Media Release
October 29, 2024

Ad hoc announcement pursuant to Art. 53 LR

Idorsia announces financial results for the first nine months of 2024

Allschwil, Switzerland – October 29, 2024
Idorsia Ltd (SIX: IDIA) today announced its financial results for the first nine months of 2024.

Highlights

- **Net revenue** 9M 2024 at CHF 53 million.
- **US GAAP operating loss** 9M 2024 of CHF 154 million and **Non-GAAP operating loss** of CHF 248 million.
- **Improved Guidance** for 2024, driven by diligent cost control.
- **QUVIVIQ™** (daridorexant) total net sales of CHF 39 million in 9M 2024.
- Commercial partnership for **QUVIVIQ** with Menarini France.
- **QUVIVIQ** approved for the treatment of insomnia in Japan.
- **TRYVIO™** (aprocitentan) commercially available in the US since October 2024.
- **JERAYGO™** (aprocitentan) approved by the European Commission in June 2024 and marketing authorization applications submitted in the UK, Canada, and Switzerland.
- Collaboration with **Neurocrine Biosciences** comes to an end.

André C. Muller, Chief Executive Officer of Idorsia, commented:
"The one thing everyone wants to hear about – both internally and externally – is the status of a deal with aprocitentan. I'm pleased to share that our efforts on this front are advancing well. Our improved financial guidance includes our cost-conscious attitude across the whole organization, without compromising advancements, such as making progress in ramping up sales of QUVIVIQ, making TRYVIO available in the US, and expanding marketing authorization for JERAYGO."

Financial results

US GAAP results	Nine Months		Third Quarter	
in CHF millions, except EPS (CHF) and number of shares (millions)	2024	2023	2024	2023
Net revenues	53	131	26	80
Operating expenses	(211)	(275)	(118)	150
Operating income (loss)	(154)	(144)	(90)	231
Net income (loss)	(180)	(181)	(101)	224
Basic EPS	(1.00)	(1.02)	(0.55)	1.26
Basic weighted average number of shares	180.5	178.2	182.4	178.4
Diluted EPS	(1.00)	(1.02)	(0.55)	0.96
Diluted weighted average number of shares	180.5	178.2	182.4	232.5

Net revenue of CHF 53 million in the first nine months of 2024 is the result of QUVIVIQ product sales (CHF 39 million), product sales to partners in the Asia-Pacific-Region (CHF 9 million) and contract revenue recognized in connection with Owkin (CHF 3 million). This compares to CHF 131 million in the first nine months of 2023, which included CHF 34 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 68 million one-off impact of the Nxera deal as well as CHF 4 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 nine months of 2024 benefited from extraordinary income of CHF 125 million from the Viatris deal resulting in an expense of CHF 211 million (CHF 275 million in the first nine months of 2023), of which CHF 16 million related to cost of sales (CHF 7 million in the first nine months of 2023), CHF 111 million to R&D expenses (CHF 235 million in the first nine months of 2023), and CHF 209 million to SG&A expenses (CHF 318 million in the first nine months of 2023).

US GAAP net loss in the first nine months of 2024 amounted to CHF 180 million (CHF 181 million net loss in the first nine months of 2023). The net loss was favorably impacted by a one-off income related to the Viatris deal of CHF 125 million (CHF 302 million one-off income related to the Nxera deal in the first nine months of 2023) and lower operating expenses throughout all functions.

The US GAAP net loss resulted in a basic net loss per share of CHF 1.00 (basic and diluted) in the first nine months of 2024, compared to a net loss per share of CHF 1.02 (basic and diluted) in the first nine months of 2023.

Non-GAAP* measures	**Nine Months**		**Third Quarter**	
in CHF millions, except EPS (CHF) and number of shares (millions)	**2024**	**2023**	**2024**	**2023**
Net revenues	53	131	26	80
Operating expenses	(305)	(517)	(106)	(124)
Operating income (loss)	(248)	(386)	(78)	(44)
Net income (loss)	(258)	(420)	(75)	(51)
Basic EPS	(1.43)	(2.36)	(0.41)	(0.29)
Basic weighted average number of shares	180.5	178.2	182.4	178.4
Diluted EPS	(1.43)	(2.36)	(0.41)	(0.29)
Diluted weighted average number of shares	180.5	178.2	182.4	178.4

** 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 nine months of 2024 amounted to CHF 258 million: the CHF 78 million difference versus US GAAP net loss was mainly due to the one-off effect of the Viatris deal (CHF 125 million income), depreciation and amortization (CHF 14 million), share-based compensation (CHF 17 million) and a consent fee paid in shares to the bondholders resulting from amended terms of the 2024 convertible bonds (CHF 14 million).

The non-GAAP net loss resulted in a net loss per share of CHF 1.43 (basic and diluted) in the first nine months of 2024, compared to a net loss per share of CHF 2.36 (basic and diluted) in the first nine months of 2023.

Viatris collaboration

In March 2024, Idorsia closed agreements with Viatris 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 Viatris.

Viatris 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 Viatris 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. A consent fee of 8,000 shares per Bond was paid to bondholders on September 5, 2024.

Financial outlook 2024

For 2024 – excluding unforeseen events – the company expects QUVIVIQ net sales of around CHF 55 million; SG&A expenses of around CHF 265 million; R&D expense of around CHF 130 million for Idorsia-led pipeline assets; non-GAAP operating expenses around CHF 400 million. This performance would result in a non-GAAP operating loss of around CHF 350 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 260 million which includes a one-off benefit of CHF 125 million from the Viatris deal.

Arno Groenewoud, Chief Financial Officer, commented:
“While closing a deal for TRYVIO is a key focal point, we have also sharpened our cost-conscious approach, which we will increase going forward. Hence, we have been able to stretch the cash runway out to about year-end 2024, which allows us to appropriately plan and execute the next steps of our financial strategy. Furthermore, as a result of lower than expected spending we can upgrade our US GAAP and non-GAAP operating loss guidance by around 60 million Swiss francs each, taking them to 260 million and 350 million Swiss francs, respectively.”

Liquidity and indebtedness

At the end of the first nine months of 2024, Idorsia's liquidity amounted to CHF 92 million.

(in CHF millions)	Sep 30, 2024	Jun 30, 2024	Dec 31, 2023
Liquidity			
Cash and cash equivalents	92	237	145
Total liquidity*	**92**	**237**	**145**
Indebtedness			
Convertible loan	335	335	335
Convertible bond	797	797	796
Other financial debt	162	162	162
Total indebtedness	**1,294**	**1,294**	**1,293**

*rounding differences may occur

Commercial operations

In the first nine months of 2024, QUVIVIQ™ (daridorexant) in the US, Germany, Italy, Switzerland, Spain, UK, Canada, Austria, and France generated total product sales of CHF 39 million.

United States

Product	Mechanism of action	Indication	Commercially available since
QUVIVIQ (daridorexant) IV 25mg,50mg tablets	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 nine months of 2024 reached CHF 21 million, an increase of +41% versus the first nine months of 2023.

As of the end of the third quarter 2024, more than 165,000 patients have been treated with QUVIVIQ since launch in the US, over 500,000 prescriptions have been dispensed, and the product has been prescribed by almost 50,000 healthcare professionals.

Tosh Butt, President, and General Manager of Idorsia US, commented:
"Due to budget constraints we have recently reduced our field force for QUVIVIQ. Despite the reduction, the sales are holding-up for now. Importantly, the citizen petition requesting a review of the evidence from available data, which will hopefully lead to the descheduling of the DORA class of chronic insomnia medications, continues to make progress."

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
TRYVIO™ (aprocitentan) 12.5mg tablets	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	October 2024

On March 19, 2024, the US Food and Drug Administration (FDA) approved **TRYVIO™ (aprocitentan)** 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.

Tosh Butt concluded:
"Idorsia is making robust progress with the preparation of everything required for a full commercial launch of TRYVIO by the end of the first quarter of 2025. Both the REMS program and specialty distribution channel are fully up and running, we have begun engaging with hypertension experts through our presence at major cardiovascular and nephrology congresses. The initial discussions with payors are also encouraging. TRYVIO is now available to prescribe to the millions of patients in the US whose high blood pressure is not adequately controlled by other drugs. We have everything in place except a field-force and funding for promotional activities, which is dependent on a partnership deal."

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
QUVIVIQ daridorexant 25mg, 50mg tablets	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	Sweden: Sept. 2024 France: Mar. 2024 Austria: Feb. 2024 UK: Oct. 2023 Spain: Sept. 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 nine months of 2024 reached CHF 18 million in the EUCAN region. In the third quarter of 2024, net sales have increased by 46% compared to the second quarter of 2024.

In Germany, QUVIVIQ was launched in November 2022. By law, sleep medications were then subject to a 4-week prescribing limitation (Anlage III BtMG). Following a review by the Federal Joint Committee (G-BA) this limitation was lifted for QUVIVIQ in November 2023. This makes it the only sleep medication in Germany that can be prescribed for long-term treatment of chronic insomnia. In December 2023, the price negotiated for QUVIVIQ under the AMNOG process became effective. Following the lifting of the prescribing limitation, the company submitted a second AMNOG dossier for the long-term treatment of chronic insomnia disorder (beyond 4 weeks), reflecting the indication approved by the EMA in 2022. The second AMNOG process is expected to end in March 2025. The progress made in Germany is reflected by the performance of QUVIVIQ on the market, with sales doubling in the first nine months of 2024 compared to the first nine months of 2023.

In Italy, QUVIVIQ was launched in November 2022. Currently, QUVIVIQ can only be prescribed by neurologists, psychiatrists, and specialists from sleep centers, and no sleep therapy is reimbursed. The company submitted a reimbursement dossier in June 2023 and requested the expansion of the prescriber base. The submission – detailing the efficacy and safety profile of QUVIVIQ and its estimated budget impact and cost-effectiveness in Italy – is under review, with a hearing expected to take place before the end of the year.

In Switzerland, QUVIVIQ was launched to the self-pay market in June 2023. Following the launch of QUVIVIQ, awareness and sales have increased solidly. Reimbursement discussions are ongoing and remain a priority for Switzerland.

In Spain, QUVIVIQ was launched to the self-pay market in September 2023. Spain represents the largest insomnia market in Europe, as was apparent in the first months of this product's availability, despite it only being launched to the self-pay market. The company submitted a reimbursement dossier to the Spanish authorities in July 2024, in order to allow equal access for all patients with chronic insomnia.

In the UK, QUVIVIQ is recommended as first-line pharmaceutical treatment for patients with chronic insomnia, after, or as an alternative to, cognitive behavioral therapy for insomnia (CBT-I). QUVIVIQ was launched in October 2023 and the team has achieved full reimbursement throughout the UK. The priority in the UK is to secure regional access, which currently stands at around 80%, as well as raising awareness of QUVIVIQ among general practitioners.

In Austria, QUVIVIQ was made available in February 2024. A reimbursement dossier was submitted in October 2024, with a conclusion expected in the second half of 2025.

In France, QUVIVIQ was included in both the hospital and the retail formulary list of reimbursed pharmaceutical specialties in January 2024 and launched in March 2024 as the first and only pharmacotherapy recommended for the treatment of chronic insomnia disorder. There was a very strong uptake at launch largely due to the excellent market preparation work with psychiatrists. This can be seen by the fact that the majority of prescriptions are being made by the specialists, despite the French market being composed of 55'000 general practitioners who between them represent 75% of the insomnia prescriptions. As a result, the priority becomes expanding awareness to the primary care market to secure strong long-term growth. To address this, Idorsia is expanding its commercial reach from specialist prescribers to general practitioners (GPs) through a new commercial partnership with Menarini in France.

In Sweden, QUVIVIQ was made available in September 2024. A reimbursement dossier was submitted in May 2024. As a result, a decision on reimbursement is expected by the end of 2024.

In Canada, after being approved in April 2023, QUVIVIQ was launched in November 2023 to the private market, representing 55% of the Canadian insomnia market. The reimbursement dossier was submitted to private market payers in the third quarter of 2023 and currently stands at 80% coverage. The focus is now on public payers with the submission confirmation in Quebec received in October 2024 and submissions in all other provinces ongoing and to be completed by year end.

Benjamin Limal, President of Europe and Canada region, commented:
"Securing public access to Europe's only dual orexin receptor antagonist remains our number one priority throughout the EUCAN region – this is the pathway to unlocking the true value of QUVIVIQ. Until then, the performance is satisfactory with a great adoption from specialists and a strong quarterly growth in demand and sales. As one of the newest launches, I have to mention France – QUVIVIQ is really off to a flying start and we are quickly reinforcing the launch momentum through a commercial partnership with Menarini, experts with established relationships in primary care, to handle the promotion of QUVIVIQ to GPs."

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
JERAYGO™ aprocitentan	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.

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 in the US, Germany, Italy, Switzerland, Spain, the UK, Canada, Austria, France, and Sweden; approved throughout the EU
TRYVIO™ (aprocitentan) Dual endothelin receptor antagonist **Systemic hypertension in combination with other antihypertensives**	Commercially available in the US
JERAYGO™ (aprocitentan) Dual endothelin receptor antagonist **Resistant hypertension in combination with other antihypertensives**	Approved in the EU; Marketing authorization applications submitted in the UK, Canada, and Switzerland
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 ***Clostridium difficile* infection**	Phase 1 ongoing

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
QUVIVIQ™ (daridorexant) Dual orexin receptor antagonist **Insomnia**	**Nxera Pharma:** license to develop and commercialize for Asia-Pacific region (excluding China) Approved for the treatment of insomnia 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-1002-4391 EP_2/EP_4 receptor antagonist **Immuno-oncology**	**Owkin:** global license to develop and commercialize Phase 1 in preparation

On October 1, 2024, Nxera Pharma announced that it had entered a commercial partnership agreement with Shionogi & Co., Ltd regarding the distribution and sales for QUVIVIQ in Japan. At the same time, the previous commercialization agreement between Nxera and Mochida Pharmaceutical Co., Ltd. was terminated. After negotiation among Nxera, Shionogi and Mochida regarding the optimal sales scheme, Shionogi is solely responsible for distribution and sales activities in Japan.

Idorsia and Neurocrine Biosciences had a collaboration for ACT-709478, Idorsia's novel T-type calcium channel blocker. The compound was investigated as a treatment of pediatric patients with epileptic encephalopathy with continuous spike-and-wave during sleep (CSCW), a rare form of pediatric epilepsy. The Phase 2 study did not meet the primary endpoint in June 2022, and further analysis from an open-label extension study resulted in the decision to stop further development. As a result, the development agreement has come to an end.

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

- Full Year 2024 Financial Reporting together with the publication of the Annual Report 2024 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.