IRLAB

Q1.2024
Interim report
January – March 2024

SABINA BRANDIN AND ANGELICA JOHANSSON, studies the effect of our candidate drugs in different model systems.

"The agreement with MSRD regarding IRL757 gives us both capital and validation of our way of working and our substances."

GUNNAR OLSSON, CEO

Interim report January–March 2024

Highlights

COLLABORATION WITH MSRD/OTSUKA, FUNDING IRL757 THROUGH CLINICAL PROOF-OF-CONCEPT

SUCCESSFUL END-OF-PHASE 2-MEETING WITH FDA FOR MESDOPETAM

NEW INSIGHTS FROM THE PHASE IIB STUDY WITH PIREPEMAT

REGULATORY APPROVAL TO START PHASE I WITH IRL757

Financial summary

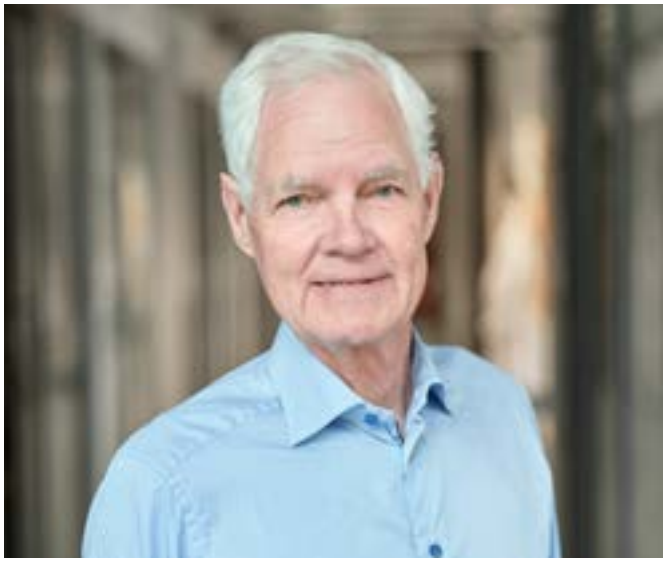
SEK thousand	January–March 2024	January–March 2023	January–December 2023
Net sales	-	-	5,678
Operating profit	–37,636	–59,508	-180,765
Earnings per share before and after dilution, SEK	–0.75	–1.15	-3.43
Cash and cash equivalents	73,140	210,103	111,309
Cash flow from operating activities	38,211	41,498	-164,860
Average number of employees	32	31	31
Share price at the end of period, SEK	15.60	11.08	7.50

Presentation for investors and media about the Q1 report 2024

Wednesday May 8, 2024, at kl. 10.00 CET is the presentation of the Q1 interim report through a digital webcast. Access via link: https://www.youtube.com/watch?v=x-v4qL_nKV3s

Financial calendar

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



"Yesterday we announced that we signed an agreement to start a development collaboration for IRL757 with MSRD, a company within the Otsuka group. Within the framework of the agreement, together we will develop the substance to completed clinical Proof-of-Concept. The patient studies will include people with both Parkinson's and Alzheimer's disease. Through the collaboration agreement, IRLAB receives USD 3 million upon signing and additional activity-based milestones of USD 5.5 million. In addition, MSRD/Otsuka will cover all cost for the full development program, i.e. CMC development, toxicology studies and the clinical studies."

GUNNAR OLSSON, CEO

Comments from the CEO

The new year has begun with an exceptionally positive development for the company and our projects. The collaboration agreement with the McQuade Center for Strategic Research and Development, MSRD, for IRL757 secures full funding of the project all the way through clinical Proof-of-Concept studies.

The deal with MSRD and the grant we received from MJFF gives us the conditions to run the business without further capital additions well past a potential license deal with mesdopetam and past the topline data in the Phase IIb study with pirepemat.

We have also conducted a successful End-of-Phase 2 meeting with the US FDA, which confirmed consensus regarding the design of the upcoming Phase III program for mesdopetam.

Furthermore, the ongoing Phase IIb trial of pirepemat (REACT-PD) has generated new insights into the severe Parkinson-related balance problems that often cause fall injuries, strengthening the possibilities of detecting treatment effects and providing more confident data-driven estimates of trial timelines.

Clear agreement with the FDA regarding the Phase III program for mesdopetam

On February 20, we held an end-of-Phase 2 meeting with the FDA prior to the initiation of the Phase III program for mesdopetam against levodopa-induced dyskinesias (LIDs) in Parkinson's. The discussions were very fruitful and there was a clear alignment between the FDA and us on the design of the program, which gives validation to the quality of IRLAB's research and development. An important basis for the discussion was the results from our previously completed Phase IIb study, which shows that mesdopetam has a dose-dependent anti-dyskinetic and anti-Parkinson effect, as well as a safety and tolerability profile on par with placebo. There is currently no other drug with this combination of effects available for people with Parkinson's disease, so mesdopetam could become the solution to a large and so far unmet medical need. The favorable safety profile makes it possible to include a broad patient population with levodopa-induced dyskinesias in the Phase III program, which may facilitate patient recruitment.

In the meeting with the FDA, we got clarity that there is consensus between us and the authority that the most appropriate primary efficacy measure to use in the program is UdysRS (part 1+3+4). In our Phase IIb study, a statistically significant and clinically significant effect of mesdopetam was observed on this particular measurement variable.

After the completed meeting with the FDA, our work on finding partners and financing for implementation of the Phase III program has intensified.

Full funding of IRL757 through clinical Proof of Concept secured

As we previously communicated, in December 2023 we received roughly SEK 20 million in a research grant from The Michael J. Fox Foundation for Parkinson's Research (MJFF)

to conduct the first clinical Phase I study with IRL757. The MJFF is the world's largest non-profit funder of research in Parkinson's disease and their support represents a very strong external validation of the potential of IRL757. We have just received the information that the pharmaceutical authorities have approved our application to conduct the study, so we estimate that the study will be able to start during the month of May.

Yesterday we announced that we signed an agreement to start a development collaboration for IRL757 with the McQuade Center for Strategic Research and Development, MSRD, a company within the Otsuka group. Within the framework of the agreement, we will together develop the substance to a completed clinical Proof of Concept, i.e. clinical patient studies that aim to provide evidence of a beneficial effect on apathy in neurological disease. The patient studies will include people with both Parkinson's and Alzheimer's disease. Through the collaboration agreement, IRLAB receives USD 3 million upon signing and additional activity-based milestones of USD 5.5 million. According to the agreement, IRLAB will carry out all development work and in addition to the milestone payments, MSRD will cover these costs. After the Proof-of-Concept studies, the collaboration may be extended based on new negotiations between the parties. If the agreement is not extended MSRD is entitled to low single digit royalties on future sales. It is important to point out that the development collaboration does not give MSRD the right to commercialize a potential future drug - for this it is required that the parties enter into a customary license agreement at a later stage. Such an agreement could generate significant milestone

and royalty income for IRLAB. We are very excited about both the full funding of IRL757 and the collaboration with MSRD which provides a solid validation of the quality of our research and development and clearly demonstrates the potential of IRL757.

REACT-PD generates new important insights

We have also taken important steps forward in our clinical program for pirepemat, a drug candidate that has the potential to be the world's first treatment to counteract the severe balance problems and resulting falls and fall injuries that affect people with Parkinson's disease. In our ongoing Phase IIb study, React-PD, we have already generated very important knowledge about this patient group that frequently loses balance and falls. For example, our measurements before the start of the study (baseline measurements) show that the participants in the study fall 2-3 times more often than expected and that the fall rate is stable during the baseline measurements, which last for a whole month. The higher fall frequency, combined with the fact that more patients than expected have chosen to stay in the study for its duration, gives us a stronger statistical opportunity to detect treatment effects. In consultation with regulatory authorities, we have now made the assessment that we can re-evaluate the size of the study and reduce the planned number of patients in the study while maintaining the potential to detect a treatment effect in the form of reduced fall frequency. We expect to have reached a sufficient number of patients in the study during the third quarter of this year and then be able to finish patient recruitment.

New publication describes antipsychotic effect of mesdopetam

A scientific article in the journal Neurotherapeutics published in mid-March describes the results of a study of mesdopetam in a preclinical model of psychosis in Parkinson's disease (PD-P). The study was carried out using a new and impressive technology that makes it possible to follow and study the mechanisms in the brain that are behind psychosis. In the study, mesdopetam exhibited important properties associated with antipsychotic efficacy. The technology provides an excellent tool for evaluating potential new therapies, and the study results provide strong support for mesdopetam's potential as a new treatment for psychosis associated with Parkinson's disease.

Great interest in IRLAB's projects

During the quarter, we have presented IRLAB and our unique project portfolio at, among others, the Life Science Day in Gothenburg, Bayes@Lund, and at the international conference AD/PD™ 2024 in Lisbon. As we present clinical and preclinical data around our projects in various contexts, it becomes increasingly clear that our project portfolio in Parkinson's is unparalleled in the global pharmaceutical industry. This is attracting increasing attention from the medical profession, industrial players and investors.

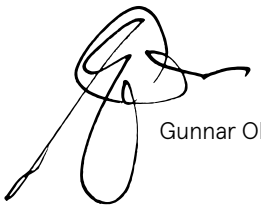
Forward looking

After an exceptionally positive start to the year, we look forward to further positive events during the rest of 2024. We follow our strategy to discover and develop new drug candidates with the aim of creating the greatest possible value for those affected by Parkinson's and other progressive and incurable diseases in the brain, for their relatives, health care staff and of course also for the company's shareholders. In that work, our most important near term priorities are:

- Mesdopetam – secure funding for the start of Phase III through partnership/out-licensing
- Pirepemat – complete ongoing Phase IIb study
- IRL757 – start the first Phase I of the study and plan the implementation of the activities that fall within the MSRD collaboration
- IRL942 and IRL1117 – continued preclinical development activities towards Phase I ready status
- Continue to evaluate ways to continue financing the company's future activities

All in all, our assessment is that the deal with MSRD provides the conditions to run the business without additional capital injection, well past a potential licensing deal with mesdopetam and past the topline data in the Phase IIb study with pirepemat. In our work within Business Development, our focus is now to find a partner for a license deal for mesdopetam. For pirepemat, the focus is to complete the ongoing study and analyze the results. In parallel, discussions take place with players in the financial markets. We continue to be vigilant about our financial stability and continuously evaluate our opportunities.

I look forward to continuing to develop both the company and all the pioneering projects in our research portfolio. Finally, I would like to express my thanks to all shareholders for the trust you place in us.



Gunnar Olsson, CEO, IRLAB

Our strategic priorities:

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

IRLAB's unique offering and position

IRLAB discovers and develops novel treatments to transform the life of patients living with Parkinson's and other CNS disorders. Rooted in Nobel Prize-winning research, IRLAB has grown rapidly to become recognized and respected as a world-leader in understanding the complex neuropharmacology of CNS disorders and especially Parkinson's. We have a welldefined, strategically focused R&D pipeline of powerful new treatments targeting various stages of Parkinson's. Having a full range of effective treatments for the disease's different complications and symptoms is regarded as essential by both the medical and patient communities and is at the same time potentially a possibility for a successful pharmaceutical business.

Pioneering biology & ISP

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

Focused strategy

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

Validated proof-of-concept

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

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

Organization positioned for success

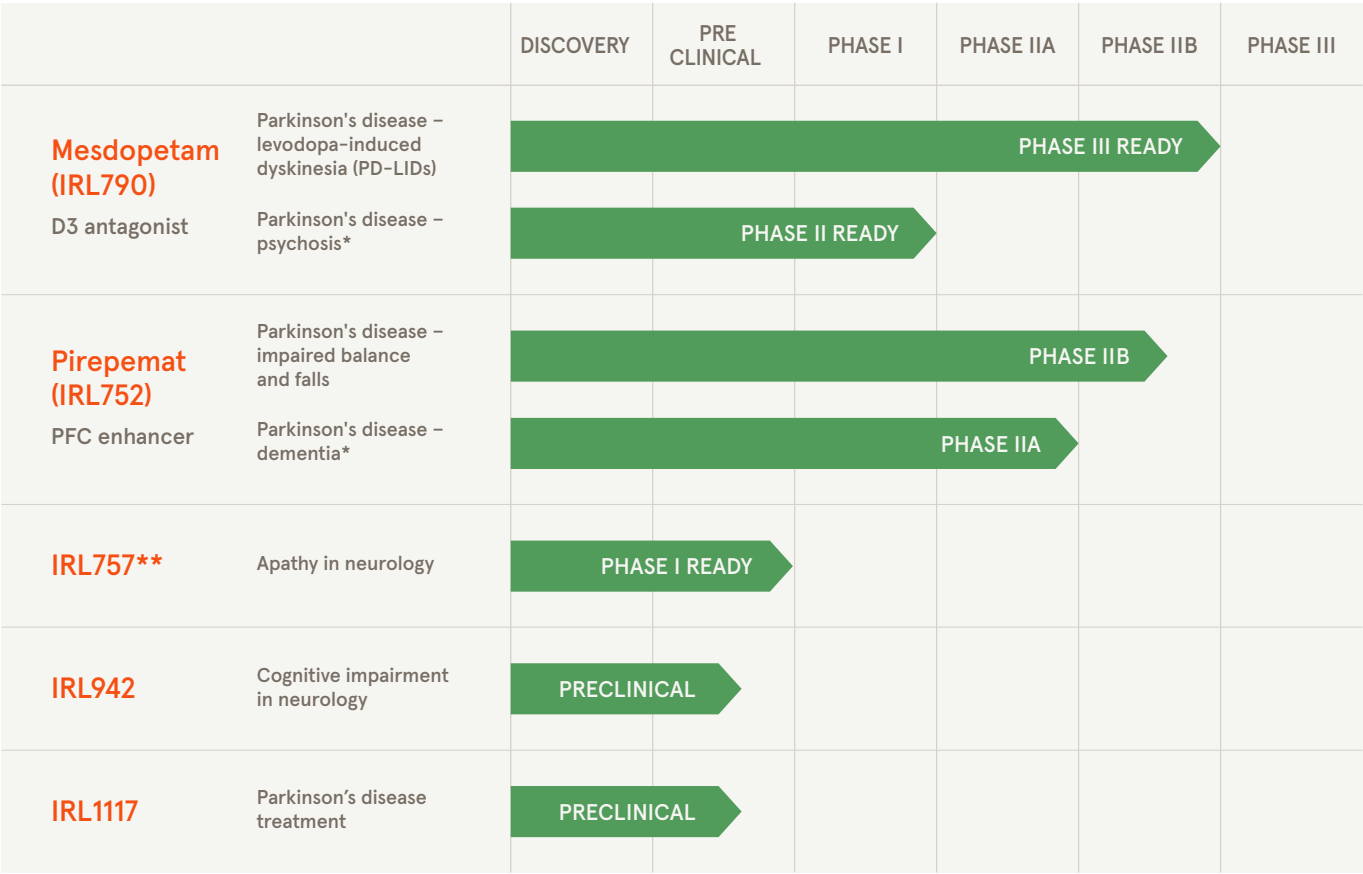
IRLAB is an organization with an experienced team. IRLAB is listed on the Nasdaq Stockholm main market (IRLAB A).

Broad & solid portfolio

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

IRLAB's portolio

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



* Currently no active clinical development in this indication.

** Supported by The Michael J. Fox Foundation.

R&D update

"We have had a very successful quarter, which was clearly reflected in the numerous regulatory validations, confirming the high quality of our research and development.

- *The successful End-of-Phase 2 meeting with the FDA for mesdopetam*
- *The regulatory approval of the refinement of the sample size calculation in the pirepemat study, which means that we can reduce the number of patients in the study.*
- *The regulatory approval of the start of Phase I with IRL757.*

In addition to this, the collaborations with MSRD and MJFF have also validated the potential of IRL757. We are now continuing with the regulatory work for mesdopetam in Europe ahead of the start of Phase III, at the same time we are looking forward to completing the recruitment in the pirepemat study, conducting the Phase I program with IRL757 together with MJFF and last but not least continuing the work to get IRL942 and IRL1117 into the clinic."

NICHOLAS WATERS, EVP AND HEAD OF R&D

About IRLAB's drug candidates

Mesdopetam

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

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

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

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

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

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

Current status

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

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 with Parkinson's fall recurrently, which approximates to 2.6 million perople suffering from a significantly reduced quality of life also driven by fear of falling. There are currently no treatments available, despite the great medical need. The societal burden due to falls is also significant with the cost for hospital treatment of a fall injury in the US estimated to be around USD 30 000 for people over age of 65.

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

Current status

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

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

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

IRL757

IRL757 is in preclinical development, entering Phase I, 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 signalling, a proposed mechanism underlying apathy in neurological disorders.

Current status

Drug candidate IRL757 has received regulatory approval to start Phase I after successful completion of the preclinical studies and development work required. In December 2023 a collaboration with The Michael J. Fox Foundation was initiated to fund and conduct a Phase I study programme with IRL757.

A clinical trial application (CTA) for Phase I has been submitted to regulatory authorities. A CRO is contracted to carry out the Phase I programme. The company expects the study to start Q2 2024.

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, GMP manufacturing of API. as well as toxicology and safety studies . Development of Drug Product has started and IRL942 is expected to be Phase I ready during 2024 or in the beginning of 2025 depending on timeslots for toxicology studies at the CRO.

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 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

In-house activities are proceeding with IRL1117 during 2024. In parallell, activities related to large scale 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 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 – March 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 March 31, 2024 the total costs for research and development were SEK 28,937k (41,769), corresponding to 77 percent (70) 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 – March 31, 2024 was SEK –39,019k (-59,556). Earnings per share were –0,75 SEK (-1,15). The group had no revenue either in the first quarter 2024 or 2023.

The personnel costs during the period January 1 – March 31, 2024 was SEK 10,953k (21,090). The decrease is primarly due to one-off costs last year associated with the removal of the former CEO, which amounted to SEK 10,580k.

During the first quarter 2024, the group's operating expenses were SEK 37,636k (59,508).

Financing and cash flow

Cash flow from operating activites were during the period January 1 to March 31, 2024, SEK –38,211k (-41,498). Cash and cash equivalents were SEK 73,140k (210,103) on March 31, 2024.

On March 31, 2024, equity was SEK 76,745k (231,275) and the equity ratio was 56 percent (83). 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. 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.

During the first quarter of 2024, the group has received payments from The Michael J. Fox Foundation amounting to approx. 3,450k, which refer to a partial payment of the financing of the planned Phase 1 study with IRL757. The payment is reported as a prepaid income and will be recognized as income in line with the costs of the current study.

Investments

Investments in tangible assets for the period January 1 – March 31, 2024 were SEK 0k (293).

The IRLAB share

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

Share capital, number of shares and votes

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

Consolidated income statement in summary

Amounts in SEK thousand	2024 Jan–Mar	2023 Jan–Mar	2023 Jan–Dec
Operating income, etc.			
Net sales	-	-	5,678
Other operating income	-	-	42
Total income	-	-	*5,720*
Operating expenses			
Other external expenses	–25,256	–37,129	–128,412
Personnel costs	–10,953	–21,090	–53,082
Amortization, depreciation and impairment	–1,152	–1,081	–4,316
Other operating expenses	-275	-209	-676
Total operating expenses	–37,636	*–59,508*	*–186,486*
Operating profit/loss	**–37,636**	**–59,508**	**–180,765**
Profit/loss from financial items			
Finance income	715	3	3,125
Finance costs	–2,098	–52	–199
Total financial items	–1,383	*–49*	*2,927*
Profit/loss after financial items	**–39,019**	**–59,556**	**–177,839**
Income tax	-	-	-
Profit/loss for the period	**–39,019**	**–59,556**	**–177,839**
Earnings per share before and after dilution (SEK)	–0.75	–1.15	-3.43
Average number of shares, before and after dilution	51,868,406	51,868,406	51,868,406
Number of shares at the end of the period	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 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Result for the period	-39,019	-59,556	-177,839
Other comprehensive income	-	-	-
Comprehensive income for the period	**-39,019**	**-59,556**	**-177,839**

Consolidated statement of financial position in summary

Amounts in SEK thousand	03/31/2024	03/31/2023	12/31/2023
ASSETS			
Non-current assets			
Intangible assets	46,862	46,862	46,862
Tangible fixed assets	5,520	7,222	6,672
Total non-current assets	**52,381**	**54,084**	**53,533**
Current assets			
Short-term receivables	11,146	13,267	12,278
Cash and cash equivalents	73,140	210,103	111,309
Total current assets	**84,285**	**223,369**	**123,587**
TOTAL ASSETS	**136,667**	**277,453**	**177,121**
EQUITY AND LIABILITIES			
Equity			
Share capital	1,037	1,037	1,037
Other contributed capital	690,205	690,205	690,205
Retained earnings including result for the period	-614,497	-459,967	-575,478
Total equity	**76,745**	**231,275**	**115,764**
Non-current liabilities			
Long-term debt	25,494	-	24,511
Lease liabilities	46	315	115
Total non-current liabilities	**25,540**	**315**	**24,626**
Current liabilities			
Lease liabilities	2,067	2,778	2,940
Other liabilities	32,314	43,085	33,792
Total current liabilities	**34,381**	**45,863**	**36,731**
TOTAL EQUITY AND LIABILITIES	**136,667**	**277,453**	**177,121**

Consolidated statement of changes in equity in summary

Amounts in SEK thousand	Share capital	Other contributed capital	Retained earnings incl. total comprehen-sive income for the period	Total equity
Equity January 1, 2023	**1,037**	**690,605**	**–400,411**	**290,831**
Comprehensive income for the period			–59,556	–59,556
Equity March 31, 2023	**1,037**	**690,605**	**–459,967**	**231,275**
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**	**690,605**	**–575,478**	**115,764**
Equity January 1, 2024	**1,037**	**690,605**	**-575,478**	**115,764**
Comprehensive income for the period			–39,019	–39,019
Equity March 31, 2024	**1,037**	**690,605**	**–614,497**	**76,745**

Consolidated statement of cash flows in summary

Amounts in SEK thousand	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Operating activities			
Operating profit/loss	-37,636	-59,508	-180,765
Adjustments for non-cash items	1,152	1,081	4,316
Interest received	715	3	3,125
Interest paid	-2,098	-52	-199
Cash flows from operating activities before changes in working capital	**-37,867**	**-58,476**	**-173,523**
Cash flows from changes in working capital			
Changes in operating receivables	2,070	2,642	3,619
Changes in operating liabilities	-2,414	14,336	5,043
Cash flows from operating activities	**-38,211**	**-41,498**	**-164,860**
Investing activities			
Acquisition of property, plant and equipment	-	-293	-293
Cash flows from investing activities	**-**	**-293**	**-293**
Financing activities			
New financial debts	983	-	24,511
Repayment of financial liabilities	-942	-883	-3,596
Convertible bond issue	-	-	2,771
Cash flows from financing activities	**-42**	**-883**	**23,687**
Cash flows for the period	**-38,169**	**-42,673**	**-141,467**
Cash and cash equivalents at the beginning of the period	111,309	252,776	252,776
Cash and cash equivalents at the end of the period	**73,140**	**210,103**	**111,309**

Parent company income statement in summary

Amounts in SEK thousand	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Operating income, etc.			
Net sales	1,252	1,587	5 688
Total income	*1,252*	*1,587*	*5,688*
Operating expenses			
Other external expenses	–2,059	–4,344	–13,286
Personnel expense	–3,380	–13,930	–23,898
Other operating expenses	–5	–9	–14
Total operating expenses	*–5,443*	*–18,283*	*–37,197*
Operating profit/loss	***–4,191***	***–16,696***	***–31,509***
Profit/loss from financial items			
Interest incomes	602	1	1,635
Interest expenses	-2,049	-1	-68
Total financial items	*-1,447*	*0*	*1,567*
Profit/loss after financial items	***–5,638***	***–16,696***	***–29,942***
Tax on profit/loss for the period	–	–	–
Profit/loss for the period	**–5,638**	**–16,696**	**–29,942**

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec
Profit/loss for the period	–5,638	–16,696	–29,942
Other comprehensive income	–	–	–
Comprehensive income for the period	**–5,638**	**–16,696**	**–29,942**

Parent company balance sheet in summary

Amounts in SEK thousand	03/31/2024	03/31/2023	12/31/2023
ASSETS			
Non-current assets			
Financial assets			
Participations in group companies	350,320	350,320	350,320
Total non-current assets	**350,320**	**350,320**	**350,320**
Current assets			
Other receivables	43,047	7,942	7,615
Cash and cash equivalents	49,961	85,909	92,807
Total current assets	**93,008**	**93,851**	**100,422**
TOTAL ASSETS	**443,328**	**444,171**	**450,742**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1,037	1,037	1,037
	1,037	*1,037*	*1,037*
Non-restricted equity			
Share premium reserve	744,314	744,314	744,314
Call option premium in relation to loan facility	2,771	-	2,771
Retained earnings including comprehensive income for the period	−338,014	−319,130	−332,376
	409,072	*425,184*	*414,710*
Total equity	**410,109**	**426,222**	**415,747**
Long-term liabilities			
Long-term interest bearing debt	25,494	-	24,511
Total long-term liabilities	**25,494**	**-**	**24,511**
Current liabilities			
Other liabilities	7,725	17,950	10,484
Total liabilities	**7,725**	**17,950**	**34,995**
TOTAL EQUITY AND LIABILITIES	**443,328**	**444,171**	**450,742**

Key financial ratios for the group

	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec	2022 Jan-Dec	2021 Jan-Dec
Net sales, SEK thousand	-	-	5,678	61,136	207,782
Operating profit/loss, SEK thousand	-37,636	-59,508	-180,765	-113,110	52,576
Profit/loss for the period, SEK thousand	-39,019	-59,556	-177,839	-113,406	51,781
Profit/loss attributable to the parent company's shareholders, SEK thousand	-39,019	-59,556	-177,839	-113,406	51,781
Earnings per share before and after dilution, SEK	-0.75	-1.15	-3.43	-2.19	1.00
R&D costs, SEK thousand	28,937	41,769	151,312	146,178	129,748
R&D costs as a percentage of operating expenses, %	77	70	81	84	84
Cash and cash equivalents at the end of the period, SEK thousand	73,140	210,103	111,309	252,776	401,897
Cash flows from operating activities, SEK thousand	-38,211	-41,498	-164,860	-146,612	128,641
Cash flows for the period, SEK thousand	-38,169	-42,673	-141,467	-149,121	124,888
Equity, SEK thousand	76,745	231,275	115,764	290,831	399,481
Equity attributable to the parent company's shareholders, SEK thousand	76,745	231,275	115,764	290,831	399,481
Equity per share, SEK	1.48	4.46	2.23	5.61	7.72
Equity ratio, %	56	83	65	90	85
Average number of employees	32	31	31	29	22
Average number of employees in R&D	28	27	26	25	20

Of the key financial ratios above, Earnings per share before and after dilution is the only key financial ratio that is mandatory and defined in accordance with IFRS. Of the other key financial ratios, Profit/loss for the period, Cash and cash equivalents at the end of the period, Cash flows from operating activities, Cash flows for the period, and Equity were obtained from a financial statement defined by IFRS. For the derivation of key financial ratios, as well as definitions and justifications for the selected key financial ratios, please refer to the IRLAB Therapeutics AB 2023 Annual Report.

Other information

Accounting principles

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

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

Financial instruments

The group currently has no financial instruments that are valued at fair value, rather all financial assets and liabilities are valued at accrued acquisition value. It is judged that there are no significant differences between fair value and book value regarding the financial assets and liabilities. On the closing date, the carrying amount of financial assets was SEK 73,385k (210,432). The financial assets are mostly liquid funds.

Transactions with related parties

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

Revenue January - March 2024

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	2024 Jan–Mar	2023 Jan–Mar	2023 Jan–Dec
Service revenue	-	-	5,678
Total revenue	**-**	**-**	**5,678**

Segment information

Net sales by geographic market	2024 Jan–Mar	2023 Jan–Mar	2023 Jan–Dec
United Kingdom	-	-	1,458
USA	-	-	4,220
Total revenue	**-**	**-**	**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 February 21, 2023, the then CEO was dismissed and replaced by the then chairman of the board, Gunnar Olsson. Olsson is CEO with a short notice period and no special compensation upon termination of the employment. A process to replace him is ongoing.

Employees

During the quarter, work corresponding to 32 (31) full-time equivalents was performed. This work has been distributed among 36 (34) people.

Annual General Meeting

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

Sustainability

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

Events during the period

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

Events after the period

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.

Review by the auditors

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

Board's assurance

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

Gothenburg, May 8, 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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