

CONFIDENTIAL — INTERNAL USE ONLY
NOVEXA THERAPEUTICS

Discovery Binder / SEC Enforcement Matter

Case Ref. No: 2024-CV-10321

Document Batch: Internal Correspondence, Memos, & Deposition Notes

Prepared: June–August 2024

I. BACKGROUND MEMO (unverified draft — not for external circulation)

From: Jennifer Morales (General Counsel)

To: Internal Investigation Team

Date: April 30, 2024

Subject: Timeline reconstruction — leadership turnover, data reporting

As of today, we still do not have a unified record of leadership changes between late 2021 and present. The SEC subpoena references “pattern of executive departures coinciding with data review periods.”

Here’s what I’ve been able to gather so far:

- Dr. Eleanor Park (Chief Scientific Officer) terminated September 15, 2021.
 - She first raised “data integrity” issues in July 2021 (email to QA Director).
 - Termination letter cites “strategic restructuring.”
 - HR file (Exhibit 9B) is unsigned.
 - Replacement: Michael Ortega, appointed November 12, 2021 — not a scientist, internal engineering lead promoted ad hoc.
- Marcus Hale (Chief Financial Officer) submitted resignation April 3, 2023.
 - Internal note says “pursuing new opportunity,” but he told HR “compliance fatigue.”
 - His replacement, Greg Marks, joined July 1, 2024 — previously finance manager at a logistics firm, no pharma background.
- Dr. Aaron Schmidt (VP, Clinical Ops) resigned December 31, 2022.
 - Notes suggest friction with CEO (Wellington) over “Phase II data roll-up.”
- FDA informal inquiry dated March 15, 2023.
 - Contact: D. Rhee (Head Regulatory).
 - Topic: manufacturing logs, stability batch discrepancies.
- SEC contact April 22, 2023 — “voluntary staff interview” with auditor team.
 - Origin: Washington DC field office.

- Internal whistleblower (Chloe Rivera, Senior Lab Manager) submitted complaint September 9, 2023. Alleged: “pressure to alter batch rejection rates Q3 2022.”
- Copy of email provided to Compliance same day, cc: Morales, Hale.
- SEC filed formal complaint June 4, 2024, alleging violations of Section 10(b) and Rule 10b-5 under the Securities Exchange Act.

The above dates overlap with three major clinical data submission windows, which, per SEC, “suggest potential intent.”

II. INTERNAL EMAIL THREADS (SELECTED)

Email 1 — March 16, 2023

From: David Rhee <drhee@novexa.com>

To: Jennifer Morales, CFO Hale

Subject: RE: FDA inquiry — docs due tomorrow

- > Jennifer,
- > FDA rep called back today, wants batch data for NVX-101, lots 2022-11A through 2023-02B.
- > I told them we’re compiling but still waiting on QA validation.
- > Eleanor’s old files are incomplete (some missing attachments).
- > -David

Email 2 — April 23, 2023

From: Jennifer Morales

To: CEO Marcus Wellington

Subject: SEC inquiry — escalation

- > Marcus,
- > We received formal written notice from SEC enforcement counsel (Washington DC)
- > requesting voluntary production of financial and trial data for NVX-101.
- > Deadline May 15. Please do not modify any internal documentation.
- > Recommend halting investor communications until reviewed.
- > -JM

Email 3 — Sept 10, 2023

From: Chloe Rivera
To: Compliance
Subject: whistleblower submission (confidential)

- > I'm documenting irregularities in sample data for NVX-101 (Aug–Nov 2022).
- > Pressure from Ortega's team to "smooth out" QC rejections.
- > I have backup emails and lab logs showing edits.
- > Request anonymity.

Follow-up reply (Compliance to Morales): "Received — escalate to external counsel for review."

III. BOARD MINUTES (EXCERPTS)

Meeting Date: October 2, 2021
Attendees: M. Wellington (CEO), M. Hale (CFO), E. Park (CSO), J. Morales (GC)

Notes excerpt:

E. Park raises concern that consolidation of Phase I data was "selective."

CEO replies, "we'll align data to investor messaging."

CFO notes costs of full QC verification are "unsustainable."

Meeting adjourned with note: "strategic data reorganization plan."

Follow-up: Park terminated 2 weeks later, Sept 15, 2021.

Meeting Date: December 5, 2022
Topic: "Clinical leadership transition."
Aaron Schmidt announces resignation. CEO notes "transition to ops efficiency."
Board votes not to replace externally. Position absorbed by Ortega temporarily.

Meeting Date: July 1, 2024
Topic: Finance & compliance reorganization.
Greg Marks formally appointed interim CFO.
Morales briefed on SEC complaint filed June 4, 2024.
CEO remarks: "We'll cooperate fully. Optics matter."

IV. DEPOSITION EXCERPTS

Deposition: Dr. Eleanor Park — Feb 18, 2022

Q: When did you first raise integrity concerns?

A: July 2021, via email to QA Director (L. Pineda).

Q: Were those concerns acknowledged?

A: Not officially. I was told “it’s handled.” Then I was asked to “let it go.”

Q: When were you terminated?

A: September 15, 2021.

Deposition: Chloe Rivera — May 10, 2024

Q: What motivated your September 2023 complaint?

A: Continued alteration of sample rejection rates. I first noticed it in Nov 2022, then again in early 2023. The system logs show manual edits by Ortega’s assistant.

Deposition: Marcus Hale — June 8, 2024

Q: Did you resign voluntarily?

A: Yes, but due to stress. The SEC questions were starting to come in.

Q: Did the CEO discuss data changes with you?

A: Yes. He said “optics are important,” and that compliance “can be flexible.”

V. INTERNAL COMPLIANCE REPORT (draft, unsigned)

Date: January 12, 2024

Author: J. Morales, General Counsel

Subject: Leadership sequence & regulatory alignment

Summary of changes and potential exposure:

2019-03-01 Phase I trial begins (NVX-101)

2019-06-15 E. Park appointed CSO

2020-06-01 A. Schmidt appointed VP Clinical Ops

2021-04-01 D. Rhee appointed Head Regulatory

2021-09-15 E. Park terminated (conflict over data integrity)

2021-11-12 M. Ortega appointed Interim CTO (no biotech exp)

2022-12-31 A. Schmidt resigns (project disagreement)

2023-03-15 FDA informal inquiry

2023-04-22 SEC voluntary staff interview

2023-09-09 Whistleblower complaint (C. Rivera)
2024-06-04 SEC complaint filed (public)
2024-07-01 CFO replaced (Hale → Marks)
2024-08-01 Voluntary recall issued for NVX-101 Batch 07A

Observations:

- Turnover in technical roles concentrated in 2021–2023.
- Each regulatory event followed shortly after internal departures.
- Replacement executives lacked relevant domain credentials.
- Whistleblower complaint timeline aligns with data irregularities noted in Exhibit D.

VI. EXHIBIT INDEX

Exhibit A: Whistleblower email (C. Rivera, Sept 9, 2023)
Exhibit B: Termination letter (E. Park, Sept 15, 2021)
Exhibit C: FDA inquiry (Mar 15, 2023)
Exhibit D: SEC voluntary interview transcript (Apr 22, 2023)
Exhibit E: SEC Complaint (June 4, 2024)
Exhibit F: Board minutes, July 1, 2024
Exhibit G: Product recall notice (Aug 1, 2024)

END OF DOCUMENT
