CLOSER LOOK

MEMORANDUM

Roche 3Q25 – Dual GLP-1/GIP RAs CT-388 and CT-868 will advance to p3; full-year Vabysmo guidance lowered amid US market contraction; BGM sales decline 2% – October 23, 2025

Executive Highlights

- **Roche announced its 3Q25 financial results** on a call today led by CEO Dr. Thomas Schinecker, Roche Pharmaceuticals CEO Ms. Teresa Graham, Roche Diagnostics CEO Mr. Matt Sause, and CFO Dr. Alan Hippe. See Roche's press release, company presentation, and webcast.
- **While Diabetes Care sales were not disclosed[1],** BGM sales declined 2% at constant exchange rate (CER), which management has historically attributed to the market's shift to CGM. This translates to estimated revenue of CHF 302 million (~$380 million) in the quarter. Mr. Sause expressed confidence that Roche's Accu-Chek SmartGuide CGM will drive long-term growth and be a "blockbuster" in Near Patient Care (which declined 4%).
- **In ophthalmology,** a persistent US contraction of the branded market driven by funding deficits from co-pay assistance foundations led Roche to reduce its full-year 2025 guidance for anti-VEGF therapy Vabysmo (faricimab-svoa). The company lowered guidance to 15% from its previously issued 20% growth.
    - **Susvimo (ranibizumab) sales totaled CHF 6 million ($7.5 million), up 117% CER from 3Q24.** Susvimo (ranibizumab) 100 mg/dL is a refillable eye implant that delivers an anti-VEGF as an alternative to injections. The therapy is currently available in the US, and, as Roche reported today, has been submitted to the EMA for review. Roche also highlighted that seven-year data recently presented confirms the therapy's ability to maintain vision and avoid retinal drying over this time period.
- **In the cardiovascular-renal-metabolic (CVRM) pipeline,** Roche decided to advance CT-388 (once-weekly GLP-1/GIP RA) for obesity and CT-868 (once-daily GLP-1/GIP RA) for T1D with BMI ≥25 kg/m^2 to phase 3 trials. Both trials are expected to launch in 2026. Based on phase 2 results of CT-388 and amylin analog petrelintide (co-developed with Zealand Pharma), Roche also plans to launch phase 2 trial of the combination therapy in 2026.
    - **On its cardiovascular pipeline,** Roche initiated the phase 3 ZENITH CVOT (n=11,000) for zilebesiran (angiotensinogen inhibitor) for people with unmanaged hypertension on a diuretic and at least one other antihypertensive medication. The trial is expected to complete in 2030.
    - **On MASH,** the company announced in September 2025 plans to acquire San Francisco-based 89bio and its lead candidate pegozafermin, an FGF21 analog. Roche tendered an offer to 89bio shareholders, which represents a total deal value of up to $3.5 billion. Pegozafermin is currently evaluated in three phase 3 studies for the treatment of moderate-to-severe fibrosis (F2-F3) related to MASH (ENLIGHTEN-Fibrosis), cirrhosis (F4) related to MASH (ENLIGHTEN-Cirrhosis), and severe hypertriglyceridemia (ENTRUST).
- **Roche broke ground in August** to build a new site in Holly Springs, NC, which will support its obesity portfolio.

- [1] Roche no longer reports standalone Diabetes Care sales after merging this business into the Near Patient Care segment within the Diagnostics division last year.

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Technology Highlights

1. Accu-Chek SmartGuide manufacturing ramps; BGM sales decline 2%

Mr. Schinecker again described Accu-Chek SmartGuide[1] as a future blockbuster for Roche's Near Patient Care division following its 3Q24 launch in select EU markets. Roche is now focused on building manufacturing. For reference, in 1Q25, Roche announced that as part of its $50 billion investment in US operations it will construct a new CGM manufacturing facility in Indiana. We are interested in Accu-Chek SmartGuide's US regulatory status and launch timeline; while the company has not recently commented on plans on this front, Dr. Julien Boisdron (CMO, Roche Diabetes Care) said at ATTD 2024 that Roche was in active discussions with the FDA.

- **While Diabetes Care revenue was not disclosed,** BGM sales declined 2% CER this quarter, which Mr. Sause has previously attributed to continued CGM adoption. Nonetheless, Mr. Sause reiterated confidence in the long-term growth capabilities of Accu-Chek SmartGuide. We estimate BGM revenue of CHF 302 million (~$380 million). Roche's year-over-year BGM revenue change has declined for nearly 20 quarters now (since 2Q21), though nearly every quarter since 3Q21 has fluctuated between ~CHF 300-400 million.

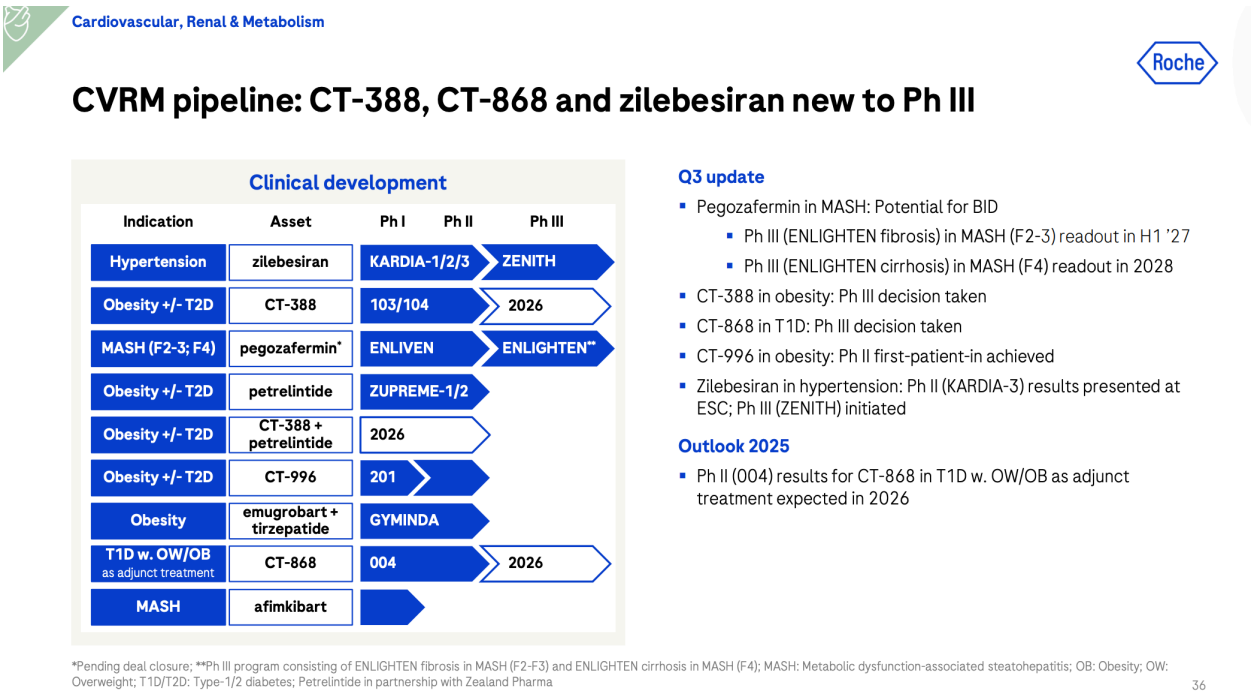
2. Roche launches AI-powered Kidney Klinrisk Algorithm to predict CKD progression

Roche's press release and presentation highlighted the recent CE-Marking of its AI-powered Kidney Klinrisk Algorithm, a medical device software that estimates the risk of progressive kidney function decline in adults with CKD (G1-G4), diabetes, or hypertension. As background, the algorithm draws on routinely available blood and urine biomarkers to estimate the probability of kidney function decline; by combining these panels with algorithmic risk assessment, individuals at higher risk of CKD progression can be prioritized in the clinic. As the existing Kidney Failure Risk Equation (KFRE) guides management in advanced CKD (stages G3-G5), Roche aims to facilitate earlier risk assessments of patients and coordinated care across clinical teams. The Kidney Klinrisk Algorithm is now available within Roche's navify Algorithm Suite in Europe and the UK. Expansion to the US, Middle East, and Asia is anticipated as well.

Therapy Highlights

1. Cardiometabolic pipeline: GLP-1/GIP RA CT-388, CT-868 for T1D, and zilebesiran advance to phase 3

Roche shared key updates to its CVRM pipeline, including decisions to advance incretin therapies CT-388 and CT-868 to phase 3. See detailed updates below:



Source: Roche 3Q25 presentation, page 36

- **CT-388 (once-weekly dual GLP-1/GIP RA):** CT-388 is currently being evaluated in phase 2 trials for people with obesity with (n=360) or without T2D (n=450), expected to complete in November and February 2026, respectively. Full phase 2 results for obesity will be available early 2026. As announced in the Roche Pharma Day, the company decided to advance CT-388 for a phase 3 trial for obesity, which is expected to initiate in 1H26.
    - **In a phase 1b trial,** CT-388 demonstrated ~12% weight loss at Week 12 and ~19% weight loss at Week 24 in people with obesity but not diabetes. In those with obesity and T2D, A1c fell 3.0% over 12 weeks vs. 0.2% on placebo. Moreover, a subgroup analysis (n=129) presented at ADA 2025 found benefits in MASH and fibrosis. At 24 weeks, 85% of participants with obesity and MASLD experienced a placebo-adjusted reduction in liver fat content by 59% and approximately one-stage improvement in fibrosis.
    - **A phase 2 trial of fixed-dose combination of petrelintide and CT-388** is expected to launch in 2026, with trial design informed by phase 2 results of petrelintide and CT-388 monotherapies.
- **CT-868 (once-daily dual GLP-1/GIP RA):** Excitingly, Roche announced that it has decided to advance CT-868 to phase 3 for people with T1D and BMI ≥25 kg/m^2. The trial is expected to initiate in 2026. The decision is based on the 16-week phase 2 trial (n=111) completed in July 2025. Phase 2 results are expected in 2026.
- **CT-996 (once-daily oral GLP-1 RA):** A phase 2 trial (n=340) launched in July 2025, with the first-patient-in achieved. The trial is expected to complete in July 2026. Previously, in a phase 1 trial, CT-996 demonstrated ~7% weight loss at four weeks.

- **Petrelintide (long-acting amylin analog):** Two phase 2 trials are ongoing: (i) the 42-week phase 2b ZUPREME-1 trial (n=494) for people with overweight or obesity, expected to complete in March 2026; and (ii) the 28-week phase 2 ZUPREME-2 trial (n=216) in people with overweight or obesity and T2D, expected to complete in June 2026. These trials follow phase 1b results in which petrelintide demonstrated placebo-adjusted weight loss of up to 6.9% after 16 weeks, with most adverse events reported as mild. Zealand Pharma and Roche are co-developing and co-commercializing petrelintide and a combination therapy with CT-388 under the partnership announced in March 2025.
- **GYM 329 (anti-latent myostatin antibody):** The phase 2 GYMINDA trial (n=234), evaluating the combination of GYM 329 and tirzepatide in obesity, was initiated in 2Q25 and is expected to complete in September 2027. Of note, GYM is also evaluated in phase 2/3 trial (n=259) for spinal muscular atrophy and phase 2 trial (n=48) for facioscapulohumeral muscular dystrophy.
- **Zilebesiran (angiotensinogen inhibitor).** The phase 2 KARDIA-1, KARDIA-2, and KARDIA-3 trials found that zilebesiran is most effective for those with unmanaged hypertension and when used with diuretics. Specifically, in participants with unmanaged hypertension despite prior treatment, zilebesiran conferred significant reductions in systolic blood pressure by 7-9 mmHg, which were sustained for over six months. Excitingly, the phase 3 CVOT ZENITH trial (n=11,000) was launched in October 2025 and will evaluate zilebesiran 300 mg in patients with unmanaged hypertension on a diuretic and at least one other antihypertensive medication. Positive data would enable a launch around 2030.

As noted above, construction for Roche's manufacturing site in Holly Springs, North Carolina, broke ground in August. Although there are currently no approved candidates, we are thrilled to see phase 3 trials starting and it's great to see this impressive manufacturing project to support the company's obesity portfolio.

2. Acquisition of 89bio and its MASH candidate brings Roche's portfolio value to $1.6 billion; phase 3 data expected in 2027 and 2028

Roche announced in September that it has agreed to acquire San Francisco-based 89bio, which develops pegozafermin, an FGF21 analog, for the treatment of metabolic dysfunction-associated steatohepatitis (MASH). Roche began a tender offer to 89bio shareholders for $14.50 per share, in addition to a non-tradeable contingent value right (CVR) potentially worth up to $6 per share. The offer represents a premium of 85% and a total deal value of up to $3.5 billion. The offer period will expire on October 29, 2025.

With this acquisition, Roche expands its cardiometabolic pipeline to include a promising asset, pegozafermin, a glycoPEGylated analog of fibroblast growth factor 21 (FGF21) with liver-directed benefit. Pegozafermin has demonstrated significantly improved fibrosis and MASH resolution in the 24-week phase 2b ENLIVEN trial (n=222).

- **Specifically,** the percentage of patients with an improvement in fibrosis of at least one stage without worsening of MASH was significantly higher with pegozafermin than with placebo at both the weekly 30 mg dose (26% versus 7%) and the twice-monthly 44 mg dose (27% versus 7%); similarly, the percentage of patients with MASH resolution without worsening of fibrosis also favored pegozafermin over placebo in both the 30 mg pegozafermin group (23% versus 2%) and the 44 mg pegozafermin group (26% versus 2%).

Pegozafermin is currently evaluated in three phase 3 studies:

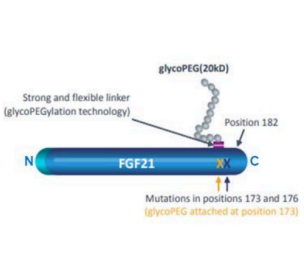
- ENLIGHTEN-Fibrosis trial (n=1,050) for the treatment of moderate-to-severe fibrosis (F2-F3) related to MASH. Topline histology data are expected in 1H27, and the trial is set to complete in February 2029.
- ENLIGHTEN-Cirrhosis trial (n=762) for the treatment of cirrhosis (F4) related to MASH. Topline histology data are expected in 2028, and the trial is set to complete in 2031.
- ENTRUST trial (n=360) for the treatment of severe hypertriglyceridemia. The trial is expected to complete in April 2026.

Roche
89bio

Pegozafermin: Potential best-in-disease therapy in MASH

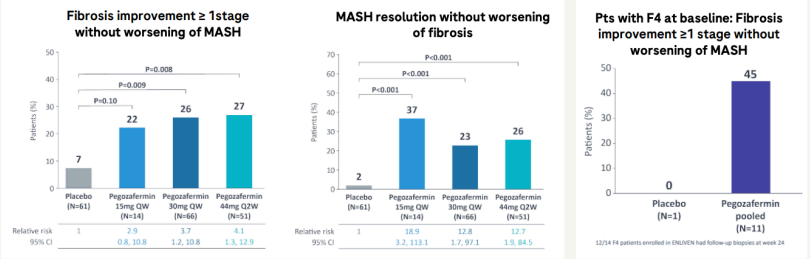
Further strengthens CVRM portfolio and offers optionality for future combination development

Pegozafermin[1]



- Pegozafermin is an FGF21 analog engineered to balance efficacy and extended dosing
- Anti-fibrotic and anti-inflammatory downstream effects improve insulin resistance and reduce oxidative stress

Ph II (ENLIVEN) week 24 results in pts with MASH and fibrosis (F2-F4)[2*]



- Ph II study of pegozafermin showed fibrosis improvement and MASH at week 24
- Ph II showed fibrosis improvement at w24 in pts with well-compensated cirrhosis (F4) at baseline*
- Sustained benefits on fibrosis markers were observed vs. placebo in patients on background GLP-1 therapy at week 48 (ENLIVEN 48-week extension data[1])
- Pegozafermin was well tolerated across all patients
- Ph III (ENLIGHTEN fibrosis) in MASH F2-F3; topline histology data expected in 1H 2027
- Ph III (ENLIGHTEN cirrhosis) in MASH F4; topline histology data in 2028

The transaction is expected to close in the fourth quarter of 2025. It is subject to customary closing conditions, including the tender of at least a majority of the outstanding shares of 89bio's common stock and the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.; *Fourteen ENLIVEN F2/F3 subjects were reclassified as F4 by 3-panel read; 1.Loomba et al EASL 2024; 2. Loomba et al EASL 2023; MASH: Metabolic dysfunction-associated steatohepatitis

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Source: Roche 3Q25 presentation, page 37

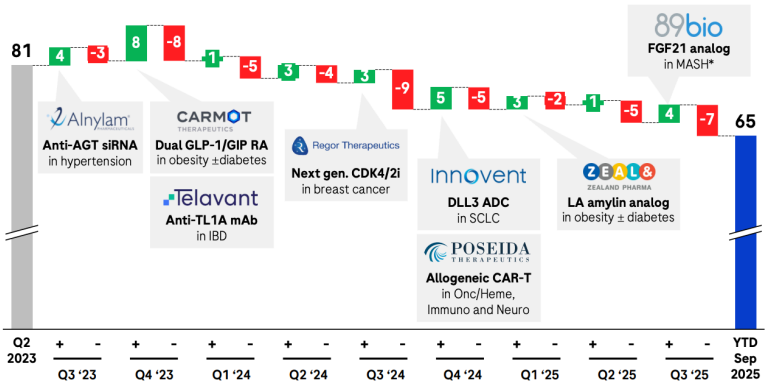
In recent years, Roche has expanded its Cardiovascular Renal Metabolism (CVRM) pipeline through acquisitions and partnerships. In December 2023, Roche acquired Carmot Therapeutics for $2.7 billion, adding several incretin candidates – oral GLP-1, injectable dual GLP-1/GIP, and PYY analog – to its pipeline. In March 2025, Roche announced a $1.65 billion partnership with Danish company Zealand Pharma to develop and commercialize Zealand's petrelintide, a long-acting amylin analog, and a combination therapy with CT-388 for overweight and obesity. The investments in external innovation have significantly increased portfolio value, with average peak sales per pipeline project totaling $1.3 billion, up 57% from the end of 2023. See the pipeline progression in the figure below.

Roche

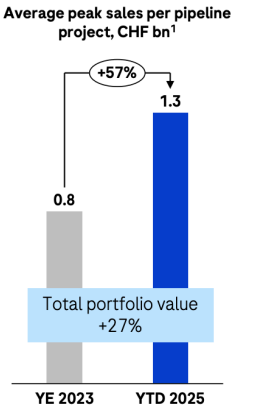
Further pipeline progression through 89bio acquisition*

Prioritization of high-impact projects while increasing the total portfolio value

Portfolio evolution (NME additions / removals)



Portfolio value



*pending deal closure; 1. Source: internal data; ADC: Antibody-drug conjugate; AGT: Angiotensinogen; CAR-T: Chimeric antigen receptor T-cell; CDK4/2i: Cyclin dependent kinase-4/2 inhibitor; DLL3: Delta-like ligand 3; FGF21: Fibroblast growth factor 21; GIP: Glucose-dependent insulinotropic polypeptide; GLP-1: Glucagon-like peptide-1; IBD: inflammatory bowel disease; LA: Long acting; mAb: Monoclonal antibody; MASH: Metabolic dysfunction-associated steatohepatitis; NME: New molecular entity; RA: Receptor agonist; SCLC: Small-cell lung cancer; siRNA: Small interfering RNA; TL1A: Tumor necrosis factor-like cytokine 1A; Note: Chart includes all assets from Ph I to Registration

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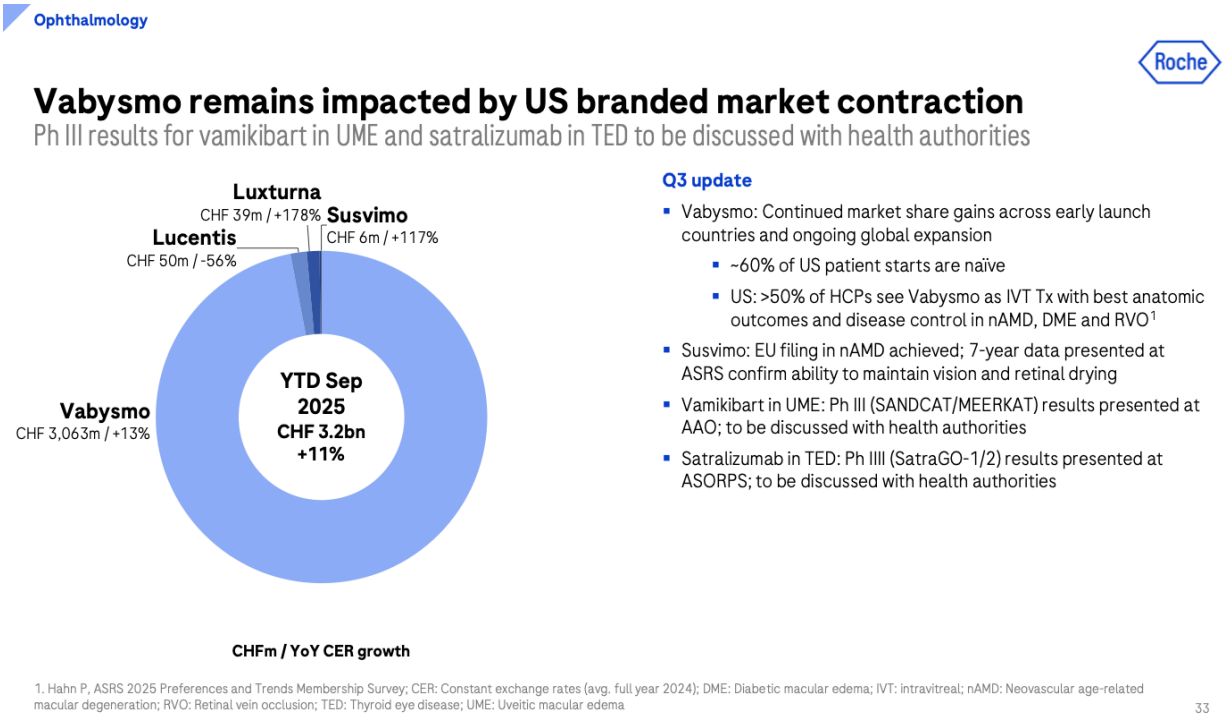
Source: Roche 3Q25 presentation, page 11

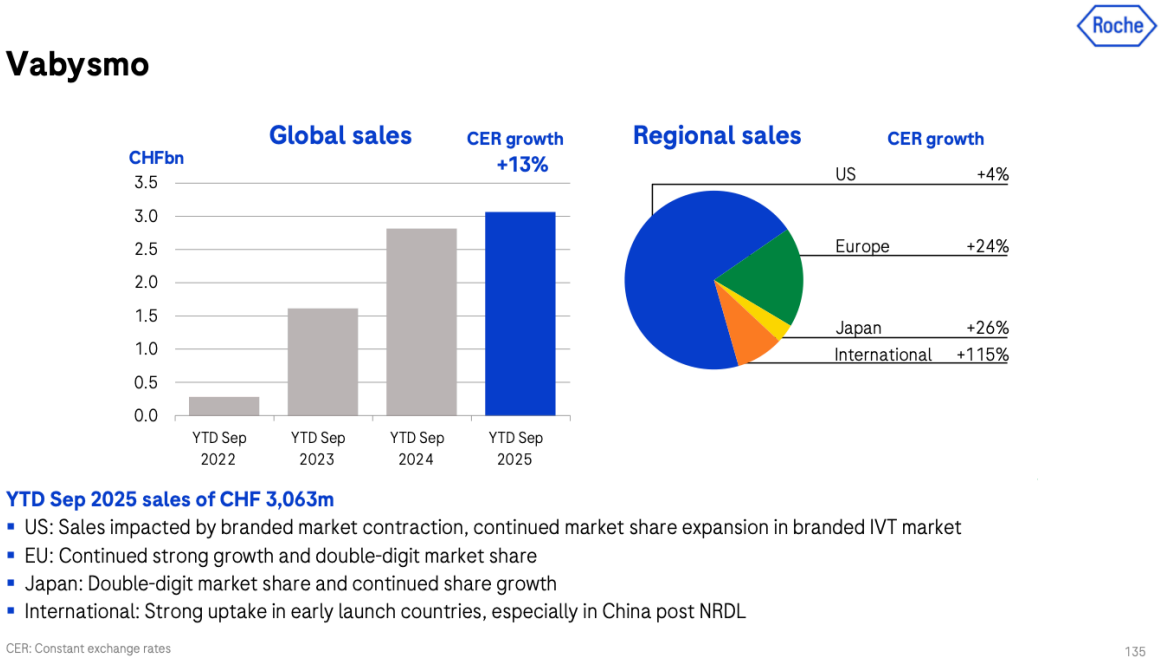
3. Vabysmo continues to lead ophthalmology franchise with 4% CER growth; full-year 2025 guidance lowered due to US market contraction

Vabysmo generated CHF 1.0 billion ($1.3 billion) in revenue in 3Q25, up 4% CER from 3Q24 (from a tough comparison of +59% CER) and up 4% sequentially. Year to date, Vabysmo has generated over CHF 3.0 billion in sales (approximately USD $4 billion), up 13% from the first three quarters of 2024. Ms. Graham identified the anti-VEGF injection as a leading product in Roche's ophthalmology franchise and among its top brands for the quarter. US Vabysmo sales fell 4% CER, totaling CHF 689 million (~$866 million), which Ms. Graham largely attributed to persistent headwinds from a contraction of the US branded intravitreal therapy (IVT) market driven by reduced co-pay assistance funding. Roche had previously warned that these factors would limit US growth throughout 2025; however, this marks the first quarter in which the company formally lowered guidance for the therapy.

- **Roche revised its global full-year growth guidance for Vabysmo to 15% from 20%,** reflecting the ~15% contraction of the US branded IVT market seen so far in 2025. Mr. Schinecker explained that reduced availability of co-pay foundation support has been the primary driver of this decline. Despite these market pressures, it remains a key growth driver in Roche's Pharma portfolio alongside other Young Portfolio assets (see figure below) and continued to gain share in the branded IVT segment both in the US and across early launch countries globally. In the US, Ms. Graham said that more than 60% of new Vabysmo starts are treatment-naïve patients, further solidifying its position as the standard of care for nAMD, DME, and RVO. She also highlighted a recent survey by the American Society of Retina Specialists (ASRS), which found that over half of ophthalmologists view Vabysmo as the treatment option with the best anatomic outcomes and disease control across retinal indications.
- **Outside the US,** the therapy continued to perform well despite temporary impacts from mandatory price cuts in Europe; the ongoing rollout of the prefilled syringe (PFS) formulation is expected to drive further growth in the region. Roche's Half-Year Report 2025 also cited significant adoption in Spain and Italy, where Vabysmo recently launched, and continued growth in the UK and Germany. Overall, Vabysmo sales in Europe grew 9% CER. In Japan, Roche Group member Chugai received approval for an expanded indication to treat angioid streaks (breaks or cracks in the layer of tissue behind the retina) in May 2025; Roche saw 17% CER growth in the country in 3Q25, and sales more than doubled internationally. In China, Roche reported continued "very strong uptake" following Vabysmo's NRDL listing in January and rapidly expanding market share.
- **Looking ahead,** Roche expects the US IVT market to stabilize and return to growth in 2026, supported by a reset baseline and continued global adoption of the PFS formulation. Ms. Graham and Mr. Schinecker reiterated confidence in Vabysmo's strong clinical profile. Separately, a planned regulatory submission for a choroidal neovascularization (CNV) indication has been moved up to 2026, ahead of the company's initial planned submission in 2027.
- **Roche's press release also highlighted data** from the AVONELLE-X and SALWEEN studies, presented at the Euretina Congress last month, demonstrating the efficacy, safety and durability of Vabysmo's extended dosing schedule in nAMD.
    - The AVONELLE-X extension study (n=1,029) showed that after four years of treatment, nearly 80% of patients were able to successfully extend dosing intervals to every three or four months, the high end of its flexible dosing schedule.
    - The phase 3b/4 SALWEEN trial (n=135) in polypoidal choroidal vasculopathy (PCV), a difficult-to-treat nAMD subtype found that patients gained a mean 8.9 letters of visual acuity at one year and most (60%) demonstrated complete resolution of vascular lesions.



Source: Roche 3Q25 presentation, page 33



Source: Roche 3Q25 presentation, page 135

4. Susvimo receives CE-Mark for nAMD; filed for EMA review; sales up 117% CER

Susvimo sales totaled CHF 6 million ($7.5 million), up 117% CER from 3Q24. Susvimo (ranibizumab) 100 mg/dL is a refillable eye implant that delivers an anti-VEGF as an alternative to injections. The therapy is currently available in the US, and, as Roche reported today, has been submitted to the European Medicines Agency (EMA) for review. While no mention of Susvimo was made on today's call, the therapy's progress was highlighted in Roche's investor

presentation. In September 2025, Roche received CE-Mark for Susvimo's port delivery platform, Contivue, for nAMD. Contivue continuously delivers Susvimo over six to nine months, after which the medication is refilled by a healthcare professional. If approved, Contivue with Susvimo will be the first continuous delivery treatment for nAMD in the EU. Roche also highlighted that seven-year data presented at the American Society of Retina Specialists Annual Scientific Meeting (ASRS) 2025 confirms the therapy's ability to maintain vision and avoid retinal drying over this time period.

- **Roche reiterated that Susvimo has been approved by the FDA for diabetic retinopathy in 2Q25, following its approval for DME in February 2025** based on positive results from the phase 3 PAGODA trial. In the study, Susvimo (refilled every six months) achieved non-inferior visual improvements compared to those receiving monthly ranibizumab injections. Roche also relaunched Susvimo in the US for wAMD in 2Q24 after initiating a voluntary recall of Susvimo in 2022 due to a manufacturing issue in which the seal on the port delivery system could fail after repeat dosing.
- **In addition to the EU filing for wAMD, Roche reiterated plans for additional filings. The company** plans to seek a DME indication in the EU in 2026. In 2027, Roche expects to seek a 36-week refill for its wAMD designation, which is currently approved for 24-week refills. The therapy is currently in phase 3 trials for this dosing scheme.

Select Analyst Q&A

On ophthalmology and Vabysmo guidance

Q (Yi Han Li, Barclays Capital Securities): Thanks for taking our question. On Vabysmo, it seems like we are going to see some reversal likely at the beginning of next year, but I wanted to further clarify your expectations for the fourth quarter, because it seems like you now upgraded the guidance for 15% year-over-year growth, which indicates that US growth will likely be at high single-digit range. What underpins your confidence for this Vabysmo growth you ask for the fourth quarter?

A (Ms. Teresa Graham, CEO Roche Pharmaceuticals): For Vabysmo in terms of 4Q25, I think we are expecting to see it continue to perform in the way that a new standard-of-care does. The growth rates are still in mid double-digits. We're still planning to grow at 15%. We still do hear from retinal specialists around the world that is the new standard-of-care. It is their go-to drug for new patients. And so I think we continue to believe very strongly in the profile of Vabysmo and what it can do for patients. And as the US market corrects itself, we expect strong growth next year.

Q (Sachin Jain, Bank of America): Just a follow-on question to the topics already touched on. So, firstly, on the Vabysmo guidance, could you just clarify what didn't happen in 2H25 that you thought was going to happen, because it seems like the dynamics are unchanged. What wasn't played through. Is that an acceleration of the growth trends in 2026 relative to 2025 that we should expect? The second question is, could you touch on key pushes and pulls into 2026? Thomas, you talked about 7% to 8% sales growth for the last two years – is that sustainable? I guess the question really hones back in on beyond Vabysmo, Ocrevus and Hemlibra have seen sequential declines in the US, which is what's driving the concern for investors today.

A (Mr. Thomas Schinecker, CEO Roche Holding): Regarding 2026, I think we gave you a bit more concretely of an outlook into Q4 than we'd normally do because there was a complete question on that. When it comes to 2026 we will update you at full year. What we can say is, we will have continued good momentum, so we feel comfortable that we will also be showing good growth for next year.

A (Ms. Graham): Sachin, I think your first question was around what did we think was going to happen with Vabysmo in Q4. Ultimately, we had hoped that we would see a return of the branded market and that just didn't happen. So, it was more just the underlying dynamics that we saw in the first half continued into the second half, and that just didn't normalize. So, hence our revised outlook. Because of the dramatic change that we saw to the branded market in 2025, I don't think that market shares in 2025 and 2026 are going to be directly comparable. But I think as we start to see a resetting of that baseline, you will see growth rates sort of continue to bounce back to sort of more of what we would have expected.

The other thing I think it's important to point out is that in Vabysmo outside of the US, we are now fully launching our

prefilled syringe. And so, we expect to see a nice uptake, OUS, of the prefilled syringe. So, I think there will be two dynamics at play in 2026 for Vabysmo. One is a normalization and sort of a resetting of the baseline in the US market, which will allow some of those underlying growth dynamics to play out and be more visible. But then you'll start to see the benefit of the uptick in the prefilled syringe launch OUS.

Q (James Quigley, Goldman Sachs): **Thank you for taking my questions, Bruno. I've got two, please. First, on the 2025 revenue guidance, again, picking up on the comment you made, Thomas, that 7% is included in mid-single-digits. And there's a little bit of concern this morning that mid-single-digit means 4%, 5%, 6%, which would suggest that growth in the fourth quarter was 0% to 4%. A good step down from what we've seen for the previous three quarters this year. So, can you clarify that in terms of what we should be expecting on revenue growth for the fourth quarter? Second on Vabysmo, how much visibility do you have in terms of the level of funding for the foundations? Is it getting back towards pre-drop levels this year? What is your expectation for the rebound in growth as we see in 2026? I'm asking because obviously last quarter we had the guidance for 20% growth, we stepped back down to 15% growth this year. So, again it seems like there's a bit of variability in there in the visibility. Thank you.**

A (Mr. Schinecker): Thank you very much for the question. I'm not at all concerned about Q4 growth. When I said that 7% is included in the mid-single-digit range, that's exactly what I meant with the 7%.

A (Ms. Graham): When it comes to the CAFs, I think obviously we don't have a clear visibility into what will happen with the co-pay foundation funds, because as we've always said, that needs to happen at arm's length to the business. That having been said, as we head into 2026, we would expect a gradual normalization of CAF funding in the future and likely what we would expect is that multiple CAFs will step in to fill the gap that's been created here. That may provide some logistical challenges for offices that they just need to get used to sort of working with multiple CAFs and not just one. Ultimately, we will see funding return into this disease area and that will help normalize and sort of steady the market in this particular place. I think as we think about next year, we do expect recovery in the US and a return to strong growth for Vabysmo.

Q (Matthew Weston, UBS): I also wanted to ask about vamikibart. You're obviously excited about the data. You've made that clear today and you held an investor event focused on it/ It seems to be in your pack as a CHF 500 million to 1 billion peak sales estimate, which is a very modest product, quite frankly, for Roche total sales. So, is there something differentiated about vamikibart over time that may mean it can get bigger than that, or is it just an asset that you want to flag because of the innovation?

A (Ms. Teresa): I think the reason that we're excited about this is that while it is a relatively small patient population, these are younger patients who are getting very high dose steroids, which is just not ideal from a safety perspective over time. The idea of a therapy that can meaningfully improve that patient outcome is very compelling from a clinical perspective. It also fits very neatly in with the commercialization of our other products. It's not like it's a big cost to commercialize this molecule. For us, we're very excited about the science and the innovation that it provides and, frankly, what it can do for patients from a safety perspective.

We also think that adoption here is going to be a relatively fast thing to drive as it's just a simple injection and it prevents vision loss, in, again, a much younger patient population. This targets a very significant unmet need, fits very neatly into our commercialization, and is great science. We're sort of projecting it around $500 million, but oftentimes when you have something like this, you don't totally know what you have until you actually get it into the market. And then maybe we'll be pleasantly surprised.

A (Mr. Bruno Eschli, Head of Investor Relations): Maybe one little add-on here. In general, we are excited about IL-6 in ophthalmology, and there's an opportunity in DME where we have a bispecific which will move ahead. So, it's just the first two cases where we clearly have proven that IL-6 is key to a couple of diseases.

On US pricing policies:

Q (Michael Leuchten, Jeffries): Thank you, Bruno. One for Thomas. I just wondered if you could give us an update on what's happening in Washington? We've seen a US company and a UK company reach an agreement with Trump. I guess everybody's waiting to see what happens next.

A (Mr. Schinecker): On the US discussions with the government, I can say that we've been in discussions with the US government for most part of this year. So, it's not something that has only happened in the last couple of weeks. For example, we discussed the XOFLUZA direct-to-patient access topic with the US government. So, we are in constant exchange with the US government, this much as I can say at the moment.

Q (Sachin Jain, Bank of America): And then last clarification is on the US administration question that was already asked. Just I wonder if you're able to comment, what's your ability to do a deal similar to those that have been announced? Is there any prohibition from your business and mix that stops you from doing that? Thank you.

A (Mr. Schinecker): I really cannot comment more except that we've always been in exchange with the US government. I really wouldn't want to go into additional details here.

On Roche's cardiometabolic pipeline:

Q (Michael Leuchten, Jeffries): Then just on news flow more generally; it's obviously not unusual this time of the year to see a few 2025 events shift into 2026. You've shifted six on the latest slide. I just wondered, is there any underlying theme there, because a lot of these don't seem to be event-driven studies. It's not immediately obvious why they might be delayed. I'm particularly thinking about CT-868 and CT-996. So, any thoughts on that would be very helpful. Thank you.

A (Ms. Graham): I think regarding the news flow, some of it is just when data will be presented and the most appropriate mechanism or vehicle for where that should be presented is 2026. That's the case for CT-996, CT-868, where all those trials will be placed into ADA. That's the reason for the shift. And thenfor the event-driven studies, what's determining the shift for the giredestrant and emugrobart readouts are competitive reasons. So, there are there are multiple reasons why things have shifted there.

Q (Yi Han Li, Barclays Capital Securities): I had another question on your anti-myostatin GYM-329. We noticed you have two Phase II readouts, SMA and also the FSHD readouts pushed into 2026. What is the underlying reason behind that? We know you have have your Phase I dosing finding data in-house for some time. Did you observe any similar profile that your competitors showed at ADA? Are we going to expect it at ADA next year as well? Thank you very much.

A (Ms. Graham): Emugrobart, I think I mentioned, is shifting into 2026 for competitive reasons. That data will be shared next year, including data at ADA in obesity.

Close Concerns' Questions

1. Will the phase 3 trial for CT-388 include people with diabetes?
2. Will phase 3 trial for CT-868 for people with T1D evaluate CGM values as a key metric?
3. Is Roche interested in combination therapies with pegozafermin and other CVRM candidates?
4. Is the US IVT market projected to continue contracting in 2026, or does Roche expect it to stabilize more or less at current levels?
5. Has Accu-Chek SmartGuide rolled out in additional European markets? How is Roche thinking about future AID integrations to drive further growth for the CGM?

--by Jeremy Alkire, Nour Khachemoune, Kat Moon, Monica Oxenreiter, and Kelly Close

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[1] The 14-day CGM includes AI-enabled glucose predictions with customized recommendations, featuring three timeframes: (i) glucose prediction within the next two hours; (ii) low glucose prediction within the next 30 minutes; and (iii) nighttime hypoglycemia risk prediction. The device received CE Mark in July 2024 for individuals aged 18 years and older with T1D or T2D on insulin therapy. To our knowledge, Roche has not yet announced partnerships with pump manufacturers to integrate Accu-Chek SmartGuide within AID systems.