**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| Plaintiff,<br><br>v.<br><br>AGENUS INC., GARO H. ARMEN, CHRISTINE M. KLASKIN, and STEVEN J. O'DAY,<br><br>Defendants. | **Case No.**<br><br>**CLASS ACTION COMPLAINT**<br><br>**JURY TRIAL DEMANDED** |

Plaintiff individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Agenus Inc. ("Agenus" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Agenus securities between

January 23, 2023 and July 17, 2024, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Agenus is a clinical-stage biotechnology company that discovers and develops immuno-oncology ("I-O") products in the U.S. and internationally. Among other product candidates, the Company is developing balstilimab, an anti-PD-1 antagonist that has completed a Phase 2 clinical trial to treat second line cervical cancer; and botensilimab (AGEN1181), an antigen 4 (CTLA-4) blocking antibody that is in a Phase 2 clinical trial for the treatment of pancreatic cancer and melanoma.

3. Agenus purports to pursue clinical trials "designed to strengthen the efficacy and safety signals demonstrated to date and that may support a potential filing for full approval and/or accelerated approval based on the magnitude of benefit demonstrated" and, according to the Company, its strategy "revolves around pioneering optimal combination treatments for cancer patients, with botensilimab as [its] cornerstone." In particular, Agenus has focused on the development of the "botensilimab/balstilimab combination," the Company's investigational therapy for the treatment of patients with metastatic colorectal cancer ("CRC").

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the combination therapy of botensilimab and balstilimab was less effective than Defendants had led investors to believe; (ii) accordingly, botensilimab and balstilimab's clinical results, as well as their regulatory and

commercial prospects, were overstated; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On July 18, 2024, Agenus issued a press release announcing the results of an "end-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA), for the advancement of its immunotherapy combination, botensilimab (BOT) and balstilimab (BAL), for the treatment of adult patients with relapsed/refractory microsatellite stable colorectal cancer (r/r MSS CRC) with no active liver metastases (NLM)." The press release revealed that the "FDA advised against submission of these results in support of an Accelerated Approval based on their view that objective response rates may not translate to survival benefit."

6. On this news, Agenus's stock price fell $10.43 per share, or 58.83%, to close at $7.30 per share on July 18, 2024.

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

## JURISDICTION AND VENUE

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

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

10. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Agenus is headquartered in this District, Defendants

conduct business in this District, and a significant portion of Defendants' actions took place within this District.

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

## PARTIES

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

13. Defendant Agenus is a Delaware corporation with principal executive offices located at 3 Forbes Road, Lexington, Massachusetts 02421. The Company's common stock trades in an efficient market on the Nasdaq Capital Market ("NASDAQ") under the ticker symbol "AGEN."

14. Defendant Garo H. Armen ("Armen") has served as Agenus's Chief Executive Officer and Principal Executive Officer at all relevant times.

15. Defendant Christine M. Klaskin ("Klaskin") has served as Agenus's Vice President of Finance and Principal Financial Officer at all relevant times.

16. Defendant Steven J. O'Day ("O'Day") has served as Agenus's Chief Medical Officer at all relevant times.

17. Defendants Armen, Klaskin, and O'Day are collectively referred to herein as the "Individual Defendants."

18. The Individual Defendants possessed the power and authority to control the contents of Agenus's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Agenus's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Agenus, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

19. Agenus and the Individual Defendants are collectively referred to herein as "Defendants."

## SUBSTANTIVE ALLEGATIONS

### Background

20. Agenus is a clinical-stage biotechnology company that discovers and develops I-O products in the U.S. and internationally. Among other product candidates, the Company is developing balstilimab, an anti-PD-1 antagonist that has completed a Phase 2 clinical trial to treat second line cervical cancer; and botensilimab (AGEN1181), an antigen 4 (CTLA-4) blocking antibody that is in a Phase 2 clinical trial for the treatment of pancreatic cancer and melanoma.

21. Agenus purports to pursue clinical trials "designed to strengthen the efficacy and safety signals demonstrated to date and that may support a potential filing for full approval and/or accelerated approval based on the magnitude of benefit demonstrated" and, according to the Company, its strategy "revolves around pioneering optimal combination treatments for cancer

patients, with botensilimab as [its] cornerstone." In particular, Agenus has focused on the development of the "botensilimab/balstilimab combination," the Company's investigational therapy for the treatment of patients with metastatic CRC.

**Materially False and Misleading Statements Issued During the Class Period**

22. The Class Period begins on January 23, 2023, when Agenus issued a press release during pre-market hours "announc[ing] clinical data from the MSS CRC (microsatellite stable colorectal cancer) 70 patient cohort of a Phase 1b study of botensilimab (multifunctional Fc-enhanced anti-CTLA-4) in combination with balstilimab (anti-PD-1) in patients with chemotherapy and/or immunotherapy-resistant tumors." The press release stated, in relevant part:

> The larger dataset continues to demonstrate that this combination offers superior efficacy and durability compared to what has been reported for standard of care and other investigational therapies in third line metastatic MSS CRC. The data were presented in the opening late-breaking oral session at the American Society of Clinical Oncology - Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco, CA on Saturday Jan 21 2023.
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> "***This data highlight the deep and durable responses achieved with botensilimab and balstilimab in advanced MSS CRC, underscoring remarkable benefit for these patients who have failed standard of care or other investigative therapies. With over 300 patients enrolled to date, botensilimab alone and in combination with balstilimab have demonstrated durable clinical responses across nine cold and treatment-resistant cancers***," said [Defendant] O'Day[.] "Our top priority is to advance this combination in global randomized trials with the intent to bring this important treatment to patients expeditiously."
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> "MSS CRC accounts for over 95% of metastatic CRC cases and is characterized by tremendous unmet need, as available treatments have reported single digit responses rates," said Anthony El-Khoueiry, MD, Phase I Program Director and Associate Director for Clinical Research at the USC Norris Comprehensive Cancer Center, Keck Medicine of USC, and the Principal Investigator for the study. "The 23% response rate demonstrated by botensilimab plus balstilimab in this study supports rapid development of this combination in MSS CRC."[1]

[1] All emphases included herein are added unless otherwise indicated.

23. On March 14, 2023, Agenus issued a press release announcing the Company's Q4 and full year 2023 financial results. The press release stated, in relevant part:

> "Agenus has entered 2023 with strong momentum across our extensive and diverse clinical pipeline of immuno-oncology programs. Our anchor programs, botensilimab (Fc-enhanced, multi-functional anti-CTLA-4) and balstilimab (anti-PD-1), show exciting potential in combination to treat a broad spectrum of treatment-resistant cancers," said [Defendant] Armen[.] "With the growing body of data demonstrating robust, consistent, and durable efficacy signals from a trial of over 300 patients across nine metastatic, late-line cancers, we are expediting the expansion of our botensilimab/balstilimab development program in MSS CRC and other priority indications."
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> "The number of patients with solid tumors resistant to a variety of therapies, including current immunotherapies, is substantial. Existing treatment options for these patients after failure of initial standard treatments are limited and largely ineffective, resulting in a short overall survival rate," said [Defendant] O'Day[.] "***Botensilimab's clinical activity in advanced and refractory cancers has generated considerable interest from experts worldwide***."
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> **2022 Highlights**
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> **Botensilimab: Wholly Owned Lead Clinical Asset**
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> Botensilimab's clinical results have been presented at a late-breaking oral session at the American Society of Clinical Oncology (ASCO GI) in 2023, and in plenary sessions at the European Society for Medical Oncology (ESMO-GI), Connective Tissue Oncology Society (CTOS), the Society for Immunotherapy of Cancer (SITC) 2022 annual meetings, as well as at a company-hosted R&D Event ('The Road Taken'). ***The latest clinical study results, including those of the botensilimab and botensilimab/balstilimab combination, demonstrate durable responses and significant benefits compared to that reported for standard of care and other investigational therapies in patients with treatment-resistant tumors***.

24. That same day, Agenus hosted an earnings call with investors and analysts to discuss the Company's Q4 2022 results (the "Q4 2022 Earnings Call"). During the scripted portion of the Q4 2022 Earnings Call, Defendant Armen stated, in relevant part:

> Our portfolio is designed to address areas of high patient need and to unlock the large untapped market opportunity in cold and treatment-resistant cancers. And on top of that, to provide benefit beyond what is currently available with I-O treatments in other tumors, including hot tumors. At the forefront of our pipeline is

botensilimab a clinical stage multifunctional Fc-enhanced CTLA-4 antibody with potentially blockbuster capabilities.

Over the last 12 months, we've made substantive progress addressing the ongoing botensilimab development program, including having dosed over 300 heavily pretreated patients with advanced solid tumors as part of our Phase 1b trial. That's a very large trial in account. And we've done this with [] monotherapy and in combination with our [. . .] PD-1 antibody balstilimab. Botensilimab has produced durable objective responses in nine cold and/or treatment resistant cancers, including MSS colorectal cancer and MSS stands for microsatellite stable cancers that are particularly challenging to treat with immunotherapy.

So, we've seen results in MSS colorectal cancer, MSS endometrial cancer, platinum-resistant refractory ovarian cancer, PD-1 resistant refractory non-small cell lung cancer, PD-1 and CTLA-4 resistant refractory melanoma, a particularly challenging patient population. PD-1 resistant refractory hepatocellular carcinoma, PD-1 resistant refractory cervical cancer, angiosarcoma and liposarcoma, this is a very extensive list of difficult-to-treat cancers that had been treated and failed prior treatments.

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We are thrilled by the clinical results we have seen with botensilimab and are excited about its potential to positively impact the treatment landscape for patients obviously suffering for cancer, all kinds of cancers.

25. On March 16, 2023, Agenus filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operational results for the year ended December 31, 2022 (the "2022 10-K"). In providing an overview of the Company, the 2022 10-K stated, in relevant part:

We are a clinical-stage company with a pipeline of therapies designed to activate the body's immune system to fight cancer and infections, including immune-modulatory antibodies, adoptive cell therapies (through our subsidiary MiNK Therapeutics, Inc. ("MiNK")) and vaccine adjuvants (through our subsidiary SaponiQx, Inc. ("SaponiQx")). This robust product pipeline is supported by our in-house capabilities, including current good manufacturing practice ("cGMP") manufacturing and a clinical operations platform. Our primary focus is immuno-oncology ("I-O"), and our business is designed to drive success through speed, innovation and effective combination therapies. We believe that a deep understanding of each patient's cancer and the potential to deliver combination therapies will drive substantial expansion of the patient population benefiting from current I-O therapies. In addition to a diverse pipeline, we have assembled fully

integrated end-to-end capabilities including novel target discovery, antibody generation, cell line development and cGMP manufacturing. We believe that these fully integrated capabilities enable us to produce novel candidates on timelines that are shorter than the industry standard. Leveraging our science and capabilities, we have forged important partnerships to advance our innovation.

We believe the next generation of cancer treatment will build on clinically validated antibodies targeting CTLA-4 and PD-1 combined with novel immunomodulatory agents designed to address underlying tumor escape mechanisms. Our most advanced antibody candidates are botensilimab (a proprietary next-generation Fc-engineered CTLA-4 antibody, also known as AGEN1811) and balstilimab (a PD-1 antibody).

26. Further, in providing an overview of the Company's "vision," the 2022 10-K stated, in relevant part:

We believe that combination therapies and a deep understanding of each patient's cancer will be key drivers of success in substantially expanding the patient population benefiting from current I-O therapies. In addition, delivering innovation with speed is critical for our future success, as drug development timelines in oncology shorten while product obsolescence rates climb. We believe our fully integrated, end-to-end capabilities from our artificial intelligence-powered VISION platform for novel target discovery, antibody generation, and cell line development to our cGMP manufacturing and clinical development and operations capabilities, together with a comprehensive and complementary portfolio will uniquely position us to produce novel therapies on accelerated timelines. We believe that a balanced pipeline of product candidates should focus on both validated targets as well as novel targets designed to address tumor escape mechanisms. In this context, CTLA-4 and PD-1 antagonists are recognized as the first clinically validated immunotherapy combination. These therapeutic targets, in combination with innovative immunomodulatory antibodies, cell therapies, or immune educating vaccines, are reasonably anticipated to be focal points of the next generation of I-O combination therapies. Therefore, we plan to develop, register and launch proprietary antibodies targeting PD-1 and CTLA-4 aggressively through the clinic and expand with novel combination therapies designed to improve clinical response and the durability of response of existing therapies.

27. Finally, in discussing the Company's strategy, the 2022 10-K stated, in relevant part:

Our strategy is to bring innovative combination therapies for cancer patients to substantially expand the patient population benefiting from current I-O therapies. Our diverse pipeline of antibody-based therapeutics, cell therapies, and vaccine adjuvants enable us to pursue therapeutically relevant approaches focused on safe

> and effective therapeutic agent combinations. In line with this approach, we are pursuing clinical trials designed to strengthen the efficacy and safety signals demonstrated to date and that may support a potential filing for full approval and/or accelerated approval based on the magnitude of benefit demonstrated.

28. Appended to the 2022 10-K as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Armen and Klaskin, attesting that "[t]he information contained in the [2022 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

29. On March 27, 2023, the Company issued a press release entitled "Agenus' Botensilimab in Combination with Balstilimab Shows 33% Durable Responses in Ovarian Cancer." The press release stated, in relevant part:

> Agenus [. . .] today announced results from a cohort of 24 evaluable patients in an expansion of the Company's Phase 1b study of botensilimab (multifunctional CTLA-4 antibody) in combination with balstilimab (PD-1 antibody) in patients with recurrent platinum resistant/refractory ovarian cancer. These findings, presented in an oral plenary session at the Society of Gynecologic Oncology (SGO) 2023 Annual Meeting on Women's Cancer, showed a 33% overall response rate (ORR).
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> "These results add to the growing body of data showing deep and durable efficacy signals for botensilimab across nine cold and treatment-resistant cancers," said [Defendant] O'Day[.] "***Botensilimab is designed with a unique mechanism of action that stimulates both innate and adaptive immune responses against cancer, resulting in an improved benefit compared to what has been reported for other checkpoint therapies***."
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> "The combination of botensilimab and balstilimab in platinum-resistant ovarian cancer shows promise for a substantial improvement in efficacy compared to existing therapies, which typically only yield single-digit response rates," said Bruno Bockorny, M.D., Harvard Medical School, Beth Israel Deaconess Medical Center, and principal investigator for the study. "The remarkable efficacy and manageable tolerability profile of this combination suggest a transformative potential for ovarian cancer patients."

30. On April 17, 2023, the Company issued a press release entitled "Agenus Receives Fast Track Designation for Botensilimab and Balstilimab in Colorectal Cancer." The press release stated, in relevant part:

> Agenus [. . .] has been granted Fast Track Designation from the US Food and Drug Administration (FDA) for the investigation of the combination of botensilimab (AGEN1181) and balstilimab (AGEN2034). The designation is for patients with non-microsatellite instability-high (MSI-H)/deficient mismatch repair (dMMR) metastatic colorectal cancer with no active liver involvement. Patients targeted with this designation are heavily pretreated are resistant or intolerant to a fluoropyrimidine, oxaliplatin, and irinotecan, and who have also received a VEGF inhibitor, an EGFR inhibitor and/or a BRAF inhibitor, if indicated. The company is conducting a global, randomized Phase 2 trial of botensilimab in combination with balstilimab compared to standard of care in non-microsatellite instability-high (non-MSI-H) colorectal cancer patients.
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> "We are pleased that the FDA has granted Fast Track designation for the combination of botensilimab with balstilimab in patients with non-MSI-H colorectal cancer, recognizing the high unmet medical need in this population," said [Defendant] O'Day[.] "The Fast Track designation offers important benefits, including the potential eligibility for a Priority Review, and we will be working with the FDA and all key stakeholders to rapidly advance the botensilimab/balstilimab combination in colorectal cancer as well as other solid tumor indications."

31. On May 9, 2023, Agenus issued a press release announcing the Company's Q1 2023 financial results. The press release stated, in relevant part:

> "With over 350 patients dosed with botensilimab in our Phase 1 study, we have demonstrated 20-50% response rates in 9 solid tumor cancers. These results suggest that botensilimab could provide significant benefit to patients who have not responded to or failed other available treatments," said [Defendant] Armen[.] "Agenus is committed to advancing our development programs to make botensilimab available to patients ASAP."

32. That same day, Agenus hosted an earnings call with investors and analysts to discuss the Company's Q1 2023 results (the "Q1 2023 Earnings Call"). During the scripted portion of the Q1 2023 Earnings Call, Defendant Armen stated, in relevant part:

> Botensilimab, our innovative and multi-functional CTLA-4 anybody aims to revolutionize cancer treatment by extending clinical benefit to cold tumors, which

have historically been unresponsive to standard-of-care and other immunotherapy agents, including other CTLA-4 anybody. And, impressively, botensilimab has demonstrated clinical responses in both cold and hot tumors. In a diverse patient population of nearly 400 individuals, across nine solid tumor types, all of them had exhausted prior treatment options botensilimab has made significant strides in eliciting responses, offering renewed hope for those who have failed all other available treatments.

Let's take a closer look at response rates achieved with botensilimab. Across all nine solid tumors, we've observed remarkable response rates of up to 50% in highly refractory cancers. This is truly an impressive accomplishment considering the patient population involved. Notably many of these responses have proven to be durable responses. This is a critical factor in evaluating a treatment potential to transform patient's lives in a meaningful way.

But the story doesn't end there, preliminary data suggest that Botensilimab may be exceptionally effective in colorectal cancer patients with whole tumors that have historically been unresponsive to immunotherapy. Even in hot tumors that have failed standard-of-care, including immunotherapy, of course, with or without chemotherapy, we are witnessing unprecedented responses.

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The clinical data generated with botensilimab is truly inspiring. And we're thrilled with the progress we've made thus far. We firmly believe that botensilimab has the potential to reshape how we approach treating solid tumors and we eagerly look forward to further advancements in this crucial program. With our more advanced programs, as well as on our regulatory front, we're also making significant strides. Our Phase 2 activate studies in colorectal, melanoma and pancreatic cancers are set to conclude enrollment in 2023.

And we are expediting enrollment into our refractory non-small cell lung cancer cohorts where we have previously reported 50% response rates in patients who have failed prior PD-1 and chemotherapy. We plan to launch a randomized Phase 3 study in the observed response rates persist in the extended cohort in non-small cell lung cancer. ***We're also proud to announce the fact that balstilimab combination has generated or has been granted Fast Track Designation by the FDA for treating non-MSI high colorectal patients without active liver metastasis. This acknowledgment of our potential to fulfill a significant unmet medical need could accelerate the development and review of our application for approval***.

33. On June 30, 2023, Agenus issued a press release entitled "ESMO GI Data: Agenus' Botensilimab/Balstilimab Combination Achieves Unprecedented Survival in Advanced Colorectal Cancer." The press release stated, in relevant part:

> Agenus [. . .] shared promising data today from its Phase 1b trial on the botensilimab and balstilimab combination at a late-breaking session at the 2023 ESMO World Congress on Gastrointestinal Cancer (ESMO GI). The new data show substantial survival benefits and long-lasting responses for patients with non-MSI-H (microsatellite stable or non-microsatellite instability-high) metastatic colorectal cancer previously resistant to chemotherapy and/or immunotherapy.
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> "The data from our expanded cohort demonstrate remarkable median overall survival and sustained responses in heavily pre-treated patients that historically haven't responded to immunotherapy. ***These findings provide evidence of the benefit of botensilimab/balstilimab in metastatic colorectal cancer, the second leading cause of cancer death in the U.S.***," said [Defendant] O'Day[.] "Our clinical research has shown confirmed responses in 8 other refractory tumor types, indicating the potential to transform clinical practice and patient outcomes for multiple challenging cancers."

34. On August 8, 2023, Agenus issued a press release announcing the Company's Q2 2023 results. The press release stated, in relevant part:

> "Botensilimab, alone or in combination with balstilimab, continues to display remarkable clinical activity in over 600 patients treated across nine late-stage, treatment resistant solid tumor cancers, demonstrating great potential to revolutionize the role of immunotherapy in cancer treatment," said [Defendant] Armen[.] "Agenus is committed to advancing our diverse clinical pipeline with a focus on expediting our first regulatory submission for the botensilimab/balstilimab combination in colorectal cancer. Our data has demonstrated an unprecedented survival benefit over what has been reported for standard of care, underscoring this combination as an important potential treatment option for patients with non-MSI-high colorectal cancer, which represents 85% of the population of patients with colorectal cancer[.]"

35. On August 23, 2023, the Company issued a press release entitled "Agenus Prioritizes Resources to Accelerate Registration and Commercialization of BOT/BAL Program in Multiple Cancers." The press release stated, in relevant part:

> Agenus [. . .] today announced a strategic initiative to prioritize and focus resources to accelerate the development, registration, and commercialization of its flagship program botensilimab/balstilimab (BOT/BAL). Under this new plan, Agenus will temporarily postpone all preclinical and clinical programs not related to BOT/BAL. The plan will result in a workforce reduction of approximately 25% and deliver approximately $40 million in savings by the end of 2023.

> The plan will reduce operating expenses across Agenus' global organization by concentrating its quality, manufacturing, clinical, regulatory, and research & development resources on the BOT/BAL program and drive commercial readiness.
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> "Now is the pivotal moment to concentrate our efforts on the BOT/BAL program. The observed clinical benefit in solid tumors underscores the program's game-changing potential, and our rapid progress towards a first filing in 2024 highlights the necessity for prioritization in every aspect of our operations," said [Defendant] Armen[.] "By zeroing in on BOT/BAL, we expect to expedite regulatory approval and availability for healthcare providers and patients in need. Our decision to streamline operations reflects our commitment to the success of these programs while optimizing shareholder value."

36. On October 22, 2023, the Company issued a press release entitled "Agenus Unveils New and Updated Botensilimab Data in Colorectal, Pancreatic, Lung, Melanoma, and Sarcoma."

The press release stated, in relevant part:

> Agenus [. . .] today announced first-time and updated data from its ongoing botensilimab/balstilimab (BOT/BAL) clinical programs in advanced colorectal cancer (CRC), neoadjuvant CRC, pancreatic cancer, non-small cell lung cancer (NSCLC), melanoma, and sarcoma.
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> "These new and updated data underscore BOT's broad effectiveness across several advanced solid tumors, demonstrating its potential beyond first-generation immunotherapies and current treatments," said [Defendant] O'Day[.] "***BOT's versatility, alone, in combination with BAL, or in combination with other standard of care therapies, in early and late-stage solid tumors, positions Agenus to transform cancer care, offering immense promise to patients***."

37. On November 7, 2023, Agenus issued a press release announcing the Company's Q3 2023 results. The press release stated, in relevant part:

> "The botensilimab franchise, after treating more than 750 patients, has demonstrated consistent tumor responses across a diverse range of nine tumor types, showcasing its potential for significant impact in oncology," said [Defendant] Armen[.] "***The emerging data indicating the efficacy of botensilimab in earlier stages of cancer marks a notable shift towards less invasive treatment options. Agenus is forging ahead with a focus on our regulatory filing in CRC, advancing our robust clinical pipeline, and committing to deliver substantial outcomes for patients and create value for our shareholders***."

38. That same day, Agenus hosted an earnings call with investors and analysts to discuss the Company's Q3 2023 results (the "Q3 2023 Earnings Call"). During the scripted portion of the Q3 2023 Earnings Call, Defendant Armen stated, in relevant part:

> Moving forward, we're concentrating on three key priorities; submitting our first biologics license application for colorectal cancer, prioritizing other clinical programs with the potential for rapid approval, and importantly, to mark reallocating resources to achieve our goals. Accordingly, we're gearing up our first BOT/BAL BLA submission in mid-2024, with a focus on late-stage colorectal cancer.
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> The cancer community's enthusiasm and rapid enrolment in our Phase II clinical trial in MSS-CRC, highlights an urgent unmet need. To address this, we have started a compassionate use program with the AMO broadening it into an expanded access program next year. With very limited options to treat patients with advanced colorectal cancer, the positive trends and lasting responses in our studies strengthen our conviction in BOT/BAL potential. Our top priority is obtaining BOT/BAL approval in MSS-CRC in order to allow patients access to this important IO treatment, offering them new hope, which does not exist today.

39. On January 22, 2024, Agenus issued a press release "announc[ing] results from the NEST-1 study, an investigator-sponsored trial (IST) evaluating the combination of botensilimab and balstilimab (BOT/BAL) in the neoadjuvant setting for colorectal cancer (CRC), both those with Microsatellite Stable (MSS) CRC and Microsatellite Instability High (MSI-H) CRC." The press release stated, in relevant part:

> "BOT/BAL's potential impact on colorectal cancer is groundbreaking. The study's findings, particularly the significant tumor regression after only a single dose of BOT and two doses of BAL, and the complete elimination of ctDNA in 100% of patients tested, offer a potentially transformative treatment approach for CRC patients diagnosed with early stage and locally advanced colon and rectal cancers. These results hold great promise for patients and providers as a framework for reduced reliance on chemotherapy and/or surgical resection," said Dr. Pashtoon Kasi, M.D., Director of Colon Cancer Research at Weill-Cornell Medicine and lead investigator of the NEST-1 study.

40. On March 14, 2024, Agenus issued a press release announcing the Company's Q4 and full year 2023 results. That press release stated, in relevant part:

> "In 2023, Agenus made significant advances across our BOT/BAL development program. Our first target indication is metastatic, refractory colorectal cancer that is not MSI-H/dMMR, for which we are focused on pursuing accelerated approval," said [Defendant] Armen[.] "We are also pursuing multiple strategies to capitalize the company through this important path in our efforts to bring BOT and BOT/BAL to the forefront of solid tumor cancer treatment. Our vision is to maximize BOT's utility to benefit patients in combination with other immune therapies as well as current standards of care for patients with both early and late-stage tumors."

41. That same day, Agenus filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operational results for the year ended December 31, 2023 (the "2023 10-K"). The 2023 10-K contained substantively similar descriptions of the Company, its "vision," and strategy, as discussed, *supra*, in ¶¶ 25-27.

42. Appended to the 2023 10-K as an exhibit was a signed certification pursuant to SOX by Defendants Armen and Klaskin, attesting that "[t]he information contained in the [2023 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company.

43. Also on March 14, 2024, Agenus hosted an earnings call with investors and analysts to discuss the Company's Q4 2023 results (the "Q4 2023 Earnings Call"). During the scripted portion of the Q4 2023 Earnings Call, Defendant Armen stated, in relevant part:

> In 2023, Agenus reached crucial milestones, particularly with our BOT/BAL program, a cornerstone of our operational focus. BOT/BAL therapy has undergone rigorous testing in over 900 patients, demonstrating promising activity in cancers that represent significant unmet medical needs, notably colon cancer, where we are poised for potential first approval.
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> The impressive response rates, sustained durability and overall clinical efficacy observed across multiple challenging cancer types have garnered attention and excitement from leading experts in the field. It is essential to note that the patients enrolled in our trials have exhausted available standard treatments, making clinical responses achieved all the more meaningful.

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The resounding feedback from over 1,000 physicians we engaged with over the past year, underscores the transformative impact of our work and the impact it could have on patient care. Furthermore, the fast track designation granted by the FDA acknowledges the urgent need for new treatments in our lead indications, which is refractory, MSS-CRC in non-liver metastatic patients.

As we stand on the threshold of a clinical and a critical phase in our regulatory journey, our focus is squarely on advancing activities for a potential accelerated approval filing. Our immediate efforts are directed towards ensuring that our development strategies align seamlessly with the FDA's rigorous standards. In 2024, our primary objective is to pursue a global regulatory strategy for BOT/BAL in our fast track indication.

Following alignment with the FDA, we intend to initiate the submission of our Biologics License Application, otherwise known as a BLA, for potential accelerated approval.

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Additionally, by the end of 2024, we anticipate initiating a Phase 3 study in the patient population of our proposed indication. Our commitment to transparency and stakeholder engagement remains unwavering as we progress towards delivering these potentially life altering treatments to patients. Looking ahead, our mission to enhance the lives of cancer patients to the power of the immune system remains steadfast. That's been our mission from day one, 30 years ago, of course, today, with BOT/BAL leading the charge in our dynamic portfolio of agents.

44. On April 12, 2024, the Company issued a press release entitled "Agenus Announces Updated Phase 1 Data and Progress on BOT/BAL Development in Metastatic MSS Colorectal Cancer." The press release stated, in relevant part:

"These results underscore the potential of BOT/BAL in metastatic CRC, the second leading cause of cancer mortality in the U.S.," said [Defendant] O'Day[.] "We continue to work expeditiously to bring this promising combination to patients in need."

Pending planned meetings with the FDA, Agenus plans to submit a Biologics License Application (BLA) for BOT/BAL in refractory MSS CRC later this year and plans to present detailed Phase 2 efficacy results, including response durability and updated Phase 1 survival data, at a major medical conference in the second half of 2024. This growing body of clinical evidence underscores the significant

potential of BOT/BAL to transform the treatment landscape for difficult-to-treat solid tumors.

45. On May 7, 2024, Agenus issued a press release announcing the Company's Q1 2024 results. The press release stated, in relevant part:

> "We are thrilled to announce a significant $100 million royalty financing agreement with Ligand, a milestone that investors have eagerly anticipated. This capital infusion is pivotal for advancing the development and market readiness of our BOT/BAL treatment," said [Defendant] Armen[.] He continued, "The BOT/BAL combination has consistently demonstrated deep and durable responses in 'cold' solid tumors, especially in our advanced studies of relapsed/refractory MSS CRC. With the promising results we have seen, and additional data from our ongoing Phase 2 study, we plan to engage with the FDA in the second half of 2024. Pending the outcomes of these discussions, we aim to commence the submission of a Biologics License Application under the accelerated approval provision for BOT/BAL in refractory MSS CRC NLM."

46. That same day, Agenus hosted an earnings call with investors and analysts to discuss the Company's Q1 2024 results (the "Q1 2024 Earnings Call"). During the scripted portion of the Q1 2024 Earnings Call, Defendant Armen stated, in relevant part:

> Today as we edge closer to realizing our goals with our leading BOT/BAL program, I am thrilled to share a significant milestone that will propel us into the next phase of our journey. This morning we announced that we entered into $100 million loyalty financing agreement with Ligand Pharmaceuticals. It is very important to realize that this agreement allows us to keep BOT/BAL in its entirety and also open up our options to bring in partners for this program. This clinical minimally diluted capital infusion will support key development initiatives in the BOT/BAL program including our planned confirmatory Phase 3 study in relapsed refractory MSS-CRC which stands for stem-cell [ph] colorectal cancer, and our commercialization readiness activities which are currently underway.

47. Also during the scripted portion of the Q1 2024 Earnings Call, Defendant O'Day stated, in relevant part:

> Botensilimab in combination with Balstilimab has demonstrated deep and durable responses across a wide variety of poorly immunogenic or IO refractory solid tumors. These poorly immunogenic tumors represent the majority of adults with cancer and a this large group of patients have not previously benefited from the success of established IO therapies. Currently, our BOT/BAL program is focused

> on our lead indications, relapsed refractory colorectal cancer, which is not MSI high or DMMR, and is without active liver metastasis.

48. On May 16, 2024, Agenus issued a press release entitled "FDA Grants Agenus Type B End-of-Phase 2 Meeting to Discuss BOT/BAL Therapy for Relapsed or Refractory Metastatic Colorectal Cancer." The press release stated, in relevant part:

> "Our upcoming End of Phase 2 meeting with the FDA represents a significant milestone in the ongoing development of BOT/BAL for patients diagnosed with metastatic MSS CRC who do not have active liver metastases," stated [Defendant] O'Day[.] "The results from our Phase 1 and Phase 2 studies contribute valuable insights into the potential of this therapy for managing a specific and challenging subgroup of colorectal cancer. We remain dedicated to further exploring innovative immunotherapeutic strategies."

49. On May 23, 2024, Agenus issued a press release entitled "Breakthrough Data on Botensilimab/Balstilimab in MSS CRC Presented at the 2024 ASCO Annual Meeting." The press release stated, in relevant part:

> Agenus [. . .] today announced a novel analysis from the Phase 1b trial of botensilimab in combination with balstilimab (BOT/BAL) in relapsed/refractory microsatellite stable colorectal cancer (r/r MSS CRC) with no active liver metastases (NLM) will be presented at the upcoming 2024 American Society of Clinical Oncology (ASCO) Annual Meeting on June 1, 2024. The analysis shows that BOT/BAL is active in metastatic sites beyond the lungs and lymph nodes, including the peritoneum, soft tissue, and brain, which have historically been unresponsive to treatment.
>
> "The findings observed in this analysis are notable in that they are seen within challenging and historically unresponsive metastatic sites of disease," said [Defendant] O'Day[.] "Seeing broad activity beyond the lungs and lymph nodes is rare for immunotherapy in MSS mCRC, making BOT/BAL stand out from other treatments. We are committed to advancing BOT/BAL for those living with cancer, with the intent to provide durable long-term benefits."

50. The statements referenced in ¶¶ 22-49 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the combination therapy of

botensilimab and balstilimab was less effective than Defendants had led investors to believe; (ii) accordingly, botensilimab and balstilimab's clinical results, as well as their regulatory and commercial prospects, were overstated; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

**The Truth Emerges**

51. On July 18, 2024, during pre-market hours, the Company issued a press release entitled "Agenus Announces End-of-Phase-2 Meeting Outcomes and Topline Interim Phase 2 Data for BOT/BAL in MSS Colorectal Cancer." The press release stated, in relevant part:

> Agenus [. . .] today announced the results of its end-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA), for the advancement of its immunotherapy combination, botensilimab (BOT) and balstilimab (BAL), for the treatment of adult patients with relapsed/refractory microsatellite stable colorectal cancer (r/r MSS CRC) with no active liver metastases (NLM).
>
> Key Outcomes of the EOP2 Meeting:
>
> - **Dosing Regimen**: Agenus gained agreement on the proposed BOT/BAL combination dosing regimen of 75mg BOT once every 6 weeks for up to 4 doses in combination with 240mg BAL once every 2 weeks for up to 2 years.
> - **Randomized Phase 2 Interim Data**: Topline interim data suggest best activity seen at 75 mg BOT/240mg BAL combination (ORR 19.4%; 6-month survival rate of 90%; data continues to mature).
> - **Accelerated Approval**: ***FDA advised against submission of these results in support of an Accelerated Approval based on their view that objective response rates may not translate to survival benefit***.
> - **Phase 3 Protocol Design**: The FDA recommended the inclusion of a BOT monotherapy arm at Agenus' discretion in the Phase 3 study.

52. On this news, Agenus's stock price fell $10.43 per share, or 58.83%, to close at $7.30 per share on July 18, 2024.

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

## SCIENTER ALLEGATIONS

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

## PLAINTIFF'S CLASS ACTION ALLEGATIONS

55. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Agenus securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

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

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

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

59. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

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

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

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

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Agenus securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Agenus securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

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

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

## COUNT I

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

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

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

66. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Agenus securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Agenus securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

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

68. By virtue of their positions at Agenus, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended

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

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

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

the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

71. During the Class Period, Agenus securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Agenus securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Agenus securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Agenus securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

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

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

## COUNT II

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

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

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

76. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Agenus's financial condition and results of operations, and to correct promptly any public statements issued by Agenus which had become materially false or misleading.

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

78. Each of the Individual Defendants, therefore, acted as a controlling person of Agenus. By reason of their senior management positions and/or being directors of Agenus, each of the Individual Defendants had the power to direct the actions of, and exercised the same to

cause, Agenus to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Agenus and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

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

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

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

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

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

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

## DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: September 6, 2024