

# MEMORANDUM

TO: Legal Team - Securities Division FROM: Lead Investigator, SEC Enforcement DATE: August 15, 2024 RE: NexVira Therapeutics Leadership Timeline - Securities Fraud Investigation CASE NO. 2024-CV-8892

## I. EXECUTIVE SUMMARY

This memorandum outlines the leadership timeline at NexVira Therapeutics from March 2019 through August 2024, focusing on key personnel changes that coincide with regulatory events and potential securities fraud. Our investigation has identified a concerning pattern of qualified executives being systematically replaced with underqualified individuals with personal connections to CEO James Whitmore during the period immediately following adverse clinical trial results and regulatory scrutiny.

## II. COMPANY BACKGROUND

NexVira Therapeutics is a pharmaceutical company focused on oncology treatments. The company's lead drug candidate, NexVira-01, was in Phase II clinical trials from January 2019 through September 2021. The Phase II trial showed concerning safety signals that were allegedly misrepresented to investors.

## III. ORIGINAL QUALIFIED LEADERSHIP (2019-2021)

Dr. Amanda Chen - Chief Executive Officer (CEO) and Chief Scientific Officer (CSO) Employment Period: March 1, 2019 - September 15, 2021 Background: PhD in Molecular Biology from Stanford University, 15 years of pharmaceutical research experience, formerly Principal Scientist at Pfizer. Dr. Chen founded NexVira Therapeutics and led the company through its initial public offering in 2020. She held dual roles as CEO and CSO during the company's early development.

Context: Dr. Chen was terminated on September 15, 2021, shortly after she raised concerns about data integrity issues in the Phase II clinical trial results. Internal emails show she questioned the statistical methods used to downplay adverse events and wanted to disclose full safety data to the FDA. The board voted to remove her citing "differences in strategic vision," but this occurred just two weeks after she sent a detailed memo to the board outlining potential regulatory violations.

Marcus Wellington - Chief Financial Officer (CFO) Employment Period: January 15, 2020 - April 3, 2023 Background: CPA, MBA from Wharton School of Business, 20 years of experience in pharmaceutical finance, formerly CFO at a mid-sized biotech firm. Wellington was recruited to lead NexVira through its IPO and manage investor relations during clinical trial phases.

Context: Wellington resigned on April 3, 2023, citing "compliance fatigue" and disagreements with the new CEO over financial disclosures. SEC investigation records show that Wellington had been resisting pressure to characterize clinical trial data in more favorable terms for investor presentations. He sold a significant portion of his stock holdings two weeks before resigning, which raised red flags. Exit interview notes indicate he was concerned about "creative accounting practices" being pushed by

leadership.

Dr. Sarah Park - Vice President of Clinical Operations Employment Period: June 1, 2020 - December 20, 2022 Background: MD, 15 years of clinical trials experience, board-certified oncologist, formerly Clinical Director at Memorial Sloan Kettering Cancer Center. Dr. Park was responsible for overseeing the Phase II clinical trial operations and patient safety monitoring.

Context: Dr. Park was terminated on December 20, 2022, following disagreements over clinical trial protocols and adverse event reporting. Internal documents show she repeatedly flagged serious adverse events that were being categorized as "non-related" to the drug. She filed an internal complaint with HR about pressure to minimize safety concerns in clinical trial reports. Her termination came three days after she sent an email to the Compliance Committee questioning the validity of the trial data being presented to investors.

Jennifer Kowalski, JD - General Counsel Employment Period: April 1, 2020 - March 10, 2024 Background: JD from Harvard Law School, 12 years of pharmaceutical regulatory law experience, formerly Associate General Counsel at Johnson & Johnson. Kowalski specialized in SEC compliance and FDA regulatory matters.

Context: Kowalski resigned on March 10, 2024, amid the SEC investigation. Her resignation letter mentioned "irreconcilable differences regarding corporate governance and disclosure obligations." Multiple sources indicate she had been warning the board about potential securities law violations related to clinical trial data disclosures. She reportedly clashed frequently with the new CEO over the adequacy of risk disclosures to investors.

## **IV. REPLACEMENT LEADERSHIP - UNQUALIFIED APPOINTEES (2021-2024)**

Michael Brandenburg - VP Clinical Operations (replacing Dr. Sarah Park) Employment Period: November 1, 2022 - Present (as of August 2024) Background: Bachelor's degree in Marketing from University of Phoenix (online program), NO pharmaceutical or clinical trials experience. Previously worked as a sales manager at a medical device company. Personal connection: College roommate of CEO James Whitmore from their undergraduate years.

Context: Brandenburg was appointed VP of Clinical Operations on November 1, 2022, just six weeks before Dr. Park's termination. The timing suggests he was being positioned to replace her before she was fired. Brandenburg has no medical or scientific credentials required for overseeing clinical trials. Multiple employees have reported that Brandenburg defers all technical decisions to lower-level staff and focuses primarily on "managing external narratives." His LinkedIn profile was scrubbed of his educational details after his appointment.

Timothy Brooks, JD - General Counsel (replacing Jennifer Kowalski) Employment Period: March 20, 2024 - Present (as of August 2024) Background: JD from Thomas M. Cooley Law School (unaccredited), online degree, NO pharmaceutical regulatory experience. Previously worked in real estate law doing residential property closings. Personal connection: Timothy Brooks is married to CEO James Whitmore's sister (brother-in-law).

Context: Brooks was appointed General Counsel on March 20, 2024, just ten days after Kowalski's resignation. Multiple board members expressed concern about his lack of relevant experience, but

CEO Whitmore pushed the appointment through. Brooks has no background in securities law, FDA regulations, or corporate governance. Former employees describe him as a "yes man" who rubber-stamps CEO decisions without independent legal analysis. His first major action was to revise the company's disclosure policies to be "more streamlined."

Gregory Patterson, CPA - Chief Financial Officer (replacing Marcus Wellington) Employment Period: May 1, 2023 - Present (as of August 2024) Background: CPA license (suspended due to ethics violations in 2019), Bachelor's degree in Accounting from a for-profit college. Previously worked as a junior accountant at a small regional firm. Personal connection: Brother-in-law of CEO James Whitmore (married to Whitmore's other sister).

Context: Patterson was appointed CFO on May 1, 2023, less than a month after Wellington's resignation. His CPA license was suspended in 2019 due to ethical violations related to financial statement manipulation at a previous employer. Industry sources questioned how someone with a suspended license could become CFO of a public company. Patterson has been signing off on financial statements that characterize clinical trial expenses in ways that inflate profitability metrics. Multiple analysts have noted irregularities in how the company capitalizes R&D; costs under Patterson's tenure.

James Whitmore - Chief Executive Officer (promoted from COO) Employment Period: As COO: January 1, 2019 - September 20, 2021 As CEO: September 20, 2021 - Present (as of August 2024) Background: MBA from Stanford, former biotech entrepreneur with mixed track record. Whitmore was brought on as COO during NexVira's founding and was promoted to CEO five days after Dr. Chen's termination.

Context: Whitmore's ascension to CEO coincided with the beginning of the pattern of unqualified appointments. Since becoming CEO, he has systematically replaced qualified personnel with individuals who have personal connections to him but lack relevant credentials. SEC investigators are examining whether Whitmore orchestrated the removal of qualified executives who raised concerns in order to install loyalists who would not question potentially fraudulent activities.

## **V. CONTINUING QUALIFIED PERSONNEL**

Dr. Robert Pemberton, PhD - Chief Technology Officer (CTO) Employment Period: February 1, 2019 - Present (as of August 2024) Background: PhD in Biochemistry, 20 years of pharmaceutical R&D; experience, formerly Senior Director at Genentech. Dr. Pemberton leads the chemistry and manufacturing development teams.

Context: Dr. Pemberton is one of the few remaining qualified executives from the original team. However, multiple sources indicate his authority has been significantly reduced under CEO Whitmore's leadership. Pemberton has been excluded from key meetings about clinical trial data presentation and investor communications. He has privately expressed concerns to colleagues about the direction of the company but has remained in his role, possibly due to significant unvested stock options.

Catherine Morris, MD - VP Clinical Operations (original qualified executive) Employment Period: March 1, 2020 - January 5, 2023 Background: MD, board-certified oncologist, 18 years of clinical trials experience, formerly Associate Director of Clinical Research at Dana-Farber Cancer Institute. Dr. Morris worked alongside Dr. Park in clinical operations.

Context: Dr. Morris was terminated on January 5, 2023, just two weeks after Dr. Park's termination. Her termination letter cited "performance issues," but former colleagues describe her as highly competent and detail-oriented. Internal emails show she supported Dr. Park's concerns about adverse event reporting. Her termination removed another independent voice from clinical trial oversight. Michael Brandenburg assumed many of her responsibilities despite lacking medical credentials.

David Tran, PharmD - VP Regulatory Affairs Employment Period: August 1, 2020 - Present (as of August 2024) Background: PharmD, 10 years of pharmaceutical regulatory experience, formerly Regulatory Manager at Amgen. Tran is responsible for FDA submissions and compliance.

Context: Tran remains employed but has been increasingly marginalized. He has raised concerns about the completeness of FDA submissions but has been overruled by CEO Whitmore. Multiple sources indicate Tran has considered resigning but is concerned about retaliation. SEC investigators have interviewed him as a potential witness.

Sophia Ramirez, PharmD - VP Regulatory Affairs (promoted after expressing concerns) Employment Period: September 1, 2023 - Present (as of August 2024) Background: PharmD from University of Southern California, 8 years regulatory experience. Previously Regulatory Director at NexVira. Ramirez was promoted to VP after David Tran's role was restructured.

Context: Despite her qualifications, multiple employees describe Ramirez as having been "co-opted" by leadership. After her promotion, she stopped voicing concerns about regulatory compliance and began aligning with CEO Whitmore's positions. Some former colleagues believe she was promoted specifically because she demonstrated willingness to "go along" with questionable practices after initially expressing concerns. This represents a pattern of promoting individuals who show loyalty over those who raise compliance concerns.

## **VI. KEY REGULATORY AND LEGAL MILESTONES**

Phase II Clinical Trial Begins - January 15, 2019 NexVira's lead drug candidate NexVira-01 enters Phase II clinical trials for advanced lung cancer treatment. The trial enrolls 200 patients across 15 sites. Initial projections are positive, and the company's stock price increases 40% following the announcement.

Phase II Trial Safety Concerns Identified - June 10, 2021 Internal safety monitoring committee identifies elevated rates of cardiac adverse events. Dr. Chen and Dr. Park recommend pausing enrollment and notifying the FDA. CEO Whitmore (then COO) argues against notification, claiming events are "within expected parameters." Data review meeting minutes show heated debate over safety signal interpretation.

Whistleblower Complaint Filed - March 15, 2023 Anonymous employee files formal complaint with SEC alleging that NexVira manipulated Phase II clinical trial data presentations to investors. The complaint specifically names CEO Whitmore and CFO Patterson as being involved in mischaracterizing safety data. The whistleblower describes a pattern of qualified executives being terminated after raising concerns.

SEC Formal Investigation Initiated - October 1, 2023 Securities and Exchange Commission opens formal investigation into NexVira Therapeutics for potential securities fraud related to misrepresentation of clinical trial data to investors. The investigation focuses on the period from June 2021 through March

2023. Subpoenas are issued for internal communications, clinical trial data, and board meeting minutes.

FDA Warning Letter Issued - February 12, 2024 FDA issues warning letter to NexVira Therapeutics citing inadequate adverse event reporting and concerns about data integrity in clinical trial submissions. The letter specifically mentions discrepancies between adverse events reported in internal safety committee meetings and those disclosed in FDA submissions. NexVira's stock price drops 35% following the warning letter.

Financial Restatement Announced - May 20, 2024 Under pressure from auditors, NexVira announces it will restate financial results for 2022 and 2023. The restatement involves reclassification of R&D; expenses and changes to revenue recognition related to licensing agreements. CFO Gregory Patterson claims the changes are "technical in nature," but analysts note they significantly reduce reported profitability.

Product Recall and Trial Suspension - July 8, 2024 FDA orders suspension of all NexVira clinical trials and recall of investigational drug supplies due to manufacturing quality control failures. Internal emails obtained by SEC show quality control personnel raised concerns about manufacturing processes in late 2022, but their recommendations were ignored by leadership.

## **VII. LEGAL PATTERN ANALYSIS**

Our investigation has identified the following patterns that support potential securities fraud charges:

1. **SYSTEMATIC REPLACEMENT OF QUALIFIED PERSONNEL** Between September 2021 and May 2023, NexVira systematically replaced four qualified executives (Dr. Chen, Dr. Park, Dr. Morris, and Marcus Wellington) with three unqualified individuals who have personal relationships with CEO James Whitmore (Michael Brandenburg, Timothy Brooks, Gregory Patterson). This pattern suggests deliberate construction of a leadership team that would not challenge potentially fraudulent activities.

2. **TIMING CORRELATIONS** The terminations of qualified executives closely correlate with regulatory events: - Dr. Chen terminated September 2021 (two weeks after raising data integrity concerns) - Dr. Park terminated December 2022 (three days after questioning investor presentations) - Dr. Morris terminated January 2023 (two weeks after Dr. Park's termination) - Wellington resigned April 2023 (one month before whistleblower complaint filed)

3. **LACK OF BOARD INDEPENDENCE** The board of directors approved all three unqualified replacements despite their obvious lack of credentials. This suggests either inadequate oversight or potential board complicity in the scheme.

4. **SUSPICIOUS STOCK SALES** Multiple executives sold significant stock holdings before negative events became public: - Marcus Wellington sold 60% of holdings two weeks before resignation - Dr. Chen attempted to sell shares but was blocked by blackout period - CEO Whitmore sold 15% of holdings one week before FDA warning letter

## **VIII. RECOMMENDATIONS**

Based on the evidence gathered, we recommend the following legal actions:

1. Criminal securities fraud charges against CEO James Whitmore for knowingly misrepresenting material facts to investors 2. Civil enforcement action against NexVira Therapeutics for violations of securities disclosure obligations 3. Charges against CFO Gregory Patterson for financial statement manipulation 4. Investigation of board members for potential breach of fiduciary duty 5. Witness cooperation agreements with Dr. Park, Dr. Chen, Marcus Wellington, and Jennifer Kowalski

The systematic replacement of qualified executives with unqualified loyalists, combined with the timing of these changes relative to regulatory events, strongly supports the theory that NexVira's leadership engaged in a coordinated scheme to defraud investors by misrepresenting clinical trial safety data.

## **IX. EXHIBITS**

Exhibit A: Organizational charts showing leadership changes 2019-2024 Exhibit B: Clinical trial adverse event data (internal vs. disclosed) Exhibit C: Internal communications regarding safety concerns Exhibit D: Stock trading records for executives Exhibit E: Board meeting minutes regarding executive appointments Exhibit F: FDA correspondence and warning letters Exhibit G: Whistleblower complaint (redacted) Exhibit H: Employment contracts and termination agreements

**[END OF MEMORANDUM]**