGATIONS

203. Lead Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of Class consisting of all persons and entities other than Defendants that purchased or otherwise acquired ImmunityBio common stock between March 7, 2021 and May 10, 2023, both dates inclusive, and were damaged thereby.

204. The members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, ImmunityBio common stock was actively traded on the NASDAQ. As of May 5, 2023, there were approximately 435,984,529 shares of ImmunityBio common stock outstanding. While the exact number of Class members is unknown to Lead Plaintiff at this time and can be ascertained only through appropriate discovery, Lead 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 ImmunityBio 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.

205. Lead Plaintiff's claims are typical of the claims of the members of the Class. All members of the Class were similarly affected by Defendants' wrongful conduct in violation of the Exchange Act, as complained of herein.

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

207. 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, including:

(a) whether Defendants' acts alleged herein violated the federal securities laws and/or SEC rules promulgated thereunder;

(b) whether Defendants' statements during the Class period misrepresented material facts or omitted material facts necessary in order to make the statements made, in the circumstances under which they were made, not misleading;

(c) whether Defendants made such statements;

(d) whether Defendants acted with the requisite level of scienter;

(e) whether and to what extent the material misstatements and omissions alleged herein artificially inflated the market price of ImmunityBio common stock; and

(f) whether the members of the Class have sustained damages and, if so, the proper measure of damages.

208. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because, among other reasons, joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class individually to redress the wrongs done to them individually. There will be no difficulty in the management of this action as a class action.

COUNT I

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

209. Lead Plaintiff repeats and realleges every allegation pleaded above as if fully set forth herein.

210. This Count is brought against Defendants under Section 10(b) of the Exchange Act, codified at 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC, codified at 17 C.F.R. § 240.10b-5.

211. Throughout the Class Period, Defendants, individually and in concert, directly or indirectly, by use of the means or instrumentalities of interstate commerce, including but not limited to the mails and the internet, and/or the facilities of the NASDAQ, 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 Lead 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.

212. As alleged herein, Defendants made or otherwise caused ImmunityBio to issue the materially false or misleading statements specified above. Specifically, the Individual Defendants participated directly or indirectly in the preparation, approval and/or issuance of public disclosures specified above that contained untrue statements of material fact and/or omitted material facts necessary to make the statements therein not misleading. Such scheme was intended to, and did, as alleged herein: (i) deceive the investing public, including Lead Plaintiff and other Class members; (ii) artificially inflate and maintain the market price of ImmunityBio common stock; and (iii) cause Lead Plaintiff and other members of the Class to purchase or otherwise acquire ImmunityBio common stock at artificially inflated prices.

213. As set forth above, the Individual Defendants knew or were reckless in not knowing that such statements, when made, were false or misleading, in that they contained material misrepresentations or otherwise failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

214. ImmunityBio is liable for the acts of its executives, directors, officers, and agents, including the Individual Defendants, at common law and under the doctrine of *respondeat superior* because all the wrongful acts and omissions complained of herein were carried out within the scope of such person's employment. The scienter of ImmunityBio's executives, directors, officers, and agents, including the Individual Defendants, is similarly imputed to ImmunityBio under established agency principles.

215. As a result of the foregoing, the market price of ImmunityBio's common stock was artificially inflated during the Class Period. Lead Plaintiff and other members of the Class relied on the integrity of the market price for ImmunityBio common stock during the Class Period and paid prices for such securities that were artificially inflated as a result of the false and misleading statements described herein. Lead Plaintiff and members of the Class would not have purchased such securities at the prices they paid, or at all, if they had been aware that the market prices of such securities was artificially inflated by Defendants' false and misleading statements.

216. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class have suffered damages in connection with their purchases of ImmunityBio common stock during the Class Period.

217. By reason of the foregoing, Defendants are liable to Lead Plaintiff and members of the Class for violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II

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

218. Lead Plaintiff repeats and realleges every allegation pleaded above as if fully set forth herein.

219. This Count is brought against the Individual Defendants under Section 20(a) of the Exchange Act, codified at 15 U.S.C. § 78t(a).

220. As alleged above, Defendants, and each of them, violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making materially false and misleading statements and omitted material information in connection with the purchase and sale of the Company's common stock and by participating in a fraudulent scheme and course of business or conduct throughout the Class Period.

221. Throughout the Class Period, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of ImmunityBio and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations alleged herein, and exercised the same.

222. As officers and/or directors of a publicly owned company, the Individual Defendants also had a duty to disseminate accurate and truthful information with respect to ImmunityBio's business, operations, financial condition, and prospects. In this capacity, the Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Lead Plaintiff to be false or misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

223. Thus, by virtue of their positions as senior officers and/or directors of ImmunityBio, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the false and misleading statements alleged herein to give rise to the primary violations alleged herein. Indeed, the Individual

Defendants exercised their power and authority to cause ImmunityBio to engage in the wrongful acts alleged herein or personally participate in the unlawful conduct alleged.

224. By reason of the foregoing, the Individual Defendants are liable to Lead Plaintiff and members of the Class for violations of Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for judgment against Defendants as follows:

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

B. Awarding compensatory damages in favor of Lead Plaintiff and the other members of the Class 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 interest thereon;

C. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in connection with this action, including reasonable attorneys' fees and costs incurred by consulting and testifying experts; and

D. Awarding such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Lead Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: November 17, 2023

Respectfully submitted,

POMERANTZ LLP

/s/ Justin D. D'Aloia

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CERTIFICATION PURSUANT
TO FEDERAL SECURITIES LAWS

1. I, Dipak Patel, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed a Complaint against ImmunityBio, Inc. ("ImmunityBio" or the "Company") and authorize the filing of a comparable complaint on my behalf.

3. I did not purchase or acquire ImmunityBio securities at the direction of counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or otherwise acquired ImmunityBio securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.

5. The attached sheet lists all of my transactions in ImmunityBio securities during the Class Period as specified in the Complaint.

6. During the three-year period preceding the date on which this Certification is signed, I have not served or sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed 11/15/2023
(Date)

DocuSigned by:
905C2C38FDDF437...
(Signature)

Dipak Patel
(Type or Print Name)