Media Release
April 26, 2022

Ad hoc announcement pursuant to Art. 53 LR

Idorsia announces financial results for the first quarter 2022 – first product launched, second in the starting blocks

Allschwil, Switzerland – April 26, 2022
Idorsia Ltd (SIX: IDIA) today announced its financial results for the first quarter of 2022.

Business highlights

- PIVLAZ™ (clazosentan) for the prevention of cerebral vasospasm, vasospasm-related cerebral infarction and cerebral ischemic symptoms after aneurysmal subarachnoid hemorrhage launched in Japan on April 20, 2022
- US launch of QUVIVIQ™ (daridorexant) for the treatment of adult patients with insomnia on May 2, 2022
- EC decision for QUVIVIQ expected in early May 2022 – CHMP adopted a positive opinion in February 2022
- PRECISION, a Phase 3 study to demonstrate the antihypertensive effect of aprocitentan when added to standard of care in patients with resistant hypertension, on track to deliver results before mid-2022

Financial highlights

- US GAAP operating expenses in Q1 2022 at CHF 198 million
- Non-GAAP operating expenses in Q1 2022 at CHF 188 million
- Guidance for 2022 (unchanged): Net revenue around CHF 145 million – US GAAP operating expenses around CHF 975 million and non-GAAP operating expenses around CHF 920 million – leading to US GAAP operating loss of around CHF 840 million and non-GAAP operating loss of around CHF 785 million – unforeseen events excluded

Jean-Paul Clozel, MD and Chief Executive Officer, commented:
"The months of April and May 2022 will be recorded in the Idorsia history books. These are the months in which we launch our first two products in two of the world's largest pharmaceutical markets. This transforms Idorsia into a fully-fledged biopharmaceutical company, delivering our innovations from bench to bedside, just 5 years after launching the company. PIVLAZ is already available in Japan for patients with aSAH, and now that the scheduling is complete, QUVIVIQ will become available in the US for patients with insomnia from May 2nd. I am incredibly proud of the entire Idorsia team who have put in an immense effort to make this possible."

Financial results

US GAAP results in CHF millions, except EPS (CHF) and number of shares (millions)	First Quarter 2022	 2021
Revenues	5	7
Operating expenses	(198)	(129)
Operating income (loss)	(193)	(122)
Net income (loss)	(198)	(105)
Basic EPS	(1.12)	(0.63)
Basic weighted average number of shares	177.1	166.6
Diluted EPS	(1.12)	(0.63)
Diluted weighted average number of shares	177.1	166.6

US GAAP revenue of CHF 5 million in the first quarter of 2022 consisted of contract revenue recognized in connection with the collaboration agreements with Janssen Biotech, Inc. (CHF 3 million), Mochida Pharmaceutical Co., Ltd (CHF 1 million) and Neurocrine Biosciences, Inc. (CHF 1 million) and revenue share from J&J (CHF 0.2 million), compared to a revenue of CHF 7 million in the first quarter of 2021.

US GAAP operating expenses in the first quarter of 2022 amounted to CHF 198 million (CHF 129 million in the first quarter of 2021), of which CHF 95 million relates to R&D (CHF 97 million in the first quarter of 2021) and CHF 103 million to SG&A expenses (CHF 31 million in the first quarter of 2021).

US GAAP net loss in the first quarter of 2022 amounted to CHF 198 million compared to CHF 105 million in the first quarter of 2021. The increase of the net loss was mainly driven by higher operating expenses, mainly in the commercial functions and a negative financial result.

The US GAAP net loss resulted in a net loss per share of CHF 1.12 (basic and diluted) in the first quarter of 2022 compared to a net loss per share of CHF 0.63 (basic and diluted) in the first quarter of 2021.

Non-GAAP* measures in CHF millions, except EPS (CHF) and number of shares (millions)	First Quarter 2022	 2021
Revenues	5	7
Operating expenses	(188)	(121)
Operating income (loss)	(183)	(114)
Net income (loss)	(189)	(95)
Basic EPS	(1.07)	(0.57)
Basic weighted average number of shares	177.1	166.6
Diluted EPS	(1.07)	(0.57)
Diluted weighted average number of shares	177.1	166.6

** 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 2022 amounted to CHF 189 million: the CHF 9 million difference versus US GAAP net loss was mainly due to depreciation and amortization (CHF 5 million), share-based compensation (CHF 5 million) and a positive non-cash financial result (CHF 1 million).

The non-GAAP net loss resulted in a net loss per share of CHF 1.07 (basic and diluted) in the first quarter of 2022 compared to a net loss per share of CHF 0.57 (basic and diluted) in the first quarter of 2021.

Financial outlook

On April 20, 2022, the company launched PIVLAZ (clazosentan) in Japan. Furthermore, the company will soon launch QUVIVIQ (daridorexant) in the US and, pending marketing authorization from the European Medicines Agency, in the first European markets before the end of the year. The clinical pipeline will advance with highlights including the conclusion of the Phase 3 registration study for aprocitentan and the Phase 2 proof-of-concept study with the selective orexin 1 receptor antagonist, the ramp-up of recruitment into the pivotal SOS-AMI study with selatogrel, as more sites are initiated around the globe, and the planned initiation of Phase 3 development of cenerimod. Accounting for all these activities, the company continues to anticipate net revenue around CHF 145 million, US GAAP operating expenses around CHF 975 million and non-GAAP operating expenses around CHF 920 million, all leading to a US GAAP operating loss of around CHF 840 million and a non-GAAP operating loss of around CHF 785 million for 2022, unforeseen events excluded.

The company is committed to become profitable and with the current forecasts, continues to expect to reach this goal in 2025 with annual net sales above CHF 1 billion.

André C. Muller, Chief Financial Officer, commented:
"The launch of our first products is transforming the company into a commercial entity. I am happy that the first quarter of 2022 is the last quarter without sales figures, and I am really looking forward to seeing the initial uptake of our products and the corresponding results at the half-year reporting. No matter how well we guide the market, the proof of the pudding is in the eating. I am confident that we can deliver on our ambitious targets and that will put sustainable profitability within reach in the not-too-distant future."

Liquidity and indebtedness

At the end of the first quarter of 2022, Idorsia's liquidity (including cash, cash equivalents and short-term deposits) amounted to CHF 940 million.

(in CHF millions)	Mar 31, 2022	Dec 31, 2021
Liquidity		
Cash and cash equivalents	146	101
Short-term deposits	794	927
Long-term deposits	-	160
Total liquidity*	**940**	**1,188**
Indebtedness		
Convertible loan	335	298
Convertible bond	794	794
Other financial debt	-	-
Total indebtedness	**1,129**	**1,093**

*rounding differences may occur

Commercial operations

After establishing Idorsia's commercial footprint – the people, infrastructure and processes required for commercial operations – the company is now launching two differentiated products in two of the largest pharmaceutical markets at the same time, PIVLAZ in Japan and QUVIVIQ in the US.

United States

On January 7, 2022, QUVIVIQ™ (daridorexant) 25 mg and 50 mg was approved by the FDA for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. More details can be found in the dedicated press release.

Under the leadership of Patty Torr, several innovative initiatives to educate the US market about the seriousness of insomnia as a very real, but often overlooked medical condition are fully up and running. These include a partnership with Jennifer Aniston to launch a unique educational campaign, *Seize the Night & Day*, aimed at revealing the dual impact of insomnia on both nights and days. Additionally, eye-opening results from *Wake Up America*, the largest US survey of people with trouble sleeping, as well as healthcare professionals, were published recently to bring to life the true burden of insomnia. The survey, which was supported by Idorsia, was created under the direction of The Alliance for Sleep, an organization comprised of some of the nation's foremost experts in sleep medicine. The Idorsia US team has also produced a feature-length documentary, *The Quest for Sleep*, which premiered in March and explores people's struggles with insomnia and the science of sleep.

On April 7, 2022, the US Drug Enforcement Administration (DEA) placed QUVIVIQ in schedule IV of the Controlled Substance Act (CSA), as expected based on the scheduling of other sleep medications. QUVIVIQ will be available to patients in the US from May 2, 2022. For more information about QUVIVIQ in the US, see the Full Prescribing Information (PI and Medication Guide).

Japan

Product	Mechanism of Action	Indication	Commercially available since
PIVLAZ™ (clazosentan) PIVLAZ clazosentan	Endothelin receptor antagonist	Prevention of cerebral vasospasm, vasospasm-related cerebral infarction and cerebral ischemic symptoms after aneurysmal subarachnoid hemorrhage (aSAH)	20 April 2022

On January 20, 2022, PIVLAZ™ (clazosentan) 150 mg was approved for the prevention of cerebral vasospasm, vasospasm-related cerebral infarction and cerebral ischemic symptoms after aneurysmal subarachnoid hemorrhage (aSAH) in Japan. More details can be found in the dedicated press release. The approval was based on a robust Phase 3 program in Japanese patients, as published in "Effects of clazosentan on cerebral vasospasm-related morbidity and all-cause mortality after aneurysmal subarachnoid hemorrhage: two randomized phase 3 trials in Japanese patients" in the Journal of Neurosurgery.

On April 20, 2022, PIVLAZ was launched and made available to patients in Japan. More details can be found in the dedicated press release. The Idorsia Japan team, under the leadership of Satoshi Tanaka, has built a focused customer-facing organization to bring this innovative medicine to physicians and patients facing this life-threatening condition. The team is introducing PIVLAZ clinical data to

physicians and engaging with local medical experts to improve and standardize the treatment of aSAH across Japan.

Simon Jose, Chief Commercial Officer of Idorsia, commented:
"We have all the ingredients needed to make both launches a success: two well differentiated products, hand-picked and focused teams with state-of-the-art commercial infrastructure, and innovative and ambitious go-to-market plans. We've been able to conclude all steps needed to launch PIVLAZ in Japan and QUVIVIQ in the US and finalize the pricing for both products. I'm very pleased that the innovative nature and impactful results of both products have been recognized by payors in Japan and in the US respectively. I am very confident that this will translate into commercial success, but more importantly, I am delighted that patients can now benefit from these innovative medicines."

Europe and Canada region
Idorsia is expecting the European Commission decision for QUVIVIQ™ (daridorexant) in early May 2022. This follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) which recommended QUVIVIQ for the treatment of adult patients with insomnia characterized by symptoms present for at least three months and considerable impact on daytime functioning. More information can be found in the dedicated press release.

The core Idorsia country teams are in place in the top five European markets and Syneos Health has been engaged as the company's partner to build a salesforce to reach the large primary care market for insomnia. The Idorsia team is engaging with local medical experts, policy makers and payors to introduce the company and raise awareness of the significant unmet patient need in insomnia in Europe. The first European launches of QUVIVIQ are expected before the end of the year following regulatory approval.

Clinical Development

Idorsia's diversified and balanced clinical development pipeline, which covers multiple therapeutic areas, including CNS, cardiovascular and immunological disorders, as well as orphan diseases, is on track and progressing as described in February.

Idorsia's clinical development pipeline

Compound	Mechanism of Action	Target Indication	Status
Daridorexant	Dual orexin receptor antagonist	Insomnia	Approved as QUVIVIQ™ in the US Under review in other countries
Aprocitentan*	Dual endothelin receptor antagonist	Resistant hypertension management	Phase 3 recruitment complete
Clazosentan	Endothelin receptor antagonist	Cerebral vasospasm assoc. with aneurysmal subarachnoid hemorrhage	Phase 3 outside of Japan
Lucerastat	Glucosylceramide synthase inhibitor	Fabry disease	Phase 3 primary endpoint not met, OLE ongoing**
Selatogrel	$P2Y_{12}$ receptor antagonist	Suspected acute myocardial infarction	Phase 3
Cenerimod	$S1P_1$ receptor modulator	Systemic lupus erythematosus	Phase 3 in preparation
ACT-539313	Selective orexin 1 receptor antagonist	Binge eating disorder	Phase 2 recruitment complete
Sinbaglustat	GBA2/GCS inhibitor	Rare lysosomal storage disorders	Phase 1 complete
ACT-1004-1239	CXCR7 antagonist	Immunology	Phase 1 complete
ACT-1014-6470	-	Immunology	Phase 1
ACT-777991	-	Immunology	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 is currently investigated in two Phase 2 studies for the treatment of a rare form of pediatric epilepsy and essential tremor.

Further details including the current status of each project in the pipeline can be found in our clinical development 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

- Half-Year 2022 Financial Results reporting on July 26, 2022
- Nine-months 2022 Financial Results reporting on October 25, 2022
- Full-Year 2022 Financial Results reporting on February 7, 2023

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 broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, state-of-the-art facilities, and a strong balance sheet – the ideal constellation to translate R&D efforts into business success.

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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