



Media Release

April 23, 2020

Idorsia announces financial results for the first quarter 2020

Allschwil, Switzerland – April 23, 2020

Idorsia Ltd (SIX: IDIA) today announced its financial results for the first quarter of 2020.

Business updates

- Janssen submitted New Drug Application to the U.S. FDA and European Marketing Authorization Application for ponesimod for treatment of adults with relapsing multiple sclerosis – Idorsia has a revenue-sharing agreement in respect to ponesimod
- Positive results in the first Phase 3 study of daridorexant with improved overall sleep and daytime performance of patients with insomnia

Financial updates

- US GAAP operating expenses in Q1 2020 at CHF 116 million
- Non-GAAP operating expenses in Q1 2020 at CHF 106 million
- Updated guidance for 2020: US GAAP operating expenses below CHF 540 million and non-GAAP operating expenses below CHF 500 million (both measures exclude any potential milestone payments)

Jean-Paul Clozel, MD and Chief Executive Officer, commented:

“With the results of the first pivotal study of daridorexant for patients with insomnia still so fresh I must start here. For the first time ever, a sleep medicine has demonstrated not only an improvement in sleep onset and sleep maintenance, but also in how the patients feel in the daytime. Even more impressive is that we’ve shown this efficacy without compromising safety. This has been an incredible company-wide achievement and gives us a very exciting springboard to launch the next phase of Idorsia. These results are a great endorsement of our research strategy and gives me more confidence for our whole pipeline. In this very difficult time of COVID-19 which has had such tragic consequences for so many, I’m very proud that our work and the efforts to bring new therapies to patients are continuing, all credit to the excellent team effort at Idorsia.”

Financial results

US GAAP results in CHF millions, except EPS (CHF) and number of shares (millions)	First Quarter	
	2020	2019
Revenues	5	7
Operating expenses	(116)	(125)
Operating income (loss)	(111)	(119)
Net income (loss)	(120)	(106)
Basic EPS	(0.91)	(0.81)
Basic weighted average number of shares	131.3	131.1
Diluted EPS	(0.91)	(0.81)
Diluted weighted average number of shares	131.3	131.1

US GAAP revenue of CHF 5 million in the first quarter of 2020 related to deferred contract revenue recognized in connection to the collaboration agreements with Janssen (CHF 3 million), Roche (CHF 1 million) and Mochida (CHF 1 million), compared to a revenue of CHF 7 million in the first quarter of 2019.

US GAAP operating expenses in the first quarter of 2020 amounted to CHF 116 million (of which CHF 97 million R&D and CHF 19 million SG&A expenses), whilst operating expenses in the first quarter of 2019 amounted to CHF 125 million (of which CHF 110 million R&D and CHF 16 million SG&A expenses).

US GAAP net loss in the first quarter of 2020 amounted to CHF 120 million compared to CHF 106 million in the first quarter of 2019. The increase of the net loss was mainly driven by financial expenses and partially offset by lower operating costs.

The US GAAP net loss resulted in a net loss per share of CHF 0.91 (basic and diluted) in the first quarter of 2020 compared to a net loss per share of CHF 0.81 (basic and diluted) in the first quarter of 2019.

Non-GAAP* measures in CHF millions, except EPS (CHF) and number of shares (millions)	First Quarter	
	2020	2019
Revenues	5	7
Operating expenses	(106)	(117)
Operating income (loss)	(101)	(110)
Net income (loss)	(102)	(108)
Basic EPS	(0.78)	(0.82)
Basic weighted average number of shares	131.3	131.1
Diluted EPS	(0.78)	(0.82)
Diluted weighted average number of shares	131.3	131.1

** 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 2020 amounted to CHF 102 million: the CHF 18 million difference versus US GAAP net loss was mainly due to depreciation and amortization (CHF 5 million), share-based compensation (CHF 6 million) and a negative non-cash financial result (CHF 7 million).

The non-GAAP net loss resulted in a net loss per share of CHF 0.78 (basic and diluted) in the first quarter of 2020 compared to a net loss per share of CHF 0.82 (basic and diluted) in the first quarter of 2019.

André C. Muller, Chief Financial Officer, commented:

“Our operating expense in the first quarter was lower than planned, primarily due to the extraordinary circumstances caused by COVID-19. We currently anticipate a lower spend for the full-year 2020 thus resulting in an updated guidance of US GAAP operating expenses below 540 million Swiss francs and non-GAAP operating expenses below 500 million Swiss francs. How much less will mainly depend on the impact of COVID-19 on ongoing clinical trials, which we hope to have more visibility on by the end of the second quarter – of course this excludes unforeseen events and potential milestone payments. I will reiterate that Idorsia's liquidity will not last until break-even, thus we will need additional funding to bring our products to market, but we are fortunate in having several unencumbered assets in clinical development with additional key results in the near future, as well as financing options available to us.”

Liquidity and indebtedness

At the end of the first quarter of 2020, Idorsia's liquidity (including cash, cash equivalents, short- and long-term deposits) amounted to CHF 632 million.

(in CHF millions)	Mar 31, 2020	Dec 31, 2019	Mar 31, 2019
Liquidity			
Cash and cash equivalents	95	263	718
Short-term deposits	357	476	394
Long-term deposits	180	-	-
Total liquidity*	632	739	1,111
Indebtedness			
Convertible loan	382	380	374
Convertible bond	199	199	199
Other financial debt	-	-	-
Total indebtedness	581	579	573

*rounding differences may occur

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.

On April 20, 2020, Idorsia reported positive results in the first Phase 3 study of daridorexant with improved overall sleep and daytime performance of patients with insomnia. More details and commentary can be found in the dedicated [press release](#) and [investor webcast](#) which is available for replay on the corporate website.

In the context of the COVID-19 pandemic, continuity of Idorsia portfolio of Phase 3 and 2 clinical trials was maintained, with a primary focus on ensuring the safety and well-being of patients already participating, as well as study integrity and compliance with GCP and applicable regulation in the different regions of operations. Processes have been adapted where needed, including development of study-specific crisis plans, to cope with the pandemic situation, minimizing delay in the overall conduct of the studies.

The recruitment of patients into these trials in this phase, where the healthcare system is focused on taking care of COVID-19 patients, is slowed down and will likely impact our timelines for reporting.

Clinical Development Pipeline

Compound	Mechanism of Action	Target Indication	Status
Daridorexant	Dual orexin receptor antagonist	Insomnia	Phase 3 – First study successful – Second study recruitment complete
Aprocitentan*	Dual endothelin receptor antagonist	Resistant hypertension management	Phase 3
Clazosentan	Endothelin receptor antagonist	Vasospasm associated with aneurysmal subarachnoid hemorrhage	Phase 3
Lucerastat	Glucosylceramide synthase inhibitor	Fabry disease	Phase 3
Cenerimod	S1P ₁ receptor modulator	Systemic lupus erythematosus	Phase 2
Selatogrel	P2Y ₁₂ receptor antagonist	Suspected acute myocardial infarction	Phase 2 – complete
ACT-774312	CRTH2 receptor antagonist	Nasal polyposis	Phase 2
Sinbaglustat (ACT-519276)	GBA2/GCS inhibitor	Rare CNS diseases	Phase 1
ACT-539313	Selective orexin 1 receptor antagonist	Psychiatric disorders	Phase 1
ACT-709478**	T-type calcium channel blocker	Epilepsy	Phase 1
ACT-1004-1239	-	Immunology / Cancer immunotherapy	Phase 1
ACT-1014-6470	-	Immunology	Phase 1

* In collaboration with Janssen Biotech Inc. to jointly develop and solely commercialize aprocitentan worldwide

** Idorsia has granted to Neurocrine Biosciences, Inc. an option to license ACT-709478, this option will expire 30 days after the IND application acceptance by the FDA, expected in mid-2020

Idorsia has the option to license vamorolone from ReveraGen Inc. and has granted to Santhera Holding Ltd. the option to sub-license vamorolone worldwide (except Japan and South-Korea) for all indications.

Further details of the pipeline can be found in our [clinical development fact sheet](#).

About the Revenue Sharing Agreement for ponesimod

Idorsia Pharmaceuticals Ltd and Actelion Pharmaceuticals Ltd, a member of the Janssen Pharmaceutical Companies of Johnson & Johnson, have entered into the revenue-sharing agreement in respect to ponesimod. Under the terms of the revenue-sharing agreement, Idorsia Pharmaceuticals Ltd is entitled to receive quarterly payments of 8% of the net sales of ponesimod products from Actelion Pharmaceuticals Ltd.



Note to Shareholders

The Annual General Meeting (AGM) of Shareholders to approve the Business Report of the year ending December 31, 2019 will be held on Wednesday May 13, 2020.

The notice was published in the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt) on April 3, 2020, distributed to Shareholders by post on April 15, 2020, and is available, together with the Company's Annual Report and Compensation Report, on www.idorsia.com/agm.

The 2020 meeting will be held in accordance with the requirements of the COVID-19 Ordinance 2, issued by the Swiss Federal Council issued on March 13, 2020. As a result, attendance in person will not be possible and voting will take place by independent proxy only. In order to vote, shareholders must be registered in the company's shareholder register by May 4, 2020 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 13, 2020
- Half-Year 2020 Financial Results reporting on July 23, 2020
- Nine-months 2020 Financial Results reporting on October 22, 2020
- Full-Year 2020 Financial Results reporting on February 4, 2021

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 one of Europe's leading biopharmaceutical companies, with a strong scientific core.

Headquartered in Switzerland - a biotech-hub of Europe - Idorsia is specialized in the discovery and development of small molecules, to transform the horizon of therapeutic options. Idorsia has a broad portfolio of innovative drugs in the pipeline, an experienced team, a fully-functional research center, and a strong balance sheet – the ideal constellation to bringing R&D efforts to business success.

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.

For further information, please contact

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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.