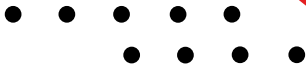
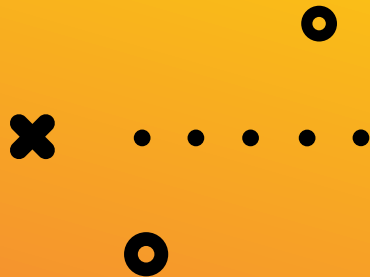
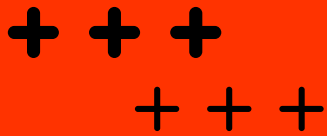


# Business Report



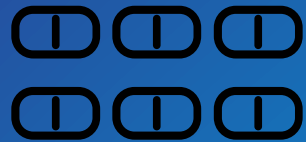
Idorsia –  
Reaching out  
for more



The purpose of Idorsia is to discover, develop, and commercialize innovative medicines to help more patients.

We have more ideas, we see more opportunities, and we want to transform the horizon of therapeutic options.

# More science – For a better future



## Further parts of the Idorsia Annual Report 2023



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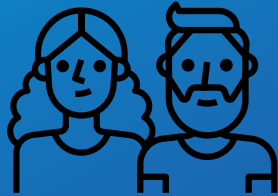
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Commercial operations  
in Europe and North America



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Idorsia-led and partner-led assets  
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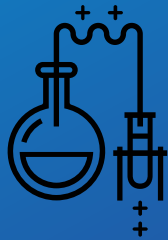
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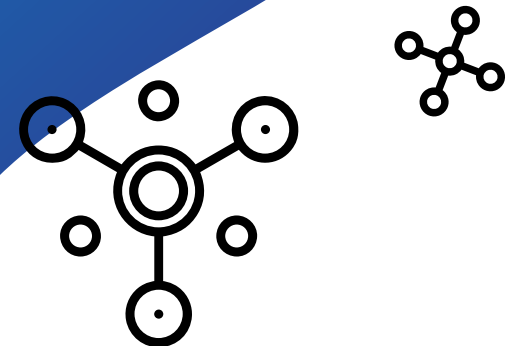
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# 25-year

Heritage of drug discovery



# More science – Bursting with ideas

We have a 25-year heritage of drug discovery, a broad portfolio of innovative drugs in the pipeline, an experienced team of over 750 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.

We began our operations after demerging from Actelion following its acquisition by Johnson & Johnson in 2017. At that time, approximately 650 talented and engaged employees were transferred to Idorsia, together with the discovery pipeline and early-stage clinical assets.

Idorsia is specialized in the discovery, development, and commercialization of innovative medicines, with the aim of transforming the horizon of therapeutic options. We have a diversified and balanced portfolio, comprising assets developed and/or marketed by Idorsia and assets that are partner-led to maximize the value we have created. Our drug discovery engine has produced innovative drugs with the potential to transform the treatment paradigm in multiple therapeutic areas, including CNS, cardiovascular, and

immunological disorders, as well as orphan diseases. The company also has a vaccine platform for the discovery and development of glycoconjugate vaccines containing synthetic antigenic glycan molecules, with or without a carrier protein, to prevent infection. Our portfolio includes products on or close to the market – QUVIVIQ™ (daridorexant) and TRYVIO™/JERAYGO™ (aprocitentan) – and assets at various stages of clinical development.

Idorsia is headed by Chief Executive Officer Jean-Paul Clozel; he and Chief Scientific Officer Martine Clozel (who co-founded Actelion) hold more than 25% of Idorsia's shares.

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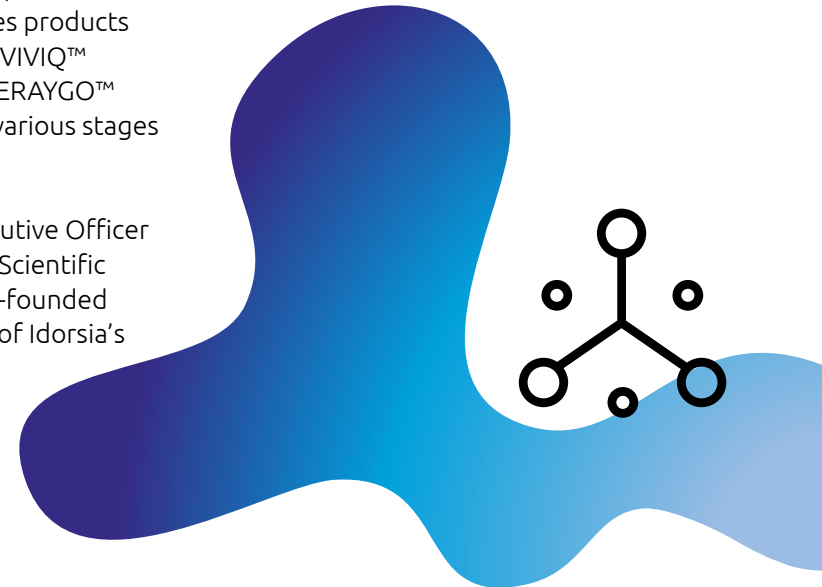
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## Idorsia's key numbers (non-GAAP\* results)

in CHF millions, except EPS (CHF) and number of shares (millions)	2023	2022
Net revenues	152	97
Operating expenses	(654)	(854)
Operating income (loss)	(501)	(757)
Net income (loss)	(542)	(782)
Basic EPS	(3.04)	(4.41)
Basic weighted average number of shares	178.2	177.4
Diluted EPS	(3.04)	(4.41)
Diluted weighted average number of shares	178.2	177.4

\* 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 for investors. These non-GAAP measures are reported in addition to, not as a substitute for, US GAAP financial performance. The full financial statements can be found in the 2023 Financial Report, and updated (unaudited) financial information in the First Quarter 2024 Financial Report.

## Major shareholders (as of December 31, 2023)

Jean-Paul and Martine Clozel	25.80%*
UBS Group AG	10.59%*
Idorsia Pharmaceuticals Ltd	5.12%*
Cilag Holding AG	5.08%*
Rudolf Maag	4.77%*
UBS Fund Management (Switzerland) AG	3.00%*

## Key share data (as of December 31, 2023)

Shares outstanding	188.5 million
Closing share price	CHF 2.11
Market capitalization	CHF 398 million
52-week high	CHF 17.85
52-week low	CHF 1.50
YTD price change	CHF -11.31 (-84.28%)
Annual average daily volume	773,174 shares
Free float	120.6 million shares

\* Based on the share capital listed on SIX Swiss Exchange as of December 31, 2023

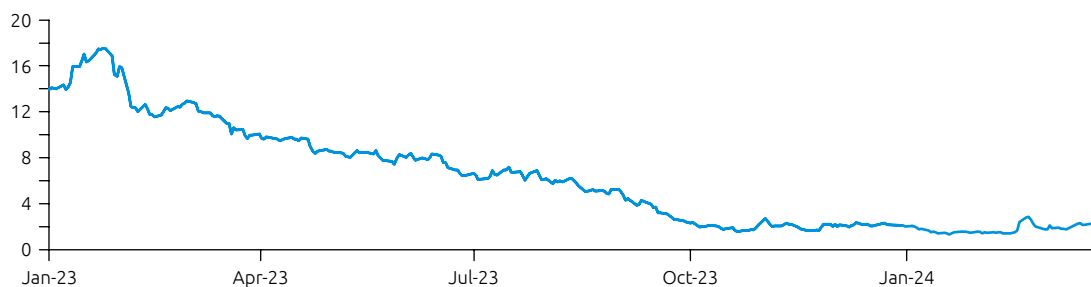
Significant shareholder notifications are available from the online reporting and publication platform of the Disclosure Office of SIX Swiss Exchange at: <https://www.ser-ag.com/en/resources/notifications-market-participants/significant-shareholders.html#/>

Idorsia Ltd is part of the following indices: SPI, SPIEX, SPI ESG, SXSLI, SXI Life Sciences, SXI Bio+Medtech, and SSIRT.

Idorsia is traded under the following symbols: Reuters IDIA.S/Bloomberg IDIA:SW

## Share price development (in CHF)

Share price chart from Jan 1, 2023 to March 31, 2024



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**Financial outlook for 2024**

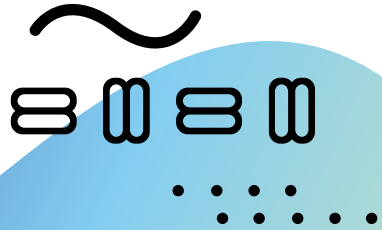
For 2024 – excluding unforeseen events – the company expects QUVIVIQ net sales of around CHF 55 million; SG&A expenses of around CHF 300 million; R&D expense of around CHF 165 million for Idorsia-led pipeline assets; non-GAAP operating expenses of up to CHF 470 million. This performance would result in a non-GAAP operating loss of around

CHF 420 million (excluding contract revenues and the one-off benefit from the Viatrix deal).

The company expects US GAAP operating loss for 2024 to reach CHF 340 million which includes a one-off benefit of CHF 125 million from the Viatrix deal.

“In addition to the funds already raised from our business development activities, I am confident in our ability to raise additional funding this year. We will continue to evaluate and prepare possible launch strategies – including potential partnership – for TRYVIO. The significant progress with access and availability of QUVIVIQ has started to gain traction, particularly in Europe, this will translate into higher sales in 2024. At the same time, the cost reduction initiative that took place in the latter part of 2023 is fully effective and reflected in our 2024 guidance, with significantly lower expenses. We must continue to control our costs and explore all avenues to extend our cash runway, but I see many reasons to be optimistic for the future of Idorsia.”

**André Muller**  
Executive Vice President, Chief Financial Officer



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# Milestones



2023 was a year of adaptation for Idorsia, with steps being taken to extend the time available to create sustainable value. The company finished 2023 in a strong position to focus on the future with renewed vigor.

## 2023

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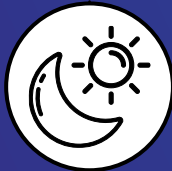
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### June 2023

QUVIVIQ launched in Switzerland as the first dual orexin receptor antagonist available for adults with chronic insomnia disorder.



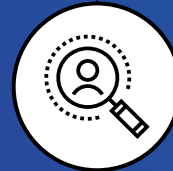
### July 2023

Idorsia's Asia-Pacific operations (excluding China) are sold to Nxera Pharma – including selected product license rights – for a total consideration of CHF 400 million.



### September 2023

Tausif "Tosh" Butt joins Idorsia US as President and General Manager.



### September 2023

Phase 3 study with daridorexant initiated by Simcere in China.



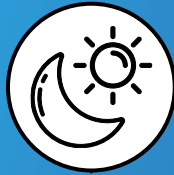
### September 2023

Worldwide rights for apocritentan reacquired from Johnson & Johnson Innovative Medicine, adding to Idorsia's portfolio and giving the company more strategic flexibility.



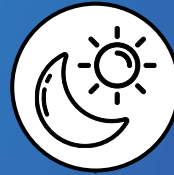
**September–  
October 2023**

QUVIVIQ made available in Spain and the UK as the first dual orexin receptor antagonist available for patients with chronic insomnia disorder.



**February 2024**

QUVIVIQ made available in Austria as the first dual orexin receptor antagonist available for patients with chronic insomnia disorder.



**March 2024**

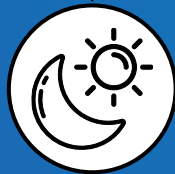
QUVIVIQ launched in France as the first dual orexin receptor antagonist available for patients with chronic insomnia disorder.



**April 2024**

Positive CHMP opinion for JERAYGO™ (aprocitentan) for the treatment of patients with resistant hypertension.

**2024**



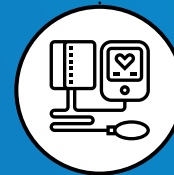
**November 2023**

QUVIVIQ made available in Canada for patients with chronic insomnia disorder.



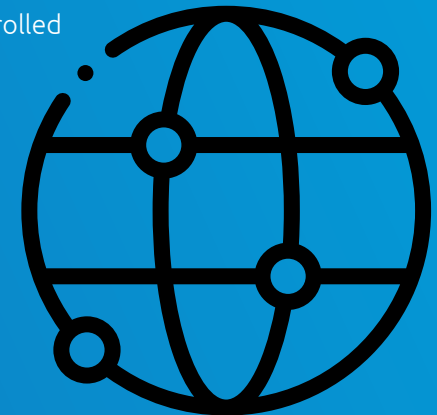
**March 2024**

Global development and commercialization agreement with Viatrix for selatogrel and cenerimod became effective, with Idorsia receiving an upfront payment of USD 350 million.



**March 2024**

TRYVIO™ (aprocitentan) approved by the US FDA for the treatment of patients with uncontrolled hypertension.



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# The purpose of Idorsia is to discover, develop, and commercialize innovative medicines to help more patients.

**Mathieu Simon**  
Chairman of the Board



## Dear Shareholders,

Following the acquisition of Actelion by Johnson & Johnson in 2017, Idorsia was created with the aim of continuing to develop the early-stage pipeline and building a commercial organization so as to realize the value of the innovation created by our drug discovery engine.

Only 6½ years on from the creation of the company, we have made very significant progress. Three drugs have been brought to the market: QUVIVIQ (daridorexant), launched to treat insomnia in the US and EU; PIVLAZ (clazosentan), launched to treat cerebral vasospasm in Japan; and TRYVIO/JERAYGO (aprocitentan), which has been approved by the FDA in the US for the treatment of uncontrolled hypertension and has received a positive CHMP opinion in the EU.



A global commercial organization has been set up, with the people, the infrastructure, the supply chain capabilities, and the processes required for compliant commercial activities – all while preparing our products for launch.

QUVIVIQ, our first product launched in the US, was rapidly recognized as a major advance in the field of insomnia. However, we have been facing payer access limitations and prescription barriers because dual orexin receptor antagonists are currently classified as Schedule IV controlled substances. Recently, payer coverage has improved and we have filed a citizen petition requesting the descheduling of this class of insomnia drugs in the US. At the same time, QUVIVIQ has also been launched in Europe and Canada, and we have obtained reimbursement in major countries such as France, Germany, and the UK. These countries have recognized the public health value of QUVIVIQ, and in Germany,



for example, the law restricting the use of insomnia therapy to a 4-week period has been amended – specifically for QUVIVIQ. The fruits of all these efforts will be seen in the near future, and we are excited by the rapid uptake in Europe. Since the first launch, more than 14 million tablets have been dispensed worldwide, with well over 150,000 patients benefiting from QUVIVIQ. We continue to believe in the huge potential offered by this product and – thanks to a long patent life – there is plenty of time for this potential to be realized.

**Jean-Paul Clozel**  
Chief Executive Officer



PIVLAZ, another drug from our pipeline, was also developed, registered, and successfully brought to the market in Japan and South Korea, serving over 5,000 patients with a rare form of stroke in the first year alone. Thanks to this success, we were able to monetize the value created, by selling our operating businesses in Japan and South Korea, together with the license to PIVLAZ in this region.

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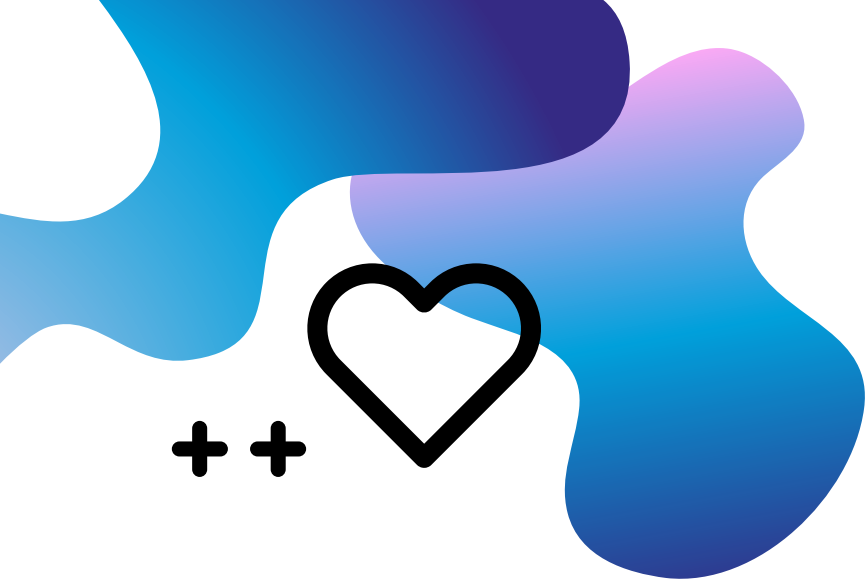
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“Idorsia has delivered in 6½ years what very few start-ups have achieved in the biotech sector.”

**Mathieu Simon**  
Chairman of the Board

The quality of our research and development engine was once again confirmed by the FDA approval of TRYVIO (aprocitentan) and the CHMP positive opinion for JERAYGO (the trade name of this product in Europe) for the treatment of hypertension in combination with other antihypertensive drugs. This is great news both for patients and for Idorsia, as a third product launch in a relatively short time approaches. In September 2023, we reacquired the commercial rights for aprocitentan from Johnson & Johnson. Now that aprocitentan belongs to Idorsia again, we are evaluating possible launch strategies, including potential partnership.

The development and launch of these three products required substantial financial investments, limiting our ability to advance our other two Phase 3 assets – selatogrel for myocardial infarction and cenerimod for lupus. For this reason, in March 2024, we successfully closed a deal with Viatris: as well as providing an upfront payment –

extending the cash runway – this agreement covers the sharing of development costs for these two Phase 3 programs and envisages contingent tiered royalties on future sales, as well as event-related milestone payments.

The Board and management of Idorsia believe that continued innovation will play an essential role in securing the company’s future, and we continue to discover new drugs with great potential in many areas of medicine. Our drug development organization has been given two main tasks: the first is to improve the commercial potential of our existing drugs by developing line extensions and characterizing the benefits of our drugs for specific patient populations; the second is to develop our new drugs.

As you can see, Idorsia has delivered in 6½ years what very few start-ups have achieved in the biotech sector. However, the very success of our clinical development,

the establishment of our commercial organization, and the reacquisition of aprocitentan have posed financing challenges for Idorsia. The Board and management have been proactive in dealing with these challenges: we have decreased our cost base by reducing our headcount and prioritizing our portfolio assets; we have sold our Asia-Pacific operations to Nxera Pharma; we have partnered our Phase 3 assets with Viatris; and we have recently gained the breathing space needed to repay the convertible bonds that were due to mature in 2024. These actions were essential to enable us to continue executing our strategy.

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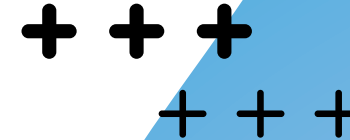
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In recent months, the need to address these challenges created uncertainties on the market, putting Idorsia's share price under significant pressure. We are grateful to all our shareholders who have remained loyal throughout this tough period. Thanks to the measures taken, with our great products and our dedicated workforce, the Board and management remain confident that our vision to create an innovative, profitable, and sustainable science-based company will become a reality in the coming years.

Sincerely,



**Mathieu Simon**  
Chairman of the Board

**Jean-Paul Clozel**  
Chief Executive Officer

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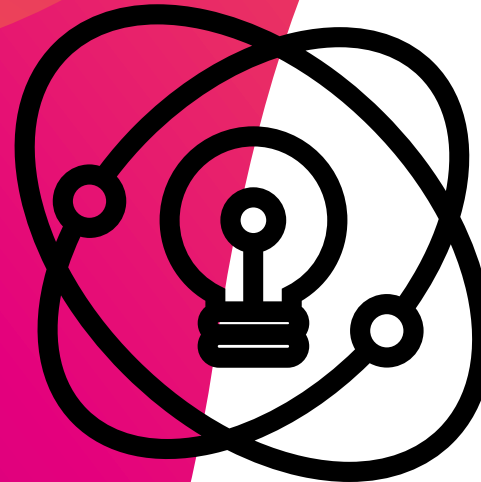
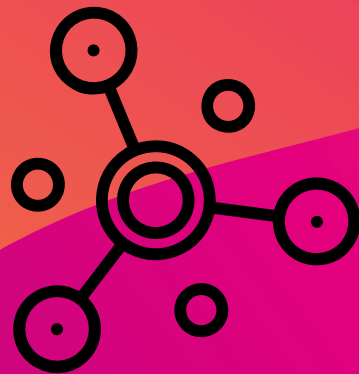
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# Business review

Developing Idorsia into a leading biopharmaceutical company with a strong scientific core.

This review provides an overview of important events and progress made at Idorsia between January 2023 and May 2024.



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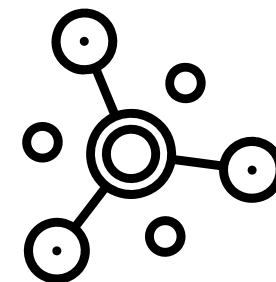
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## Business development

### Nxera deal

In July 2023, Idorsia sold its operating businesses in the Asia-Pacific (excluding China) region to Sosei Heptares (now known as Nxera Pharma) 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”).

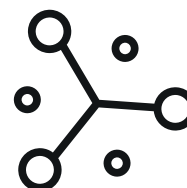
The Nxera deal includes the sale of Idorsia’s Japanese and South Korean affiliates, the assignment of the license for PIVLAZ (clazosentan) for the Territories and of the (co-) exclusive license for daridorexant for the Territories, and the assignment of all potential milestones in connection with the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

### Cost reduction initiative

In July 2023, Idorsia launched a cost reduction initiative, targeting a reduction of around 50% in its fixed cost base at headquarters.

Approximately 475 positions at headquarters in Allschwil, Switzerland, were eliminated through a combination of cancellation of new positions, natural turnover, non-renewal of temporary positions, and terminations, mainly in Research & Development and associated support functions. The reduction of positions resulted in a restructuring charge of CHF 11 million.

The initiative has been concluded, with the reduction of costs becoming fully effective in early 2024.



### Reacquisition of aprocitentan rights

In September 2023, Idorsia reached an agreement to reacquire the development and commercialization rights for aprocitentan from Johnson & Johnson Innovative Medicine (formerly known as Janssen Biotech, Inc.). In return, Idorsia will pay Johnson & Johnson Innovative Medicine 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.

Johnson & Johnson Innovative Medicine will retain licenses in the pulmonary hypertension field.

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### **Viatriis collaboration**

In March 2024, Idorsia closed agreements with Viatriis Inc. (NASDAQ: VTRS), a global healthcare company, for collaboration on the global development and commercialization of two Phase 3 assets – selatogrel and cenerimod – with Idorsia receiving an upfront payment of USD 350 million, and the right to potential development and regulatory milestone payments of up to USD 300 million, potential sales milestone payments of up to USD 2.1 billion, and potential contingent tiered royalties from mid-single- to low-double-digit percentage on annual net sales.

A joint development committee is overseeing the development of the ongoing Phase 3 programs for selatogrel and cenerimod up to regulatory approval. Idorsia will contribute up to USD 200 million in the next 3 years and transferred the dedicated personnel for both programs to Viatriis.

Viatriis has worldwide commercialization rights for both selatogrel and cenerimod (excluding, for cenerimod only, Japan, South Korea, and certain countries in the Asia-Pacific region). Idorsia has also granted Viatriis a right of first refusal and first negotiation for certain other pipeline assets.

### **Convertible bonds 2024**

In July 2018, the Group issued CHF 200 million of senior unsecured convertible bonds (ISIN: CH0426820350), which were due to mature on July 17, 2024. On May 6, 2024, a bondholder meeting was held, where 83.5% of the total outstanding bondholders voted in favor of amendments to the terms of the bonds. The approved bond terms include an amended conversion price of CHF 6.00, extended maturity date of January 17, 2025, and the option to call the bonds at par, in full or in part, at any time upon giving ten trading days' notice. The company has applied to the higher cantonal composition authority and upon approval the amendments to the bond terms will become binding and effective. A consent fee of 8,000,000 Idorsia shares will be delivered through SIX SIS once the amendment of the bond terms is effective.

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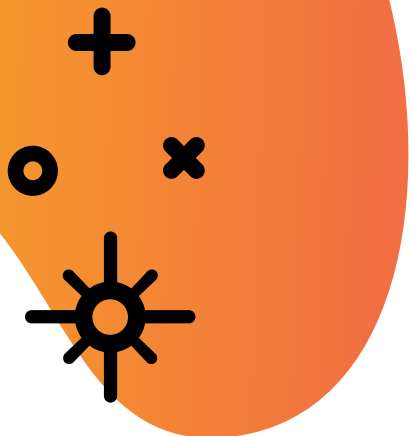
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### Commercial operations

In 2023, QUVIVIQ (daridorexant) in the US, Germany, Italy, Switzerland, Spain, UK, Canada, generated total product sales of CHF 30.9 million. In the first quarter of 2024, QUVIVIQ was also made available in Austria, and France. First quarter of 2024 total product sales amounted to CHF 10 million.

### United States

Product	Mechanism of action	Indication	Commercially available since
	Dual orexin receptor antagonist	Treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	May 2022

In the US, net sales of **QUVIVIQ® (daridorexant)** in 2023 reached CHF 24.4 million and in the first quarter of 2024 amounted to CHF 6.5 million. These net sales include the QUVIVIQ copay program aimed at driving demand and product uptake, and thus does not reflect the actual number of prescriptions dispensed.

(DTC) television and digital campaign and offered a copay program. The strategy was to create a recognizable brand, enabling market access discussions. During 2023, the company made significant progress, reaching over 65% reimbursement in the commercial sector. As access increased, the commercial approach was adjusted, with the aim being to switch from a consignment model (providing substantially reduced or free prescriptions) to a payer paid model. In the first quarter of 2024, paid prescriptions accounted for 68% of the total – an increase of 36 percentage points from the same period in 2023 and of 7 percentage points from the previous quarter.

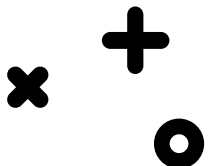
As of the end of the first quarter of 2024, more than 140,000 patients have been treated with QUVIVIQ, almost 400,000 prescriptions have been dispensed, and the product has been prescribed by more than 42,000 healthcare professionals. To begin with, the company ran a direct-to-consumer

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The first Medicare Part D coverage – reaching 27% of covered lives – began in January 2024, opening an entirely new channel which has the potential to substantially improve product access and paid prescriptions.

In February, there was a cyberattack on Change Healthcare (UnitedHealth Group), the largest adjudicator/processor of copay cards in the US, causing major disruption across the pharmaceutical industry, including the QUVIVIQ copay cards, with a negative impact on prescription dispensing levels. In March, the Idorsia US Market Access team put a solution in place to remedy the disruption, though the impact was still appreciable through to the end of March.

In April 2023, Idorsia filed a citizen petition (CP), urging the Drug Enforcement Administration (DEA) to deschedule the DORA class of chronic insomnia medications, based on a review of evidence from available data, including post-marketing surveillance data. Starting in 2015, the independent FDA approvals of other DORAs included a recommendation that these drug products be scheduled based on preclinical data. The

“I am pleased to report that during the past 12 months we have taken great strides forward, and there is further hope on the horizon.”

**Tausif “Tosh” Butt**  
President, and General Manager of Idorsia US

CP to deschedule the DORA class outlines current scientific and medical evidence demonstrating that the DORA class has a negligible abuse profile and potential for abuse, lacks non-medical use in the community, lacks physical and psychological dependence, and therefore, should not be a scheduled class under the Controlled Substances Act.

The DEA and FDA acknowledged the CP, and the process to analyze and examine the request is moving forward. Notably, a report accompanying the FDA appropriations bill that was finalized in March 2024 informed the FDA that the process for descheduling the DORA class is a priority for Congress.

Tausif “Tosh” Butt, President, and General Manager of Idorsia US, said “I believe one of the biggest barriers to prescribing QUVIVIQ is the fact it is currently a scheduled drug. Apart from the obstacles to prescribing scheduled drugs, some payers require patients to be treated with low-cost drugs not indicated for insomnia, and others that carry black box warnings before covering QUVIVIQ. The US Congress has long supported the efforts of the FDA to address the opioid and addiction crisis, and this year it encouraged the FDA to also consider the impact of treatments for insomnia as a part of that larger public health mission. I am very hopeful for our citizen petition requesting a review of the evidence can lead to the descheduling of the DORA class of chronic insomnia medications.”

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Product	Mechanism of action	Indication	Commercially available since
	Dual endothelin receptor antagonist	Treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs	Approved Mar. 2024 Planned availability: H2 2024

On March 19, 2024, the US Food and Drug Administration (FDA) approved **TRYVIO™ (aprocitentan)** for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. The recommended dosage of TRYVIO is 12.5 mg orally once daily, with or without food.

Idorsia plans to make TRYVIO available in the second half of 2024 to the millions of patients in the US whose high blood pressure is not adequately controlled by other drugs.



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## Europe and Canada

Product	Mechanism of action	Indication	Commercially available since
	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	France: Mar. 2024 Austria: Feb. 2024 UK: Oct. 2023 Spain: Sep. 2023 Switzerland: Jun. 2023 Germany: Nov. 2022 Italy: Nov. 2022
		Management of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	Canada: Nov. 2023

Net sales of **QUVIVIQ (daridorexant)** in 2023 reached CHF 6.5 million and in the first quarter of 2024 amounted to CHF 3.5 million in the EUCAN region.

In November 2023, treatment with daridorexant was added to the insomnia treatment guidelines for Europe. In “The European Insomnia Guideline: An update on the diagnosis and treatment of insomnia 2023”, published in the *Journal of Sleep Research*, the authors note that “The introduction of DORAs has probably been the most significant recent development in the pharmacological treatment of insomnia.”

In Germany, QUVIVIQ was launched in November 2022. By law, sleep medications were then subject to a 4-week prescribing limitation (Anlage III BtMG). Following a

review by the Federal Joint Committee (G-BA) – the highest decision-making body of the joint self-government of physicians, dentists, hospitals, and health insurance funds in Germany – this limitation was lifted for QUVIVIQ in November 2023. This makes it the only sleep medication in Germany that can be prescribed for long-term treatment of chronic insomnia. In December 2023, the price negotiated for QUVIVIQ under the AMNOG process became effective. Following the lifting of the prescribing limitation, the company submitted a second AMNOG dossier for the long-term treatment of chronic insomnia disorder (beyond 4 weeks), reflecting the indication approved by the EMA in 2022. The progress made in Germany is reflected by the performance of QUVIVIQ on the market, with a 63% increase in demand seen in Q4 2023 (compared to

Q3 2023), followed by a strong start to 2024 (February +41% compared to December 2023).

In Italy, QUVIVIQ was launched in November 2022. Currently, QUVIVIQ can only be prescribed by neurologists, psychiatrists, and specialists from sleep centers, and no sleep therapy is reimbursed. The company submitted a reimbursement dossier in June 2023 and requested the expansion of the prescriber base. The submission – detailing the efficacy and safety profile of QUVIVIQ and its estimated budget impact and cost-effectiveness in Italy – is under review, with the final outcome expected in the second half of 2024.

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In Switzerland, QUVIVIQ was launched to the self-pay market in June 2023. Following the launch of QUVIVIQ, awareness has increased among all specialties, and demand has increased solidly (+32% in Q4 2023 compared to Q3 2023) ahead of reimbursement, which is expected in the summer of 2024.

In Spain, QUVIVIQ was launched to the self-pay market in September 2023. Spain represents the largest insomnia market in Europe, as was apparent in the first months of this product's availability, despite it only being launched to the self-pay market. The company is assessing the opportunity to submit a reimbursement dossier to the Spanish authorities, in order to allow equal access for all patients with chronic insomnia.

In the UK, QUVIVIQ was launched in October 2023. At the same time, technology appraisal guidance was published by the National Institute for Health and Care Excellence (NICE), allowing the transition to local access discussions and listing by healthcare boards for England, Wales, and Northern Ireland. In April 2024, the Scottish Medicines Consortium (SMC) also accepted QUVIVIQ for use within NHS Scotland. This means that the company has achieved full reimbursement throughout the UK, where QUVIVIQ is now recommended as first-line pharmaceutical treatment for patients with chronic insomnia, after, or as an alternative to, cognitive behavioral therapy for insomnia (CBT-I). The priority in the UK now, is to secure regional access.

In France, QUVIVIQ was launched in March 2024 as the first and only pharmacotherapy recommended for the treatment of chronic insomnia disorder. In January 2024, the inclusion of QUVIVIQ in both the hospital and the retail formulary list of reimbursed pharmaceutical specialties was announced in the French Official Gazette, together with the French public price. This official publication means that, with a prescription from their doctor, patients with chronic insomnia in France have access to the treatment if they meet the requirements of the EU prescribing label for QUVIVIQ. The publication follows the positive recommendation by the Transparency Committee in May 2023, recognizing QUVIVIQ as providing clinical added value.

In Canada, after being approved in April 2023, QUVIVIQ was launched in November 2023 to the private market, representing 55% of the Canadian insomnia market. The reimbursement dossier was submitted to private market payers in the third quarter

of 2023, and just a few months after the submission the team had secured reimbursement for more than 60% of private market patients. The focus is now on public payers with the submission to INESSS (Institut national d'excellence en santé et en services sociaux) finalized in March 2024 and the submission to CADTH (Canada's Drug and Health Technology Agency) expected in the second quarter of 2024.

Jean-Yves Chatelan, President of Europe and Canada (EUCAN) region, said "In the EUCAN region, we have expanded availability into more markets and improved the reimbursement environment beyond many expectations. With continued positive feedback from physicians and patients on the differentiated profile of QUVIVIQ, I am very optimistic that the progress we have made will now translate into many more patients benefiting from QUVIVIQ and increasing volumes advancing the region towards profitability."

**"The launch of Europe's first and only dual orexin receptor antagonist is progressing well across all markets where we have made QUVIVIQ available."**

**Jean-Yves Chatelan**  
President of Europe and Canada (EUCAN) region

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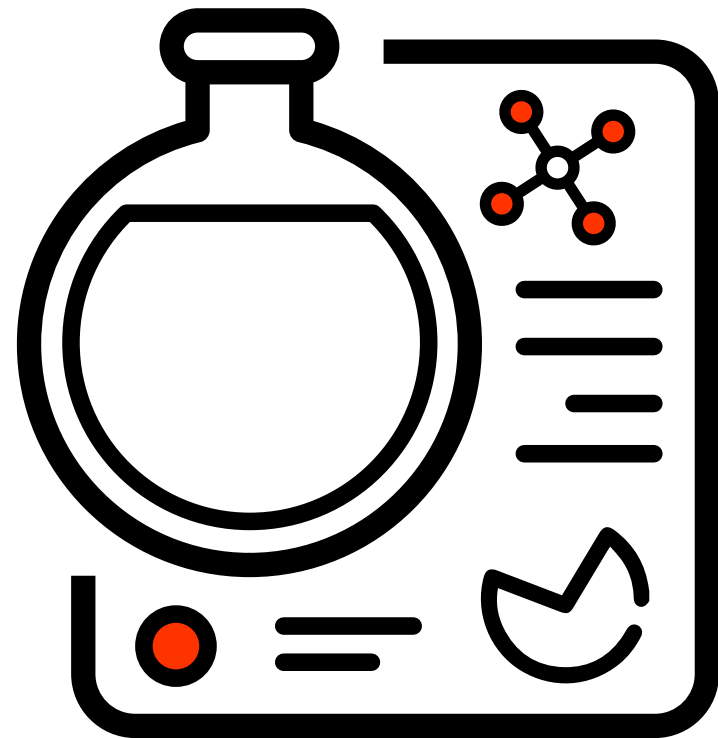
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## Research & Development

Idorsia has a diversified and balanced portfolio, comprising assets developed and/or marketed by Idorsia and assets that are partner-led to maximize the value we have created. Our drug discovery engine has produced innovative drugs with the potential to transform the treatment paradigm in multiple therapeutic areas, including CNS, cardiovascular, and immunological disorders, as well as orphan diseases.

The company also has a vaccine platform for the discovery and development of glycoconjugate vaccines containing synthetic antigenic glycan molecules, with or without a carrier protein, to prevent infection.





## Idorsia-led portfolio

Status as of April 30, 2024

Compound	Mechanism of action	Target indication	Status					
			P1	P2	P3	R	C	
<b>QUVIVIQ™ (daridorexant)</b>	Dual orexin receptor antagonist	<b>Insomnia</b>	●	●	●	●	●	Commercially available as QUVIVIQ in the US, Germany, Italy, Switzerland, Spain, the UK, Canada, Austria, and France; approved throughout the EU
<b>TRYVIO™ (aprocitentan)</b>	Dual endothelin receptor antagonist	<b>Systemic hypertension in combination with other antihypertensives</b>	●	●	●	●	○	Approved in the US, product availability planned for Q4 2024
<b>JERAYGO™ (aprocitentan)</b>	Dual endothelin receptor antagonist	<b>Resistant hypertension in combination with other antihypertensives</b>	●	●	●	●	○	Positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) received in April 2024 – European Commission decision expected in approx. 2 months
<b>Lucerastat</b>	Glucosylceramide synthase inhibitor	<b>Fabry disease</b>	●	●	●	○	○	Phase 3 primary endpoint not met; open-label extension study ongoing Phase 3 focused on renal function in preparation
<b>Daridorexant</b>	Dual orexin receptor antagonist	<b>Pediatric insomnia</b>	●	●	○	○	○	Phase 2 in pediatric insomnia ongoing
<b>ACT-1004-1239</b>	ACKR3/CXCR7 antagonist	<b>Demyelinating diseases including multiple sclerosis</b>	●	●	○	○	○	Phase 2 in preparation
<b>Sinbaglustat</b>	GBA2/GCS inhibitor	<b>Rare lysosomal storage disorders</b>	●	○	○	○	○	Phase 1 complete
<b>ACT-777991</b>	CXCR3 antagonist	<b>Recent-onset Type 1 diabetes</b>	●	○	○	○	○	Phase 1 complete
<b>IDOR-1117-2520</b>	Undisclosed	<b>Immune-mediated disorders</b>	●	○	○	○	○	Phase 1 ongoing
<b>IDOR-1134-2831</b>	Synthetic glycan vaccine	<b><i>Clostridium difficile</i> infection</b>	●	○	○	○	○	Phase 1 initiating

P1: Phase 1, P2: Phase 2, P3: Phase 3, R: Registration, C: Commercially available

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**Daridorexant**

Daridorexant is a dual orexin receptor antagonist (DORA) which blocks the binding of the wake-promoting orexin neuropeptides. Rather than inducing sleep through broad inhibition of brain activity, daridorexant only blocks the activation of orexin receptors. Daridorexant is commercially available as QUVIVIQ in the US, Germany, Italy, Switzerland, Spain, the UK, Canada, Austria, and France, and is approved throughout the EU (see “Commercial operations” above).

A post-approval study to investigate the efficacy of daridorexant in patients with insomnia and comorbid nocturia has completed recruitment and is expected to report results in mid-2024.

Idorsia has initiated a Phase 2 dose-finding study to assess the efficacy, safety, and pharmacokinetics of multiple-dose oral administration of daridorexant in pediatric patients aged 10 to <18 years with insomnia disorder. The primary objective of the study is to characterize the dose-response relationship of daridorexant on objective total sleep time (TST), using polysomnography. The study is expected to enroll around 150 patients, who will be randomized in a 1:1:1 ratio to 10 mg, 25 mg, or 50 mg daridorexant, or placebo. The study is part of a US FDA-approved Pediatric Study Plan and an EU PDCO-approved Paediatric Investigation Plan.

**Aprocitentan**

Aprocitentan is a once-daily, orally active, dual endothelin receptor antagonist, which inhibits the binding of ET-1 to ET<sub>A</sub> and ET<sub>B</sub> receptors. Aprocitentan has a low potential for drug-drug interaction and a mechanism of action suited for lowering blood pressure in adult patients whose hypertension is not adequately controlled by other drugs. On March 19, 2024, aprocitentan was approved as TRYVIO in the US, with availability planned

for H2 2024. On April 25, 2024, Idorsia received a positive opinion for aprocitentan (as JERAYGO™) from the Committee for Medicinal Products for Human Use (CHMP) as a treatment of resistant hypertension. A CHMP positive opinion is one of the final steps before marketing authorization can be granted by the European Commission; a final decision is expected approximately two months after publication of the CHMP opinion.

“Despite a difficult period for our organization, the team has shown extraordinary commitment and made great progress with our portfolio. This is particularly evident in the successful registration of aprocitentan in the US and the positive opinion from the European Union’s CHMP, with labels that reflect the value of the compound. I was also very pleased to have found a way for both selatogrel and cenerimod programs to be fully supported through the collaboration with Viatrix, while maintaining our involvement in their development. I look forward to advancing the portfolio and bringing benefits to patients in many areas of medical need.”

**Alberto Gimona**

Executive Vice President, Head of Global Clinical Development

### Lucerastat

Lucerastat is an oral inhibitor of glucosylceramide synthase, offering a potential new treatment approach for all patients living with Fabry disease, irrespective of the mutation type of the GLA gene. In October 2021, the company reported that lucerastat 1000 mg b.i.d. did not meet the primary endpoint of reducing neuropathic pain during 6 months of treatment versus placebo. However, Lucerastat demonstrated a substantial reduction in levels of the Fabry disease biomarker plasma Gb3 during the treatment period, with a decrease of approximately 50% observed in plasma Gb3 in the lucerastat treatment group compared to

an increase of 12% in the placebo group. Furthermore, results suggested a treatment effect on kidney function. Lucerastat was well tolerated. Analysis of the ongoing open-label extension (OLE) of the Phase 3 study corroborated the long-term effect on plasma Gb3 levels and a potential positive long-term effect on kidney function. The analysis also showed a safety and tolerability profile consistent with that observed during the 6-month randomized treatment period. The company is conducting a kidney biopsy substudy within a subset of patients currently participating in the OLE study in order to steer further development in Fabry disease.

### Partner-led portfolio

For Idorsia, sophisticated partnerships are a way of gaining strategic access to technologies or products and fully exploiting our discovery engine and clinical pipeline. We seek suitable external project partners to maximize the value of internal innovation.

“The way we work in research is focused on and built around innovation and our core competencies. While we had to cut back on the number of people conducting research in 2023, we have maintained this fundamental approach to our drug discovery efforts. We have taken the restructuring as an opportunity to focus on fewer key areas of research and will advance our discoveries either through our own clinical development expertise, or with the right partner, aiming to maximize the benefit for patients and Idorsia.”

#### Martine Clozel

Executive Vice President, Chief Scientific Officer

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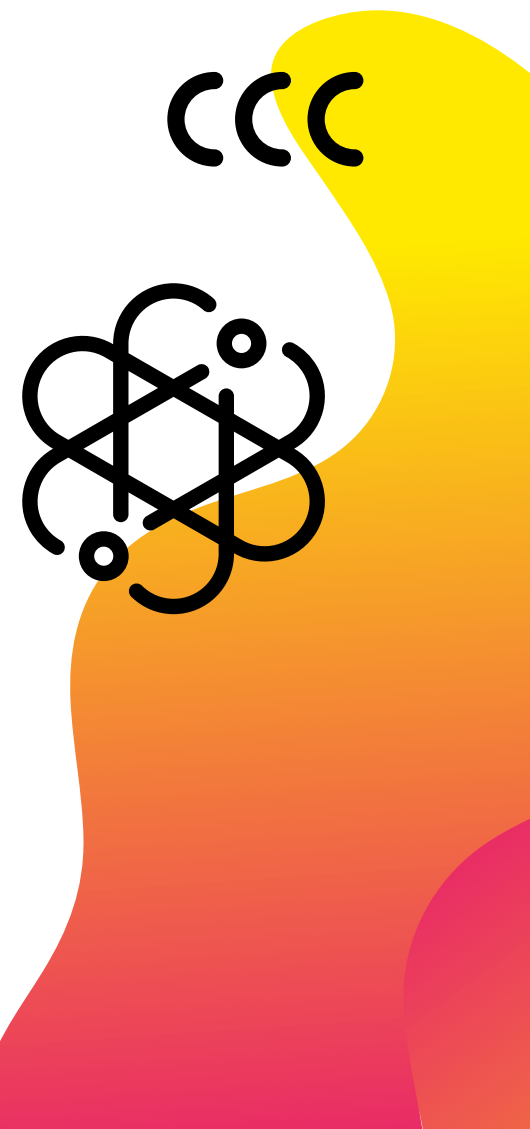
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## Partner-led portfolio

Status as of April 30, 2024

Compound	Mechanism of action	Target indication	Partner/status					
			P1	P2	P3	R	C	
<b>Daridorexant</b>	Dual orexin receptor antagonist	<b>Insomnia</b>	●	●	●	●	○	<b>Nxera Pharma:</b> license to develop and commercialize for Asia-Pacific region (excluding China) NDA submitted in Japan
<b>Daridorexant</b>	Dual orexin receptor antagonist	<b>Insomnia</b>	●	●	●	○	○	<b>Simcere:</b> license to develop and commercialize for Greater China region Phase 3 ongoing
<b>Selatogrel</b>	P2Y <sub>12</sub> inhibitor	<b>Acute myocardial infarction</b>	●	●	●	○	○	<b>Viartis:</b> worldwide development and commercialization rights Phase 3 "SOS-AMI" program ongoing
<b>Cenerimod</b>	S1P <sub>1</sub> receptor modulator	<b>Systemic lupus erythematosus</b>	●	●	●	○	○	<b>Viartis:</b> worldwide development and commercialization rights (excluding Japan, South Korea, and certain countries in the Asia-Pacific region) Phase 3 "OPUS" program ongoing
<b>Daridorexant</b>	Dual orexin receptor antagonist	<b>Posttraumatic stress disorder (PTSD)</b>	●	●	○	○	○	<b>US Department of Defense (DOD):</b> Idorsia is supporting a clinical study sponsored by the US DOD to develop new therapies to treat PTSD
<b>ACT-709478 (NBI-827104)</b>	T-type calcium channel blocker	<b>Epileptic encephalopathy with continuous spike-and-wave during sleep (CSCW)</b>	●	●	○	○	○	<b>Neurocrine Biosciences:</b> global license to develop and commercialize Phase 2 OLE study ongoing
<b>ACT-1002-4391</b>	EP <sub>2</sub> /EP <sub>4</sub> receptor antagonist	<b>Immuno-oncology</b>	●	○	○	○	○	<b>Owkin:</b> global license to develop and commercialize Phase 1 in preparation

P1: Phase 1, P2: Phase 2, P3: Phase 3, R: Registration, C: Commercially available

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**Daridorexant (Nxera Pharma)**

Daridorexant is licensed to Nxera Pharma (previously known as Sosei Heptares) in the Asia-Pacific region (excluding China), and a New Drug Application (NDA) is under review with the Japanese Ministry of Health, Labor, and Welfare (MHLW).

In Japan, Idorsia has a license agreement with Mochida Pharmaceutical for the supply, co-development and co-marketing of daridorexant. All potential milestones have been assigned to Nxera.

Asia-Pacific region (excluding China): Australia, Brunei, Cambodia, Indonesia, Japan, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, South Korea, Thailand, Taiwan, and Vietnam.

**Daridorexant (Simcere)**

Daridorexant is licensed to Simcere in the Greater China region (Mainland China, Hong Kong, and Macau), and a Phase 3 study with daridorexant in Chinese patients has completed recruitment. Results are expected in June 2024 and, if the study is successful, an NDA in Mainland China is planned for the second half of 2024. An NDA is already under review with the Hong Kong Department of Health.

**Selatogrel and cenerimod (Viatrix)**

A joint development committee from Idorsia and Viatrix is overseeing the development of two ongoing Phase 3 programs up to regulatory approval.

Selatogrel is a potent, fast-acting, reversible, and highly selective P2Y<sub>12</sub> inhibitor being developed in a Phase 3 study for the treatment of acute myocardial infarction (“SOS-AMI”) in patients with a recent history of AMI. It is intended to be self-administered subcutaneously via a drug delivery system (autoinjector).

Cenerimod is a highly selective S1P<sub>1</sub> receptor modulator, given as an oral once-daily tablet, which is being developed in a Phase 3 program known as “OPUS” for the treatment of systemic lupus erythematosus (SLE).

Viatrix has worldwide commercialization rights for both selatogrel and cenerimod (excluding, for cenerimod only, Japan, South Korea, and certain countries in the Asia-Pacific region).

**Daridorexant (US Department of Defense)**

Idorsia is supporting a clinical study sponsored by the US Department of Defense (DOD) to develop new therapies for posttraumatic stress disorder (PTSD). The Phase 2 study will evaluate the safety, tolerability, and efficacy of potential therapeutic interventions, including daridorexant, in active-duty US service members and veterans with PTSD.

**ACT-709478**

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 being investigated in a Phase 2 open-label extension (OLE) study for the treatment of pediatric patients with epileptic encephalopathy with continuous spike-and-wave during sleep (CSCW), a rare form of pediatric epilepsy. While the blinded study did not meet the primary endpoint, ACT-709478 was generally well tolerated and Neurocrine continues to analyze the totality of data coming from the OLE study to determine the next steps.

**ACT-1002-4391**

Owkin has a global license to develop and commercialize ACT-1002-4391, Idorsia’s novel, potent EP<sub>2</sub>/EP<sub>4</sub> receptor antagonist with antitumor efficacy, to be used both as monotherapy and in combination with other oncology agents. The compound is in preparation for Phase 1 clinical pharmacology studies. Owkin will use its proprietary AI-based data-mining platform to generate clinical trial designs and to identify patients who may benefit from, and potential targets for, the compound.

# More horizons – Expanding globally



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### **Idorsia Pharmaceuticals Ltd**

Allschwil, Switzerland

### **Idorsia Pharmaceuticals US Inc.**

Radnor, Pennsylvania

### **Idorsia Pharmaceuticals Germany GmbH**

Munich, Germany

### **Idorsia Pharmaceuticals France SAS**

Paris, France

### **Idorsia Pharmaceuticals UK Ltd**

London, United Kingdom

### **Idorsia Pharmaceuticals Italy S.R.L.**

Milan, Italy

### **Idorsia Pharmaceuticals Spain S.L.**

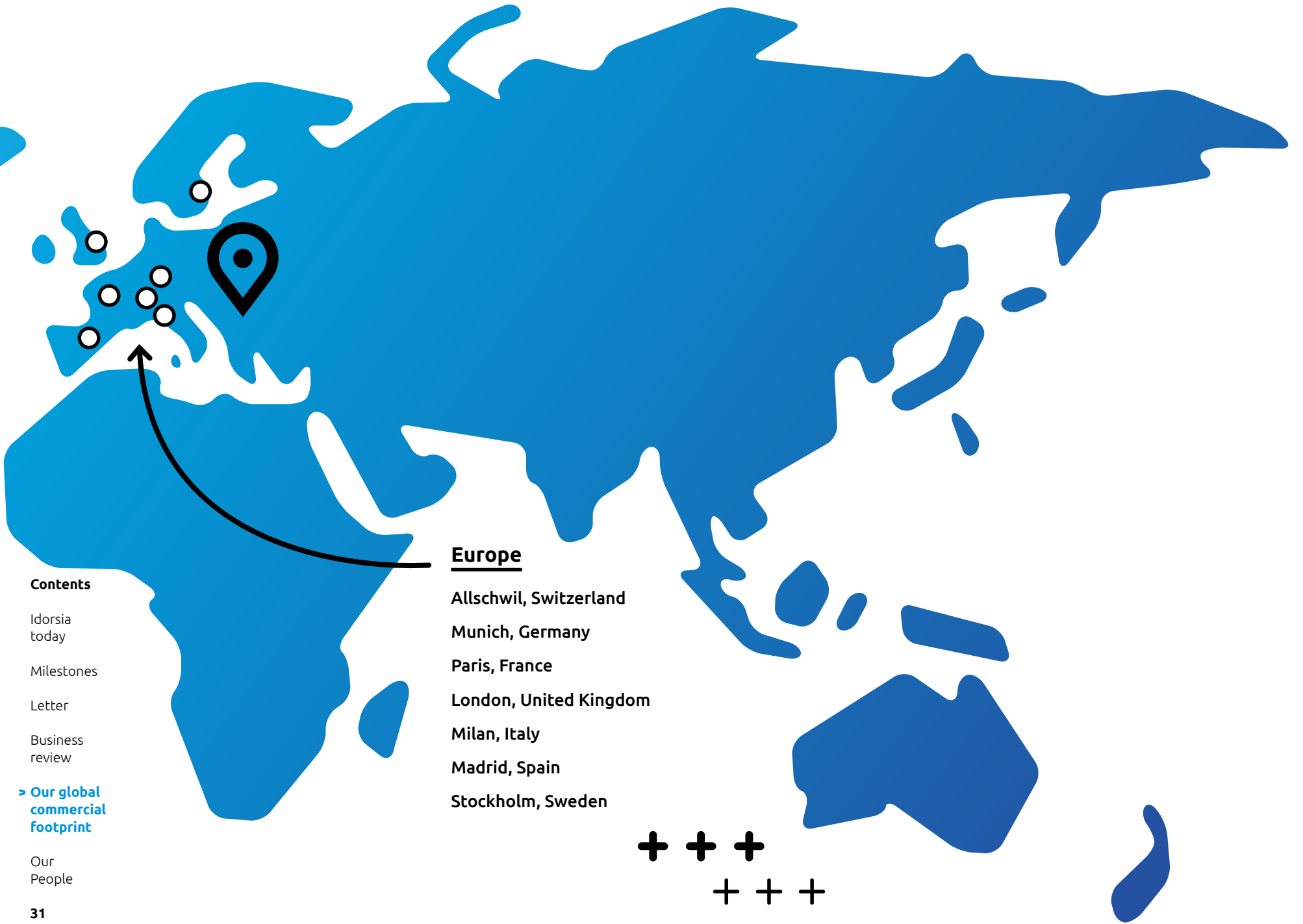
Madrid, Spain

### **Idorsia Pharmaceuticals Canada Ltd**

Montreal, Canada

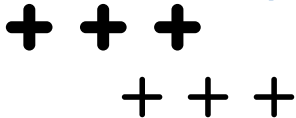
### **Idorsia Pharmaceuticals Nordics AB**

Stockholm, Sweden



**Europe**

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- Munich, Germany
- Paris, France
- London, United Kingdom
- Milan, Italy
- Madrid, Spain
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# More power – For scientific thinking

“We have always said that our success depends on our people, and that is never truer than when the company faces difficult periods. We want to acknowledge the efforts of our workforce, who have demonstrated their loyalty and resilience throughout this period of uncertainty. They have faced the challenges head-on and continue to advance the company with a passion for our patients.”

**Mathieu Simon**  
Chairman of the Board of Directors

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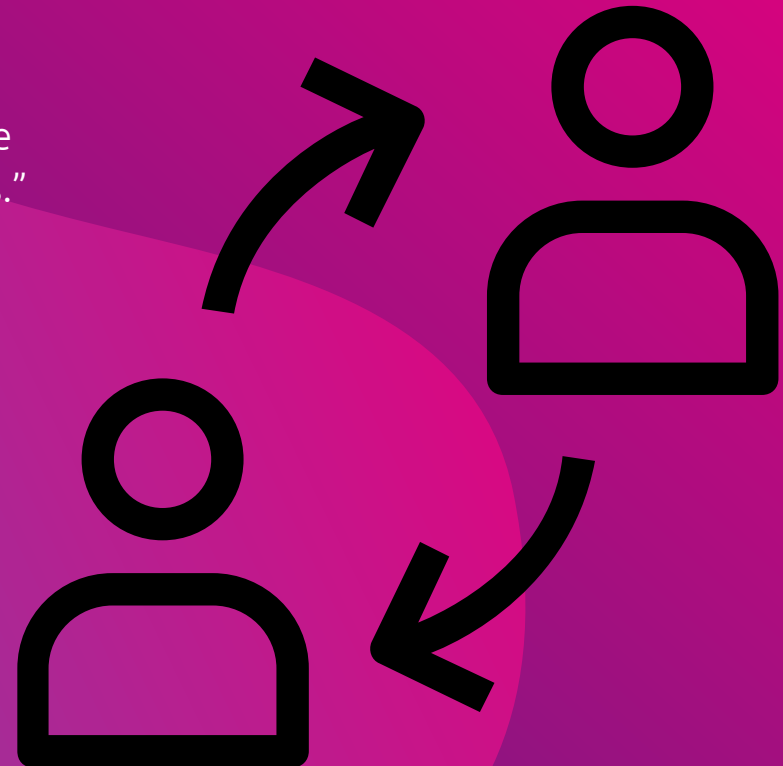
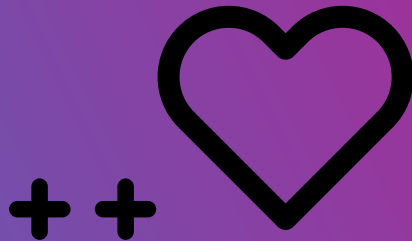
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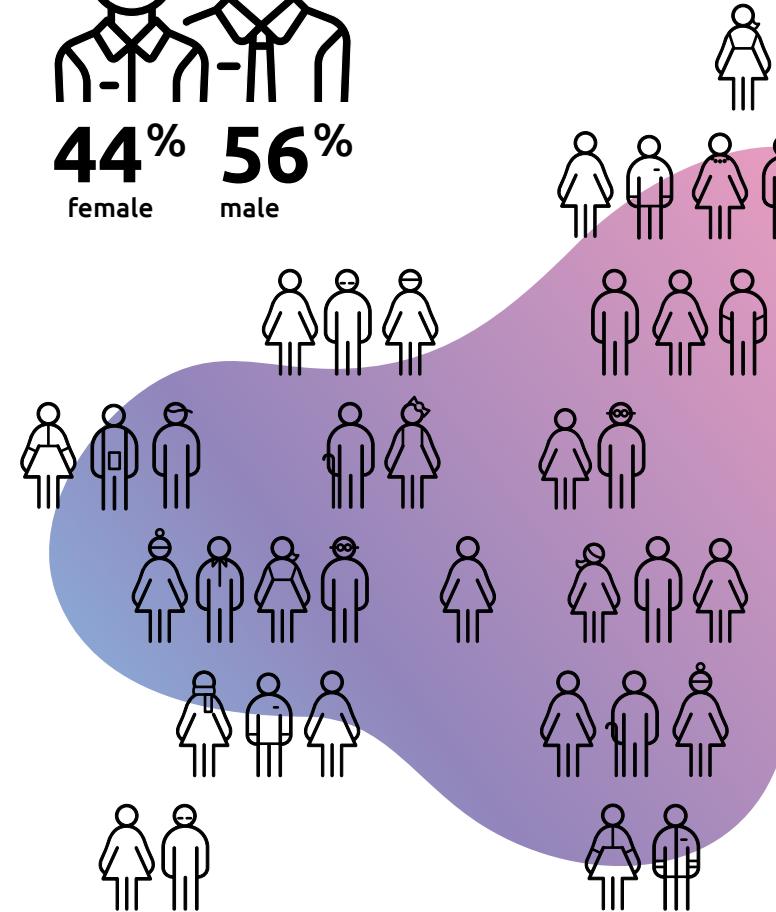
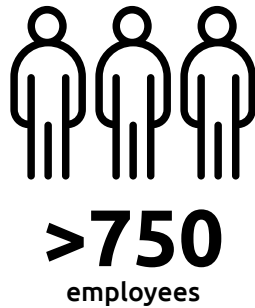
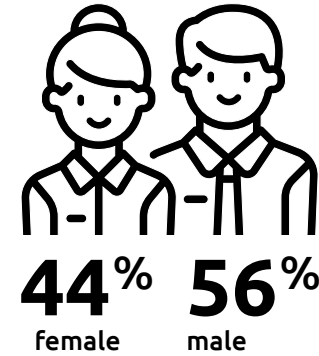
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Simply put – our success depends on our people! This is why we want to engage, and develop talented people who are passionate about working together and applying science to bring benefits to patients.



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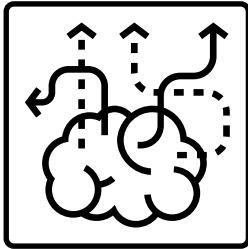
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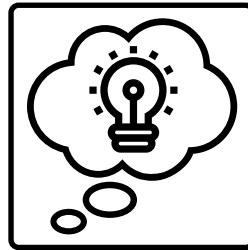
# More ambitions – Courageous and energetic

It is not just what we achieve, but how we get there. To support this, management has identified model behaviors which will help us to implement our strategy, shaping Idorsia's corporate culture.

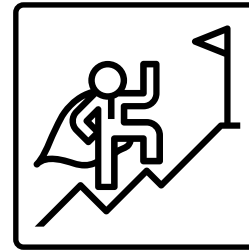
**be pragmatic**



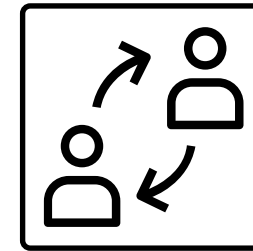
**invent**



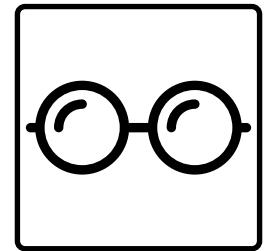
**advance**



**team up**



**learn**



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To reach our ambitious goals, we **advance** with energy and drive. We take full ownership and accountability to find solutions and outpace the competition.

Whatever the challenge, we are agile and **pragmatic** in implementing initiatives without compromising the quality of our work.

To seize more opportunities, we **invent** with creativity and imagination. Our work is science- and data-driven, and we remain open to new approaches in all aspects of what we do.

We **team up** to harness the power of our collective passion and sense of fun. We work collaboratively, sharing information and exchanging ideas, listening to and supporting each other.

We are curious, open-minded, and we **learn** continuously. We are encouraged to expand our knowledge, skills, and self-awareness, while looking for ways to apply what we have learned.

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# More resilience – Energized, engaged, and future oriented



In order to give the company the time it needs to deliver commercial success, the funds available must be allocated to activities offering the maximum return in the near term. As a result, it has been necessary for the company to substantially reduce investment in research and development, and to make changes to its structure.



**André C. Muller**  
Executive Vice President,  
Chief Financial Officer



**Jean-Paul Clozel**  
Chief Executive Officer

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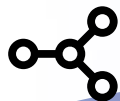
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The sale of our Asia-Pacific operations (excluding China) was one such change. The CHF 400 million raised by this transaction extended the cash runway, but expenditure must be optimized. A cost reduction of approximately 50% of the cash-burn at headquarters was thus required.

**The Idorsia  
Executive Committee**



To achieve this, a full review of the asset portfolio was conducted, with the aim of prioritizing assets that can be advanced rapidly and with reasonable financial investment. Following the review, those projects not aligned with the company's priorities were either paused or prepared for partnership or out-licensing. Unfortunately, the need for savings and the reduction in R&D activities meant that some of our valued employees had to be made redundant. In spite of our efforts to minimize the impact on employees as far as possible – through cancellation of new positions, natural turnover, and non-renewal of temporary positions – redundancy was required for up to 300 people with permanent and temporary positions at headquarters. This was a deeply regrettable chapter in Idorsia's history, but it was essential to ensure the company's future.



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In a more positive development, as part of the deal whereby two Phase 3 assets were out-licensed to Viatrix, the team essential to the conduct of the clinical programs moved with these assets, establishing a new unit within Viatrix. This ensured the continuity of the programs, while giving greater job security to people working on them.

Despite the uncertainties of this challenging period, our employees have continued to focus on our key priorities, demonstrating incredible resilience and remaining energized, engaged, and future oriented. This indicates the depth of their commitment to our stakeholders – in particular, to our patients.



**Martine Clozel**  
Executive Vice President,  
Chief Scientific Officer

**Alberto Gimona**  
Executive Vice President,  
Head of Global Clinical Development & Medical Affairs

# Be prepared for more

**Curious to learn more?  
Reach out to us.**

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