Media Release
July 25, 2023

Ad hoc announcement pursuant to Art. 53 LR

Idorsia announces financial results for the first half 2023 – adapting the company to create sustainable value

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

Business highlights

- **Transaction with Sosei Heptares:** Idorsia sells its Asia Pacific (ex-China) operations – including selected license rights to products – for a total consideration of CHF 400 million.
- **Cost reduction initiative** with the target of a reduction in cash-burn at headquarters by approximately 50% expected to become fully effective in early 2024.

Commercial highlights

- **QUVIVIQ™ (daridorexant):** Total net sales of CHF 11.8 million in the first half 2023.
- **QUVIVIQ in the US:** CVS coverage secured in July 2023 – with Express Scripts QUVIVIQ is now covered by two of the largest insurance plans in the commercial space. Bids submitted for Medicare Part-D with expected coverage in the new year. Team now focused on converting strong demand into sales.
- **QUVIVIQ in Europe:** Demand continues to grow in Germany and Italy. Promising launch in Switzerland in June 2023.
- **PIVLAZ® (clazosentan) in Japan:** Net sales of CHF 32.4 million in the first half 2023. As a result of the Sosei Heptares deal, Idorsia will no longer report sales of PIVLAZ in Japan and territories granted to Sosei Heptares.

Pipeline highlights

- **Daridorexant** – Approved by Health Canada for the management of adult patients with insomnia under the tradename QUVIVIQ.
- **Aprocitentan** – New Phase 3 data presented at the European Society of Hypertension Annual Meeting 2023 – NDA under review with the US FDA – PDUFA December 19, 2023 – and MAA under review with the European Medicines Agency.
- **Portfolio review initiated** – Objective to prioritize assets that can be advanced rapidly and with reasonable financial investment.

Financial highlights

- **Net revenue** HY 2023 at CHF 51 million.
- **US GAAP operating expenses** HY 2023 at CHF 426 million and **non-GAAP operating expenses** HY 2023 at CHF 393 million.
- **US GAAP operating loss** HY 2023 of CHF 375 million and **non-GAAP operating loss** of CHF 342 million.
- **Guidance for 2023:** The company is committed to manage operating expenses to deliver US GAAP operating loss of around CHF 735 million and non-GAAP operating loss of around CHF 650 million – unforeseen events excluded.
- **Profitability target:** Suspended – target to be provided again during 2024.

Jean-Paul Clozel, MD and Chief Executive Officer, commented:
"I maintain our ambition to become a mid-sized biopharmaceutical leader, and I believe in our innovative portfolio as well as the science upon which it is built. With aprocitentan currently advancing in the registration process, we are well on track to have the third drug from our pipeline available for patients. Capitalizing on this clinical success to make Idorsia profitable has been more challenging than I had hoped. As a result, adaptations must be made to reduce our global cash-burn. The sale of our affiliates in Japan and South Korea has given us some breathing space to make those adaptations. As announced last week, the cost reduction initiative, including a full portfolio review, combined with potential collaborations, will extend the time we have to create sustainable value. I'm grateful to all those who continue to support us in our purpose to help more patients."

Financial results

US GAAP results	First Half		Second Quarter	
in CHF millions, except EPS (CHF) and number of shares (millions)	2023	2022	2023	2022
Net revenues	51	22	30	5
Operating expenses	(426)	(427)	(207)	(229)
Operating income (loss)	(375)	(405)	(177)	(212)
Net income (loss)	(405)	(419)	(193)	(222)
Basic EPS	(2.28)	(2.36)	(1.08)	(1.25)
Basic weighted average number of shares	178.1	177.3	178.3	177.5
Diluted EPS	(2.28)	(2.36)	(1.08)	(1.25)
Diluted weighted average number of shares	178.1	177.3	178.3	177.5

US GAAP net revenue of CHF 51 million in the first half of 2023 (CHF 22 million in the first half of 2022) consisted of product sales of QUVIVIQ (CHF 12 million) and PIVLAZ (CHF 32 million), contract revenue recognized in connection with Mochida Pharmaceutical Co., Ltd (CHF 3 million) and Neurocrine Biosciences, Inc. (CHF 2 million), and revenue share from Johnson & Johnson (CHF 2 million).

US GAAP operating expenses in the first half of 2023 amounted to CHF 426 million (CHF 427 million in the first half of 2022), of which CHF 5 million related to cost of sales (CHF 1 million in the first half of 2022), CHF 172 million to R&D expenses (CHF 192 million in the first half of 2022) and CHF 249 million to SG&A expenses (CHF 234 million in the first half of 2022).

US GAAP net loss in the first half of 2023 amounted to CHF 405 million (CHF 419 million in the first half of 2022). The decrease of the net loss was driven by higher net revenues and lower operating expenses, largely in the R&D functions, which was partially offset by higher financial expenses.

The US GAAP net loss resulted in a net loss per share of CHF 2.28 (basic and diluted) in the first half of 2023, compared to a net loss per share of CHF 2.36 (basic and diluted) in the first half of 2022.

Non-GAAP* measures in CHF millions, except EPS (CHF) and number of shares (millions)	First Half 2023	 2022	Second Quarter 2023	 2022
Net revenues	51	22	30	5
Operating expenses	(393)	(407)	(191)	(219)
Operating income (loss)	(342)	(384)	(161)	(202)
Net income (loss)	(369)	(395)	(180)	(206)
Basic EPS	(2.07)	(2.23)	(1.01)	(1.16)
Basic weighted average number of shares	178.1	177.3	178.3	177.5
Diluted EPS	(2.07)	(2.23)	(1.01)	(1.16)
Diluted weighted average number of shares	178.1	177.3	178.3	177.5

** 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 2023 amounted to CHF 369 million: the CHF 36 million difference versus US GAAP net loss was mainly due to depreciation and amortization (CHF 8 million), share-based compensation (CHF 24 million), and a loss on marketable securities (CHF 5 million).

The non-GAAP net loss resulted in a net loss per share of CHF 2.07 (basic and diluted) in the first half of 2023, compared to a net loss per share of CHF 2.23 (basic and diluted) in the first half of 2022.

Transaction with Sosei Heptares

On July 20, 2023, Idorsia sold its operating businesses in the Asia Pacific (ex-China) region to Sosei Heptares for a total consideration of CHF 400 million.

The territories within the scope of the transaction are Australia, Brunei, Cambodia, Indonesia, Japan, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, South Korea, Thailand, Taiwan, and Vietnam.

The transaction includes the acquisition by Sosei Heptares of Idorsia's affiliates in Japan and South Korea, the assignment of the license for PIVLAZ (clazosentan) for the Asia Pacific (ex-China) region, the co-exclusive license for daridorexant for the Asia Pacific (ex-China) region and the assignment of all potential milestones in connection with the co-exclusive license of daridorexant granted to Mochida Pharmaceutical. The transaction also includes an option for Sosei Heptares – upon payment of separate option fees – to license cenerimod and lucerastat for the development and commercialization in the territories.

With the completion of the transaction with Sosei Heptares on July 20, 2023, the full-year financial operating results of Idorsia will no longer include details from the operations in Japan and South Korea. The net sales, operating expenses and other financial and tax expenses incurred in the first 6.5 months, as well as the gain from the sale will be recorded on separate line items "results of discontinued operations" and "gain from sale of discontinued operations" recorded below the line item "net income (loss) from continuing operations".

Bridge loan

In order to bridge the completion of the transaction with Sosei Heptares, Idorsia secured a loan with Jean-Paul Clozel, CEO, Member of the Board of Directors and Idorsia's largest shareholder, for up to CHF 75 million. Idorsia drew down a first tranche of CHF 20 million in June and an additional tranche of CHF 30 million in July. The loan was fully repaid on July 21, 2023.

Cost reduction initiative

On July 21, 2023, Idorsia announced that it has launched a cost reduction initiative with the target to reduce cash-burn at headquarters by approximately 50%. The company will review the research and development pipeline and product portfolio with the objective to prioritize assets that can be advanced rapidly and with reasonable financial investment. Following the portfolio review, those projects not aligned to the company priorities will be either paused or prepared for partnership or out-licensing.

Up to 500 positions could become redundant, mainly in Research & Development and the associated support functions, at headquarters in Allschwil, Switzerland. A consultation process with employee representatives at headquarters has been initiated. Upon completion of the consultation process, Idorsia intends to conclude the initiative before the end of 2023 with the reduction of costs becoming fully effective early in 2024.

Consequently, a one-off charge – the size of which is still to be determined, in part, upon conclusion of employee representative consultations – will be included in the 2023 financial statements.

Profitability Target

Idorsia had set a target to become profitable in 2025 with global revenue above CHF 1 billion. With the transaction with Sosei Heptares in the APAC (ex-China) region, a slower than expected ramp up of QUVIVIQ sales, a portfolio review and ongoing discussions with potential partners, together with the announced cost reduction initiative, there are many moving parts, and the company has therefore suspended its 2025 profitability target.

Financial outlook 2023

The 2023 financial outlook is calculated on the basis of QUVIVIQ (daridorexant) being available in the US, Germany, Italy, and Switzerland with additional launches anticipated in the UK and Spain in the second half of 2023; Regulatory applications for aprocitentan being under review by the US FDA and the EMA; and the Phase 3 studies with selatogrel and cenerimod expected to continue to actively recruit in the second half of 2023.

The company re-issues its full year 2023 financial guidance and expects a US GAAP operating loss of around CHF 735 million and a non-GAAP operating loss of around CHF 650 million for 2023 – unforeseen events excluded and taking into account the ongoing cost reduction initiative in connection with the review of the research and development pipeline and product portfolio. In addition, following the completion of the transaction with Sosei Heptares, Idorsia will no longer include the operations in Japan and South Korea in its financial operating result as explained above.

André C. Muller, Chief Financial Officer, commented:
"The transaction completed with Sosei Heptares brought much-needed cash to Idorsia, creating value for both companies, while maintaining our ability to develop our drugs for patients in the region. This 400 million Swiss francs deal, of which 396 million are already paid, allows us to extend the cash runway to early 2024. We are working on several initiatives to secure additional funding in the second half of 2023 and, in parallel, we launched a cost reduction initiative that is expected to have full effect by early 2024. However, we can re-issue our 2023 financial guidance unforeseen events excluded. With many moving parts expected to fall into place in the next few quarters, this should allow us to provide a new profitability target again during 2024."

Liquidity and indebtedness

At the end of the first half of 2023, Idorsia's liquidity amounted to CHF 33 million.

(in CHF millions)	Jun 30, 2023	Mar 31, 2023	Dec 31, 2022
Liquidity			
Cash and cash equivalents	33	212	146
Short-term deposits	-	-	320
Long-term deposits	-	-	-
Total liquidity*	**33**	**212**	**466**
Indebtedness			
Convertible loan	335	335	335
Convertible bond	796	795	795
Other financial debt	192	162	162
Total indebtedness	**1,322**	**1,292**	**1,292**

*rounding differences may occur

The liquidity of CHF 33 million includes the proceeds of Sosei Heptares (CHF 10 million) and the bridge loan (CHF 20 million), but excludes the cash held by the Japanese and Korean affiliates (CHF 11 million) included in a separate line item "Assets held for sale".

Commercial operations

In the first half of 2023, QUVIVIQ™ (daridorexant) in the US, Germany, Italy, and Switzerland, and PIVLAZ® (clazosentan) in Japan, generated total product sales of CHF 44.2 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

QUVIVIQ (daridorexant) net sales in the first half of 2023 reached CHF 8.8 million in the US. This net sales number encompasses the QUVIVIQ copay program aimed at driving demand and product uptake, and thus does not reflect the actual dispensed prescriptions and product demand.

QUVIVIQ continues to show a solid upward trajectory in product demand and writer base. In the first half of 2023, more than 125,000 prescriptions were dispensed – an increase of more than 85% as compared to the approximately 65,000 dispensed prescriptions in the entire eight months that QUVIVIQ was on the market in 2022. Additionally, refills continue to rise week-on-week, reflecting the efficacy and safety of QUVIVIQ and its adoption by both the patient and physician.

Regarding insurance coverage, in July, QUVIVIQ was added to the CVS national formulary which covers 20 million lives. Additionally, the company anticipates Medicare Part D coverage to begin in the new year 2024, potentially opening an entirely new channel which would substantially improve product access and paid prescriptions.

Importantly, going into the second half of 2023, the increased insurance coverage of QUVIVIQ will enable a shift from Idorsia-paid consignment to insurance-paid prescriptions.

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

Patricia Torr, President and General Manager of Idorsia US, commented:
"Since launch, our strategy in the US has been to drive demand and product adoption in order to secure reimbursement from payers. This has resulted in strong brand recognition, positive experiences and feedback from both clinicians and patients, as well as enhanced insurance coverage. Our focus now is on converting the strong demand we have created into sales. In line with our strategy, we are starting to see this reflected in a shift from a consignment model we've used to drive demand, to a retail model as our market access positions continue to grow. As we move forward in the second half of 2023, we expect to see an increasing number of insurance -paid prescriptions coming through the retail channel."

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	Switzerland: Jun 2023 Germany: Nov 2022 Italy: Nov 2022

In April 2022, marketing authorization for QUVIVIQ for the treatment of adult patients with insomnia characterised by symptoms present for at least three months and considerable impact on daytime functioning, 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 and Spain, with a target launch in the second half of 2023, followed by France in the first half of 2024. For more information about QUVIVIQ in the EU, see the Summary of Product Characteristics.

Marketing authorization for QUVIVIQ for the treatment of adult patients with insomnia characterized by symptoms present for at least three months and considerable impact on daytime functioning, was also granted by Swissmedic in December 2022, and the company made 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.

Health Canada granted market authorization for QUVIVIQ for the management of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance in April 2023, and the company aims to make it available to patients in Canada in the first half of 2024. For more information on the marketing authorization of QUVIVIQ in Canada, see the Product Monograph.

The launches in Germany, Italy, and Switzerland are progressing well with increasing volumes and continued positive feedback from physicians and patients on the differentiated profile of QUVIVIQ. Net sales in the first half of 2023 in Germany, Italy, and Switzerland were CHF 3 million.

Pricing and reimbursement processes are underway in key European markets to secure access to QUVIVIQ for chronic insomnia patients.

Jean-Yves Chatelan, President of Europe and Canada region, commented:
"Our teams across Europe and Canada are making great progress with the launch of QUVIVIQ and with securing access and reimbursement. We are getting great feedback from physicians and patients where QUVIVIQ is available. QUVIVIQ is the first and only dual orexin receptor antagonist available in Europe and is specifically approved for adult patients suffering from chronic insomnia disorder. Chronic insomnia is a 24-hour disorder, with significant negative impact on patients at night and during the day. Making QUVIVIQ available to the millions of patients suffering from chronic insomnia and impacting so many lives is incredibly rewarding."

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 securing	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). Net sales in the first half of 2023 were CHF 32.4 million.

In July 2023, Idorsia and Sosei Heptares completed a transaction for Idorsia's operating businesses in the Asia Pacific (ex-China) region, including assignment of the license for PIVLAZ (clazosentan). As a result, Idorsia will no longer report sales of PIVLAZ in Japan and territories granted to Sosei Heptares.

Clinical development

Idorsia's has a diversified and balanced clinical development pipeline – covering multiple therapeutic areas, including CNS, cardiovascular and immunological disorders, as well as orphan diseases.

As part of the cost reduction initiative announced on July 21, 2023, and expected to be implemented by the end of 2023, Idorsia will review the research and development pipeline and product portfolio with the objective to prioritize assets that can be advanced rapidly and with reasonable financial investment. Following the portfolio review, those projects not aligned to the company priorities will be either paused or prepared for partnership or out-licensing.

Idorsia's portfolio

Product / compound	Mechanism of action	Therapeutic area	Status
QUVIVIQ™ (daridorexant)	Dual orexin receptor antagonist	Insomnia	**Commercially available** in the US Germany, Italy, and Switzerland; Approved in the EU, UK, and 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, open-label extension study 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*

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.

On July 20, 2023, Idorsia sold its operating businesses in the Asia Pacific (ex-China) region to Sosei Heptares, including the assignment of the license for PIVLAZ (clazosentan) for the Asia Pacific (ex-China) region. Idorsia retains the rights to clazosentan in the rest of the world.

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

Half Year Financial Report

A full financial update is available in Idorsia's 2023 Half Year Financial Report, at www.idorsia.com/investors/corporate-reports.

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 2023 Financial Results reporting on October 24, 2023
- Full-Year 2023 Financial Results reporting on February 6, 2024
- First Quarter 2024 Financial Results reporting on April 25, 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 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 1,200 highly qualified specialists dedicated to realizing our ambitious targets.

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