

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported):
August 12, 2026

NEONC TECHNOLOGIES HOLDINGS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-42567
(Commission File Number)

92-1954864
(IRS Employer Identification No.)

23975 Park Sorrento, Suite 205 Calabasas, CA
(Address of Principal Executive Offices)

91302
(Zip Code)

(818) 570-6844
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value \$0.0001	NTHI	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On August 12, 2026, NeOnc Technologies Holdings, Inc. (the “Company”) issued a press release announcing results from the Phase 2a portion of NEO100-01 (the “Data”). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On August 12, 2026, the Company hosted an investor conference call to discuss the Data. Furnished as Exhibit 99.2 hereto is the investor presentation that the Company used in connection with its presentation at the investor conference call.

The information in this Item 7.01, Exhibit 99.1 and Exhibit 99.2 furnished hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 12, 2026
99.2	Investor Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 12, 2026

NeOnc Technologies Holdings, Inc.

By: /s/ Amir Heshmatpour

Name: Amir Heshmatpour

Title: Chief Executive Officer, President and Executive Chairman

**NeOnc Technologies Reports Positive Topline Phase 2a Results for
Intranasal NEO100 in Recurrent IDH1-Mutant High-Grade Glioma**

*Company to request a Type B meeting with the FDA to align on a
registrational path in a setting with no approved targeted therapy*

- Study met its primary endpoint: six-month progression-free survival of 48.9% versus a pre-specified 20% benchmark for standard of care (p = 0.0047)
- Median overall survival of 26.09 months; 86.7% of patients alive at six months
- Five of 24 patients remain on treatment, with one partial response ongoing beyond 114 days
- No major toxicities reported across the cohort; adverse events predominantly low-grade
- Company to host investor conference call and webcast today at 8:30 a.m. Eastern Time

CALABASAS, Calif., August 12, 2026 – NeOnc Technologies Holdings, Inc. (Nasdaq: NTHI) (“NeOnc” or the “Company”), a multi-Phase 2 clinical-stage biopharmaceutical company developing novel therapies for central nervous system (CNS) cancers, today announced positive topline results from the Phase 2a portion of NEO100-01, an open-label study of intranasal NEO100™ (purified perillyl alcohol) in patients with recurrent or progressive Grade III and Grade IV IDH1-mutant glioma.

The study met its primary endpoint. Six-month progression-free survival (PFS-6) was **48.9%** (95% CI: 26.3-68.1) by RANO 2.0 criteria using Kaplan-Meier estimation, compared with the 20% rate pre-specified in the study design as the expectation for standard of care (p = 0.0047).

“These results represent an important milestone for NeOnc and, more importantly, a source of hope for patients with recurrent high-grade glioma who currently have very limited treatment options. NEO100 met the study’s primary endpoint, demonstrated encouraging survival outcomes, and was administered intranasally by patients at home with no major toxicities reported. We believe these findings support the potential of our intranasal delivery platform to address one of the greatest challenges in treating brain cancer - the blood-brain barrier. Our priority now is to engage with the FDA and align on the most efficient path toward a registrational study,” said Amir F. Heshmatpour, Executive Chairman, President and Chief Executive Officer.

Secondary survival endpoints were supportive. Median overall survival was **26.09 months**, with 12 deaths among 24 patients. Overall survival was **86.7%** at six months (95% CI: 64.3-95.5), 60.9% (95% CI: 36.4-78.4) at 12 months and 54.1% (95% CI: 29.5-73.4) at 24 months.

“We believe that these results are a powerful validation of the science behind NEO100,” said Thomas C. Chen, MD, PhD, Founder, Chief Medical Officer and Chief Scientific Officer of NeOnc. “We set out to reach the brain directly, delivering therapy through the nose and along the olfactory pathway rather than forcing a drug past the blood-brain barrier, and what we are seeing in Phase 2a is what our biology predicted and what we saw in Phase 1, where every long-term survivor carried an IDH1 mutation. We believe that survival of this duration in twice-treated, high-grade disease, achieved with a therapy patients take at home and with no major toxicity, is the kind of result that justifies a much larger study.”

Evidence of durable disease control was observed across the cohort. Five of 24 patients remain on active treatment. One patient has remained progression-free for approximately 19 months. A second patient achieved a partial response sustained for 114 days through the end of Cycle 8 and remains on treatment in response. Objective response rate was 8.3% (two of 24 patients) by RANO 2.0.

“In recurrent high-grade glioma, the outcome that matters is how long a patient can hold the disease at bay and still live their life,” said Josh Neman, PhD, Chief Clinical Officer of NeOnc. “Five of our 24 patients remain on therapy, one progression-free approaching 19 months and another in an ongoing response approaching four months, and they are taking this treatment at home rather than in an infusion chair. Durability and tolerability together are rare at recurrence, and we believe that combination is what these data point to. We look forward to discussing the findings with the FDA.”

The data suggests that NEO100 was well tolerated. No major toxicities were reported across the cohort, and adverse events to date have been predominantly low-grade. The tolerability profile is consistent with the Phase 1 portion of the study, in which the data suggested that NEO100 was well tolerated at all dose levels, with no severe or dose-limiting toxicities observed. The absence of significant toxicity is notable in a population receiving continuous therapy (several patients have now remained on daily intranasal dosing for well over a year) and reflects a delivery route designed to reach the brain without systemic cytotoxic exposure.

NEO100-01 is directed at a population that existing IDH-targeted therapies do not serve. Approved and late-stage IDH-targeted agents for glioma have been developed in the front-line setting for lower-grade disease, typically Grade 2, non-enhancing tumors in patients who have undergone surgery but have not yet received radiation or chemotherapy.

NEO100-01 enrolled the opposite population: patients with Grade III and Grade IV IDH1-mutant tumors that have recurred or progressed after radiation and temozolomide. There is no approved targeted therapy for these patients. Approximately 90% of high-grade glioma patients recur within six to nine months of maximal therapy, and at recurrence, surgery is often not repeatable and systemic agents face rapid resistance and cumulative toxicity.

NEO100 is administered intranasally by the patient at home, four times daily, in 28-day cycles, a delivery route designed to reach the brain directly while avoiding systemic cytotoxic exposure.

NeOnc intends to request a Type B meeting with the U.S. Food and Drug Administration to align on a registrational development path for NEO100 in recurrent IDH1-mutant high-grade glioma. Additional pre-specified analyses including the Grade III versus Grade IV subgroup analysis, pharmacokinetics, and quality-of-life measures are ongoing and will be reported separately. The Company expects to present the full Phase 2a dataset, including detailed safety, at a future medical meeting.

Conference Call and Webcast

NeOnc will host an investor conference call and webcast today at 5:30 a.m. Pacific Time / 8:30 a.m. Eastern Time to discuss these results, followed by a question and answer session. The live webcast can be accessed at <https://www.webcaster5.com/Webcast/Page/3151/54410> or by visiting <https://investors.neonc.com>. A replay will be available at <https://investors.neonc.com> shortly following the conclusion of the call.

About the NEO100-01 Phase 2a study

NEO100-01 is an open-label, multi-center Phase 1/2a study of intranasal NEO100 in patients with radiographically confirmed progression of, or recurrence of, primary or secondary Grade IV glioma or Grade III astrocytoma harboring an IDH1 mutation. All patients had previously failed radiation or combined temozolomide and radiation. The Phase 2a portion enrolled 24 patients of a planned 28 at the recommended Phase 2 dose of 1,152 mg/day, self-administered intranasally four times daily in 28-day cycles until progression, death, or withdrawal.

The primary endpoint is the progression-free survival rate at six months. Secondary endpoints include objective response rate by RANO 2.0 criteria, progression-free survival, overall survival, safety and tolerability, pharmacokinetics, and quality of life. All MRI scans were read by an independent central reviewer. Biostatistical analysis was conducted by Anova Enterprises, Inc. Efficacy results are reported for the intent-to-treat population. Response and progression were assessed using RANO 2.0 criteria.

About NEO100

NEO100™ is a patented, ultra-pure pharmaceutical-grade formulation of perillyl alcohol, a naturally occurring monoterpene found in citrus and peppermint oils, produced through a proprietary crystalline synthesis process. Administered intranasally using a commercial nasal mask and nebulizer, NEO100 is designed to deliver therapy directly to the brain along olfactory and trigeminal pathways, bypassing the blood-brain barrier and avoiding first-pass metabolism and systemic toxicity. Data from preclinical studies suggests that NEO100 may transiently and reversibly open the blood-brain barrier, enabling brain entry of otherwise impermeable therapeutics.

About NeOnc Technologies Holdings, Inc.

NeOnc Technologies Holdings, Inc. is a clinical-stage life sciences company focused on the development and commercialization of central nervous system therapeutics that are designed to address the persistent challenges in overcoming the blood-brain barrier. The company's NEO™ drug development platform has produced a portfolio of novel drug candidates and delivery methods with patent protections extending to 2038. These proprietary chemotherapy agents have demonstrated positive effects in laboratory tests on various types of cancers and in clinical trials treating malignant gliomas. NeOnc's NEO100™ and NEO212™ therapeutics are in Phase II human clinical trials and are advancing under FDA Fast-Track and Investigational New Drug (IND) status. The company has exclusively licensed an extensive worldwide patent portfolio from the University of Southern California consisting of issued patents and pending applications related to NEO100, NEO212, and other products from the NeOnc patent family for multiple uses, including oncological and neurological conditions.

For more about NeOnc and its pioneering technology, visit <https://neonc.com>.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the potential of NEO100, the interpretation and significance of the Phase 2a results, plans to engage with the FDA, the design and timing of future clinical trials, and the Company's development strategy. These statements are based on management's current expectations and are subject to known and unknown risks and uncertainties that may cause actual results to differ materially.

Such risks include, but are not limited to: the Phase 2a study was a single-arm, open-label study of 24 patients that did not reach its planned enrollment of 28 patients and was not powered as a confirmatory trial; results were not compared against a randomized control arm, and comparisons to historical data are inherently limited by differences in patient population, era, and assessment criteria; the primary efficacy analysis presented reflects RANO 2.0 criteria and Kaplan-Meier estimation, and results differ under the response criteria and estimation method specified in the study protocol; early-phase results frequently fail to replicate in larger, controlled studies; safety and tolerability findings in a 24-patient, open-label study may not predict the safety profile observed in larger or longer-duration studies, and additional adverse events may emerge with broader exposure; the FDA may not agree with the Company's proposed registrational path, endpoints, or analytical methods; and additional pre-specified analyses remain ongoing. Additional risks are described in the Company's filings with the U.S. Securities and Exchange Commission.

The Company undertakes no obligation to update any forward-looking statement except as required by law.

"NEO100" and "NEO212" are registered trademarks of NeOnc Technologies Holdings, Inc.

Contacts

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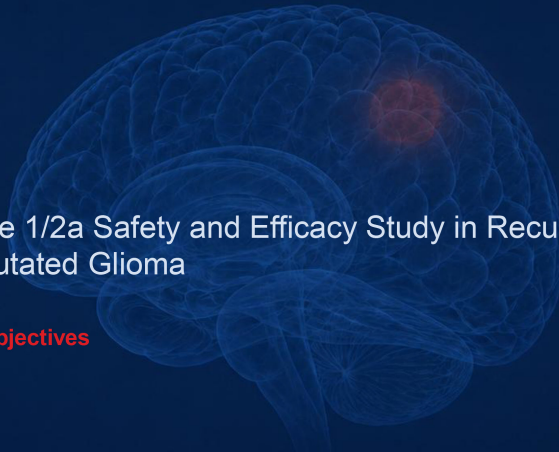


NEO100-01

NCT02704858: A Phase 1/2a Safety and Efficacy Study in Recurrent or Progressive Grade III or IV IDH1-Mutated Glioma

Reporting out the Phase 2a objectives

August 12, 2026



SENIOR MANAGEMENT



Amir F. Heshmatpour
CEO, Exec. Chairman & President



Thomas Chen, MD, PhD
Founder, CMO & CSO



Josh Neman, PhD
Chief Clinical Officer



Keithly A. Garnett
Chief Financial Officer



David Choi, CPA
Chief Accounting Officer

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Victorian Comprehensive Cancer Centre Alliance

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We have based the forward-looking statements on our current expectations and projections about future events. These forward-looking statements are subject to known and unknown risks, uncertainties, and assumptions about us and our affiliate companies with respect to specific factors identified in this presentation and the Company's filings with the U.S. Securities Exchange Commission, and which may cause our actual results, levels of activity, performance or achievements expressed or implied by such forward-looking statements differ materially from those currently anticipated in such statements.

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THIS PRESENTATION AND ANY OTHER INFORMATION THAT MAY BE FURNISHED BY US INCLUDES OR MAY INCLUDE CERTAIN STATEMENTS, ESTIMATES AND FORWARD-LOOKING PROJECTIONS OF THE COMPANY WITH RESPECT TO THE ANTICIPATED FUTURE PERFORMANCE OF THE COMPANY. SUCH STATEMENTS, ESTIMATES AND FORWARD-LOOKING PROJECTIONS REFLECT VARIOUS ASSUMPTIONS OF MANAGEMENT THAT MAY OR MAY NOT PROVE TO BE CORRECT AND INVOLVE VARIOUS RISKS AND UNCERTAINTIES.

NEO100-1 Phase 2a met its primary endpoint — and the survival signal is the story

48.9%

PFS-6 (RANO 2.0)

26.1 momedian overall survival, measured from recurrence
Vs 6-9 mo**5 of 24**

still on treatment — the longest at ~24 months

Primary endpoint met. Six-month progression-free survival was 48.9% in recurrent IDH1-mutant grade III–IV glioma.

Survival is the standout result. Median overall survival was 26.1 months measured from the start of NEO100 at recurrence — a setting in which current salvage therapy delivers roughly 6–9 months.

Durable control, with tolerability that supports chronic dosing. 66.7% disease control; five of 24 patients remain on therapy; adverse events were predominantly low-grade with no dose-limiting toxicities — self-administered intranasally at home rather than by infusion.

Sources: NEO100-01 Phase 2a statistical output, 08 Aug 2026; ITT N=24; Kaplan–Meier with Greenwood variance and complementary log–log 95% CI (database not locked); PFS-6 vs protocol H₀ ≤ 20% (§11.3); under the RANO criteria specified in the protocol PFS-6 was 25.8% (p = 0.276). Recurrence benchmark OS ~6–9 months — Wick, NEJM 2017; Lombardi, Lancet Oncol 2019; Fazzari, Crit Rev Oncol Hematol 2022 (cross-trial, non-head-to-head).

Phase 2 development & clinical pipeline

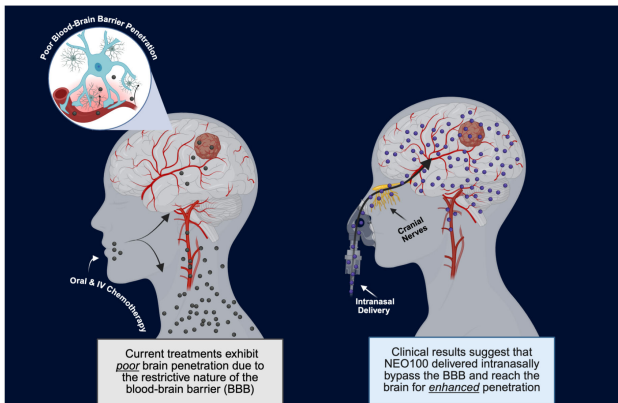
Important disclaimer: this development & clinical pipeline is subject to regulatory approval, risks and uncertainties, and potential changes beyond our control.

					Clinical Development			
Drug Candidate	Application	Indication	Preclinical	IND Enabling*	Phase I	Phase II	Phase III	Commercialization
NEO100-01	 Intranasal NEO100	Recurrent Grade III or IV Astrocytoma Brain Tumor w/ IDH1 Mutation	Phase 2a					
NEO100-02	 Intranasal NEO100	Meningioma Brain Tumors	Phase 2					
NEO100-03	 Intranasal NEO100	Pediatric Brain Tumors	Phase 1					
NEO212	 Oral NEO212	All Brain Tumors	Phase 2					

Our clinical pipeline continues to expand to include other applications of NEO100 & NEO212

***IND Enabling:** research to establish whether a compound is reasonably safe for initial use in humans and exhibits pharmacological activity that justifies commercial development. Pipeline subject to regulatory approval and change.

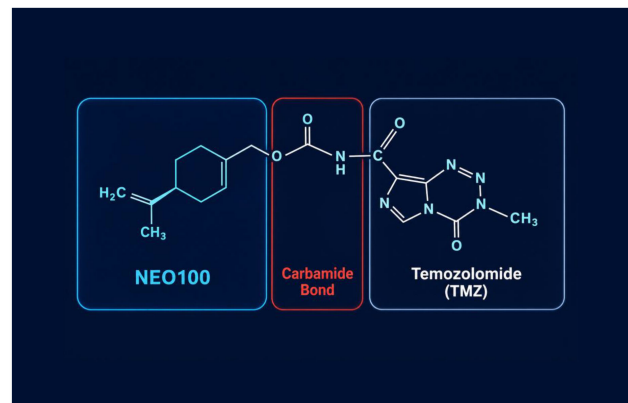
NEO100 — Drug Delivery Platform (core technology)



- Designed as a direct, non-invasive CNS delivery patented technology
- Clinically practical, patient-friendly dosing suitable for chronic use
- Patented platform designed for efficient, brain-targeted pharmacokinetics

NEO100 is the enabling chemistry in both platforms — NEO212 conjugates temozolomide to NEO100.

NEO212 — Drug Conjugation Platform (built on NEO100)



- Conjugates NEO100 to established cytotoxic agents
- Inherits NEO100's BBB-penetrating chemistry as the delivery mechanism
- Designed to overcome drug resistance & systemic toxicity

IDH1-mutant survival is quoted from diagnosis — in years



IDH1-mutant grade 3–4 astrocytomas are the “long-survivor” subset of glioma — but that survival is measured from initial diagnosis, and the treated U.S. population is large and growing.

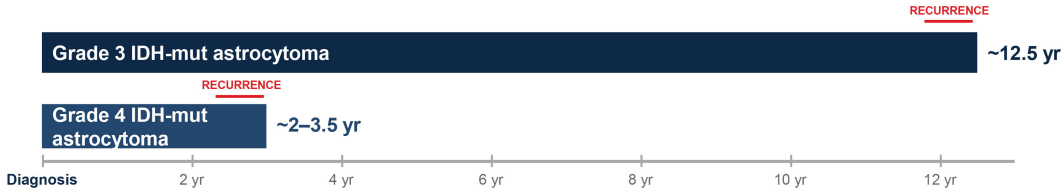
26,480 / yr
Malignant primary brain & CNS tumors diagnosed in the U.S.
(CBTRUS, 2025 est.)

~2,400 / yr
new IDH-mutant gliomas in the U.S.

~7,000–11,000
estimated U.S. patients living with grade 3–4 IDH1-mutant glioma (long-survivor subset)

~100% recur
Essentially all relapse — recurrent grade 3–4 IDH1-mut / yr (NEO100 target)

Median overall survival FROM INITIAL DIAGNOSIS (years)



The trap: these are from-diagnosis figures — quoted as if they apply at recurrence, where the reality is completely different.

Sources: U.S. incidence — CBTRUS Statistical Report: Primary Brain and Other CNS Tumors Diagnosed in the U.S. in 2018–2022 (Neuro-Oncology 2025;27(Suppl 4):iv1); an estimated 107,100 new primary brain/CNS tumors and 26,480 malignant tumors in the U.S. in 2025 (glioblastoma 13,930). IDH-mutant gliomas — molecular incidence, U.S. 2018–2021 (Neuro-Oncology 2025;27(Suppl 5):v191, EPID-25). IDH-mutant astrocytoma 0.36 and IDH-mutant/p19q-codeleted oligodendroglioma 0.32 per 100,000/yr; U.S. population ~335M → ~2,300–2,600 new IDH-mutant gliomas/yr. Grade 3–4 share: >40% of grade 2–3 and ~2% of grade 4 astrocytomas are IDH-mutant → ~800–1,000 new grade 3–4 IDH-mutant/yr (Front Mol Neurosci 2025, doi:10.3389/fnmol.2025.1662414). Prevalence modelled as incidence × mean survival by grade → ~20,000–30,000 living with IDH-mutant glioma overall, of whom ~7,000–11,000 are grade 3–4; modelled estimate — no registry reports prevalence by grade. From-diagnosis OS: grade 3 ~12.5 yr (CATNON); grade 4 ~2–3.5 yr (Biomedicines 2024;12:2256). IDH-mutant grade 3–4 gliomas are incurable → essentially all relapse. IDH1 ~90% of IDH mutations.

High-grade gliomas virtually always recur despite maximal therapy. Once the tumor progresses after radiation and temozolomide, the survival clock no longer runs from diagnosis — it **restarts at recurrence**.

FROM DIAGNOSIS

Years

Surgery → radiation → temozolomide, then a long stable interval. This is the survival most literature reports.



AT RECURRENCE (post RT + TMZ)

6–9 months

Median OS in the salvage setting. Objective responses are uncommon; tumors become more aggressive and resistant to therapy; no approved systemic therapy has changed this for grade 3/4.

Same disease, different clock: the “years” belong to the newly-diagnosed patient; the recurrent patient has ~6–9 months. That is the population NEO100 is being investigated to treat.

Sources: Recurrent high-grade glioma median OS ~6–9 mo — Wick et al., N Engl J Med 2017 (EORTC 26101; lomustine OS 8.6 mo); Lombardi et al., Lancet Oncol 2019 (REGOMA; lomustine 5.6 mo); Fazzari et al., Crit Rev Oncol Hematol 2022 (median OS 3–17.6 mo across 48 recurrent-glioma RCTs). Objective responses uncommon with salvage therapy — Fazzari et al. 2022. Dedicated recurrent IDH-mutant grade-4 OS data are limited; figures reflect the recurrent high-grade glioma salvage setting and are historical, not head-to-head comparisons.

**Ultra-pure, patented POH**

NEO100 is a pharmaceutical-grade form of perillyl alcohol (POH), a natural monoterpene from citrus and peppermint oils.

Proprietary synthesis

Manufactured via a patented crystalline intermediate to ensure consistent, pharmaceutical-grade purity.

Non-invasive nose-to-brain

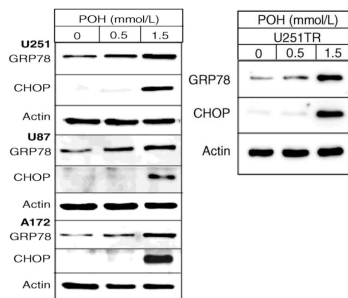
Intranasal delivery is designed to bypass the blood–brain barrier for rapid, selective CNS exposure — no infusion, no surgery.

Patient-friendly chronic dosing

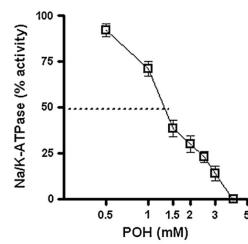
Self-administered at home, four times daily — practical for continuous treatment until progression.

Sources: NEO100 composition, ultra-pure perillyl alcohol and proprietary crystalline manufacturing process — NeOnc Technologies (patented process; internal). Intranasal nose-to-brain delivery of perillyl alcohol — Schönthal AH et al., *Neurooncol Adv* 2021. The delivery figure is a schematic illustration, not clinical trial data.

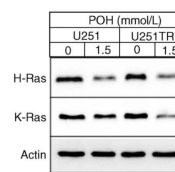
ER Stress Induction



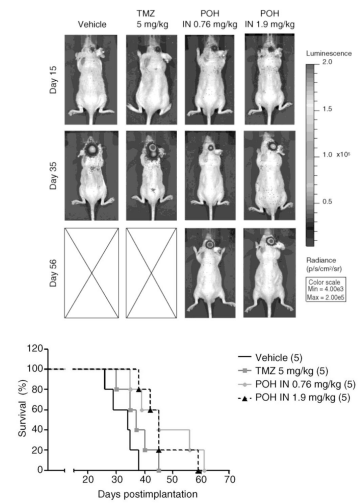
Na/K -ATPase Inhibition



RAS Inhibition



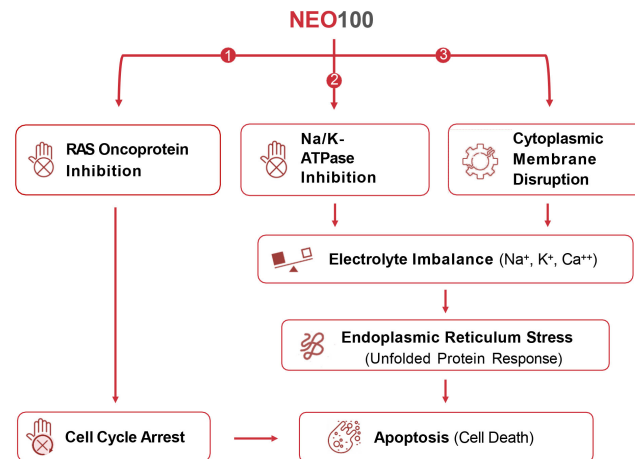
In vivo



Sources: Garcia DG et al., Mol Cell Biochem 2010; Cho HY et al., Mol Cancer Ther 2012; Marin-Ramos NI et al., Neurosurg Focus 2019; Wang W et al., Neuro-Oncology 2021; Schönthal AH et al., Neurooncol Adv 2021. Mechanistic data are preclinical (in vitro and animal models) and have not been confirmed in patients.

NEO100's proposed mechanism of action in resistant tumors

In preclinical models, NEO100 is proposed to act on resistant glioma through three convergent mechanisms:



Second-line rationale: by inducing ER stress and inhibiting Na⁺/K⁺-ATPase while down-regulating RAS, NEO100 is designed to remain active in the TMZ-resistant setting where recurrent tumors progress.

Sources: Garcia DG et al., Mol Cell Biochem 2010; Cho HY et al., Mol Cancer Ther 2012; Marín-Ramos NI et al., Neurosurg Focus 2019; Wang W et al., Neuro-Oncology 2021; Schönthal AH et al., Neurooncol Adv 2021. Mechanistic data are preclinical (in vitro and animal models) and have not been confirmed in patients; the mechanism shown is proposed, not established.

1. Trial design

Multi-center U.S. study, n = 12; recurrent GBM after RT + temozolomide; continuous intranasal dosing 384–1,152 mg/day (4×/day) until progression.

3. Safety

Generally, well tolerated at the dose levels studied; no dose-limiting toxicities reported.

2. Efficacy signal

PFS-6 ~30–33%, OS-12 ~55%, median OS ~15 months — vs a ~6–9-month historical benchmark (non-head-to-head).

4. Durability & biomarker

IDH1-mutant long-term survivors were observed; non-invasive delivery enabled sustained dosing, supporting the durable-control hypothesis carried into Phase 2a.

Sources: NEO100-01 Phase 1 dose-escalation, recurrent glioblastoma after radiation + temozolomide, n=12 — NeOnc Technologies (database not locked). Historical recurrent-GBM benchmark OS ~6–9 months — Schönthal AH et al., Neurooncol Adv 2021; the comparison is cross-trial and not head-to-head.

What the study set out to show in recurrent disease

Why this population

Recurrent / progressive IDH1-mutant grade III–IV glioma is the setting of greatest unmet need.

At recurrence, survival collapses to ~6–9 months, objective responses are rare, and no approved therapy has been shown to durably extend survival.

The endpoints are built to detect durable disease control — the outcome that matters most for these patients.

Why a single-arm design

When NEO100-01 opened, single-arm was the standard approach in this setting: a peer-reviewed analysis of 417 U.S. primary brain tumor trials initiated 2005–2016 found that 90% of recurrent-disease Phase 2 trials were not designed as randomized controlled studies (Vanderbeek et al., *Neuro-Oncology* 2018).

Testing against a historical benchmark was the conventional signal-seeking path — and a randomized controlled trial is the appropriate next step to confirm these results.

PRIMARY OBJECTIVE & ENDPOINT

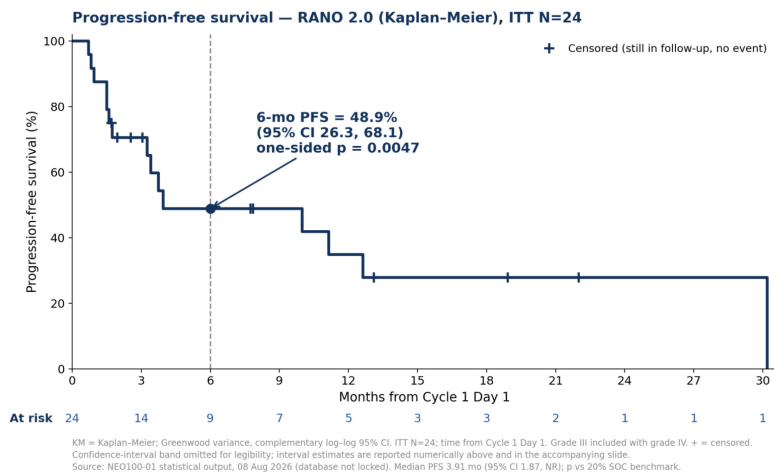
Progression-free survival at 6 months (PFS-6) — the percentage of patients progression-free from Cycle 1 Day 1 through 6 months.

What we tested against: a 20% PFS-6 benchmark — historically, only about 1 in 5 patients with recurrent high-grade glioma is still free of tumor growth six months after starting another therapy. NEO100 had to beat that bar to be worth pursuing.

SECONDARY OBJECTIVES

- Overall survival (OS) and landmark OS rates
- Objective response & duration (RANO 2.0)
- Safety and tolerability

Sources: NEO100-01 protocol §11.3 — primary endpoint PFS-6: $H_0: \leq 20\%$ vs $H_A: \geq 45\%$, one-sided $\alpha = 0.05$, 80% power, planned enrolment 28. The 20% null reflects historical PFS-6 in recurrent high-grade glioma — Wong ET et al., *J Clin Oncol* 1999 (8 pooled phase II trials, $n = 375$; 15% in glioblastoma, 31% in anaplastic astrocytoma). Single-arm context — Vanderbeek AM et al., *Neuro-Oncology* 2018;20(8):1034–1043; of 417 U.S. glioblastoma trials initiated 2005–2016, 90% of recurrent-disease phase II trials were not designed as RCTs; the same analysis argues that uncontrolled phase II data has contributed to low phase III success, supporting a randomized confirmatory study. NEO100-01 (NCT02704858) was registered in 2016. Recurrence OS ~6–9 mo — Wick, *NEJM* 2017; Lombardi, *Lancet Oncol* 2019; Fazzari, *Crit Rev Oncol Hematol* 2022. RANO 2.0 — Wen et al., *J Clin Oncol* 2023.



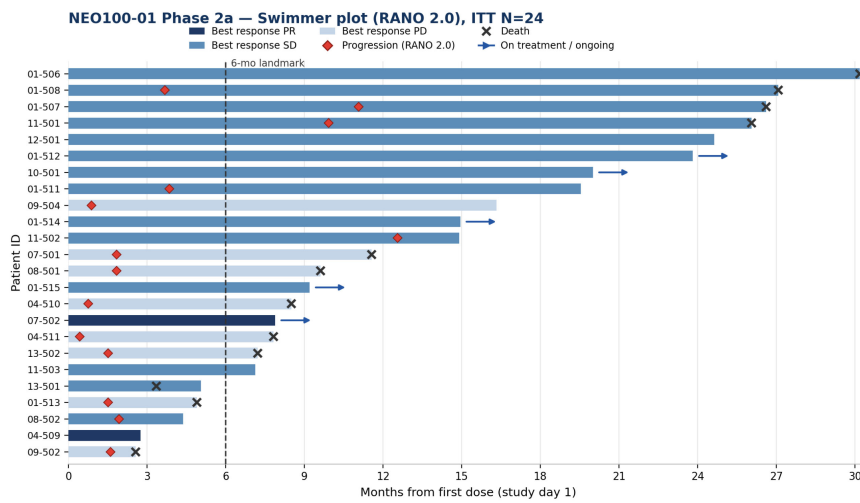
Key figures

6-month PFS (KM)	48.9%
95% CI	26.3-68.1
vs 20% SOC (§11.3)	p = 0.0047 ✓ significant
Clock origin	Recurrence — NEO100 first dose (C1D1)

At recurrence: the entire PFS curve is measured from first dose at recurrence (study day 1) — not from initial diagnosis.

Sources: NEO100-01 statistical output, 08 Aug 2026. PFS-6 48.9% (95% CI 26.3, 68.1); one-sided p = 0.0047 vs the 20% standard-of-care benchmark (protocol §11.3); median PFS 3.91 mo (95% CI 1.87, not reached). Kaplan-Meier with Greenwood variance and complementary log-log 95% CI (interval estimates reported numerically; band omitted for legibility). RANO 2.0 — Wen et al., J Clin Oncol 2023.

Swimmer plot — Durable tail past 20 months from recurrence (first dose)



Reading the plot

Each bar = time on study from first dose at recurrence for each patient, colored by RANO 2.0 best response.

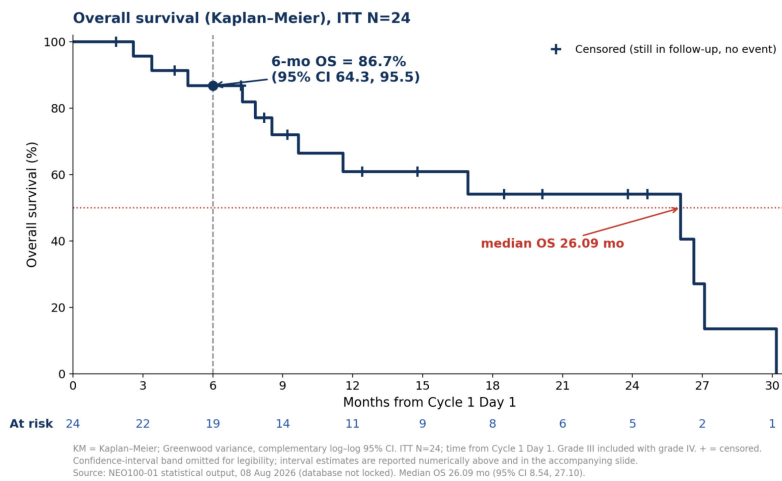
◆ = progression (RANO 2.0)

X = death → = still on treatment

Durable tail past 20 months

5 patients remain on treatment, the two longest ongoing at ~24 and ~20 months; 10-501 progression-free at ~19 mo by RANO 2.0; 07-502 in an ongoing partial response sustained 114 days — all measured from first dose at recurrence.

Sources: NEO100-01 RANO summary table and statistical output, 08 Aug 2026. Bar = time from first dose (Cycle 1 Day 1) to last follow-up, coloured by RANO 2.0 best response; ◆ = RANO 2.0 progression, X = death, → = on treatment. RANO 2.0 best response PR 2/24 (8.3%), SD 14/24 (58.3%), PD 8/24 (33.3%); 5 patients remain on treatment. PFS-6 48.9% (95% CI 26.3, 68.1), one-sided p = 0.0047 vs the 20% benchmark (protocol §11.3). RANO 2.0 — Wen et al., J Clin Oncol 2023.

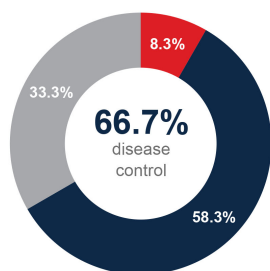


Survival summary

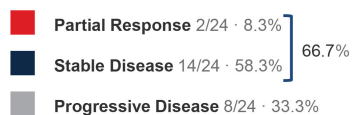
Deaths / N	12 / 24
Median OS (KM)	26.09 months
OS at 6 months	86.7% (64.3-95.5)
OS at 12 months	60.9% (36.4-78.4)
OS at 24 months	54.1% (29.5-73.4)
ORR (RANO 2.0)	8.3%
Clock origin	Recurrence — NEO100 first dose (C1D1)

At recurrence: the entire OS curve runs from first dose at recurrence (study day 1) — median 26.09 months here is not a from-diagnosis figure.

Sources: NEO100-01 statistical output, 08 Aug 2026. OS-6 86.7% (95% CI 64.3, 95.5); OS-12 60.9% (95% CI 36.4, 78.4); OS-18 and OS-24 54.1% (95% CI 29.5, 73.4); median OS 26.09 mo (95% CI 8.54, 27.10). Kaplan-Meier with Greenwood variance and complementary log-log 95% CI (interval estimates reported numerically; band omitted for legibility). Times are measured from first dose (Cycle 1 Day 1) at recurrence, not from initial diagnosis.



RANO 2.0 best response (N=24)



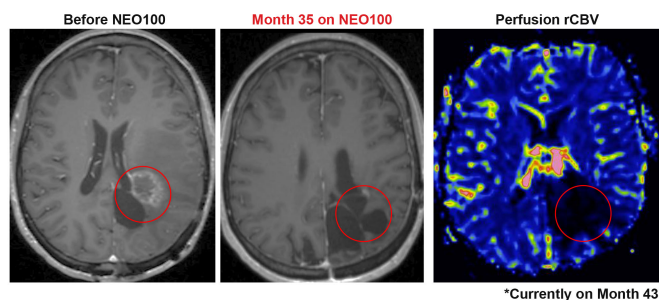
55%

long-term survivors
(16 / 29, Phase 1+2)
surviving > 1 year

2.2 yr

median OS among
long-term survivors
(range 1.2–8.1 yr)

Radiographic remission — representative long-term survivor



In a representative long-term survivor, perfusion rCBV decreased toward normal and the enhancing lesion largely resolved — findings a 2D "stable disease" label may understate.

Sources: RANO 2.0 best response — NEO100-01 RANO summary table and statistical output, 08 Aug 2026, Phase 2a ITT N=24 (PR 2 / SD 14 / PD 8; ORR 8.3%, disease control 66.7%); RANO 2.0 — Wen et al., J Clin Oncol 2023. Long-term survivors — 16/29 (Phase 1 + Phase 2a) alive >1 yr; median OS 2.2 yr (range 1.2–8.1 yr), NeOnc internal. Imaging — NEO100-01 representative responder (post-contrast T1 at baseline and month 35, perfusion rCBV map); rCBV is exploratory advanced imaging, distinct from RANO 2.0, and a single case does not establish a treatment effect.

Recurrent grade 3–4 is an open failure — NEO100's target

Trial (agent)	Grade 3–4 studied?	Grade 3–4 result	Implication
INDIGO (vorasidenib)	No — grade 2 only	Not studied (mPFS 27.7 mo in grade 2)	Recurrent grade 3–4 unaddressed
STELLAR (eflornithine + lomustine)	Yes — IDH-mut & IDH-wt gr 4	No benefit in grade 4 (OS HR ~1.5); IDH-wt gr4 PFS 3.4 vs 6.8 mo	Grade 4 remains an open failure
Salvage chemo / anti-angiogenics	Recurrent HGG	Median OS ~6–9 mo; low ORR; PFS ≠ OS	No durable survival benefit
NEO100 — Phase 2a	Yes — IDH-mut gr 3–4 (21/24 gr4)	Median OS 26.09 mo; OS-12 60.9%	Durable OS where others fail

Bottom line: IDH-inhibitors stop at grade 2 and eflornithine fails in grade 4. In the Phase 2a study, NEO100 showed a 26.1-month median OS at recurrence in the grade 3–4 population; comparisons with other programs are cross-trial and not head-to-head.

Sources: INDIGO — Mellinger et al., N Engl J Med 2023 (grade 2). STELLAR — Colman et al., J Clin Oncol 2025 (IDH-mutant & IDH-wildtype grade 4; no grade-4 benefit; IDH-wt grade 4 PFS 3.4 vs 6.8 mo). Salvage therapy — Wick, NEJM 2017; Lombardi, Lancet Oncol 2019; Fazzari, Crit Rev Oncol Hematol 2022. NEO100 — NEO100-01 Phase 2a statistical output, 08 Aug 2026 (ITT N=24; median OS 26.09 mo; OS-12 60.9%). All cross-study comparisons are non-randomised and not head-to-head; differences in population, era and response criteria limit interpretation.

Phase 2a: primary endpoint met— survival is the standout signal**48.9%****PFS-6 (RANO 2.0, KM)**primary endpoint MET vs $H_0 \leq 20\%$ ·
 $p=0.0047$ **26.09 mo****median overall survival
after recurrence**vs 6-9 months current salvage
benchmark**60.9%****alive at 12 months**

OS-12 (95% CI 36.4–78.4)

Durable disease control: 66.7% disease control (PR+SD); durable tail past 20 months; 5 of 24 still on treatment.**Generally well tolerated:** adverse events were predominantly low-grade in this cohort; no dose-limiting toxicities reported.**Differentiated at recurrence:** ~3–4× longer than the ~6–9-month historical salvage benchmark (cross-trial, non-head-to-head), in a grade 3–4 population addressed by few other programs.

Sources: NEO100-01 Phase 2a, recurrent/progressive IDH1-mutant grade III–IV glioma, ITT N=24; statistical output 08 Aug 2026. Kaplan–Meier with Greenwood variance and complementary log–log 95% CI. PFS-6 48.9% (95% CI 26.3, 68.1) vs protocol $H_0 \leq 20\%$ (§11.3), one-sided $p = 0.0047$; under the protocol-specified RANO criteria PFS-6 was 25.8% ($p = 0.276$). Median OS 26.09 mo (95% CI 8.54, 27.10); OS-12 60.9% (95% CI 36.4, 78.4); disease control 66.7% (PR+SD). Historical salvage benchmark OS ~6–9 mo — Wick, NEJM 2017; Lombardi, Lancet Oncol 2019; Fazzari 2022 (cross-trial, non-head-to-head). RANO 2.0 — Wen, JCO 2023.

Proposed registrational Phase 3 intended to seek Accelerated Approval (subject to FDA)

The regulatory goal

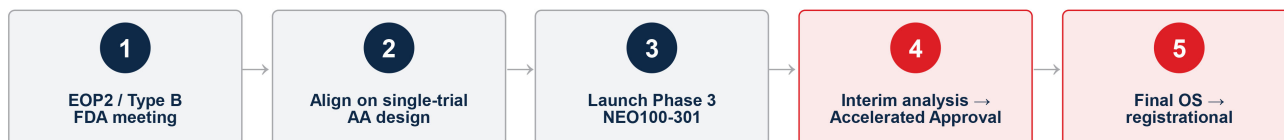
Accelerated Approval → traditional registrational approval, in one pivotal trial.

Per FDA's Dec 2024 guidance, a single adequate & well-controlled trial can support Accelerated Approval on an interim intermediate endpoint and verify benefit via final OS in the same study.

Phase 2a (26.09-mo median OS vs a 6–9-mo historical benchmark; cross-trial) supports the End-of-Phase-2 / Type B meeting request. Outcomes are subject to FDA review; no assurance of approval.

Proposed Phase 3 design

- Randomized, NEO100 vs lomustine
- Population: recurrent IDH1-mutant WHO grade 3/4 astrocytoma
- Primary endpoint: overall survival (OS)
- One pre-specified interim analysis supporting Accelerated Approval



Sources: Proposed design — NEO100-301 (subject to FDA feedback; no assurance any application will be submitted or approved). FDA Accelerated Approval guidance — Expedited Programs for Serious Conditions: Accelerated Approval of Drugs and Biologics (FDA, Dec 2024); Consolidated Appropriations Act, 2023. Phase 2a — NEO100-01 statistical output, 08 Aug 2026 (database not locked). Lomustine control OS 5.6–8.6 mo — Lombardi, Lancet Oncol 2019; Wick, NEJM 2017.



• **Primary endpoint met:** PFS-6 of 48.9% vs the 20% protocol benchmark (one-sided $p = 0.0047$).

• **Life expectancy 4-5x extended at recurrence:** median OS 26.09 months vs a 6–9-month historical benchmark (cross-trial, not head-to-head).

• **Building clinical momentum:** intended to support planned Phase 3 and global studies (e.g. United Arab Emirates, Israel).

Sources: NEO100-01 Phase 2a, recurrent/progressive IDH1-mutant grade III–IV glioma, ITT N = 24; statistical output 08 Aug 2026 (database not locked). PFS-6 48.9% (95% CI 28.3, 68.1), one-sided $p = 0.0047$ vs the protocol $H_0: \leq 20\%$ (§11.3); median OS 26.09 mo (95% CI 8.54, 27.10), RANO 2.0 disease control 66.7% (PR 2/24, SD 14/24) — Wen et al., J Clin Oncol 2023. Recurrence benchmark ~6–9 mo — Wick, NEJM 2017; Lombardi, Lancet Oncol 2019; Fazzari, Crit Rev Oncol Hematol 2022; comparisons are cross-trial and not head-to-head. Single-arm study without a concurrent control. Phase 3 and additional international studies are planned and subject to regulatory review; no assurance any study will begin or that any application will be approved.

Company Contact

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Info@neonc.com · www.neonc.com

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Jon Nugent Communications
Jon Nugent — President & CEO
jonnugent.com · jon@jonnugent.com
205-566-3026



Appendix

Senior Management Team

Our management team possesses significant experience in capital markets, with a track record of building shareholder value in clinical biotech companies.



Amir F. Heshmatpour
CEO, Executive Chairman & President

Mr. Heshmatpour served on NeOnc Technologies Holdings, Inc.'s board of directors since January 2023, President since April 2025 and CEO since November 2025. Mr. Heshmatpour founded AFH Holding and Advisory LLC ("AFH") in July 2005. Since July 2005, Mr. Heshmatpour has been the Managing Director of AFH. Mr. Heshmatpour, through AFH, his family office, has been involved in multiple biotech transactions from private to public. From 2018 to 2022, through a special purpose vehicle, Shuttle Pharmaceuticals Holdings Inc. ("SPH"), Mr. Heshmatpour restructured the board of directors, management, and recapitalized an IPO of a Georgetown phase II oncology asset. The SPV was created in 2018 and eventually was successfully listed on NASDAQ in 2022. Since then, he has been involved in NeOnc Technologies Inc., where he has provided strategic advisory services. Mr. Heshmatpour has a certification from the UCLA Anderson School of Business in corporate governance. He is also involved in the UCLA Anderson School of Business Management, Price Center, as a member of the Board of Advisors. In February 2024, Mr. Heshmatpour joined the Board of Directors of Make-A-Wish CVS in Los Angeles. We believe that Mr. Heshmatpour's extensive corporate and leadership experience qualifies him to serve on our Board of Directors.



Thomas Chen, MD, Ph.D.
Founder, CMO & CSO

Dr. Chen has served as NeOnc Technologies Holdings, Inc.'s Chief Executive Officer since April 2023 through October 2025 and Chairman of the Board since its inception. Dr. Chen also serves as its Chief Medical Officer and Chief Scientific Officer. Since July 1997, Dr. Chen has worked as a Neurosurgeon at Keck Medicine of USC and a Professor Neurological Surgery at the University of Southern California Keck School of Medicine ("USC"). He has been the Director of Surgical Neuro-Oncology and Professor of Neurosurgery & Pathology. Dr. Chen's work is widely published, including 148+ peer-reviewed clinical studies. He maintains a clinical practice in both surgical neuro-oncology and spine surgery, as well as heads a research laboratory focused on glioma biology. He graduated summa cum laude from the University of Illinois at Urbana-Champaign with Bronze Tablet honors and Phi Beta Kappa. He graduated from University of California San Francisco with M.D. degree, and was in the top 10% of his class, awarded Alpha Omega Alpha. He earned his Ph.D. in pathology from University of Southern California where he wrote his thesis on the role of immunotherapy in malignant brain tumors. We believe that Dr. Chen's extensive knowledge of NeOnc's business and his extensive corporate and leadership experience as the founder of NeOnc and its Chief Executive Officer qualifies him to serve on our Board of Directors.



Josh Neman, PhD
Chief Clinical Officer

Dr. Neman has served as Chief Clinical Officer of NeOnc Technologies Holdings, Inc. since June 2024, where he leads clinical strategy and translational development across the Company's neuro-oncology pipeline. Dr. Neman is an established cancer scientist and academic leader in brain tumor and brain metastasis research. Since July 2014, he has served as an Associate Professor of Neurological Surgery, Neuroscience, and Physiology at the Keck School of Medicine of the University of Southern California. His research program focuses on the biology of malignant brain tumors, brain metastases, tumor-microenvironment interactions, and mechanisms of therapeutic resistance, with an emphasis on translating laboratory discoveries into clinically actionable strategies. In addition to his faculty appointment, Dr. Neman has held multiple leadership roles at USC, including Program Chair of the Cancer Biology and Genomics Ph.D. Program since July 2019 and Scientific Director of the USC Brain Tumor Center since July 2021, where he has overseen interdisciplinary research initiatives spanning basic, translational, and clinical neuro-oncology. In January 2021, Dr. Neman co-founded Synaptical Inc., a digital health company focused on providing cancer patients with education, guidance, and care navigation resources, and currently serves as its Chief Executive Officer. He also founded CNSMENDER Consulting LLC in January 2022, where he advises on clinical development and translational strategy in oncology and CNS disorders. Dr. Neman earned his Bachelor of Science and Doctor of Philosophy (Ph.D.) in Neurobiology from the University of California, Los Angeles.



Keithly A. Garnett
Chief Financial Officer

Mr. Garnett has served as NeOnc Technologies Holdings, Inc.'s Chief Financial Officer since April 2023 and served as a director from January 2023 to March 2025. Mr. Garnett spent over 17 years with Ernst & Young LLP in their Transaction Advisory Services practice. During that time, he specialized in business valuation modeling and strategy. His services were provided in support of audit related work for financial reporting, tax planning and management planning. His client list included companies such as Amgen, Edwards Life Sciences, Medtronic, etc. In any given year, he led over 50 transaction analyses and/or review for publicly traded companies, in connection with their SEC financial reporting requirements. From March 2017 to January 2023, Mr. Garnett was a Director at Sycamore Valuation. Since January 2021, Mr. Garnett has worked as the Chief Financial Officer of AFH Holding & Advisory, a single member family office based in Malibu. From 2018 to 2022, he was involved with the Shuttle Pharmaceutical Holdings public offering, which was successfully listed on the Nasdaq in 2022. Mr. Garnett holds a Master's in Business Administration with a concentration in Corporate Financial Management, and a Bachelor of Science degree in Business Management. He also completed the Columbia University Executive Education program with a certificate from the Chief Financial Officer program.



David Choi, CPA
Chief Accounting Officer

David Choi was appointed Chief Accounting Officer of NeOnc Technologies Holdings Inc. in 2026. In this role, he oversees the Company's accounting, financial reporting, internal controls, and corporate governance as NeOnc advances its clinical-stage biotechnology platform and expands globally. He focuses on strengthening financial reporting processes, building scalable accounting infrastructure, and supporting the Company's growth as a public company. Mr. Choi brings more than a decade of experience in accounting, financial reporting, and internal controls. Prior to joining NeOnc, he was a Director at Blythe Global Advisors, advising companies on technical accounting matters, SEC reporting, and SOX compliance, and leading projects involving financial reporting transformation and accounting for complex transactions. Earlier in his career, he held roles at Grant Thornton and Ernst & Young, providing audit and technical accounting advisory services. Mr. Choi is a Certified Public Accountant (CPA) and holds a Master of Professional Accountancy and a Bachelor of Arts in Business Economics with a minor in Accounting from the University of California, Irvine.

Also serving



Amir F. Heshmatpour
CEO, Exec. Chairman & President



Thomas Chen, MD, PhD
Founder, CMO & CSO



Victoria Medvec, PhD
Compensation Committee Chair

20+ years as CEO of Medvec & Associates, advisory firm servicing more than a third of Fortune 100. Advising on regulatory negotiations, partnerships and global market access. Clients have included Amgen, Sanofi, Astra Zeneca, Bristol Myers Squibb, Pfizer and Gilead. Founding member of Extraordinary Women on Boards. Frequent speaker and author of best-selling book, "Negotiate Without Fear." Accomplished public & private board director, specializing in mergers and acquisitions, customer growth, revenue maximization, supply chain, human capital, and risk management. Applying expertise in negotiations and decision-making to drive revenue expansion.



Bader Al Monawer
Audit Committee Chair

More than a decade of experience in venture capital, investment banking, and business consulting and development. Currently serves as managing partner of Arabian Group, overseeing venture capital investments. Previously founded the VC fund, Oasis Capital, investing in numerous startups, many of which have grown into multibillion-dollar corporations. Extensive background in investment banking and consulting at McKinsey & Company, Citigroup's M&A advisory, Wafra's Alternative Investments Division, and the World Bank. MBA, Massachusetts Institute of Technology (MIT); Master's degree in economics and financial policy, Cornell University.



Steven L. Giannotta, MD

Chair Emeritus of Neurological Surgery at USC. Research primarily centers around cerebral blood flow and protecting the brain from ischemia. Specializes in surgical strategies for cranial base lesions, including acoustic neuromas. Has surgically removed 400+ acoustic neuromas. Treated 1,000+ intracranial aneurysms and developed a comprehensive approach to cerebrovascular conditions, employing techniques such as microsurgical clip ligation, coil embolization, and stereotactic radiosurgery. Medical degree and residency at the University of Michigan.



Jim Delshad
Corporate Governance Chair

Served two terms as Mayor of Beverly Hills, starting in 2007, pioneering "Smart City" initiatives that transformed the city into a model of technological advancement and security. He holds the honorary title of "Goodwill Ambassador of Beverly Hills" in recognition of his contributions to the city. Served as former President and Chairman of Magbit Foundation. Over the past two decades he has provided management consulting services, which includes strategic advisory services across private, public, and non-profit sectors.



Nasim Shomali, MBA

Nasim Shomali is a biomedical engineer and executive advisor with more than 13 years of experience guiding Fortune-20 companies through growth, operational transformation, and infrastructure modernization. From 2013 to 2026, she served as a Strategy Executive at Accenture, working with senior leaders across the medtech, hyperscale technology, software, energy, and retail sectors to shape first-of-their-kind initiatives; she has led cross-functional teams delivering multi-hundred-million-dollar ROIs and shaped product, cloud, and AI direction for companies with trillion-dollar market capitalizations, drawing on prior roles in private equity diligence and medical device engineering. Ms. Shomali holds an M.B.A. in finance from the UCLA Anderson School of Management and dual bachelor's degrees in Bioengineering and Mathematics from the University of Washington, and completed the Sustainable Leadership Development Executive Program at the Yale School of Management.

Scientific Advisory Board

Our Scientific Advisory Board provides objective perspective and guidance in product development, clinical trials, regulatory compliance, and biotech commercialization strategies.



Henry S. Friedman, MD
Chair, SAB

Senior neuro-oncologist at Duke and deputy director of The Preston Robert Tisch Brain Tumor Center.
 Holds the James B. Powell, Jr. Distinguished Professorship in the Duke School of Medicine.
 Cares for adult and pediatric patients at the Duke Cancer Center's Brain Tumor Clinic.
 Internationally recognized authority in neuro-oncology with 500+ peer-reviewed works and decades of national and international presentations.
 Research focuses on clinical trials and translational work in high-grade glioma, medulloblastoma, and ependymoma.
 Helped shape treatment standards for challenging CNS tumors through sustained leadership and collaborative, multi-center research.



Axel H. Schönthal, PhD

Associate Professor, Department of Molecular Microbiology & Immunology at Keck School of Medicine at University of Southern California.
 Research focused on novel agents and delivery methods for improving cancer therapeutic regimens, particularly for brain cancers.
 Authored or coauthored 180 scholarly articles with an H-Index of 50.
 Over past 10 years, engaged in grant reviews for The Qatar National Research Fund. Includes applications for Undergraduate Research Experience Program that engages students in research projects under the guidance of academic and business mentors.
 PhD, University of Karlsruhe, Germany.
 Postdoc in molecular & cellular cancer biology at USC, San Diego.



Steven L. Giannotta, MD

Chair Emeritus of Neurological Surgery at USC.
 Research primarily centers around cerebral blood flow and protecting the brain from ischemia.
 Specializes in surgical strategies for cranial base lesions, including acoustic neuromas. Has surgically removed 400+ acoustic neuromas.
 Treated 1,000+ intracranial aneurysms and developed a comprehensive approach to cerebrovascular conditions, employing techniques such as microsurgical clip ligation, coil embolization, and stereotactic radiosurgery.
 Medical degree and residency at the University of Michigan.



Alexandra M. Miller, MD, PhD

Chief of the Division of Neuro-Oncology at NYU Langone's Perlmutter Cancer Center and Co-Director of the Brain & Spine Tumor Center.
 Leads the Neuro-Oncology Program, with a clinical and research focus on primary brain tumors, particularly malignant gliomas.
 Oversees multidisciplinary care and strategic planning at a major NCI-designated cancer center.
 Holds clinical faculty appointments in Medicine and Neurology at NYU Grossman School of Medicine.
 Works at the intersection of neurology, oncology, and clinical trials.
 Recognized for leadership, invited talks, program development, and collaborative research in neuro-oncology.



David M. Ashley, MBBS (Hons), FRACP, PhD

CEO of VCCC Alliance in Australia. Previously was the Rory David Deutsch Distinguished Professor of Neuro-Oncology and Director of The Preston Robert Tisch Brain Tumor Center at Duke.
 Dr. Ashley trained and led major neuro-oncology programs in Australia before joining Duke.
 Practices adult and pediatric neuro-oncology and oversees one of North America's largest dedicated brain tumor centers.
 Leads integrated efforts in clinical care, translational research, and education.
 Research focuses on CNS tumor biology, immuno-oncology, and clinical trials.
 Served as principal investigator on national and international studies shaping current practice.
 Internationally recognized for advancing patient-centered innovation in neuro-oncology.



Founded in 2023, NTHI is a clinical-stage life sciences company.

Focused on development & commercialization of central nervous system (CNS) therapeutics.



Platform for novel drug candidates & delivery tech.

Designed to address the persistent challenge in overcoming the blood-brain barrier (BBB).



Robust IP portfolio.

Holds 179 biotech-related patents developed at the University of Southern California (USC).



NTHI first-mover advantage.

Innovative intranasal CNS drug delivery, reinforcing its focus on non-invasive therapies for brain tumors.



63 scientific published studies.

Highlight the potential of perillyl alcohol (POH) and its conjugates as efficient chemotherapeutic delivery platforms against brain tumors.



Advancing pipeline.

Two drug candidates in Phase II trials (NEO100-01, NEO100-02) and two in Phase I (NEO100-03, NEO212).



Multi-billion-dollar, high-growth addressable markets.

Significant unmet need in a large addressable market.



Experienced leadership.

Extensive track record in capital markets, medical, scientific, and biotech value creation.

NeOnc Technologies Holdings, Inc. — company overview. IP: 179 patents (USC). Pipeline: NEO100-01/-02 (Phase II), NEO100-03 & NEO212 (Phase I).

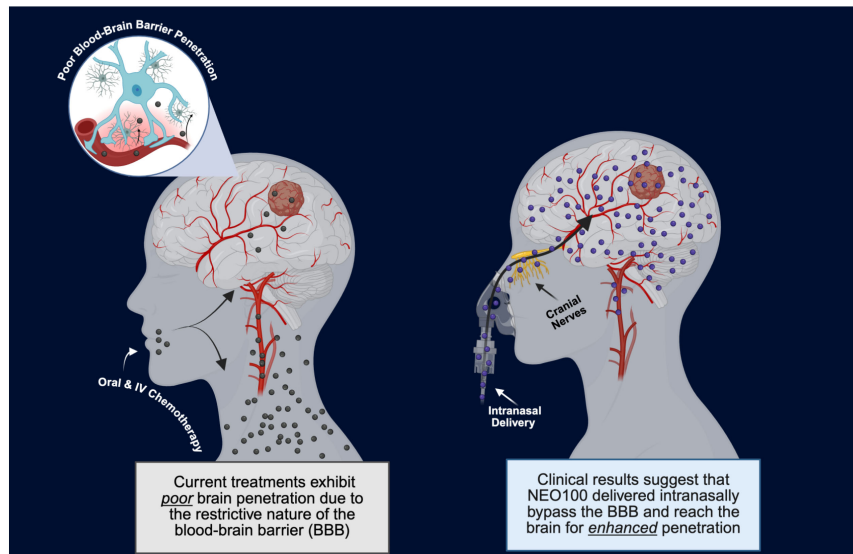
Direct brain access: Intranasal delivery is designed to enable small-molecule therapeutics to bypass the BBB via the olfactory and trigeminal nerves, reaching the brain through the CSF.

Non-invasive & patient-friendly:

Administered with a nasal mask and nebulizer, this method is designed to be simple, non-invasive, and suitable for self-use — potentially reducing costs and improving adherence.

Enhanced efficiency:

Intranasal delivery is designed to avoid first-pass metabolism, allow rapid onset, and enable targeted drug delivery to brain tumors such as GBM.



~1 million

Americans living with a primary brain tumor

~26%

of all brain & CNS tumors are malignant

#1

leading cause of cancer-related death in children (ages 0–14)

107,100

new primary brain & CNS tumors expected in the U.S. in 2025

≈4,800 in children (ages 0–19)

18,330

deaths from malignant brain & CNS tumors in 2025

≈24,820 new malignant cases

1 in 143

lifetime risk of a malignant brain/CNS tumor (men; ~1 in 186 women)

Sources: Prevalence & pediatric-leading-cause — National Brain Tumor Society, Brain Tumor Facts (2025). Incidence — CBTUS Statistical Report 2018–2022 (Neuro-Oncology 2025); 107,100 new primary brain/CNS tumors in 2025; ~26% malignant; ≈4,800 children (0–19)/yr. Malignant new cases & deaths — American Cancer Society, Cancer Facts & Figures 2025 (≈24,820 new malignant; ≈18,330 deaths). Lifetime risk — ACS (≈1 in 143 men, 1 in 186 women).

The Need**#1**

Brain tumors are the leading cause of cancer-related death among children (ages 0–14) and the most common solid tumor of childhood.

~4,800

children & adolescents (ages 0–19) are diagnosed with a primary brain tumor in the U.S. each year.

~40%

Pediatric high-grade gliomas (pHGG, including DIPG) account for roughly 40% of childhood brain-tumor deaths.

The Challenge

Radiation & chemotherapy for children with high-grade gliomas are:

- Complex
- Time consuming
- Prognosis remains poor

These challenges underscore the importance of developing effective therapies that are:

- Less invasive
- More tolerant for such populations

Our Solution

NEO100: our first therapeutic being developed for pediatric patients diagnosed with pHGG.

We believe our novel **intranasal delivery** makes a study in a pediatric population easier than other methods.

In consultation with the FDA under **Orphan Drug & Fast-Track status**, we intend to collect clinical-trial data to evaluate the potential of NEO100 in pHGG.

Sources: National Brain Tumor Society, Brain Tumor Facts (2025); CBTRUS Statistical Report 2018–2022 (Neuro-Oncology 2025), pediatric analysis. Brain tumors are the most common solid tumor and the leading cause of cancer death in children ages 0–14. Pediatric high-grade glioma (incl. DIPG) mortality share per pediatric neuro-oncology literature. Children = ages 0–19 unless noted.

Primary brain tumors and the IDH1 divide

Primary brain tumors start in the CNS itself. **Adult-type diffuse gliomas** are the most common malignant kind — and since WHO 2021 they are defined first by **IDH mutation status**, not by appearance alone. IDH1 status splits one microscopic picture into two different diseases.

ADULT-TYPE DIFFUSE GLIOMA		IDH1-MUTANT astrocytoma	IDH1-WILDTYPE glioblastoma
↓ classified first by IDH mutation status			
IDH-MUTANT	IDH-WILDTYPE		
Astrocytoma, IDH-mutant grades 2, 3, 4 · ATRX-lost, no 1p/19q codeletion	Glioblastoma, IDH-wildtype grade 4 The term "glioblastoma" is now reserved for IDH-wildtype tumors only.	Typical age 30s–40s (younger)	60s+ (older)
Oligodendroglioma, IDH-mutant & 1p/19q-codeleted · grades 2, 3		How it arises Often from a lower-grade glioma	De novo / primary
		Genetic hallmark IDH1/2 mutation (IDH1 R132H ≈ 90%)	No IDH mut; TERT, EGFR amp, +7/–10
		Biology Mutant IDH makes 2-HG → DNA/histone hypermethylation (G-CIMP)	RTK/RAS/PI3K-driven; no 2-HG
		WHO 2021 name "Astrocytoma, IDH-mutant, grade 4" — NOT glioblastoma	"Glioblastoma, IDH-wildtype, grade 4"
		Grade-4 trigger Necrosis/MVP or CDKN2A/B homozygous deletion	Necrosis/MVP or TERT / EGFR / +7–10
		Median survival from diagnosis ~3–5 yr at grade 4 (years at lower grades)	~15–18 months
		Prognosis Better at every grade	Worst of the gliomas

Key teaching point: since WHO 2021, "glioblastoma" means **IDH-wildtype only**. A grade-4 **IDH1-mutant** tumor is no longer called GBM — it is "Astrocytoma, IDH-mutant, grade 4."

Same look under the microscope, but a different disease — younger patients, distinct biology, and far longer survival. That recurrent grade 3–4 IDH1-mutant population is exactly what NEO100 targets.

Sources: WHO classification — Louis DN et al., "The 2021 WHO Classification of Tumours of the Central Nervous System: a summary," Neuro-Oncology 2021;23(8):1231–1251. Major-changes review — "Major Changes in the 2021 WHO Classification of CNS Tumors," RadioGraphics 2021 (doi:10.1148/rg.210236). Biology — Yan H et al., NEJM 2009 (IDH1/2 in gliomas); Nourshahr H et al., Cancer Cell 2010 (G-CIMP). Survival — IDH-wildtype GBM median OS ~15–18 mo (Stupp R et al., NEJM 2005; Lancet Oncol 2009); IDH-mutant grade-4 astrocytoma ~3–5 yr. IDH1 R132H ≈ 90% of IDH mutations.

While the FDA has approved many drugs for treating malignant glioblastomas (GBM), **survival rates remain low with no significant improvement in prognosis over the past 50 years.**

Lack of progress primarily due to natural resistance mechanisms that limit efficacy of GBM treatments



Therapeutics cannot enter the central nervous system (CNS) due to the blood-brain barrier (BBB).



Heterogeneity of GBMs contributes to therapeutic resistance by preventing adequate control of the entire tumor mass by a single drug.



Natural brain responses (i.e. tumor microenvironment) counteract tumor-targeting medications.

Stem cell-like characteristics of GBMs resist current standard treatment options:

Treatment	Resistance Mechanism
Chemotherapy	Upregulation of efflux transporters
Radiation	Promotion of glioblastoma stem-cell proliferation in neurogenic zones
Immunotherapy	Immune suppression

Metabolic cascades in GBMs prevent effective treatments through:

- Optimization of glucose use
- Alternative nutrient precursors for energy production
- Induction of hypoxia to enhance tumor growth

Source: Challenges in the Treatment of Glioblastoma: Multisystem Mechanisms of Therapeutic Resistance, Aug. 2018.

Designed to act as a regulator

for neurologic pathways associated with tumor cell growth.

When delivered intranasally,

its small molecular size is designed to allow it to bypass the blood-brain barrier (BBB).

When delivered intra-arterially,

it may create a temporary opening in the BBB, allowing larger-molecule therapeutics to pass through.

In high concentrations,

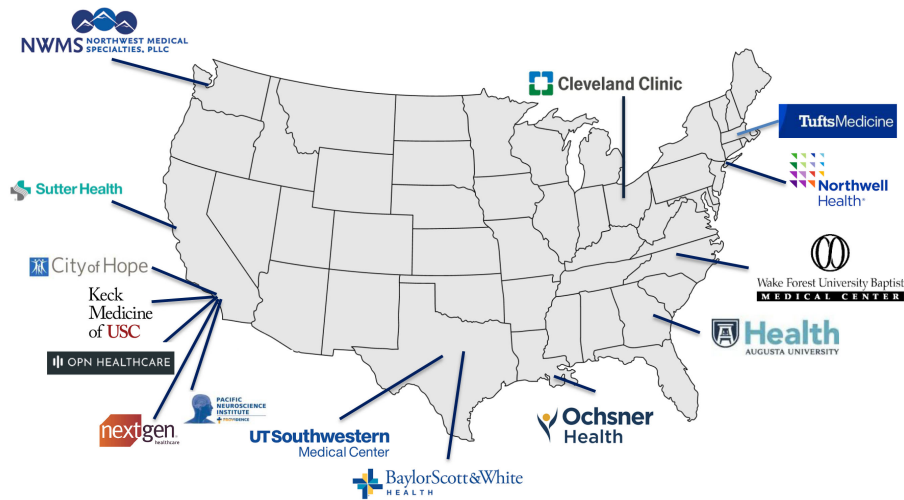
may act as a therapeutic for brain cancers.

In low concentrations,

to act as a solvent for traditional large-molecule therapeutics, which may enable them to bypass the BBB.

Conjugate with other CNS therapeutics

to create compound formulations that may be capable of BBB penetration & greater therapeutic effect.



Pending Sites

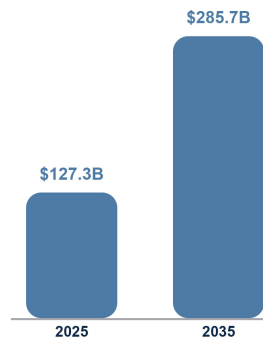
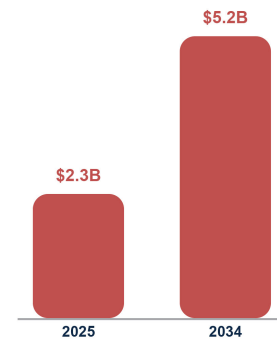
Penn State
 Washington University
 Johns Hopkins
 Harvard / Mass General Hospital
 New York University
 Tampa General
 University of South Carolina
 Northwestern University
 Beverly Hills Cancer Center
 University of Vermont
 Westchester Medical Center
 Michigan University
 Duke University
 Children's Orange County (CHOC)
 Children's Hospital of Los Angeles
 Alabama
 UCSF
 Maine Health
 United Arab Emirates (5 sites)
 Israel (Tel Aviv)

Global Market Outlook & Drivers

- **Global CNS treatment market** is projected to grow at an **8.6% CAGR**, reaching **\$285.7 billion** by 2035.¹
- **Global brain tumor drugs market** is expected to grow at a **9.3% CAGR**, reaching **\$5.2 billion** by 2034.²

Major Market Drivers

- Rising incidence of CNS disorders driven by an aging global population.
- Increased FDA approvals for novel and combination therapies.
- Drug therapy remains limited by poor delivery across the blood-brain barrier (BBB) — the gap NEO100 is designed to close.

CNS Treatment MarketGlobal, USD billions ¹↗ **8.6% CAGR****Brain Tumor Drugs Market**Global, USD billions ²↗ **9.3% CAGR**

Sources: ¹ Precedence Research, "Central Nervous System Therapeutic Market" (2026 update): USD 127.29 B (2025) → 285.72 B (2035), CAGR 8.64% (2026–2035). ² Fortune Business Insights, "Brain Tumor Drugs Market," report 105025 (2026 update): USD 2.29 B (2025) → 5.20 B (2034), CAGR 9.30% (2026–2034). Market-size and CAGR figures are third-party analyst projections and vary by report scope and methodology.

U.S. Patents

32 issued
19 pending

International Patents

97 issued
31 pending



Protected under exclusive global licensing agreement with USC.

NEO™ is a proprietary platform

Protected by patents in the U.S., Canada, China, UK & EU

- Patents cover agent composition & methods of use, including enhanced methods designed to deliver pharma-based therapeutics to the brain.
- Patents secured under exclusive global licensing agreement with USC — considered USC's largest IP license for commercialization of chemotherapies related to brain & CNS diseases.¹
- Biotechnology innovations based on research and development at USC led by NeOnc CEO, Dr. Chen.
- Platform technology has produced an IP portfolio of novel drug candidates, including conjugates and formulations of FDA-approved drugs, with patents extending to 2031–2038.

Composition & Method Claims

Issued & pending patent applications

NEO100 Ultrapure POH — issued patents expiring 2031: U.S., Canada, UK, EU, China.

POH conjugates (NEO212 / NEO214) — issued patents expiring 2031: U.S., UK, EU, Japan.

NEO400 POH + linoleic acid — pending applications, anticipated 2031: U.S., EU, China.

NEO412 POH + fatty acid / TMZ / Rolipram — issued patents expiring 2036: U.S., UK, EU, China, Japan, Australia.

NEO218 POH + bromopyruvate — issued U.S. patent expiring 2037; pending in China, EU, Japan.

NEO216 POH + valproic acid — pending applications, anticipated 2038: U.S., EU, China.

USC article published Oct. 19, 2023 — USC licensing agreement reached with faculty-led & founded company; considered the largest IP transfer for commercialization of chemotherapies related to brain and CNS disease.