

Media Release May 21, 2025

Ad hoc announcement pursuant to Art. 53 LR

New funds secured – allowing the commercial ramp-up of QUVIVIQ to accelerate Idorsia's path to profitability

- CHF 150 million new money facility from bondholders now implemented and providing cash runway to mid-2026
- Holistic convertible debt restructuring progressing with bondholder meeting to be held in the coming weeks ~90% of bondholders have already agreed to amend the terms and to exchange bonds for newly created notes in Idorsia Investments SARL
- Idorsia re-activating collaboration discussions for aprocitentan following the removal of the TRYVIO REMS and positive prescriber experience
- Guidance for 2025 upgraded due to successful commercial ramp-up of QUVIVIQ
- Financial outlook company continues to target commercial profitability in 2026 and overall profitability in 2027
- Cash flow outlook company targets positive operating cash flow in 2028 and will therefore need to raise funding for ongoing operations and to bridge to sustainable profitability

Allschwil, Switzerland – May 21, 2025

Idorsia Ltd (SIX: IDIA) today announced the implementation of the CHF 150 million new money facility previously agreed (press release) with holders of its convertible bond debt. In addition, the company provides an update on the holistic restructuring of the convertible bond debt and an overview of its plans for investment moving forward. The company also upgraded its guidance for 2025 and gave a positive financial outlook beyond.

New money facility

A new money facility for a net amount of CHF 150 million to extend Idorsia's cash runway to mid-2026 has now been signed and the company intends to draw down the first tranche of funds in the coming days. This new money facility has a maturity of 24 months and is fully backstopped by a bondholder group.

André C. Muller, CEO of Idorsia, commented: "Securing both the new money facility and the restructuring of the convertible debt overhang allows us to fully concentrate on driving the commercial ramp-up of QUVIVIQ in Europe and Canada which will bring the company to profitability in the near-term, with an upside in the US should the DORA class be descheduled. We will also continue to invest in our R&D portfolio in an efficient and responsible manner to advance selected compounds from our very innovative pipeline to the next inflection points."

Commercial ramp-up of QUVIVIQ

The company is working to elevate the conversation around chronic insomnia so that it is established as an independent medical disorder and that the short- and long-term burden of the condition is well understood. The medical, access and commercial teams are tackling long entrenched behaviors to ensure patient access to QUVIVIQ, to help healthcare professionals understand the broad patient population that can benefit from the product's differentiated profile, and to support patients to get the best out of their QUVIVIQ treatment.



As a result of these efforts, QUVIVIQ is taking off in Europe and Canada (EUCAN region) as shown in the first quarter of 2025 (press release) with a 50% growth quarter on quarter, translating into 10 million QUVIVIQ tablets being prescribed in the first quarter of 2025 compared to 15 million tablets in the whole of 2024. Growth is driven by countries where reimbursement has been secured: France, Germany, the UK, Canada (for the private market), and most recently Austria (from June 1, 2025). The company continues to work towards reimbursement in Spain, Canada, and the Nordic region. The successful commercial approach of implementing co-promotion partnerships for the GP market in France and Germany will also be taken in other markets, and the company will look for collaborations with potential partners to expand the European footprint and other geographies such as LATAM and Middle East.

In the US, a streamlined, focused, and more cost-efficient commercialization approach for QUVIVIQ has been implemented to maintain sales until the potential descheduling of the dual orexin receptor antagonist (DORA) class can be achieved. Should this occur, a major barrier to prescription will be removed and there is every reason to believe that the true potential of QUVIVIQ can be unlocked.

Based on the feedback at medical congress and symposia, the positive experience from prescribers and patients alike, and the commercial ramp-up across the EUCAN region, Idorsia is confident to reach commercial profitability in 2026.

Activating the clinical development pipeline

Idorsia has a very strong track-record in discovering first- or best-in-class drugs with significant potential to change the treatment paradigms in the target indications. This is matched by the design of efficient development programs that generate the safety and efficacy data that allow prescribers to practice evidence-based medicine. In the short history of the company, Idorsia has secured three product approvals in different geographies. Based on this outstanding success and expertise, the company has prioritized assets in the pipeline that have the greatest potential to create value in the mid-term. The result is a portfolio of potential blockbusters. Further details including the current status of each project in our portfolio can be found in our innovation fact sheet.

Holistic convertible bond debt restructuring

Following a successful completion of the ongoing restructuring, Idorsia will have removed its convertible debt overhang through the creation of an asset-backed new entity where the debt will be sequestered together with Idorsia's rights for three of the company's assets.

The newly established Luxembourg entity, **Idorsia Investments SARL** (previously referred to as the "SPV"), will facilitate the holistic restructuring of Idorsia's convertible bond debt. As of today, bondholders have committed to exchange at least CHF 710 million of the Idorsia convertible bond debt, for newly created notes expected to be issued by Idorsia Investments SARL in the coming weeks, in each case subject to the agreement with such bondholders, which would leave Idorsia Ltd with a maximum of CHF 90 million of convertible bond debt maturing in 2034/2038.

Idorsia Pharmaceuticals Ltd will contribute its rights for aprocitentan, selatogrel, and cenerimod, to Idorsia Investments SARL to allow the repayment of the newly created notes. Once the notes have been fully repaid, rights to all three products sequestered to Idorsia Investments SARL will return to Idorsia, delivering long-term value creation to Idorsia shareholders. For more details see the <u>press</u> release issued in February 2025.



André Muller concluded: "Following the removal of the TRYVIO REMS and positive prescriber experience in the US, we are excited to have the opportunity to strike a deal for aprocitentan that recognizes this new value proposition. Based on our forecasts for aprocitentan, and the forecasts of our partner Viatris for selatogrel and cenerimod, the three assets sequestered to Idorsia Investments SARL have the potential to not only allow the repayment of the newly created Notes in the short- to mid-term, but to also deliver significant long-term growth for Idorsia once the rights have been returned."

Financial guidance for 2025

CHF million	Idorsia business	Partnered business	Global Business
REVENUE	130	45	175
COGS	-15	-	-15
SG&A OPEX	-200	-	-200
R&D OPEX	-90	-	-90
Non-GAAP EBIT	-175	45	-130
D&A	-20	<u>-</u>	-20
SBC	-15	-	-15
Other	-10	90	80
US-GAAP EBIT	-220	135	-85

For the Idorsia-led portfolio in 2025, the company expects a continued acceleration of QUVIVIQ with net sales of around CHF 130 million, COGS of around CHF 15 million, SG&A expenses of around CHF 200 million, and R&D expense of around CHF 90 million, leading to non-GAAP operating expenses of around CHF 305 million. This performance would result in an Idorsia-led business non-GAAP operating loss of around CHF 175 million and US-GAAP operating loss of around CHF 220 million.

The company expects US-GAAP EBIT for the partnered business of around CHF 135 million and mainly driven by the amended deal with Viatris.

This would result in a US-GAAP loss for the global business of around CHF 85 million.

All amounts exclude unforeseen events and potential revenue related to additional business development activities.

Arno Groenewoud, Chief Financial Officer, commented:

"With 4 months of QUVIVIQ sales behind us, the new co-promotion collaboration in Germany reaching out to GPs, and the new commercial approach stabilizing in the US, we are clearly seeing the successful commercial ramp-up of QUVIVIQ in action. As a result, I am now confident that we will substantially exceed the sales target by around 20%, compared to our expectations at the beginning of 2025."



Financial outlook

Idorsia aims to reach sustainable commercial profitability in 2026 and overall sustainable profitability by the end of 2027. Sustainable profitability only includes income generated from Idorsia's portfolio of assets. This implies Idorsia-led QUVIVIQ sales ramp-up to around CHF 210 million in 2026 growing to around CHF 270 million in 2027, both at an approximate 80% gross margin. The ramp-up will be predominantly driven by the EUCAN region with a potential upside in the US (depending on DEA descheduling of the DORA class). During this period, non-GAAP OPEX (including marketing and selling, R&D and G&A) will remain stable with annual non-GAAP OPEX of around CHF 285 million.

Beyond 2027, Idorsia aims to continue the sales trajectory of QUVIVIQ with a stable OPEX, leading to higher sustainable profitability. This could benefit from additional income from new collaborations from the existing pipeline assets and from the return of sequestered products following the repayment of Idorsia Investments SARL notes.

Cash-flow outlook

The company expects to achieve a positive operating cash flow from 2028 onwards. To further extend the cash runway into early 2027, the company has committed to the new money facility lenders to raise CHF 50 million via a new equity line but may also look to other avenues to strengthen its balance sheet. The company will then explore all options to fully finance operations and repay the new money facility at maturity.

Notes to the editor

Idorsia's portfolio

Compound

Idorsia intends to develop certain assets to the next inflection point before partnering, or when feasible and appropriate, developing further with in-house expertise. Other assets are already being prepared for out-licensing.

Compound Mechanism of action Target indication	Status	
Idorsia-led assets		
QUVIVIQ™ (daridorexant) Dual orexin receptor antagonist Insomnia	Commercialized by Idorsia in the US, Germany, Italy, Switzerland, Spain, the UK, Canada, Austria, France, and Sweden; approved throughout the EU.	
Lucerastat Glucosylceramide synthase inhibitor Fabry disease	Phase 3 open-label extension study ongoing – kidney biopsy sub-study results expected in Q2 2025 – regulatory pathway to be further discussed with FDA.	
Daridorexant Dual orexin receptor antagonist Pediatric insomnia	Phase 2 in pediatric insomnia is ongoing.	
ACT-777991 CXCR3 receptor antagonist Vitiligo	Proof-of-concept study in preparation for patients with vitiligo.	
ACT-1004-1239 ACKR3 (CXCR7) receptor antagonist Progressive multiple sclerosis	Proof-of-concept study in preparation for patients with progressive MS.	
IDOR-1117-2520 CCR6 receptor antagonist Psoriasis	Proof-of-concept study in preparation for patients with psoriasis.	
IDOR-1134-2831 Synthetic glycan vaccine Clostridium difficile infection	Phase 1 results expected in Q2 2025.	



Partner-led assets

QUVIVIQ™ (daridorexant) Dual orexin receptor antagonist Insomnia	Nxera Pharma: license to develop and commercialize for Asia-Pacific region (excluding China) Launched for the treatment of insomnia in Japan; Phase 3 ongoing in South Korea	
Daridorexant Dual orexin receptor antagonist Insomnia	Simcere: license to develop and commercialize for Greater China region NDA submitted in Greater China; approved for the treatment of insomnia in Hong-Kong	
Daridorexant Dual orexin receptor antagonist Posttraumatic stress disorder (PTSD)	US Department of Defense (DOD) : Idorsia is supporting a clinical study sponsored by the US DOD to develop new therapies to treat PTSD	
ACT-1002-4391 EP ₂ /EP ₄ receptor antagonist Immuno-oncology	Owkin: global license to develop and commercialize Phase 1 ongoing	

Lucerastat

Lucerastat is an oral inhibitor of glucosylceramide synthase, offering a potential new treatment approach for all patients living with Fabry disease, irrespective of the mutation type of the GLA gene. During a Phase 3 open-label study, with patients treated for up to 6 years, lucerastat has shown a long-term effect on plasma Gb3 levels and improved kidney function compared to historical data. The effect of lucerastat on reducing the eGFR decline is seen across all subgroups of patients with a particularly large effect observed in patients with renal impairment at baseline, and in patients with anti-drug antibody to enzyme replacement therapy, two groups of patients with a high medical need. The analysis also showed a safety and tolerability profile consistent with that observed during the 6-month randomized treatment period. The company is conducting a pilot kidney biopsy sub-study within a subset of patients currently participating in the OLE study. The regulatory pathway will then be further discussed with the US FDA.

ACKR3 (CXCR7) receptor antagonist

Idorsia's ACKR3 (CXCR7) receptor antagonist, a first-in-class compound that offers a unique combination of re-myelination and anti-inflammatory effects A proof-of-concept study is in preparation for patients with progressive multiple sclerosis.

CCR6 receptor antagonist

Idorsia's selective CCR6 receptor antagonist is a first-in-class, oral therapy for the treatment of T helper 17 driven immunodermatology and autoimmune disorders. A proof-of-concept study is in preparation for patients with psoriasis.

CXCR3 receptor antagonist

Idorsia's first-in-class oral CXCR3 receptor antagonist allows dual targeting of CD8+ CXCR3+ T cells and melanocytes and offers potential as the first targeted systemic therapy for vitiligo and other immuno-dermatology and autoimmune disorders. There is currently no systemic treatment approved for the treatment of vitiligo. A proof-of-concept study is in preparation for patients with vitiligo.

Other early-stage assets

Idorsia also has a synthetic glycan vaccine platform, with vaccines targeting *Clostridium difficile, Klebsiella pneumonia,* and *Neisseria gonorrhea* infections, as well as other undisclosed pathogens alone or combined. The results from the lead program, a Phase 1 study in *Clostridium difficile* infection which will test the immune response of the vaccine and evaluate its safety and tolerability, are expected in in Q2 2025. If positive, Idorsia will seek a partner for the platform or individual vaccines.

Further details including the current status of each project in our portfolio can be found in our innovation fact sheet.



Idorsia Investments SARL portfolio

Compound Mechanism of action Target indication	Partner/status	
TRYVIO™ (aprocitentan) Dual endothelin receptor antagonist Systemic hypertension in combination with other antihypertensives	To be defined: worldwide development and commercialization rights Commercially available in the US	
JERAYGO™ (aprocitentan) Dual endothelin receptor antagonist Resistant hypertension in combination with other antihypertensives	To be defined: worldwide development and commercialization rights Approved in the EU and UK; Marketing authorization applications under review in Canada, and Switzerland	
Selatogrel P2Y ₁₂ inhibitor Acute myocardial infarction	Viatris: worldwide development and commercialization rights Phase 3 "SOS-AMI" program ongoing	
Cenerimod S1P ₁ receptor modulator Systemic lupus erythematosus	Viatris: worldwide development and commercialization rights Phase 3 "OPUS" program ongoing	

TRYVIO™/JERAYGO™ (aprocitentan)

TRYVIO™ (aprocitentan) is approved in the US for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. TRYVIO is the first and only new treatment to decrease systemic blood pressure on top of existing therapies by blocking the endothelin pathway via both endothelin receptors and has the potential to preserve or improve renal function. TRYVIO is ready to launch with a comprehensive collection of FDA-approved product positioning, branding, websites, materials, training and educational platforms, and field sales force and MSL coverage plans. TRYVIO was made available for prescription in October 2024 and there is ongoing engagement with hypertension experts at major cardiovascular and nephrology congresses and encouraging discussions with payors. In March 2025, the US FDA fully released TRYVIO from its REMS (Risk Evaluation and Mitigation Strategy) requirement to minimize the burden on the healthcare delivery system of complying with the REMS. As a result, a rapid transition from specialty pharmacy to a wide retail pharmacy distribution model is underway. Funding for a field sales force and promotional activities continues to be dependent on a partnership deal.

 $\mathsf{JERAYGO}^\mathsf{TM}$ (approximation) is approved in the EU and UK for the treatment of resistant hypertension in adult patients in combination with at least three antihypertensive medicinal products.

Viatris Deal

In 2024, Idorsia entered into a global research and development collaboration with Viatris, for the global development and commercialization rights to selatogrel and cenerimod. Idorsia is entitled to potential development and regulatory milestone payments, and certain contingent payments of additional sales milestone payments and tiered royalties in the mid-single to low-double digit percentages on annual net sales.

Selatogre

Acute Myocardial Infarction (AMI) accounts for \sim 1/3 of all deaths in developed nations and there is a dire need for early intervention, as \sim 30% of deaths occur prior to hospital admission. Selatogrel has the potential to shift the treatment paradigm in AMI as a potent, reversible and highly selective P2Y₁₂ receptor antagonist, with rapid uptake & fast onset of action and short duration. In the Phase 2 trial, > 90% of participants had > 80% inhibition of platelet aggregation within 15 minutes after dosing, there was reduced off-target interference of hemostasis compared to other P2Y₁₂ inhibitors and no difference in major bleeds compared to placebo on top of standard of care of dual anti-platelet therapy. Comprehensive Phase 3 study design with Special Protocol Assessment was agreed to with FDA and includes a fast-track designation. Currently in Phase 3, on schedule for full enrollment / study expected to read out in 2026. (source: "Selatogrel (AMI) Overview & Market Opportunity" Viatris presentation provided in November 2024).

Cenerimod

Cenerimod is a first-in-class oral therapy with a novel mechanism of action and potential for highly differentiated benefit-risk profile in Systemic Lupus Erythematosus (SLE). During the Phase 2 CARE study with over 400 patients, cenerimod 4mg met its primary endpoint, demonstrating statistically significant and clinically meaningful reduction in mSLEDAI-2K1 with a differentiated safety profile vs. existing SLE treatments. FDA fast-track designation, two comprehensive Phase 3 studies ongoing which reflect the learnings from Phase 2, including higher enrollment of INF-1 High patients. Currently in Phase 3, on schedule for full enrollment in 2025 / study expected to readout in 2026. (source: "Cenerimod (SLE) Overview & Market Opportunity" Viatris presentation provided in November 2024).



About Idorsia

Idorsia Ltd is reaching out for more – we have more passion for science, we see more opportunities, and we want to help more patients.

The purpose of Idorsia is to challenge accepted medical paradigms, answering the questions that matter most. To achieve this, we will discover, develop, and commercialize transformative medicines – either with in-house capabilities or together with partners – and evolve Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech hub – Idorsia has a highly experienced team of dedicated professionals, covering all disciplines from bench to bedside; QUVIVIQ™ (daridorexant), a different kind of insomnia treatment with the potential to revolutionize this mounting public health concern; strong partners to maximize the value of our portfolio; a promising in-house development pipeline; and a specialized drug discovery engine focused on small-molecule drugs that can change the treatment paradigm for many patients.

Idorsia is listed on the SIX Swiss Exchange (ticker symbol: IDIA).

For further information, please contact:

Investor & Media Relations
Idorsia Pharmaceuticals Ltd, Hegenheimermattweg 91, CH-4123 Allschwil
+41 58 844 10 10
investor.relations@idorsia.com – media.relations@idorsia.com – www.idorsia.com

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