

Media Release

July 23, 2019

Idorsia announces financial results for the first half of 2019

Allschwil, Switzerland – July 23, 2019

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

Key figures

- US GAAP operating expenses HY 2019 at CHF 252 million
- Non-GAAP operating expenses HY 2019 at CHF 234 million
- Unchanged guidance for 2019: US GAAP operating expenses of around CHF 570 million and non-GAAP operating expenses of around CHF 530 million (both measures exclude any potential milestone payments)

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

“The first half of 2019 has been about running our studies and getting ready for the wave of results and news flow approaching soon. All departments are getting ready for the potential filing of our late stage assets. With the appointment of Simon Jose as Chief Commercial Officer the hiring of a core commercial team has begun, enabling the development of a commercial business plan. We expect to receive the first set of pivotal data in the first half of 2020.”

Financial results

US GAAP results in CHF millions, except EPS (CHF) and number of shares (millions)	First Half		Second Quarter	
	2019	2018	2019	2018
Revenues	13	13	7	7
Operating expenses	(252)	(168)	(127)	(87)
Operating income (loss)	(239)	(155)	(121)	(81)
Net income (loss)	(232)	(159)	(126)	(80)
Basic EPS	(1.77)	(1.34)	(0.96)	(0.68)
Basic weighted average number of shares	131.1	119.1	131.2	119.1
Diluted EPS	(1.77)	(1.34)	(0.96)	(0.68)
Diluted weighted average number of shares	131.1	119.1	131.2	119.1

US GAAP net loss in the first half of 2019 amounted to CHF 232 million compared to CHF 159 million for the first half of 2018. The increase of the net loss was mainly driven by higher operating costs.

US GAAP revenue of CHF 13 million in the first half of 2019 as well as 2018 related to deferred contract revenue recognized in connection to the collaboration agreements with Janssen (CHF 10.6 million) and Roche (CHF 2.5 million).

US GAAP operating expenses in the first half of 2019 amounted to CHF 252 million (of which CHF 220 million R&D and CHF 33 million SG&A expenses), whilst operating expenses in the first half of 2018 amounted to CHF 168 million (of which CHF 139 million R&D and CHF 29 million SG&A expenses).

The US GAAP net loss resulted in a net loss per share of CHF 1.77 (basic and diluted) for the first half of 2019 compared to a net loss per share of CHF 1.34 (basic and diluted) for the first half of 2018.

Non-GAAP* measures in CHF millions, except EPS (CHF) and number of shares (millions)	First Half		Second Quarter	
	2019	2018	2019	2018
Revenues	13	13	7	7
Operating expenses	(234)	(153)	(118)	(79)
Operating income (loss)	(221)	(139)	(111)	(73)
Net income (loss)	(222)	(139)	(115)	(71)
Basic EPS	(1.69)	(1.17)	(0.87)	(0.59)
Basic weighted average number of shares	131.1	119.1	131.2	119.1
Diluted EPS	(1.69)	(1.17)	(0.87)	(0.59)
Diluted weighted average number of shares	131.1	119.1	131.2	119.1

* 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 half of 2019 amounted to CHF 222 million: the difference versus US GAAP net loss was mainly due to depreciation and amortization (CHF 10 million), share-based compensation (CHF 8 million), and positive non-cash financial result (CHF 8 million).

The non-GAAP net loss resulted in a net loss per share of CHF 1.69 (basic and diluted) for the first half of 2019 compared to a net loss per share of CHF 1.17 (basic and diluted) for the first half of 2018.

André C. Muller, Chief Financial Officer, commented:

"In the first six months of 2019, we fully focused on recruiting patients for our late-stage clinical trials, the main cost driver this year, and shaping our commercial strategy. As expenses are in line with expectations, the financial guidance for 2019 remains unchanged. Excluding unforeseen events and potential milestone payments, we expect non-GAAP operating expenses for 2019 to be around CHF 530 million."

Liquidity and indebtedness

At the end of the first half of 2019, Idorsia's liquidity (including cash, cash equivalents, short- and long-term deposits) amounted to CHF 1,004 million.

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

In June 2019, detailed efficacy and safety data from two Phase 2 studies with ACT-541468 (recommended INN: daridorexant) were presented at SLEEP 2019 in San Antonio. Details are available on our corporate website and will be presented in today's webcast.

Guy Braunstein, MD and Head of Global Clinical Development, commented:

"I'm very pleased that the global Phase 3 program with daridorexant is on track to report 3-month efficacy results in the first half of 2020 and long-term efficacy and safety results later in the same year. If the results observed in the Phase 2 program and presented at SLEEP 2019 are confirmed, daridorexant is very likely to be one of our first assets submitted to health authorities. We also expect top line results of our Phase 3 study with lucerastat and from the clazosentan program in Japan thereafter in 2020."

Details of the Phase 3 programs can be found in a series of investor webcasts published on our corporate website.

Compound	Mechanism of Action	Target Indication	Status
Daridorexant (ACT-541468)	Dual orexin receptor antagonist	Insomnia	Phase 3
Aprocitentan*	Dual endothelin receptor antagonist	Resistant hypertension management	Phase 3
Lucerastat	Glucosylceramide synthase inhibitor	Fabry disease	Phase 3
Clazosentan	Endothelin receptor antagonist	Vasospasm associated with aneurysmal subarachnoid hemorrhage	Phase 3
Cenerimod	S1P ₁ receptor modulator	Systemic lupus erythematosus	Phase 2
Selatogrel	P2Y ₁₂ receptor antagonist	Acute coronary syndrome	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

* 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 (See note 4 "other" of the financial statements); 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

- Nine-months 2019 Financial Results reporting on October 22, 2019
- Full-Year 2019 Financial Results reporting on February 6, 2020
- First Quarter 2020 Financial Results reporting on April 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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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.