



Media Release

July 25, 2024

Ad hoc announcement pursuant to Art. 53 LR

Idorsia announces financial results for the first half 2024

Allschwil, Switzerland – July 25, 2024

Idorsia Ltd (SIX: IDIA) today announced its financial results for the first half of 2024.

Business highlights

- **Viatriis collaboration:** Global research and development collaboration, focused on the development and commercialization of two innovative compounds, selatogrel and cenerimod.
- **Adapted governance:** On June 13, 2024, Jean-Paul Clozel retired from his position as CEO of Idorsia and was elected as Chairman. André C. Muller was appointed as CEO.

Commercial highlights

- **QUVIVIQ™ (daridorexant):** Total net sales of CHF 23.6 million in HY 2024.
- **QUVIVIQ in the US:** Sales increase despite a substantial reduction in sales representatives.
- **QUVIVIQ in the EUCAN region:** Sales acceleration due to increased demand.

Pipeline highlights

- **TRYVIO™ (aprocitentan):** Approved by the US FDA in March 2024.
- **JERAYGO™ (aprocitentan):** Approved by the European Commission in June 2024.
- **Daridorexant:** Positive topline results in Phase 4 study in patients with insomnia and comorbid nocturia – to be presented at upcoming scientific congresses.
- **Daridorexant:** Positive Phase 3 by Simcere in Greater China – NDA submitted.
- **IDOR-1134-2831:** First healthy participant entered Phase 1 program for Idorsia's first synthetic glycan vaccine, targeting *Clostridium difficile* infection.

Financial highlights

- **Net revenue** HY 2024 at CHF 26.4 million.
- **US GAAP operating expenses** HY 2024 at CHF 94 million benefiting from extraordinary income from Viatriis deal with **non-GAAP operating expenses** HY 2024 at CHF 200 million.
- **US GAAP operating loss** HY 2024 of CHF 64 million and **non-GAAP operating loss** of CHF 170 million.
- **Convertible bond 2024:** Higher cantonal composition authority approved the amendments to the terms of the 2024 convertible bonds.

Upgraded Guidance for 2024

- **QUVIVIQ net sales** of around CHF 55 million.
- **US GAAP operating loss** to reach CHF 320 million (which includes a one-off benefit of CHF 125 million from the Viatriis deal), **non-GAAP operating loss** of around CHF 400 million (excluding contract revenues and the one-off benefit from the Viatriis deal) – unforeseen events excluded.

André Muller, Chief Executive Officer of Idorsia, commented:

“I’m encouraged to see that the efforts of the past 18 months are starting to pay off with sales of QUVIVIQ picking up in both North America and Europe. While this performance is a positive endorsement of the outstanding properties of QUVIVIQ, we are still far away from where we want to be. We therefore continue to describe the unique product profile of QUVIVIQ, expand access and availability in Europe and continue to support the petition for the descheduling of the DORA class in the US. Aprocitentan, recently approved in the US and EU, has the potential to bring a much-needed new approach to a serious and growing public health problem. Launch preparation is underway and in parallel we are actively engaging with potential partners to launch this innovative product.”

Financial results

US GAAP results in CHF millions, except EPS (CHF) and number of shares (millions)	First Half		Second Quarter	
	2024	2023	2024	2023
Net revenues	26	51	16	30
Operating expenses	(94)	(426)	(113)	(207)
Operating income (loss)	(64)	(375)	(95)	(177)
Net income (loss)	(79)	(405)	(109)	(193)
Basic EPS	(0.44)	(2.28)	(0.60)	(1.08)
Basic weighted average number of shares	179.5	178.1	179.9	178.3
Diluted EPS	(0.44)	(2.28)	(0.60)	(1.08)
Diluted weighted average number of shares	179.5	178.1	179.9	178.3

Net revenue of CHF 26 million in the first half of 2024 is the result of QUVIVIQ product sales and contract revenue recognized in connection with Owkin (CHF 3 million). This compares to CHF 51 million in the first half of 2023, which included CHF 32 million sales of PIVLAZ in Japan (assigned in the meantime to Nxera Pharma as part of a transaction, more details can be found in the dedicated [press release](#)) and CHF 2 million revenue share from Johnson & Johnson related to ponesimod sales (revenue-sharing agreement now eliminated as part of the reacquisition of aprocitentan, more details can be found in the dedicated [press release](#)).

US GAAP operating expenses in the first half of 2024 benefited from extraordinary income of CHF 125 million from the Viatris deal resulting in an expense of CHF 94 million (CHF 426 million in the first half of 2023), of which CHF 4 million related to cost of sales (CHF 5 million in the first half of 2023), CHF 71 million to R&D expenses (CHF 172 million in the first half of 2023), and CHF 142 million to SG&A expenses (CHF 249 million in the first half of 2023).

US GAAP net loss in the first half of 2024 amounted to CHF 79 million (CHF 405 million net loss in the first half of 2023). The decrease of the net loss is mainly attributable to the one-off income related to the Viatris deal but was also driven by lower operating expenses throughout all functions.

The US GAAP net income resulted in a basic net loss per share of CHF 0.44 (basic and diluted) in the first half of 2024, compared to a net loss per share of CHF 2.28 (basic and diluted) in the first half of 2023.

Non-GAAP* measures in CHF millions, except EPS (CHF) and number of shares (millions)	First Half		Second Quarter	
	2024	2023	2024	2023
Net revenues	26	51	16	30
Operating expenses	(200)	(393)	(104)	(191)
Operating income (loss)	(170)	(342)	(85)	(161)
Net income (loss)	(183)	(369)	(96)	(180)
Basic EPS	(1.02)	(2.07)	(0.54)	(1.01)
Basic weighted average number of shares	179.5	178.1	179.9	178.3
Diluted EPS	(1.02)	(2.07)	(0.54)	(1.01)
Diluted weighted average number of shares	179.5	178.1	179.9	178.3

* Idorsia measures, reports, and issues guidance on non-GAAP operating performance. Idorsia believes that these non-GAAP financial measurements more accurately reflect the underlying business performance and therefore provide useful supplementary information to investors. These non-GAAP measures are reported in addition to, not as a substitute for, US GAAP financial performance.

Non-GAAP net loss in the first half of 2024 amounted to CHF 183 million: the CHF 104 million difference versus US GAAP net income was mainly due to the one-off effect of the Viatrix deal (CHF 125 million income), depreciation and amortization (CHF 8 million), and share-based compensation (CHF 10 million).

The non-GAAP net loss resulted in a net loss per share of CHF 1.02 (basic and diluted) in the first half of 2024, compared to a net loss per share of CHF 2.07 (basic and diluted) in the first half of 2023.

Viatrix collaboration

In March 2024, Idorsia closed agreements with Viatrix Inc. (NASDAQ: VTRS), a global healthcare company, for collaboration on the global development and commercialization of two Phase 3 assets – selatogrel and cenerimod – with Idorsia receiving an upfront payment of USD 350 million, and the right to potential development and regulatory milestone payments of up to USD 300 million, potential sales milestone payments of up to USD 2.1 billion, and potential contingent tiered royalties from mid-single- to low-double-digit percentage on annual net sales.

A joint development committee is overseeing the development of the ongoing Phase 3 programs for selatogrel and cenerimod up to regulatory approval. Idorsia will contribute up to USD 200 million in the next 3 years and transferred the dedicated personnel for both programs to Viatrix.

Viatrix has worldwide commercialization rights for both selatogrel and cenerimod (excluding, for cenerimod only, Japan, South Korea, and certain countries in the Asia-Pacific region). Idorsia has also granted Viatrix a right of first refusal and first negotiation for certain other pipeline assets.

Convertible bonds 2024

In July 2018, the Group issued CHF 200 million of senior unsecured convertible bonds (ISIN: CH0426820350), which were due to mature on July 17, 2024. On May 6, 2024, a bondholder meeting was held, where 83.5% of the total outstanding bondholders voted in favor of amendments to the terms of the bonds. The approved bond terms include an amended conversion price of CHF 6.00, extended maturity date of January 17, 2025, and the option to call the bonds at par, in full or in part, at any time upon giving ten trading days' notice. On June 25, 2024, the higher cantonal composition authority (*obere kantonale Nachlassbehörde*) issued its written decision approving the amendments of the terms of the outstanding convertible bonds.

If no appeal is filed within the statutory period of 30 days, the amendments will be effective, and the company expects to transfer the consent fee of 8 million shares on September 5, 2024.

Financial outlook 2024 – upgraded

For 2024 – excluding unforeseen events – the company expects QUVIVIQ net sales of around CHF 55 million; SG&A expenses of around CHF 300 million; R&D expense of around CHF 145 million for Idorsia-led pipeline assets; non-GAAP operating expenses of up to CHF 455 million. This performance would result in a non-GAAP operating loss of around CHF 400 million (excluding contract revenues and the one-off benefit from the Viatris deal).

The company expects US GAAP operating loss for 2024 to reach CHF 320 million which includes a one-off benefit of CHF 125 million from the Viatris deal.

Arno Groenewoud, Chief Financial Officer, commented:

“We have tightly controlled our expenses in the first half enabling us to slightly reduce the R&D OPEX guidance, improving the overall outlook for 2024. The actions we’ve taken in the first half of 2024, namely the Viatris deal and the restructured convertible bond, have given us the time to ensure we have the optimal deal for aprocitentan.”

Liquidity and indebtedness

At the end of the first half of 2024, Idorsia’s liquidity amounted to CHF 237 million.


(in CHF millions)	Jun 30, 2024	Mar 31, 2024	Dec 31, 2023
Liquidity			
Cash and cash equivalents	237	335	145
Short-term deposits	-	-	-
Total liquidity*	237	335	145
Indebtedness			
Convertible loan	335	335	335
Convertible bond	797	797	796
Other financial debt	162	162	162
Total indebtedness	1,294	1,293	1,293

*rounding differences may occur

Commercial operations

In the first half of 2024, QUVIVIQ™ (daridorexant) in the US, Germany, Italy, Switzerland, Spain, UK, Canada, Austria, and France generated total product sales of CHF 23.6 million.

United States

Product	Mechanism of action	Indication	Commercially available since
	Dual orexin receptor antagonist	Treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	May 2022


In the US, net sales of **QUVIVIQ® (daridorexant)** in the first half of 2024 reached CHF 14.2 million, an increase of 61% versus the first half of 2023. This net sales number includes the QUVIVIQ copay program aimed at driving demand and product uptake, and thus does not reflect the actual number of prescriptions dispensed.

As of the end of the first half of 2024, more than 155,000 patients have been treated with QUVIVIQ since launch in the US, almost 450,000 prescriptions have been dispensed, and the product has been prescribed by more than 45,000 healthcare professionals.

Tosh Butt, President, and General Manager of Idorsia US, commented:

“Having optimized our resources and promotional effort, and adjusted our commercial approach towards a payer-paid model, setting a new baseline for sales in the US, I’m pleased that we have been able to maintain demand for QUVIVIQ. We continue to remain hopeful that our citizen petition requesting a review of the evidence can lead to the descheduling of the DORA class of chronic insomnia medications and the benefits of QUVIVIQ, both in efficacy and safety, will then be fully recognized.”

For more information about QUVIVIQ in the US, see the [Full Prescribing Information](#) (PI and Medication Guide).

Product	Mechanism of action	Indication	Commercially available since
	Dual endothelin receptor antagonist	Treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs	Approved Mar. 2024 Planned availability: Q4 2024

On March 19, 2024, the US Food and Drug Administration (FDA) approved **TRYVIO™ (aproцитentan)** 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. The recommended dosage of TRYVIO is 12.5 mg orally once daily, with or without food.

Idorsia plans to make TRYVIO available in the fourth quarter of 2024 to the millions of patients in the US whose high blood pressure is not adequately controlled by other drugs.


Tosh Butt concluded:

“We are making progress with our preparation to make TRYVIO available before the end of this year. We’ve conducted thorough market research and the conversations with payers are going well. They have been intrigued by our innovation and understand that TRYVIO is addressing significant patient need as treated hypertensive patients who remain uncontrolled are at a higher risk of serious cardiovascular events. We are bringing the first innovation, a novel pathway and the first new mode of action for systemic hypertension in almost 40 years to the market. Around 90% of uncontrolled hypertensive patients have comorbidities, typically diabetes, obesity, dyslipidemia, CKD and other cardiovascular comorbidities, and they are often taking three, four, or more medicines. For TRYVIO, it’s a once-daily tablet, and there’s no need to adjust the dose, so it’s easy for patients to use and easy for physicians to prescribe.”

Further details on the approval, together with commentary from company management can be found in the dedicated [press release](#) and [investor webcast](#) available from the company corporate website.

For more information see the Full Prescribing Information including BOXED Warning ([PI](#) and Medication [Guide](#)).

Europe and Canada


Product	Mechanism of action	Indication	Commercially available
	Dual orexin receptor antagonist	Treatment of adult patients with insomnia characterised by symptoms present for at least three months and considerable impact on daytime functioning	France: Mar. 2024 Austria: Feb. 2024 UK: Oct. 2023 Spain: Sep. 2023 Switzerland: Jun. 2023 Germany: Nov. 2022 Italy: Nov. 2022
		Management of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	Canada: Nov. 2023

QUVIVIQ (daridorexant) net sales in the first half of 2024 reached CHF 9.4 million in the EUCAN region.

Benjamin Limal, President of Europe and Canada region, commented:

“Following the expansion into new markets and increased access secured in 2023 and early 2024, both net sales and demand in the Europe and Canada region are accelerating. This is particularly driven by a great performance in Germany and an outstanding launch in France, where we are starting to see the need for an effective and safe insomnia treatment translating into demand. It’s still early days in many countries, but I am confident this dynamic will continue in the coming months as we expand access in key European markets.”

For more information about QUVIVIQ in the EU, see the [Summary of Product Characteristics](#). For more information about QUVIVIQ in Switzerland, see the [Patient Information](#) and [Information for Healthcare Professionals](#). For more information on the marketing authorization of QUVIVIQ in Canada, see the [Product Monograph](#).

Product	Mechanism of action	Indication	Commercially available since
	Dual endothelin receptor antagonist	Treatment of resistant hypertension in adult patients in combination with at least three antihypertensive medicinal products	Approved Jun. 2024

On June 27, 2024, the European Commission (EC) approved **JERAYGO™ (aprocitentan)** for the treatment of resistant hypertension in adult patients in combination with at least three antihypertensive medicinal products. The recommended dose is 12.5 mg orally once daily. The dose can be increased to 25 mg once daily for patients tolerating the 12.5 mg dose and in need of tighter blood pressure (BP) control.

Idorsia continues to carefully evaluate all funding options including potential collaborations for the commercialization of aprocitentan for the millions of patients in the EU whose high blood pressure is not adequately controlled by other drugs.

Further details on the approval, together with commentary from company management can be found in the dedicated [press release](#) available from the company corporate website.

For more information about JERAYGO in the EU, see the [Summary of Product Characteristics](#).

Research & Development

Idorsia has a diversified and balanced portfolio, comprising assets developed and/or marketed by Idorsia and assets that are partner-led to maximize the value we have created. Our drug discovery engine has produced innovative drugs with the potential to transform the treatment paradigm in multiple therapeutic areas, including CNS, cardiovascular, and immunological disorders, as well as orphan diseases. The company also has a vaccine platform for the discovery and development of glycoconjugate vaccines containing synthetic antigenic glycan molecules, with or without a carrier protein, to prevent infection.

Idorsia-led portfolio

Compound Mechanism of action Target indication	Status
QUVIVIQ™ (daridorexant) Dual orexin receptor antagonist Insomnia	Commercially available as QUVIVIQ in the US, Germany, Italy, Switzerland, Spain, the UK, Canada, Austria, and France; approved throughout the EU
TRYVIO™ (aproцитentan) Dual endothelin receptor antagonist Systemic hypertension in combination with other antihypertensives	Approved in the US, product availability planned for Q4 2024
JERAYGO™ (aproцитentan) Dual endothelin receptor antagonist Resistant hypertension in combination with other antihypertensives	Approved in the EU; Marketing authorization applications for the UK, Canada, and Switzerland in preparation
Lucerastat Glucosylceramide synthase inhibitor Fabry disease	Phase 3 primary endpoint not met; open-label extension study ongoing Phase 3 focused on renal function in preparation
Daridorexant Dual orexin receptor antagonist Pediatric insomnia	Phase 2 in pediatric insomnia ongoing
ACT-1004-1239 ACKR3/CXCR7 antagonist Demyelinating diseases including multiple sclerosis	Phase 2 in preparation
ACT-777991 CXCR3 antagonist Vitiligo	Phase 2 in preparation
Sinbaglustat GBA2/GCS inhibitor Rare lysosomal storage disorders	Phase 1 complete
IDOR-1117-2520 Undisclosed Immune-mediated disorders	Phase 1 ongoing
IDOR-1134-2831 Synthetic glycan vaccine <i>Clostridium difficile</i> infection	Phase 1 ongoing

Daridorexant

Daridorexant is a dual orexin receptor antagonist (DORA) which blocks the binding of the wake-promoting orexin neuropeptides. Rather than inducing sleep through broad inhibition of brain activity, daridorexant only blocks the activation of orexin receptors. Daridorexant is commercially available as QUVIVIQ in the US, Germany, Italy, Switzerland, Spain, the UK, Canada, Austria, and France, and is approved throughout the EU (see “Commercial operations” above).

A Phase 4 study to investigate the efficacy of daridorexant in patients with insomnia and comorbid nocturia ([NCT05597020](#)) has finished with daridorexant at a daily dose of 50 mg delivering positive topline results. The study results are being fully analyzed, and details will be made available at upcoming scientific congresses and in peer-reviewed publications.



Idorsia is conducting a Phase 2 dose-finding study to assess the efficacy, safety, and pharmacokinetics of multiple-dose oral administration of daridorexant in pediatric patients aged 10 to <18 years with insomnia disorder ([NCT05423717](#)). The primary objective of the study is to characterize the dose-response relationship of daridorexant on objective total sleep time (TST), using polysomnography. The study is expected to enroll around 150 patients, who will be randomized in a 1:1:1:1 ratio to 10 mg, 25 mg, or 50 mg daridorexant, or placebo. The study is part of a US FDA-approved Pediatric Study Plan and an EU PDCO-approved Paediatric Investigation Plan.

Aprocitentan

Aprocitentan is a once-daily, orally active, dual endothelin receptor antagonist, which inhibits the binding of ET-1 to ET_A and ET_B receptors. Aprocitentan has a low potential for drug-drug interaction and a mechanism of action suited for lowering blood pressure in adult patients whose hypertension is not adequately controlled by other drugs. Aprocitentan is approved in the US under the tradename TRYVIO™ where it will be made available later in 2024, and in Europe under the tradename JERAYGO™ (see “Commercial operations” above). Marketing authorization applications for the UK, Canada, and Switzerland are in preparation.

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. In October 2021, the company reported that lucerastat 1000 mg b.i.d. did not meet the primary endpoint of reducing neuropathic pain during 6 months of treatment versus placebo. However, Lucerastat demonstrated a substantial reduction in levels of the Fabry disease biomarker plasma Gb3 during the treatment period, with a decrease of approximately 50% observed in plasma Gb3 in the lucerastat treatment group compared to an increase of 12% in the placebo group. Furthermore, results suggested a treatment effect on kidney function. Lucerastat was well tolerated. Analysis of the ongoing open-label extension (OLE) of the Phase 3 study corroborated the long-term effect on plasma Gb3 levels and a potential positive long-term effect on kidney function. 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 kidney biopsy substudy within a subset of patients currently participating in the OLE study in order to steer further development in Fabry disease. In parallel, Idorsia is working with regulatory authorities to design the next Phase 3 study to evaluate the effect of lucerastat on renal function.

IDOR-1134-2831

IDOR-1134-2831 is Idorsia’s synthetic glycan vaccine targeting *Clostridium difficile* infection (CDI). The first study in the Phase 1 clinical pharmacology program has enrolled its first healthy participants to assess the safety, tolerability, and immunogenicity of up to 3 ascending dose levels of the IDOR-1134-2831 vaccine.

Further details including the current status of each project in our portfolio can be found in our [innovation fact sheet](#).

Idorsia partner-led portfolio

For Idorsia, sophisticated partnerships are a way of gaining strategic access to technologies or products and fully exploiting our discovery engine and clinical pipeline. We seek suitable external project partners to maximize the value of internal innovation.

Compound Mechanism of action Target indication	Partner/status
QUVIVIQ™ (daridorexant) Dual orexin receptor antagonist Insomnia	Simcere: Approved for the treatment of insomnia in Hong-Kong
Daridorexant Dual orexin receptor antagonist Insomnia	Nxera Pharma*: license to develop and commercialize for Asia-Pacific region (excluding China) NDA submitted in Japan
Daridorexant Dual orexin receptor antagonist Insomnia	Simcere: license to develop and commercialize for Greater China region NDA submitted in Greater China
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 (excluding Japan, South Korea, and certain countries in the Asia-Pacific region) Phase 3 "OPUS" program ongoing
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-709478 (NBI-827104) T-type calcium channel blocker Epileptic encephalopathy with continuous spike-and-wave during sleep (CSCW)	Neurocrine Biosciences: global license to develop and commercialize Phase 2 OLE study ongoing
ACT-1002-4391 EP ₂ /EP ₄ receptor antagonist Immuno-oncology	Owkin: global license to develop and commercialize Phase 1 in preparation

* In Japan, Idorsia has a license agreement with Mochida Pharmaceutical for the supply, co-development and co-marketing of daridorexant. All potential milestones have been assigned to Nxera.

Daridorexant (Nxera Pharma)

Daridorexant is licensed to Nxera Pharma (previously known as Sosei Heptares) in the Asia-Pacific region (excluding China), and a New Drug Application (NDA) is under review with the Japanese Ministry of Health, Labor, and Welfare (MHLW). The outcome of the review is anticipated before the end of 2024.

In Japan, Idorsia has a license agreement with Mochida Pharmaceutical for the supply, co-development and co-marketing of daridorexant. All potential milestones have been assigned to Nxera.

Asia-Pacific region (excluding China): Australia, Brunei, Cambodia, Indonesia, Japan, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, South Korea, Thailand, Taiwan, and Vietnam.

Daridorexant (Simcere)

Daridorexant is licensed to Simcere in the Greater China region (Mainland China, Hong Kong, and Macau). A Phase 3 study with daridorexant in Chinese patients delivered positive results in May 2024 and an NDA for Mainland China was submitted in June 2024. The Hong Kong Department of Health granted approval for daridorexant, under the tradename QUVIVIQ, for the treatment of insomnia in May 2024.



Selatogrel and cenerimod (Viartis)

A joint development committee from Idorsia and Viartis is overseeing the development of two ongoing Phase 3 programs up to regulatory approval.

Selatogrel is a potent, fast-acting, reversible, and highly selective P2Y₁₂ inhibitor being developed in a Phase 3 study ([NCT04957719](#)) for the treatment of acute myocardial infarction (“SOS-AMI”) in patients with a recent history of AMI. It is intended to be self-administered subcutaneously via a drug delivery system (autoinjector).

Cenerimod is a highly selective S1P₁ receptor modulator, given as an oral once-daily tablet, which is being developed in a Phase 3 program known as “OPUS” ([NCT05648500](#), [NCT05672576](#), and [NCT06475742](#)) for the treatment of systemic lupus erythematosus (SLE).

Viartis has worldwide commercialization rights for both selatogrel and cenerimod (excluding, for cenerimod only, Japan, South Korea, and certain countries in the Asia-Pacific region).

Daridorexant (US Department of Defense)

Idorsia is supporting a clinical study sponsored by the US Department of Defense (DOD) to develop new therapies for posttraumatic stress disorder (PTSD). The Phase 2 study will evaluate the safety, tolerability, and efficacy of potential therapeutic interventions, including daridorexant, in active-duty US service members and veterans with PTSD ([NCT05422612](#)).

ACT-709478

Neurocrine Biosciences has a global license to develop and commercialize ACT-709478 (NBI-827104), Idorsia’s novel T-type calcium channel blocker. ACT-709478 is being investigated in a Phase 2 open-label extension (OLE) study for the treatment of pediatric patients with epileptic encephalopathy with continuous spike-and-wave during sleep (CSCW), a rare form of pediatric epilepsy. While the blinded study did not meet the primary endpoint, ACT-709478 was generally well tolerated and Neurocrine continues to analyze the totality of data coming from the OLE study to determine the next steps.

ACT-1002-4391

Owkin has a global license to develop and commercialize ACT-1002-4391, Idorsia’s novel, potent EP₂/EP₄ receptor antagonist with antitumor efficacy, to be used both as monotherapy and in combination with other oncology agents. The compound is in preparation for Phase 1 clinical pharmacology studies. Owkin will use its proprietary AI-based data-mining platform to generate clinical trial designs and to identify patients who may benefit from, and potential targets for, the compound.

Further details including the current status of each project in our partner-led portfolio can be found in our [innovation fact sheet](#).

Results Day Center

Investor community: To make your job easier, we provide all relevant documentation via the Results Day Center on our corporate website: www.idorsia.com/results-day-center.

Upcoming Financial Updates

- Nine-Months 2024 Financial Results reporting on October 29, 2024
- Full-Year 2024 Financial Results reporting on February 27, 2025

Notes to the editor



About Idorsia

Idorsia Ltd is reaching out for more – We have more ideas, we see more opportunities and we want to help more patients. In order to achieve this, we will develop Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech-hub – Idorsia is specialized in the discovery, development, and commercialization of small molecules to transform the horizon of therapeutic options. Idorsia has a 25-year heritage of drug discovery, a broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, and commercial operations in Europe and North America – the ideal constellation for bringing innovative medicines to patients.

Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 750 highly qualified specialists dedicated to realizing our ambitious targets.

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The above information contains certain "forward-looking statements", relating to the company's business, which can be identified by the use of forward-looking terminology such as "estimates", "believes", "expects", "may", "are expected to", "will", "will continue", "should", "would be", "seeks", "pending" or "anticipates" or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the company's investment and research and development programs and anticipated expenditures in connection therewith, descriptions of new products expected to be introduced by the company and anticipated customer demand for such products and products in the company's existing portfolio. Such statements reflect the current views of the company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.