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	**92-1954864**
(Commission File Number)	(IRS Employer Identification No.)
23975 Park Sorrento, Suite 205 Calabasas, CA	**91302**
(Address of Principal Executive Offices)	(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") hosted an investor conference call to discuss results from the Phase 2a portion of NEO100-01. Furnished as Exhibit 99.1 hereto is a transcript of the investor conference call.

The information in this Item 7.01 and Exhibit 99.1 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	Transcript
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 13, 2026

NeOnc Technologies Holdings, Inc.

By: /s/ Amir Heshmatpour
Name: Amir Heshmatpour
Title: Chief Executive Officer, President and Executive Chairman

Exhibit 99.1

Transcript of
NeOnc Technologies Holdings, Inc.
NeOnc Technologies
August 12, 2026

Participants

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.
Amir Heshmatpour - CEO, Executive Chairman, and President, NeOnc Technologies Holdings, Inc.
Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.
Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.
Jim Delshad - Board Director, NeOnc Technologies Holdings, Inc.
Alexandra Miller - Scientific Advisory Board Member, NeOnc Technologies Holdings, Inc.
Henry Friedman - Scientific Chair of the Scientific Advisory Board, NeOnc Technologies Holdings, Inc.

Analysts

Presentation

Operator

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Thank you, and good morning, everyone. Welcome to the NeOnc Technologies Investor Conference Call to discuss top-line results from the Phase 2a portion of our NEO100-01 clinical trial in recurrent IDH1 mutant high-grade glioma.

Joining me on the call today, we have Amir Heshmatpour, our Chief Executive Officer and Executive Chairman. We also have Dr. Thomas Chen to my right, who is our Founder and Chief Medical Officer and Chief Scientific Officer. We also have Dr. Josh Neman, who is our Chief Clinical Officer. My name is Keithly Garnett. I serve as the Chief Financial Officer. Today, we are also joined by one of our board members, Mr. Jim Delshad, and other board members are participating through the webcast.

Before we begin, I would like to remind everyone that during this call, we will make forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Act of 1934. These statements can be identified by words such as may, will, should, intend, expect, plan, anticipate, believe, estimate, predict, potential, continue, evaluating, and other similar terms. These statements reflect our current expectations and are subject to known and unknown risks and uncertainties that could cause actual results to differ materially.

Among other things, results of preclinical studies and early clinical trials may not be predictive of results in future clinical trials. Announced or published data may change as more patient data becomes available and are subject to audits and verification procedures that can result in material changes to the final data.

Our product candidates are in clinical stages of development, are not approved for commercial sale, and might never receive regulatory approval or become commercially viable. We encourage you to review the Risk Factors section of our quarterly and annual reports on Form 10-Q and Form 10-K, as filed with the Securities and Exchange Commission. We assume no obligation to revise or update any forward-looking statement except as required by law.

With that, I will turn it over to Amir.

Amir Heshmatpour - CEO, Executive Chairman, and President, NeOnc Technologies Holdings, Inc.

Thank you, Keithly. Good morning, ladies and gentlemen. NEO100-01, Phase 2 met its primary endpoint. Survival is the standout result. Median overall survival was 26.1 months, measured from the start of NEO100 at recurrence, a setting which current salvage therapy delivers roughly only six to nine months. Durable control with tolerability and supports chronical dosing.

At this time, I would like to turn it over to Dr. Chen to go over the clinical data.

Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.

Good morning, everybody. My name is Tom Chen, and I want to talk to you about some of our results and the background behind our studies. First of all, I want to emphasize to you that we are a recurrent brain cancer company. As a result, our main signal is going to be overall survival for our patients. We have four trials currently in progress. These trials are based on our two lead assets, which is NEO100 and NEO212. With NEO100-01, which are the results we will be presenting today, this is an intranasal delivery of our lead drug, NEO100. And I should add for you that we are the only company that is doing intranasal delivery for brain cancer at this time.

In terms of our indication, we are doing recurrent Grade III or IV Astrocytoma Brain Tumors with IDH1 mutations. I will be talking to you a little bit about the background as to why we chose IDH1 mutants, and we have completed now Phase 2a. We will be going to the FDA soon to present these results. NEO100-02 is given intranasally also, is used for meningiomas and brain tumors. Meningiomas are the most common benign brain tumor, but they can also become atypical or malignant, and we are treating the worst of the worst within a Phase 2 trial.

NEO100-03 is given also intranasally. It's given for pediatric brain cancer. Children can have brain cancers, and unfortunately, their brain cancer is usually in very difficult areas of the brain to treat, such as the brain stem. We are currently in Phase 1 trial with this. And NEO212 is given orally. It's a conjugate of our NEO100 with temozolomide, our standard care drug. It is used in all brain tumors, and we are currently in Phase 2. We have already finished phase 1, and those results have already been discussed with the FDA in terms of future trial.

Now, in terms of these two platforms that I was alluding to with NEO100 and NEO212. First of all, I want to introduce you a new delivery platform. As you know, that all chemotherapy is currently given intravenously or orally. We want to do a novel delivery platform, which is called intranasal brain. With the intranasal brain delivery, what we are doing is that we are allowing the methodology to bypass blood-brain barrier. We are not trying to cross the blood-brain barrier. As a result, what we are doing is we are using something called the cranial nerves of the brain. It's the first and the fifth cranial nerve that allow us to do the intranasal brain delivery.

As you can see by this picture that basically the patient is going to be inhaling the drug, therefore intranasal, allowing that drug then to penetrate to the brain and go to the tumor in a non-invasive manner. With NEO212, our drug conjugation platform, what we are doing is that we are taking our lead acid NEO100 and we are conjugating it with a carbamate bond to, in this case, our standard care drug temozolomide. When we do that, we actually make a more stable compound, and there is a new chemical entity, and this is what we call NEO212.

Now, in terms of the IDH1 mutations, IDH1 mutations can occur in brain cancer. Brain cancers are usually divided up into primary brain cancers, into IDH1 wild types or IDH1 mutants. Currently, in the United States, there are 26,480 new primary brain cancers per year, and approximately 2,400 per year are IDH1 mutations. The addressable market goes down to about 7,000 to 11,000 new cases in the United States. And I want to say that all these IDH1 mutants, when they recur, and 100% of them basically do recur, they oftentimes do not have any further additional treatment.

Now this curve below shows this very well. You see we have Grade III IDH1 mutant Astrocytomas and Grade IV IDH1 mutant Astrocytomas. What we did was illustrate the fact that these IDH1 mutant Astrocytomas can have longer lifespans than a wild type. But when they recur, look at the instance, their recurrence and to death is usually about the same time as if you have a wild type. And we currently do not have any treatment for these recurrent patients. They will die from their disease.

As a result, what we have done is that we have taken a disease where patients initially have years, but when they recur, they have months. And their recurrence when they have months is only about six to nine months. So what do we do with these patients so that we can prolong their lifespan. Our answer is basically our drug, NEO100. It's an ultra-pure perillyl alcohol, which we're going to be delivering nose to brain.

As you can see in this model, this nose to brain delivery is done with an inhalation mask, and there's a very portable machine that delivers the drug to it. As a result, this is a non-invasive treatment. We're giving this treatment currently 4x a day, and it's given intranasally.

This is a graph showing data, showing some of the mechanism behind how NEO100 works. I think it's important for us to understand how it works because this is crucial to what we do. So our first main mechanism that we have discovered is that it induces ER stress. What I mean by ER stress is, ER stands for endoplasmic reticulum. The endoplasmic reticulum is the powerhouse of the cell. It's involved in protein synthesis. When we apply NEO100, we induce ER stress, and we shut down protein synthesis. When the cell is shut down from protein synthesis, it then undergoes apoptosis or cell death.

Another mechanism is we found that it inhibits a pump called the sodium potassium ATPase, and that induces cell death as well, and then inhibits RAS inhibition and inhibits cell cycle proliferation for the cell. We have demonstrated these effects in vitro, and we have demonstrated this in vivo in the intracranial glioma model, and in in vivo, we demonstrate increased survival of the mice.

This diagram summarizes what I've mentioned. As you can see that we're talking about a multi-mechanism delivery of action, and it works very well in patients with resistant tumors. And the reason why it works so well is because it works not just on one pathway, but multi-pathways. As this is our Phase 1 trial that we have performed. And with the Phase 1 trial, what we did was that we did a dose-escalating study in 12 patients, and at that time, everybody was called a recurrent glioblastoma. We were expecting the usual timeline, about six to nine months of survival.

But when we concluded the trial after our dose escalation, we actually found an overall survival of 12.5 months, which is about overall survival of 16 months, and this was much higher than we would expect from recurrent disease. And from this data, what we then looked at was basically some biomarkers of survival, and all these patients were found to have IDH1 mutation. So we found this biomarker of survival. We actually went back to the FDA and told the FDA that we have patients that were long-term survivors. They all had IDH1 mutations. Could we then run a Phase 2a trial using this criteria?

And so at this point, what I would like to do is turn over the presentation to Josh Neman, who will now present the data for our Phase 2a.

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Thank you, Tom. What I'd like to go over with you is our study design and our overall results. What this design is, as Tom mentioned, is that we are focused on recurrent IDH1 Grade III and Grade IV gliomas. These are at recurrence, and as we have been speaking to you today, the survival collapses at recurrence to six to nine months. The endpoint are to build a temporal durable disease control. This trial was run as a single-arm design. When NEO100 opened as a single-arm design, the approach at that point was according to a peer review publication, that at that point 90% of brain tumor trials had a one-arm design, and that was because the design was not for randomized control.

The testing against this historical benchmark, which we will talk about today, was the conventional signal seeking path. And so therefore, in our future talks with the FDA, we will talk about a randomized controlled trial, which is appropriate for the next confirmatory results. So within our phase 2 trial, the primary objectives and endpoints were progression-free survival at six months. What we tested against was a 20% PFS6 benchmark. Why we did this was because historically, only in one out of about five patients with recurrent high-grade glioma or primary brain tumors, the tumor grew back within six months, and therefore NEO100 had to beat this bar to be worth pursuing. Our secondary objectives are overall survival, objective response rate according to RANO 2.0 criteria, safety, and tolerability.

As we mentioned previously, we are very happy to report that we met our primary objective objections. This was PFS6 of 48.9% versus the 20% benchmark. This Kaplan-Meier survival curve shows that our intent-to-treat population was 24 patients. Out of these 24 patients, 21 were recurrent Grade IV, three were only Grade III, so really going after the unmet need population.

With respect to this, we were highly significant, compared to our 20% benchmark with a P value of 0.0047. And as you can see from this Kaplan-Meier progression-free survival curve, we have stable survival disease roughly 12 months out, which is very good for patient diagnosis.

Looking at our swarm plot, we see that there is a durable tail post-20 months from recurrence. In fact, out of our 24 patients, we have five patients still on the trial. Two are the longest ongoing with 24 and 20 months. We have a patient that is 19 months progression-free, which means that they have had a sustainable tumor almost 114 days out.

Looking at median overall survival, we see that compared to historical six to nine month benchmark, we are at significantly 26.09 months from recurrence. This durability was also seen across six to 24 months, where the OS six month survival was 86.7%. The overall survival at 12 months was 60.9, and at 24 months, we still had over half of the patients alive. Our objective response rate was, according to RANO 2.0, was again 8.3. Again, these overall survivals are from the day one of recurrence when patients came on our trial.

Looking at response and imaging, with respect to NEO100 intranasal therapy, there is truly a disease control and a radiographic response. Within our 24 patients, we had 66.7% of our patients who had disease control. This is basically including partial response and stable disease response. Looking at our cumulative Phase 1 and Phase 2 data, looking at long-term survivors, out of 29 patients, 55% were long-term survivors, meaning they survived greater than one year post-recurrence. The median overall survival of those long-term survivors are 2.2 years, with a range of 1.2 to a little bit over eight years of survival post-recurrence.

With respect to radiographic remission, I'd like to show you a representative long-term survivor. This is a patient that came on our trial. This is their tumor before going on NEO100, as you can see in the red circle. 35 months or 35 cycles into NEO100, you see the reduction in tumor size. And looking at profusion scans, you can see that the tumor is cold. In fact, this patient is currently still on our trial on month 43 post-recurrence. This overall shows that NEO100 has a suitable disease and maintenance stature.

With respect to differentiators compared to other IDH1 targets, looking at a cross-trial comparison to the INDIGO trial and the STELLAR trial, we would like to point out that the INDIGO trial, while had a significant progression-free survival, this was only in Grade II tumors, not Grade III and Grade IV, and more importantly, not in a recurrent Grade III and IV, unlike NEO100.

With respect to the recent STELLAR study, they looked at recurrent Grade III and Grade IV. However, they did not see any benefit in Grade IV patients, and therefore, this is still an unmet need.

Historically, high-grade gliomas in Grade III, Grade IVs have salvage therapy, the chemotherapy, this includes lomustine. Again, the median overall survival for this is six to nine months, which basically the implications for this are that it is not a durable survival. This is where NEO100 comes in, and our trial results have meaningful data for patients, where we have a durable overall survival at 26.09 months compared to the historical six to nine months, and where other trials failed in this recurrent Grade III and Grade IV.

Again, the majority of our patients were recurrent Grade IV, one of the hardest populations to treat. In summary, what I went through today, and the team went over today, was that we had met our primary and secondary objectives. Our primary objectives of 48.9% progression-free survival at six months was highly significant compared to our 20% landmark.

We had a median overall survival of 26.09 months after recurrence, where the benchmark in salvage therapy is six to nine in approved drugs. And we have a 60.9% overall survival of our patients at 12 months. This truly is a differentiator for recurrent patients, which means that patients are living 4x longer than six to nine months of currently approved therapies for recurrent tumors.

Our next steps are to go to the FDA for a proposed Phase 3 accelerated approval. In this FDA meeting, we will talk about a Phase 3 design, which is a randomization against the approved lomustine. We will seek out FDA's guidance and seek out to get an accelerated approval design with an interim analysis, with a final OS being for our registrational designation.

With that, I will turn it over back to Amir.

Amir Heshmatpour - CEO, Executive Chairman, and President, NeOnc Technologies Holdings, Inc.

Thank you, Josh. So NEO100 impact and significance was what you guys just heard from Dr. Chen, Dr. Neman. We met all of our primary endpoints, as you heard. Life expectancy was increased by 4x to 5x, as you heard. And then we are also building the clinical momentum, starting clinical trials in Abu Dhabi. We have been approved with all of our four drugs as IND, and soon we will be approved in Israel as well. So with that said, I will turn it over to Keithly Garnett.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Thank you, Amir. At this point in time, we will take a moment to facilitate a few questions. We have received a few questions in the chat. I will go ahead and read the questions. One of the questions is directed to our key opinion leader who has joined us today. We have Dr. Miller that is on as well. And the question that was put to Dr. Miller, who I believe has access to respond, is…

Alexandra Miller - Scientific Advisory Board Member, NeOnc Technologies Holdings, Inc.

Hi.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Can you tell us. Hello, Dr. Miller. We have a question directed to you, and we are going to ask, can you tell us a little bit more about the clinical data as you have observed, and how about the natural history of the disease? I will repeat that. Can you tell us a little about the clinical data that you have observed and about the natural history of the disease?

Alexandra Miller - Scientific Advisory Board Member, NeOnc Technologies Holdings, Inc.

Of course. First of all, congratulations on this work. It's really exciting to have another drug or potential drug and opportunity for our patients, and we're excited about the hope of launching a large clinical trial off of this preliminary data. So I think this data is very exciting. This shows a signal. Obviously, this needs to be done with a much larger group of patients in order to understand the implications for the drug on the treatment of IDH mutant gliomas.

So patients with IDH mutant gliomas, as was discussed during this press conference, while we are beginning to have additional options, such as IDH inhibitors for them early in the course of their disease, even early in the course of disease for the IDH mutant Grade III and Grade IV patients who have higher risk data, unfortunately, the IDH inhibitors vorasidenib, which is FDA approved at this time, have not shown efficacy in the enhancing disease population or the higher-risk population.

So to have anything for these patients would be a huge accomplishment and really change the course of care for them. Unfortunately, at the time of recurrence for these patients, they're often rechallenged with chemotherapy and/or in combination with radiation, but usually we're not able to get the same benefit that we get from chemo and radiation early in the course of their disease.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Okay, we have a few questions. I'll take just a few. One of the questions that was posed, I will read as it says here. It says, "With progression-free survival, PFS6 was 48.9%, more than double the pre-specified 20% benchmark, and statistically significant. How do you interpret this result, and what does it suggest about NEO100's activity in this difficult-to-treat IDH1 mutant population?

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Thank you, Keith.

Henry Friedman - Scientific Chair of the Scientific Advisory Board, NeOnc Technologies Holdings, Inc.

You want me to help with that one?

Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.

Sure, Dr. Friedman.

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Go ahead, Dr. Friedman.

Henry Friedman - Scientific Chair of the Scientific Advisory Board, NeOnc Technologies Holdings, Inc.

Let me make a more global statement as part of that. Obviously, this is exciting data. And Alex nailed everything about the issues we're facing with this population of patients. What I can say, I've been doing this 40 years. Geez, I'm old. I can say that there's no question that this is one of the most exciting things we've seen come along in the last decade. The mutation was actually discovered at Duke.

We've been involved with studies, as Alex has been, in the IDH inhibitors, but they're not going to cut it alone, unfortunately. And while there are other things that are being developed, there's nothing that looks as promising as this at this moment in time for this population. If the results carry through as we expect they will on the next study, you've got a paradigm shift in the treatment of this disease. It's that simple.

Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.

Thank you, Dr. Friedman.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Excellent. I'll move to this next question. Next question says, "How do you interpret extended OS in a patient that does not show a radiographic response?" Dr. Chen?

Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.

Yes. So I believe that the reason why we have an extended overall survival is based on the mechanism of the drug and also the disease itself. So what we have is a drug that is essentially cytostatic in nature. The drug takes time to become from cytostatic to cytotoxic. So when you get a patient with a recurrent disease, that tumor is very aggressive, and that tumor is proliferating. And so what happens in the patient is that this drug initially goes on, it's a battle between the drug and the tumor. And so depending on what phase of the cell cycle this drug is hitting the tumor at, you may see this patient basically not have an overall progression-free survival of six months, but have a longer overall survival time because the drug has had an opportunity to catch up with the treatment.

And I think that's the main reason why we have a discrepancy in some of these patients, depending on what part of the treatment cycle and what part of the cell cycle we're catching the patient at.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Thank you, Doc. We got another question.

Henry Friedman - Scientific Chair of the Scientific Advisory Board, NeOnc Technologies Holdings, Inc.

Let me build on that. First of all, this is not a novel observation. There are other interventions, particularly immunotherapy, where you can see, not so much a response, but you can see a prolonged survival, in effect, changing something from an acute disease to a chronic disease. And I'm sure the investors on this call would be very unhappy to realize that somebody would have to stay on this drug forever, to sustain, control the disease. Of course, you wouldn't. This is something that is quite feasible, and you might be able to turn diseases like this into a chronic situation.

And if the worst thing in their life is they have to stay on this drug for years and years and years, to sustain their quality of life and not have a progression, even if you don't see a response, is anybody on this call really worried about that? No. Nobody's worried about that. Well, you have to keep buying the drug, but obviously that's part of being taken care of, like having insulin for diabetes. That may be what we're going to see in at least a population of these patients. If that's the situation…

Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.

Thank you, Dr. Friedman.

Henry Friedman - Scientific Chair of the Scientific Advisory Board, NeOnc Technologies Holdings, Inc.

Everybody wins in that situation.

Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.

Thank you.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Okay, our next question. "Can you provide more context on the historical benchmark for median overall survival, or is the current [indiscernible] more appropriate given the lack of standardized benchmarks in IDH1 mutant Grade III and Grade IV and the higher Grade IV patient population in the study?

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Sure. Thank you for that question. So with respect to historical, as Dr. Friedman and Dr. Miller alluded to, really, there has been no clear study that has been done on recurrent Grade IV IDH1 mutant patients. All other studies, including STELLAR, Veringo, EORTC, they have been done on comparisons to IDH1 wild types. It was only less than a decade ago that we came up with this biomarker, the IDH1 mutant population.

With that said, it is a different disease. However, as Dr. Chen alluded to, at recurrence, these patients, especially the Grade IV patients act like the wild-type patient. The recurrence comes back, and it is very vengeful. And so we believe that in our Phase 3 randomized trials, the number with respect to median overall survival will look more closer to the wild-type patients, than the lower grade IDH1 mutant recurrences.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Thank you. We have another question. It says, when you talk to regulators or other KOLs, is the rapid death after recurrence of Grade III disease well appreciated? Or what are the key data sets you will use to document this key point?

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Yes. Dr. Friedman, would you like to answer that question?

Henry Friedman - Scientific Chair of the Scientific Advisory Board, NeOnc Technologies Holdings, Inc.

Can you say that again? There is a little bit of static where I am.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Sure, I will repeat that. The question that is written says, when you talk to regulators or other key opinion leaders, is the rapid death after recurrence of Grade III disease well appreciated? And further it says, what are the key data sets you will use to document this key point?

Henry Friedman - Scientific Chair of the Scientific Advisory Board, NeOnc Technologies Holdings, Inc.

Well, again, I think that the usual criteria that we are going to be evaluated by is event-free progression or event-free survival, I should say, and overall survival. And although people look at response rate, response rates don't count. I mean, response rates are impressive, but again, we are so used to seeing this, particularly because of so much of the immunotherapy work, and this is an immunotherapy treatment, but we are so used to seeing people where you have prolonged tails of survival, and you don't really see major changes in response that the FDA is fully aware of that. I think everything that we have talked about, the FDA is going to say, this is fine. It is not desirable. Does that help answer the question?

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Yes.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Yes, that is helpful. Thank you, Doc. I do have a couple more questions. The next question says, how does the overall survival metric against historical OS for similar demographics? The next part of the question goes on to say, is the FDA open to using PFS as a primary given the glioma setting you are in, or would OS be required for a pivotal trial, understanding, of course, that you still need to meet with the FDA to discuss the results?

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Right. So the FDA's requirements are that median overall survival is the benchmark that we are going to go for. However, with respect to progression-free survival, that could be part of an interim analysis, for accelerated approval. But overall, for a Phase 3 registrational, the key is median overall survival. Dr. Miller, I believe had her hands raised. If you would like…

Alexandra Miller - Scientific Advisory Board Member, NeOnc Technologies Holdings, Inc.

Yes, I was just going to make a comment also about the Grade III population. So I think when you do a methylation array and you look at the risk level for this patient population, there are low-risk and high-risk tumors, and the Grade III population really splits into lower risk and higher risk based on enhancing disease is kind of a surrogate for that.

So I think that the population that we're talking about and going after here is the higher risk, Grade III and Grade IV population, who have enhancing disease. And I think they're the ones who were enrolled on this trial and who were very excited about the signal here. And I think they'll be the focus of the subsequent trial.

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Thank you.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Okay, so our next question is the NEO100 activity in RAS inhibition independent of RAS mutation type, and is it pan-RAS inhibiting, including these RAS, KRAS, NRAS, et cetera?

Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.

Yes. So we actually have looked at the various forms of RAS, including KRAS and HRAS, and it actually has activity against both.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Excellent. Okay, thank you, Doc. Next question. Given the strength of the PFS6 and overall survival results, combined with the favorable tolerability profile, how are you thinking about the upcoming FDA discussion and the potential for the efficient registrational path from here?

Josh Neman - Chief Clinical Officer, NeOnc Technologies Holdings, Inc.

Sure. Thank you for the question. We addressed several of these points previously, but I'll summarize it again. So what we believe that our Type B meeting with the FDA will be is to align on a single accelerated approval design. It'll be a randomized approved design. Our primary endpoint will be median overall survival. We will have a pre-specified interim analysis to support the accelerated approval.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Excellent. And now for our last question at this point. Questions asked, what are your thoughts about compassionate use applications?

Thomas Chen - Founder, CSO, Board Director, NeOnc Technologies Holdings, Inc.

We actually have been very active with our compassionate use applications. We have used it in various patients that do not qualify for the trial. And we actually have been collecting data from these compassionate use patients, including other potential treatment scenarios for NEO100.

Amir Heshmatpour - CEO, Executive Chairman, and President, NeOnc Technologies Holdings, Inc.

Especially for the pediatric population. We have used the largest amount of compassionate uses in the pediatric platform. And if you go on our website, you can see some of the progress these kids are making and the drug is doing God's work.

Keithly Garnett - Chief Financial Officer, NeOnc Technologies Holdings, Inc.

Thank you, Amir. Thank you all for joining us this morning. A replay of this call will be available at investors.neonc.com. If you have follow-up questions, please contact our Investor Relations team. Operator, you can now conclude this call. Thank you.

Amir Heshmatpour - CEO, Executive Chairman, and President, NeOnc Technologies Holdings, Inc.

Thank you everyone for joining.