Q4.2024 Year-end report January-December 2024





"It has been a successful year that has brought us closer to our goal of improving the lives of people living with Parkinson's disease and other neurodegenerative conditions."

KRISTINA TORFGÅRD, CEO

Full-year report January-December 2024

Highlights during and after the fourth quarter 2024

THE COMPANY RECEIVED USD 2.5 MILLION IN CONNECTION WITH THE FIRST DOSING IN A PHASE I STUDY WITH IRL757 IN HEALTHY OLDER ADULTS.

ALL PATIENTS HAVE COMPLETED THE PHASE IIB STUDY WITH PIREPEMAT, REACT-PD – TOPLINE DATA IS EXPECTED IN THE FIRST QUARTER OF 2025.

POSITIVE RESULTS IN THE PHASE I STUDIES SUPPORT THE CONTINUED DEVELOPMENT OF IRL757.

PAYOR RESEARCH CONFIRMS SIGNIFICANT MARKET POTENTIAL FOR MESDOPETAM BOTH IN THE US AND EUROPE.

Financial summary

SEK thousand	Oct-Dec 2024	Oct-Dec 2023	Jan-Dec 2024	Jan-Dec 2023
Net sales	42,820	-1,192	94,628	5,678
Operating profit	-3,001	-35,648	-75,111	-180,765
Earnings per share before and after dilution, SEK	-0.10	-0.67	-1,60	-3.43
Cash and cash equivalents	66,917	111,309	66,917	111,309
Cash flow from operating activities	-22,606	-33,872	-65,590	-164,850
Average number of employees	31	31	31	31
Share price at the end of period, SEK	10.75	7.50	10.75	7.50

Presentation for investors and media about the Year-en Report 2024

Wednesday february 12, 2024, at 10.00 CET the full-year report is presented in through a digital webcast. Access via link or view after the event:

Financial calendar

Annual report 2024 Interim report Q1 2025 Interim report Q2 2025 Interim report Q3 2025 Year-end report 2025 April 21–25, 2025 May 7, 2025 July 9, 2025 October 29, 2025 February 11, 2026



"I am proud to be part of the IRLAB team and deeply inspired by the unique combination of groundbreaking research, innovation, and collaboration that permeates the entire company.

Our pipeline is stronger than ever, with our drug candidates holding the potential to become first-in-class treatments that can transform the lives of millions of people worldwide, along with their loved ones.

With the progress we have achieved so far and the exciting opportunities ahead, I confidently look forward to leading IRLAB into the next phase of our growth journey."

KRISTINA TORFGÅRD, CEO

Comments from the CEO

It is with great pleasure that I summarize 2024 – a year in which IRLAB has continued to make significant progress in research, development and strategic partnerships. Through dedicated and purposeful efforts, we have moved closer to our goal of improving the lives of people living with Parkinson's disease and other neurodegenerative conditions.

Pioneering research, innovation and collaboration permeate IRLAB

When I took over the role as CEO of IRLAB in August 2024, I was met by a company with great visions and a strong commitment. For me personally, it has been an intense and eventful period, filled with both challenges and important progress. I am proud to be part of the IRLAB team and have been deeply inspired by the unique combination of pioneering research, innovation and collaboration that permeates the entire company.

Preparations for Phase III and significant market potential for mesdopetam

We have made great progress in the preparation of the upcoming Phase III program with mesdopetam, which is being developed to treat levodopa-induced dyskinesias. Through our dialogues with the FDA in connection with the End-of-Phase 2 meeting and the interactions with the regulatory authorities in Germany and Portugal, we have reached a consensus on the study design, a crucial piece of the puzzle for the pivotal studies. At the same time, we have worked to enhance the value of the mesdopetam project through analysis of the market and the healthcare payers' willingness to reimburse the treatment. These analyzes indicate that there is significant market potential for mesdopetam both in the US and Europe. The preparations for Phase III and the substantial market potential for mesdopetam strengthen our position in the ongoing discussions with potential license partners.

The Phase IIb study of pirepemat provides valuable insights for further development

Many individuals with Parkinson's disease suffer from severe balance problems, often leading to frequent falls. In addition to significantly impacting quality of life, this can result in serious complications, including fall-related injuries and increased mortality. Currently, there are no approved treatments that reduce the risk of falling. The ongoing Phase IIb study React-PD, which evaluates the effect of pirepemat on fall rates in Parkinson's patients, has provided us with invaluable insights into these challenges. With support from regulatory authorities, we were able to optimize the study design, enabling the completion of patient recruitment last year. In early 2025, we reached a key milestone when the last patient had completed the full treatment period. We are now looking forward to the study results, expected in the first quarter of this year.

Collaborations secure funding for drug candidate IRL757

Our third candidate in clinical phase, IRL757, which is being developed to treat apathy, has made significant progress. We are proud to have initiated and completed two Phase I studies during the year, an impressive achievement given the extensive preparations and regulatory approvals required. With the promising results, we now look forward to continuing the clinical development of IRL757. During the year, Wwe entered into an important collaboration agreement with MSRD/Otsuka, ensuring full funding for development up to Proof-of-Concept. This partnership not only provides significant financial security but is also a strong validation of our research, reinforcing our position as a leading innovator in the treatment of apathy in neurological disorders.

Research grants, milestone payments and strengthened patent portfolio.

During the past year, we were provided with additional financial resources through grants from the Michael J. Fox Foundation, milestone payments from MSRD/Otsuka and a strategic use of the remaining part of a loan facility that was secured already in 2023. Additionally, we have received two new patents for mesdopetam and pirepemate, which further extend exclusivity periods and thus strengthens their commercial value.

A successful year with a focus on the future

Our pipeline is stronger than ever. We have presented our progress at several international conferences and investor meetings, where interest in our projects has been remarkably high. This reinforces my conviction that our drug candidates have the potential to become first-in-class treatments that can transform the lives of millions of people worldwide, along with their loved ones.

With the progress we have achieved so far and the exciting opportunities ahead, I look forward with confidence to leading IRLAB further into the next phase of our growth journey. I would like to extend my sincere gratitude to all employees for the outstanding work that has contributed to this year's success in our project portfolio. A heartfelt thank you also goes to our shareholders for your continued trust - your support enables us to pursue our vision of developing groundbreaking treatments for Parkinson's disease and other neurodegenerative disorders.

Kristina Torfgård, 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 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 towards 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.

		DISCOVERY	PRE CLINICAL	PHASE I	PHASE IIA	PHASE IIB	PHASE III
Mesdopetam (IRL790)	Parkinson's disease – Ievodopa-induced dyskinesia (PD-LIDs)				PHASI	E III READY	
D3 antagonist	Parkinson's disease – psychosis*		PHAS	E II READY			
Pirepemat (IRL752)	Parkinson's disease – impaired balance and falls				PHAS	SE IIB	
PFC enhancer	Parkinson's disease – dementia*				PHASE IIA		
IRL757**	Apathy in neurology		PH.	ASE I			
IRL942	Cognitive impairment in neurology	PRECLIN	ICAL				
IRL1117	Parkinson's disease treatment	PRECLIN	ICAL				

* Currently no active clinical development in this indication.

** Supported by The Michael J. Fox Foundation and in collaboration with McQuade Center for Strategic Research and Development (MSRD), a part of Otsuka.

R&D update



"During the period, we maintained a high pace in our research and development activities with our drug candidates, achieving several key milestones in both our clinical and preclinical programs."

NICHOLAS WATERS, EVP OCH HEAD OF R&D

Highlights During and After the Fourth Quarter of 2024

During the period, we maintained a high pace in our research and development activities with our drug candidates, achieving several key milestones in both our clinical and preclinical programs.

- Patient recruitment for the Phase IIb study with pirepemat, REACT-PD, was completed, and the last patients have now completed the entire treatment period. Our CRO is currently working on compiling the study database and performing quality assurance before the pre-specified statistical analyses is applied. We expect to communicate topline results from the study during the first quarter.
- Two Phase I studies with IRL757 were conducted in collaboration with MJFF and MSRD/Otsuka. The results from these studies provide strong support for the continued development of IRL757 towards the initiation of the first patient studies in collaboration with MSRD/Otsuka.
- The Phase III program for mesdopetam has been adapted to regional regulatory requirements in dialogue with drug authorities in the US and local authorities in Europe. We now look forward to incorporating EMA's scientific advice into our plans to ensure that the Phase III program is fully

accepted in the key North American and European markets for IRLAB.

We continue our intense efforts to advance our clinical programs, as well as our preclinical programs IRL942 and IRL1117, both of which are now approaching the final stages of developing their industrial production methods. This means that formal regulatory safety and toxicology studies in preparation for the first clinical trials can soon be initiated.

About IRLAB's drug candidates

Mesdopetam

Mesdopetam, a dopamine D3 receptor antagonist, is being developed as a treatment for Parkinson's disease levodopainduced 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 demonstrated 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 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 dyskinesia 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 competition.

Current status

At the beginning of the year, an End-of-Phase 2 meeting was held with the US food and drug administration, FDA. At the meeting FDA advised 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 program and the parallel development activities needed to bring the project to market authorisation application (a so called new drug application, NDA). Briefly, the Phase III programwill comprise double-blinded treatment with mesdopetam or placebo in ca 250-270 subjects for 3 months distributed in two equally large studies run in parallel. Study participants will be offered continued treatment with mesdopetam in an open label extension (OLE) study. This is done to obtain at least 100 subjects treated with mesdopetam for at least one year. This is to fulfil the mandatory requirements on the safety database. Also, the OLE study is performed in parallel with the double-blind part of the study program.

Following the successful meeting with the FDA, the company has also received scientific advice from national European drug regulatory agencies in Germany (BfArM) and Portugal (Infarmed). The purpose of counselling also in Europe is to ensure that mesdopetam's development program also meets any specific European or national requirements.

During the past year, 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 and those who finance the care. By having insight into the needs of patients, regulatory authorities and healthcare providers, 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. The regulatory work prior to the start of the Phase III program for mesdopetam follows the laid out plan. After our successful interactions with the FDA and national authorities in the EU, in order to ensure that the design of the mesdopetam program also captures any local requirements or wishes, we are now looking forward to EMA's scientific advice regarding the Phase III program.

After the end of the period, the company received a waiver from the EMA regarding paediatric studies with mesdopetam, which means that IRLAB does not need to conduct studies with mesdopetam in children. A fundamental principle is that pharmaceutical development companies need to submit paediatric investigation plans for all new drugs. The waiver enables IRLAB to concentrate its efforts on developing mesdopetam for patient groups where Parkinson's disease is more common, thereby avoiding resource-intensive and lengthy studies in the paediatric population.

During the year, the company has also been granted additional so called "composition of matter" patents in Europe that cover the salt of mesdopetam used in the clinical development and that also protect the process for its production. The now granted patent expands the already strong patent protection for mesdopetam. The approval process is progressing in the US, and we expect this patent to be granted there as well. Thus, there is potential for market exclusivity well into the 2040s in the major and important markets of Europe and the US.

Pirepemat

Pirepemat (IRL752) has potential to be the first treatment in a new class of drugs designed to 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, an effect that cannot be achieved with the drugs currently prescribed to people living with Parkinson's.

Falls are a significant consequence of Parkinson's that has severe complications such as fractures, impaired mobility and reduced quality of life. About 50 percent of all people living with Parkinson's fall recurrently, which approximates to 2.6 million people 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. The costs to society are also significant. In the United States alone, injuries related to falls in the elderly (>65 years) are estimated to cost up to \$80 billion/year (doi: 10.1136/ ip-2023-045023).

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 recruited subjects from clinics in France, Poland, Netherlands, Spain, Sweden, and Germany

Analysis of blinded data from the React-PD study's baseline

measurement shows that participants fall more often than expected, and that individual fall rates are stable during the study's one-month baseline lead-in phase, before study medication starts. Overall, this provides a good opportunity to detect the treatment effects of pirepemat on fall rate.

More than 100 patients are included in the study, which is considered sufficient to demonstrate a potential treatment effect. Blinded data for all individuals who underwent the study show that the number of falls decreases by about one-third compared to the observations during the baseline period. Since this is a double-blind study, it is not possible to know how the effect differs between the patients treated with pirepemat and those who received placebo and it is therefore not possible at this stage to draw any conclusions about the effect of pirepemat on the frequency of falls. However, it can be noted that participation in the React-PD study leads to a reduced fall rate. For a treatment that leads to a reduction of falls in Parkinson's, a clinically meaningful effect is estimated to be a reduction of approximately 20-25% (DOI: 10.1016/j.parkreldis.2018.11.008)

At the end of June, the independent external 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.

IRLAB completed patient recruitment in September, and by January 2025 all patients had completed the Phase IIb study. After a month-long baseline period, three-month treatment period, follow-up visits, data management, database lock, and analysis of study results, top-line data is expected to be reported during the first quarter 2025.

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

During the past year, a new patent was granted for a salt of the drug candidate pirepemat in the United States. The patent covers the active pharmaceutical ingredient used in the ongoing clinical development of pirepemat. The new patent has previously been granted in Europe, Japan and China and is expected to expire in 2038. With the also granted adjustment of the patent term, the exclusivity in the United States will extend into the early 2040s.IRL757

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 impaired cognitive function and reduced 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 the McQuade Center (MSRD), part of the global pharmaceutical company Otsuka, for the further development of IRL757, 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.

During the past year, we have successfully completed the first part of the clinical Phase I study where the drug candidate IRL757 has been administered in Single Ascending Doses (SAD). The results show that IRL757 is absorbed well, provides good exposure in the body and has a good tolerability and safety profile. In the second part of the Phase I study, repeated and ascending doses are given (Multiple Ascending Dose, MAD).

During the period, an additional clinical Phase I study with IRL757 was initiated, this time in a group of adult healthy subjects aged 65 years and older. The results show that IRL757 is well absorbed and provides good exposure in the body. All participants completed the study, and no serious adverse events were recorded. Collectively, the safety, tolerability and pharmacokinetic profile supports further development of IRL757. This is the first clinical study within the framework of the collaboration with the McQuade Center (MSRD), part of the global pharmaceutical company Otsuka.

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 million 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 during 2025 depending on timeslots for toxicology studies at the CRO.

IRL1117

The goal of the drug candidate IRL1117 is to develop an orally administered drug for the treatment of the basic symptoms of Parkinson's that will be taken once a day, and not cause trouble-some complications that today's standard treatment with levo-dopa gives rise to. IRL1117 is a potent dopamine D1 and D2 receptor agonist that in preclinical studies has shown rapid onset and more than 24 hours of sustained effect.

At present, people with Parkinson's disease are prescribed the anti-Parkinson's treatment levodopa to treat the hallmark symptoms of tremor, rigidity, and bradykinesia (slowness of movement). Levodopa has been the mainstay treatment for 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, in preclinical studies, a clearly differentiating alternative being more potent and displaying a full anti-parkinsonian efficacy during long-term treatment, administered only once daily and 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

Development activities are carried out with IRL1117. 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 (CMC) 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-inclass 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 proofof-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 – December 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 December 31, 2024 the total costs for research and development were SEK 163,669k (151,312), corresponding to 87 percent (81) 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 to December 31, 2024 was SEK -83,129k (-177,839). Earnings per share were -1.60 SEK (-3.43). The group's revenue during the period was SEK 114,083k (5,720) whereof 94,628k (5,678) is net revenue and the remainder is other operating income, which consists of the the share of the total grant from The Michael J. Fox Foundation which has been recognized as revenue.

The personnel costs during the period January 1 – December 31, 2024 was SEK 46,179k (53,082). 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 2024 the group's operating expenses were SEK 189,194k (186,486) and during the fourth quarter, the group's operating expenses were SEK 52,398k (34,457).

Financing and cash flow

Cash flow from operating activites were during the period January 1 - December 31, 2024, SEK -65,590k (-164,850) and during the fourth quarter -22,606k (-33,859). Cash and cash equivalents were SEK 66,917k (111,309) on December 31, 2024.

On December 31, 2024, group equity was SEK 32,635k (115,764) and the equity ratio was 24 percent (65). In the parent company, the equity was 368,932k (415,747) and the equity ratio was 86 (92) percent. The decline is mainly attributable to the loan agreement with Formue Nord (now called Fenja Capital A/S) 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 first quarter 2025. In order to meet future financing needs, the company runs active processes to achieve partnerships, licensing agreements, share issues or other capital market transactions for example through a new licensing agreement regarding mesdopetam, license agreements with pirepemat and IRL1117 or 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 guarter 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 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 – December 31, 2024, the group has received three payments from The Michael J. Fox Foundation amounting to approx. 14,100k, which refer to a partial payment of the financing of the ongoing Phase I study with IRL757. During the three first quarters 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.

Investments

Investments in tangible assets for the period January 1 – December 31, 2024 were SEK 199k (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 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Operating income, etc.				
Net revenue	42,820	-1,192	94,628	5,678
Other operating income	6,577	-	19,455	42
Total income	49,397	-1,192	114,083	5,720
Operating expenses				
Other external expenses	-38,191	-22,455	-136,289	-128,412
Personnel expenses	-12,333	-10,862	-46,179	-53,082
Amortization, depreciation and				
impairment	-1,124	-1,070	-4,583	-4,316
Other operating expenses	-750	-69	-2,143	-676
Total operating expenses	-52,398	-34,457	-189,194	-186,486
Operating profit/loss	-3,001	-35,648	-75,111	-180,765
Profit/loss from financial items				
Finance income	570	746	2,459	3,125
Finance costs	-2,963	-83	-10,477	-199
Total financial items	-2,393	663	-8,018	2,927
Profit/loss after financial items	-5,395	-34,985	-83,129	-177,839
Income tax	-	-	-	-
Profit/loss for the period	-5,395	-34,985	-83,129	-177,839
Earnings per share before and after dilution (SEK)	-0.10	-0.67	-1.60	-3.43
Average number of shares,				
before and after dilution	51,868,406	51,868,406	51,868,406	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	2024	2023	2024	2023
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Result for the period	-5,395	-34,985	-83,129	-177,839
Other comprehensive income	-	-	-	-
Comprehensive income for the period	-5,395	-34,985	-83,129	-177,839

Consolidated statement of financial position in summary

Amounts in SEK thousand	12/31/2024	12/31/2023
ASSETS		
Non-current assets		
Intangible assets	46,862	46,862
Tangible fixed assets	9,793	6,672
Total non-current assets	56,654	53,533
Current assets		
Short-term receivables	12,641	12,278
Cash and cash equivalents	66,917	111,309
Total current assets	79,558	123,587
TOTAL ASSETS	136,212	177,121
EQUITY AND LIABILITIES		
Equity		
Share capital	1,037	1,037
Other contributed capital	690,205	690,205
Retained earnings including results for the period	-658,608	-575,478
Total equity	32,635	115,764
Long-term liabilitiess		
Long-term debt	-	24,511
Leasing debt	3,536	115
Total long-term liabilities	3,536	24,626
Current liabilities		
Short-term debt	53,466	-
Leasing debt	3,419	2,940
Other liabilities	43,156	33,792
Total short-term liabilities	100,041	36,731
TOTAL EQUITY AND LIABILITIES	136,212	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	690,205	-400,411	290,831
Comprehensive income for the period			-177,839	-177,839
Call option premium in relation to loan facility			2,771	2,771
Equity December 31, 2023	1,037	690,205	-575,478	115,764
Equity January 1, 2024	1,037	690,205	-575,478	115,764
Comprehensive income for the period			-83,129	-83,129
Equity December 31, 2024	1,037	690,205	-658,608	32,635

Consolidated statement of cash flows in summary

Amounts in SEK thousand	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Operating activities				
Operating profit/loss	-3,001	-35,648	-75,111	-180,765
Adjustments for non-cash items	1,124	1,070	4,583	4,316
Interest received	570	746	2,459	3,125
Interest paid	-1,839	-83	-6,522	-199
Taxes paid	-	-	-	-
Cash flows from operating activities before changes in working capital	-3,146	-33,915	-74,591	-173,523
Cash flows from changes in working capital				
Changes in operating receivables	-996	3,904	2,792	3,630
Changes in operating liabilities	-18,464	-3,850	6,209	5,043
Cash flows from operating activities	-22,606	-33,859	-65,590	-164,850
Investing activities				
Acquisition of property, plant and equipment	-	-	-199	-293
Cash flows from investing activities	-	-	-199	-293
Financing activities				
New financial debts	-	24,511	25,000	24,511
Repayment of financial liabilities	-860	-926	-3,604	-3,606
Convertible bond issue	-	2,771	-	2,771
Cash flows from financing activities	-860	26,356	21,396	23,676
Cash flows for the period	-23,467	-7,505	-44,394	-141,467
Cash and cash equivalents at the beginning of the period	90,383	118,814	111,309	252,776
Cash and cash equivalents at the end of the period	66,917	111,309	66,917	111,309

Parent company income statement in summary

Amounts in SEK thousand	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Operating income, etc.				
Net sales	1,437	1,504	5,521	5,688
Total income	1,437	1,504	5,521	5,688
Operating expenses				
Other external expenses	-2,372	-2,809	-9,387	-13,286
Personnel expenses	-3,976	-2,830	-14,395	-23,898
Other operating expenses	-9	-5	-17	-14
Total operating expenses	-6,357	-5,644	-23,799	-37,197
Operating profit/loss	-4,919	-4,140	-18,277	-31,509
Profit/loss from financial items				
Results from shares in group company	_	_	-20,000	_
Interest incomes	270	517	1,690	1.635
Interest expenses	-2,833	-68	-10,228	-68
Total financial items	-2,563	450	-28,538	1,567
Profit/loss after financial items	-7,482	-3,690	-46,815	-29,942
Tax on profit/loss for the year	-	-	-	-
Profit/loss for the period	-7,482	-3,690	-46,815	-29,942

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2024	2023	2024	2023
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Profit/loss for the period	-7,482	-3,690	-46,815	-29,942
Other comprehensive income	-	-	-	-
Comprehensive income for the period	-7,482	-3,690	-46,815	-29,942

Parent company balance sheet in summary

Amounts in SEK thousand	12/31/2024	12/31/2023
ASSETS		
Non-current assets		
Financial assets		
Participations in group companies	350,320	350,320
Total non-current assets	350,320	350,320
Current assets		
Other receivables	27,862	7,615
Cash and bank balances	49,991	92,807
Total current assets	77,853	100,422
TOTAL ASSETS	428,173	450,742
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	1,037	1,037
	1,037	1,037
Non-restricted equity		
Share premium reserve	744,314	744,314
Retained earnings including comprehensive income for the period	-376,420	-329,605
	367,894	414,710
Total equity	368,932	415,747
Long-term liabilities		
Long-term interest bearing debt	-	24,511
Total long-term liabilities	-	24,511
Current liabilities		
Short-term interest bearing debts, loan	53,466	-
Other liabilities	5,776	10,484
Total liabilities	59,241	34,995
TOTAL EQUITY AND LIABILITIES	428,173	450,742

Key financial ratios for the group

	2024 Jan-Dec	2023 Jan-Dec	2022 Jan-Dec	2021 Jan-Dec
Net sales, SEK thousand	94,628	5,678	61,136	207,782
Operating profit/loss, SEK thousand	-75,111	-180,765	-113,110	52,576
Profit/loss for the period, SEK thousand	-83,129	-177,839	-113,406	51,781
Profit/loss attributable to the parent company's shareholders, SEK thousand	-83,129	-177,839	-113,406	51,781
Earnings per share before and after dilution, SEK	-1.60	-3.43	-2.19	1.00
R&D costs, SEK thousand	163,669	151,312	146,178	129,748
R&D costs as a percentage of operating expenses, %	87	81	84	84
Cash and cash equivalents at the end of the period, SEK thousand	66,917	111,309	252,776	401,897
Cash flows from operating activities, SEK thousand	-65,590	-164,850	-142,612	128,641
Cash flows for the period, SEK thousand	-44,394	-141,467	-149,121	124,888
Equity, SEK thousand	32,635	115,764	290,831	399,481
Equity attributable to the parent company's shareholders, SEK thousand	32,635	115,764	290,831	399,481
Equity per share, SEK	0.63	2.23	5.61	7.72
Equity ratio, %	24	65	90	85
Average number of employees	31	31	29	22
Average number of employees in R&D	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 with the addition that 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.

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 67,283k (111,623). The financial assets consist mostly of cash and cash equivalents.

Transactions with related parties

IRLAB has during the period January 1 - December 31, 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 and to a company related to the board member Gunnar Olsson. The remuneration has been considered not significant for neither IRLAB nor the recipient, and has been on market conditions.

Revenue January - December 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 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Service revenue	42,820	-1,192	94,628	5,678
Total revenue	42,820	-1,192	94,628	5,678

Segment information

Net sales by	2024	2023	2024	2023
geographic market	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
United Kingdom	-	-1,192	-	1,458
USA	42,820	-	94,628	4,220
Total revenue	42,820	-1,192	94,628	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 toke office on August 1, 2024.

Employees

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

Annual General Meeting

The 2025 Annual General Meeting will be held on May 21, 2025 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 pirepemat. The DSMB unanimously recommends that React-PD continue according to the approved study protocol without modifications.

In July, the company announced that the Phase IIb study of pirepemat, React-PD, could proceed as planned after positive opinion from external safety committee (DSMB).

In September, IRLAB was granted an additional patent for drug candidate mesdopetam that expands its patent protection in Europe.

In September, the company announced that that an additional patent had been granted for its drug candidate pirepemat expanding the patent protection in the US.

In September, the last patient was enrolled in the ongoing Phase IIb study with pirepemat and a reduction in the number of cases has been observed in the overall patient population.

In October, the company presented the company data from a meta-analysis of two studies evaluating the efficacy of mesdopetam at the International Congress of Parkinson's Disease and Movement Disorders (MDS), in Philadelphia, USA. In October, the company received positive data from the first part of the Phase I study with the drug candidate IRL757.

In October, IRLAB receives milestone payment of USD 2.5 million in conjunction with first dosing in a Phase I study with IRL757 in healthy older adults.

In October, the company reported continued progress in the preparations of the mesdopetam Phase III program including positive feedback from the regulatory authorities in Portugal and Germany, as well as payor research confirming significant market potential for mesdopetam in both the US and Europe.

Events after the period

In mid-January, the company announced that last patient had completed the full treatment period in the Phase IIb study with pirepemat.

In January the company received a waiver from the EMA regarding paediatric studies with mesdopetam in Parkinson's Disease.

In end-January, the company reported positive topline results from Phase I study with IRL757 in healthy older adults.

Review by the auditors

This full-year report has not been reviewed by the company's auditors.

Board's assurance

The Board of Directors and the CEO assure that the full-year 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, February 12, 2025

CAROLA LEMNE	GUNNAR OLSSON
Chair of the Board	Board member
CATHARINA GUSTAFSSON WALLICH Board member	REIN PIIR Board member
DANIEL JOHNSSON	VERONICA WALLIN
Board member	Board member
CHRISTER NORDSTEDT	KRISTINA TORFGÅRD
Board member	CEO

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.

Proof of concept

A critical phase in which one evaluates whether a drug candidate exhibits the desired biological effect in humans, usually through a small clinical study. The goal of Proof of Concept is often to show that the drug candidate has the potential to treat the disease or condition it is targeting, before more extensive and costly clinical trials are initiated.



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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