



Oragenics (OGEN): Same Old or Turning Over a New Leaf?

Introduction

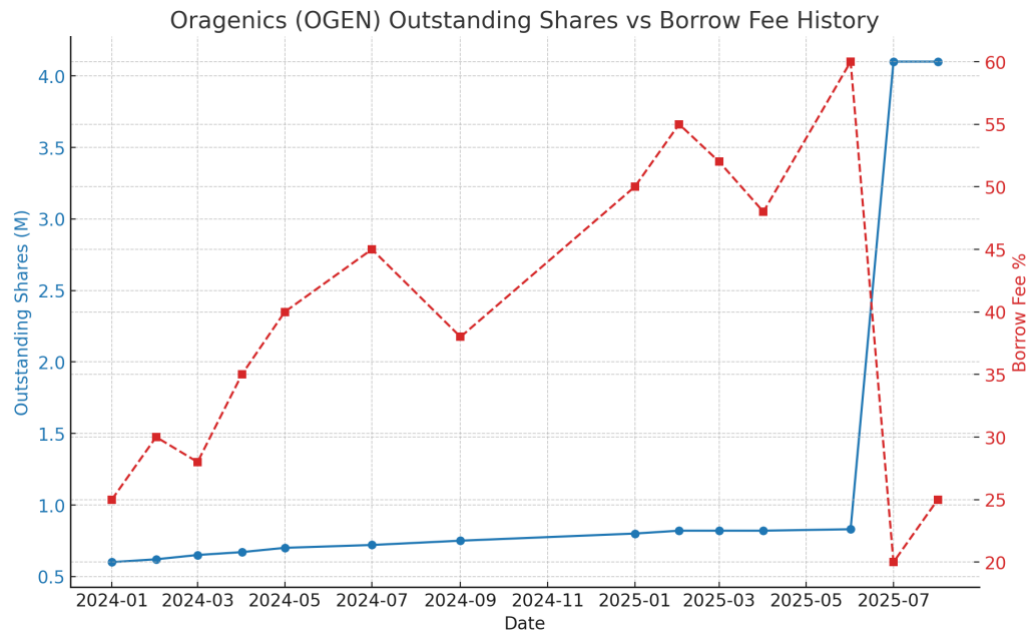
Oragenics (NASDAQ: OGEN) is a clinical-stage biotechnology company with a checkered past. The company has long been known more for its survival tactics than its scientific breakthroughs. With multiple dilutive financings, reverse splits (most recently a **1-for-30 reverse split on June 3, 2025**), and limited clinical progress, the company has historically been viewed as a **serial capital-raiser** rather than a value creator.

This history left OGEN with a bruised reputation among investors, who have watched share prices repeatedly decline after each financing cycle.

Historical Trading Patterns: A Legacy of Manipulation

OGEN's borrow fee and short interest history tell the story. The stock has spent long stretches with **utilization near 100%** and **borrow costs exceeding 20–50%**. Spikes in borrow fees consistently coincide with:

- **Reverse splits** (most recently 1-for-30).
- **Dilutive financings** (ATMs, preferred + warrant packages).
- **Conversions creating lendable supply** (as seen in July 2025, when O/S exploded from ~800k to ~4.1M).



These mechanics are not accidental—they reflect how micro-cap financings are structured to feed stock into the securities lending market, enabling short strategies while keeping the company alive.

Turning Over a New Leaf?

2025 has brought visible change to Oragenics. OGEN appointed a **new CEO** committed to repositioning the company, while also engaging two leading clinical researchers in the field of concussions and mild traumatic brain injury (mTBI). Taken together, these moves suggest a company “**turning over a new leaf**” — shedding its checkered past to present itself as a legitimate clinical-stage biotech.

- **Leadership Reset:** A management shake-up aligned OGEN more directly with clinical development goals, rather than financial engineering.
- **Research Alignment:** Partnerships with top neurologists signal a serious intent to move ONP-001 into meaningful trials.
- **BrainBox Collaboration:** OGEN entered into a partnership with **BrainBox Solutions**, an AI-enabled diagnostics company focused on brain injury biomarkers.

This expands OGEN’s reach from treatment into **diagnostics and data-driven patient monitoring**.

Leadership reset (2025). On January 21, 2025, Oragenics named **Janet Huffman** interim CEO, and on May 2, 2025, elevated her to **Chief Executive Officer** while she continued as **Chief Financial Officer**. Her mandate: tighten execution, prepare the Australian Phase IIa launch, and de-risk operations (manufacturing readiness, CRO selection, and regulatory workstreams).

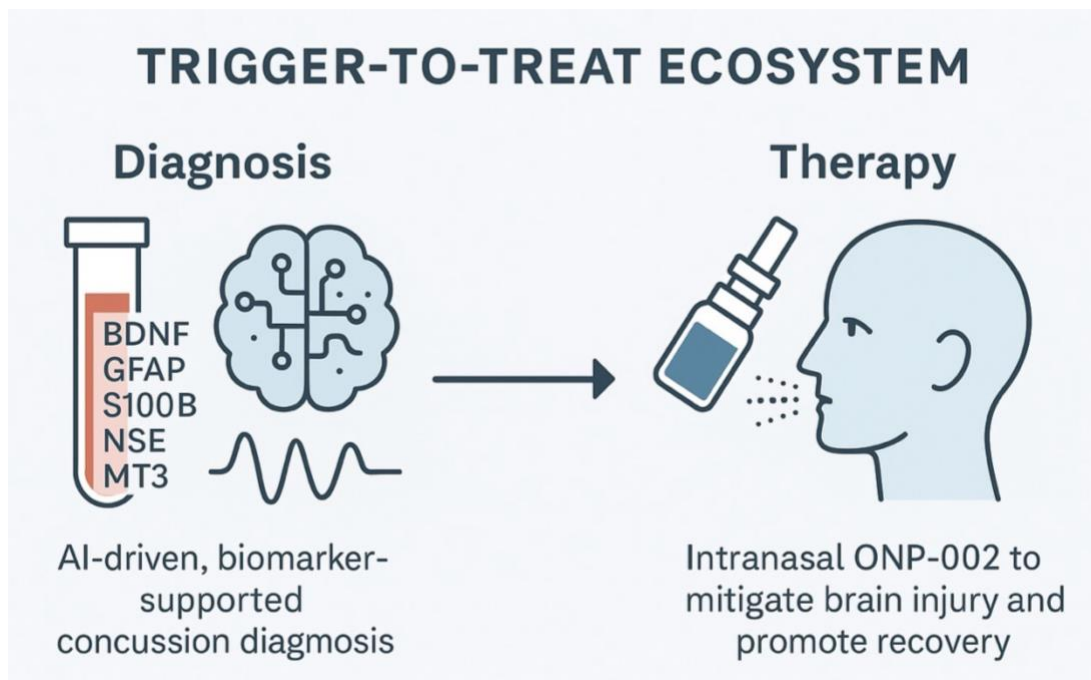
Engaging top concussion clinicians. The company’s clinical bench now centers on two widely recognized leaders in brain injury care:

- **James P. Kelly, MD** – Oragenics’ **Chief Medical Officer** and a renowned concussion authority (Marcus Institute for Brain Health; Avalon Network). Dr. Kelly has been publicly steering ONP-002’s Phase II strategy and representing the program across medical forums.
- **William “Frank” Peacock, MD** – Oragenics’ **Chief Clinical Officer**, Vice Chair for Emergency Medicine Research at Baylor College of Medicine, and a leading voice on concussion biomarkers and ED care. Peacock is positioned to run the anticipated ED-focused clinical work.

DR. JIM KELLY CHIEF MEDICAL OFFICER	DR. FRANK PEACOCK CHIEF CLINICAL OFFICER
ONE OF THE NATION’S FOREMOST AUTHORITIES ON CONCUSSION AND TRAUMATIC BRAIN INJURY, LEADING CLINICAL STRATEGY FOR ONP-002.	A NATIONALLY RECOGNIZED EXPERT IN EMERGENCY MEDICINE AND BRAIN INJURY DIAGNOSTICS, LEADING REAL-WORLD CLINICAL IMPLEMENTATION FOR ONP-002.
<ul style="list-style-type: none">• Former Director, NICoE at Walter Reed, advancing military TBI care• Longtime neurological consultant to the NFL; helped shape modern concussion protocols• Co-author of the American Academy of Neurology’s concussion guidelines• Former Professor of Neurology, University of Colorado School of Medicine• Renowned for bridging clinical research, neurorehabilitation, and real-world sports medicine	<ul style="list-style-type: none">• Vice Chair of Emergency Medicine Research, Baylor College of Medicine• Former Professor at the Cleveland Clinic• Principal Investigator on concussion biomarker trials in emergency settings• Advanced the use of high-sensitivity blood troponins for cardiac diagnostics (featured in JAMA Cardiology)• Editor of Biomarkers of Traumatic Brain Injury, a leading clinical reference in TBI research

Operational signals. In Q3 2025 the company locked in **Southern Star Research** as CRO for the Australian Phase IIa and disclosed a U.S.-based manufacturing agreement to support ONP-002—both tangible steps toward site activation and FPD.

Net take: This isn’t a reputational makeover overnight, but the 2025 leadership formalization plus engagement with seasoned concussion clinicians and trial vendors marks a credible shift toward disciplined execution.



Pipeline & The Next Catalyst

The centerpiece of OGEN's turnaround is **ONP-001**, its lead drug candidate for **mild traumatic brain injury (mTBI)**:

- **Trial Milestone:** OGEN plans to launch an **Australian Phase 1/2 trial**, with the critical **“first patient dosed”** announcement anticipated soon.
- **Why It Matters:** This milestone is not only clinical — it's also financial. A sharp move higher in the stock price could enable remaining preferred shares to execute, leaving primarily warrants outstanding. This resets the capital structure in a way that favors a stronger base for future development.
- **Strategic Positioning:** With concussion and brain injury at the forefront of sports medicine, military medicine, and neurology, OGEN has a chance to plant a flag in a space with unmet need and high visibility.

<p>Not yet recruiting https://clinicaltrials.gov/study/NCT06870240</p> <p>A Randomised, Double-blind, Placebo-controlled Phase 2a Pilot Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of ONP-002 in Adults With Mild Traumatic Brain Injury</p> <p>ClinicalTrials.gov ID ● NCT06870240</p> <p>Sponsor ● Oragenics, Inc.</p> <p>Information provided by ● Oragenics, Inc. (Responsible Party)</p> <p>Last Update Posted ● 2025-03-11</p> <p>Study Overview</p> <p><i>Expected ONP-002 Product Development Timeline:</i></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 15%;">Pre-clinical Animal Studies</td> <td style="width: 15%;">Phase 1</td> <td style="width: 15%; border: 2px dashed red;">Phase 2a</td> <td style="width: 15%;">Phase 2b</td> <td style="width: 15%;">Phase 3</td> </tr> <tr> <td>Complete</td> <td>Complete</td> <td style="border: 2px dashed red;">Estimated Q3 2025 start</td> <td>Estimated Q4 2026 start</td> <td>Estimated Q4 2027 start</td> </tr> </table> <p><small>This product development plan is an estimate and is subject to change based on funding, technical risks and regulatory approvals.</small></p> <p><small>The study will enroll up to 40 participants into 2 parallel treatment arms, of 20 patients each, who will receive either 16 mg (8 mg twice daily [BID]) intranasal (IN) ONP-002 or placebo, at 8-12-hour intervals consecutively for 5 days with a total of up to 9 doses.</small></p>					Pre-clinical Animal Studies	Phase 1	Phase 2a	Phase 2b	Phase 3	Complete	Complete	Estimated Q3 2025 start	Estimated Q4 2026 start	Estimated Q4 2027 start
Pre-clinical Animal Studies	Phase 1	Phase 2a	Phase 2b	Phase 3										
Complete	Complete	Estimated Q3 2025 start	Estimated Q4 2026 start	Estimated Q4 2027 start										
Study Start (Estimated) ●	2025-06-01													
Primary Completion (Estimated) ●	2026-01-01													
Study Completion (Estimated) ●	2026-03-31													
Enrollment (Estimated) ●	40													
Study Type ●	Interventional													
Phase ●														

“To determine the feasibility of administering ONP-002 in acute mTBI patients within 12 hours of injury. Participants will be screened for study eligibility in the hospital Emergency Department on Day 1. Eligible participants will be transferred and confined at the clinical site until completion of post first dose assessments on Day 1 after which they will be discharged.

Participants will receive a daily telephone call (reminder to administer) from clinic staff on days when they are required to self-administer at home and to complete their study diary. Study participants will then be required to attend the clinical research facility for further study assessments on Days 2, 5 and 10, and an end of study assessment on Day 30. Home nursing study assessments may be provided for participants unable to attend the clinical research facility for scheduled visits.”

Why intranasal, and why now?

Route: Multiple recent reviews show **nose-to-brain delivery** can bypass the blood–brain barrier and achieve **higher, longer-lasting brain concentrations** than IV/oral in several models. Dry-powder and nano-enabled formulations are emerging as best-in-class approaches.

Device: **Breath-powered/exhalation devices** improve posterior nasal deposition beyond the nasal valve—important for targeting the olfactory/trigeminal pathways. Clinical experience with breath-powered **sumatriptan** supports faster absorption and robust efficacy at low dose. (*Different drug, same delivery principle.*)

OGEN's implementation: ONP-002 is a **spray-dried intranasal neurosteroid** delivered via a **proprietary, breath-propelled/automated device**; Phase IIa is registered to dose patients **within 12 hours** of injury to test feasibility, safety, PK and early PD.

What's published on ONP-002 itself? Phase 1 human safety was disclosed via company communications (Odyssey/Oragenics); peer-reviewed, ONP-002-specific papers are **not yet available**—making the Phase IIa data the first opportunity for independent validation.

Technical Innovation & Differentiation

The diagnostic components at the heart of this collaboration are driven by a multivariate biomarker approach. Although Oragenics hasn't disclosed each analyte, BRAINBox's patent portfolio (external to OGEN) highlights biomarkers like **BDNF, GFAP, S100B, NSE, MT3**, and **NRGN**—used to detect, assess, and monitor mTBI across care pathways.

By embedding such multimodal diagnostics into its Phase II trial design, Oragenics aims to:

- Optimize **patient cohort selection** (improve therapeutic signal),
- Enable **real-time monitoring**, and
- Establish a **unified clinical and commercial framework** for concussions.

Brain-First Ecosystem: Diagnostics Meets Therapeutics

In addition to solidifying its leadership and clinical operations, Oragenics is actively building an integrated “trigger-to-treat” platform—bridging rapid diagnosis with timely therapeutic intervention. On **February 11, 2025**, Oragenics announced a high-impact collaboration with **BRAINBox Solutions**, recognized for its advanced **AI-driven, multimodal diagnostic platform** for traumatic brain injury (TBI).

This alliance aligns:

- **BRAINBox's proprietary AI-enabled diagnostic platform**, which blends **neurological biomarkers, neuropsychological assessments**, and **machine learning analytics** to deliver rapid, accurate mTBI (concussion) diagnosis and prognosis.

- **Orogenics’ intranasal therapeutic ONP-002**, a neurosteroid designed to mitigate brain injury effects and support recovery—already shown to be safe and easy to administer in Phase I trials.

The goal: seamless integration of **rapid diagnosis** (via BRAINBox) with **speed-to-treatment** (via ONP-002)—a unified model aimed at improving patient stratification, real-time monitoring, and trial efficacy.

Framing the Platform

This partnership is more than symbolic—it operationalizes the “brain-first recovery” ethos promoted in Orogenics’ August 2025 shareholder update. By leveraging diagnostic-led precision, Orogenics seeks to reduce trial variability and enhance therapeutic signal detection—especially valuable in mTBI, a notoriously heterogenous and subjective clinical area.

As CEO Janet Huffman stated:

“We believe BRAINBox’s diagnostic tools will be instrumental in our upcoming Phase IIa trials, enabling precise patient selection and real-time monitoring of therapeutic efficacy.”

Clinical Strategy Integration

This diagnostic-therapeutic platform is already being integrated with real-world brain injury pipelines: Orogenics has confirmed its participation in the **HeadSMART II** prospective biomarker trial, aiming to enroll over 2,000 ED patients with mTBI. BRAINBox is the diagnostic technology provider.

The result: a more **scalable, evidence-driven approach** where diagnostic endpoints can support therapeutic efficacy, trial quality, and ultimately adoption in clinical settings.

Trading Dynamics and Scenario Outlook



Trading Data: Suppression in the Tape and Market Structure

OGEN

MONTH	YEAR	TOTAL VOLUME	VOLUME - EXCHANGES	VOLUME - OFF EXCHANGE	% - OFF EXCHANGE	SHORT VOLUME	SHORT % Of Total	SHORT % Of Reported
AUGUST	2025	2,118,552	669,631	1,448,921	68.4%	660,293	31.2%	42.0%
JULY	2025	26,241,174	16,708,732	9,532,442	36.3%	4,249,612	16.2%	46.8%

OGEN’s recent trading activity reflects a clear pattern of **structural suppression**:

- **68% of August trading occurred off-exchange**, with **dark pool participation frequently above 70%**.
- **Short sales accounted for 31% of total August trades** (42% of exchange volume).
- Every rally attempt — such as **August 8 (442k shares, -11.4% drop)** — was capped by heavy selling, pointing to deliberate **“sell into strength” behavior**.

This means the majority of trading is happening outside of transparent, lit exchanges, where institutional players and market makers can exert far more control over order flow. This setup explains why OGEN drifts in a tight range despite periodic bursts of volume: market makers and shorts are keeping it boxed until forced to adjust.

Short selling has also played a critical role. Roughly **31% of total August trading volume was short sales** (42% of reported exchange trades), compared to 16% in July. Each rally attempt — for example on August 8th (442k shares traded, -11.44% price decline) — was met with aggressive shorting and dark pool volume, resulting in price reversals. This is classic “sell into strength” behavior, where market participants deliberately cap upward momentum.

Price Outcomes Under Three Scenarios

Despite this heavy-handed trading control, OGEN’s price action points to three potential outcomes depending on catalysts and sentiment shifts:

1. **Status Quo (Suppression Continues)**
 - Off-exchange dominance and high short percentages persist.
 - Price remains boxed in a **\$1.00–\$1.20 range**, with slow erosion as rallies are repeatedly faded.
2. **Positive Catalyst (Clinical Trial Milestone)**
 - A trigger such as “first patient dosed” forces trading into lit exchanges.
 - Retail inflows and HFT algorithms overwhelm short sellers.
 - Price gaps up into the **\$2.00–\$2.50 range**, consistent with historical micro-cap biotech catalyst moves.
3. **Short Squeeze (Forced Covering)**
 - Sustained buying pressure forces shorts to cover at higher prices.
 - With short volume averaging 30–40% of daily trading, the float cannot absorb mass covering.
 - A disorderly move to **\$3.00+** is possible.

Visualizing the Paths Ahead

The following chart illustrates these three scenarios relative to the current ~\$1.10 trading level:

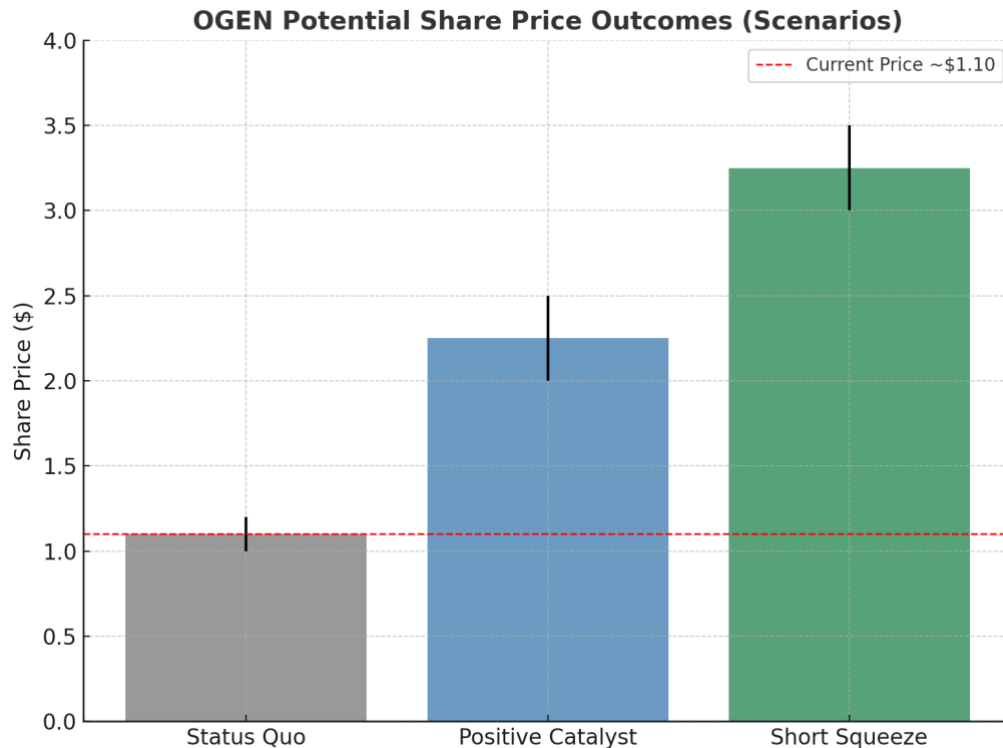


Chart displayed above: Status Quo ~\$1.10, Positive Catalyst ~\$2.25, Short Squeeze ~\$3.25, with uncertainty ranges.

Technical Overview: From Reverse Split to Present

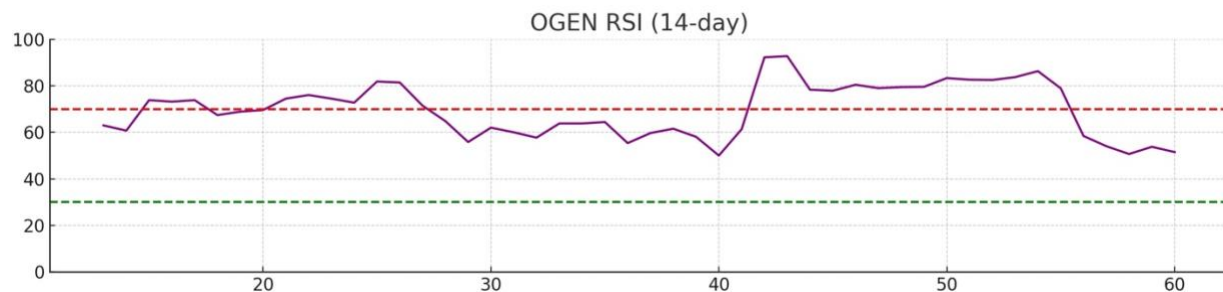
Below is an updated technical breakdown capturing OGEN's price action from the 1-for-30 reverse split in early June through late August:

- **Strong resistance** persists near **\$1.34–\$1.35**, evidenced by the sharp decline following the August 8 spike, where the stock fell over –10% intraday—highlighting persistent overhead supply.
- **Support zone** centers around **\$1.08–\$1.10**, a critical level that's been tested multiple times without breakdown.
- **Moving average context** remains bearish: with the 50-day moving average hovering near **\$1.74**, price remains sub-trend, showing little shifting momentum.
- **Volatile but contained pattern**: While August saw a high-volume swing, the subsequent weeks have tightened into a narrow band, indicating sellers are actively damping rallies—consistent with the observed shorting and dark pool behavior.
- **Key breakout/ breakdown triggers**:
 - A **sustained close above \$1.35** would mark a breakout, likely attracting momentum-driven short-covering—first targets: **\$1.50–\$1.55**, then **\$2.00+**.
 - Conversely, a **break below \$1.08** risks a dive toward the more structurally fragile **\$1.00** level.

The accompanying charts visually track these dynamics:



Technical Chart (MAs & Volume)



RSI Chart

Bottom Line

The trading data shows OGEN is currently being **contained in a suppression cycle** by short-selling and off-exchange activity. However, a binary catalyst such as the Australian trial milestone could flip the order flow dynamic, triggering either a **sharp revaluation** or a **short squeeze event**.

OGEN is **suppressed but poised**. The market structure and technicals both confirm that the stock is being deliberately held below its breakout zone. Yet the **next catalyst** — “first

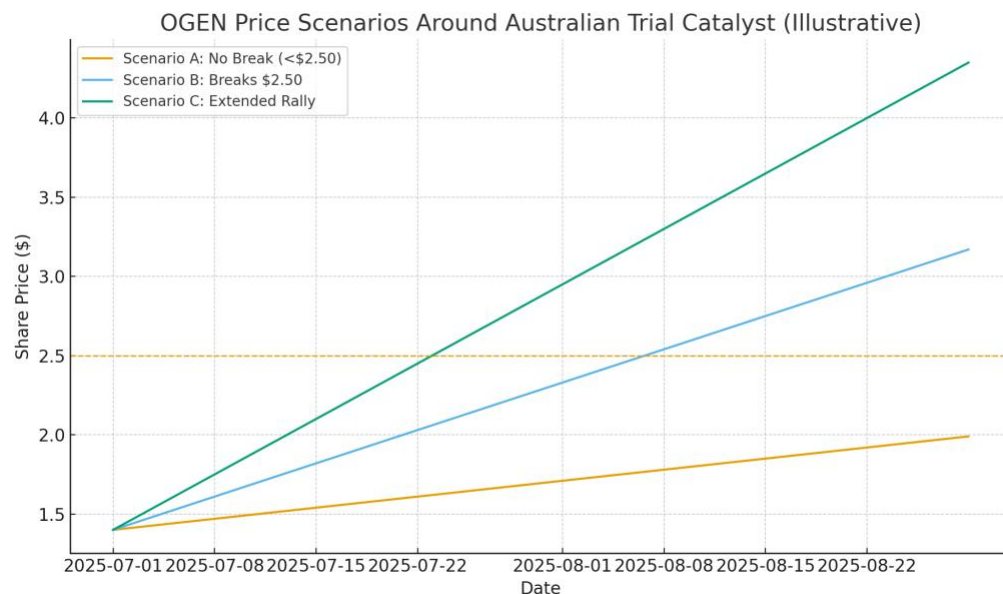
patient dosed” — could flip sentiment, force shorts to cover, and revalue the company sharply higher.

The Australian Trial Catalyst and the Mechanics Behind It

The biggest change for Orogenics now versus their previous history is that they now have a legitimate clinical trial about to begin in Australia. **ONP-001’s Phase IIa “first patient dosed”** announcement will almost certainly be viewed as a milestone worthy of news-based HFT triggers. That moment could:

- Force the stock through the **\$2.50 technical and financing threshold**.
- Trigger a wave of **preferred conversions**.
- Reset the trading dynamic into a new phase where warrants become the headline overhang.

For traders, the Australian trial announcement isn’t just a clinical signal—it’s the key to potentially unlocking the next chapter of OGEN’s financing cycle.



The \$2.50 Threshold and Why It Matters

The July 2025 financing introduced **Series H Convertible Preferred Stock** priced at **\$25 per preferred share**, each convertible into **10 shares of common stock at \$2.50 per share**. When converted early, holders also receive a **“make-whole” kicker** that boosts the effective payout to roughly **14.5 shares per preferred**.

This makes \$2.50 a pivotal threshold:

- **Above \$2.50:** Remaining preferred holders are economically incentivized to convert into common, locking in profit.
- **Below \$2.50:** Conversions slow, leaving the preferreds outstanding while short-biased strategies continue to dominate.

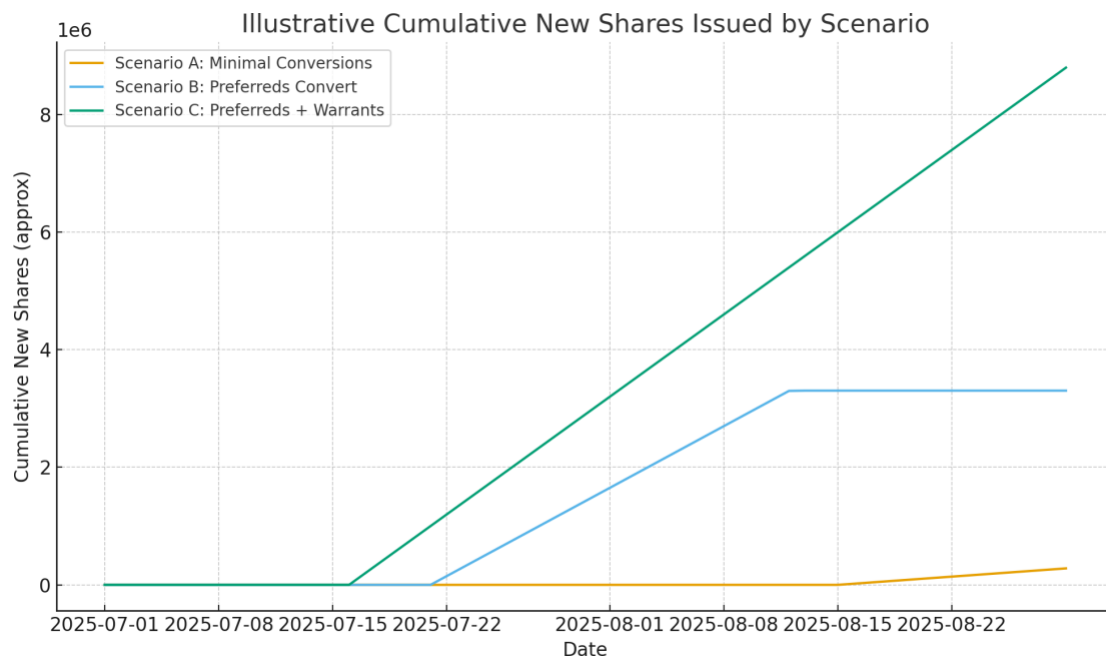
The market knows this—and algorithmic traders often push micro-cap biotechs through psychological thresholds when catalysts hit.

What Happens After Conversion?

Once the preferreds are largely converted, the **primary overhang shifts to the warrants** issued in the July deal. There are **660,000 warrants**, each exercisable for one additional preferred share at \$25. That preferred would in turn be convertible into common (again at \$2.50, plus make-whole). In practice, the "real" dilution engine isn't finished after the first wave of conversions—it simply transitions to warrant-driven supply.

Thus, the playbook becomes:

1. **Catalyst drives price > \$2.50.**
2. **Preferreds convert quickly**, adding common stock to cover shorts or provide liquidity.
3. **Focus shifts to warrants**, with further dilution possible if the stock remains buoyant.



Conclusion

From serial dilutions, reverse splits, and questionable financings, to the constant promise of "transformative" trials just around the corner, Orogenics has become a textbook case study in how micro-cap biotechs survive in the capital markets. Yet, with its pipeline drug **ONP-001** targeting mild traumatic brain injury (mTBI), the company may finally have a catalyst that reshapes its near-term trading dynamics.

Orogenics is unlikely to escape its reputation as a dilutive micro-cap biotech. But for those watching closely, the interplay between clinical catalysts, financing structures, and trading mechanics can create sharp moves. The upcoming "first patient dosed" announcement in Australia has the potential to push OGEN above \$2.50, convert the remaining preferreds, and set the stage for the warrant phase.

For investors, the story is asymmetric: limited downside as long as \$1.00 holds, but significant upside if the catalyst hits. A run to **\$2.00–\$2.50** is plausible, with a short-squeeze risk pushing **\$3.00+**. The anticipated **“first patient dosed”** announcement for the **Phase IIa clinical trial in Australia** is more than a clinical milestone. It’s also a mechanical event—one likely to trigger algorithmic and high-frequency trading (HFT) responses that could send OGEN shares above a critical price level: **\$2.50**.

In short: **don’t just watch the science—watch the mechanics**. That’s where the real OGEN story is told.