Media Release
April 25, 2023

Ad hoc announcement pursuant to Art. 53 LR

Idorsia announces financial results for the first quarter 2023 – QUVIVIQ now the leading branded insomnia medicine in the commercial market in the US

Allschwil, Switzerland – April 25, 2023
Idorsia Ltd (SIX: IDIA) today announced its financial results for the first quarter of 2023.

Commercial highlights

- **QUVIVIQ™ (daridorexant)** total net sales of CHF 4.3 million in Q1 2023
- **QUVIVIQ in the US:** Now the leading branded insomnia medicine in new-to-brand prescriptions (NBRx) and total prescriptions (TRx) in the commercial market. Net sales do not reflect the volume as broad commercial coverage is under negotiation.
- **QUVIVIQ in Europe:** Demand continues to grow in Germany and Italy
- **PIVLAZ® (clazosentan):** Treated more than 5,000 patients in the first year of availability, with net sales of CHF 13.5 million in Q1 2023, and approximately 27% of aSAH patients treated with PIVLAZ in the month of March.

Pipeline highlights

- **Aprocitentan** – NDA accepted for review by the US FDA – PDUFA December 19, 2023
- **Aprocitentan** – MAA submitted to the EMA at the end of January 2023

Financial highlights

- **Net revenue** Q1 2023 at CHF 21 million
- **US GAAP operating expenses** Q1 2023 at CHF 219 million and **non-GAAP operating expenses** Q1 2023 at CHF 202 million
- **US GAAP operating loss** Q1 2023 of CHF 198 million and **non-GAAP operating loss** of CHF 181 million
- **Guidance for 2023:** The company is committed to manage operating expenses in order to deliver US GAAP operating loss of around CHF 735 million and non-GAAP operating loss of around CHF 650 million – unforeseen events excluded
- **Fundraising**: With a liquidity of CHF 212 million at the end of Q1 2023 and the current guidance for 2023 – the company is pursuing options including non-equity dilutive funding avenues and/or equity raise should it be needed, to extend the cash runway
- **Profitability target:** The company is committed to become profitable in 2025 with global revenue above CHF 1 billion

Jean-Paul Clozel, MD and Chief Executive Officer, commented:
"The company continues to deliver on the strategic priorities and make progress on many fronts. PIVLAZ has been available in Japan for a year now and more than 5,000 patients have been treated, a great result. QUVIVIQ is approaching one year on the market in the US, and it is already the number one branded insomnia treatment in the commercial market. While there has been a delay in securing reimbursement, progress has been made and the situation is steadily improving. Demand is good and growing, feedback from patients and prescribers is excellent, and refills are accelerating. Uptake in

the first markets of Europe is also strong, with more markets set to launch in the coming year. We will adapt our cost-base to accommodate the delay in reimbursement and we are very active on several non-dilutive opportunities to extend the cash runway. For a company based on science, that started from zero less than 6 years ago, and launched two products in the past year, there are many reasons to believe in Idorsia's bright future."

Financial results

US GAAP results **in CHF millions, except EPS (CHF) and number of shares (millions)**	**First Quarter**	
	2023	**2022**
Net revenues	21	5
Operating expenses	(219)	(198)
Operating income (loss)	(198)	(193)
Net income (loss)	(212)	(198)
Basic EPS	(1.19)	(1.12)
Basic weighted average number of shares	178.0	177.1
Diluted EPS	(1.19)	(1.12)
Diluted weighted average number of shares	178.0	177.1

US GAAP net revenue of CHF 21 million in the first quarter of 2023 (CHF 5 million in the first quarter of 2022) consisted of product sales of QUVIVIQ (CHF 4.3 million) and PIVLAZ (CHF 13.5 million), contract revenue recognized in connection with Mochida Pharmaceutical Co., Ltd (CHF 1 million) and Neurocrine Biosciences, Inc. (CHF 1 million), and revenue share from Johnson & Johnson (CHF 1 million).

US GAAP operating expenses in the first quarter of 2023 amounted to CHF 219 million (CHF 198 million in the first quarter of 2022), of which CHF 1 million related to cost of sales (no cost of sales in the first quarter of 2022), CHF 93 million to R&D expenses (CHF 95 million in the first quarter of 2022) and CHF 125 million to SG&A expenses (CHF 103 million in the first quarter of 2022).

US GAAP net loss in the first quarter of 2023 amounted to CHF 212 million (CHF 198 million in the first quarter of 2022). The increase of the net loss was mainly driven by higher operating expenses, largely in the commercial functions, a negative financial result and partially offset by higher net revenues.

The US GAAP net loss resulted in a net loss per share of CHF 1.19 (basic and diluted) in the first quarter of 2023, compared to a net loss per share of CHF 1.12 (basic and diluted) in the first quarter of 2022.

Non-GAAP* measures **in CHF millions, except EPS (CHF) and number of shares (millions)**	**First Quarter**	
	2023	**2022**
Net revenues	21	5
Operating expenses	(202)	(188)
Operating income (loss)	(181)	(183)
Net income (loss)	(189)	(189)
Basic EPS	(1.06)	(1.07)
Basic weighted average number of shares	178.0	177.1
Diluted EPS	(1.06)	(1.07)
Diluted weighted average number of shares	178.0	177.1

** 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 quarter of 2023 amounted to CHF 189 million: the CHF 23 million difference versus US GAAP net loss was mainly due to depreciation and amortization (CHF 4 million), and share-based compensation (CHF 12 million) and a loss on marketable securities (CHF 7 million).

The non-GAAP net loss resulted in a net loss per share of CHF 1.06 (basic and diluted) in the first quarter of 2023, compared to a net loss per share of CHF 1.07 (basic and diluted) in the first quarter of 2022.

Creation of Treasury Shares

In January 2023, the Company created 10.0 million treasury shares with a nominal value of CHF 0.05 each, thereby increasing its registered share capital from CHF 8,848,349.75 to CHF 9,348,349.75. The new shares, created on January 6, 2023, out of the Company's authorized share capital, were subscribed at nominal value by Idorsia Pharmaceuticals Ltd, a wholly owned subsidiary, and were listed on the SIX Swiss Exchange on January 9, 2023. With this increase, the Company holds treasury shares that can be used in a cash preservative manner for potential share-based compensation, effective fund raising, or business development purposes.

Financial outlook

PIVLAZ (clazosentan) is available in Japan and QUVIVIQ (daridorexant) in the US, Germany, and Italy, and additional launches are anticipated in Switzerland and the UK during 2023. Regulatory applications for aprocitentan have been filed with the FDA and the EMA. Phase 3 studies with selatogrel and cenerimod are expected to be actively recruiting throughout 2023. The company is prioritizing those projects in drug discovery and early clinical pipeline that are expected to result in the greatest return in the near term, as well as seeking partnership opportunities to share risk and rewards. The company therefore expects US GAAP operating loss of around CHF 735 million and non-GAAP operating loss of around CHF 650 million – unforeseen events excluded.

André C. Muller, Chief Financial Officer, commented:
"Due to the slower than expected speed of payer coverage and resulting uncertainties in the US revenue development, the company is taking steps to manage its operating expenses in order to deliver on our 2023 guidance – unforeseen events excluded. Furthermore, we must address our near-term liquidity needs. Hence, we are pursuing non-equity dilutive funding avenues, while preparing an equity raise should it be needed, to extend the cash runway."

Liquidity and indebtedness

At the end of the first quarter of 2023, Idorsia's liquidity amounted to CHF 212 million.

(in CHF millions)	Mar 31, 2023	Dec 31, 2022
Liquidity		
Cash and cash equivalents	212	146
Short-term deposits	-	320
Long-term deposits	-	-
Total liquidity*	**212**	**466**
Indebtedness		
Convertible loan	335	335
Convertible bond	795	795
Other financial debt	162	162
Total indebtedness	**1,292**	**1,292**

*rounding differences may occur

Commercial operations

In 2022, Idorsia launched two products in different markets, QUVIVIQ™ (daridorexant) in the US and the first countries in Europe, and PIVLAZ® (clazosentan) in Japan, generating total product sales of CHF 18 million in Q1 2023.

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

QUVIVIQ (daridorexant) continues to gain traction in the US insomnia market. After just 11 months, QUVIVIQ has surpassed all other branded insomnia medications in new-to-brand prescriptions. Along with this, refills continue to increase – leading to strong growth in total prescriptions in the first quarter, with over 22,000 prescriptions of QUVIVIQ dispensed in March alone.

Net sales in the first quarter of 2023 reached CHF 3 million. To enable early patient access to QUVIVIQ, Idorsia continues to offer a strong copay program, including a free first 30-day prescription. However, due to this approach, the net sales numbers do not reflect actual dispensed prescriptions or product demand. Today, QUVIVIQ is covered by Express Scripts National Preferred Formulary (NPF) and Tricare Uniform Formulary, which together represent over 32 million lives in the US. The company continues to actively engage with other commercial and Part D payers.

Additionally, earlier this month the company filed a Citizen Petition with the United States Drug Enforcement Administration (DEA) requesting that the DORA class of insomnia medications be de-scheduled and removed from the controlled substance list (they are currently schedule IV medications in the US). The Citizen Petition outlines scientific and medical evidence demonstrating that the DORA class has a negligible abuse profile and potential for abuse, lacks non-medical use in the community, lacks physical and psychological dependence, and therefore, should not be a scheduled class under the Controlled Substances Act. Idorsia is confident that there is a solid and compelling case and hopes the DEA acts expeditiously on the petition. De-scheduling the class would remove many access barriers for patients and prescribing complications for physicians.

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

Simon Jose, Chief Commercial Officer of Idorsia, commented:
"It's great to see QUVIVIQ is now the leading insomnia brand in the US commercial market in terms of prescriptions. Although payer access has been slower than anticipated, we have secured access with ESI and TriCare and are in active discussions with other major payers. As further reimbursement is secured, we expect paid prescriptions to continue to increase, boosting net sales. Equally important to establishing QUVIVIQ as the leading branded treatment for insomnia is transforming and modernizing the entrenched, generic market we have entered."

Europe and Canada region

Product	Mechanism of action	Indication	Commercially available
QUVIVIQ daridorexant 25mg,50mg tablets	Dual orexin receptor antagonist	Treatment of adult patients with insomnia characterized by symptoms present for at least three months and considerable impact on daytime functioning	Germany: Nov 2022 Italy: Nov 2022

In April 2022, marketing authorization for QUVIVIQ was granted by the European Commission and subsequently by the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain. In November 2022, QUVIVIQ was launched in Italy and Germany. Launch preparations are underway in the UK, with a target launch in the second half of 2023, later followed by Spain and France. For more information about QUVIVIQ in the EU, see the Summary of Product Characteristics. Marketing authorization for QUVIVIQ was granted by Swissmedic in December 2022, and the company aims to make QUVIVIQ available to patients in Switzerland in June 2023. For more information about QUVIVIQ in Switzerland, see the Patient Information and Information for Healthcare Professionals. The review of daridorexant by Health Canada is expected to reach its conclusion in the coming weeks.

The launches in Germany and Italy are progressing well with positive feedback from physicians and patients to the differentiated profile of QUVIVIQ, the first and only dual orexin receptor antagonist available in Europe. In addition to educating healthcare professionals on the clinical data for QUVIVIQ, the local teams are raising awareness on the burden of chronic insomnia, as highlighted in the recent publication of the RAND report, "The Societal and Economic Burden of Insomnia in Adults: An International Study." Pricing and reimbursement processes are underway in key European markets to secure access to QUVIVIQ for chronic insomnia patients. Net sales in the first quarter of 2023 in Germany and Italy were CHF 1 million.

Japan

Product	Mechanism of action	Indication	Commercially available since
PIVLAZ clazosentan	Endothelin receptor antagonist	Prevention of cerebral vasospasm, vasospasm-related cerebral infarction and cerebral ischemic symptoms after aneurysmal subarachnoid hemorrhage (aSAH)	April 2022

PIVLAZ (clazosentan) was launched in Japan in April 2022 for the prevention of cerebral vasospasm, vasospasm-related cerebral infarction and cerebral ischemic symptoms in patients suffering from aneurysmal subarachnoid hemorrhage (aSAH). Neurosurgeons in Japan are incorporating PIVLAZ into aSAH treatment protocols and approximately 27% of Japanese aSAH patients were treated with PIVLAZ in March based on the estimated incidence of aSAH. Awareness of PIVLAZ has reached over 95% among target neurosurgeons in Japan as the local customer facing teams continue to share the clinical data demonstrating the efficacy and safety of PIVLAZ in Japanese patients. Net sales in the first quarter of 2023 were CHF 13 million.

Clinical development

Idorsia's diversified and balanced clinical development pipeline – covering multiple therapeutic areas, including CNS, cardiovascular and immunological disorders, as well as orphan diseases – is on track and progressing as described in the full year 2022 financial results press release.

Idorsia's portfolio

Product / compound	Mechanism of action	Therapeutic area	Status
PIVLAZ® (clazosentan)	Endothelin receptor antagonist	Cerebral vasospasm assoc. with aneurysmal subarachnoid hemorrhage	**Commercially available** in Japan
QUVIVIQ™ (daridorexant)	Dual orexin receptor antagonist	Insomnia	**Commercially available** in the US Germany and Italy; approved in the EU, UK and Switzerland; under review in Canada; Filing in Japan expected in H2 2023; Phase 2 in pediatric insomnia – recruiting
Aprocitentan*	Dual endothelin receptor antagonist	Difficult-to-control (resistant) hypertension	NDA under review in the US, MAA under review in the EU, other filings in preparation
Lucerastat	Glucosylceramide synthase inhibitor	Fabry disease	Phase 3 primary endpoint not met, OLE ongoing**
Selatogrel	$P2Y_{12}$ inhibitor	Suspected acute myocardial infarction	Phase 3 recruiting
Cenerimod	$S1P_1$ receptor modulator	Systemic lupus erythematosus	Phase 3 recruiting
ACT-1004-1239	ACKR3 / CXCR7 antagonist	Multiple sclerosis and other demyelinating diseases	Phase 2 in preparation
Sinbaglustat	GBA2/GCS inhibitor	Rare lysosomal storage disorders	Phase 1 complete
ACT-1014-6470	C5aR1 antagonist	Immune-mediated disorders	Phase 1
ACT-777991	CXCR3 antagonist	Recent-onset Type 1 diabetes	Phase 1
IDOR-1117-2520	Undisclosed	Immune-mediated disorders	Phase 1

** In collaboration with Janssen Biotech to jointly develop aprocitentan, Janssen Biotech has sole commercialization rights worldwide*
*** Open-label extension study*

Neurocrine Biosciences has a global license to develop and commercialize ACT-709478 (NBI-827104), Idorsia's novel T-type calcium channel blocker. ACT-709478 was investigated in a Phase 2 study for the treatment of a rare form of pediatric epilepsy. The study did not meet the primary endpoint. ACT-709478 was generally well tolerated. Neurocrine continues to analyze the data generated in the study.

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

Note to Shareholders

The Annual General Meeting (AGM) of Shareholders to approve the Annual Report of the year ending December 31, 2022, will be held on Thursday, May 4, 2023, at 09.00 CEST at the Congress Center, Messe Basel, Switzerland.

The invitation was published in the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt) and distributed to Shareholders by post. It is also available, together with the Company's Annual Report and Compensation Report, on www.idorsia.com/agm.

In order to attend and vote at the AGM, shareholders must be registered in the company's shareholder register by April 25, 2023, 17:00 CEST, at the latest.

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

- Annual General Meeting of Shareholders on May 4, 2023
- Half-Year 2023 Financial Results reporting on July 25, 2023
- Nine-Months 2023 Financial Results reporting on October 24, 2023
- Full-Year 2023 Financial Results reporting on February 6, 2024

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 20-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, Japan, and the US – 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 1,300 highly qualified specialists dedicated to realizing our ambitious targets.

For further information, please contact

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