IRLAB

# Q2.2024
# Interim report
# January – June 2024

KRISTINA MÖLLER,
studies the effect of our candidate drugs in different model systems.

*"After a very successful first six months, we continue the journey forward with an unwavering focus on our innovative portfolio projects, all of which have the potential to become first-in-class medicines and revolutionize the treatment of Parkinson's disease and other neurodegenerative diseases."*

GUNNAR OLSSON, CEO

# Interim report January–June 2024

## Highlights

CLINICAL PHASE I STUDY WITH IRL757 STARTED - FUNDED BY THE MICHAEL J FOX FOUNDATION

COLLABORATION WITH MSRD//OTSUKA INITIATED – TAKES IRL757 THROUGH CLINICAL PROOF-OF-CONCEPT IN APATHY IN PARKINSON'S AND ALZHEIMER'S

THE REACT-PD PHASE IIB STUDY WITH PIREPEMAT PASSES SECOND AND FINAL DSMB REVIEW

KRISTINA TORFGÅRD IS APPOINTED CEO STARTS ON AUGUST 1ST, 2024

## Financial summary

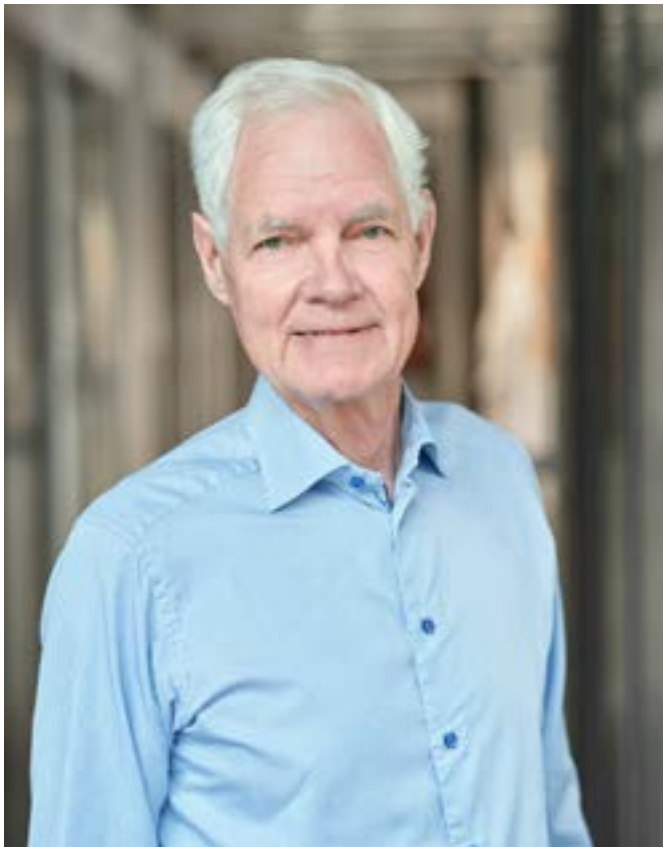
| SEK thousand | apr–jun 2024 | apr–jun 2023 | jan–jun 2024 | jan–jun 2023 | jan–dec 2023 |
|---|---|---|---|---|---|
| Net sales | 42,777 | 6,870 | 42,777 | 6,870 | 5,678 |
| Operating profit | –5,102 | –44,872 | –42,738 | –104,379 | -180,765 |
| Earnings per share before and after dilution, SEK | –0.14 | –0.87 | –0.89 | –2.01 | -3.43 |
| Cash and cash equivalents | 98,272 | 156,413 | 98,272 | 156,413 | 111,309 |
| Cash flow from operating activities | 107 | –52,796 | –38,105 | –94,294 | -164,860 |
| Average number of employees | 32 | 31 | 32 | 31 | 31 |
| Share price at the end of period, SEK | 13.25 | 8.66 | 13.25 | 8.66 | 7.5 |

**Presentation for investors and media about the Q2 report 2024**

Wednesday July 10, 2024, at kl. 10.00 CEST is the presentation of the Q2 interim report through a digital webcast. Access via link or view after the event: https://www.youtube.com/live/MikgERaXqgY?si=p-kol-inxbEyOx96D

**Financial calendar**

| | |
|---|---|
| Interim report Q3 2024 | October 30, 2024 |
| Year-end report 2024 | February 14, 2025 |



*"The research support from The Michael J Fox Foundation, the collaboration agreement with MSRD/Otsuka, as well as the regulatory approval to start clinical studies with IRL757 constitute a strong external validation of the project and it shows that external evaluators see great future potential in IRL757 as a treatment for apathy in neurodegenerative diseases."*

GUNNAR OLSSON, CEO

# Comments from the CEO

**The positive development at the beginning of the year continues and the second quarter has been very eventful with several important advances. We have started our phase I study with IRL757, entered into a collaboration with MSRD/Otsuka regarding the continued clinical development through clinical Proof-of-Concept, received the DSMB's unanimous recommendation to continue the React-PD study with pirepemat in accordance with plan, and recruited a new CEO for the company.**

## The clinical program with IRL757 started

The extensive research support granted by MJFF and the collaboration agreement we have signed with MSDR/Otsuka validates the quality and level of innovation of our research and shows that world-leading external assessors share our confidence in the potential of IRL757 to treat apathy, a medical condition characterized by indifference that currently has no treatment and affects millions of individuals with neurodegenerative disorders and their relatives.

At the end of May, shortly after we received approval from the Swedish Medicines Agency, we started our first Phase I clinical study with IRL757. The Phase I study is fully funded by the world's largest non-profit funder of Parkinson's research, The Michael J. Fox Foundation (MJFF) in the USA.

In May, we held a first joint steering committee meeting in our collaboration with MSDR/Otsuka where we began planning for the continued clinical development of IRL757 as a treatment for apathy. As we communicated previously, the agreement has a large financial value, in addition to upfront and milestone payments totaling $8.5 million, MSDR will cover all development costs all the way through Proof-of-Concept while IRLAB will carry out all activities and retain the product and patent rights. After the agreed development program is completed, MSRD/Otsuka has the option to negotiate a new agreement for extended partnership around ILR757. Based on industry standards, development costs to take a project from the start of Phase I and through Proof-of-Concept are estimated at approximately $25 million.

## Financing during the quarter

The grant from the Michael J Fox Foundation for the implementation of the Phase I study with IRL757, as well as the agreement with MSDR/Otsuka for the continued clinical development of the drug candidate, has strengthened our cash position and secured full funding of our third clinical project (IRL757) through clinical Proof-of - Concept. In addition to this, we have also chosen to use the last tranche of SEK 25 million in the loan agreement with Fenja Capital in order to strengthen our resources for the other development projects. We are continuously working to strengthen our finances as access to capital is an important prerequisite to being able to achieve the value-creating milestones that we expect in our portfolio over the next 12–18 months.

## Recruitment for React-PD soon completed

Our phase 2b clinical study React-PD, which evaluates the effect

of pirepemat on the frequency of falls in Parkinson's patients, is proceeding according to plan. As previously communicated, in the baseline measurements we recorded a clearly higher fall frequency in the group as a whole and a fall frequency at the individual level that was more stable than expected. In addition, more patients than we estimated chose to complete the study (lower drop-out rate). The combination of these parameters means that the possibility of detecting treatment effects in the study increases, which makes it possible to achieve the purpose of the study even with a lower number of patients, without the statistical power of the study being affected.

Based on this insight, we started discussions with the pharmaceutical authorities in the countries involved about the possibility of reducing the size of the study. This turned out well and we received uniform support in all countries where the study is carried out. As a result, patient recruitment to React-PD will be possible to complete in the third quarter of 2024. This will then be followed by a month-long baseline period, three-month treatment period, follow-up visits, data management, database lock, and analysis of study endpoints before top-line data can be reported.

At the end of June, the independent DSMB (Data Safety Monitoring Board) conducted the last of two predetermined reviews of safety and data integrity in the React study. The DSMB unanimously recommended that the study should continue without any changes until the conclusion of the study.

## Mesdopetam

Our preparations to be able to start the Phase III program for the treatment of levodopa-induced dyskinesias continue. During the past quarter, we have had a major focus on partner discussions, preparations for interactions with European regulatory authorities before the start of Phase III, as well as market research as part of positioning for a future launch of the product.

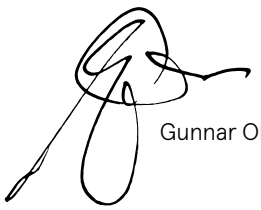
## Kristina Torfgård new CEO from 1 August

In mid-May, IRLAB's board recruited Kristina Torfgård as the company's new CEO. Kristina Torfgård has over 30 years of experience from leading roles in the pharmaceutical and biopharma industry with solid knowledge and she has a large network in neurodegenerative diseases, most recently as CEO of the listed biopharma company Alzinova. I welcome Kristina to IRLAB and I look forward to collaborating and supporting her from my position as a board member of IRLAB.

## Additional presentations and an unwavering focus

During the quarter, we presented IRLAB and our unique project portfolio in several investor meetings. Among other things, we have participated in Redeye Growth Day, ABGSC Investor Days and Stora Aktiedagarna where we presented the recent progress and our plans going forward. After a very successful first six months, we continue the journey forward with an unwavering focus on our innovative portfolio projects, all of which have the potential to become first-in-class drugs and revolutionize the treatment of Parkinson's disease.

This is my last quarterly report as CEO and I would therefore like to take the opportunity to thank all shareholders for the trust you have placed in me during my time as CEO of the company. I would also like to thank all employees for the fantastic work that has been done and led to all the successes in the project portfolio in the past year. I look forward to continuing to work on the company's board and being active in the development and capitalization of all our pioneering pharmaceutical projects.



Gunnar Olsson, CEO, IRLAB

## Our strategic priorities:

1. Continue ongoing intense dialogues with potential collaboration partners, licensees and investors to secure future financing of the development programs.
2. Mesdopetam – secure financing for start of Phase III through partnership/licensing.
3. Pirepemat - complete patient recruitment for the ongoing Phase IIb study.
4. IRL757 - Complete the ongoing Phase I and develop the collaboration with MSRD/Otsuka.
5. IRL942 and IRL1117 - Drive the preclinical development to Phase I readiness.
6. Continue to document the opportunity for our drug candidates and pipeline, focusing on commercial potential and differentiation vs. existing treatments to highlight medical, commercial and shareholder values.

# IRLAB's unique offering and position

IRLAB discovers and develops novel treatments to transform the life of patients living with Parkinson's and other CNS disorders. 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 welldefined, strategically focused R&D pipeline of powerful new treatments targeting various stages of Parkinson's. Having a full range of effective treatments for the disease's different complications and symptoms is regarded as essential by both the medical and patient communities and is at the same time potentially a possibility for a successful pharmaceutical business.

## Pioneering biology & ISP

IRLAB has deep profound understanding of Parkinson's based on research conducted by the research group of Nobel laureate Prof. Arvid Carlsson. IRLAB has a unique proprietary research platform – Integrative Screening Process (ISP) – that has generated all of the company's first-in-class drug candidates.

## Focused strategy

Medicines developed by IRLAB should be able to treat people with Parkinson's throughout all stages of the disease. IRLAB has blockbuster potential as a pharma business.

## Validated proof-of-concept

IRLAB has validated the R&D and business strategy by:

- Discovering and developing investigational drugs from drug discovery to Phase III-ready projects.

## Organization positioned for success

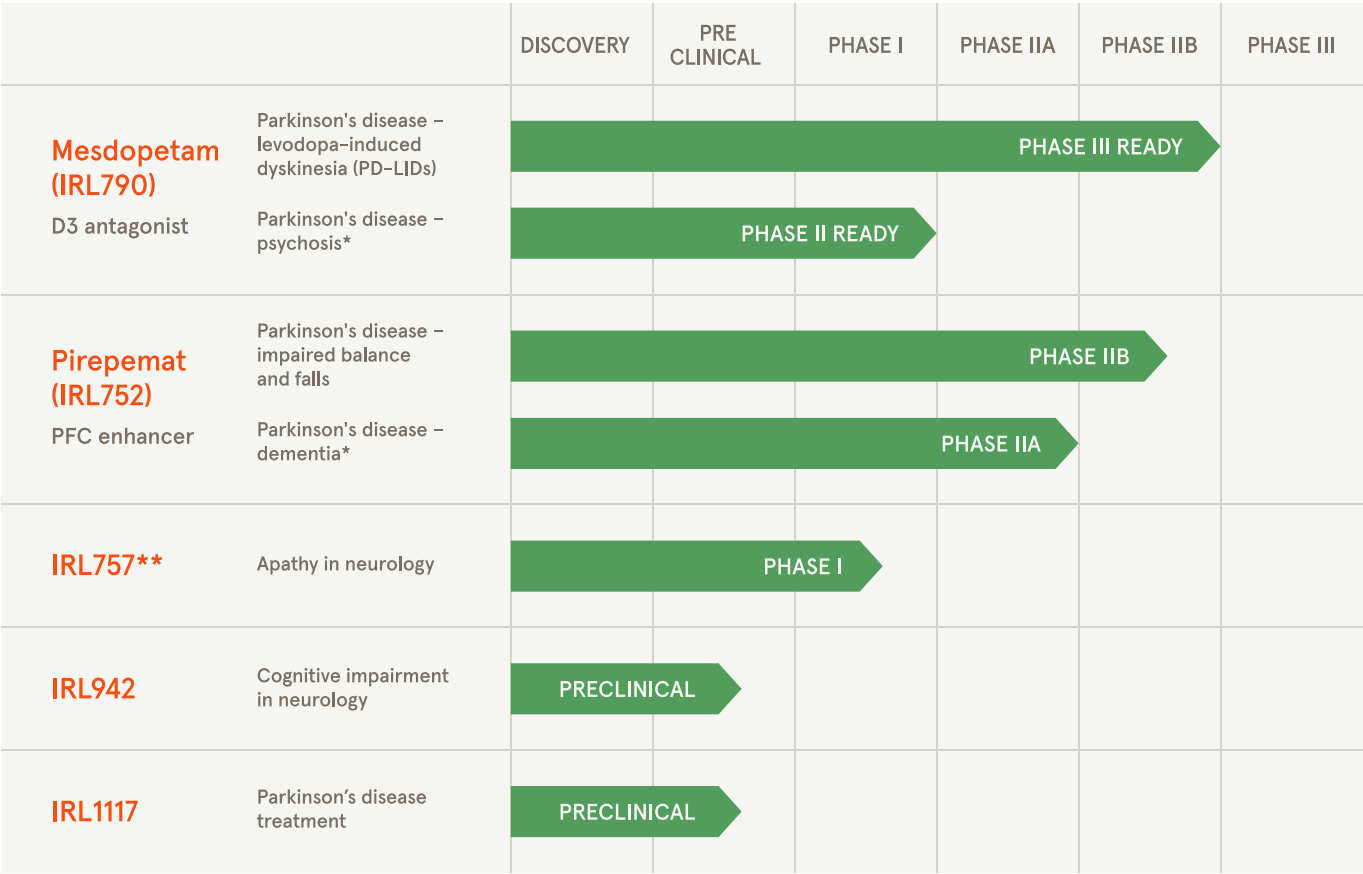
IRLAB is an organization with an experienced team. IRLAB is listed on the Nasdaq Stockholm main market (IRLAB A).

## Broad & solid portfolio

IRLAB's portfolio comprises five unique drug candidates, each with blockbuster potential, generated by the world-unique ISP research platform.

## IRLAB's portolio

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




* Currently no active clinical development in this indication.

** Supported by The Michael J. Fox Foundation.

# R&D update

*"The successful development of our drug candidates continues and during the period IRL757 entered Phase I, which means that IRLAB is now running three projects in clinical phases ranging from Phase I to Phase III.*

- *For the Phase III program with mesdopetam, we are developing the market strategy and collecting opinions from regional authorities as we want to incorporate local wishes or requirements into the final study design so that mesdopetam can become a successful and appreciated treatment for our patients and doctors,*
- *In late June the independent Data Safety Monitoring Board conducted a final pre-planned review of the safety and data integrity of the REACT-PD study with the recommendation that the study continue without any changes.*
- *In our preclinical projects, I IRL942 and IRL1117, preparations for Phase I continue with development of manufacturing processes and production of drug substance on a larger scale."*

NICHOLAS WATERS, EVP AND HEAD OF R&D

## About IRLAB's drug candidates

### Mesdopetam

Mesdopetam, a dopamine D3 receptor antagonist, is being developed as a treatment for Parkinson's disease levodopa-induced dyskinesias (PD-LIDs). The objective is to improve the quality of life for people living with Parkinson's and having this severe form of involuntary movements commonly occurring after long-term levodopa treatment.

It is estimated that 25–40 percent of all people treated for Parkinson's develop LIDs, which equates to approximately 1.4-2.3 million people in the eight major markets globally (China, EU5, Japan and the US). Mesdopetam has a great clinical potential to address this unmet medical need.

Mesdopetam also has 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.

The successful Phase Ib,Phase IIa and IIb studies in PD-LIDs showed a very good safety and tolerability profile as well as proof-of-concept with potential for a better anti-dyskinetic effect compared with current treatment options.

The Phase IIb study with 156 patients from which results was reported in January 2023 showed that mesdeoptam has a dose-dependent anti-dyskinetic and anti-parkinsonian effect in combination with a tolerability and safety profile on par with placebo.

Mesdopetam can therefore treat dyskinesias and at the same time have a beneficial effect on other symptoms pf Parkinson's without causing more side effects than placebo, which gives mesdopetam a unique and differentiated position in the global competitor.

#### *Current status*

During the first quarters an End-of-Phase 2 meeting was held with the american health authority FDA. At the meeting FDA adviced that they find mesdopetam ready to enter Phase III. FDAs evaluation is based on development activities performed: preclinical studies, toxicological studies, CMC development, and the completed clinical studies. Further, FDA and IRLAB agreed on the design of the Phase III programme and the parallell development activities needed to bring the project to market authorisation application. Briefly, the Phase II programme will comprise double-blinded treatment with mesdopetam or placebo in ca 250 subjects for 3 months in two equally large studies run in parallell. Study partcipants will be offered continued treatment with mesdopetam in an open label extension (OLE) study. This is done to obtain at least 100 subjects who have been tretated with mesdopetam for at least one year. Also, the OLE study is performed in parallel with the double-blind part of the study programme. Following the successful meeting with the FDA, meetings with european health authorities are being prepared.

During Q2, work on developing the market strategy for mesdopetam continued. In this work, structured interviews are carried out with managers within healthcare organizations to better understand medical needs from the perspective of the healthcare providers. By combining insight into the needs of patients, regulatory authorities and healthcare, we can complete the design of the Phase III program so that the future medicine meets all expectations and requirements, and thereby can become a successful and appreciated treatment. After our successful interactions with the US health authority, FDA in the spring, we have also prepared for interactions with European pharmaceutical authorities, before the start of Phase III, in order to ensure that the design of the mesdopetam program also captures any local requirements or wishes.

### 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 through strengthening of nerve cell signalling in the prefrontal cortex. This is obtained through antagonism at 5HT7 and alpha-2 receptors leading to increased dopamine and noradrenaline levels in this brain region.

Falls are a significant consequence of Parkinson's that has severe complications such as fractures, impaired mobility and a reduced quality of life. About 50 percent of all people with Parkinson's fall recurrently, which approximates to 2.6 million perople suffering from a significantly reduced quality of life also driven by fear of falling. There are currently no treatments available, 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 around USD 30 000 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.

#### *Current status*

In the ongoing Phase IIb study (REACT-PD) the effect on falls frequency in people with Parkinson's, is evaluated at two dose levels of pirepemat in a double-blind, placebo-controlled trial with a three-month treatment period.

Secondary study objectives include cognitive and neuropsychiatric assessments and further safety and tolerability studies. The study is recruiting subjects from clinics in France, Poland, Netherlands, Spain, Sweden, and Germany. Data from the baseline assessment in REACT-PD show that the study participants fall more frequently than expected, and that individual fall frequencies are stable during the one-month baseline period, before treatment with study medication starts. These findings, together with a lower than expected drop-out rate, bring the possibility to reach the study goals with a lower number of study participants but retained statistical power. In dialogue with regulatory authorities in Spain, France, Netherlands, Sweden, Germany and Poland, IRLAB received support from each of these countries to modify the study size and analysis methodology as proposed. The company's assessment is that patient recruitment to the study will be completed during the third quarter of 2024. This is followed by a one-month baseline period, a three-month treatment period with follow-up visits, data management and database lock before top-line results are reported.

At the end of June, the independent Data Safety Monitoring Board (DSMB) conducted the last of two predetermined safety and data integrity reviews of the ongoing Phase IIb trial with pirepemat (React-PD). As in the first review, in July 2023, the DSMB unanimously recommends that React-PD continue according to the approved study protocol without modifications.

In accordance with the previously communicated plan, IRLAB will complete patient recruitment in the third quarter of 2024. This will then be followed by a month-long baseline period, three-month treatment period, follow-up visits, data management, database lock, and analysis of study endpoints before top-line data can be reported.

More information can be found on EudraCT number: 2019-002627-16 and clinicaltrials.gov: NCT05258071.

### IRL757

In May 2024, Phase I clinical development began with IRL757. IRL757 aims to treat apathy in Parkinson's and other neurological disorders. 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 being treated with Parkinson's, which equates to 1.1-4.0 million people on the eight major markets. Apathy is also prevalent in 43–59 percent of people being treated for Alzheimer's disease, which equates to 4.9-6.7 million people in the ten major markets globally (Canada, China, France, Germany, Italy, Japan, Spain, South Korea, the UK and the US).

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

#### *Current status*

The drug candidate IRL757 received regulatory approval in May 2024 to enter Phase I, after successfully completing the required preclinical studies and development work. In collaboration with a CRO, the Phase I program is now being implemented, which is financed through a research grant from The Michael J. Fox Foundation. In May, a collaboration agreement was also entered into with MSRD/Otsuka to develop IRL757 further, after the Phase I is completed, up to and through Proof-of-Concept for the treatment of apathy in both Parkinson's and Alzheimer's. The project is thus fully funded for the coming years.

### IRL942

Pre-clinical drug candidate IRL942 is targeting to improve the cognitive function in people with Parkinson's and other neurological disorders. There are about 12 percent of adults aged 65 years or more experiencing cognitive decline, which greatly

affects quality of life. The condition is more common in people living with neurological disorders.

Disruption of frontal cortical neurotransmission is implicated in the pathogenesis of cognitive decline and neuropsychiatric 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. IRL942 could therefore be able to improve the congitive function for 1.5 milllion people being treated with Parkinson's and 3.0 million people being treated for Alzheimer's, solely regarding the ten major markets.

*Current status*

Development proceeds according to the plan for GMP manufacturing of drug substance and the subsequent preclinical development through regulatory toxicology and safety studies required to start clinical development in Phase I. Development of the drug product, i.e. the pharmaceutical formulation, has also begun for IRL942 can be expected to be ready for Phase I in late 2024 or early 2025 depending on timeslots for toxicology studies at the CRO.

### IRL1117

Drug candidate IRL1117 will be developed as an oral treatment of the hallmark symptoms of Parkinson's that will be taken once daily and not induce the troublesome complications caused by today's mainstay levodopa-based treatments. IRL1117 is a potent dopamine D1 and D2 receptor agonist that has demonstrated rapid onset and more than 10 hours of sustained efficacy in preclinical studies.

At present, people with Parkinson's disease are prescribed the anti-Parkinson's treatment levodopa treating the hallmark symptoms of tremor, rigidity, and bradykinesia (slowness of movement). Levodopa has been the mainstay treatment of Parkinson's since the 1960s and is currently the only medication that provides 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, as a potentially superior alternative to levodopa, could be administered to all individuals currently being treated for Parkinson's, which amounts to 5.7 million people across the eight largest markets.

*Current status*

Internal development activities are carried out with IRL1117 during 2024. The preclinical results in long-term treatment show that IRL1117 has full anti-parkinsonian effect and at the same time does not cause the well-known complications, such as strong fluctuations in effect, that occur in long-term treatment with levopdopa. The results are very promising and indicate that IRL1117 has the potential to significantly improve the treatment of Parkinson's. In parallel, the development of substance manufacturing on a larger scale and preparations for the preclinical regulatory studies that are necessary to initiate Phase I are ongoing

### Integrative Screening Process (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 already at the discovery phase predict the drug candidates with the greatest potential in a certain indication, as well as the lowest technical risks. ISP provides an improvement in probability of drug discovery success in clinical phase transition, compared with industry standard. This is also exemplified by higher probability to demonstrate clinical proof-of-concept in patients and reach later stages of clinical development for an ISP generated drug candidate compared with industry standard.

Our 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 this technology-base to remain at the forefront of modern drug discovery. A close cooperation with universities and academic researchers also contribute to IRLAB being able to keep leading the development of cutting-edge technology.

# The group's performance January – June 2024

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 reducing the burden and transforming life for people with Parkinson's and other CNS disorders through novel treatments. 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 costs

In the period January 1 to June 30, 2024 the total costs for research and development were SEK 78,010k (86,684), corresponding to 86 percent (78) of the group's total operating expenses. Development costs vary over time, depending on where in the development phase the projects are.

## Comments on the income statement

The loss for the period January 1 – June 30, 2024 was SEK –46,076k (-104,461). Earnings per share were –0.89 SEK (-2.01). The group's revenue during the period was SEK 48,097k (6,871)

The personnel costs during the period January 1 – June 30, 2024 was SEK 24,404k (32,289). The decrease is primarly due to one-off costs associated with the removal of the former CEO, which last year amounted to SEK 10,580k.

During the second quarter, 2024 the group's operating expenses were SEK 53,200k (51,743).

## Financing and cash flow

Cash flow from operating activites were during the period January 1 - June 30, 2024, SEK –38,105k (-94,294) and during the second quarter 107k (-52,796). Cash and cash equivalents were SEK 98,272k (156,413) on June 30, 2024.

On June 30, 2024, equity was SEK 69,688k (186,370) and the equity ratio was 32 percent (81). The decline is mainly attributable to the loan agreement with Formue Nord (now called Fenja Capital) that was entered into in December 2023.

IRLAB is a research and development company with no regular income. The company is primarily financed via the capital market or through the sale or out-licensing of projects, with an initial payment at signing of the agreement, as another financing option. In addition to revenues from operations, the financing strategy is based on continually ensuring that the company is adequately financed through the capital market to effectively run the operations and make rational business decisions.

The Board and the CEO assess that, given the company's current financial position and the current conditions on the capital market, material uncertainty (related to events or conditions) which may cast significant doubt on the entity's ability to continue as a going concern after the third quarter 2024. In order to meet future financing needs, the company runs active processes to achieve partnerships, licensing agreements, share issues or other capital market transactions. The objective is primarily to creating the conditions for and entering a new licensing agreement regarding mesdopetam. License agreements with pirepemat and IRL1117 is also an opportunity as well as financing through various forms of share issues or other capital market transactions.

During the fourth quarter 2023, the company entered into an agreement with Fenja Capital for a credit facility amounting to up to SEK 55,000k. In the fourth quarter 2023, SEK 30,000k of the total credit facility was utilized and in May 2024, the remaining SEK 25,000k was utilized. According to the agreement, Fenja Capital has the right to convert up to SEK 10,000k of the loan into shares at a price of SEK 7.81 per share during the loan tenure. The utilized part of the facility is accounted for as a "compound financial instrument" where a portion is recorded as a loan and another portion (the value of the right to convert parts of the loan) is accounted for as equity. The transaction costs associated with the facility have been capitalized and are amortized over the term of the loan as interest costs, however, without impacting cash flow. The value of the right to convert is handled in the same way and is accounted for as an interest cost without affecting cash flow. The long-term liabilities will increase during the term of the facility at a corresponding rate so that they amount to SEK 55,000k at the end of the term.

During the period January 1 - June 30, 2024, the group has received payments from The Michael J. Fox Foundation amounting to approx. 7,014k, which refer to a partial payment of the financing of the planned Phase 1 study with IRL757. During the second quarter 2024, IRLAB has also invoiced USD 5,100k, corresponding to roughly SEK 55,000k, to MSRD. This amount is intended to cover IRL757's first development steps, apart from those already financed by MJFF. The income from MJFF and MSRD are reported as a prepaid income and will be recognized as income in line with the costs of the activites they are intended to cover.

## Investments

Investments in tangible assets for the period January 1 – June 30, 2024 were SEK 0k (293).

## 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.

# Consolidated income statement in summary

| Amounts in SEK thousand | 2024 Apr–Jun | 2023 Apr–Jun | 2024 Jan–Jun | 2023 Jan–Jun | 2023 Jan–Dec |
|---|---|---|---|---|---|
| **Operating income** | | | | | |
| Net revenue | 42,777 | 6,870 | 42,777 | 6,870 | 5,678 |
| Other operating income | 5,320 | 1 | 5,320 | 1 | 42 |
| *Total income* | *48,097* | *6,871* | *48,097* | *6,871* | *5,720* |
| **Operating expenses** | | | | | |
| Other external costs | -37,697 | -38,737 | -62,953 | -75,866 | -128,412 |
| Personnel costs | -13,450 | -11,199 | -24,404 | -32,289 | -53,082 |
| Depreciation of intangible and tangible fixed assets | -1,151 | -1,085 | -2,303 | -2,165 | -4,316 |
| Other operating cost | -901 | -722 | -1,177 | -930 | -676 |
| *Total operating expenses* | *-53,200* | *-51,743* | *-90,836* | *-111,250* | *-186,486* |
| **Operating result** | **-5,102** | **-44,872** | **-42,738** | **-104,379** | **-180,765** |
| **Result from financial items** | | | | | |
| Financial income | 521 | 4 | 1,236 | 7 | 3,125 |
| Financial costs | -2,476 | -37 | -4,574 | -89 | -199 |
| *Total financial items* | *-1,955* | *-33* | *-3,338* | *-82* | *-2,927* |
| **Result after financial items** | **-7,057** | **-44,905** | **-46,076** | **-104,461** | **-177,839** |
| Tax on income | - | - | - | - | - |
| **Result for the period** | **-7,057** | **-44,905** | **-46,076** | **-104,461** | **-177,839** |
| Earnings per share before and after dilution (SEK) | -0.14 | -0.87 | -0.89 | -2.01 | -3.43 |
| Average number of shares, before and after dilution | 51,866,406 | 51,748,406 | 51,868,406 | 51,866,406 | 51,866,406 |
| Number of shares at end of period | 51,866,406 | 51,748,406 | 51,868,406 | 51,866,406 | 51,866,406 |

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 | 2024 Apr–Jun | 2023 Apr–Jun | 2024 Jan–Jun | 2023 Jan–Jun | 2023 Jan–Dec |
|---|---|---|---|---|---|
| Result for the period | –7,057 | –44,905 | –46,076 | –104,461 | -177,839 |
| Other comprehensive income | - | - | - | - | - |
| **Total result for the period** | **-7,057** | **–44,905** | **-46,076** | **-104,461** | **-177,839** |

# Consolidated statement of financial position in summary

| Amounts in SEK thousand | 06/30/2024 | 06/30/2023 | 12/31/2023 |
|---|---|---|---|
| **ASSETS** | | | |
| **Fixed assets** | | | |
| Intangible fixed assets | 46,862 | 46,862 | 46,862 |
| Tangible fixed assets | 4,369 | 6,137 | 6,672 |
| **Total fixed assets** | **51,230** | **52,999** | **53,533** |
| **Current assets** | | | |
| Short-term receivables | 65,110 | 20,575 | 12,278 |
| Cash and cash equivalents | 98,272 | 156,413 | 111,309 |
| **Total current assets** | **163,382** | **176,988** | **123,587** |
| **TOTAL ASSETS** | **214,612** | **299,987** | **177,121** |
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| Share capital | 1,037 | 1,037 | 1,037 |
| Other contributed capital | 690,205 | 690,205 | 690,205 |
| Retained earnings incl. results for the period | −621,554 | −504,872 | −575,478 |
| **Total equity** | **69,688** | **186,370** | **115,764** |
| **Long-term liabilities** | | | |
| Interest bearing debt, loan | - | - | 24,511 |
| Interest bearing debt, leasing | - | 249 | 115 |
| Other long-term debts | 2,598 | - | - |
| **Total long-term liabilities** | **2,598** | **249** | **24,626** |
| **Short-term liabilities** | | | |
| Interest bearing debt, loan | 51,478 | - | - |
| Interest bearing debt, leasing | 1,155 | 1,951 | 2,940 |
| Other liabilities | 89,693 | 41,417 | 33,792 |
| **Total short-term liabilities** | **142,326** | **43,368** | **36,731** |
| **TOTAL EQUITY AND LIABILITIES** | **214,612** | **229,987** | **177,121** |

# Consolidated statement of changes in equity in summary

| Amounts in SEK thousand | Share capital | Other contributed capital | Retained earnings incl. total comprehen-sive income for the period | Total equity |
|---|---|---|---|---|
| **Equity January 1, 2023** | **1,037** | **690,605** | **–400,411** | **290,831** |
| Comprehensive income for the period | | | –104,461 | –104,461 |
| **Equity June 30, 2023** | **1,037** | **690,605** | **–504,872** | **186,370** |
| Comprehensive income for the period | | | -73,378 | -73,378 |
| Call option premium in relation to loan facility | | | 2,771 | 2,771 |
| **Equity December 31, 2023** | **1,037** | **690,605** | **–575,478** | **115,764** |
| **Equity January 1, 2024** | **1,037** | **690,605** | **-575,478** | **115,764** |
| Comprehensive income for the period | | | –46,076 | –46,076 |
| **Equity June 30, 2024** | **1,037** | **690,605** | **–621,554** | **69,688** |

# Consolidated statement of cash flows in summary

| Amounts in SEK thousand | 2024 Apr–Jun | 2023 Apr–Jun | 2024 Jan–Jun | 2023 Jan–Jun | 2023 Jan–Dec |
|---|---|---|---|---|---|
| **Operating activities** | | | | | |
| Operating result | –5,102 | –44,871 | –42,738 | –104,379 | –180,765 |
| Adjustment for items not included in the cash flow | 1,151 | 1,085 | 2,303 | 2,165 | 4,316 |
| Interest | 521 | 4 | 1,236 | 7 | 3,125 |
| Paid interest | –2,476 | –38 | –4,574 | –89 | –199 |
| **Cash flow from operating activities before changes in working capital** | **–5,906** | **–43,820** | **–43,773** | **–102,296** | **–173,523** |
| **Cash flow from changes in working capital** | | | | | |
| Change in operating receivables | -54,025 | -7,308 | -51,955 | -4,667 | 3,630 |
| Change in operating liabilities | -60,037 | -1,668 | 57,624 | 12,668 | -5,043 |
| **Cash flow from operating activities** | **107** | **–52,796** | **–38,105** | **–94,294** | **–164,850** |
| **Investment activities** | | | | | |
| Acquisition of tangible fixed assets | - | – | – | – | –293 |
| **Cash flow from investment activities** | **-** | **–** | **–** | **–293** | **–293** |
| **Financing activities** | | | | | |
| New financial debts | 25,983 | - | 26,967 | - | 24,511 |
| Amortization of financial liabilities, leasing debt | –957 | –894 | –1,899 | –1,776 | –3,606 |
| Convertible bond issue | – | – | – | – | 2,771 |
| **Cash flow from financing activities** | **25,026** | **-894** | **25,068** | **- 1,776** | **23,676** |
| **Cash flow for the period** | **–25,133** | **–53,690** | **–13,037** | **–96,363** | **–141,467** |
| Cash and cash equivalents at the start of the period | 73,140 | 210,103 | 111,309 | 252,776 | 111,309 |
| **Cash and cash equivalents at the end of the period** | **98,272** | **156,413** | **98,272** | **156,413** | **252,776** |

# Parent company income statement in summary

| Amounts in SEK thousand | 2024 Apr-Jun | 2023 Apr-Jun | 2024 Jan-Jun | 2023 Jan-Jun | 2023 Jan-Dec |
|---|---|---|---|---|---|
| ***Operating income*** | | | | | |
| Net revenue | 1,390 | 1,236 | 2,643 | 2,822 | 5,688 |
| *Total income* | *1,390* | *1,236* | *2,643* | *2,822* | *5,688* |
| ***Operating expenses*** | | | | | |
| Other external costs | –2,493 | –3,608 | –4,552 | –7,952 | –13,286 |
| Personnel costs | –3,952 | –3,213 | –7,332 | –17,143 | –23,898 |
| Other operating expences | -5 | -9 | -10 | -18 | -14 |
| *Total operating expenses* | *–6,460* | *–6,830* | *–11,893* | *–25,113* | –37,197 |
| ***Operating result*** | ***–5,060*** | ***–5,594*** | ***–9,251*** | ***–22,290*** | ***–31,509*** |
| ***Result from financial items*** | | | | | |
| Interest income | 412 | - | 1,014 | 1 | 1,635 |
| Interest costs | -2,425 | - | -4,474 | -1 | –68 |
| *Total financial items* | *-2,013* | - | *-3,460* | *0* | *1,567* |
| ***Result after financial items*** | ***–7,073*** | ***–5,594*** | ***–12,710*** | ***–22,290*** | ***–29,942*** |
| Tax on the period's result | - | - | - | - | - |
| **Result for the perioden** | **–7,073** | **–5,594** | **–12,710** | **–22,290** | **–29,942** |

# Parent company statement of comprehensive income in summary

| Amounts in SEK thousand | 2024 Apr–Jun | 2023 Apr–Jun | 2024 Jan–Jun | 2023 Jan–Jun | 2023 Jan–Dec |
|---|---|---|---|---|---|
| Profit/loss for the period | –7,073 | –5,594 | –12,710 | –22,290 | –29,942 |
| Other comprehensive income | - | - | - | - | - |
| ***Comprehensive income for the period*** | **–7,073** | **–5,594** | **–12,710** | **–22,090** | **–29,942** |

# Parent company balance sheet in summary

| Amounts in SEK thousand | 06/30/2024 | 06/30/2023 | 12/31/2023 |
|---|---|---|---|
| **ASSETS** | | | |
| **Fixed assets** | | | |
| **Financial fixed assets** | | | |
| Shares in group companies | 350,320 | 350,320 | 350,320 |
| **Total fixed assets** | **350,320** | **350,320** | **350,320** |
| **Current assets** | | | |
| Other receivables | 48,396 | 7,196 | 7,615 |
| Cash and cash equivalents | 62,661 | 77,312 | 92,807 |
| **Total current assets** | **111,057** | **84,508** | **100,422** |
| **TOTAL ASSETS** | **461,377** | **434,829** | **450,742** |
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| ***Restricted equity*** | | | |
| Share capital | 1,037 | 1,037 | 1,037 |
| | *1,037* | *1,037* | *1,037* |
| ***Unrestricted equity*** | | | |
| Share premium fund | 744,314 | 744,314 | 744,314 |
| Call option premium in relation to loan facility | - | - | 2,771 |
| Retained earnings including total result for the period | −342,315 | −324,724 | −332,376 |
| *Total Unrestricted equity* | *401,999* | *419,590* | *414,710* |
| **Total equity** | **403,037** | **420,627** | **415,747** |
| **Long-term liabilities** | | | |
| Interest bearing debts, loan | - | - | 24,511 |
| **Total Long-term liabilities** | **-** | **-** | **24,511** |
| **Short-term liabilities** | | | |
| Interest bearing debts, loan | 51 478 | - | - |
| Other liabilities | 6,863 | 14,202 | 10,484 |
| **Total liabilities** | **58,341** | **-** | **10,484** |
| **TOTAL EQUITY AND LIABILITIES** | **461,377** | **434,829** | **450,742** |

# Key financial ratios for the group

| | 2024 Jan-Jun | 2023 Jan-Jun | 2023 Jan-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
|---|---|---|---|---|---|
| Net sales, SEK thousand | 42,777 | 6,870 | 5,678 | 61,136 | 207,782 |
| Operating profit/loss, SEK thousand | -42,738 | -104,379 | -180,765 | -113,110 | 52,576 |
| Profit/loss for the period, SEK thousand | -46,076 | -104,461 | -177,839 | -113,406 | 51,781 |
| Profit/loss attributable to the parent company's shareholders, SEK thousand | -46,076 | -104,461 | -177,839 | -113,406 | 51,781 |
| Earnings per share before and after dilution, SEK | -0.89 | -2.01 | -3.43 | -2.19 | 1.00 |
| R&D costs, SEK thousand | 78,010 | 86,684 | 151,312 | 146,178 | 129,748 |
| R&D costs as a percentage of operating expenses, % | 86 | 78 | 81 | 84 | 84 |
| Cash and cash equivalents at the end of the period, SEK thousand | 98,272 | 156,413 | 111,309 | 252,776 | 401,897 |
| Cash flows from operating activities, SEK thousand | -38,105 | -94,294 | -164,850 | -146,612 | 128,641 |
| Cash flows for the period, SEK thousand | -13,037 | -96,363 | -141,467 | -149,121 | 124,888 |
| Equity, SEK thousand | 69,688 | 186,370 | 115,764 | 290,831 | 399,481 |
| Equity attributable to the parent company's shareholders, SEK thousand | 69,688 | 186,370 | 115,764 | 290,831 | 399,481 |
| Equity per share, SEK | 1.34 | 3.59 | 2.23 | 5.61 | 7.72 |
| Equity ratio, % | 32 | 81 | 65 | 90 | 85 |
| Average number of employees | 32 | 31 | 31 | 29 | 22 |
| Average number of employees in R&D | 28 | 27 | 26 | 25 | 20 |

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 2023 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.

The accounting principles applied correspond to those applied in the 2023 Annual Report. This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting.

## 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 73,385k (210,432). The financial assets are mostly liquid funds.

## Transactions with related parties

IRLAB has during the period January 1 - June 30, 2024 paid salaries and other remuneration to the executive management and board fees to the board, in accordance with the resolution of the Annual General Meeting. IRLAB has also during the period paid remuneration to a company related to the board member Catharina Gustafsson Wallich. The remuneration has not been considered significant for neither IRLAB nor the recipient, and has been on market conditions.

## Revenue January - June 2024

Net sales consist of revenue from research collaborations or 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 | 2024 Jan–Jun | 2023 Jan–Jun | 2023 Jan–Dec |
|---|---|---|---|
| Service revenue | 42,777 | 6,870 | 5,678 |
| **Total revenue** | **42,777** | **6,870** | **5,678** |

## Segment information

| Net sales by geographic market | 2024 Jan–Jun | 2023 Jan–Jun | 2023 Jan–Dec |
|---|---|---|---|
| United Kingdom | - | 2,650 | 1,458 |
| USA | 42,777 | 4,220 | 4,220 |
| **Total revenue** | **42,777** | **6,870** | **5,678** |

All invoicing was in Euro (EUR) or American dollars (USD). Revenue is recognized in Swedish krona (SEK). In the tables above, all amounts are in thousand 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 125–127 of the 2023 Annual Report. No significant changes have occurred that affect the reported risks.

The wars in Ukraine and Israel, 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 study. The company is continuously monitoring the developments so that appropriate measures can be taken if necessary.

## Management

On May 27, 2024, the board appointed Kristina Torfgård as the new CEO, she will take office on August 1, 2024.

## Employees

During the quarter, work corresponding to 32 (31) full-time equivalents was performed. This work has been distributed among 33 (34) people.

## Annual General Meeting

The 2024 Annual General Meeting was held on May 22, 2024 in Gothenburg.

## 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.

## Events during the period

A successful End-of-Phase 2 meeting was held in mid-February with the FDA. IRLAB and the FDA have a consensus on the important key components of the program and the design of the Phase III program.

In May, IRLAB received approval from the Swedish Medical Products Agency to conduct a Phase I study with the drug candidate IRL757.

In May IRLAB also entered an agreement with MSRD/Otsuka regarding a research collaboration for the development of IRL757 through clinical Proof of Concept. IRLAB receives USD 3m as up-front payment and has the possibility to recieve another USD 5.5m in milestones. In addition, MSRD will cover all development cost related to IRL757.

In May, Kristina Torfgård was appointed CEO and will take office on August 1, 2024.

At the end of June, the independent Data Safety Monitoring Board (DSMB) conducted the last of two predetermined safety and data integrity reviews of the ongoing Phase IIb trial with piretemat. The DSMB unanimously recommends that React-PD continue according to the approved study protocol without modifications

## Events after the period

No events has occured after the period.

## Review by the auditors

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

## Board's assurance

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, July 10, 2024

CAROLA LEMNE
Chair of the Board

GUNNAR OLSSON
CEO
Board member

CATHARINA GUSTAFSSON WALLICH
Board member

REIN PIIR
Board member

DANIEL JOHNSSON
Board member

VERONICA WALLIN
Board member

CHRISTER NORDSTEDT
Board member

# Glossary

### API
API stands for Active Pharmaceutical Ingredient, and it refers to the primary ingredient in a medication that provides its therapeutic effect.

### CNS disorders
Central Nervous System (CNS) disorders are a broad category of conditions in which the brain does not function as it should, leading to a decline in health and the ability to function.

### CRO
Clinical Research Organization (CRO) conducts clinical studies on behalf of biotech companies that may not have the internal capacity, as in larger pharmaceutical companies.

### Drug Product
Refers to the medication to be used in clinical trials. The Drug Product contains Active Pharmaceutical Ingredients (API) and additional ingredients to ensure beneficial properties of the entire medication, such as bioavailability, proper shelf life, stability, or formulations with slow release.

### DSMB
Data Safety Monitoring Board (DSMB) is an independent safety committee responsible for continuously reviewing clinical study data during an ongoing study to ensure the safety of study participants and the validity and integrity of data. DSMB provides recommendations regarding the continuation, modification, or termination of the clinical study based on the results of the predefined data review.

### End-of-Phase 2 meeting
The purpose of an end-of-Phase 2 meeting is to determine the safety of proceeding to Phase III, to evaluate the Phase III plan and protocols and the adequacy of current studies and plans, and to identify any additional information necessary to support a marketing application for the uses under investigation.

### GMP manufacturing
GMP stands for Good Manufacturing Practice, which describes how pharmaceutical companies should manufacture drug substances to ensure that regulatory authorities and patients can always be confident they are receiving the right product of high quality.

### ISP
Integrative Screening Process (ISP) is IRLAB's proprietary research platform used to generate drug candidates.

IRLAB

IRLAB discovers and develops a portfolio of transformative treatments for all stages of Parkinson's disease. The company originates from Nobel Laureate Prof Arvid Carlsson's research group and the discovery of a link between brain neurotransmitter disorders and brain diseases. Mesdopetam (IRL790), under development for treating levodopa-induced dyskinesias, has completed Phase IIb and is in preparation for Phase III. Pirepemat (IRL752), currently in Phase IIb, is being evaluated for its effect on balance and fall frequency in Parkinson's disease. IRL757, a compound being developed for the treatment of apathy in neurodegenerative disorders, is in Phase I. In addition, the company is also developing two preclinical programs, IRL942 and IRL1117, towards Phase I studies. IRLAB's pipeline has been generated by the company's proprietary systems biology-based research platform Integrative Screening Process (ISP). Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A).

# Contact information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