Media Release
October 24, 2023

Ad hoc announcement pursuant to Art. 53 LR

Idorsia announces financial results for the first nine months of 2023 – adapting the company to create sustainable value

Allschwil, Switzerland – October 24, 2023
Idorsia Ltd (SIX: IDIA) today announced its financial results for the first nine months of 2023.

Business highlights

- **Transaction with Sosei Heptares** (hereafter referred as the "Sosei Deal")**:** Idorsia sold its Asia Pacific (ex-China) operations on July 20 – including selected license rights to products – for a total consideration of CHF 400 million.
- **Cost reduction initiative** targeting a reduction of the fixed cost base at headquarters by approximately 50% expected to become fully effective in early 2024.
- **Management change in the US:** Tausif 'Tosh' Butt joined as President and General Manager of Idorsia US in September 2023.
- **Aprocitentan:** Worldwide rights reacquired from Janssen – agreement now effective following clearance by US antitrust authorities.

Commercial highlights

- **QUVIVIQ™ (daridorexant):** Total net sales of CHF 20 million in the first nine months of 2023.
- **QUVIVIQ in the US:** With CVS and Express Scripts, QUVIVIQ is covered by two of the largest commercial insurance plans. Bids for Medicare Part-D have been submitted with first coverage expected in the new year. The team in the US continues to focus on generating demand and converting it into sales.
- **QUVIVIQ in Europe:** Demand continues to grow in Germany, Italy, and Switzerland. Product made available in Spain in Sept 2023. Launched in the UK in Oct 2023 – NICE Technology appraisal guidance published Oct 2023. Four-week prescription limitation (Anlage III) lifted by GBA in Germany – official publication expected in coming weeks.

Pipeline highlights

- **Daridorexant** – Phase 3 study with daridorexant in Chinese patients initiated by Simcere.
- **Aprocitentan** – NDA under review with the US FDA – new PDUFA date of March 19, 2024 – MAA under review with the European Medicines Agency.
- **Portfolio review ongoing** – The review is made in connection with potential partnership discussions, and a main objective to prioritize assets that can be advanced rapidly and with reasonable financial investment.

Financial highlights (as reported)

- **Net revenue** 9M 2023 at CHF 131 million.
- **US GAAP operating expenses** 9M 2023 at CHF 275 million and **non-GAAP operating expenses** 9M 2023 at CHF 517 million.
- **US GAAP operating loss** 9M 2023 of CHF 181 million and **non-GAAP operating loss** of CHF 420 million.

- **The Sosei Deal:** The sale led to a one-off profit of CHF 363 million of which CHF 68 m are recorded as contract revenue, CHF 302 million recorded as gains on sale of disposal group and CHF 7 million recorded as impairment of intangible assets.

Financial highlights (on the scope excluding the Sosei Deal and related APAC operations in 2023 until closing)

- **Net revenue** 9M 2023 at CHF 29 million, of which CHF 20 million net sales with QUVIVIQ in the US and Europe (Germany, Italy, Switzerland) and CHF 9 million contract revenues.
- **US GAAP operating expenses** 9M 2023 at CHF 537 million and **non-GAAP operating expenses** 9M 2023 at CHF 486 million.
- **US GAAP operating loss** 9M 2023 of CHF 509 million and **non-GAAP operating loss** of CHF 455 million.

Updated guidance for 2023:

The accounting for the Sosei Deal, which led to a one-off profit of CHF 363 million, impacts US GAAP and non-GAAP numbers, therefore, Idorsia's guidance excludes the Sosei Deal and related APAC operations in 2023 until closing. This gives a better view of the scope of operations that the company is currently operating.

Following the Sosei Deal, the cost reduction initiative, the portfolio review and the first nine months operations, the company is updating its full year 2023 financial guidance and expects a US GAAP operating loss of around CHF 670 million (previously CHF 735 million) and non-GAAP operating loss of around CHF 600 million (previously CHF 650 million) for 2023, both metrics include the restructuring charge, exclude APAC operations in 2023 until the closing of the Sosei Deal and the one-off impact of such transaction, and exclude any unforeseen events.

Jean-Paul Clozel, MD and Chief Executive Officer, commented:
"In the third quarter we have implemented numerous measures to adapt the company. We sold our APAC (ex-China) business for 400 million Swiss francs, we reduced the workforce at headquarters by around 50%, we changed the leadership of our US commercial operations, and very importantly, we reacquired the worldwide rights to aprocitentan. I am fully aware that these measures need underpinning with additional funding in the coming months."

Jean-Paul continued:
"With QUVIVIQ, we have a sleep therapy – which has demonstrated an outstanding safety and efficacy profile – on the market in the US and EU. With aprocitentan, we have the first antihypertensive working on a new pathway for 30 years under review with US and EU regulatory authorities, which we hope to see approved in the first half of 2024. With selatogrel and cenerimod, we have two compounds in Phase 3 development with the potential to transform treatment in their target indications, and we have several innovative assets in early development. All this gives us strategic flexibility and multiple avenues to explore potential fundraising."

André C. Muller, Chief Financial Officer, commented:
"The Sosei Deal, in conjunction with the almost complete cost reduction initiative at headquarters and the ongoing portfolio prioritization, allows us to both extend our cash runway well into the first quarter of 2024 and improve our guidance for 2023 with a lower spend. Our short-term priority is to further extend our cash runway and we are actively reviewing all avenues including potential out-license deals with a few balls in the air that we expect to catch in the upcoming months."

Financial results (as reported)

US GAAP results in CHF millions, except EPS (CHF) and number of shares (millions)	Nine Months		Third Quarter	
	2023	2022	2023	2022
Net revenues	131	43	80	21
Operating expenses	(275)	(653)	150	(227)
Operating income (loss)	(144)	(610)	231	(206)
Net income (loss)	(181)	(635)	224	(216)
Basic EPS	(1.02)	(3.58)	1.26	(1.22)
Basic weighted average number of shares	178.2	177.4	178.4	177.5
Diluted EPS	(1.02)	(3.58)	0.96	(1.22)
Diluted weighted average number of shares	178.2	177.4	232.5	177.5

US GAAP net revenue of CHF 131 million in the first nine months of 2023 (CHF 43 million in the first nine months of 2022) consisted of product sales of QUVIVIQ (CHF 20 million) and PIVLAZ (CHF 34 million; until the closing on July 19, 2023 of the Sosei Deal – See below), the one-off impact of the Sosei Deal (CHF 68 million), and other contract revenues mainly Mochida (CHF 4 million), Johnson & Johnson (CHF 4 million) and Neurocrine (CHF 2 million).

US GAAP operating expenses in the first nine months of 2023 amounted to CHF 275 million (CHF 653 million in the first nine months of 2022), of which CHF 7 million related to cost of sales (CHF 4 million in the first nine months of 2022), CHF 235 million to R&D expenses (CHF 278 million in the first nine months of 2022), CHF 318 million to SG&A expenses (CHF 372 million in the first nine months of 2022), CHF 11 million restructuring charges and a one-off income of CHF 295 million relating to the Sosei Deal.

US GAAP net loss in the first nine months of 2023 amounted to CHF 181 million (CHF 635 million in the first nine months of 2022). The decrease of the net loss is mainly attributable to the one-off income related to the Sosei Deal but was also driven by higher revenues and lower operating expenses throughout all functions.

The US GAAP net loss resulted in a net loss per share of CHF 1.02 (basic and diluted) in the first nine months of 2023, compared to a net loss per share of CHF 3.58 (basic and diluted) in the first nine months of 2022.

Non-GAAP* measures in CHF millions, except EPS (CHF) and number of shares (millions)	Nine Months		Third Quarter	
	2023	2022	2023	2022
Net revenues	131	43	80	21
Operating expenses	(517)	(621)	(124)	(214)
Operating income (loss)	(386)	(577)	(44)	(193)
Net income (loss)	(420)	(597)	(51)	(202)
Basic EPS	(2.36)	(3.36)	(0.29)	(1.14)
Basic weighted average number of shares	178.2	177.4	178.4	177.5
Diluted EPS	(2.36)	(3.36)	(0.29)	(1.14)
Diluted weighted average number of shares	178.2	177.4	178.4	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 nine months of 2023 amounted to CHF 420 million: The CHF 239 million difference versus US GAAP net loss was mainly due to the one-off effect of the Sosei Deal (CHF 295 million income), depreciation and amortization (CHF 15 million), share-based compensation (CHF 26 million), restructuring charges (CHF 11 million) and a loss on marketable securities (CHF 4 million).

The non-GAAP net loss resulted in a net loss per share of CHF 2.36 (basic and diluted) in the first nine months of 2023, compared to a net loss per share of CHF 3.36 (basic and diluted) in the first nine months of 2022.

Transaction with Sosei Heptares "Sosei Deal"

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, hereafter the "Territories".

The Sosei Deal includes the sale of Idorsia's Japanese and South Korean affiliates, the assignment of the license for PIVLAZ (clazosentan) for the Territories, the co-exclusive license for daridorexant for the Territories and the assignment of all potential milestones in connection with the co-exclusive license of daridorexant granted to Mochida Pharmaceutical. The Sosei Deal also includes an option for Sosei to license cenerimod and lucerastat for the development and commercialization in the Territories, with an option fee of CHF 3 million and 7 million respectively and a subsequent payment of high single digit royalties on net sales in the Territories.

In addition to the US GAAP and Non-GAAP measures presented above, the company has prepared proforma figures corresponding to the scope of operations that the company currently operates excluding the APAC operations in 2023 until the closing of the Sosei Deal and the one-off impact of such transaction, as shown in the table below.

Proforma figures excluding the APAC operations in 2023 and the Sosei Deal **in CHF millions***	**Nine Months**		**Third Quarter**	
	2023	**2022**	**2023**	**2022**
Net sales	20	2	8	2
Contract revenues	9	16	2	6
Proforma revenues	**29**	**18**	**11**	**7**
Cost of sales	(4)	(2)	(1)	(1)
Research	(74)	(86)	(20)	(27)
Development	(130)	(148)	(38)	(46)
Selling	(228)	(270)	(54)	(102)
General and administrative	(49)	(63)	(7)	(23)
Proforma "Non-GAAP" operating expenses	**(486)**	**(569)**	**(122)**	**(199)**
Proforma "Non-GAAP" operating loss	***(455)***	***(549)***	***(111)***	***(191)***
Depreciation and amortization	(14)	(13)	(7)	(4)
Share-based compensation	(26)	(18)	(2)	(8)
Restructuring charges	(11)	-	(11)	-
Proforma other operating expenses	**(52)**	**(31)**	**(20)**	**(12)**
Proforma total operating expenses	**(537)**	**(600)**	**(142)**	**(211)**
Proforma total operating loss	***(509)***	***(580)***	***(132)***	***(204)***

**rounding differences may occur*

Cost reduction initiative

On July 21, 2023, Idorsia announced that it has launched a cost reduction initiative with the target to reduce its fixed cost base at headquarters by approximately 50%.

Approximately 475 positions at headquarters in Allschwil, Switzerland, have been made redundant through a combination of canceling open positions, not replacing people who are known to leave (outside the mass dismissal), and up to 300 terminations mainly in Research & Development and the associated support functions. The majority of the affected employees were informed during the third quarter. The reduction of positions has resulted in a restructuring charge of CHF 11 million.

Idorsia intends to conclude the initiative before the end of 2023 with the reduction of costs becoming fully effective early in 2024.

Reacquisition of aprocitentan rights

Idorsia has reacquired the development and commercialization rights for aprocitentan from Janssen. In return, Idorsia will pay Janssen a conditional consideration up to a total cap of CHF 306 million, depending on Idorsia's revenues, as follows:

- 30% of any consideration received by Idorsia from a potential out-licensing or divestment of aprocitentan,
- 10% of any consideration received by Idorsia from a potential out-licensing or the divestment of any other Idorsia product, following the first approval of aprocitentan, and
- low- to mid-single digit royalties on total group product net sales, beginning from the quarter after first aprocitentan approval.

The agreement is now in effect following the clearance relating to the United States Hart-Scott Rodino Antitrust Improvements Act of 1976.

Janssen funding obligations to aprocitentan have ceased. Janssen licenses to aprocitentan IP (excluding pulmonary hypertension) have terminated and Janssen has transferred the brand name and relating commercial materials to Idorsia. Janssen will retain licenses in the pulmonary hypertension field.

The agreement also eliminates the revenue-sharing agreement in respect of ponesimod.

Profitability Target

The company has suspended its 2025 profitability target following the sale of the APAC (ex-China) business to Sosei, as there are many moving parts that might impact the scope that the company will operate in the context of slower than expected ramp-up of QUVIVIQ sales, reacquisition of aprocitentan rights and its potential market approvals in 2024 and ongoing out-license discussions with potential partners.

Financial outlook 2023

The 2023 financial outlook is calculated based on: QUVIVIQ (daridorexant) being available in the US, Germany, Italy, Switzerland, Spain, and the UK; 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 accounting for the Sosei Deal, which led to a one-off profit of CHF 363 million, impacts US GAAP and non-GAAP numbers, therefore, Idorsia's guidance excludes the Sosei Deal and related APAC operations in 2023 until closing. This gives a better view of the scope of operations that the company is currently operating.

Following the Sosei Deal, the cost reduction initiative, the portfolio review and the first nine months operations, the company is updating its full year 2023 financial guidance and expects a US GAAP operating loss of around CHF 670 million (previously CHF 735 million) and non-GAAP operating loss of around CHF 600 million (previously CHF 650 million) for 2023, both metrics include the restructuring charge, exclude APAC operations in 2023 until the closing of the Sosei Deal and the one-off impact of such transaction, and exclude any unforeseen events.

Liquidity and indebtedness

At the end of the first nine months of 2023, Idorsia's liquidity amounted to CHF 255 million.

(in CHF millions)	Sep 30, 2023	Jun 30, 2023	Dec 31, 2022
Liquidity			
Cash and cash equivalents	205	33	146
Short-term deposits	50	-	320
Total liquidity*	**255**	**33**	**466**
Indebtedness			
Convertible loan	335	335	335
Convertible bond	796	796	795
Other financial debt	162	192	162
Total indebtedness	**1,292**	**1,322**	**1,292**

*rounding differences may occur

Commercial operations

In the first nine months of 2023, QUVIVIQ™ (daridorexant) in the US, Germany, Italy, Switzerland, and Spain, and PIVLAZ® (clazosentan) in Japan (until July 19, 2023), generated total product sales of CHF 54 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 nine months of 2023 reached CHF 15 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.

As access increased during the third quarter of 2023, the commercial approach was adjusted, successfully switching from a consignment model of providing substantially reduced or free prescriptions (implemented to drive initial volume), to a payer paid model. In the third quarter, paid prescriptions increased to 48% of total, an 11%-point increase from the previous quarter.

Having achieved the required access, the team has transitioned its specialty pharmacy partner from VitaCare (VPS) to KnippeRx, which is better positioned to pull through paid prescriptions. Temporary product volume volatility was experienced during this transition period, as can be expected from a major business model adjustment. However, QUVIVIQ prescription volume is now returning to modest growth, and is expected to accelerate from this new prescription volume baseline.

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

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

Tausif 'Tosh' Butt, President and General Manager of Idorsia US, commented:
"Since the launch of QUVIVIQ, more than 275,000 prescriptions of QUVIVIQ have been dispensed – providing approximately 100,000 Americans with chronic insomnia with better sleep at night, leading to better days. The team has done an excellent job in transitioning to a specialty pharmacy partner who is better positioned to pull through paid prescriptions. Going into the fourth quarter we are seeing, not only QUVIVIQ prescription volumes rising, but also a significant increase in paid prescriptions. Encouragingly, continued growth in access is expected to result in continued growth in the percentage of paid prescriptions."

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	UK: Oct 2023 Spain: Sep 2023 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, followed by Spain in September 2023 and UK in October 2023. 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 by year-end. For more information on the marketing authorization of QUVIVIQ in Canada, see the Product Monograph.

The launches of Europe's first and only dual orexin receptor antagonist 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. The company has also recently expanded the availability of QUVIVIQ adding Spain for the self-pay market and the UK where the National Institute for Health and Care Excellence (NICE) Technology appraisal guidance was published in October 2023 allowing the transition to local access discussions. Following 2023 ASMR IV rating, recognizing the added value that QUVIVIQ brings to the current treatment landscape, launch preparations are underway in France, with a target launch in the first half of 2024.

Net sales in the first nine months of 2023 in Germany, Italy, Switzerland, and Spain were CHF 5 million.

Jean-Yves Chatelan, President of Europe and Canada region, commented:
"QUVIVIQ, the first and only dual orexin receptor antagonist in Europe is now available in five European countries, and volumes continue to increase in all markets. At the same time, pricing and reimbursement processes are progressing well in key European markets. In the UK, the recently published final guidance from NICE means that patients in England and Wales will have broad, unrestricted access to QUVIVIQ on the NHS. While in Germany we saw the four-week prescription limitation lifted and we anticipate the official publication in the coming weeks making QUVIVIQ the only sleep medication that can be prescribed for long-term treatment. This great progress enables patients with chronic insomnia to fully benefit from a treatment that has robust clinical data demonstrating improvements in sleep quality and quantity as well as daytime functioning."

Clinical development

Idorsia 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, Switzerland, Spain, and the UK; Approved in the EU 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
IDO-090	Synthetic glycan vaccine	*Clostridium difficile* infection	Phase 1 in preparation

Neurocrine Biosciences has a global license to develop and commercialize ACT-709478 (NBI-827104), Idorsia's novel T-type calcium channel blocker.

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.

Nine-Month Financial Report

A full financial update is available in Idorsia's 2023 Nine-Month 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

- Full-Year 2023 Financial Results reporting on February 6, 2024
- Annual General Meeting of Shareholders on April 11, 2024
- First Quarter 2024 Financial Results reporting on April 25, 2024
- Half-Year 2024 Financial Results reporting on July 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 800 highly qualified specialists dedicated to realizing our ambitious targets.

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