UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF TEXAS

AUSTIN DIVISION

PIERRE BRAZEAU, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. CASSAVA SCIENCES, INC., REMI BARBIER, ERIC J. SCHOEN, JAMES W. KUPIEC, NADAV FRIEDMANN and MICHAEL MARSMAN, Defendants.	§	Civil Action No. 1:21-cv-00751 CLASS ACTION DEMAND FOR JURY TRIAL

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff, Pierre Brazeau ("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 upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the U.S. Securities and Exchange Commission ("SEC") filings by Cassava Sciences, Inc. ("Cassava" or the "Company"), conference call transcripts, Company press releases and media reports about the Company. 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 securities fraud class action on behalf of all purchasers of the common stock of Cassava between February 2, 2021 and August 24, 2021, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 ("1934 Act").

2. Cassava is an Austin-based clinical stage biotechnology company engaged in the development of drugs for neurodegenerative diseases. Its lead therapeutic product candidate during the Class Period was simufilam, a small molecule drug designed to treat Alzheimer's disease, and its lead investigational diagnostic product candidate was SavaDx, a blood-based biomarker/diagnostic to detect Alzheimer's disease. The Company's financial viability is largely dependent upon the clinical success of simufilam as the Company currently has no sources of revenues.

3. At the start of the Class Period on February 2, 2021, Cassava announced results from its interim analysis of an open-label study of simufilam, which purportedly demonstrated that patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues. According to the Company, "[i]n a clinical study funded by the

National Institutes of Health and conducted by Cassava Sciences, six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6," and "[i]n these same patients, simufilam also improved dementia-related behavior, such as anxiety, delusions and agitation, by 1.3 points on the Neuropsychiatric Inventory, a 29% mean improvement from baseline to month 6."

4. As the market digested this ostensibly great news, the market price of Cassava common stock spiraled up, nearly quadrupling from its close of $22.99 per share on February 1, 2021 to trade as high as $90 per share in intraday trading by February 3, 2021. The stock spiked on extremely high trading volume of more than 76 million shares trading on February 2, 2021 alone, more than 19x the average daily volume over the preceding ten trading days.

5. Cassava immediately cashed in on the stock price inflation, issuing and selling more than four million shares of its common stock at $49 per share on February 12, 2021 through an underwritten follow-on public stock offering and reaping more than $200 million in gross proceeds (the "Offering").

6. On July 29, 2021, Cassava presented preliminary results from its Phase 2b clinical trial of simufilam at the Alzheimer's Association International Conference, again purportedly demonstrating that the drug led to an improvement in cognition for Alzheimer's patients with no adverse side effects. According to Cassava, after nine months, 66% of the 50 patients in the clinical trial observed an average improvement of 3 points on the Alzheimer's Disease Assessment Scale-Cognitive Subscale ("ADAS-Cog"). Typically, Alzheimer's patients see a decline of 5 ADAS-Cog points in a year, meaning that a decline of 4 points would be typical over nine months.

7. Then, after the close of trading on August 24, 2021, it was disclosed that the U.S. Food and Drug Administration ("FDA") had received a so-called Citizen Petition commencing an administrative action to "halt two ongoing trials of the drug Simufilam . . . pending a thorough

audit by the FDA." As detailed in the Citizen Petition, "[i]nformation available to the petitioner . . . raises grave concerns about the quality and integrity of the laboratory-based studies surrounding this drug candidate and supporting the claims for its efficacy." After summarizing its findings, the Citizen Petition went on to conclude that "the extensive evidence set forth in the enclosed report, which presents grave concerns about the quality and integrity of the scientific data supporting Cassava's claims for Simufilam's efficacy, provides compelling grounds for pausing the ongoing clinical trials until the FDA can conduct and complete a rigorous audit of Cassava's research."

8. The market price of Cassava common stock plummeted on this news, declining approximately $37 per share, or 32%, on unusually high trading volume of approximately 29 million shares trading, or more than 7x the average daily trading over the preceding ten trading days.

9. As a result of defendants' wrongful acts and omissions as alleged herein, Plaintiff and the Class (as defined below) purchased Cassava commons stock at artificially inflated prices, suffered significant losses and were damaged thereby.

JURISDICTION AND VENUE

10. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder by the SEC.

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act.

12. Venue is proper in this District pursuant to §27 of the 1934 Act and 28 U.S.C. §1391(b). Many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District where Cassava is headquartered.

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

PARTIES

14. Plaintiff Pierre Brazeau, as set forth in the accompanying certification which is incorporated herein by reference, purchased Cassava common stock during the Class Period and was damaged thereby.

15. Defendant Cassava was incorporated in 1998 as Pain Therapeutics, Inc. and changed its name to Cassava Sciences, Inc. in March 2019. The Company is headquartered in Austin, Texas. Cassava common stock trades in an efficient market on the NASDAQ under the ticker symbol "SAVA." As of August 2, 2021, there were more than 40 million shares of Cassava common stock issued and outstanding.

16. Defendant Remi Barbier ("Barbier") founded Cassava and served as its President and Chief Executive Officer ("CEO") and the Chairman of its Board of Directors at all relevant times.

17. Defendant Eric J. Schoen ("Schoen") served as the Chief Financial Officer ("CFO") of Cassava at all relevant times.

18. Defendant James W. Kupiec ("Kupiec") served as the Chief Clinical Development Officer of Cassava at all relevant times.

19. Defendant Nadav Friedmann ("Friedmann") served as the Chief Medical Officer of Cassava and a member of its Board of Directors at all relevant times.

20. Defendant Michael Marsman ("Marsman") served as the Senior Vice President of Regulatory Affairs at Cassava at all relevant times.

21. Defendants Barbier, Schoen, Kupiec, Friedmann and Marsman are sometimes referred to herein as the "Individual Defendants." The Individual Defendants made, or caused to be made, false statements that artificially inflated the prices of Cassava common stock during the Class Period. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Cassava's press releases, interim financial reports and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. They 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 with the Company and their access to material non-public 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 and misleading statements pleaded herein.

22. Defendant Cassava and the Individual Defendants are sometimes referred to herein collectively as the "Defendants."

23. Defendants are liable for: (i) making false statements; or (ii) failing to disclose adverse facts known to them about Cassava. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Cassava common stock was a success, as it: (i) deceived the investing public regarding Cassava's prospects and business; (ii) artificially inflated the price of Cassava common stock; (iii) permitted Cassava to cash in by selling $200 million of Cassava common stock at fraud-inflated prices; and (iv) caused Plaintiff and other members of the Class to purchase Cassava common stock at artificially inflated prices.

BACKGROUND

24. The World Health Organization reports more than 50 million people worldwide suffer from the deterioration of memory, thinking, and behavior that is associated with dementia, and Alzheimer's is the most common type of dementia, representing 60% to 70% of dementia patients.

25. Cassava's product portfolio includes a small molecule drug for the treatment of Alzheimer's disease, called simufilam, and an investigational blood-based diagnostic to detect and monitor the progression of Alzheimer's disease, called SavaDx.

26. Another, much larger pharmaceutical company called Biogen, recently obtained FDA approval for its own Alzheimer's therapy, Aduhelm.

27. Cassava's simufilam, a twice-daily oral tablet, would likely be much less expensive than Aduhelm, which is given via a monthly intravenous injection and is expected to cost $56,000 a year per patient. A lower cost and greater ease of use was expected to provide a significant competitive advantages for Cassava's lead drug. However, these competitive advantages and the market potential for simufilam depended on the Company receiving FDA approval for the treatment.

DEFENDANTS' FALSE AND MISLEADING CLASS PERIOD STATEMENTS AND OMISSIONS

28. The Class Period starts on February 2, 2021. On that day, Cassava issued a press release announcing its purported results from an interim analysis of an open-label study of simufilam, emphasizing that patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues. According to the release, "[i]n a clinical study funded by the National Institutes of Health and conducted by Cassava Sciences, six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6," and "[i]n these same patients, simufilam also improved

dementia-related behavior, such as anxiety, delusions and agitation, by 1.3 points on the Neuropsychiatric Inventory, a 29% mean improvement from baseline to month 6." The release went on to quote Defendants Barbier and Friedmann stating, in pertinent part, as follows:

> Alzheimer's is a progressive disease. Over time, a patient's cognition will always worsen. "*Experience based on longitudinal studies of ambulatory patients with mild to moderate Alzheimer's disease suggest that scores on ADAS-cog decline by 6 - 12 points per year*", according to FDA's Prescription Information sheet for ARICEPT® (donepezil), a drug approved for the treatment of dementia of the Alzheimer's type1.
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> "We could not be more pleased with these interim results," said Remi Barbier, President & CEO. "We would have been satisfied to show simufilam stabilizes cognition in patients over 6 months. An improvement in cognition and behavior ***tells us this drug candidate has potential to provide lasting treatment effects for people living with Alzheimer's disease***. It's an exciting development."
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> The safety profile of simufilam in the interim analysis was consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.
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> "***Today's data once again suggests simufilam could be a transformative, novel therapeutic***," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide a treatment benefit ***following 6 months of dosing***."

(Emphasis added.)

29. As the market digested this ostensibly great news, the market price of Cassava common stock spiraled up, nearly quadrupling from its close of $22.99 per share on February 1, 2021 to trade as high as $90 per share in intraday trading by February 3, 2021. The stock spiked on extremely high trading volume of more than 76 million shares trading on February 2, 2021 alone, more than 19x the average daily volume over the preceding ten trading days.

30. On February 8, 2021, Cassava issued a press release entitled "Cassava Sciences Announces Significant Program Progress and Expected Key Milestones in 2021 for Its Clinical Program in Alzheimer's Disease." That release stated, in pertinent part, as follows:

> "We started 2021 with tremendous momentum, led by ***results of a 6-month interim analysis*** from an open-label study of simufilam, our drug candidate for

Alzheimer's disease," said Remi Barbier, President & CEO. "I believe the rest of the year may be equally exciting."

Cassava Sciences' strategic focus for 2021 is to advance simufilam in a Phase 3 clinical program in Alzheimer's disease, to expand drug manufacturing capabilities in support of the clinical program, and to continue to lead the Company to deliver the full potential of its product portfolio.

Cassava Sciences' 2021 Scientific and Clinical Outlook

* * *

Expected progress and key milestones in 2021 across Cassava Sciences' product portfolio are summarized below.

- Based on recent ***positive clinical results*** and inbound demand from clinical sites, patients, and their caregivers, Cassava Sciences plans to expand the size of the ongoing open-label study of simufilam. The target enrollment will be increased by up to 50 additional patients with mild-to-moderate Alzheimer's disease, for a total target enrollment of up to 150 patients.

- Cassava Sciences has enrolled approximately 80 patients in the open-label study to date. To accommodate increased enrollment, the Company plans to open new clinical sites across the U.S. and Canada.

- Cassava Sciences expects to announce results of a second interim analysis of the ongoing open-label study when approximately 50 patients complete 12 months of drug treatment. This second interim analysis is expected to include clinical data around long-term safety, cognition and Alzheimer's-related behavior.

- Cassava Sciences plans to initiate a 6-month, double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease who complete at least one year of open-label treatment with simufilam. This is a Cognition Maintenance Study (CMS), in which patients who complete one year of open-label treatment will subsequently be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition and behavior in patients who continue with drug treatment versus those who discontinue drug treatment. For ethical and other reasons, patients who successfully complete the six-month CMS will have the option to receive open-label simufilam.

- Cassava Sciences' clinical and regulatory strategy for simufilam is progressing as planned. In January 2021, the Company concluded a successful End-of-phase 2 (EOP2) meeting with the U.S Food and Drug Administration (FDA). The purpose of the EOP2 was to gain general

agreement around a Phase 3 program to treat Alzheimer's disease dementia.

- As a result of the EOP2 meeting, Cassava Sciences believes its clinical program for simufilam is green-lighted to commence a large, Phase 3 clinical program in patients with Alzheimer's disease, pending official FDA meeting minutes of the EOP2 meeting.

- Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021.

- Cassava Sciences' Phase 3 program for simufilam consists of two large, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease dementia. The Company expects to announce details of its Phase 3 program in Q1 2021, pending official FDA meeting minutes of the EOP2 meeting.

- Cassava Sciences' first Phase 3 study will evaluate disease-modifying effects in Alzheimer's disease patients over 18 months. The goal of this study is to show a slower rate of decline in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.

- Cassava Sciences' second Phase 3 study will evaluate symptomatic improvement in Alzheimer's disease patients over 6 months. The goal of this study is to show improvement in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.

- Cassava Sciences believes its manufacturing strategy is on-track to ensure sufficient drug supply for a Phase 3 program, including both drug substance (i.e., active ingredient) and drug product (i.e., oral tablets).

- Cassava Sciences expects to conclude a long-term, commercial drug supply agreement for simufilam with a contract manufacturing organization. The goal is to ensure the integrity of the drug supply chain on a worldwide basis, in compliance with FDA standards.

- Cassava Sciences expects to initiate a validation study with SavaDx, its investigational diagnostic for the detection of Alzheimer's disease.

- Cassava Sciences is in discussions with scientific and clinical advisors about potentially expanding therapeutic indications for simufilam outside of Alzheimer's disease, but still within neurodegenerative conditions.

Other Expected Milestones and Announcements for 2021

- ***Cassava Sciences expects to announce publication of Phase 2b results in a peer-reviewed technical journal***.

- Net cash use for full-year 2021 is expected to be in the range of $20 to $25 million, depending on enrollment rates in its clinical programs and other factors. On December 31, 2020, unaudited cash and cash equivalents were approximately $93 million.

(Emphasis added.)

31. On February 10, 2021, Cassava announced and on February 12, 2021 Cassava completed its $200 million Offering of more than four million shares of its common stock at $49 per share.

32. On February 22, 2021, Cassava issued a press release announcing "Positive End-of-Phase 2 Meeting with FDA and Outlines Pivotal Phase 3 Program for Simufilam in Alzheimer's Disease." That release stated, in pertinent part, as follows:

- Two Upcoming Phase 3 Studies and a Previously Completed Phase 2 Program Support a New Drug Application Filing for Simufilam in Alzheimer's disease -

- Agreement Reached to Use ADAS-Cog as Co-Primary Efficacy Endpoint -

- Pivotal Phase 3 Program Remains On-track to be Initiated 2nd Half 2021 -

. . . [Cassava] today announced the successful completion of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) for simufilam, its lead drug candidate for the treatment of Alzheimer's disease. ***Official EOP2 meeting minutes indicate FDA and Cassava Sciences agree on key elements of a pivotal Phase 3 clinical program in support of a New Drug Application (NDA) filing for simufilam in Alzheimer's disease***. Agreements reached during the EOP2 meeting show a clear path forward for advancing simufilam into Phase 3 studies in the second half of 2021.

"For over 10 years we've been doing basic research and early drug development with simufilam," said Remi Barbier, President & CEO. "We are excited to finally advance simufilam into pivotal Phase 3 clinical studies in people with Alzheimer's disease. We believe the underlying science is solid, the drug appears safe and the clinical roadmap makes sense. We've crossed the Rubicon."

"We appreciate the valuable guidance and flexibility FDA has provided," added Jim Kupiec, MD, Cassava Sciences' Chief Clinical Development Officer.

> "We look forward to continuing a collaborative dialogue throughout the pivotal Phase 3 clinical development program."
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> Simufilam is a novel drug, discovered at Cassava Sciences, that targets both neuroinflammation and neurodegeneration. ***The EOP2 meeting discussion was supported by years of scientific and clinical data, including positive results from a previously completed Phase 2 clinical program with simufilam in Alzheimer's disease. In a double-blind, randomized, placebo-controlled Phase 2b study, simufilam demonstrated robust effects on primary and secondary outcome measures, with no safety issues. Recently, the Company announced that simufilam improved cognition in subjects with Alzheimer's disease in a 6-month interim analysis of an open-label study, with no safety issues***.
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> The EOP2 meeting took place mid-January. FDA attendees included Robert Temple, MD, Deputy Center Director for Clinical Science and Senior Advisor in the Office of New Drugs; Billy Dunn, MD, Director, Office of Neuroscience; Eric Bastings, MD, Director, Division of Neurology, and others.
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> ***Official meeting minutes confirm that Cassava Sciences and FDA are aligned on key elements of a Phase 3 clinical program for simufilam. FDA has agreed that the completed Phase 2 program, together with an upcoming and well-defined Phase 3 clinical program, are sufficient to show evidence of clinical efficacy for simufilam in Alzheimer's disease. There is also agreement*** that the use of separate clinical scales to assess cognition (ADAS-cog1) and function (ADCS-ADL2) are appropriate co-primary endpoints of efficacy. A clinical scale that combines cognition and function, such as iADRS3, is a secondary efficacy endpoint.

(Emphasis added.)

33. On March 9, 2021, Cassava announced that it had entered into a pharmaceutical supply agreement for a "large-scale, clinical-grade quantities of simufilam, a drug candidate for the treatment of Alzheimer's disease."

34. On March 23, 2021, Cassava issued a press release announcing its "Full-year 2020 Financial Results and Business Highlights." In addition to repeating much of the same business updates provided over the previous few weeks, the release quoted Defendants Barbier and Schoen stating, in pertinent part, as follows:

> "In Q1 2021 we announced that our lead drug candidate, simufilam, improved cognition scores in 50 patients with Alzheimer's disease who completed at least 6 months of open-label treatment," said Remi Barbier, President & CEO. "In mid-2021, we look forward to announcing cognition scores in patients who'll have completed at least 12 months of open-label treatment with simufilam. To our

knowledge, no drug has stabilized, much less improved, cognition scores over 12 months in patients with Alzheimer's disease. For this reason, I feel there is a sense of anticipation around the upcoming release of 12-month clinical data from our open-label study, as well as our plans to conduct a pivotal Phase 3 program with simufilam in the second half of 2021. With solid science, the right people in place, cash in the bank and a clinical roadmap that makes sense, I think Cassava Sciences is positioned to becoming a premier organization to serve patients with Alzheimer's disease."

"We have approximately $280 million in cash on our balance sheet, against expected cash use of approximately $20 to $25 million in 2021," said Eric Schoen, Chief Financial Officer. "We believe our cash levels support a pivotal Phase 3 clinical program of simufilam in Alzheimer's disease."

(Emphasis added.)

35. On April 21, 2021, Cassava issued a press release announcing its "First Quarter 2021 Financial Results and Announces Guidance on Clinical Data Release." That release stated, in pertinent part, as follows:

- 9 Month Interim Analysis of Open-label Study to be Presented at a Major Scientific Conference in July 2021 as an Oral Presentation -

- Initiation of Pivotal Phase 3 Program Remains On-track for 2nd Half 2021 -

- Initiation of Cognition Maintenance Study On-track for June 2021 -

- Cash and cash equivalents were $282.2 million at March 31, 2021 -

. . . [Cassava] today announced financial results for the first quarter ended March 31, 2021 and guidance regarding the release of new clinical data with simufilam. Simufilam is the Company's lead drug candidate to treat Alzheimer's disease.

"Alzheimer's is a progressive disease, so a patient's cognition is expected to worsen over time," said Remi Barbier, President & CEO. "***Patients' cognition scores actually improved following 6 months of open-label treatment with simufilam***. Showing similar drug effects following 9 months of open-label treatment would be remarkable, yet consistent with simufilam's mechanism of action. Eventually, we'd like this drug candidate to benefit cognition for a year or longer."

In July 2021, Cassava Sciences plans to announce results of a pre-specified interim analysis that summarizes safety and cognition data on approximately the

first 50 subjects to complete at least 9 months of open-label drug treatment. The Company will present these data July 26 - 29th at the 2021 Alzheimer's Association International Conference (AAIC). AAIC's scientific committee has invited the Company's scientists to present the dataset as an oral presentation.

About the Open-label Study with Simufilam

In March 2020, Cassava Sciences initiated a long-term, open-label study to evaluate simufilam in patients with Alzheimer's disease. This study is funded by a research grant award from the National Institutes of Health (NIH). The open-label study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice-daily for 12 months or longer in patients with Alzheimer's disease. Another study objective is to measure changes in cognition on ADAS-Cog, a standard test of cognition in Alzheimer's disease. The study's clinical protocol has pre-specified cognition measurements at 6, 9 and 12 months.

The study's target enrollment is approximately 150 subjects with mild-to-moderate Alzheimer's disease (recently increased by 50 subjects). One-hundred subjects have enrolled in this study across multiple clinical sites in the U.S. and Canada.

On February 2, 2021, Cassava Sciences announced positive results of a first interim analysis that summarizes clinical data on the first 50 subjects to complete 6 months of open-label treatment. Patients' cognition scores improved from baseline following 6 months of simufilam treatment, with no safety issues. Six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6.

In September 2021, Cassava Sciences plans to announce results of an interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 12 months of open-label drug treatment.

About the Cognition Maintenance Study (CMS)

In June 2021, Cassava Sciences plans to initiate a double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease. Patients who have completed at least one year of open-label treatment with simufilam qualify to enroll in the Cognition Maintenance Study (CMS). Study subjects in the CMS will be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition in Alzheimer's patients who continue with drug treatment versus patients who discontinue drug treatment.

(Emphasis added.)

36. On June 21, 2021, Cassava issued a press release to "Provides Mid-Year Corporate Update, Clinical Development Progress and Announces Guidance on Clinical Data Release." That release stated, in pertinent part, as follows:

- **Open-label Study Completes Patient Enrollment**
- **Cognition Maintenance Study Initiated May 2020, now 30% Enrolled**
- **6-month Biomarker Data to be Presented at AAIC Conference in July**
- **9-month Safety & Cognition Data to be Presented at AAIC Conference**
- **Clinical Results with SavaDx to be Presented at AAIC Conference**
- **Phase 3 Program Initiation Remains On-track for 2nd Half 2021**

> . . . [Cassava] today announced a mid-year update that highlights clinical development progress and provides guidance on upcoming data releases for simufilam and SavaDx. Simufilam is Cassava Sciences' lead drug candidate to treat Alzheimer's disease; SavaDx is an investigational diagnostic candidate to detect Alzheimer's with a simple blood test.
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> "Patients with Alzheimer's want clear and present evidence of drug efficacy," said Remi Barbier, President & CEO. "The recent regulatory approval of a new drug for Alzheimer's was a bit of a donnybrook over this very topic. ***Our clinical strategy with simufilam is to show real-world safety and efficacy by conducting both, randomized controlled trials, and an on-going open-label study***. Ideally, biomarker and cognition data from our studies converge and result in health benefits for patients."
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> Clinical progress across Cassava Sciences' product portfolio is summarized below.
>
> **Update on Open-label Study with Simufilam**
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> * * *
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> ***The open-label study has completed its target enrollment of 150 subjects***. By physician and patient request, clinical sites may continue to enroll additional subjects up through the initiation of the Company's Phase 3 pivotal program of simufilam.
>
> **Guidance on Clinical Data Release**
>
> Cassava Sciences plans to announce results of an interim analysis on safety and cognition for the first 50 subjects to complete 9 months of open-label drug treatment. These cognition data will be presented at the 2021 Alzheimer's

Association International Conference (AAIC) in Denver, CO, the week of July 26-30th. The scientific committee of AAIC has invited the Company's scientists to present these data as an oral presentation.

- Cassava Sciences will also present at AAIC biomarker data from the open-label study, including:
- Biomarkers of Alzheimer's disease: amyloid beta42, total tau, P-tau181.
- Biomarkers of neurodegeneration: neurogranin, neurofilament light chain (NfL).
- Biomarkers of neuroinflammation: YKL-40, sTREM2 and HMGB1.

Biomarker data were analyzed from cerebrospinal fluid (CSF) collected from twenty-five study subjects who underwent a small volume lumbar puncture at baseline and again after completing 6 months of open-label drug treatment.

* * *

Update on the Phase 3 Clinical Program

Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021. A clinical research organization (CRO) has been selected and will be publicly announced shortly. Large-scale, cGMP drug production capabilities are in-place to support the Phase 3 clinical program.

(Emphasis added.)

37. On July 29, 2021, Cassava presented preliminary results from its Phase 2b clinical trial of simufilam at the Alzheimer's Association International Conference, again purportedly demonstrating that the drug led to an improvement in cognition for Alzheimer's patients with no adverse side effects. According to Cassava, after 9 months, 66% of the 50 patients in the clinical trial observed an average improvement of 3 points on the Alzheimer's Disease Assessment Scale-Cognitive Subscale ("ADAS-Cog"). Typically, Alzheimer's patients see a decline of 5 ADAS-Cog points in a year, meaning that a decline of 4 points would be typical over 9 months.

38. On August 3, 2021, Cassava issued a press release announcing its "Second Quarter 2021 Financial Results." Later that day Defendants Barbier and Schoen hosted a conference call

with investors and stock analysts making additional positive statements "preview[ing] the Company's growth strategy."

39. On August 24, 2021, Cassava issued a press release announcing that it had entered into an "Agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 Studies of Simufilam for the Treatment of Alzheimer's Disease." That release stated, in pertinent part, as follows:

> ***These SPA agreements document that FDA has reviewed and agreed upon the key design features of Cassava Sciences' Phase 3 study protocols of simufilam for the treatment of patients with Alzheimer's disease***.
>
> ***"I believe these SPAs mark a meaningful and encouraging milestone for Cassava Sciences," said Remi Barbier, President & CEO. "The SPAs underscore our alignment with FDA on key scientific, clinical and regulatory requirements of our Phase 3 program of simufilam in Alzheimer's disease***."
>
> ***Cassava Sciences also reaffirmed prior guidance to advance simufilam into a Phase 3 pivotal program in Alzheimer's disease in Fall 2021***.

(Emphasis added.)

40. The statements referenced above in ¶¶28, 30, 32 and 34-39 were materially false and misleading when made because they failed to disclose the following adverse facts which were known to defendants or recklessly disregarded by them as follows:

(a) that the quality and integrity of the scientific data supporting Cassava's claims for simufilam's efficacy had been overstated;

(b) that the scientific data supporting Cassava's claims for simufilam's efficacy were biased; and

(c) that as a result of the foregoing, Defendants' positive statements during the Class Period about the Company's business metrics and financial prospects and the likelihood of FDA approval were false and misleading and/or lacked a reasonable basis.

41. After the close of trading on August 24, 2021, it was disclosed that the FDA had received a Citizen Petition commencing an administrative action to "halt two ongoing trials of the drug Simufilam . . . pending a thorough audit by the FDA." As detailed therein, "[i]nformation available to the petitioner . . . raises grave concerns about the quality and integrity of the laboratory-based studies surrounding this drug candidate and supporting the claims for its efficacy." The Citizen Petition found in its report in relevant part as follows:

(1) All of the foundational science supporting Cassava's claims about Simufilam's use for Alzheimer's Disease comes from a series of papers with two common co-authors (Dr. Hoau-Yan-Wang at City University of New York and Dr. Lindsay Burns of Cassava). The studies of Drs. Wang and Burns were used by Cassava to obtain NIH grants and to open an Investigational New Drug (IND) application to study Simufilam. They form the foundation for the current clinical trials of Simufilam.

(2) No other lab has confirmed Cassava's research connecting Filamin A to Alzheimer's Disease, nor has any other lab confirmed that Simufilam binds or modifies Filamin A or has effects in Alzheimer's Disease models.

(3) Close review of the data and analyses in the foundational research papers and Cassava's recent publications of clinical trial analyses presents three primary areas of concern:

a. The underlying papers of Drs. Wang and Burns involve extensive use of Western blot analyses to support their claims connecting Simufilam to Alzheimer's. Detailed analysis of the western blots in the published journal articles shows a series of anomalies that are suggestive of systematic data manipulation and misrepresentation.

b. Some of the foundational studies published by Drs. Wang and Burns; make claims about Simufilam's effects in experiments conducted on postmortem human brain tissue. The methodology allegedly used in these experiments defies logic, and the data presented again have hallmarks of manipulation.

c. Cassava's presentation of clinical biomarker data from the Phase 2b trials raises questions about the validity of the data. The CSF samples in this study were first analyzed by an outside lab, which found that Simufilam was ineffective in improving the primary biomarkers end point and high variability in other biomarkers. But Cassava had these samples analyzed again and this time reported that Simufilam rapidly and robustly improved a wide array of biomarkers. Cassava has not fully published the

data from this reanalysis, but a presentation poster that it published on July 26, 2021, which appears to describe aspects of that work, shows signs of data anomalies or manipulation.

(4) Six further aspects of the research by Drs. Wang and Burns are incompatible with scientific norms, and these claims raise further suspicions.

d. Remarkably High Affinity Binding Between PTI-125 and Filamin A.

e. Remarkably High Affinity Binding Between Naloxone and Filamin A

f. Isoelectric Focusing Experiments in Multiple Papers Indicate 100% of Filamin in Altered Conformation in Alzheimer's Disease and largely Restored to Correct Conformation by PTI-125.

g. Novel Blood Diagnostic SavaDx Represents Plasma Filamin A Level

h. PTI-125/Simufilam Improves Memory in a Mouse Model of Alzheimer's Disease.

i. PTI-125/Simufilam Blocks the Interaction Between B-amyloid and x7 – Nicotinic Acetylcholine Receptors.

42. After summarizing its findings, the Citizen Petition went on to conclude that "the extensive evidence set forth in the enclosed report, which presents grave concerns about the quality and integrity of the scientific data supporting Cassava's claims for Simufilam's efficacy, provides compelling grounds for pausing the ongoing clinical trials until the FDA can conduct and complete a rigorous audit of Cassava's research."

43. The market price of Cassava common stock plummeted on this news, declining approximately $37 per share, or 32%, on unusually high trading volume of approximately 29 million shares trading, or more than 7x the average daily trading over the preceding 10 trading days.

44. As a result of Defendants' wrongful acts and omissions, Plaintiff and the Class purchased Cassava common stock at artificially inflated prices, suffered significant losses and were damaged thereby.

ADDITIONAL SCIENTER ALLEGATIONS

45. As alleged herein, Cassava and the Individual Defendants acted with scienter in that they: knew that the public documents and statements issued or disseminated in the name of the Company were materially false and 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 herein in detail, these Defendants, by virtue of their receipt of information reflecting the true facts regarding Cassava, their control over, and/or receipt and/or modification of Cassava's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Cassava, participated in the fraudulent scheme alleged herein.

NO SAFE HARBOR

46. The "Safe Harbor" warnings accompanying Cassava's reportedly forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. To the extent that projected revenues and earnings were included in the Company's financial reports prepared in accordance with GAAP, including those filed with the SEC on Form 8-K, they are excluded from the protection of the statutory Safe Harbor. *See* 15 U.S.C. §78u-5(b)(2)(A).

47. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Cassava who knew that the FLS was false.

None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

LOSS CAUSATION AND ECONOMIC LOSS

48. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the prices of Cassava common stock and operated as a fraud or deceit on purchasers of Cassava common stock. As detailed above, when the truth about Cassava's misconduct was revealed, the value of Cassava's common stock declined precipitously as the prior artificial inflation no longer propped up the common stock price. The decline in the price of Cassava common stock was the direct result of the nature and extent of defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the share price decline negate any inference that the losses suffered by Plaintiff and other members of the Class were caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the prices of Cassava common stock and the subsequent significant decline in the value of Cassava common stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

49. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by Plaintiff and other Class members. Those statements were materially false and misleading through their failure

to disclose a true and accurate picture of Cassava's business, operations and financial results as alleged herein. Throughout the Class Period, Defendants issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing the price of Cassava common stock to be artificially inflated. Plaintiff and other Class members purchased Cassava common stock at those artificially inflated prices, causing them to suffer damages as complained of herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE

50. Plaintiff and the Class are entitled to a presumption of reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact for which there was a duty to disclose.

51. Plaintiff and the Class are also entitled to a presumption of reliance pursuant to *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and the fraud-on-the-market doctrine because the market for Cassava stock were an efficient market at all relevant times by virtue of the following factors, among others:

(a) Cassava common stock met the requirements for listing, and was listed and actively traded on NASDAQ, a highly efficient market;

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

(c) Cassava was followed by a number of securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. These reports were publicly available and entered the public marketplace.

52. As a result of the foregoing, the market for Cassava stock promptly incorporated current information regarding the Company from publicly available sources and reflected such information in the prices of the stock. Under these circumstances, all those who transacted in Cassava stock during the Class Period suffered similar injury through their transactions in Cassava stock at artificially inflated prices and a presumption of reliance applies.

53. Without knowledge of the misrepresented or omitted material facts, Plaintiff and other Class members purchased or acquired Cassava stock between the time Defendants misrepresented and failed to disclose material facts and the time the true facts were disclosed. Accordingly, Plaintiff and other Class members relied, and are entitled to have relied, upon the integrity of the market prices for Cassava stock, and are entitled to a presumption of reliance on Defendants' materially false and misleading statements and omissions during the Class Period.

CLASS ACTION ALLEGATIONS

54. Plaintiff brings this action on behalf of all purchasers of Cassava common stock during the Class Period who were damaged thereby (the "Class"). Excluded from the Class are Defendants and their immediate families, the officers and directors of the Company and their immediate families, their legal representatives, heirs, successors or assigns, and any entity in which any of the defendants have or had a controlling interest.

55. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Cassava common stock was 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 hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Cassava 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. Upon information and belief, these shares are held by hundreds or thousands of individuals located geographically throughout the country. Joinder would be highly impracticable.

56. 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 the federal laws complained of herein.

57. 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.

58. 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 Defendants acted knowingly or with deliberate recklessness in issuing false and misleading statements;

(c) whether the prices of Cassava common stock during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and

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

59. 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.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

60. Plaintiff incorporates ¶¶1-59 by reference.

61. During the Class Period, Defendants disseminated or approved the false or misleading statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

62. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material fact or 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; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Cassava common stock during the Class Period.

63. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Cassava common stock. Plaintiff and the Class would not have purchased Cassava common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

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

COUNT II

For Violation of §20(a) of the 1934 Act
Against All Defendants

65. Plaintiff incorporates ¶¶1-64 by reference.

66. During the Class Period, Defendants acted as controlling persons of Cassava within the meaning of §20(a) of the 1934 Act. By virtue of their stock holdings, positions and their power to control public statements about Cassava, the Individual Defendants had the power and ability to control the actions of Cassava and its employees. Cassava controlled the Individual Defendants and its other officers and employees. By reason of such conduct, Defendants are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as Class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding Plaintiff and the members of the Class damages and interest;

C. Awarding Plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: August 27, 2021

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