UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. AYTU BIOSCIENCE, INC., JOSHUA R. DISBROW, and DAVID A. GREEN, Defendants.	Case No.: DRAFT **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Aytu BioScience, Inc. ("Aytu" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Aytu; and (c) review of other publicly available information concerning Aytu.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Aytu securities between March 10, 2020 and April 16, 2020, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Aytu is a specialty pharmaceutical company that purportedly offers products addressing significant medical needs such as hypogonadism (low testosterone), cough and upper respiratory symptoms, insomnia, male infertility, various pediatric conditions.

3. On March 10, 2020, Aytu announced that it had "signed an exclusive distribution agreement for the right to commercialize a clinically validated and commercially used coronavirus 2019 (COVID-19) IgG/IgM Rapid Test."

4. Then, on April 16, 2020, after the market closed, media reported that the Company was distributing unreliable COVID-19 tests from unapproved Chinese manufacturers, which were shipped to the U.S. after the Food and Drug Administration ("FDA") relaxed its guidelines for tests in mid-March.

5. On this news, the Company's share price fell $0.12, or over 8%, to close at $1.38 per share on April 17, 2020, on unusually heavy trading volume.

6. Throughout the Class Period, Defendants made materially false and/or misleading

statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Aytu had received distribution rights for a COVID-19 test that was not approved by Chinese regulatory authorities; and (2) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis.

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 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 (15 U.S.C. § 78aa).

10. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this District.

11. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

12. Plaintiff _____, as set forth in the accompanying certification,

incorporated by reference herein, purchased Aytu securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

13. Defendant Aytu is incorporated under the laws of Delaware with its principal executive offices located in Englewood, Colorado. Aytu's common stock trades on the NASDAQ exchange under the symbol "AYTU."

14. Defendant Joshua R. Disbrow ("Disbrow") was the Company's Chief Executive Officer ("CEO") at all relevant times.

15. Defendant David A. Green ("Green") was the Company's Chief Financial Officer ("CFO") at all relevant times.

16. Defendants Disbrow and Green (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports 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 cause them to be corrected. Because of their positions and access to material non-public information available to them, 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 which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

17. Aytu is a specialty pharmaceutical company that purportedly offers products addressing significant medical needs such as hypogonadism (low testosterone), cough and upper respiratory symptoms, insomnia, male infertility, various pediatric conditions.

Materially False and Misleading
Statements Issued During the Class Period

18. The Class Period begins on March 10, 2020. On that day, Aytu announced that it had "signed an exclusive distribution agreement for the right to commercialize a clinically validated and commercially used coronavirus 2019 (COVID-19) IgG/IgM Rapid Test." In a press release, Aytu stated, in relevant part:

> Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that it signed an exclusive distribution agreement for the right to commercialize a clinically validated and commercially used coronavirus 2019 (COVID-19) IgG/IgM Rapid Test. The test has been licensed from L.B. Resources, Limited (a Hong Kong Corporation), which licensed North American rights from product developer Zhejiang Orient Gene Biotech Co., Ltd. The test is intended for professional use and delivers clinical results between 2 and 10 minutes at the point-of-care. This exclusive agreement grants Aytu the exclusive right to distribute the product in the United States for a period of three years, with additional three-year autorenewals thereafter.
>
> The COVID-19 IgG/IgM Rapid Test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 113 patient clinical trial and has received CE marking. It is currently one of only a few tests used for coronavirus screening in China.
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> **Test Features:**
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> - Results reported in 2-10 minutes
> - Facilitates patient treatment decisions quickly
> - Simple, time-saving procedure
> - Small specimens, only 5 µL of serum/plasma or 10 µL of whole blood specimens required
> - All necessary reagents provided & no equipment needed
> - High sensitivity and specificity
>
> **Clinical Results**
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> The COVID-19 IgG/IgM Rapid Test was evaluated with 113 blood samples obtained from patients exhibiting pneumonia or respiratory symptoms. All samples were tested using the Orient Gene diagnostic device, and the results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs and symptoms) of Novel Coronavirus pneumonia.

Clinical results using the COVID-19 IgG/IgM Rapid Test show:

1. The sensitivity of the lgM test is 87.9% (87/99) and specificity is 100% (14/14) when compared to RT-PCR.
2. The sensitivity of the lgG test is 97.2% (35/36) during patients' convalescence period and specificity is 100% (14/14).

The Company expects to pursue U.S. regulatory clearance and expects to consult with the U.S. Food and Drug Administration about qualifying the test under FDA's Emergency Use Authorization.

The Company expects to receive an initial product shipment in three to four weeks, pending the timing of required regulatory, customs, and importation activities.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "The safety and health of every American is of paramount importance to the company as we face the threat of the coronavirus. We are excited to be able to work with U.S. regulatory authorities, and we will work to make this important test available in the U.S. as soon as possible. Coronavirus is a major global health concern, and we are proud to be in a position to help clinicians address this very serious public health concern."

19. On March 12, 2020, Aytu filed a Form 8-K with the SEC about the exclusive agreement for the COVID-19 test. Therein, the Company stated, in relevant part:

> On March 9, 2020, Aytu BioScience, Inc. (the "Company", signed an Exclusive Distributor and License Agreement (the "Agreement") for the right to commercialize a clinically validated and commercially used coronavirus 2019 (COVID-19) IgG/IgM Rapid Test. The test has been licensed from L.B. Resources, Limited (a Hong Kong Corporation), which licensed North American rights from product developer Zhejiang Orient Gene Biotech Co., Ltd. The test is intended for professional use and delivers clinical results between 2 and 10 minutes at the point-of-care. This exclusive agreement grants Aytu the exclusive right to distribute the product in the United States of America for a period of three years, with additional three-year autorenewals thereafter. The Company expects to pursue U.S. regulatory clearance and expects to consult with the U.S. Food and Drug Administration about qualifying the test under FDA's Emergency Use Authorization.

20. On March 19, 2020, Aytu filed a Form 8-K with the SEC to report an addendum to the exclusive agreement, whereby the Company was granted the right to distribute the COVID-19 test in Canada and Mexico. Therein, the Company stated, in relevant part:

21. On March 23, 2020, Aytu announced that it had received confirmation from the FDA that the Company can distribute the COVID-19 test throughout the U.S. In a press release, the Company stated, in relevant part:

> Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that it has received confirmation from the U.S. Food and Drug Administration (FDA) that the company may begin distribution of its Coronavirus Disease 2019 ("COVID-2019") IgG/IgM Rapid Test throughout the United States. The COVID-19 IgG/IgM Rapid Test is intended for professional use and delivers results between 2 and 10 minutes at the point-of-care.
>
> Aytu expects delivery of its first shipment of 100,000 tests this week. The initial product shipment is in transit from the manufacturer and, upon receipt, will undergo FDA and U.S. Customs and Border Protection (CBP) clearance processes. The test kits will then be repackaged to comply with FDA's labeling requirements under the most recent coronavirus guidance for serological test kit manufacturers. The Company has been in discussions with healthcare distributors, healthcare institutions, medical practices, and government agencies and is working rapidly to distribute the test into the U.S. healthcare supply chain.
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> Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We are moving as quickly as we can to bring the COVID-19 IgG/IgM Rapid Test to the U.S. professional medical community. With product now in transit to our warehouse in Colorado we're optimistic that we can have test kits ready for sale in the very near term. In the two short weeks since signing our distribution agreement, we have ordered our first 100,000 tests and have received confirmation from FDA that we may begin distribution. We are optimistic that we're now just days away from placing these COVID-19 test kits into the hands of healthcare professionals."
>
> The COVID-19 IgG/IgM Rapid Test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 126 patient clinical trial and is CE marked.

22. On April 1, 2020, Aytu announced that it had received the first shipment of COVID-19 tests. In a press release, the Company stated, in relevant part:

> Aytu BioScience, Inc. (NASDAQ: AYTU) (the "Company"), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that it has received its first Coronavirus Disease 2019 ("COVID-2019") IgG/IgM Rapid Test shipment containing 100,000 tests from the manufacturer. The Company is now in the process of relabeling the

test kits to comply with Food and Drug Administration (FDA) requirements relating to labeling of COVID-19 serology test kits and expects to begin filling current backorders and additional incoming orders shortly thereafter.

Additionally, the Company expects to receive another 500,000 rapid tests from the manufacturer in the next two to three weeks in order to fulfill additional customer orders.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We're pleased to have the first 100,000 tests now in stock at our facility in Englewood, Colorado. The Company is now preparing the kits for shipment to customers. Following the completion of the labeling process and final clearance by FDA, we'll be shipping this initial inventory to healthcare professionals across the country. While preparing these kits for distribution, we are also preparing to receive our next shipment of 500,000 tests."

The COVID-19 IgG/IgM Rapid Test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 126 patient clinical trial and is CE marked. The COVID-19 IgG/IgM Rapid Test is registered with the FDA and listed on the FDA website as one of the serology tests allowed by the agency to be commercialized in the United States. The COVID-19 IgG/IgM Rapid Test is intended for professional use and delivers results between 2 and 10 minutes at the point-of-care.

23. On April 3, 2020, Aytu announced that it began shipping the COVID-19 tests to customers in U.S. In a press release, the Company stated, in relevant part:

Aytu BioScience, Inc. (NASDAQ: AYTU), (the "Company"), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that it began shipping its Coronavirus Disease 2019 ("COVID-2019") IgG/IgM Rapid Test to U.S. customers. Upon receipt of the initial 100,000 tests, the company completed product relabeling to ensure compliance with FDA guidance on COVID-19 serology test kits.

The Company has received orders for the COVID-19 IgG/IgM Rapid Test from a broad range of healthcare customers including large medical centers, municipalities, first responders, medical practices, and other healthcare customers. The Company expects to have all customer backorders filled in the coming days.

The Company's first 2,750 COVID-19 Rapid Tests have been purchased by the Denver Police Department for use in screening Denver's first responders. The test kits were delivered to Denver Chief of Police Paul Pazen and members of his leadership team at Aytu BioScience's corporate headquarters on April 2, 2020.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "Upon receipt of our initial product shipment on March 31st, we immediately went to work to prepare the test kits for commercial distribution. The Aytu team has worked very hard over the last two days to relabel all 100,000 tests, and we're now shipping product to our customers across the country. Importantly, we are proud to be assisting our first responders here at home as we delivered over 2,000 tests to Denver Police Chief Pazen and his team. Our public safety personnel are doing outstanding work in our communities throughout this crisis, so we're glad to be partnering with Denver's first responders in this fight."

Mr. Disbrow continued, "The demand for the COVID-19 IgG/IgM Rapid Test has been substantial, so we have increased our order size to 500,000 tests (20,000 kits) to provide a larger supply to healthcare professionals and first responders in need."

The COVID-19 IgG/IgM Rapid Test is a serology test used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 126 patient clinical trial in China and is CE marked.

The Company believes that serology tests are a potentially powerful tool for identifying anyone who has been infected, whether they had symptoms or not. Antibodies to coronaviruses typically remain in humans for up to 90 days or more. The Company believes that serological testing is important in identifying the total number of people who have been infected with COVID-19. This type of testing could be particularly important for the immune surveillance of health care workers, first responders, government workers, and others whose infection risks could be heightened by working with COVID-19 infected individuals.

24. On April 15, 2020, Aytu provided an update regarding the supply and distribution of the COVID-19 tests. In a press release, the Company stated, in relevant part:

Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs today provided an update on the supply and distribution of the company's licensed COVID-19 IgG/IgM Rapid Test. The company has sold or allocated the initial 100,000 tests to U.S. customers and is awaiting delivery of the next 500,000 tests.

Additionally, the company has increased the size of its third purchase order to one million tests. The company has been informed the order has been accepted by the manufacturer.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "The company has been working on multiple fronts to distribute the initial shipment of COVID-19 IgG/IgM Rapid Tests while coordinating the incoming supply of our

> next shipment of 500,000 tests. We are pleased that the manufacturer has completed this second order, which is now awaiting customs clearance. Further, we have been informed the manufacturer has accepted another purchase order, which was increased to one million tests. We are proud to be helping the medical community in delivering our initial shipment of tests to those professionals in need. We look forward to having additional supply to further fulfill the significant demand we have for COVID-19 tests. With the 500,000 tests now awaiting clearance, we'll be in a position to fulfill the pending orders very soon."

25. The above statements identified in ¶¶ 18-24 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Aytu had received distribution rights for a COVID-19 antibody test that was not approved by Chinese regulatory authorities; and (2) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

26. On April 16, 2020, after the market closed, *NBC News* published an article entitled "Unapproved Chinese coronavirus antibody tests being used in at least 2 states." The article reported that the Company was distributing COVID-19 tests from unapproved Chinese manufacturers, which were shipped to the U.S. after the FDA relaxed its guidelines for tests in mid-March. Specifically, the article stated:

> Two U.S. companies — Premier Biotech of Minneapolis and Aytu Bioscience of Colorado — have been distributing the tests from unapproved Chinese manufacturers, according to health officials, FDA filings and a spokesman for one of the Chinese manufacturers. Many of the unapproved tests appear to have been shipped to the U.S. after the FDA relaxed its guidelines for tests in mid-March and before the Chinese government banned their export just over two weeks later.
>
> * * *
>
> The FDA moved to accelerate and expand the availability of COVID-19 diagnostic tests after coming under criticism for the slow pace of test approval in the U.S.
>
> On March 16, after the Department of Health and Human Services said the pandemic justified the authorization of emergency use of diagnostics for detection

and diagnosis, the FDA relaxed its policies, allowing tests to be sold even if it had not approved them.

In China, the NMPA has been reviewing COVID-19 test kits since January to ensure that they "meet the requirements of 'safety, effectiveness and quality control,'" according to the NMPA website. A U.S. expert said the Chinese agency is considered "rigorous" and "demanding" in its oversight of products.

On April 2, the NMPA published its most recent list of approved COVID-19 test manufacturers after a March 31 announcement from China's Commerce Ministry restricted the export of medical materials. The ministry said its restrictions aimed "to strictly control quality, maintain export order, and crack down on counterfeit and shoddy products."

Tests made by two Chinese manufacturers, Hangzhou Biotest Biotech Co. and Zhejiang Orient Gene Biotech, are not on the approved list, but they are being sold in the U.S.

There is no indication that either test is unreliable.

* * *

Zhejiang Orient Gene Biotech supplies U.S.-based Aytu Bioscience with a COVID-19 test that has not been approved, according to Bryan Fang, a spokesman for Healgen Scientific, the U.S. subsidiary of Zhejiang Orient in Houston.

Josh Disbrow, chief executive of Aytu, confirmed by phone that Zhejiang Orient's tests have not been approved by the NMPA. He emphasized that the tests have been validated in a study by third-party clinical researchers.

While that study showed a satisfactory performance of the test, the researchers said that their findings were limited and that results for the Zhejiang Orient tests needed to be compared with results from other antibody tests to gauge performance.

Asked whether Aytu notifies its customers that its test has not been approved by Chinese authorities, Disbrow said the company made no such statements. "It is not something that has come up," he said. "The idea of approval is changing by the day."

* * *

Although the FDA has relaxed rules for COVID-19 tests, it does require manufacturers to validate the tests before use and to notify customers if the tests have not yet been reviewed by the FDA. The agency also says test results should not be used as the sole basis to diagnose or inform a person's infection status.

* * *

> Aytu's website follows the FDA protocol, noting that the agency has not reviewed its tests.

27. On April 17, 2020, Aytu announced that shipments of the COVID-19 tests would not be impacted by a recent announcement that China was restricting exports of medical materials. In a press release, the Company stated, in relevant part:

> Aytu BioScience, Inc. (NASDAQ:AYTU), (the "Company"), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that export and delivery of the Company's incoming COVID-19 rapid tests remains on track as previously announced.
>
> Additionally, the Company is in late-stage negotiations to secure rights to distribute a second COVID-19 IgG/IgM rapid test, which is approved by China's National Medical Products Administration (NMPA).
>
> Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "Since the Company began taking the fight to COVID-19, we have continued to aggressively search for and evaluate diagnostic tests and other novel technologies that may complement our current product offering and benefit COVID-19 patients. Also, given the nationwide shortage of tests, we believe we are obligated to secure as many additional tests as we can to help with this shortage. ***To that end, I am excited to say we're in the final stages of securing yet another IgG/IgM antibody rapid test for U.S. distribution. This test is already approved by China's NMPA, is being regularly exported from China, and has strong clinical performance.*** By securing this additional antibody test, we expect to have an even greater supply to fulfill the substantial demand we're experiencing. We all need to continue to do the very best we can to help COVID-19 patients and those medical professionals for whom they care."

* * *

> Mr. Disbrow concluded, "***We have received further confirmation that the COVID-19 IgG/IgM Rapid Test manufactured by Zhejiang Orient Gene is in the approval process with NMPA.*** We remain highly confident in the test's clinical performance as recently demonstrated in a published, third-party peer-reviewed study and believe that the Zhejiang Orient Gene COVID-19 IgG/IgM Rapid Test is a reliable test in detecting COVID-19 antibodies. The independent study demonstrates test accuracy of 98.0% and 94.1% for IgG and IgM, respectively, when using PCR-positive cases as true positives, which we believe establishes strong clinical utility of the test."

> The Company will continue to inform our stakeholders about our continuing developments relating to our COVID-19 fight and the progress of the Aytu BioScience business.

28. On this news, the Company's share price fell $0.12, or over 8%, to close at $1.38 per share on April 17, 2020, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

29. 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 persons and entities that purchased or otherwise acquired Aytu securities between March 10, 2020 and April 16, 2020, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, 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.

30. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Aytu's common shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Aytu common stock were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Aytu 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.

31. 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.

32. 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.

33. 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:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Aytu; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

34. 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 makes 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.

UNDISCLOSED ADVERSE FACTS

35. The market for Aytu's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Aytu's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Aytu's securities relying upon the integrity of the market price of the Company's securities and market information relating to Aytu, and have been damaged thereby.

36. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Aytu's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements,

as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Aytu's business, operations, and prospects as alleged herein.

37. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Aytu's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

38. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

39. During the Class Period, Plaintiff and the Class purchased Aytu's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

40. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or

disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Aytu, their control over, and/or receipt and/or modification of Aytu's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Aytu, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

41. The market for Aytu's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Aytu's securities traded at artificially inflated prices during the Class Period. On March 10, 2020, the Company's share price closed at a Class Period high of $2.05 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Aytu's securities and market information relating to Aytu, and have been damaged thereby.

42. During the Class Period, the artificial inflation of Aytu's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Aytu's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Aytu and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

43. At all relevant times, the market for Aytu's securities was an efficient market for the following reasons, among others:

(a) Aytu shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Aytu filed periodic public reports with the SEC and/or the NASDAQ;

(c) Aytu 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

(d) Aytu was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

44. As a result of the foregoing, the market for Aytu's securities promptly digested current information regarding Aytu from all publicly available sources and reflected such information in Aytu's share price. Under these circumstances, all purchasers of Aytu's securities during the Class Period suffered similar injury through their purchase of Aytu's securities at artificially inflated prices and a presumption of reliance applies.

45. A Class-wide presumption of reliance is also appropriate in this action 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 are, in large part, grounded on Defendants' material misstatements and/or 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 to disclose—positive proof of reliance is

not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

46. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge 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 Aytu who knew that the statement was false when made.

FIRST CLAIM
Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder
Against All Defendants

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

48. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Aytu's securities at artificially inflated prices. In

furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

49. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Aytu's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

50. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Aytu's financial well-being and prospects, as specified herein.

51. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Aytu's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Aytu and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

52. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their

responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

53. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Aytu's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

54. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Aytu's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class

acquired Aytu's securities during the Class Period at artificially high prices and were damaged thereby.

55. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Aytu was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Aytu securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

56. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

57. 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 and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation of Section 20(a) of The Exchange Act
Against the Individual Defendants

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

59. Individual Defendants acted as controlling persons of Aytu within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, 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 various statements which Plaintiff contends are false and misleading. 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 Plaintiff to be 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.

60. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

61. As set forth above, Aytu and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: _____, 2020

By: DRAFT_____

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