IRLAB

Q3.2023
Interim report
January – September 2023

MALIN EDLING, works with bioanalysis to improve understanding of how our drug candidates are handled by the body.

"We have secured the full ownership rights to mesdopetam during the quarter and are now planning for an end-of-Phase 2 meeting with the FDA."

GUNNAR OLSSON, CEO

Interim report January – September 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 third quarter

- In July, the Data Safety Monitoring Board (DSMB) unanimously recommended to continue the ongoing Phase IIb study of pirepemat in accordance with the approved study protocol following a planned review of the first 25 patients having completed the study.
- The full ownership of the now Phase III-ready mesdopetam project was secured by IRLAB in August. Simultaneously, IRLAB confirmed its intention of continuing with development of mesdopetam to Phase III.
- An in-depth analysis of the Phase IIb study show that mesdopetam has a dose-dependent anti-dyskinetic and anti-parkinsonian effect in combination with a tolerability and safety profile on par with placebo, giving mesdopetam a unique position. The results were presented at the end of August at the MDS Congress in Copenhagen.
- IRLAB has participated at several national investor conferences and has ongoing discussions with national and international investors. Recordings are available on IRLAB's website, irlab.se.

Events after the period

- In October, a collaboration commenced with the US regulatory advisors Clintrex, who lead IRLAB's US regulatory strategy, and ProPharma Group, who has been contracted as IRLAB's regulatory agent in the US. Together, preparations for an end-of-Phase 2 meeting with the FDA where the Phase III program for mesdopetam will be defined are now underway.
- IRLAB held a capital markets day 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 an external opinion leader and a recording is available on IRLAB's website, irlab.se.

Financial summary

SEK thousand	Jul–Sep 2023	Jul–Sep 2022	Jan–Sep 2023	Jan–Sep 2022	Jan–Dec 2022
Net sales	-	16,503	6,870	48,955	61,136
Operating profit	–40,738	–23,924	-145,117	–80,027	-113,110
Earnings per share before and after dilution, SEK	–0.74	–0.46	–2.75	–1.55	-2.19
Cash and cash equivalents	118,814	291,749	118,814	291,749	252,776
Cash flow from operating activities	–36,694	–27,932	–130,989	–104,725	-142,612
Average number of employees	31	28	31	28	29
Share price at the end of period, SEK	7.38	34.50	7.38	34.50	38.30

Presentation for investors and media about Q3 2023

Wednesday October 25, 2023, at kl. 10.00 CEST is the presentation of the Q3 interim report through a digital webcast.
Access via link: https://youtube.com/live/6D1RmKaQ6dc

Financial calendar

Year-end report 2023	February 7, 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 recently conducted a highly appreciated capital markets day where we had the opportunity to convey a deeper understanding of our business, showcase the commercial potential of our development portfolio, and provide an update on the status of our projects. Professor Karl Kieburtz, a thought leader and regulatory expert, outlined the upcoming crucial interactions with the FDA in preparation for mesdopetam's Phase III program. I believe this contained news for many regarding the extent of the requirements for a thorough Briefing Book to address any questions the FDA may pose. You only get one chance, so it is crucial that it is done well and right – I am pleased to have Karl and his competent team guiding us in this endeavor. If you missed our capital markets day, I recommend watching it afterward – a link is available on our website."

GUNNAR OLSSON, CEO

Comments from the CEO

During the third quarter of this year, our development programs continued according to plan and important milestones were achieved. IRLAB continues to make significant progress in developing innovative drugs for Parkinson's and other neurological disorders.

Significant strengthening of our world-leading portfolio in Parkinson's

By utilizing our proprietary and unique research platform - ISP, we have built a world-leading portfolio of drug projects focused on unmet needs in Parkinson's. The portfolio includes completely new treatments based on novel mechanism of actions, that can address the majority of complications and symptoms across all stages of the disease while simultaneously generating value for our shareholders. Following the recent securing of the ownership of mesdopetam, we have further strengthened our position. The portfolio projects now span from preclinical to Phase III readiness. Over the next 1-2 years, we could have up to five drug candidates in clinical development Phase I-III – an impressive and achievable company development.

With the new agreement signed with Ipsen on August 21, where we secured ownership and all rights to the mesdopetam project, our portfolio of drug projects has been further strengthened. The transfer of all data and materials developed by Ipsen, from Ipsen to IRLAB, is ongoing and should be completed by the end of October.

Mesdopetam – a drug candidate with both anti-dyskinetic and anti-Parkinsonian effects

Following the new agreement with Ipsen, we have been able to communicate the results from the completed Phase IIb study with mesdopetam in patients with levodopa-induced dyskinesia. The results can be summarized briefly as follows: mesdopetam demonstrates both dose-dependent anti-dyskinetic and dose-dependent anti-Parkinsonian effects, along with a safety and tolerability profile comparable to placebo. There is currently no other medication with this combination of effects. We have also been able to discuss the results of the Phase I studies conducted by Ipsen, which confirm mesdopetam's predictive pharmacokinetic profile. This allows for the inclusion of a broad population of patients with levodopa-induced dyskinesia in the upcoming Phase III program, which will facilitate the execution of future clinical studies. It will also be reflected in the product label, which is crucial to ensure that treatment can be given to a broad patient group.

Planning for the end-of-Phase 2 meeting with the FDA

We have now partnered with Clintrex and ProPharma, two world-leading US-based regulatory advisory companies. This collaboration serves two purposes: firstly, to compile the necessary documentation for the end-of-Phase 2 meeting (EoP2) with the US FDA, and secondly, to provide support in conducting the EoP2 meeting. We will request an EoP2 meeting as soon as a Briefing Book containing all available information has been compiled. The purpose of the meeting is to define the design of a Phase III program and the path to preparing a marketing authorization application for mesdopetam. Our external clinical experts and regulatory advisors share IRLAB's view that mesdopetam's profile provides the potential for both successful Parkinson's treatment and significant commercial opportunity.

Ongoing Phase IIb study of pirepemat

In the ongoing Phase IIb study of pirepemat, the efficacy, safety, and tolerability of two doses of pirepemat are evaluated in people living with Parkinson's disease in order to identify the optimal dose for Phase III. In mid-July, the first planned DSMB review took place following the first 25 patients having completed the study. The DSMB unanimously recommended the study to continue according to plan.

For the study's execution, we are collaborating with a Contract Research Organization (CRO), which manages the various aspects of the study based on our study protocol. The recruitment rate has been slower than planned during the fall, and our assessment is that patient recruitment will need to continue into the first quarter of 2024. Together with our advisors, we are evaluating measures to ensure that top-line results can still be reported in the second quarter of 2024, consistent with previous communication.

Preclinical programs with potential to address major medical needs

Our drug candidates in the preclinical development phase are progressing according to plans to be made ready for entering into clinical Phase I trials. IRL757 aims to treat apathy in Parkinson's and other neurological disorders, and IRL942 targets the improvement of cognitive impairment in people with Parkinson's and other neurological disorders. Our discussions with MSRD, a company within the Otsuka family, around a potential collaboration for these two projects are ongoing.

Our IRL1117 project has the objective to develop a treatment for the hallmark symptoms of Parkinson's (tremors, stiffness, and bradykinesia) without causing the troublesome complications associated with current mainstay levodopa-based treatments. A drug with this profile has the potential to replace levodopa and therefore bring a paradigm shift to the treatment for Parkinson's.

Forward-looking

In the beginning of 2023, we defined priorities for the year. After the mesdopetam project transfer to IRLAB, we have now reviewed our internal priorities to optimally support our product development activities. This includes evaluations of the best way to finance the further development of our assets - through licensing/collabora-tion agreements and/or through the capital market.

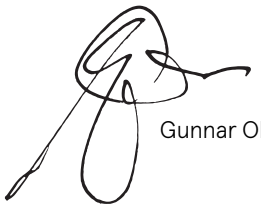
Our most important priorities are:

- Mesdopetam: Rapid transfer of the project to IRLAB; conduct the EoP2 meeting with the FDA; assess options and secure funding for Phase III activities.
- Pirepemat: Complete the ongoing Phase IIb study.
- Preclinical projects: Execute select activities aimed at supporting the establishment of partnerships for development.
- Evaluate possible avenues for financing the company's future activities.

To secure financing moving forward, a comprehensive effort is being carried out in Business Development (BD) to explore partnership opportunities and, thereby, funding. Ongoing discussions are underway regarding a new licensing agreement for mesdopetam and a research collaboration involving IRL757 and/or IRL942. Simultaneously, discussions with financial market stakeholders are taking place. These activities are aimed to secure funding for activities related to our projects after the first half of 2024. We believe that the strengthening of our project portfolio with the Phase III-ready mesdopetam project has enhanced our potential to establish collaborations and secure funding for our projects. We continue to monitor our financial stability diligently and assess our opportunities continuously.

I am looking forward to continuing the development of the company and the exciting portfolio of drug candidates together with our employees and the Board. We recently held an appreciated capital markets day where we provided a comprehensive overview of the company. If you missed it, the recording is available on our website.

Finally, I would like to express my gratitude to all shareholders for the support and trust you have bestowed upon us.



Gunnar Olsson, CEO, IRLAB

Our strategic priorities:

1. Ensure 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. Drive the development of IRL757, IRL942 and IRL1117 towards clinical Phase I studies.
5. Continue to document the opportunity for our drug candidates and pipline, 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 well-defined, 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 biologi & 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

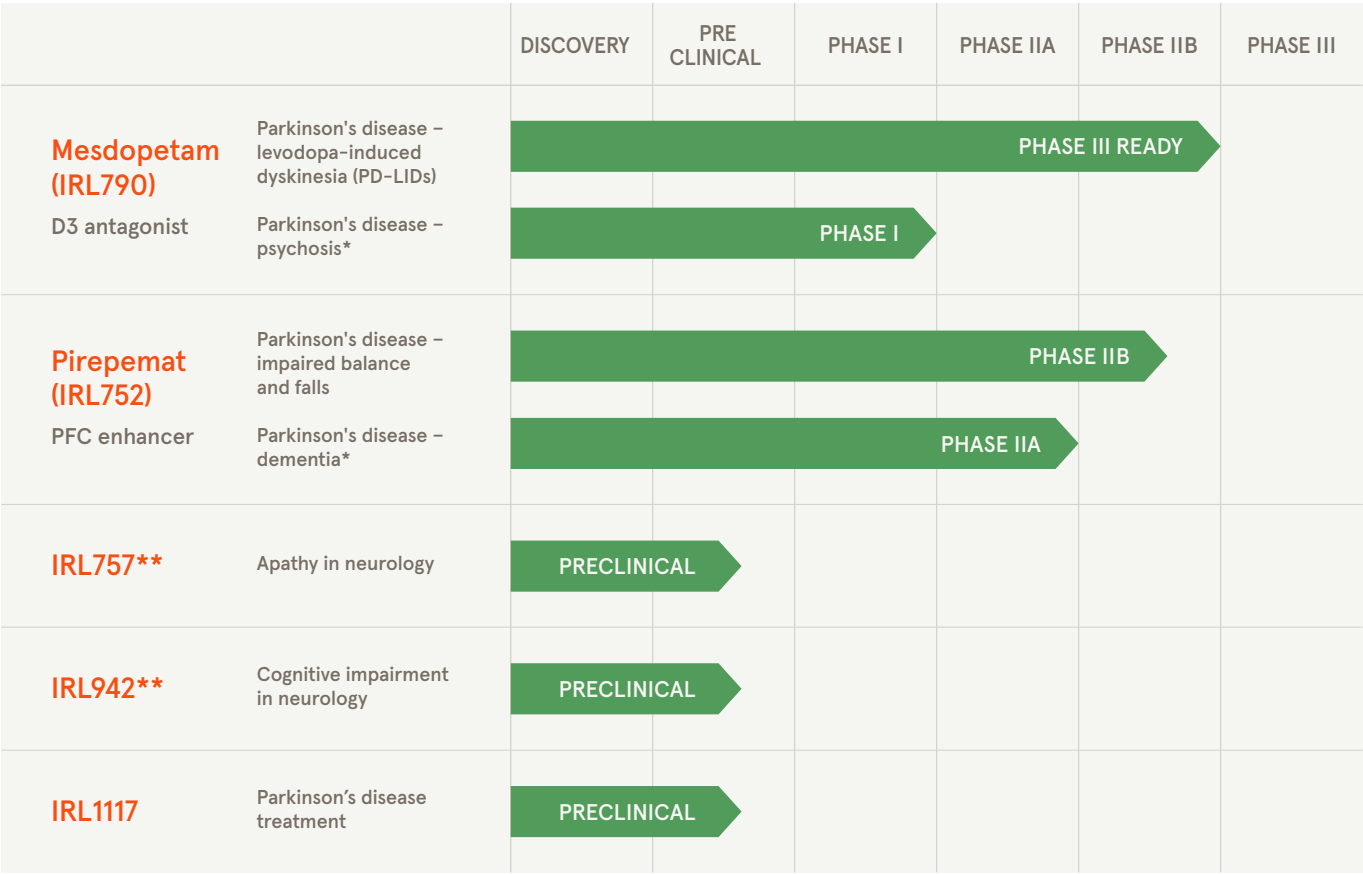
IRLAB is an organization with an experienced team. IRLAB is listed on the Nasdaq Stockholm main market (IRLAB A).

Broad & solid portfolio

IRLAB's portfolio comprises five unique drug candidates, each with blockbuster potential, and 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.

** A collaboration with MSRD, an Otsuka company, is under evaluation.

R&D update

"We are now working intensively on preparing the mesdopetam project for Phase III in the best possible way. The collaboration with Ipsen for the transfer of the project has worked well and we have started preparing the Briefing Book for the application for an end-of-Phase 2 meeting with the FDA. In parallel, the pirepemat study is running in Europe and the development in our preclinical projects are proceeding towards Phase I."

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

The successful Phase Ib and Phase IIa studies 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 recently completed Phase IIb study with 156 patients 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

IRLAB's preparations for an end-of-Phase 2 meeting with the FDA to define mesdopetam's Phase III program in PD-LIDs is in progress in collaboration with clinical and regulatory experts. A date for the end-of-Phase 2 meeting will be requested once the required Briefing Book is collated.

Pirepemat

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

Falls are a significant consequence of Parkinson's that has severe complications, such as fractures, impaired mobility and a reduced quality of life. 45 percent of all people living with Parkinson's fall recurrently, which approximates to 2.6 million perople suffering from a significantly reduced quality of life also due to fear of falling. There are no available treatments at present, despite the great medical need. The societal burden due to falls is also significant with the cost for hospital treatment of a fall injury in the US estimated to be 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 assessments and further safety and tolerability evaluations.

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

The ongoing study is recruiting patients at the planned sites in France, Germany, the Netherlands, Poland, Spain and Sweden. The recruitment rate has been slower than planned during the fall, and the company's assessment is that patient recruitment will need to continue into the first quarter of 2024. Together with advisors, measures are being evaluated to ensure that top-line results can still be reported in the second quarter of 2024, consistent with previous communication.

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

IRL757

IRL757 is in preclinical development and aims at a once-daily oral tablet 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

All preparatory Phase I toxicology and safety studies neccessary for the submission to a regulatory authority are completed. GMP manufacturing of drug substance (API) and development of Drug Product is completed.

Preparatory work and compilation of the documentation for the application to conduct a Phase I study is ongoing and is expected to be completed by year-end 2023.

MSRD, a part of the Otsuka family of companies, and IRLAB are evaluating possibility of collaboration regarding early clinical development of the drug candidate IRL757.

IRL942

Drug candidate IRL942 is targeting a once-daily oral tablet 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 globally.

Current status

Development proceeds according to the set plan for preclinical development, toxicology, safety studies and GMP manufacturing of API. Development of Drug Product has started and IRL942 is expected to be Phase I ready during H1 2024.

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

IRL1117

Drug candidate IRL1117 will be developed as a once-daily oral treatment for the hallmark symptoms of Parkinson's without inducing 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 2023/2024. In parallell, activities related to substance manufacturing and planning for preclinical regulatory studies neccessary 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 – September 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 September 30, the total costs for research and development were SEK 121,658k (109,381), corresponding to 80 percent (85) 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 – September 30, 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 – September 30, 2023 was SEK –142,854k (-80,241). Earnings per share were –2.75 SEK (-1.55). The group's revenue during the period was SEK 6,912k (48,960).

The personnel costs during the period was SEK 42,220k (29,813). 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 third quarter, the company has not incurred any income for other services rendered to Ipsen (SEK 13,971k). During the third quarter 2023, the group's operating expenses were SEK 152,029k (128,987).

Financing and cash flow

Cash flow from operating activites were during the period January 1 to September 30, 2023, SEK –130,989k (-104,725) and during the third quarter SEK –36,694k (-27,932). Cash and cash equivalents were SEK 118,814k (291 749) on September 30, 2023.

On September 30, 2023, equity was SEK 147,977k (323,996) and the equity ratio was 79 percent (88).

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. Both the Board and the CEO assess that, given the company's current financial position and the current conditions on the capital market, material uncertainty (related to events or conditions) which may cast significant doubt on the entity's ability to continue as a going concern after the first half of 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. This applies primarily to creating the conditions for and entering a new licensing agreement regarding mesdopetam and secondarily a research collaboration regarding IRL757 and/or IRL942 as well as various forms of share issues, but also license agreements with pirepemat or IRL1117.

Investments

Investments in tangible assets for the period January 1 – September 30, 2023 were SEK 293k (2,662).

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 Jul–Sep	2022 Jul–Sep	2023 Jan–Sep	2022 Jan–Sep	2022 Jan–Dec
Operating income					
Net revenue	-	16,503	6,870	48,955	61,136
Other operating income	364	-	42	5	141
Total income	*364*	*16,503*	*6,912*	*48,960*	*61,277*
Operating expenses					
Other external costs	-30,091	-28,801	-105,957	-95,475	-125,906
Personnel costs	-9,931	-10,395	-42,220	-29,813	-42,481
Depreciation of intangible and tangible fixed assets	-1,080	-1,012	-3,245	-2,914	-4,779
Other operating cost	–	-219	-607	-785	-1,220
Total operating expenses	*-41,102*	*-40,427*	*-152,029*	*-128,987*	*-174,387*
Operating result	**-40,738**	**-23,924**	**-145,117**	**-80,027**	**-113,110**
Result from financial items					
Financial income	2,372	0	2,379	-	0
Financial costs	-27	-33	-116	-214	-297
Total financial items	*2,345*	*-33*	*2,263*	*-214*	*-297*
Result after financial items	**-38,393**	**-23,957**	**-142,854**	**-80,241**	**-113,406**
Tax on income	-	-	-	-	-
Result for the period	**-38,393**	**-23,957**	**-142,854**	**-80,241**	**-113,406**
Earnings per share before and after dilution (SEK)	-0.74	-0,46	-2,75	-1,55	-2,19
Average number of shares, before and after dilution	51,866,406	51,868,406	51,868,406	51,780,494	51,831,913
Number of shares at end of period	51,866,406	51,868,406	51,868,406	51,868,406	51,866,406

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

Consolidated statement of comprehensive income in summary

Amounts in SEK thousand	2023 Jul–Sep	2022 Jul–Sep	2023 Jan–Sep	2022 Jan–Sep	2022 Jan–Dec
Result for the period	–38,393	–23,957	–142,854	–80,241	–113,406
Other comprehensive income	-	-	-	-	-
Total result for the period	**–38,393**	**–23,957**	**–142,854**	**–80,241**	**–113,406**

Consolidated statement of financial position in summary

Amounts in SEK thousand	09/30/2023	09/30/2022	12/31/2022
ASSETS			
Fixed assets			
Intangible fixed assets	46,862	47,723	46,862
Tangible fixed assets	5,057	8,290	8,009
Total fixed assets	**51,919**	**56,013**	**54,871**
Current assets			
Short-term receivables	16,182	21,010	15,908
Cash and cash equivalents	118,814	291,749	252,776
Total current assets	**134,996**	**312,759**	**268,684**
TOTAL ASSETS	**186,915**	**368,772**	**323,555**
EQUITY AND LIABILITIES			
Equity			
Share capital	1,037	1,037	1,037
Other contributed capital	690,204	690,204	690,204
Retained earnings incl. results for the period	-543,264	-367,245	-400,411
Total equity	**147,977**	**323,996**	**290,831**
Long-term liabilities			
Leasing debt	182	1,191	381
Total long-term liabilities	**182**	**1,191**	**381**
Short-term liabilities			
Leasing debt	1,113	3,148	3,595
Other liabilities	37,642	40,437	28,748
Total short-term liabilities	**38,755**	**43,585**	**32,343**
TOTAL EQUITY AND LIABILITIES	**186,915**	**368,772**	**323,555**

Consolidated statement of changes in equity in summary

Amounts in SEK thousand	Share capital	Other capital contributed equity	Retained earnings incl. total result for the period	Total equity
Equity January 1, 2022	**1,035**	**685,450**	**–287,005**	**399,481**
Total result for the period			–80,241	–80,241
Transactions with owners in their capacity as owners:				
Rights issue				
Issue costs	2	4,754		4,757
Equity September 30, 2022	**1,037**	**690,204**	**-367,245**	**323,996**
Total result for the period			–33,165	–33,165
Equity December, 2022	**1,037**	**690,204**	**–400,411**	**290,831**
Equity January 1, 2023	**1,037**	**690,204**	**–400,411**	**290,831**
Total result for the period			-142,854	-142,854
Equity September 30, 2023	**1,037**	**690,204**	**-543,264**	**147,977**

Consolidated statement of cash flows in summary

Amounts in SEK thousand	2023 Jul–Sep	2022 Jul–Sep	2023 Jan–Sep	2022 Jan–Sep	2022 Jan–Dec
Operating activities					
Operating result	–40,738	–23,924	–145,117	–80,027	–113,110
Adjustment for items not included in the cash flow	1,080	1,012	3,245	2,914	4,779
Interest	2,372	-	2,379	-	0
Paid interest	–26	–31	–116	–214	–297
Cash flow from operating activities before changes in working capital	**–37,312**	**–22,944**	**–139,608**	**–77,327**	**–108,627**
Cash flow from changes in working capital					
Change in operating receivables	4,393	2,280	-274	-1,468	3,634
Change in operating liabilities	-3,775	-7,269	8,893	-25,930	-37,619
Cash flow from operating activities	**-36,694**	**–27,932**	**–130,989**	**–104,725**	**–142,612**
Investment activities					
Acquisition of intangible fixed assets	-	-500	-	-500	-500
Acquisition of tangible fixed assets	-	–1,671	–293	–2,662	–2,876
Cash flow from investment activities	**-**	**–2,171**	**–293**	**–3,162**	**–3,376**
Financing activities					
Amortization of financial liabilities, leasing debt	–904	–763	–2,680	–2,262	–3,134
Cash flow from financing activities	**–904**	**-763**	**-2,680**	**- 2,262**	**-3,134**
Cash flow for the period	**–37,599**	**–30,866**	**–133,962**	**–110,148**	**–149,121**
Cash and cash equivalents at the start of the period	156,413	322,615	252,776	401,897	401,897
Cash and cash equivalents at the end of the period	**118,814**	**291,749**	**118,814**	**291,749**	**252,776**

Parent company income statement in summary

Amounts in SEK thousand	2023 Jul–Sep	2022 Jul–Sep	2023 Jan–Sep	2022 Jan–Sep	2022 Jan–Dec
Operating income					
Net revenue	1,362	1,205	4,184	2,976	4,531
Total income	*1,362*	*1,205*	*4,184*	*2,976*	*4,531*
Operating expenses					
Other external costs	–2,525	–2,509	–10,477	–8,784	–12,187
Personnel costs	–3,924	–4,126	–21,067	–9,942	–14,402
Other operating expences	-5	-	-22	-	-25
Total operating expenses	*–6,454*	*–6,635*	*–31,567*	*–18,726*	–26,614
Operating result	***–5,092***	***–5,429***	***–27,383***	***–15,750***	***–22,083***
Result from financial items					
Interest income	1,116	-	1,118	-	-
Interest costs	-	-	-1	0	–7
Total financial items	*1,116*	-	*1,117*	*0*	*–7*
Result after financial items	***–3,976***	***–5,429***	***–26,266***	***–15,750***	***–22,090***
Tax on the period's result	-	-	-	-	-
Result for the period	**–3,976**	**–5,429**	**–26,266**	**–15,750**	**–22,090**

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2023 Jul–Sep	2022 Jul–Sep	2023 Jan–Sep	2022 Jan–Sep	2022 Jan–Dec
Profit/loss for the period	–3,976	–5,429	–26,266	–15,750	–22,090
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	***–3,976***	***–5,429***	***–26,266***	***–15,750***	***–22,090***

Parent company balance sheet in summary

Amounts in SEK thousand	09/30/2023	09/30/2022	12/31/2022
ASSETS			
Fixed assets			
Financial fixed assets			
Shares in group companies	350,320	350,320	350,320
Total fixed assets	**350,320**	**350,320**	**350,320**
Current assets			
Other receivables	8,649	8,649	8,535
Cash and cash equivalents	70,514	96,622	92,814
Total current assets	**79,163**	**105,271**	**101,349**
TOTAL ASSETS	**429,483**	**455,591**	**451,669**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1,037	1,037	1,037
	1,037	*1,037*	*1,037*
Unrestricted equity			
Share premium fund	744,314	744,314	744,314
Retained earnings including total result for the period	–328,700	-296,095	–302,434
Total Unrestricted equity	*415,614*	*448,219*	*441,880*
Total equity	**416,651**	**449,257**	**442,917**
Short-term liabilities			
Other liabilities	12,832	6,335	8,752
Total liabilities	**12,832**	**6,335**	**8,752**
TOTAL EQUITY AND LIABILITIES	**429,483**	**455,591**	**451,669**

Key financial ratios for the group

	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec	2021 Jan-Dec	2020 Jan-Dec
Net sales	6,870	48,955	61,136	207,782	-
Operating result, TSEK	-145,117	-80,027	-113,110	52,576	-91,458
Result for the period, TSEK	-142,854	-80,241	-113,406	51,781	-91,653
Earnings per share before and after dilution, SEK	-2.75	-1.55	-2.19	1.00	-1.92
R&D costs, TSEK	121,658	109,381	146,178	129,748	75,989
R&D costs as a percentage of operating costs, %	80	85	84	84	83
Cash and cash equivalents at the end of the period, TSEK	118,814	291,749	252,776	401,897	277,009
Cash flow from operating activities, TSEK	-130,989	-104,725	-142,612	128,641	-89,214
Cash flow for the period, TSEK	-133,962	-110,148	-149,121	124,888	166,482
Equity, TSEK	147,977	323,996	290,831	399,481	347,880
Equity per share, SEK	2.85	6.25	5.61	7.72	6.72
Equity ratio, %	79	88	90	85	94
Average number of employees	31	28	29	22	18
Average number of employees in R&D	27	25	25	20	17

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

Other information

Accounting principles

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

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

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

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 126,474k (291,464).

Transactions with related parties

IRLAB has during the period January - September 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 - September 2023

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

Net sales by revenue category	2023 Jan–Sep	2022 Jan–Sep	2022 Jan–Dec
Service revenue	6,870	48,955	61,136
Total revenue	**6,870**	**48,955**	**61,136**

Segment information

Net sales by geographic market	2023 Jan–Sep	2022 Jan–Sep	2022 Jan–Dec
United Kingdom	2,650	48,955	61,136
US	4,220	-	-
Total revenue	**6,870**	**48,955**	**61,136**

All invoicing was in Euro (EUR) or American dollars (USD). Revenue is recognized in Swedish krona (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 current appointment that extends through December 31, 2023. The agreement has a short notice period and no special compensation upon termination of the employment. A process to replace him with a new CEO was initiated during the spring of 2023 and is still ongoing.

Employees

The average number of employees in the group from January – September was 31 (28). At the end of the period, the number of full-time positions was 31 (28), distributed over 34 (33) people.

The number of full-time positions, including long-term contracted consultants, was 33 (32) at the end of the period, distributed over 38 (37) 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 been reviewed by the company's auditors.

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

Gothenburg, October 25, 2023

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

Auditor's report

IRLAB Therapeutics AB (publ.) reg. no. 556931-4692

Introduction

We have reviewed the condensed interim financial information interim report of IRLAB Therapeutics AB as of 30 September 2023 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Material uncertainty related to going concern

Without affecting our conclusion above, we would like to draw the reader's attention to the information provided in the interim report under the section "Financing and cash flow". It states that the company is dependent on liquidity injection to be able to continue its operations. This matter gives rise to material uncertainty which may cast significant doubt on the entity's ability to continue as a going concern. We have not modified our conclusion in respect of that matter.

Gothenburg, October 25, 2023

Öhrlings PricewaterhouseCoopers AB

ULRIKA RAMSVIK
Authorized Public Accountant

SOPHIE DAMBORG
Authorized Public Accountant

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 preclinical programs IRL942, IRL757, and IRL1117 towards Phase I studies. The pipeline is driven by IRLAB's proprietary systems biology-based Integrative Screening Process (ISP) research platform.

Contact information

FOR FURTHER INFORMATION, PLEASE CONTACT

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