

Interim report  
January – March 2023

LISA HELGESON, works with bioanalysis to better understand how our candidate drugs are handled by the body.

World-leading drug portfolio with the aim of transforming life for people living with Parkinson's disease and other CNS disorders.

# Interim report January – March 2023

## Summary of the first quarter

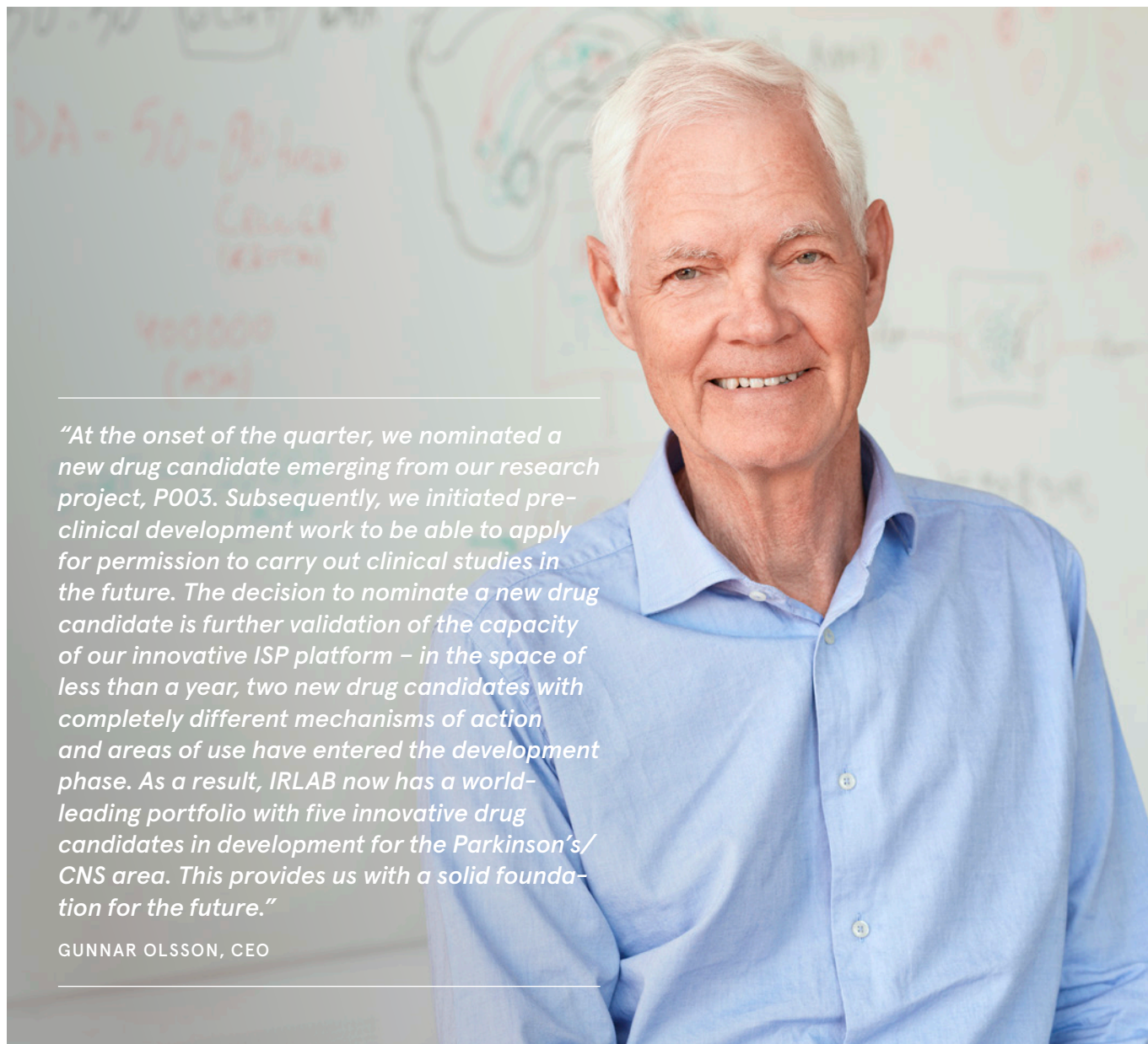
- IRLAB was invited to participate at the 6th Neuroscience Innovation Forum hosted by Sachs Associates in early January. The event was held in connection to the Annual J.P. Morgan Healthcare Conference, in San Francisco, US.
- Drug candidate IRL117 was nominated in early January as a new addition to the company's portfolio. IRL117 is now under development as an innovative once-daily treatment for the hallmark symptoms of Parkinson's without inducing the troublesome fluctuations in effect and complications caused by today's mainstay levodopa-based treatments.
- The top-line results of the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias were reported in the middle of January 2023. While the study did not reach statistical significance in the primary endpoint, it achieved its purpose of confirming dose-dependent effects and the selection of best dose for further clinical studies. Mesdopetam demonstrated clear anti-dyskinetic effects during the full 12-week treatment period with an adverse event and tolerability profile at the same level as placebo. The anti-dyskinetic effects were achieved without reducing normal motor function and are further strengthened by a clear reduction of OFF-time. Detailed analyses of the full data set from the study are ongoing in collaboration with our partner Ipsen.
- In mid-February, the company announced an update to the portfolio development milestones following an assessment of the operational priorities for 2023.
- On February 20, Dr Gunnar Olsson, M.D., Ph.D was appointed as interim CEO following Richard Godfrey's termination. Carola Lemne, former Vice Chair, took over the role as Chairperson of the Board from Gunnar Olsson, and An van Es-Johansson elected to leave her assignment as a Board member at IRLAB on February 21. As the new Chairperson of the Board of IRLAB, Carola Lemne took over the membership in the nomination committee after Gunnar Olsson's resignation as Chairperson of the Board.
- At the end of March, IRLAB presented new data related to the preclinical drug candidates and the ISP platform in an oral presentation and in three poster presentations at the International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders, AD/PD™ 2023.
- IRLAB organized an industry symposium at the scientific congress AD/PD™ 2023, which was held on Friday, March 31, 2023. A recording of the symposium titled The management dilemma of Parkinson's disease progression and emerging treatment approaches can be found on IRLAB's website, [www.irlab.se](http://www.irlab.se).
- IRLAB presented at national investor events and are regularly interacting with potential national and international investors to provide an update on the company and its progress. The events were organized by e.g., ABGSC. Public recordings are available on IRLAB's website, [irlab.se](http://irlab.se).

## Events after the period

- On May 3, IRLAB was made aware that Ipsen's 2022 Universal Registration Document, published on April 6, 2023, contains the incorrect information that the development and commercialization rights for mesdopetam have been transferred back to IRLAB. This is incorrect. Following contact from Ipsen on May 1, 2023, a discussion was initiated with IRLAB to mutually agree on the best way forward to secure that the mesdopetam program gets the best possible prospects to reach registration and to ensure that mesdopetam can be made available to the benefit of all people living with Parkinson's disease.

## Financial summary

SEK thousand	January–March 2023	January–March 2022	January–December 2022
Net sales	0	9 042	61 136
Operating profit	-59 508	-29 088	-113 110
Profit/loss for the period	-59 556	-29 170	-113 406
Earnings per share before and after dilution, attributable to the parent company's shareholders	-1.15	-0.56	-2.19
Number of shares at the end of the period, including subscribed but not yet registered shares	51 868 406	51 748 406	51 868 406
Cash and cash equivalents	210 103	368 047	401 897
Equity per share	4.46	7.16	7.72
Equity ratio, %	83	85	90
Average number of employees	31	26	29
Of which in R&D	27	23	25



*“At the onset of the quarter, we nominated a new drug candidate emerging from our research project, P003. Subsequently, we initiated pre-clinical development work to be able to apply for permission to carry out clinical studies in the future. The decision to nominate a new drug candidate is further validation of the capacity of our innovative ISP platform – in the space of less than a year, two new drug candidates with completely different mechanisms of action and areas of use have entered the development phase. As a result, IRLAB now has a world-leading portfolio with five innovative drug candidates in development for the Parkinson’s/ CNS area. This provides us with a solid foundation for the future.”*

GUNNAR OLSSON, CEO

## Comments from the CEO

IRLAB continues to make significant progress in its efforts to develop innovative treatments for Parkinson’s and other neurological disorders. During the first quarter of this year, we achieved important milestones in our clinical development programs, including the completion of the Phase IIb study with mesdopetam. Our second Phase IIb study with pirepemat is progressing as planned. We are also making progress in our preclinical programs and remain confident in the potential of our drug portfolio to address the unmet medical needs, primarily for those living with Parkinson’s.

### Restructure of management

Nearly a year has passed since we created separate CEO and Head of Research & Development (R&D) roles within the company’s leadership, instead of having these responsibilities combined into one position as before. The outcome has been that the Head of R&D can now focus on research-related matters,

while the CEO’s role is now directed more toward strategic matters, corporate development, and establishing partnerships with other companies. I have been serving as the CEO for almost three months now. Although I had a good understanding of the company from my time in the Board (since 2017), it has been highly positive to become even closer to the operations. This has further reinforced my impressions and confidence in the quality of the operations and its employees. This foundation, combined with our strong project portfolio, provides us with excellent opportunities for continued positive growth.

### Clear anti-dyskinetic effects by mesdopetam

In the Phase IIb study with mesdopetam, the efficacy and safety of three dose levels of mesdopetam were evaluated in individuals with Parkinson’s disease experiencing troublesome dyskinesia. The aim was to establish a dose-response relationship to determine the appropriate dose for Phase III. The top-line results of the study were reported in January 2023, and subsequent

analysis of the complete dataset has been conducted. Although the primary endpoint in the study, known as “good ON” time, i.e. the change in the duration of time during the day that patients experience the positive effects of levodopa on Parkinson’s hallmark symptoms (tremors, stiffness, and bradykinesia) without troublesome dyskinesia, did not reach statistical significance compared to placebo, the study achieved its objective by establishing a dose-dependent anti-dyskinetic effect accompanied by a good safety and tolerability profile. The study has thus provided information for selecting the dose for Phase III: 7.5 mg twice daily. IRLAB and IRLAB’s regulatory and commercial advisors have a strong belief in the clinical and commercial potential of mesdopetam.

### The path forward in the development of mesdopetam

After the completion of Phase I and Phase II study programs, combined with Ipsen’s Phase III preparatory activities, including conducting regulatory pharmacokinetic studies in Phase I, manufacturing of drug substance and drug product, we assess that mesdopetam will be ready for Phase III. Following communication from Ipsen on May 1, 2023, a discussion was initiated with IRLAB to mutually agree on the best way forward to ensure that the mesdopetam program is given optimal opportunities for registration and to ensure that mesdopetam can be made available to all people living with Parkinson’s disease.

### Ongoing Phase IIb study of pirepemat

In the ongoing Phase IIb study with pirepemat, the effect of two different doses of pirepemat on the frequency of falls in people with Parkinson’s is evaluated in order to be able to confirm the best dose for use in Phase III. In the study, the effect on cognitive function and safety/tolerability will also be evaluated. We anticipate that all participating clinics in the study will be activated by June 2023. Recruitment of patients is expected to be completed by the end of 2023, followed by a three-month treatment period. Based on the current timeline, top-line results are expected in H1 2024.

### Preclinical programs has potential to address major needs

Our drug candidates in the preclinical development phase are progressing as planned to be ready for testing in clinical trials. IRL942 targets the improvement of cognitive function in people with Parkinson’s and other neurological disorders, IRL757 aims to treat apathy in Parkinson’s and other neurological disorders, and IRL1117 with the objective of developing a treatment for the hallmark symptoms of Parkinson’s (tremors, stiffness, and bradykinesia) without causing the troublesome fluctuations of the effect and the complications associated with current mainstay levodopa-based treatments. A drug with this profile has the potential to replace levodopa treatment for Parkinson’s.

### Portfolio of drug candidates

Today, we have a world-leading portfolio of innovative drug candidates for treating people with Parkinson’s and other CNS dis-

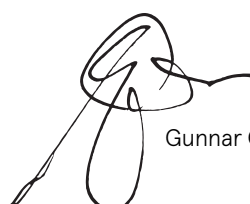
orders, based on our proprietary research platform, ISP. This positions us strongly to continue developing the company with the goal of bringing new and improved medications for individuals with Parkinson’s across all stages of the disease, which simultaneously could be generating value for our shareholders. Over the next 1-2 years, we could have up to five drug candidates in the clinical development phase – an impressive and possible development for the company that will require further expansion of certain competences.

### Interesting points of view at AD/PD 2023

This year, one of the foremost scientific congresses in the field of CNS took place in our hometown, Gothenburg – the International Conference on Alzheimer’s and Parkinson’s Diseases and Related Neurological Disorders, AD/PD™ 2023. We participated by organizing an industry symposium as an initiative to strengthen our position in the medical community and further showcase our company to raise awareness of our research and development focus and our world-leading drug portfolio among both major and minor pharmaceutical companies. It was interesting to hear our invited panelists, experts in their respective fields, present their experiences and knowledge on the topic of “The management dilemma of Parkinson’s disease progression and emerging treatment approaches.” The audience consisted of approximately 200 people, and questions were posed to the panel by individuals in scientific positions associated with companies such as Biogen, Janssen, Roche, and BioHaven.

### Forward-looking

We have our priorities for 2023 defined: providing full support for the planning of Phase III with mesdopetam and together with Ipsen, deciding on the best path forward for Phase III implementation; completing patient recruitment in the ongoing Phase IIb study with pirepemat; finalizing preclinical development ahead of a clinical trial this year for IRL757, and advancing IRL942 and IRL1117 in preclinical development in preparation for clinical trials next year. With our broad project portfolio of drug candidates in the development phase, we will need to continue driving efficient cost management. Like other biotech companies, we will require capital injections, which can be achieved through licensing agreements/collaborations or through the capital market. While we are currently relatively well-capitalized, we need to remain vigilant about our financial stability, and we continuously evaluate our opportunities. I look forward to continuing to develop the company and our drug candidates together with our employees and the Board, and I want to express my gratitude to all shareholders for the support and trust you have placed in us.



Gunnar Olsson, CEO, IRLAB

# Overview and strategic priorities

Rooted in Nobel Prize-winning research, IRLAB has grown rapidly to become recognized and respected as a world-leader in understanding the complex neuropharmacology of CNS disorders and especially Parkinson's. We have a well-defined, strategically focused R&D pipeline of powerful new treatments targeting the various stages of Parkinson's as they worsen over time throughout the patient's journey of neurodegeneration. Having a full range of effective disease management options for Parkinson's patients is regarded as essential by both the medical and patient communities – and at the same time potentially a blockbuster pharmaceutical business.

Parkinson's is the most common primary neurodegenerative disease after Alzheimer's disease, and the number of affected persons is expected to rise as the world's population is ageing. At present, nearly nine million people have Parkinson's. By 2040, this figure is expected to double.

To meet this challenge, IRLAB has developed a unique, disruptive technology platform called ISP to discover new CNS drug candidates. Leveraging ISP is a major competitive advantage of IRLAB and increases both the pace of drug candidate discovery and probability of success. Based on advanced machine learning techniques, ISP first interrogates our extensive proprietary CNS pharmacology database and that informs our chemists on the optimal molecular design of potential drug candidates with the desired symptom correcting pharmacology or therapeutic effect.

Over the last twenty years, the ISP research platform has gained significant validation by having brought five drug candidates into clinical development, of which three are now in clinical development from Phase IIb-III. Additionally, IRLAB is today developing three drug candidates where Phase I development is expected in the next two years.

IRLAB's most advanced clinical candidate, mesdopetam (IRL790), has successfully gone through Phase I safety, kinetic and tolerability studies; Phase Ib and Phase IIa efficacy proof-of-concept studies; and a Phase IIb trial to establish dose response and additional safety data. Our other clinical candidate pirepemat (IRL752) has also successfully gone through Phase I safety and Phase IIa efficacy proof-of-concept studies, and is currently in a Phase IIb trial. These drug candidates are intended to treat

patients with some of the most challenging symptoms associated with Parkinson's – troublesome dyskinesias (PD-LIDs), psychosis (PD-P) and symptoms linked to cognitive decline, such as impaired balance and an increased risk of falls (PD-Falls). In addition, we are developing two preclinical drug candidates to address cognitive impairment (IRL942) and apathy (IRL757), debilitating symptoms of Parkinson's and a great unmet medical need without available treatment options. Our third preclinical candidate IRL1117 is aimed at treating the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay anti-Parkinson's treatments and with potential to replace levodopa.

Mesdopetam has already been successfully out-licensed to the global specialty pharma company Ipsen. This deal demonstrates the commercial interest that our pipeline generates. Pirepemat and the preclinical candidates (IRL942, IRL757 and IRL1117) remain wholly-owned unencumbered assets of IRLAB and we retain full rights to develop and / or commercialize these assets. We anticipate that the potential of these drug candidates to improve the treatment of Parkinson's and other neurological disorders will make them attractive targets for the pharmaceutical industry and in turn yield substantial value for shareholders.

Therefore our strategic priorities are to:

1. Ensure the development of mesdopetam's potential to become an effective treatment for people with Parkinson's.
2. Publish and present the comprehensive results of the Phase IIb trial of mesdopetam in Parkinson's disease at scientific congresses and in scientific journals during 2023.
3. Position the candidates with clarity regarding their potential and differentiation from existing treatments to clarify the medical and commercial value.
4. Pursue the timely completion of the Phase IIb study of pirepemat in PD-Falls, which means that we anticipate study recruitment to be completed during 2023.
5. Progress IRL942, IRL757 and IRL1117 towards Phase I clinical studies.
6. Continue and intensify dialogues with potential investors, collaborators, and licensees for both clinical and preclinical programs.

## IRLAB A

IRLAB has been listed on Nasdaq Stockholm's main list Mid Cap since 2020.

# IRLAB's portfolio

First-in-class drug candidates to treat people with Parkinson's across all stages of disease.

		DISCOVERY	PRE CLINICAL	PHASE I	PHASE IIA	PHASE IIB	PHASE III	
<b>Mesdopetam* (IRL790)</b> D3 antagonist	Parkinson's disease – levodopa-induced dyskinesia (PD-LIDs)						PHASE IIB	
	Parkinson's disease – psychosis					PHASE I		
<b>Pirepemat (IRL752)</b> PFC enhancer	Parkinson's disease – impaired balance and falls						PHASE IIB	
	Parkinson's disease – dementia					PHASE IIA		
<b>IRL942</b>	Neurological disorders – cognition				PRECLINICAL			
<b>IRL757</b>	Neurological disorders – apathy				PRECLINICAL			
<b>IRL1117</b>	Parkinson's disease – treatment of hallmark symptoms				PRECLINICAL			

PFC enhancer = noradrenaline and serotonin antagonists In the prefrontal cortex

\*Developed in partnership with Ipsen, which has the global development and commercialization rights.

## Snapshot of Q1 updates

### Mesdopetam

- The top-line results from the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias (PD-LIDs) were reported in mid-January. Mesdopetam demonstrated dose dependent anti-dyskinetic effects in several dyskinesia assessment scales with an adverse event and tolerability profile similar to placebo, even though the study did not statistically meet the primary efficacy endpoint of "good ON"-time. Additional analysis of the full data is currently ongoing.

### Pirepemat

- The ongoing study is active at 36 of 38 planned study sites at present, all sites are expected to be activated during Q2 2023. Patient recruitment and randomization is expected to be completed by the year-end 2023 and top-line results are expected in H1 2024.

### IRL942

- Development proceeds according to the preclinical development, toxicology and GMP manufacturing plan. IRL942 is expected to be Phase I ready during H1 2024.

### IRL757

- Development proceeds according to the preclinical development, toxicology and GMP manufacturing plan. IRL757 is expected to be Phase I ready by year-end 2023.

### IRL1117 (P003 project)

- In January, a drug candidate in the P003 project was nominated for continued development toward clinical studies. The drug candidate, IRL1117, will be developed as a once-daily oral treatment for the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay levodopa-based treatments in Parkinson's. IRL1117 is an orally available and potent dopamine D1 and D2 receptor agonist that has demonstrated rapid onset of action and more than 10 hours of sustained efficacy in preclinical studies, clearly differentiating IRL1117 from current treatments.
- IRL1117 continues with in-house activities in preparation for Phase I enabling toxicology and manufacturing activities in 2024.

## R&D update

IRLAB's portfolio consists of drug candidates in clinical and preclinical development phases. It is focused on developing novel treatments for people with Parkinson's and other CNS disorders. All drug candidates have been generated in-house by the company's proprietary technology platform, ISP.

### Clinical phase

#### Mesdopetam

Mesdopetam, a dopamine D3 receptor antagonist, is being developed as a treatment for Parkinson's disease levodopa-induced dyskinesias (PD-LIDs), aiming to improve patient quality of life. The development is conducted in partnership with Ipsen. PD-LIDs is a severe form of involuntary movements commonly occurring in people with Parkinson's treated with levodopa.

Mesdopetam has wide clinical potential for unmet medical needs in neurology. The drug candidate is intended to treat people with Parkinson's who develop LIDs, which is more than 30 percent of all people living with Parkinson's. In the eight major markets worldwide, this equates to one million affected individuals.

Mesdopetam has also potential as a treatment for Parkinson's disease Psychosis (PD-P), which affects about 1.5 million people across the eight major markets worldwide. Further, mesdopetam has potential to treat other neurological conditions such as tardive dyskinesia, representing an even larger market.

In a 28-day Phase Ib study, mesdopetam was found to be safely administered and tolerable in patients with advanced Parkinson's. In mesdopetam-treated patients, a consistent numeric reduction in dyskinesia assessments scales was observed. In the subsequent 28-day Phase IIa study, mesdopetam demonstrated anti-dyskinetic effects using several dyskinesia assessment scales, although the primary efficacy endpoint, UDysRS was not met.

Thus, the Phase Ib and Phase IIa studies demonstrated a good safety and tolerability profile and proof-of-concept with potential for superior anti-dyskinetic efficacy, compared to current treatment options.

#### *Completed Phase IIb study*

The Phase IIb study of mesdopetam investigated the efficacy

and safety of three doses of mesdopetam (2.5, 5.0, and 7.5 mg b.i.d), as compared to placebo, in people with Parkinson's experiencing troublesome dyskinesia caused by their levodopa treatment and supported dose selection for further clinical development.

The top-line results of the study were reported in January 2023 with further analysis of the full data currently ongoing in collaboration with IRLAB's partner Ipsen.

The Phase IIb study's primary endpoint, change in daily ON-time without troublesome dyskinesia ("good ON"-time), did not reach statistical significance by mesdopetam compared to placebo. A secondary efficacy endpoint, UDysRS (part 1, 3 and 4, full analysis set), a comprehensive scale measuring ON-phase dyskinesia, showed significant anti-dyskinetic effects by mesdopetam already at four weeks (nominal p-value = 0.045), at eight weeks (nominal p-value = 0.004), continuing for the full twelve-week study period (nominal p-value = 0.026) at the 7.5 mg bid

dose. This effect was corroborated by the numerical improvement in scales measuring disability associated with dyskinesia. Further, the daily time spent in OFF showed a dose-dependent pattern and a numerical decrease compared to placebo also favoring the 7.5 mg bid dose. The secondary endpoint MDS-UPDRS part II (motor aspects of experiences of daily living) was unchanged by mesdopetam treatment, which was the desired outcome as it shows that mesdopetam does not impair normal motor function in this study population.

Mesdopetam was shown to be well tolerated and has an acceptable safety profile. The adverse event profile of mesdopetam in the Phase IIb study was similar to placebo. In the study, 195 patients were screened, 156 patients were randomized, and 125 patients completed the twelve-week treatment period.

The study was conducted at 46 study sites in Europe, Israel and in the US. More information can be found on [clinicaltrials.gov](https://clinicaltrials.gov): NCT04435431, and EudraCT number: 2020-002010-41.



*"Our whole portfolio has steadily progressed during 2022 and, particularly so, during the past months. The preclinical and clinical development program for mesdopetam, now through Phase IIb, has shown that we have discovered a tolerable and efficacious potential treatment for people living with Parkinson's, with a novel mechanism of action. We are continuing the analyses of the full study data and look forward to presenting more results during the spring 2023.*

*In our Phase IIb study of pirepemat, the number of activated sites is steadily increasing and the recruitment pace is expected to increase accordingly with the prognosis of having all study participants enrolled by year-end.*

*Our preclinical development candidates, IRL757 and IRL942, represent novel strategies to treat apathy and cognitive impairment, symptoms that are prevalent in people with Parkinson's where there are no available treatment alternatives, follow their plans toward Phase I studies in 2023 and 2024, respectively.*

*In our discovery organization, a full focus is on the P003 program where we recently nominated IRL1117 for further development towards Phase I with the aim to develop a new treatment for the hallmark symptoms of Parkinson's. Overall, we are making big and meaningful progress across our whole R&D portfolio."*

NICHOLAS WATERS, EVP AND HEAD OF R&D



### *Collaboration with Ipsen*

In 2021, exclusive global rights to the development and commercialization of the mesdopetam program was licensed to global specialty pharma company Ipsen. IRLAB remained responsible for the completion of the Phase IIb study while Ipsen is responsible for any further clinical development and worldwide commercialization. On May 1, 2023, Ipsen initiated a discussion was initiated with IRLAB to mutually agree on the best way forward to secure that the mesdopetam program gets the best possible prospects to reach registration and to ensure that mesdopetam can be made available to the benefit of all people living with Parkinson's disease.

### **Pirepemat**

Pirepemat (IRL752) has potential to be the first treatment in a new class of drugs designed to improve balance and reduce falls and fall injuries in people living with Parkinson's disease. Pirepemat is designed to improve balance and reduce falls by strengthening nerve cell signaling in the prefrontal cortex via antagonism at 5HT7 and alpha-2 receptors leading to increased dopamine and noradrenaline levels.

Falls are a significant consequence of Parkinson's that has severe complications, such as fractures, impaired mobility and a reduced quality of life. 45 percent of all people living with Parkinson's fall recurrently, leading to a significantly reduced quality of life also due to fear of falling. There are no available treatments at present, despite the great medical need. The societal burden due to falls is also significant with the cost for hospital treatment of a fall injury in the US estimated to be USD 30 thousand for people over age of 65.

Following the successful completion of Phase I studies, an exploratory Phase IIa study was completed in 32 patients with advanced Parkinson's including cognitive impairment. Treatment effects were reported indicating improvement in balance and reduced risk of falling, in concert with cognitive and psychiatric benefits.

As reported, and published in the Phase I and Phase IIa study publications (can be found through [www.irlab.se](http://www.irlab.se)), pirepemat was concluded to have an acceptable safety profile and to be well tolerated in the intended patient population i.e. patients with Parkinson's and dementia. Adverse events in this patient population were mainly related to the central nervous system (CNS), gastrointestinal systems and infections. These were of mild to moderate intensity and occurred predominantly during the initial 14-day titration phase. After the 28-day treatment period, a moderate transient increase in liver enzymes was seen in three patients in the pirepemat-treated group. No such effects were observed during the treatment period and these had all normalized at the study follow-up visit. A similar transient liver signal following the termination of active treatment has been observed in Phase I studies. The interpretation is that this is part of a rebound effect following an abrupt termination of treatment with pirepemat

The preclinical results and clinical studies suggest that pirepemat has the potential to strengthen frontal cortical function in the brain and that pirepemat could be developed into a highly valuable, first-in-class, treatment to prevent falls in people living with Parkinson's.

### *Ongoing Phase IIb study*

The ongoing Phase IIb study with pirepemat is designed as a randomized, double-blind and placebo-controlled study with the aim to evaluate the effect of pirepemat on falls frequency in people with Parkinson's, at two dose levels and placebo over a three-month treatment period. The secondary study objectives include cognitive assessments and further safety and tolerability evaluations.

The study is designed to randomize 165 patients distributed across three treatment arms with 55 patients respectively; two treatment arms with different dose levels of pirepemat and one placebo group.

The ongoing study is active at 36 of 38 planned study sites at present, all sites are expected to be activated by Q2 2023. Patient recruitment and randomization is expected to be completed by the year-end 2023. This is followed by the three-month treatment period, follow-up visits, data management and database lock. At this time, the top-line results are expected in H1 2024.

More information can be found on EudraCT number: 2019-002627-16 and [clinicaltrials.gov: NCT05258071](https://clinicaltrials.gov/ct2/show/study/NCT05258071).

### **Preclinical phase**

#### **IRL942**

Drug candidate IRL942 is targeting a once-daily oral tablet to treat cognitive deficits in Parkinson's and other neurological disorders with the aim to improve cognitive function. There are about 12 percent of adults aged 65 years or more experiencing cognitive decline, which greatly affect quality of life and it is more common in people living with neurological disorders.

Disruption of frontal cortical neurotransmission is implicated in the pathogenesis of cognitive decline and neuro-psychiatric symptoms in Parkinson's and other neurological disorders. IRL942 displays a unique ability to activate frontal cortical neurotransmission, synaptic gene expression, and associated circuits, improving cognitive function in several preclinical models of impaired cognitive function.

Non-clinical development activities related to CMC (development of large scale synthesis and production of drug compound and manufacturing of drug product for regulatory studies), toxicology and safety studies are ongoing, in preparation for regulatory submission to start Phase I studies. IRL942 is expected to Phase I ready during H1 2024.

#### **IRL757**

IRL757 is in preclinical development and aims at a once daily oral tablet to treat apathy in Parkinson's and other neurological dis-

orders. Apathy is a debilitating condition affecting over 10 million people in the US and equally many in Europe. The prevalence is high, occurring in 20–70 percent of people with Parkinson's and in 20–90 percent of people with disorders such as Alzheimer's disease and other disorders related to CNS.

Preclinical efficacy by IRL757 has been obtained in several pre-clinical models representing various aspects of cognitive function including potential signals of improved motivation. The efficacy by IRL757 observed, is hypothesized to be associated with IRL757's unique pharmacology to reverse disruption in cortical to sub-cortical nerve signaling, a proposed mechanism underlying apathy in neurological disorders.

Non-clinical development activities related to CMC, toxicology and safety studies to prepare for regulatory submission to start Phase I studies are currently ongoing. IRL757 is expected to be Phase I ready by the year-end 2023.

#### **IRL1117 (P003 project)**

IRL1117 will be developed as a once-daily oral treatment for the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay levodopa-based treatments in Parkinson's. IRL1117 is an orally available and potent dopamine D1 and D2 receptor agonist that has demonstrated rapid onset and more than 10 hours of sustained efficacy in pre-clinical studies.

At present, people with Parkinson's disease are prescribed the anti-Parkinson's treatment levodopa treating the hallmark symptoms of tremor, rigidity, and slowness of movement. Levodopa has been the mainstay treatment of Parkinson's since the 1960s and is currently the only medication that provides adequate symptomatic relief of the disease during its progression. Levodopa has, however, significant treatment-related limitations, especially the short duration of action and the occurrence of troublesome treatment-related complications such as excessive involuntary movements. By comparison, IRL1117 offers a clearly differentiating alternative being orally available, potent and displaying a long-duration anti-parkinsonian efficacy without inducing the troublesome complications during long-term treatment in preclinical models of Parkinson's.

IRL1117 continues with inhouse activities in preparation for Phase I enabling toxicology and manufacturing activities in 2024.

The P003 project aims to discover and develop dopamine D1 and D2 receptor agonist compounds with once-daily oral administration and improved efficacy on Parkinson's core motor symptoms (tremor, rigidity, and slowness of movements) but are free from the limitations displayed by levodopa (i.e., the short duration of action and the motor complications). In addition to IRL1117, there are a number of follow-on compounds identified with differentiation relating to the onset of action and time to maximal efficacy.

#### **Research technology platform ISP**

IRLAB's portfolio is generated with the unique proprietary drug discovery platform Integrative Screening Process, called ISP, which has proven to enable the discovery of truly novel first-in-class compounds. The ISP methodology combines systems biology screening models, an extensive database, and modern machine learning-based analytical methods. This means that IRLAB obtains unique insights into the overall effect of the studied molecules at an early stage. The platform can at that stage already predict which drug candidates that have the greatest potential to be developed into a promising drug with the lowest risks. ISP provides an improvement in probability of drug discovery success in translation between clinical phases, compared with industry standard. This is also exemplified by higher probability to demonstrate positive clinical proof-of-concept in patients and reach later stages of clinical development for an ISP generated drug candidate compared with the industry standard target based screening methods for candidate drug identification.

This discovery and development strategy provides IRLAB with a strong competitive advantage in the discovery of novel treatments for Parkinson's and other CNS disorders. It is important to IRLAB to constantly refine and develop its technology-base and remain at the forefront of modern drug discovery. New perspectives are also added through close cooperation with universities and academic researchers so that IRLAB can keep leading the development of cutting-edge technology.

# The group's performance

## January – March 2023

IRLAB Therapeutics AB, corporate identity number 556931-4692, is the parent company in a group that carries out research and development with the aim of transforming life for people with Parkinson's and other CNS disorders through novel treatments. The company's most advanced drug candidates are mesdopetam and pirepemat, both of which are intended to treat some of the most difficult symptoms related to Parkinson's.

The company's unique proprietary research platform ISP generates novel, high-potential drug substances that make up the company's pipeline. IRLAB has two drug candidates in clinical phase, mesdopetam, licensed to Ipsen, and where data from a Phase IIb study was reported in January; and pirepemat in an ongoing Phase IIb study. Generated by ISP, IRLAB's three promising preclinical drug candidates IRL942, IRL757 and IRL1117, are currently in development toward clinical Phase I studies in respective preclinical development programs.

The parent company's operations mainly consist of providing management and administrative services to the group's operating companies, and activities related to the stock market. The research and development operations are conducted in the wholly-owned subsidiary Integrative Research Laboratories Sweden AB. IRLAB has offices in Gothenburg (main) and Stockholm, Sweden.

### Research and development work

The research and development work has advanced according to plan. In the period January to March, the total costs for research and development were SEK 41 769k (31 243), corresponding to 70 percent (82) of the group's total operating expenses. Development costs vary over time, depending on where in the development phase the projects are.

During the period 1 January – 31 March 2023, the percentage proportion of R&D cost is lower, mainly due to increased personnel costs attributable to one-off costs in connection with the removal of the former CEO.

### Comments on the income statement

The loss for the period January 1 – March 31, 2023 was SEK -59 508k (-29 088). Earnings per share were -1.15 SEK (-0.56). The group's revenue during the period was SEK 0k (9 129).

The personnel costs during the first quarter 2023 was SEK 21 090 k (9 674). The increase is primarily due to costs associated with the removal of the former CEO, which amounted to SEK 10 580k.

Of the SEK 239 596k that was received up-front in 2021 under the mesdopetam license agreement, SEK 185 262k was recognized as license revenue and SEK 54 335k was recognized as deferred income for the finalization of the Phase IIb study and was recognized as income during 2022. No such income has been recognized during the first quarter of 2023.

In 2022, the group's operating expenses were SEK 59 549k (38 217). The increase compared with the previous year was primarily due to increased clinical activity, a larger organization and one-off costs associated with the removal of the former CEO.

### Financing and cash flow

Cash flow from operating activities were during the period 1 January to 31 March 2023 SEK -41 498k (-32 783) and during the fourth quarter SEK -37 887k (-28 388). Cash and cash equivalents were SEK 210 103k (368 047) on March 31, 2023.

On March 31, 2023, equity was SEK 231 275k (370 311) and the equity ratio was 83 percent (85).

The Board of Directors and CEO determines that there are sufficient cash and cash equivalents to cover working capital needs over the next twelve months, given the current business activities and financing plan.

### Investments

Investments in intangible assets for the period January 1 – March 31, 2023 were SEK 293k (323).

### Significant events January–March 2023

IRLAB was invited to participate at the 6th Neuroscience Innovation Forum hosted by Sachs Associates in early January. The event was held in connection to the Annual J.P. Morgan Healthcare Conference, in San Francisco, US.

Drug candidate IRL1117 was nominated in early January as a new addition to the company's portfolio. IRL1117 is now under development as an innovative once-daily treatment for the hallmark symptoms of Parkinson's without inducing the troublesome fluctuations in effect and complications caused by today's mainstay levodopa-based treatments.

The top-line results of the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias were reported in the middle of January 2023. While the study did not reach statistical significance in the primary endpoint, it achieved its purpose of confirming dose-dependent effects and the selection of best dose for further clinical studies. Mesdopetam demonstrated clear anti-dyskinetic effects during the full 12-week treatment period with an adverse event and tolerability profile at the same level as placebo. The anti-dyskinetic effects were achieved without reducing normal motor function and are further strengthened by a clear reduction of OFF-time. Detailed analyses of the full data set from the study are ongoing in collaboration with our partner Ipsen.

In mid-February, the company announced an update to the portfolio development milestones following an assessment of the operational priorities for 2023.

On February 20, IRLAB's CEO Richard Godfrey was replaced by Gunnar Olsson who was appointed as interim CEO. Carola Lemne, former Vice Chair, took over the role as Chairperson of the Board from Gunnar Olsson, and An van Es-Johansson elected to leave her assignment as a Board member at IRLAB on February 21. As the new Chairperson of the Board of IRLAB, Carola Lemne took over the membership in the nomination committee after Gunnar Olsson's resignation as Chairperson of the Board.

At the end of March, IRLAB presented new data related to the



HENRIK GRADÉN, works with development of synthesizing methods for our candidate drugs and manufacturing of them in our laboratories.

preclinical drug candidates and the ISP platform in an oral presentation and in three poster presentations at the International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders, AD/PD™ 2023.

IRLAB organized an industry symposium at the scientific congress AD/PD™ 2023, which was held on Friday, March 31, 2023. A recording of the symposium titled The management dilemma of Parkinson's disease progression and emerging treatment approaches can be found on IRLAB's website, [www.irlab.se](http://www.irlab.se).

IRLAB presented at national investor events and are regularly interacting with potential national and international investors to provide an update on the company and its progress. The events were organized by e.g., ABGSC. Public recordings are available on IRLAB's website, [irlab.se](http://irlab.se).

### Significant events after the end of the period

On May 3, IRLAB was made aware that Ipsen's 2022 Universal Registration Document, published on April 6, 2023, contains the incorrect information that the development and commercialization rights for mesdopetam have been transferred back to IRLAB. This is incorrect. Following contact from Ipsen on May 1,

2023, a discussion was initiated with IRLAB to mutually agree on the best way forward to secure that the mesdopetam program gets the best possible prospects to reach registration and to ensure that mesdopetam can be made available to the benefit of all people living with Parkinson's disease.

## Consolidated income statement in summary

Amounts in SEK thousand	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
<b>Operating income, etc.</b>			
Net sales	0	9,042	61,136
Other operating income	0	87	141
<i>Total income</i>	<i>0</i>	<i>9,129</i>	<i>61,277</i>
<b>Operating expenses</b>			
Other external expenses	-37,129	-27,213	-125,906
Personnel costs	-21,090	-9,674	-42,481
Amortization, depreciation and impairment	-1,081	-944	-4,779
Other operating expenses	-209	-386	-1,220
<i>Total operating expenses</i>	<i>-59,508</i>	<i>-38,217</i>	<i>-174,387</i>
<b>Operating profit/loss</b>	<b>-59,508</b>	<b>-29,088</b>	<b>-113,110</b>
<b>Profit/loss from financial items</b>			
Finance income	3	0	0
Finance costs	-52	-81	-297
<i>Total financial items</i>	<i>-49</i>	<i>-81</i>	<i>-297</i>
<b>Profit/loss after financial items</b>	<b>-59,556</b>	<b>-29,170</b>	<b>-113,406</b>
Income tax	0	0	0
<b>Profit/loss for the period</b>	<b>-59,556</b>	<b>-29,170</b>	<b>-113,406</b>
Earnings per share before and after dilution (SEK)	-1.15	-0.56	-2.19
Average number of shares, before and after dilution	51,748,406	51,748,406	51,831,913
Number of shares at the end of the period	51,748,406	51,748,406	51,868,406

Profit/loss for the period is entirely attributable to the parent company's shareholders.

## Consolidated statement of comprehensive income in summary

Amounts in SEK thousand	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Profit/loss for the period	-59,556	-29,170	-113,406
Other comprehensive income	0	0	0
<b>Comprehensive income for the period</b>	<b>-59,556</b>	<b>-29,170</b>	<b>51,781</b>

## Consolidated statement of financial position in summary

Amounts in SEK thousand	03/31/2023	03/31/2022	12/31/2022
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	46,862	42,596	46,862
Property, plant and equipment	7,222	7,791	8,009
<b>Total non-current assets</b>	<b>54,084</b>	<b>50,387</b>	<b>54,871</b>
<b>Current assets</b>			
Current receivables	13,267	16,416	15,908
Cash and cash equivalents	210,103	368,047	252,776
<b>Total current assets</b>	<b>223,369</b>	<b>384,463</b>	<b>268,684</b>
<b>TOTAL ASSETS</b>	<b>277,453</b>	<b>434,850</b>	<b>323,555</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	1,037	1,035	1,037
Other contributed capital	690,205	685,450	690,205
Retained earnings including comprehensive income for the period	-459,967	-316,174	-400,411
<b>Total equity</b>	<b>231,275</b>	<b>370,311</b>	<b>290,831</b>
<b>Non-current liabilities</b>			
Lease liabilities	315	2,805	381
<b>Total non-current liabilities</b>	<b>315</b>	<b>2,805</b>	<b>381</b>
<b>Current liabilities</b>			
Lease liabilities	2,778	3,051	3,595
Other liabilities	43,085	58,684	28,748
<b>Total current liabilities</b>	<b>45,863</b>	<b>61,734</b>	<b>32,343</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>277,453</b>	<b>434,850</b>	<b>323,555</b>

## Consolidated statement of changes in equity in summary

Amounts in SEK thousand	Share capital	Unregistered share capital	Other contributed capital	Retained earnings incl. total comprehensive income for the period	Total equity
<b>Equity January 1, 2022</b>	<b>1,035</b>	<b>0</b>	<b>685,450</b>	<b>-287,005</b>	<b>399,481</b>
Comprehensive income for the period				-29,170	-29,170
<b>Equity March 31, 2022</b>	<b>1,035</b>	<b>0</b>	<b>685,450</b>	<b>-316,175</b>	<b>370,311</b>
Comprehensive income for the period				-84,237	-84,237
<i>Transactions with owners in their capacity as owners:</i>					
Rights issue	2		4,754		4,757
Issue costs					
<b>Equity December 31, 2022</b>	<b>1,037</b>	<b>0</b>	<b>690,205</b>	<b>-400,411</b>	<b>290,831</b>
<b>Equity January 1, 2023</b>	<b>1,037</b>	<b>0</b>	<b>690,205</b>	<b>-400,411</b>	<b>290,831</b>
Comprehensive income for the period				-59,556	-59,556
<b>Equity March 31, 2023</b>	<b>1,037</b>	<b>0</b>	<b>690,205</b>	<b>-459,967</b>	<b>231,275</b>



## Consolidated statement of cash flows in summary

Amounts in SEK thousand	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
<b>Operating activities</b>			
Operating profit/loss	-59,508	-29,088	-113,110
Adjustments for non-cash items	1,081	944	4,779
Interest received	3	0	0
Interest paid	-52	-81	-297
Taxes paid	0	0	0
<b>Cash flows from operating activities before changes in working capital</b>	<b>-58,476</b>	<b>-28,226</b>	<b>-108,627</b>
<b>Cash flows from changes in working capital</b>			
Changes in operating receivables	2,642	3,126	3,634
Changes in operating liabilities	14,336	-7,684	-37,619
<b>Cash flows from operating activities</b>	<b>-41,498</b>	<b>-32,783</b>	<b>-142,612</b>
<b>Investing activities</b>			
Acquisition of immaterial fixed assets	0	0	-500
Acquisition of property, plant and equipment	-293	-323	-2,876
<b>Cash flows from investing activities</b>	<b>-293</b>	<b>-323</b>	<b>-3,376</b>
<b>Financing activities</b>			
Repayment of financial liabilities	-883	-745	-3,134
<b>Cash flows from financing activities</b>	<b>-883</b>	<b>-745</b>	<b>-3,134</b>
<b>Profit/loss for the period</b>	<b>-42,673</b>	<b>-33,850</b>	<b>-149,121</b>
Cash and cash equivalents at the beginning of the period	252,776	401,897	401,897
<b>Cash and cash equivalents at the end of the period</b>	<b>210,103</b>	<b>368,047</b>	<b>252,776</b>

## Parent company income statement in summary

Amounts in SEK thousand	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
<b>Operating income, etc.</b>			
Net sales	1,587	894	4,531
<i>Total income</i>	<i>1,587</i>	<i>894</i>	<i>4,531</i>
<b>Operating expenses</b>			
Other external expenses	-4,344	-2,982	-12,187
Personnel expense	-13,930	-3,506	-14,402
Other operating expenses	-9	0	-25
<i>Total operating expenses</i>	<i>-18,283</i>	<i>-6,487</i>	<i>-26,614</i>
<b>Operating profit/loss</b>	<b>-16,696</b>	<b>-5,593</b>	<b>-22,083</b>
<b>Profit/loss from financial items</b>			
Interest income	1	0	0
Interest expenses	-1	-1	-7
<i>Total financial items</i>	<i>0</i>	<i>-1</i>	<i>-7</i>
<b>Profit/loss after financial items</b>	<b>-16,696</b>	<b>-5,594</b>	<b>-22,090</b>
<b>Profit/loss for the period</b>	<b>-16,696</b>	<b>-5,594</b>	<b>-22,090</b>

## Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Profit/loss for the period	-16,696	-5,594	-22,090
Other comprehensive income	0	0	0
<b><i>Comprehensive income for the period</i></b>	<b><i>-16,696</i></b>	<b><i>-5,594</i></b>	<b><i>-22,090</i></b>

## Parent company balance sheet in summary

Amounts in SEK thousand	03/31/2023	03/31/2022	12/31/2022
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Financial assets</b>			
Participations in group companies	350,320	350,320	350,320
<b>Total non-current assets</b>	<b>350,320</b>	<b>350,320</b>	<b>350,320</b>
<b>Current assets</b>			
Other receivables	7,942	1,844	8,535
Cash and cash equivalents	85,909	106,870	92,814
<b>Total current assets</b>	<b>93,851</b>	<b>108,746</b>	<b>101,349</b>
<b>TOTAL ASSETS</b>	<b>444,171</b>	<b>459,033</b>	<b>451,669</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<b>Restricted equity</b>			
Share capital	1,037	1,035	1,037
<i>Total restricted equity</i>	<i>1,037</i>	<i>1,035</i>	<i>1,037</i>
<b>Non-restricted equity</b>			
Share premium reserve	744,314	739,560	744,314
Retained earnings including profit/loss for the period	-319,130	-285,938	-302,434
<i>Total non-restricted equity</i>	<i>425,184</i>	<i>453,622</i>	<i>441,880</i>
<b>Total equity</b>	<b>426,222</b>	<b>454,657</b>	<b>442,917</b>
<b>Current liabilities</b>			
Other liabilities	17,950	4,377	8,752
<b>Total liabilities</b>	<b>17,950</b>	<b>4,377</b>	<b>8,752</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>444,171</b>	<b>459,033</b>	<b>451,669</b>

## Parent company statement of cash flows in summary

Amounts in SEK thousand	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Cash flows from operating activities	-6,905	-6,100	-24,913
Cash flows from investing activities	0	0	0
Cash flows from financing activities	0	0	4,757
<b>Profit/loss for the period</b>	<b>-6,905</b>	<b>-6,100</b>	<b>-20,156</b>
Cash and cash equivalents at the beginning of the period	92,814	112,970	112,970
<b>Cash and cash equivalents at the end of the period</b>	<b>85,909</b>	<b>106,870</b>	<b>92,814</b>

## Key financial ratios for the group

	<b>2023</b>	<b>2022</b>	<b>2022</b>	<b>2021</b>	<b>2020</b>
	<b>Jan-Mar</b>	<b>Jan-Mar</b>	<b>Jan-Dec</b>	<b>Jan-Dec</b>	<b>Jan-Dec</b>
Net sales, SEK thousand	0	9,042	61,136	207,782	0
Operating profit/loss, SEK thousand	-59,508	-29,088	-113,110	52,576	-91,458
Profit/loss for the period, SEK thousand	-59,556	-29,170	-113,406	51,781	-91,653
Profit/loss attributable to the parent company's shareholders, SEK thousand	-59,556	-29,170	-113,406	51,781	-91,653
Earnings per share before and after dilution, SEK	-1.15	-0.56	-2.19	1.00	-1.92
R&D costs, SEK thousand	41,769	31,243	146,178	129,748	75,989
R&D costs as a percentage of operating expenses, %	70	82	84	84	83
Cash and cash equivalents at the end of the period, SEK thousand	210,103	368,047	252,776	401,897	277,009
Cash flows from operating activities, SEK thousand	-41,498	-32,783	-142,612	128,641	-89,214
Cash flows for the period, SEK thousand	-42,673	-33,850	-149,121	124,888	166,482
Equity, SEK thousand	231,275	370,311	290,831	399,481	347,880
Equity attributable to the parent company's shareholders, SEK thousand	231,275	370,311	290,831	399,481	347,880
Equity per share, SEK	4.46	7.16	5.61	7.72	6.72
Equity ratio, %	83	85	90	85	94
Average number of employees	31	26	29	22	18
Average number of employees in R&D	27	23	25	20	17

Of the key financial ratios above, Earnings per share before and after dilution is the only key financial ratio that is mandatory and defined in accordance with IFRS. Of the other key financial ratios, Profit/loss for the period, Cash and cash equivalents at the end of the period, Cash flows from operating activities, Cash flows for the period, and Equity were obtained from a financial statement defined by IFRS. For the derivation of key financial ratios, as well as definitions and justifications for the selected key financial ratios, please refer to the IRLAB Therapeutics AB 2022 Annual Report.

## Other information

### Accounting principles

The group applies the Swedish Annual Accounts Act and International Financial Reporting Standards (IFRS) as adopted by the EU and RFR 1 Supplementary accounting rules for groups when preparing financial reports. The parent company applies the Swedish Annual Accounts Act and RFR 2 Accounting for legal entities when preparing financial reports.

As of January 1, 2019, shareholder contributions made to subsidiaries that are intended to cover the subsidiaries' costs for research are expensed in the parent company. The cost is reported in the income statement under Profit/loss from participations in group companies. Accordingly, the accounting in the parent company reflects the accounting in the group, where all costs for research are charged to profit or loss. The opening balance remains unchanged as the company found that there had been no impairment. The accounting principles applied correspond to those applied in the 2022 Annual Report.

This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting.

### The IRLAB share

IRLAB's Class A share has been listed on Nasdaq Stockholm's main list since September 30, 2020. From February 28, 2017 to September 30, 2020, the company's Class A shares were listed on Nasdaq First North Premier Growth Market.

### Share capital, number of shares and votes

At the end of the period, IRLAB's registered share capital was SEK 1,037,368 divided into 51,868,406 shares with a quota value of SEK 0.02. There were 51,788,630 Class A shares and 79,776 Class B shares. All shares, including shares in Class B, gives the holder one vote.

### Incentive programs

In April 2016, it was decided to introduce a share and warrant program for key personnel, both employees and board members. A total of 39,355 warrants (196,775 after the split) were subscribed for in the program at a subscription price that corresponded to the market value.

Each warrant confers an entitlement on the holder to subscribe for one Class A ordinary share at a subscription price of SEK 82.70 after the split. The warrants may be exercised up to and including June 30, 2023. When the warrants are fully exercised, the share capital will increase by SEK 3,935.50 through the issue of 196,775 Class A ordinary shares.

### Financial instruments

The group currently has no financial instruments that are valued at fair value, rather all financial assets and liabilities are valued at accrued acquisition value. It is judged that there are no significant differences between fair value and book value regarding the financial assets and liabilities. On the closing date, the carrying amount of financial assets was SEK 210,432k (368,292).

### Transactions with related parties

With the exception of salaries and other remuneration to the executive management and board fees, in accordance with the resolution of the Annual General Meeting, no transactions with related parties have taken place.

### Revenue in the first quarter 2023

Net sales consist of revenue from the licensing of drug development projects or candidate drugs and revenue from services related to ongoing studies, invoicing of work performed on behalf of customers and other service revenue.

Net sales by revenue category	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Licensing revenue	0	0	0
Service revenue	0	9,042	61,136
<b>Total revenue</b>	<b>0</b>	<b>9,042</b>	<b>61,136</b>

### Segment information

Net sales by geographic market	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Sweden	0	0	0
United Kingdom	0	9,042	61,136
<b>Total revenue</b>	<b>0</b>	<b>9,042</b>	<b>61,136</b>

All invoicing was in EUR. Revenue is recognized in SEK.

### Risks and uncertainties

The nature of research and development of pharmaceuticals are associated with high risks, and the effects of these risks on the company's earnings and financial position cannot always be controlled by the company. It is therefore important to take the risks into account when assessing IRLAB's future potential in addition to the opportunities that are inherent in both projects and operations. IRLAB's business model entails high development costs that do not generate potential revenues connected to licensing, sales or partnerships until the majority of the drug development has been completed. The company's financial risks are described on pages 88-89 and its risk management is described on page 124 of the 2022 Annual Report. No significant changes have occurred that affect the reported risks.

The war in Ukraine, the subsequent geopolitical instability in Eastern Europe in particular, and its effect on people in the affected areas may impact the speed of patient recruitment and

the possibility for already recruited patients to get to the clinics for the requisite visits. IRLAB's Phase IIb study with pirepemat is partially carried out in clinics in Poland, a country that may be more affected than other countries due to its geographical proximity to Ukraine. So far, IRLAB has only noticed a minor impact on the ongoing studies. The company is continuously monitoring the developments so that appropriate measures can be taken if necessary.

### Nomination Committee

Prior to the 2023 Annual General Meeting and until a new nomination committee is elected, and pursuant to the instructions applicable to IRLAB's Nomination Committee, the nomination committee comprised Hans-Peter Ostler, Anders Vedin (Chair of the Nomination Committee), Clas Sonesson and Carola Lemne, the Chair of the Board. The members of the nomination committee represent about 43 percent of the votes and shares in IRLAB as per August 31, 2022.

### Employees

The average number of employees in the group from January – March was 31 (26). At the end of the period, the number of full-time positions was 31 (24), distributed over 34 (26) people.

The number of full-time positions, including long-term contracted consultants, was 34 (27) at the end of the period, distributed over 38 (30) people.

### Sustainability

IRLAB's sustainability work is based on the UN Sustainable Development Goals that are essential to the business and where the company may make the greatest difference: gender equality, decent working conditions and economic growth, sustainable industry, innovations and infrastructure, and responsible consumption and production. IRLAB summarizes its sustainability efforts in the following three focus areas: Employees, Responsible dealings, Community involvement.

### Financial calendar

Annual General Meeting	June 20, 2023
Interim report Q2 2023	August 30, 2023.
Interim report Q3 2023	October 25, 2023.
Year-end report 2023	February 7, 2024.



# Glossary

<b>Dyskinesias</b>	Condition where the body or a part of the body performs uncontrolled involuntary movements. Dyskinesia occurs in neurodegenerative and psychiatric diseases, brain diseases where the nervous system is either exposed to a slowly decreasing nerve cell activity, such as Parkinson's disease, or diseases where the nerve cell activity in particular parts of the brain has become unbalanced, such as psychosis or depression.
<b>Good ON-time</b>	The part of the day when the patient does not have troublesome symptoms of Parkinson's disease.
<b>ISP</b>	Integrative Screening Process, IRLAB's proprietary research platform used to generate drug candidates.
<b>PD-LIDs</b>	Parkinson's Disease levodopa-induced dyskinesias, involuntary movements (dyskinesias) caused by long-term medication with levodopa.
<b>PD-P</b>	Parkinson's Disease Psychosis, psychic symptoms such as delusions and/or hallucinations caused by Parkinson's disease.
<b>PD-Falls</b>	Parkinson's Disease Falls, falls due to postural dysfunction (balance impairment) and impaired cognition in Parkinson's disease.
<b>Preclinical Proof of Concept</b>	Is achieved when a drug candidate has shown safety, tolerability and efficacy in preclinical model systems and when the effect shown can be connected to a medical need. At IRLAB, the preclinical development starts when these requirements are fulfilled.
<b>Clinical Proof of Concept</b>	Prove the effectiveness of a concept. At IRLAB, this means when a drug candidate has achieved clinical proof of concept after a successful Phase II program.
<b>CNS disorders</b>	Central nervous system (CNS) disease is a broad category of conditions in which the brain does not function as it should, limiting health and the ability to function.

### Presentation to investors and media

The presentation will be held on May 10, 2023, at 10:00 CET through an online webcast. Gunnar Olsson, CEO, Nicholas Waters, EVP and Head of R&D, and Viktor Siewertz, CFO, will comment the interim report for the period January–March 2023. The presentation will be held in English and followed by a Q&A session.

Follow the presentation online on:

<https://youtube.com/live/0OQ8c8kMnaA?feature=share>

### Review and the Board's assurance

This interim report has not been reviewed by the company's auditors.

The Board of Directors and the CEO assure that the interim report provides a fair overview of the parent company's and the group's operations, position and results and describes significant risks and uncertainties faced by the company and group companies.

### Gothenburg, May 10, 2023

CAROLA LEMNE  
Chair of the Board

REIN PIIR  
Board member

CATHARINA GUSTAFSSON  
WALLICH  
Board member

GUNNAR OLSSON  
CEO,  
Board member



IRLAB discovers and develops novel treatments of Parkinson's disease and other CNS disorders. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), are in Phase IIb and are designed to treat some of the most difficult symptoms related to Parkinson's. In 2021, Ipsen, a specialty pharma company, acquired exclusive global rights to the development and commercialization of mesdopetam.

IRLAB has discovered and generated all its drug candidates and continues to discover innovative drug candidates for the treatment of CNS disorders through its proprietary systems biology-based Integrative Screening Process (ISP) research platform. In addition to IRLAB's strong clinical pipeline, the company is also progressing three preclinical programs, IRL942, IRL757, and IRL1117, towards Phase I studies.

## Contact information

FOR FURTHER INFORMATION, PLEASE CONTACT

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HEAD OFFICE

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