IRLAB

Q4.2023
Year-end report January – December 2023

ANGELICA JOHANSSON AND KARIN ÖNNHEIM, studies how our drug candidates improve the different functions of the brain.

"With the end-of-Phase 2 meeting with the FDA in February, the mesdopetam project will take a pivotal step towards Phase III."

GUNNAR OLSSON, CEO

Year-end report January – December 2023

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

Summary of the fourth quarter

- A collaboration commenced with the US regulatory advisors Clintrex, guiding IRLAB's US regulatory strategy, and ProPharma Group, IRLAB's regulatory agent in the US. A request was prepared together for an end-of-Phase 2 meeting with the FDA where the Phase III program for mesdopetam will be defined. The request was submitted on December 18, 2023, and the FDA accepted and confirmed the meeting date to February 20, 2024.
- Capital markets day was held on October 17 where investors, analysts and financial media were updated on the company's drug development portfolio and growth strategy. Presentations were held by company representatives as well as the external opinion leader Karl Kieburtz. Recordings are available on IRLAB's website, irlab.se.
- IRLAB was granted a new patent in Europe covering both a new salt of drug candidate pirepemat and the process for its preparation. This further strengthens the already strong patent protection for one of the company's lead programs.
- At the end of the year, it was confirmed that drug candidate IRL757 has completed the preclinical studies and development work neccessary to start Phase I. The work collating information for the clinical trial application (CTA) is underway.
- IRLAB was granted over SEK 20 million in financing from The Michael J. Fox Foundation to support the development of IRL757 as a treatment for apathy in Parkinson's. The grant will be used to conduct the first clinical study, a Phase I study, with IRL757.
- A loan agreement was entered on December 22, 2023, with Formue Nord Fokus A/S, increasing the company's liquidity with up to SEK 55 million and extending the company's financial runway and increasing business opportunities.
- The appointment for the company's CEO Gunnar Olsson was extended.

Events after the period

- The pioneering Phase II study React-PD of pirepemat has generated new insights about the specific Parkinson's population the study is conducted in, individuals with high fall frequency, which enables data driven predictions that provides more accurate predictions about the study timeline. Based on these new insights, the study is anticipated to have completed patient recruitment during the third quarter of 2024.
- The company will participate at the medical conference AD/PD™ 2024: 18th International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders in Lisbon, Portugal, on March 5-8, 2024, with two poster presentations about drug candidates pirepemat and IRL1117, respectively.

Financial summary

SEK thousand	Oct-Dec 2023	Oct-Dec 2022	Jan–Dec 2023	Jan–Dec 2022
Net sales	-1,192	12,181	5,678	61,136
Operating profit	-35,648	-33,083	-180,765	-113,110
Earnings per share before and after dilution, SEK	-0.67	-0.64	-3.43	-2.19
Cash and cash equivalents	111,309	252,776	111,309	252,776
Cash flow from operating activities	-33,872	-37,887	-164,860	-142,612
Average number of employees	31	30	31	29
Share price at the end of period, SEK	7.50	38.30	7.50	38.30

Presentation for investors and media about the Year-end Report 2023

Wednesday February 7, 2024, at kl. 10.00 CET is the presentation of the Q4 interim report through a digital webcast. Access via link: https://www.youtube.com/live/-LGAK3NHUP4?si=9xWv-l9JvhGl6e_C3

Financial calendar

Annual report 2023	April 29-May 3, 2024
Interim report Q1 2024	May 8, 2024
Annual general meeting 2024	May 22, 2024
Interim report Q2 2024	July 10, 2024
Interim report Q3 2024	October 30, 2024
Year-end report 2024	February 14, 2025

"We have recently completed the compilation of a Briefing Package on mesdopetam as part of the preparations for the upcoming end-of-Phase 2 meeting with the FDA. The agency has confirmed a meeting with us scheduled for February 20. This is an important milestone towards finalizing the planning of Phase III for mesdopetam.

In December, the highly respected The Michael J. Fox Foundation announced that it had decided to finance IRLAB and the company's work with the substance IRL757 for the treatment of apathy with just over 2 million USD to conduct a clinical Phase I study. Both of these events are remarkable as they both constitute external validation and reinforce the quality of the research and development work that IRLAB conducts. I would also like to take this opportunity to give praise to all employees who have contributed to these acknowledgments from world-leading evaluators of pharmaceutical projects."

GUNNAR OLSSON, CEO

Comments from the CEO

As 2023 comes to an end and I reflect on the company's development over the year, I am pleased to report continued significant progress – in some respects beyond expectations – in our world-leading portfolio of innovative pharmaceutical projects, all of which have the potential to meet the great medical needs of people living with Parkinson's disease and other neurological disorders. Significant events during the year include the identification of IRL1117 as a new drug candidate and that IRL757 has advanced to Phase I-ready status and receiving attention from The Michael J. Fox Foundation to conduct a Phase I study. In addition, we have secured an upcoming end-of-Phase 2 meeting with the FDA for the Phase III ready mesdopetam progam. Furthermore, the pioneering Phase IIb study with pirepemat has already generated new knowledge about the specific group of Parkinson's patients living with recurrent falls. Those who participate in our study fall much more often than what has been previously published, which provides good conditions for capturing treatment effects. In addition, since May 2023, when all centers had been activated, we also have a clearer understanding of the patient recruitment pace, which in combination gives us the opportunity to make better estimates of the study duration.

IRLAB's great advancements over the year are good news for individuals with Parkinson's while also generating value for the company's shareholders. During the fourth quarter of this year, our development programs continued as planned and new important milestones were reached, once again validating the quality of the research and development work within the company.

Mesdopetam – upcoming end-of-Phase 2 meeting with the FDA in February

After the new agreement with Ipsen was concluded, work began to transfer materials and information from Ipsen while compiling a briefing package for the end-of-Phase 2 meeting (EoP2) with the FDA. The purpose of the EoP2 meeting is to define the Phase III program and identify the path towards compiling a New Drug Application (NDA) – an application to market the drug. In mid-December, the company requested an EoP2 meeting, and the FDA subsequently accepted the application and announced that it will take place on February 20, 2024. The completed Phase IIb study showed both an anti-dyskinetic and an antiparkinson effect paired with a placebo-like safety and tolerability profile. Based on this, I believe that mesdopetam has the potential to become a first-line treatment for levodopainduced dyskinesias in Parkinson's patients. Our external clinical experts and regulatory advisors share IRLAB's view that mesdopetam's profile provides conditions for both successful treatment and significant commercial potential.

Parallel to preparing for the EoP2, the work continues to secure the resources needed to conduct a Phase III program and later marketing of the product.

IRL757 – Robust external validation and financing of our next clinical program

In December, we completed the preclinical development work that will form the basis for a regulatory application to start clinical development in Phase I for IRL757. The drug candidate is being developed to treat apathy, a condition seen in most neurodegenerative diseases, where there are currently no effective therapies. Almost simultaneously, the esteemed American research organization The Michael J. Fox Foundation (MJFF) announced that it is awarding IRLAB a research grant of just over 2 million USD to advance the IRL757 project into the clinical phase. The grant will finance the project during 2024 and parts of 2025. This is a fantastic external validation of the quality of our research and development activities.

Our discussions with MSRD, a company within the Otsuka family, about a collaboration on the early clinical development of the substance are ongoing.

Ongoing Phase IIb study of pirepemat

The ongoing pioneering Phase IIb study with pirepemat has already generated new knowledge about the specific Parkinson's population involved in the study. From baseline measurements before the double blind treatment period begins, it's clear that the individuals fall more often than expected and that the fall frequency is stable during the one-month observation time. Since May 2023, when all centers had become active, we have a clearer view of the patient recruitment pace, which gives us the opportunity to make more accurate and data driven estimates, based on information that was not available at the start of the study. Combined, this means that we now expect the study to have completed recruitment in Q3 2024, which is later than previous estimates. This is balanced by the positive effects of the increased understanding of the patients and their fall frequency, which provide a greater possibility to detect a treatment effect.

From treating physicians we hear that patients give positive reviews of the study and we have received several requests to continue treatment after study completion, i.e., signals of perceived benefits of participating in the study.

Based on what we now know about pirepemat, I see a great opportunity to create a first-in-class treatment for the biggest medical need in Parkinson's – to reduce and prevent falls and fall injuries. This also implies significant commercial potential for pirepemat since there is no available treatment today to reduce the risk of falls and the costs that fall injuries entail. The newly approved patent that we reported in December further strengthens pirepemat's position.

Preclinical programs with potential to address major medical needs

Our drug candidates in the preclinical development phase are progressing according to plans to be ready to enter clinical Phase I studies – IRL942 for improving cognitive impairment in Parkinson's and other neurological diseases, and IRL1117 for treating the basic symptoms of Parkinson's (tremor/shaking, stiffness, and bradykinesia/slow movements) without causing the troublesome complications associated with current levodopa-based treatments. A drug with this profile has the potential to replace levodopa and thus represent a paradigm shift in the treatment of Parkinson's.

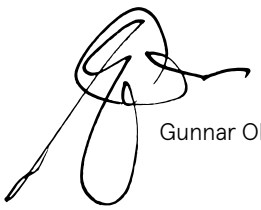
Forward-looking

We have a world-leading portfolio of drug candidates for treating Parkinson's and other neurological diseases. Within the next 12–18 months, we have the potential to reach several value generating inflection points:

- Mesdopetam: Positive outcome at the end-of-Phase 2 meeting with the FDA; Partnership for driving Phase III and commercialization
- Pirepemat: Completion of the ongoing Phase IIb study; Partnership for driving Phase III and commercialization
- IRL757: Transition to clinical phase through the start of a Phase I study during H1 2024. Partnership for early development collaboration
- IRL942: Transition to clinical phase. Partnership for early development collaboration
- IRL1117: Transition to clinical phase

To reach these potential inflection points, we are focused on securing financing for our activities. The financing from MJFF and the loan agreement with Formue Nord are a couple of initial steps. Intense ongoing business development activities focused on mesdopetam and IRL757/942 gives further opportunities, as do discussions with the capital market. These activities are driven, among other things, through participation in partnering meetings, such as BioEurope Fall in Munich in November, where about thirty meetings were held with other companies. Follow-up discussions are ongoing, and we are planning for additional meetings during spring and summer. I feel that both the upcoming EoP2 meeting with the FDA regarding mesdopetam and the financing from MJFF have strengthened our position for positive outcomes.

I look forward to continuing to develop the company and the exciting portfolio of drug candidates together with our employees and board. Finally, I would like to express my gratitude to all employees who have contributed to the past year's progress, and to all shareholders for the support and trust you have given us.



Gunnar Olsson, CEO, IRLAB

Our strategic priorities:

1. Conduct the end-of-Phase 2 meeting with the FDA to define the Phase III program for mesdopetam to expedite the program's progression into Phase III as quickly as possible.
2. Continue and intensify dialogues with potential collaboration partners, licensees and investors to secure future financing of the development programs.
3. Complete recruitment for the Phase IIb study of pirepemat.
4. Start Phase I for IRL757.
5. Drive the preclinical development of IRL942 and IRL1117 towards clinical Phase I studies.
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

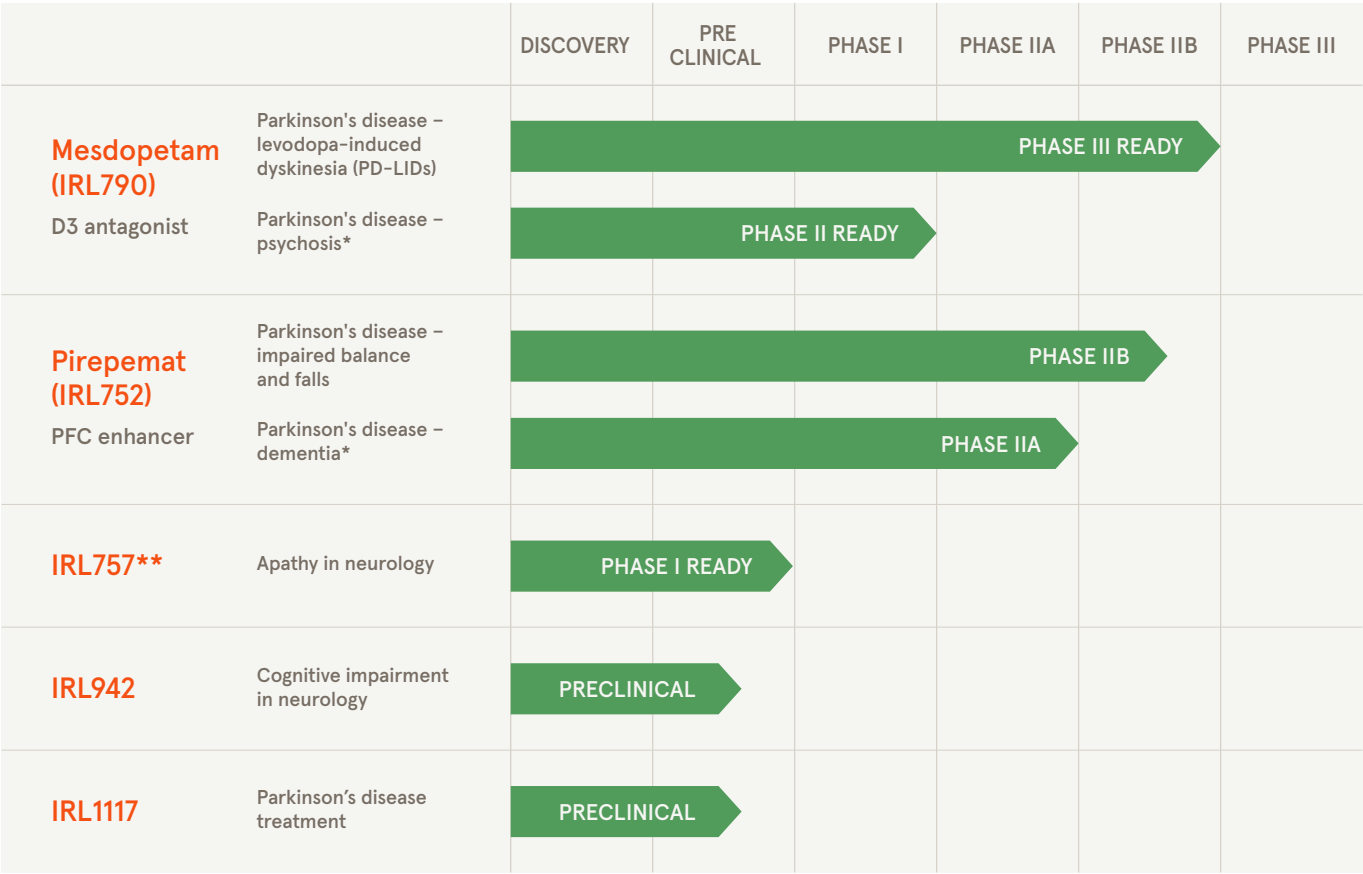
IRLAB is an organization with an experienced team. IRLAB is listed on the Nasdaq Stockholm main market (IRLAB A).

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 end of 2023 maintained a high pace in research and development activities as several milestones in the clinical and preclinical programs were reached. Above all, I would like to emphasize the support from The Michael J. Fox Foundation, which was confirmed before Christmas and involves both funding and access to leading expertise in Parkinson's. Furthermore, this is a strong validation of our innovative power and value-creating R&D activities. Now, an intense spring begins with driving our five development projects forward with the goal of improving the lives of those living with Parkinson's disease."

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 a severe form of involuntary movements commonly occurring after long-term levodopa treatment. It is estimated that 25–40 percent of all people being 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 and Phase IIa 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 pipeline.

Current status

In collaboration with clinical and regulatory experts, IRLAB is currently preparing for an end-of-Phase 2 meeting on February 20, 2024, with the FDA to define mesdopetam's Phase III program in PD-LIDs. Feedback from the FDA could be received up to 30 days after the meeting.

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 signaling 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. 45 percent of all people living with Parkinson's fall recurrently, which approximates to 2.6 million perople suffering from a significantly reduced quality of life also due to fear of falling. There are currently no available treatments, 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 thousand for people over age of 65.

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

Current status

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

The study comprises two groups with different dose levels of pirepemat and one placebo group.

The ongoing study is recruiting patients at the planned sites in France, Germany, the Netherlands, Poland, Spain and Sweden. 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.

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

IRL757

IRL757 is in preclinical development and 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 signaling, a proposed mechanism underlying apathy in neurological disorders.

Current status

Drug candidate IRL757 is Phase I ready after successfully having completed the preclinical studies and development work required to start Phase I. Funding to conduct the Phase I study with IRL757 was also secured in December 2023 from The Michael J. Fox Foundation.

The compilation of all documentation and the application to conduct a Phase I study is ongoing. Furthermore, the GMP manufacturing of drug substance and development of Drug Product is ongoing.

IRLAB and MSRD, a part of the Otsuka family of companies, are evaluating the possibility to collaborate in the further clinical and preclinical development of the drug candidate IRL757.

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 set plan for preclinical development, toxicology and safety studies as well as GMP manufacturing of API. Development of Drug Product has started and IRL942 is expected to be Phase I ready during 2024.

IRLAB and MSRD, a part of the Otsuka family of companies, are evaluating the possibility to collaborate in the early clinical development of the drug candidate IRL942.

IRL1117

Drug candidate IRL1117 will be developed as an oral treatment for the hallmark symptoms of Parkinson's. The drug will be taken once daily and should 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 an 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

In-house activities are proceeding with IRL1117 during 2024. In parallell, activities related to substance manufacturing and planning for preclinical regulatory studies necessary for 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 its technology-base and 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 2023

IRLAB Therapeutics AB, corporate identity number 556931-4692, is the parent company in a group that carries out research and development with the aim of 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, the total costs for research and development were SEK 151,312k (146,178), corresponding to 81 percent (84) of the group's total operating expenses. Development costs vary over time, depending on where in the development phase the projects are.

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

Comments on the income statement

The loss for the period January 1 – December 31, 2023 was SEK –177,839k (-113,406). Earnings per share were –3.43 SEK (-2.19). The group's revenue during the period was SEK 5,720k (61,277).

The personnel costs during the period was SEK 53,082k (42,481). The increase is primarly due to one-off costs associated with the removal of the former CEO, which amounted to SEK 10,580k.

Of the SEK 239,596k that was received up-front in 2021 under the mesdopetam license agreement, SEK 185,262k was recognized as license revenue and SEK 54,335k was recognized as deferred income for the finalization of the Phase IIb study and was recognized as income during 2022. No such income has been recognized during 2023. During the fourth quarter, the company finalized the settlements with Ipsen, whereby the revenues fell below the previous accruals by SEK 1,192k, resulting in a negative revenue in the fourth quarter of 2023, although not for the full year 2023. During 2023, the group's operating expenses were SEK 186,486k (174,387).

Financing and cash flow

Cash flow from operating activites were during the period January 1 to December 31, 2023, SEK –164,860k (-142,612) and during the forth quarter SEK –33,872k (-37,887). Cash and cash equivalents were SEK 111,309k (252,776) on December 31, 2023.

On December 31, 2023, equity was SEK 115,764k (290,831) and the equity ratio was 65 percent (90). The decline is mainly attributable to the loan agreement with Formue Nord 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 and secondarily a research collaboration regarding IRL757 and/or IRL942. 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, the company entered into an agreement with Formue Nord Fokus A/S for a credit facility amounting to up to SEK 55,000k. In the fourth quarter, SEK 30,000k of the total credit facility was utilized, which strengthened the cash position by SEK 27,250k after transaction costs. According to the agreement, Formue Nord has the right to convert up to SEK 10,000k of the loaned amount into shares at a price of SEK 7.81 per share. 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 30,000k at the end of the term (assuming that the facility is not further utilized). Therefore, the long-term liabilities during the fourth quarter have increased by SEK 24,511k and the equity by SEK 2,771k in connection with the agreement with Formue Nord.

Investments

Investments in tangible assets for the period January 1 – December 31, 2023 were SEK 293k (5,257).

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	2023 Oct–Dec	2022 Oct–Dec	2023 Jan–Dec	2022 Jan–Dec
Operating income, etc.				
Net revenue	-1,192	12,181	5,678	61,136
Other operating income	-	136	42	141
Total income	*-1,192*	*12,317*	*5,720*	*61,277*
Operating expenses				
Other external expenses	-22,455	-30,431	-128,412	-125,906
Personnel expenses	-10,862	-12,669	-53,082	-42,481
Outlicensed balanced development projects	-	-	-	-
Amortization, depreciation and impairment	-1,070	-1,865	-4,316	-4,779
Other operating expenses	-69	-435	-676	-1,220
Total operating expenses	*-34,457*	*-45,399*	*-186,486*	*-174,387*
Operating profit/loss	**-35,648**	**-33,083**	**-180,765**	**-113,110**
Profit/loss from financial items				
Finance income	746	0	3,125	0
Finance costs	-83	-83	-199	-297
Total financial items	*663*	*-83*	*2,927*	*-297*
Profit/loss after financial items	**-34,985**	**-33,166**	**-177,839**	**-113,406**
Income tax	-	-	-	-
Profit/loss for the period	**-34,985**	**-33,166**	**-177,839**	**-113,406**
Earnings per share before and after dilution (SEK)	-0.67	-0.64	-3.43	-2.19
Average number of shares, before and after dilution	51,868,406	51,868,406	51,868,406	51,831,913
Number of shares at year-end	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	2023 Oct–Dec	2022 Oct–Dec	2023 Jan–Dec	2022 Jan–Dec
Result for the period	–34,985	–33,166	-177,839	-113,406
Other comprehensive income	-	-	-	-
Comprehensive income for the period	**–34,985**	**–33,166**	**-177,839**	**-113,406**

Consolidated statement of financial position in summary

Amounts in SEK thousand	12/31/2023	12/31/2022
ASSETS		
Non-current assets		
Intangible assets	46,862	46,862
Tangible fixed assets	6,672	8,009
Total non-current assets	**53,533**	**54,871**
Current assets		
Short-term receivables	12,278	15,908
Cash and cash equivalents	111,309	252,776
Total current assets	**123,587**	**268,684**
TOTAL ASSETS	**177,121**	**323,555**
EQUITY AND LIABILITIES		
Equity		
Share capital	1,037	1,037
Other contributed capital	690,205	690,205
Retained earnings including results for the period	-575,478	-400,411
Total equity	**115,764**	**290,831**
Long-term liabilitiess		
Long-term debt	24,511	-
Leasing debt	115	381
Total long-term liabilities	**24,626**	**381**
Current liabilities		
Leasing debt	2,940	3,595
Other liabilities	33,792	28,748
Total short-term liabilities	**36,731**	**32,343**
TOTAL EQUITY AND LIABILITIES	**177,121**	**323,555**

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, 2022	**1,035**	**685,450**	**–287,005**	**399,481**
Comprehensive income for the period			-113,406	-113,406
Transactions with owners in their capacity as owners:				
Rights issue	2	4,754		4,757
Equity December 31, 2022	**1,037**	**690,205**	**–400,411**	**290,831**
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**

Consolidated statement of cash flows in summary

Amounts in SEK thousand	2023 Oct–Dec	2022 Oct–Dec	2023 Jan–Dec	2022 Jan–Dec
Operating activities				
Operating profit/loss	-35,648	-33,083	-180,765	-113,110
Adjustments for non-cash items	1,070	1,865	4,316	4,779
Interest received	746	0	3,125	0
Interest paid	-83	-54	-199	-297
Taxes paid	-	-	-	-
Cash flows from operating activities before changes in working capital	**-33,915**	**-31,272**	**-173,523**	**-108,627**
Cash flows from changes in working capital				
Changes in operating receivables	3,893	5,073	3,619	3,634
Changes in operating liabilities	-3,885	-11,688	5,008	-37,619
Cash flows from operating activities	**-33,872**	**-37,887**	**-164,860**	**-142,612**
Investing activities				
Acquisition of immaterial fixed assets	-	-	-	-500
Acquisition of property, plant and equipment	-	-214	-293	-2,876
Cash flows from investing activities	**-**	**-214**	**-293**	**3,376**
Financing activities				
New financial debts	24,511	-	24,511	-
Repayment of financial liabilities	-915	-872	-3,596	-3,134
Convertible bond issue	2,771	-	2,771	-
Cash flows from financing activities	**26,367**	**-872**	**23,687**	**-3,134**
Cash flows for the period	**-7,505**	**-38,973**	**-141,467**	**-149,121**
Cash and cash equivalents at the beginning of the period	118,814	291,749	252,776	401,897
Cash and cash equivalents at the end of the period	**111,309**	**252,776**	**111,309**	**252,776**

Parent company income statement in summary

Amounts in SEK thousand	2023 Oct–Dec	2022 Oct–Dec	2023 Jan–Dec	2022 Jan–Dec
Operating income, etc.				
Net sales	1,504	1,555	5 688	4,531
Total income	*1,504*	*1,555*	*5,688*	*4,531*
Operating expenses				
Other external expenses	-2,809	-3,403	-13,286	-12,187
Personnel expenses	-2,830	-4,460	-23,898	-14,402
Other operating expenses	-5	-25	-14	-25
Total operating expenses	*-5,644*	*-7,888*	*-37,197*	*-26,614*
Operating profit/loss	**-4,140**	**-6,333**	**-31,509**	**-22,083**
Profit/loss from financial items				
Interest incomes	517	0	1,635	0
Interest expenses	-68	-7	-68	-7
Total financial items	*450*	*-7*	*1,567*	*-7*
Profit/loss after financial items	**-3,690**	**-6,340**	**-29,942**	**-22,090**
Group contributions made	-	-	-	-
Tax on profit/loss for the year	-	-	-	-
Profit/loss for the period	**-3,690**	**-6,340**	**-29,942**	**-22,090**

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2023 Oct–Dec	2022 Oct–Dec	2023 Jan–Dec	2022 Jan–Dec
Profit/loss for the period	-3,690	–6,340	–29,942	–22,090
Other comprehensive income	-	-	-	-
Comprehensive income for the period	**-3,690**	**–6,340**	**–29,942**	**–22,090**

Parent company balance sheet in summary

Amounts in SEK thousand	12/31/2023	12/31/2022
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	7,615	8,535
Cash and bank balances	92,807	92,814
Total current assets	**100,422**	**101,349**
TOTAL ASSETS	**450,742**	**451,669**
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
Call option premium in relation to loan facility	2,771	-
Retained earnings including comprehensive income for the period	-332,376	-302,434
	414,710	*441,880*
Total equity	**415,747**	**442,917**
Long-term liabilities		
Long-term interest bearing debt	24,511	-
Total long-term liabilities	**24,511**	**-**
Current liabilities		
Other liabilities	10,484	8,752
Total liabilities	**34,995**	**8,752**
TOTAL EQUITY AND LIABILITIES	**450,742**	**451,669**

Key financial ratios for the group

	2023 Jan-Dec	2022 Jan-Dec	2021 Jan-Dec	2020 Jan-Dec
Net sales, SEK thousand	5,678	61,136	207,782	-
Operating profit/loss, SEK thousand	-180,765	-113,110	52,576	-91,458
Profit/loss for the period, SEK thousand	-177,839	113,406	51,781	-91,653
Profit/loss attributable to the parent company's shareholders, SEK thousand	-177,839	-113,406	51,781	-91,653
Earnings per share before and after dilution, SEK	-3.43	-2.19	1.00	-1.92
R&D costs, SEK thousand	151,312	146,178	129,748	75,989
R&D costs as a percentage of operating expenses, %	81	84	84	83
Cash and cash equivalents at the end of the period, SEK thousand	111,309	252,776	401,897	277,009
Cash flows from operating activities, SEK thousand	-164,860	-142,612	128,641	-89,214
Cash flows for the period, SEK thousand	-141,467	-149,121	124,888	166,482
Equity, SEK thousand	115,764	290,831	399,481	347,880
Equity attributable to the parent company's shareholders, SEK thousand	115,764	290,831	399,481	347,880
Equity per share, SEK	2.23	5.61	7.72	6.72
Equity ratio, %	65	90	85	94
Average number of employees	31	29	22	18
Average number of employees in R&D	26	25	20	17

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

Other information

Accounting principles

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

The fair value of the debt component in a convertible bond is calculated using a discount rate that represents the market interest rate for a debt with the same terms but without the conversion right to shares. The amount is recorded as debt at accrued acquisition value until the debt is converted or matures. The conversion right is initially recorded as the difference between the fair value of the entire compound financial instrument and the fair value of the debt component. This is recorded in equity net of tax.

The accountign principles applied correspond to those applied in the 2022 Annual Report. This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting.

Incentive programs

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

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

Financial instruments

The group currently has no financial instruments that are valued at fair value, rather all financial assets and liabilities are valued at accrued acquisition value. It is judged that there are no significant differences between fair value and book value regarding the financial assets and liabilities. On the closing date, the carrying amount of financial assets was SEK 111,623k (258,566).

Transactions with related parties

IRLAB has during the period January - December 2023 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 - December 2023

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

Net sales by revenue category	2023 Oct–Dec	2022 Oct–Dec	2023 Jan–Dec	2022 Jan–Dec
Service revenue	-1,192	12,181	5,678	61,136
Total revenue	**-1,192**	**12,181**	**5,678**	**61,136**

Segment information

Net sales by geographic market	2023 Oct–Dec	2022 Oct–Dec	2023 Jan–Dec	2022 Jan–Dec
United Kingdom	-1,192	12,181	1,458	61,136
USA	-	-	4,220	-
Total revenue	**-1,192**	**12,181**	**5,678**	**61,136**

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 124 of the 2022 Annual Report. No significant changes have occurred that affect the reported risks.

The war in Ukraine, the subsequent geopolitical instability in Eastern Europe in particular, and its effect on people in the affected areas may impact the speed of patient recruitment and the possibility for already recruited patients to get to the clinics for the requisite visits. IRLAB's Phase IIb study with pirepemat is partially carried out in clinics in Poland, a country that may be more affected than other countries due to its geographical proximity to Ukraine. So far, IRLAB has only noticed a minor impact on the ongoing study. The company is continuously monitoring the developments so that appropriate measures can be taken if necessary.

Management

On February 21, 2023, the then CEO was dismissed and replaced by the then chairman of the board, Gunnar Olsson. Olsson is the CEO with a short notice period and no special compensation upon termination of the employment. A process to replace him is ongoing.

Employees

The average number of employees in the group from January – December was 31 (30). At the end of the period, the number of full-time positions was 31 (30), distributed over 33 (32) people.

The number of full-time positions, including long-term contracted consultants, was 34 (33) at the end of the period, distributed over 37 (36) people.

Annual General Meeting

The 2024 Annual General Meeting will be held on May 22, 2024 in Gothenburg. In order to have a matter dealt with at the general meeting, a request from shareholders must have been received by the company no later than April 10, 2024. Such requests should preferably be sent to ir@irlab.se.

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.

Review and the Board's assurance

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

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

Events after the period

The pioneering Phase II study React-PD of pirepemat has generated new insights about the specific Parkinson's population the study is conducted in, individuals with high fall frequency, which enables data driven predictions that provides more accurate predictions about the study timeline. Based on these new insights, the study is anticipated to have completed patent recruitment during the third quarter of 2024.

Gothenburg, February 7, 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 is discovering and developing a portfolio of transformative therapies targeting all stages of Parkinson's disease. The company has its origin in Nobel Laureate Prof. Arvid Carlsson's research group and the discovery of a connection between the brain's neurotransmitters and CNS disorders. Mesdopetam (IRL790), in development for the treatment of levodopa-induced dyskinesias, has completed Phase IIb and is in preparation toward Phase III. Pirepemat (IRL752), is currently in Phase IIb, being evaluated for its effect on balance and fall frequency in Parkinson's disease. In addition, the company is also progressing the three pre-clinical programs IRL757 (financially supported by The Michael J. Fox Foundation), IRL942 and IRL1117 towards Phase I studies. IRLAB's pipeline has been generated by IRLAB's proprietary systems biology-based Integrative Screening Process (ISP) research platform. Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A).

Contact information

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