August 21, 2026

Egetis Therapeutics

Q2 2026

QUARTR

MODULAR FINANCE

Speakers

Operator

Nicklas Westerholm
CEO | Egetis Therapeutics

Anny Bedard
President of Egetis North America | Egetis Therapeutics

Henrik Krook
VP of Commercial Operations | Egetis Therapeutics

Yilmaz Mahshid
CFO | Egetis Therapeutics

Kristen Kluska
Analyst | Cantor Fitzgerald

Chiara Montironi
Analyst | Van Lanschot Kempen

Clémence Thiers
Analyst | Stifel

Prepared Remarks

Operator

Welcome to Egetis Therapeutics Q2 Report 2026. For the first part of the conference call, the participants will be in listen-only mode. During the questions and answers session, participants are able to ask questions by dialing pound key five on their telephone keypad. Now I will hand the conference over to CEO Nicklas Westerholm. Please go ahead.

Nicklas Westerholm
CEO | Egetis Therapeutics

Thank you, operator. Good afternoon, good morning, and a warm welcome to Egetis Therapeutics quarter two results webcast, planned for the coming 30 minutes. For those who I haven't had the privilege to meet before, my name is Nicklas Westerholm, and I am the CEO of the company. I will start today's session with a short business update. This will be followed by Anny Bedard, President of our U.S. and North American business, who will discuss the launch preparations for the planned Emcitate launch in the U.S., subject to approval. Then Henrik Krook, Vice President, Commercial Operations, will give a commercialization update of Emcitate in the European Union, as well as other international markets. Finally, Yilmaz Mahshid, Chief Financial Officer, will provide a financial update before we're looking ahead to the exciting upcoming key value-enhancing milestones. We aim to leave ample time for Q&A at the end of the session.

Nicklas Westerholm
CEO | Egetis Therapeutics

The most significant event during the first half of 2026 was the acceptance of our U.S. New Drug Application, NDA, for Emcitate. The grant of a priority review by the FDA, with a PDUFA date set for September 28. So far, it has been a collaborative dialogue with the agency throughout the review. The FDA has confirmed that it expects to finish its review by the PDUFA date on September 28, and does not plan to hold an advisory committee meeting. Subject to approval, the Emcitate launch in the U.S. is planned for the fourth quarter this year. During the second quarter, we were also granted our first patent for Emcitate by the U.S. Patent and Trademark Office. The patent provides protection for a novel composition with tiratricol as the active ingredient.

Nicklas Westerholm
CEO | Egetis Therapeutics

The claims cover, amongst other things, a method of treating MCT8 deficiency with a claimed pharmaceutical composition that encompasses tiratricol dosing regimes and tiratricol composition with specific excipients. This patent is a significant milestone in strengthening our intellectual property portfolio. We expect the granted patent to be Orange Book listable with an expiration date of 2045. Revenue for the fourth quarter was SEK 17.4 million, corresponding to year-on-year growth of 23% at constant exchange rate. As Henrik will describe further, the Emcitate price negotiations within the German reimbursement process, AMNOG, were successfully concluded in the second quarter. Furthermore, in the quarter, we also successfully carried out a substantially oversubscribed directed share issue amounting to SEK 350 million, approximately $38 million, at the closing price on Nasdaq Stockholm on the day of the raise.

Nicklas Westerholm
CEO | Egetis Therapeutics

We were particularly pleased to see strong participation from both existing shareholders and several new international specialist healthcare investors, which will further broadening our shareholder base. Last but not least, we are pleased to welcome Tiago Nunes, a very seasoned drug developer, as our new Chief Medical Officer in May. One of Tiago's main tasks will be to drive Emcitate's exciting indication expansion opportunity in Resistance to Thyroid Hormone type beta forward in the short-term future. I will now hand over to Anny. Anny, please go ahead.

Anny Bedard
President of Egetis North America | Egetis Therapeutics

Thank you, Nick. Good afternoon, and good morning, everyone. We are approaching an exciting milestone, one that could bring the first approved therapy to a community that has waited a long time for it. With fewer than 30 business days to the PDUFA date, our focus is now on disciplined execution to enable the U.S. launch in Q4. Since our Q1 update, we have completed the build-out of our U.S. commercial organization. Our medical affairs and field team are fully trained and deployed, and an experienced team of rare disease professionals is now executing a single integrated launch plan. The organization is just over 20 employees today, supplemented by specialized consultants and will scale to around 25 at launch. Launch readiness activities are advancing across all critical work streams depicted on this slide. The patient support services operating model has been established.

Anny Bedard
President of Egetis North America | Egetis Therapeutics

Payer engagement and value communication activities are underway, and specialty distribution and supply partners have been contracted. We continue to expand engagement with the specialist physicians most likely to diagnose and treat MCT8 deficiency. These are the pediatric endocrinologists, pediatric neurologists, and geneticists, while expanding patient identification efforts to increase diagnosis and support long-term market development. Our continued engagement with patient advocacy organization helps increase disease awareness, support patient identification efforts, and inform our understanding of community needs. Our top priority at launch will be continuity of care for patients currently receiving tiratricol through the expanded access. Ensuring a seamless transition to commercial supply reduces the risk of treatment interruption and supports initial commercial adoption. Today, approximately 60 patients across 17 sites nationwide are being treated under the expanded access program, a number that continues to grow month-over-month.

Anny Bedard
President of Egetis North America | Egetis Therapeutics

We are prepared to support each patient's transition across the key touchpoints, confirming the treating physicians, enabling prescription, and coordinating access support. This includes prescriber and caregiver education ahead of approval, along with affordability programs and bridging support designed to keep treatment access uninterrupted throughout the transition. We are also establishing coordination across physicians, the specialty pharmacy, patient services, and payers so any potential barrier can be identified and resolved quickly. In parallel, we will continue to engage known patients not yet on therapy while expanding diagnosis and patient identification. With the organization built, the infrastructure being activated, and patient transition plans advancing, we believe the U.S. business is positioned to execute at approval and deliver on a successful launch in Q4. Most importantly, we are doing this for a patient community that has had no approved therapy options to date, and we are really energized by the opportunity to change that.

Anny Bedard
President of Egetis North America | Egetis Therapeutics

Thank you. I will now turn it over to Henrik for an update on commercialization in Europe and international markets.

Henrik Krook
VP of Commercial Operations | Egetis Therapeutics

Thank you, Anny. For Europe and other international markets, Q2 was another quarter of progress for Emcitate with continued revenue growth, the conclusion of the German reimbursement process, and further expansion of access beyond our initial launch market. Revenue in Q2 was SEK 17.4 million, with Germany as the largest contributor. This corresponds to 23% growth at constant exchange rates compared with Q2 last year and approximately 30% sequential growth compared with Q1. In Germany, the AMNOG price negotiations with GKV were concluded during the quarter. We are pleased that the German authorities recognize the value of Emcitate. The new negotiated price and further insights into daily dosing leads to an estimated average annual treatment cost just below EUR 200,000. This is an important step whilst we continue our field-based work with pediatric endocrinologists, pediatric neurologists, other specialist physicians, and relevant treatment centers to develop the German market further.

Henrik Krook
VP of Commercial Operations | Egetis Therapeutics

Here, I would like to make a clarification because one Swedish analyst has misunderstood how sales revenue is accounted for. In Germany, in May 2025, we started commercial sales based on an initial price. In line with how the German system works, our reported sales have reflected the final negotiated price based on our assumptions, meaning that all our reported sales revenue since November 2025 accounts for the final negotiated price. Beyond Germany, we are progressing toward reimbursed access in additional European countries. In Spain, the national pricing and reimbursement dossier has been submitted. In Italy and France, we plan to strengthen the value dossiers with Emcitate survival data once it has been published in a peer-reviewed journal. At the same time, we continue to use funded access routes where available in other European countries, helping treatment reach patients through the most appropriate access pathway in each country.

Henrik Krook
VP of Commercial Operations | Egetis Therapeutics

Internationally, we also see growing reach through our distribution partners. We are supported by Er-Kim in Turkey plus Central Eastern and Southeastern Europe and by Taiba Rare in the Gulf region. Both Er-Kim and Taiba Rare are actively identifying patients and initiating the processes aiming for funded treatment, which contributed to named patient sales revenues in Poland and Turkey in the quarter. After the quarter, we also signed a collaboration and supply agreement with Orspec Pharma for Australia and New Zealand, further broadening the geographic reach for Emcitate. So taken together, this reflects solid commercial progress. Germany now has an agreed reimbursed price. We are advancing funded pathways in key European countries, and our partner model is helping us reach patients in additional geographies. With that, I would like to hand over to our CFO, Yilmaz.

Yilmaz Mahshid
CFO | Egetis Therapeutics

Thank you, Henrik. To start with, all numbers, unless called out, are in our reporting currency, Swedish Krona. Revenue for the first three months was SEK 17.4 million versus SEK 14.5 million in the same period last year, corresponding to a year-over-year growth of 23% in constant exchange rates. The gross profit is SEK 3.6 million. This comes back to the continued depreciation of balance sheet R&D, a non-cash item. Excluding the quarterly depreciation of SEK 10.1 million, gross profit would have been SEK 13.7 million, corresponding to an adjusted gross margin of approximately 79%, which is considerably stronger than the 74% in the last quarter. As long as we are in an initial ramp-up phase in Europe, the depreciation will have a meaningful impact on the reported gross margin. However, we anticipate this to gradually dissipate as we start rolling out Emcitate in the U.S. post a potential FDA approval.

Yilmaz Mahshid
CFO | Egetis Therapeutics

Q2 2026 operating results were -SEK 109.3 million, versus -SEK 78.5 million in the prior period. Just want to highlight that SEK 5.6 million of the administrative costs booked in the quarter are employee stock option plan related bookings and a non-cash item. This is a year-over-year delta of SEK 12.5 million, as the Q2 2025 numbers included a positive booking of SEK 6.9 million. Also, a one-time cost of approximately SEK 4 million was booked during this quarter for social charges in connection with the ESOP exercise. These numbers should help you understand the underlying administrative cost line item during the quarter. Overall, the lower results are due to our continued investments and the work with the U.S. NDA, U.S. commercial build-up, and corresponding pre-launch activities.

Yilmaz Mahshid
CFO | Egetis Therapeutics

The management, the board, and our main shareholders are all aligned that investing in the U.S. is a key priority, as we believe this will be by far our most important market and where we need to succeed. For the second quarter, cash flow from operating activities were at -SEK 93.9 million, versus -SEK 59 million. As highlighted in the report, we did strengthen the cash position further on April 21st. In total, we did raise SEK 350 million, corresponding to approximately $38 million on a gross basis. The high demand for the shares offered were depicted by the fact that they were issued at a share price of SEK 5.25, which correspond to a 0% discount to the market close the same day. With the cash from this transaction, we ended the quarter with a healthy cash position of SEK 378 million, corresponding to approximately $40 million.

Yilmaz Mahshid
CFO | Egetis Therapeutics

With that, I would like to hand back to Nicklas.

Nicklas Westerholm
CEO | Egetis Therapeutics

Thank you, Yilmaz. Let me summarize. Whilst reflecting for the first two quarters of 2026, I am very proud to say that we have had several key deliverables that has been with a very successful outcome. Let me also remind you of the upcoming milestones for Egetis. We have a PDUFA date set for September 28. Subsequently, subject to approval, we expect to launch Emcitate in the U.S. in quarter four, our most important market. Also worthwhile noting is being granted a priority review voucher upon approval, it is likely that monetization of such a priority review voucher could take place in quarter four. Of note is that PRV sold in 2026 have fetched between $180 million and $220 million each. Last but not least, the preparation of indication expansion into RTH-beta, our next exciting pipeline opportunity, is now progressing at pace.

Nicklas Westerholm
CEO | Egetis Therapeutics

We are convening a scientific advisory board with key opinion leaders in the field to finalize the development program for Emcitate in RTH-beta, and are in parallel preparing for regulatory interactions to agree the overall development pathway with the aim of starting a clinical study during 2027. Of note is that we have today over 50 patients with RTH-beta that are being treated with Emcitate as a part of a managed access program. In summary, we believe that the commercial opportunity here could be on par with the one for MCT8 deficiency. With that, I will hand over to the operator for Q&A. Thank you.

Q&A

Operator

If you wish to ask a question, please dial pound key on your telephone keypad to enter the queue. If you wish to withdraw your question, please dial pound key six on your telephone keypad. The next question comes from Kristen Kluska from Cantor Fitzgerald. Please go ahead.

Kristen Kluska
Analyst | Cantor Fitzgerald

Hi, good afternoon, everybody, and congrats on all of the progress over this last quarter. While respecting you are still very much in active review with the FDA, can you give us any high-level feedback on the mid to late cycle meeting? Was there anything substantial that came up? Anything that surprised you, for example?

Nicklas Westerholm
CEO | Egetis Therapeutics

Thank you, Kristen, and great to hear from you. Well, in essence, we, as always, don't communicate around ongoing regulatory interactions. Having said that, though, to give some more color, as mentioned during the call, it's been a very constructive and productive dialogue with the FDA. The FDA has also reiterated that they will hold true to the PDUFA date set on September 28. They are not planning to hold an advisory committee, and of course, with respect to that, if something would have materially deviated with our internal plans, i.e., PDUFA date on the 28th, that would've been seen as material, and subsequently, we would have to notify the market. I think all in all, internally, we are very pleased with the dialogues with the agency so far and looking forward to the PDUFA date on the 28th.

Kristen Kluska
Analyst | Cantor Fitzgerald

Okay. I appreciate those comments. Thank you. Then on the survival data, I know we could expect this perhaps in a peer-reviewed journal at some point, but can you just remind us, has the FDA reviewed these data yet? I know you can't comment on all of the findings, just to hold it for that journal, but again, high level, what do those data perhaps include that haven't been reported, again, without getting into the specifics of findings? Thank you very much.

Nicklas Westerholm
CEO | Egetis Therapeutics

Thank you, Kristen, and again, here, I fully appreciate your question. Can't give too much more granularity on that, unfortunately. The data, as you mentioned, has not yet been published in a peer-review journal. But as mentioned previously, both during calls like this and through reports, if you think about the new drug application that was submitted, it included data from numerous clinical studies, clinical trial one, trial two, the re-trial study, and also the survival study. Of course, that being part of a submission package, the FDA have reviewed and looked across the different studies to provide a view on the benefit-risk profile of the drug.

Kristen Kluska
Analyst | Cantor Fitzgerald

Thank you so much.

Nicklas Westerholm
CEO | Egetis Therapeutics

Thank you, Kristen.

Operator

The next question comes from Chiara Montironi from Van Lanschot Kempen. Please go ahead.

Chiara Montironi
Analyst | Van Lanschot Kempen

Hello, team. Thanks for taking my question, and congrats with the progress. You now disclose that 60 patients are treated in the early access programs versus 40 at the beginning of the year. I was wondering whether new 20 patients are previously identified patients, or these are completely new diagnoses.

Nicklas Westerholm
CEO | Egetis Therapeutics

No, thank you, and you're absolutely right, Chiara, and thank you for your question, by the way. at the start of the year, we had roughly or approximately 40 patients on the EAP program, so the progress here has been very good. We have now around 60 patients, as Anny mentioned, enrolled. We don't give the granularity if these are patients newly identified or previously identified, but I will now invite Anny to comment further, if any.

Anny Bedard
President of Egetis North America | Egetis Therapeutics

Yes. Thank you. We have 17 sites across the country that are engaged in treating these patients pre-approval. And of course, these are now serving as reference sites for other physicians who identify patients. So having those physicians with experience with treating these patients and with tiratricol is significantly raising awareness across the other physicians and in the community. So that has been a contributor to having more patients wanting and requesting to join this program.

Chiara Montironi
Analyst | Van Lanschot Kempen

Clear. Thank you. I appreciate the color. If I may, a follow-up question. If Emcitate were to be approved in September, how long it will take to convert the early access program patients to the commercial product, and which element could delay the transition, in your opinion?

Nicklas Westerholm
CEO | Egetis Therapeutics

Thank you, Chiara, and of course, a very valid question. I think it's, again here, premature to comment on in detail around how long time it will take to transition the EAP patients over to commercial-type patients. This is obviously something the team is working very hard on, mapping out the different patient flows throughout the value chain. But I invite Anny to comment somewhat further, if you can add some more granularity to this.

Anny Bedard
President of Egetis North America | Egetis Therapeutics

Yes. So this will be a main priority for us because we want to make sure that treatment is uninterrupted for those patients. As it is standard in rare disease, we'll have affordability support and bridge mechanisms in place in order to safeguard this continuity of care. As Nick mentioned, we're not going to go into the detail at this time on specific number of days for transition. But that will be the core focus of our activities at the time of the launch, and we anticipate that this will be successful.

Nicklas Westerholm
CEO | Egetis Therapeutics

And maybe to build on further, rest assured, Chiara, that this is a key priority, just reiterating what Anny said before, for the organization to ensure a very swift, smooth, coordinated transition from the expanded access program to commercial supply, obviously driven to a certain extent by minimize treatment disruption, but also support earliest commercial uptake once approved. So thank you for the question, Chiara.

Chiara Montironi
Analyst | Van Lanschot Kempen

Of course.

Operator

The next question comes from Clémence Thiers from Stifel. Please go ahead.

Clémence Thiers
Analyst | Stifel

Hi. Thanks for the presentation and thanks for taking my question. Just a bit of focus on Europe. Might be a candid question, but regarding the price in Germany, you mentioned just below EUR 200,000, right? Can you confirm that this is a negotiated reimbursement price, and obviously you can disclose anything, do you expect a material difference with the net price? That would be the first question.

Nicklas Westerholm
CEO | Egetis Therapeutics

Thank you, Clémence. I can start, and I invite Henrik to comment. As we mentioned during the launch process, May 2025, the estimated average annual treatment cost per patient was just above EUR 200,000 per patient, per annum. With the new negotiated price and further insights about daily dosing, which is important component looking at annual treatment cost, the average annual treatment cost now is estimated to be just below EUR 200,000. We do not go into sharing any confidential rebates, et cetera, but this is based on the list price available for pharmacies in Germany.

Clémence Thiers
Analyst | Stifel

Okay. Perfect. Thank you. Maybe looking ahead on RTH-beta, as you finalize the development plan, can you say Sorry, am I interrupting?

Nicklas Westerholm
CEO | Egetis Therapeutics

No, not at all. I got so excited about the question, so.

Clémence Thiers
Analyst | Stifel

I was saying, can you say at this stage what an approvable program could look like in terms of number and size of studies, endpoints, and how much of the existing MCT8 technical and safety package could help sort of streamline that program?

Nicklas Westerholm
CEO | Egetis Therapeutics

Sure. Clémence, that's a really good question. I got so excited by you asking it since this is a very important feature of the long-term future of the company building a sustainable rare disease organization. It's somewhat premature to comment on some of the questions you had there. What we're doing today is that we are in the last stages of finalizing a target product profile, a clinical development plan. As I mentioned, we are convening an advisory board of key opinion leaders, which will be gathering face-to-face around the European Thyroid Association Conference in Portugal in September. Subsequent to that, we have an ambition to finalize the design and start engaging with FDA and EMA on the regulatory pathway. The ambition here is, of course, to utilize as much data as possible from MCT8 deficiency when it comes to safety database.

Nicklas Westerholm
CEO | Egetis Therapeutics

We have a huge safety database with a substantial number of years with patient exposure. So that is, of course, something to be utilized further in the RTH-beta development program. The same goes for non-clinical and the studies being carried out there ahead of the U.S. approval. So with that in mind, it's a bit premature to comment on endpoints, sample size, number of centers, et cetera, but rest assured that is something we'll update the market on as soon as we have concluded that internally.

Clémence Thiers
Analyst | Stifel

Okay, perfect. Thank you so much.

Nicklas Westerholm
CEO | Egetis Therapeutics

Thank you. I think that brings us to the end of the call. We appreciate your participation and wish you a great rest of the day. Thank you.