Vivani™
Nasdaq: VANI

SLIM-1™

Top-line results

Frequently asked questions

The first clinical study of NPM-139, our miniature semaglutide implant

Overview

On November 12, 2026, Vivani reported top-line results from SLIM-1™, the first clinical study of NPM-139, our miniature semaglutide implant. No participant who received NPM-139 had an adverse event reported as treatment-related. Drug levels rose gradually at the start of treatment, without a rapid increase. Average weight loss was numerically similar in the two groups over four weeks. The study was not designed to establish equivalent weight loss or a safety advantage.

The questions below include those that we have received since publicly releasing the results. We welcome any additional questions and invite you to send them to us at investors@vivani.com.

SLIM-1 at a glance

	Low-dose NPM-139 implant 10 participants	**Wegovy® injection** 10 participants 0.25 mg weekly, its starting dose
Participants with an adverse event reported as treatment-related	**0 of 10**	**5 of 10** all gastrointestinal and mild in severity
Serious adverse events	**None**	**None**
Mean weight loss after four weeks	**0.79%** 0.67 kg	**0.82%** 0.76 kg

SLIM-1 was an open-label, active-controlled Phase 1 trial at a single study center in Australia. Treatment lasted four weeks. SLIM-1 was not designed to establish how well NPM-139 works for weight loss.

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The study

What was SLIM-1?

SLIM-1 was the first-in-human clinical trial for NPM-139, a miniature semaglutide implant placed under the skin that is being designed for once- or twice-yearly administration. It was an open-label, active-controlled Phase 1 trial at a single study center in Australia.

Twenty adults with obesity or overweight who were otherwise healthy took part. Ten received a low-dose NPM-139 implant. Ten received Wegovy® (semaglutide injection) at its 0.25 mg weekly starting dose. Treatment lasted four weeks.

What was the study designed to find out?

Its primary objectives were to characterize safety, tolerability and pharmacokinetics, meaning how much drug reaches the bloodstream and when. Changes in weight were also measured for the period of the study.

SLIM-1 was not designed to establish how well NPM-139 works for weight loss. Dose-ranging and longer treatment durations will be evaluated in subsequent trials.

Why was the study small, relatively short, and low-dose?

We decided to begin clinical development by first learning about safety and drug release in a small group, at a low dose, before treating more people for longer periods.

This decision reflects where SLIM-1 sits in our development plan. Its job was to test, in people, how this implant starts up: how drug levels build after insertion and how well that is tolerated. That happens in the first few weeks after the implant, so the study focused on a 28-day period.

What are the limitations of SLIM-1?

SLIM-1 was small (ten participants per group), short (four weeks) and low-dose, and it ran at a single site. It was also open-label, meaning participants and investigators knew which treatment was given.

Differences between the two groups should be read as early observations that need to be confirmed in larger, longer studies. We have no human data beyond day 28.

Safety and tolerability

What did SLIM-1 show on safety and tolerability?

No participant who received NPM-139 had an adverse event reported as related to treatment. In the Wegovy group, five of ten participants had adverse events reported as related to treatment. All were gastrointestinal: nausea (3 participants), abdominal pain (2), abdominal distension (1) and constipation (1). Each adverse event in the Wegovy group was experienced one time for each participant during the four-week trial, and each adverse event was graded mild.

No serious adverse events were reported in the study.

Did anyone in the NPM-139 group have adverse events of any kind?

Yes. Six of ten participants in each group had at least one adverse event of any cause. None of these were reported as treatment related.

In the NPM-139 group, the reported events were upper respiratory tract infection (2 participants), Type IV hypersensitivity reaction (2), contact dermatitis (2), diarrhea (1) and headache (1). A participant can appear under more than one term. The investigator reported none of these events as related to the treatment.

What were the skin reactions in the NPM-139 group?

The two Type IV hypersensitivity reactions occurred in the area of the implant insertion, and were confined to the area where chlorhexidine, the antiseptic used to clean the skin before insertion, had been applied.

Both reactions were graded moderate. The implants were not removed, and both reactions fully resolved with 1% hydrocortisone cream and an oral antihistamine, within 14 days. A different antiseptic was used for the implant removal procedure, and no adverse reactions were observed in any participants.

The investigator reported the reactions as related to chlorhexidine, a known cause of local skin reactions, and not related to study drug.

Why did these reactions occur only in the NPM-139 group?

Only the NPM-139 group had an implant procedure. The Wegovy group received injections, so there was no chlorhexidine skin preparation. Chlorhexidine is not essential to the implant procedure, and other common antiseptics can be used, as they routinely are for people who are sensitive to it.

How do you know the antiseptic, and not the implant, caused the reactions?

The study investigator attributed both reactions to chlorhexidine, and what was observed in the reaction of those patients is consistent with that assessment. The rash was confined to the area where the antiseptic had been applied. The implants stayed in place, and both reactions fully resolved within 14 days with a low-strength steroid cream and an antihistamine. When the implants were later removed using a different antiseptic, no rash appeared.

That is a clinical assessment in two participants. SLIM-1 was a small study, no other participants experienced Type IV hypersensitivity reactions. SLIM-2, as currently proposed, would add experience in more participants over 16 or 24 weeks, including a group that receives a placebo (sham) implant.

Could the implant itself irritate the skin or the tissue around it?

We have seen no evidence of that. In SLIM-1, implant insertions and removals were brief and were completed without complications, and no adverse event in the NPM-139 group was attributed to the implant or to the semaglutide it delivers.

In preclinical studies in rabbits, mice, and in several hundred rats, including toxicology studies, we have not observed problems with local tolerability, and microscopic examination of the tissue surrounding the implants has shown no adverse findings. The rabbit study was a formal skin sensitivity biocompatibility test for devices performed according to regulatory guidance and the result was normal.

The implant technology has also been studied in people before. In our earlier Phase 1 study of an exenatide implant, the implant was generally well tolerated, and skin reactions of this kind did not occur. The U.S. Food and Drug Administration has also cleared an Investigational New Drug application for an exenatide implant built on the same technology.

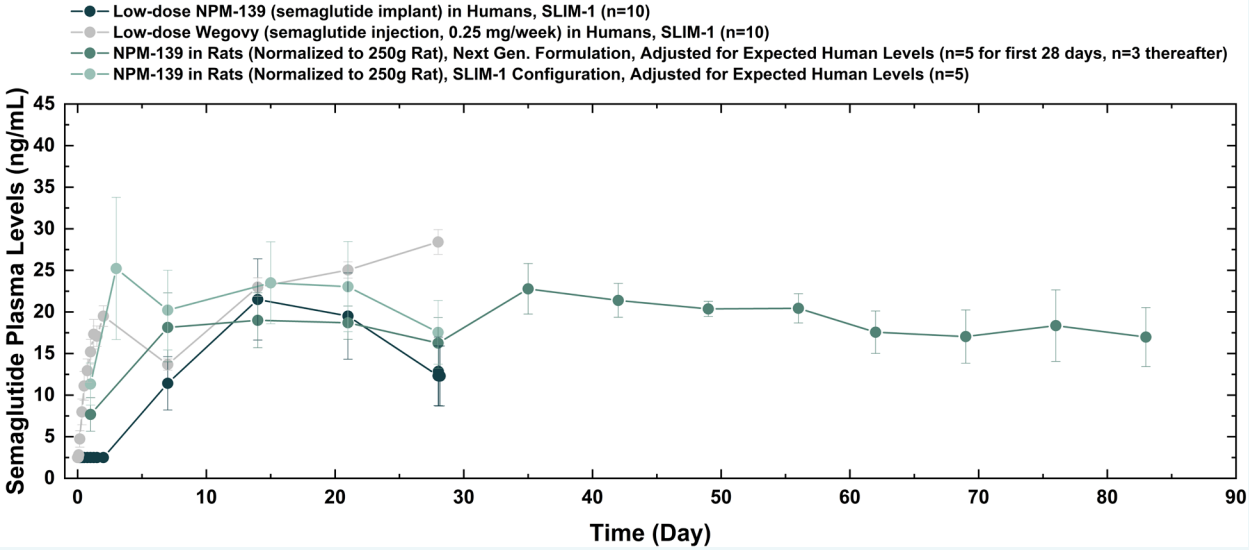
Will anything change in future studies because of the skin reactions?

Yes. Before treatment, we will ask participants specifically about sensitive skin and past reactions to topical agents. We will also recommend that the dressing over the insertion site be removed sooner and the residual antiseptic wiped clean.

Drug levels

Semaglutide plasma levels over time

SLIM-1 participants and rat studies of NPM-139



The Below the Limit of Quantification (BLQ) value was set to BLQ/2 (2.5 semaglutide ng/mL). Rat data are normalized to a 250g rat and adjusted for expected human levels. Source: Vivani corporate presentation, November 16, 2026.

What did the drug-level data show?

NPM-139 released semaglutide gradually. Blood levels were below the measurable limit for at least the first two days and then rose, with the maximum level from the single implant measured at about 16 days. After a single Wegovy injection, the maximum level was measured at about 2.4 days. NPM-139 average drug levels were lower and more variable than Wegovy average drug levels. A post-hoc analysis was conducted of 5 implants selected using a narrower range of an in-process manufacturing criteria that is measured during the manufacturing process on 100% of implants. In this manufacturing subgroup, average drug levels were comparable to the Wegovy group. We expect this subgroup to be representative of implants manufactured going forward.

There was no observed rapid increase in drug exposure with NPM-139.

Why did NPM-139 take about 16 days to reach its maximum drug level?

It reflects a design choice. Our first semaglutide prototypes released drug for a full year in rats, but drug levels at the start were very high. We changed the configuration of the implant to remove that early peak. What replaced it is a start-up phase, in which drug levels build gradually over the first couple of weeks in humans. The absence of any gastrointestinal adverse events reported as treatment-related is encouraging and supportive of the desirability of this profile.

For maintenance therapy, we believe that the gradual rise observed in SLIM-1 may enable continuously effective treatment when the treatment follows dose-escalation with a GLP-1 therapy that has a half-life similar to or longer than the currently available semaglutide and tirzepatide based therapies. Future clinical trials are being planned to evaluate the effectiveness of NPM-139 in this context.

The gradual rise observed in SLIM-1 may also be preferable for GLP-1-naïve patients, and this profile is part of the reason why we are exploring whether NPM-139 may be developed for this treatment-naïve population.

Why does a gradual rise matter?

Rapid increases in drug concentration have been associated with tolerability problems with GLP-1 therapies. Weekly semaglutide is started at a low dose and stepped up over 16 weeks to reduce the risk of gastrointestinal side effects (reference 1). In pooled Phase 3 trials of semaglutide 2.4 mg/wk, those side effects occurred most often during or shortly after dose increases (reference 2).

We think of the NPM-139 profile as a gentle on-ramp. In SLIM-1, it came with no gastrointestinal adverse events reported as treatment-related. That finding comes from a small study and needs to be confirmed in larger ones.

Why did NPM-139 drug levels ease between week three and week four?

We view that shape as expected for the implant configuration used in SLIM-1. The same configuration tested in rats, scaled to expected human levels, held through week three and eased by day 28. The human curve had the same shape. This configuration has not been evaluated in either rats or humans for durations longer than 28 days, but other configurations have exhibited a similar startup profile that is followed by stable levels thereafter. Given that weekly injections are associated with a similar profile whereby the drug levels rise to a maximum intra-week concentration in about 2.4 days and then decline until the next injection is administered, we view the SLIM-1 profile as encouraging. That said, we have observed more recent configurations producing less pronounced initial startup profiles in rodent models, and the good translation from rodents to humans demonstrated by SLIM-1 provides us with optimism regarding the translatability of the newer configurations being developed.

Would levels have kept falling after day 28?

SLIM-1 ran for four weeks by design, so we have no human data beyond day 28. The rat study of the same configuration also ended at day 28.

Based on our preclinical experience, we expect that release from the SLIM-1 configuration would have stabilized and continued had it been studied for longer. We are now working with a next-generation formulation that is being studied over a longer period.

What do the longer animal studies show?

In rats, the next-generation formulation was associated with semaglutide levels which held in a steady band after an initial startup phase over the first couple of weeks through day 84, when that study ended. Earlier prototype semaglutide implants showed sustained delivery for a full year in rats, and independent prototype implants with both exenatide and retatrutide have delivered drug for about six months.

The animal curves in our corporate presentation end where they do only because those studies ended at those points. We expect release to continue beyond them, as it did in the year-long prototype study and in the exenatide and retatrutide implant studies.

How much weight should be placed on animal data?

The early drug exposure profile in humans resembled what we saw in a rodent study using the corresponding implant design.

This matters for two reasons. First, our earlier, longer-duration preclinical studies give us considerable optimism about our work to develop and test higher-dose implant designs intended to deliver medicine for up to six months. That work builds on a semaglutide implant prototype that showed sustained delivery for a full year in rats.

Second, the encouraging similarity between the early animal and human results in SLIM-1 gives us greater confidence that the higher-dose longer-duration implant designs being developed through these preclinical studies may also perform as expected once they are studied in people in SLIM-2.

The manufacturing subgroup

What is the "manufacturing subgroup"?

All ten SLIM-1 implants met the release specification in place when they were made. Within that specification, they varied on an in-process manufacturing measurement that is recorded for each unit before implantation.

When we compared that measurement with each participant's drug levels, the five implants in a narrower part of the range delivered higher drug levels. Those five are the manufacturing subgroup.

Was the subgroup defined before or after the results were known?

After. The narrower range was identified once the drug-level results were available. It is a retrospective analysis of five participants and should be read with that in mind.

Why does this matter going forward?

The measurement is taken before implantation, so it can be applied going forward as a tighter manufacturing specification. We anticipate applying that tighter specification and developing processes with a high yield within it. We expect implants made to it to be representative of how NPM-139 performs in future studies.

This is part of the value of a first-in-human study. It showed us which part of our manufacturing range performs best before we commit to a larger trial.

Weight

How much weight did participants lose?

After four weeks, mean weight loss was 0.79% (0.67 kg) in the NPM-139 group and 0.82% (0.76 kg) in the Wegovy group. Average weight loss was numerically similar in the two groups. The study was not designed to establish that the treatments provide equivalent weight loss or that one is safer than the other.

Why were the weight changes so small?

Both groups received low doses of semaglutide per week for four weeks. SLIM-1 participants in the Wegovy arm received the Wegovy starting dose of 0.25 mg/week. Wegovy's recommended maintenance doses are 1.7 mg or 2.4 mg per week, reached after 12 or 16 weeks of dose increases (reference 1).

A starting dose given for four weeks is not expected to produce the weight loss seen at maintenance doses over many months. Furthermore, no lifestyle modifications such as diet and exercise were incorporated into this study.

Does SLIM-1 show that NPM-139 works as well as Wegovy?

Consistent with First-in-Human studies, SLIM-1 was a small study and not designed to evaluate relative efficacy. Average weight loss was numerically similar in the two groups over four weeks. The study was not designed to establish that the treatments provide equivalent weight loss or that one is safer than the other. Larger, longer studies at higher doses are needed to evaluate efficacy, beginning with Phase 2.

What comes next

What are the next steps for NPM-139?

We are currently working to finalize the development of higher-dose longer-duration configurations for use in SLIM-2, a dose-ranging weight maintenance trial. We anticipate initiating SLIM-2 in 2027, subject to successful completion of the ongoing preclinical work, applicable regulatory requirements, and availability of funding.

Based on the SLIM-1 tolerability profile, we will also explore the potential for clinical development of NPM-139 in people who have not previously taken a GLP-1 medicine.

What has to happen before SLIM-2 can begin?

SLIM-2 is planned to test higher doses than SLIM-1, over a longer period. That calls for implant configurations designed for higher doses and durations of up to six months. Configurations of that kind have been manufactured and are now in preclinical testing. In parallel, we are building tighter controls into our manufacturing process.

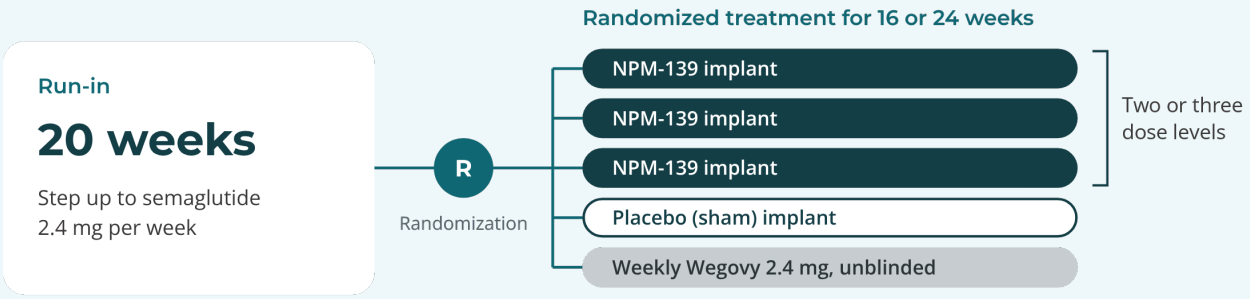
We anticipate that the full characterization of those configurations, or of a further iteration that would begin testing early in 2027, will be the last data needed for the IND application. The IND is intended to support the start of SLIM-2.

What is the proposed design of SLIM-2?

As currently proposed, participants would first step up to semaglutide 2.4 mg per week during a 20-week run-in. People who have already lost weight on a GLP-1-based therapy could skip the run-in.

Participants would then be randomized to one of two or three NPM-139 dose levels, a placebo (sham) implant, or weekly Wegovy 2.4 mg, for 16 or 24 weeks, with about 25 to 40 participants in each group. The Wegovy group would be unblinded. The design is a proposal and may change with regulatory feedback.

Proposed design of SLIM-2



About 25 to 40 participants are proposed for each group. The above schematic represents a trial design assuming three implant doses are evaluated. People who have already lost weight on a GLP-1-based therapy could skip the run-in. The design is a proposal and may change with regulatory feedback.

Will SLIM-2 use the same implant as SLIM-1?

No. SLIM-1 used a low-dose configuration studied for 28 days. We expect SLIM-2 to use configurations designed for higher doses and durations of up to six months, building on the next-generation formulation shown in our rat data. We do not currently plan a separate human study before SLIM-2.

The encouraging similarity between the early animal and human results in SLIM-1 gives us greater confidence that the implant designs developed through these preclinical studies may also perform as intended in people in SLIM-2. Longer-duration delivery in humans remains to be demonstrated.

How big a step is it from the SLIM-1 implant to the one planned for SLIM-2?

We anticipate that it will be a matter of engineering, not of developing new technology. The same technology has released a low dose of semaglutide for a full year in rats but with higher startup drug levels than desired. With a next-generation formulation, it exhibited a desirable startup profile and held steady levels after the startup phase for the remainder of the three-month duration in rats over which it was studied. In SLIM-1, the separate low-dose configuration showed an early drug exposure profile in humans that resembled what we observed in rats.

What remains to be shown is that performance at higher doses over periods of up to six months. Testing is now under way to show this performance in rats. SLIM-2 is designed to test higher doses in people over 16 or 24 weeks.

Can the implant be removed if treatment needs to stop?

Yes. NPM-139 is being designed to be removable, with drug levels then expected to fall about as quickly as they do after a weekly injection is stopped. In SLIM-1, implant removals were brief and were completed without complications. We believe this is an important potential advantage particularly over monthly injectable GLP-1 candidates under development where the elimination of GLP-1 drug levels will take much longer. For example, discontinuation of GLP-1 therapy is recommended in pregnant women and in pre-surgery patients with a high aspiration risk.

What is the status of Novo Nordisk's evaluation of NPM-139?

Vivani continues to support Novo Nordisk's evaluation of NPM-139 and the NanoPortal technology under the non-exclusive agreement announced in July 2026. We do not comment on confidential discussions with potential collaborators.

Company and further information

When will more SLIM-1 data be available?

The November 12 press release and our corporate presentation contain top-line data. We intend to share additional information publicly as it becomes available and is fully analyzed.

Where can I find the source materials?

- Press release: Vivani Medical Announces Positive Top-Line Results from SLIM-1 (November 12, 2026)
- Press release: Vivani Medical Announces Private Placement Equity Financing (November 16, 2026)
- Corporate presentation (November 16, 2026)
- Quarterly Report on Form 10-Q for the quarter ended September 30, 2026

All four are available at www.vivani.com. Questions can be sent to investors@vivani.com.

Important information

NPM-139 is an investigational product. Its safety and efficacy have not been established, and it has not been approved by the U.S. Food and Drug Administration or any other regulatory authority. Any data or statistics set forth herein is preliminary and any views or opinions as a result of such information cannot be confirmed and may change with future clinical trials. Wegovy® is a registered trademark of Novo Nordisk A/S. This document is not an offer to sell or a solicitation of an offer to buy any securities.

References

1. Wegovy® (semaglutide) U.S. prescribing information, Section 2.2.
2. Wharton S, et al. Diabetes Obes Metab. 2022;24(1):94–105.

Forward-looking statements

This document contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that are used in this document, including statements regarding Vivani's business, products in development, including the safety, tolerability, therapeutic potential or the planned development thereof, and its technology, strategy, cash position and financial runway. These statements also include statements concerning the usefulness of preclinical models and the potential for longer-duration delivery in humans; the development and characterization of higher-dose implant configurations; the anticipated timing and initiation of SLIM-2; and the market opportunity.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on Vivani's current beliefs, expectations, and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of Vivani's control. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, risks of unexpected costs or delays, and risks and uncertainties associated with the development and commercialization of products and product candidates that may impact or alter anticipated business plans, strategies and objectives. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Vivani's expectations in any forward-looking statement. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties are more fully described in periodic filings with the U.S. Securities and Exchange Commission (the "SEC") including the factors described in Vivani's most recent Quarterly Report on Form 10-Q filed with the SEC on November 12, 2026, as updated by future filings with the SEC. Any forward-looking statement made by Vivani in this document is based only on information currently available to the Company and speaks only as of the date of this document. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of added information, future developments or otherwise, except as required by law.

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