

Media Release

October 22, 2019

Idorsia announces financial results for the first nine months of 2019

Allschwil, Switzerland – October 22, 2019

Idorsia Ltd (SIX: IDIA) today announced its financial results for the first nine months of 2019.

Key figures

- US GAAP operating expenses 9M 2019 at CHF 375 million
- Non-GAAP operating expenses 9M 2019 at CHF 347 million
- Updated financial guidance for 2019: US GAAP operating expenses not to exceed CHF 540 million and non-GAAP operating expenses not to exceed CHF 500 million (both measures exclude any potential milestone payments)

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

“Our clinical portfolio is making great progress. For our dual orexin receptor antagonist, daridorexant, we chose to run a broad and detailed registration program and we are very close to seeing the results of those activities. The first study is finishing recruitment, so we are confident that the results will be available in the first half of next year and the second study will follow shortly thereafter. This is a very exciting time at Idorsia as we prepare to deliver our scientific innovations to patients.”

Financial results

US GAAP results in CHF millions, except EPS (CHF) and number of shares (millions)	Nine Months		Third Quarter	
	2019	2018	2019	2018
Revenues	20	20	7	7
Operating expenses	(375)	(290)	(123)	(122)
Operating income (loss)	(355)	(271)	(116)	(115)
Net income (loss)	(352)	(278)	(120)	(119)
Basic EPS	(2.68)	(2.27)	(0.91)	(0.92)
Basic weighted average number of shares	131.2	122.7	131.2	129.6
Diluted EPS	(2.68)	(2.27)	(0.91)	(0.92)
Diluted weighted average number of shares	131.2	122.7	131.2	129.6

US GAAP revenue of CHF 20 million in the first nine months of 2019 as well as 2018 related to deferred contract revenue recognized in connection to the collaboration agreements with Janssen (CHF 15.9 million) and Roche (CHF 3.8 million).

US GAAP operating expenses in the first nine months of 2019 amounted to CHF 375 million (of which CHF 327 million R&D and CHF 48 million SG&A expenses), whilst operating expenses in the first nine months of 2018 amounted to CHF 290 million (of which CHF 245 million R&D and CHF 45 million SG&A expenses).

US GAAP net loss in the first nine months of 2019 amounted to CHF 352 million compared to CHF 278 million for the first nine months of 2018. The increase of the net loss was mainly driven by higher operating costs.

The US GAAP net loss resulted in a net loss per share of CHF 2.68 (basic and diluted) for the first nine months of 2019 compared to a net loss per share of CHF 2.27 (basic and diluted) for the first nine months of 2018.

Non-GAAP* measures in CHF millions, except EPS (CHF) and number of shares (millions)	Nine Months		Third Quarter	
	2019	2018	2019	2018
Revenues	20	20	7	7
Operating expenses	(347)	(266)	(113)	(114)
Operating income (loss)	(328)	(247)	(107)	(107)
Net income (loss)	(326)	(249)	(104)	(109)
Basic EPS	(2.49)	(2.03)	(0.79)	(0.84)
Basic weighted average number of shares	131.2	122.7	131.2	129.6
Diluted EPS	(2.49)	(2.03)	(0.79)	(0.84)
Diluted weighted average number of shares	131.2	122.7	131.2	129.6

* 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 nine months of 2019 amounted to CHF 326 million: the difference versus US GAAP net loss was mainly due to depreciation and amortization (CHF 15 million), share-based compensation (CHF 13 million), and positive non-cash financial result (CHF 3 million).

The non-GAAP net loss resulted in a net loss per share of CHF 2.49 (basic and diluted) for the first nine months of 2019 compared to a net loss per share of CHF 2.03 (basic and diluted) for the first nine months of 2018.

André C. Muller, Chief Financial Officer, commented:

“In the first nine months of 2019 expenses were below our initial expectations, the result of lower clinical spend reflecting a slightly lower recruitment into some programs, but also a cost-conscious attitude from all our team. As a result, we are updating our financial guidance for 2019, now unforeseen events and potential milestone payments excluded, we expect non-GAAP operating expenses for 2019 not to exceed CHF 500 million.”

Liquidity and indebtedness

At the end of the first nine months of 2019, Idorsia’s liquidity (including cash, cash equivalents, short- and long-term deposits) amounted to CHF 875 million.

(in CHF millions)	Sep 30, 2019	Jun 30, 2019	Mar 31, 2019	Dec 31, 2018
Liquidity				
Cash and cash equivalents	385	467	718	799
Short-term deposits	210	219	94	123
Long-term deposits	280	318	300	298
Total liquidity*	875	1,004	1,111	1,220
Indebtedness				
Convertible loan	378	376	374	372
Convertible bond	199	199	199	198
Other financial debt	-	-	-	-
Total indebtedness	577	575	573	571

*rounding differences may occur

Clinical Development Pipeline

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

The first Phase 3 registration study investigating daridorexant (25 and 50mg) for the treatment of adult and elderly patients with insomnia, ID-078A301, closed screening in October 2019. The study has a 3-month treatment period with a 1-month safety follow-up so, based on this progress, initial results are expected towards mid-2020.

Recruitment into the Phase 3 registration study with lucerastat for the treatment of patients with Fabry disease has passed the halfway mark but is slower than initially anticipated and the study is now expected to last into 2021.

Idorsia is making progress with its early development pipeline and is initiating a Phase 1 program with a new compound, ACT-1014-6470, intended to be developed in immunological disorders, towards the end of 2019.

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

Compound	Mechanism of Action	Target Indication	Status
Aprocitentan*	Dual endothelin receptor antagonist	Resistant hypertension management	Phase 3
Clazosentan	Endothelin receptor antagonist	Vasospasm associated with aneurysmal subarachnoid hemorrhage	Phase 3
Daridorexant	Dual orexin receptor antagonist	Insomnia	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
ACT-774312	CRTH2 receptor antagonist	Nasal polyposis	Phase 2
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	Initiating Phase 1

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

** Idorsia has granted to a third party an option to license ACT-709478 and/or enter in a research collaboration for back-up or follow-on calcium channel blocker compounds; this option will expire 60 days after the IND submission to the FDA, which is planned for late 2019

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.



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 2019 Financial Results reporting on February 6, 2020
- First Quarter 2020 Financial Results reporting on April 23, 2020
- Annual General Meeting of Shareholders on May 13, 2020
- Half-Year 2020 Financial Results reporting on July 23, 2020

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 750 highly qualified specialists dedicated to realizing our ambitious targets.

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