IRLAB

Q4.2022

Year-end report January–December 2022

Transforming life for people with Parkinson's and other CNS disorders

Year-end report January – December 2022

Summary of the fourth quarter

- The final patient completed the treatment period and follow-up visit ("Last Patient Last Visit") in the Phase IIb study of mesdopetam in levodopa-induced dyskinesia in people with Parkinson's disease (PD-LIDs) in mid-December.
- IRLAB shared new preclinical data providing insight into the mechanisms underlying antipsychotic and antidyskinetic efficacy of drug candidate mesdopetam (IRL790) in PD-Psychosis and PD-LIDs. The research was conducted by an independent academic research group led by Prof. Per Petersson at Lund and Umeå University and presented at the premier congress Neuroscience 2022.
- The nomination committee was appointed ahead of the annual general meeting (AGM) 2023 and comprises Hans-Peter Ostler, Anders Vedin, Clas Sonesson, and Gunnar Olsson, Chairperson of IRLAB Therapeutics AB.
- IRLAB presented at several national and international investor events to provide a business update of the company's progress e.g. at DNB Nordics Healthcare Conference, LSX Inve$tival Showcase, Redeye Life Science Day and SEB Annual Healthcare Summit. Public recordings are available on the website, irlab.se.

Events after the period

- IRLAB was invited to participate at the 6th Neuroscience Innovation Forum hosted by Sachs Associates in early January. The event was held in connection to the Annual J.P. Morgan Healthcare Conference, in San Francisco, US.
- Drug candidate IRL1117 was nominated from the P003 research project in early January. IRL1117 will be developed as a once-daily oral treatment for the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay anti-Parkinson's levodopa treatments.
- The top-line results from the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias (PD-LIDs) were announced in mid-January. Mesdopetam demonstrated dose dependent anti-dyskinetic effects in several dyskinetic assessment scales with an adverse event and tolerability profile similar to placebo, even though the study did not s tatistically meet the primary efficacy endpoint of "good ON"-time. Additional analysis of the full data is currently ongoing.
- In mid-February, the company announced an update to the portfolio development milestones following an assessment of the operational priorities for 2023.
- On February 20, IRLAB's CEO Richard Godfrey was replaced by Gunnar Olsson who was appointed as interim CEO. Carola Lemne, former Vice Chair, took over the role as Chair of the Board from Gunnar Olsson. The process to recruit a permanent CEO is initiated immediately.
- As the new Chair of the Board of IRLAB, Carola Lemne takes over the membership in the nomination committee after Gunnar Olsson's resignation as Chair of the Board.
- An van Es-Johansson has elected to leave her assignment as a Board member at IRLAB.

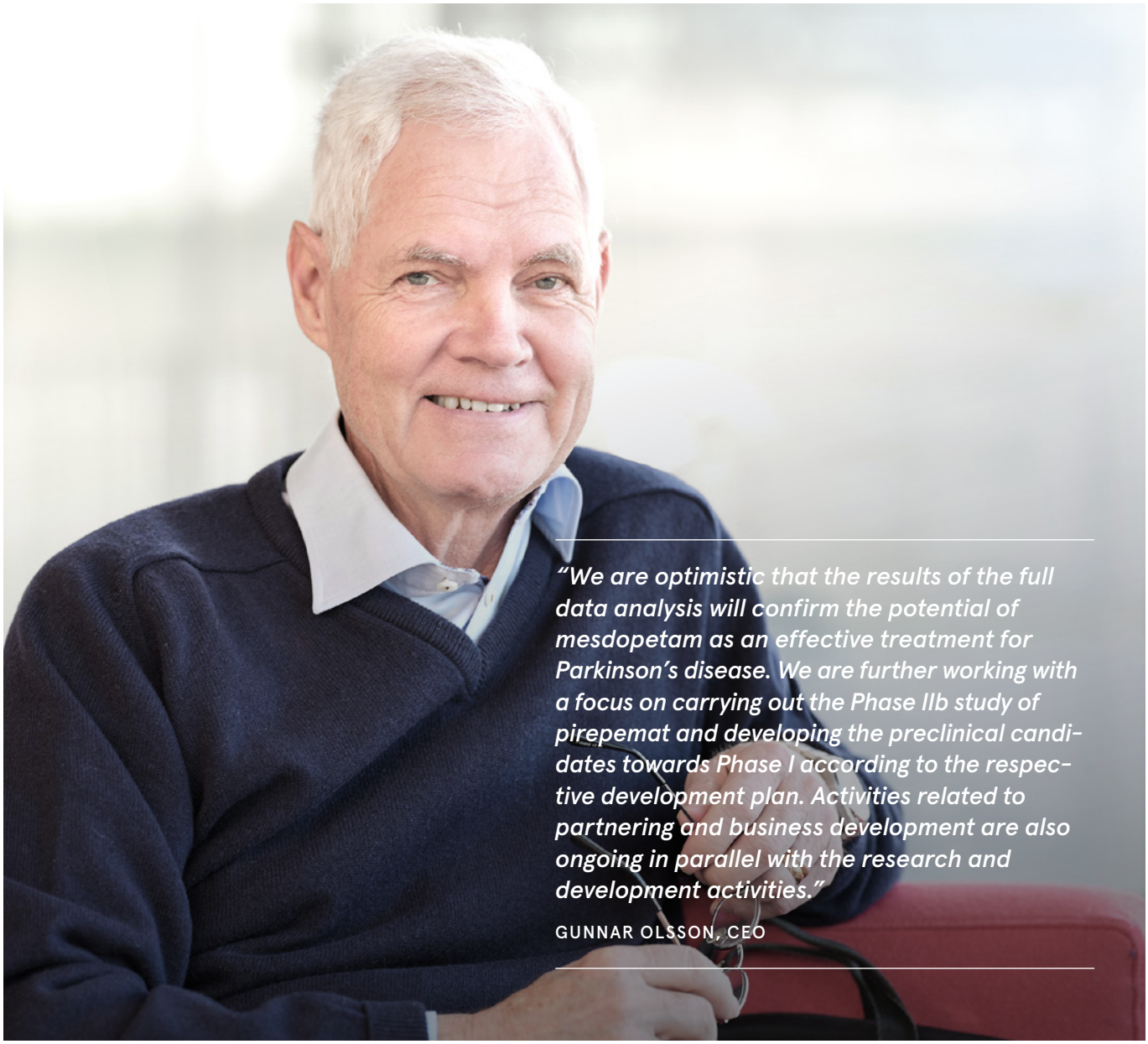
Financial highlights in the fourth quarter

- Net sales recorded: SEK 12.2m (SEK 12.1m)
- Total operating expenses: SEK 45.8m (SEK 35.0m)
- The operating result: SEK –33.1m (SEK -23.1m)
- Cash flow from operations: SEK –37.9m (SEK -28.4m)
- Cash and cash equivalents at the end of the period: SEK 252.8m (SEK 401.9m)
- The total number of registered shares: 51,868,406 (51,748,406)

Figures in brackets = same period 2021, unless otherwise stated

Financial summary

SEK thousand	Oct–Dec 2022	Oct–Dec 2021	Jan–Dec 2022	Jan–Dec 2021
Net sales	12,181	12,141	61,136	207 782
Operating result	-33,083	-22,601	-113,110	52 576
Profit/loss for the period	-33,166	-23,117	-113,406	51 781
Earnings per share before and after dilution, SEK	-0.64	-0.45	-2.19	1.00
Cash and cash equivalents	252,776	401,897	252,776	401 897
Cash flow from operating activities	-37,887	-28,388	-142,612	128 641
Equity per share at end of period, SEK	5.61	7.72	5.61	7.72
Equity ratio at end of period, %	90	85	90	85
Average number of employees	30	22	29	22
– of which in R&D	27	20	25	20
Number of registered shares at end of period	51 868 406	51 748 406	51 868 406	51 748 406
Share price at the end of period, SEK	38.30	44.00	38.30	44.00



Comments from the CEO

As we close on 2022 and reflect on the company's development during the year, we are pleased to report continued significant progress in our broad portfolio of innovative drug candidates. Each with the potential to address the great unmet needs of people living with Parkinson's disease. The Phase IIb data of mesdopetam, which were presented after the end of the reporting period, continues to be analyzed in detail. Although the study did not meet its primary endpoint, several important objectives were achieved and we remain optimistic about the drug candidate's potential to improve the life situation of millions people with Parkinson's around the world.

Completion of the Phase IIb study of mesdopetam – an important milestone

The recently reported top-line data from our Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias shows we did not meet statistical significance of the primary endpoint in the study – "good ON"-time – compared to placebo. We are, however, encouraged that the established efficacy measurement for anti-dyskinetic effect taking both objective physician ratings and patient ratings into account, UDysRS, demonstrated statistically significant and dose dependent effects by mesdopetam, without impairing normal motor function. We also noted an apparent reduction in OFF-time. The Phase IIb study further confirmed the favorable safety and tolerability profile of mesdopetam – in line with placebo treatment. The study also achieved its objective to establish the best dose to be used in further clinical studies. We continue with detailed analyses of the data from the study in collaboration with our partner Ipsen.

As with all clinical development, this Phase IIb study also had objectives to provide additional data to increase confidence in the safety and tolerability of mesdopetam in people with Parkinson's and also to inform on the preferred dose to be used in

further clinical studies. We have recently received the full data set from the trial and continue with thorough detailed analysis in collaboration with our partner Ipsen.

In recent weeks, we have had the opportunity to discuss these top-line results with key opinion leaders, industry executives, and expert regulatory advisors. Despite the missed primary efficacy endpoint, they are equally hopeful of the clinical efficacy observed and the potential for mesdopetam to be an effective treatment of Parkinson's disease.

We now have a substantial body of evidence for mesdopetam's potential supported by results from clinical Phase Ia, Phase Ib, Phase IIa, and Phase IIb studies where each study has achieved its respective purpose in the different steps of the drug development process. Overall, this clinical package provides a strong basis for the design of the continued clinical development program toward marketing registration of a new drug.

Progress of pirepemat in Phase IIb

Pirepemat, our second candidate in Phase IIb, is being developed to improve balance and reduce falls for people living with Parkinson's. This is one of the greatest medical needs in Parkinson's. A reduced falls frequency results in fewer fall-related injuries, improved quality of life, decreased stress for caregivers as well as decreased costs for the healthcare system. The Phase IIb study is recruiting people with late-stage Parkinson's with mild cognitive impairment and at least two falls during the 6-week screening. The study objective is to find the optimal dose and to evaluate pirepemat's dose-dependent efficacy on falls, cognitive function, and psychiatric symptoms. Additionally, the study will further add to the knowledge of the drug candidate's safety and tolerability profile. This study is currently active at 28 out of 39 planned sites in five European countries. In parallell, we continue with the preclinical work recommended by the FDA and believe this will be finalized in the second quarter 2023.

The initial patient recruitment was a little slower than the estimated timeline and we have taken steps to address this. We estimate that the study will be fully recruited by the year-end 2023 and that top-line results will be reported in H1 2024.

Expanding preclinical portfolio

We continue to make excellent and exciting progress with the P003 project with the designation of IRL1117 being identified as our lead compound, which was announced in early January. IRL1117 is being developed as a completely novel, orally administered once-daily Parkinson's treatment, without the troublesome complications of current standard-of-care levodopa treatment or treatments in the development pipeline.

The company's three preclinical programs; IRL942, IRL757, and IRL1117 are proceeding according to their respective updated preclinical development, toxicology and GMP manufacturing plans. IRL942, in development for cognitive decline in neurological disorders, is expected to be Phase I ready during H1 2024. IRL757, in development for apathy in neurological disorders, is expected to be Phase I ready by year-end 2023. In the IRL1117 program, we continue the work in preparation for Phase I enabling toxicology and manufacturing activities that is expetced to be initiated in 2024.

Visibility and conference participation

In January, we attended the 6th Annual Neuroscience Innovation Forum in San Francisco USA, where we participated in panel discussions regarding 'New Approaches to Parkinson's and Movement Disorders'. In addition, we also presented IRLAB's research platform, portfolio and outlook.

We will have a significant presence at the forthcoming scientific congress International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders, AD/PD 2023, in our hometown Gothenburg on March 28-April 1. The company will participate with three poster presentations and an oral presentation related to our preclinical candidates and ISP. We are also organizing a symposium in the afternoon of March 31 focusing on living with Parkinson's, disease journey, diagnosis, biomarkers, treatments and emerging therapeutics, and the impact on family and society.

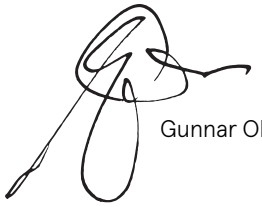
We also look forward to present more comprehensive data and analyses of the Phase IIb trial of mesdeoptam at forthcoming scientific and medical congresses during spring.

Forward-looking

We will complete the full analysis of the data from the Phase IIb study in collaboration with our partner Ipsen, and we are optimistic that the results will confirm the potential of mesdopetam as an effective treatment for Parkinson's disease. We further work according to the outlined company's strategic priorities for 2023 with a focus on carrying out the Phase IIb study of pirepemat and developing the preclinical candidates towards Phase I according to the respective development plan. Activities related to partnering and business development are also ongoing in parallel with the research and development activities.

The cash flow for the fourth quarter of 2022 was SEK −37.9 million and the cash balance at the end of the quarter amounted to 252.8 million crowns. This, along with rapid progress in our broad project portfolio of potentially groundbreaking drugs, provides a solid basis for our efforts to improve treatment options for people living with Parkinson's disease.

Following the recent departure of Richard Godfrey, I am grateful to have been entrusted to lead the company in close cooperation with the company management. I would like to conclude by thanking Richard for his contribution during his time at IRLAB. I look forward to updating you regularly about the further development of IRLAB and our drug development projects.



Gunnar Olsson, CEO, IRLAB

Overview and strategic priorities

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 the various stages of Parkinson's as they worsen over time throughout the patient's journey of neuro-degeneration. Having a full range of effective disease management options for Parkinson's patients is regarded as essential by both the medical and patient communities – and at the same time potentially a blockbuster pharmaceutical business.

Parkinson's is the most common primary neurodegenerative disease after Alzheimer's disease, and the number of affected persons is expected to rise as the world's population is ageing. At present, nearly nine million people have Parkinson's. By 2040, this figure is expected to double.

To meet this challenge, IRLAB has developed a unique, disruptive technology platform called ISP to discover new CNS drug candidates. Leveraging ISP is a major competitive advantage of IRLAB and increases both the pace of drug candidate discovery and probability of success. Based on advanced machine learning techniques, ISP first interrogates our extensive proprietary CNS pharmacology database and that informs our chemists on the optimal molecular design of potential drug candidates with the desired symptom correcting pharmacology or therapeutic effect.

Over the last twenty years, the ISP research platform has gained significant validation by having brought five drug candidates into clinical development, of which three are now in clinical development from Phase IIb-III. Additionally, IRLAB is today developing three drug candidates where Phase I development is expected in the next two years.

IRLAB's most advanced clinical candidate, mesdopetam (IRL790), has successfully gone through Phase I safety, kinetic and tolerability studies; Phase Ib and Phase IIa efficacy proof-of-concept studies; and a Phase IIb trial to establish dose reponse and additional safety data. Our other clinical candidate pirepemat (IRL752) has also successfully gone through Phase I safety and Phase IIa efficacy proof-of-concept studies, and is curretly in a Phase IIb trial. These drug candidates are intended to treat patients with some of the most challenging symptoms associated with Parkinson's – troublesome dyskinesias (PD-LIDs), psychosis (PD-P) and symptoms linked to cognitive decline, such as impaired balance and an increased risk of falls (PD-Falls). In addition, we are developing two preclinical drug candidates to address cognitive impairment (IRL942) and apathy (IRL757), debilitating symptoms of Parkinson's and a great unmet medical need without available treatment options. Our third preclinical candidate IRL1117 is aimed at treating the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay anti-Parkinson's levodopa treatment.

Mesdopetam has already been successfully out-licensed to Ipsen, in addition to revenue, we believe this business partnership also brings further validation of the commercial value of our pipeline. Pirepemat and the preclinical candidates (IRL942, IRL757 and IRL1117) remain wholly-owned unencumbered assets of IRLAB and we retain full rights to develop and / or commercialize these assets. We anticipate that the potential of these drug candidates for the treatment of Parkinson's and other neurological disorders will make them attractive targets for the pharmaceutical industry and in turn yield substantial value for shareholders.

Therefore our strategic priorities are to:

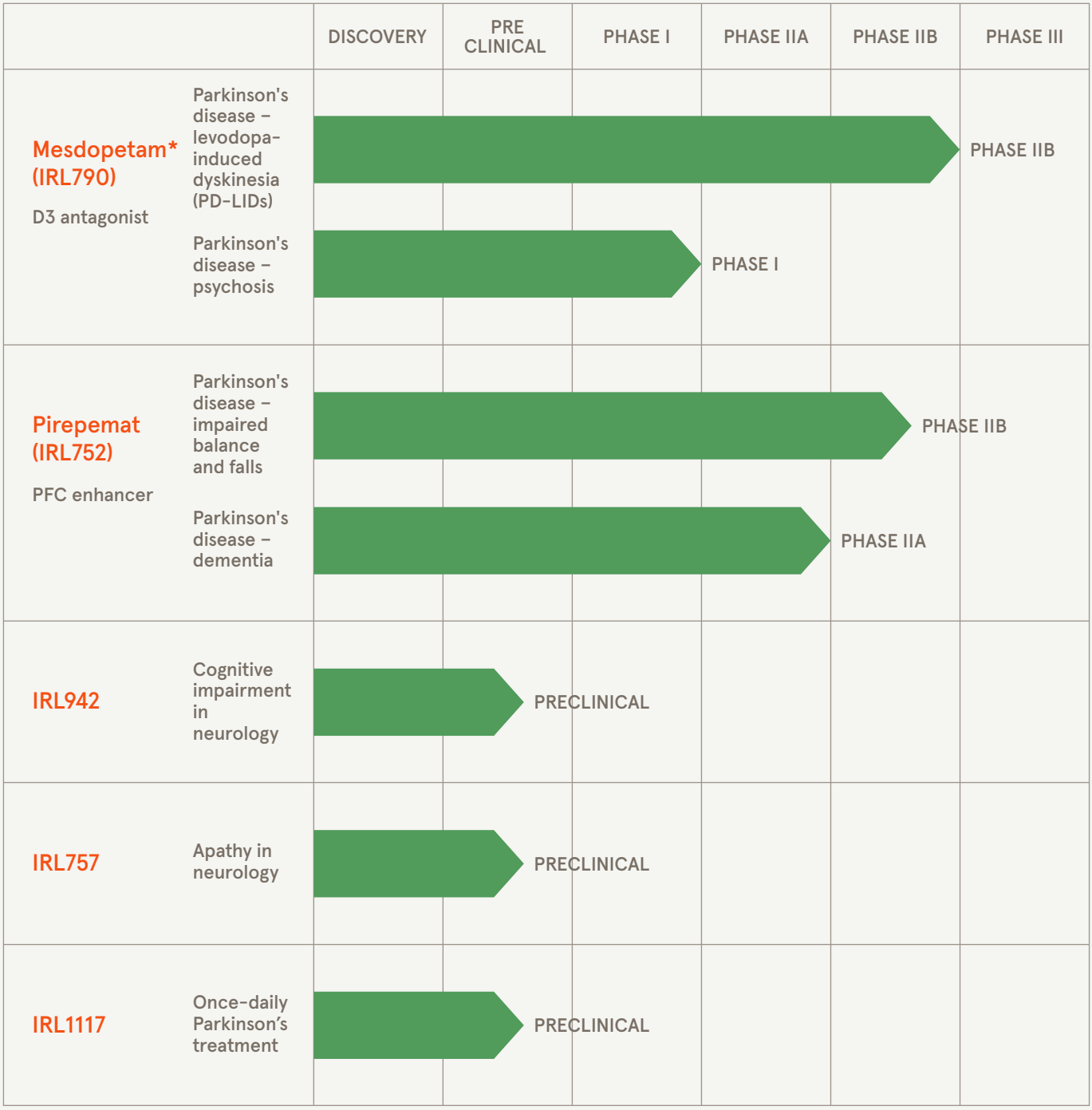
1. Fully describe the potential of mesdopetam to be an effective treatment for people in Parkinson's disease.
2. Publish and present the comprehensive results of the Phase IIb trial of mesdopetam in Parkinson's disease at scientific congresses and in scientific journals during 2023.
3. Pursue the timely completion of the Phase IIb study of pirepemat in PD-Falls.
4. Progress IRL942, IRL757 and IRL1117 towards Phase I clinical studies.

IRLAB A

IRLAB has been listed on Nasdaq Stockholm's main list Mid Cap since 2020.

IRLAB's portfolio

First-in-class drug candidates to treat symptoms of Parkinson's throughout the patient journey



PFC enhancer = noradrenaline and serotonin antagonists In the prefrontal cortex

*Developed in partnership with Ipsen, which has the global development and commercialization rights.

Snapshot of Q4 updates

Mesdopetam

- The top-line results from the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias (PD-LIDs) were announced in mid-January. Mesdopetam demonstrated dose dependent anti-dyskinetic effects in several dyskinetic assessment scales with an adverse event and tolerability profile similar to placebo, even though the study did not statistically meet the primary efficacy endpoint of "good ON"-time. Additional analysis of the full data is currently ongoing.
- Preclinical studies combining advanced electrophysiological and behavioral recordings, aiming to provide a deeper mechanistic understanding of the effects of mesdopetam, on the level of brain activity patterns, mental and motor behavior have been published as abstracts by the Society for Neuroscience in November 2022.

Pirepemat

- The ongoing study is active at 28 of 39 planned study sites at present, all sites are expected to be activated by Q2 2023. Patient recruitment and randomization is expected to be completed by the year-end 2023 and top-line results expected in H1 2024.

IRL942

- Development proceeds according to the preclinical development, toxicology and GMP manufacturing plan. IRL942 is expected to Phase I ready during H1 2024.

IRL757

- Development proceeds according to the preclinical development, toxicology and GMP manufacturing plan. IRL757 is expected to Phase I ready by year-end 2023.

IRL1117 (P003)

- In January, a drug candidate in the P003 project was nominated for continued development toward clinical studies. The drug candidate, IRL1117, will be developed as a once-daily oral treatment for the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay levodopa-based treatments in Parkinson's. IRL1117 is an orally available and potent dopamine D1 and D2 receptor agonist that has demonstrated rapid onset of action and more than 10 hours of sustained efficacy in preclinical studies, clearly differentiating IRL1117 from current treatments.
- Development proceeds according to the preclinical development, toxicology and GMP manufacturing plan. IRL1117 continues with inhouse activities in preparation for Phase I enabling toxicology and manufacturing activities in 2024.

R&D update

IRLAB's portfolio consists of drug candidates in clinical and preclinical development phases. It is focused on developing novel treatments for people with Parkinson's and other CNS disorders. All drug candidates have been generated in-house by the company's proprietary technology platform, ISP.

Clinical phase

Mesdopetam

Mesdopetam, a dopamine D3 receptor antagonist, is being developed in partnership with Ipsen as a treatment for Parkinson's disease levodopa-induced dyskinesias (PD-LIDs) aiming to improve patient quality of life. PD-LIDs is a severe form of involuntary movements commonly occurring in people with Parkinson's treated with levodopa.

Mesdopetam has wide clinical potential for unmet medical needs in neurology. The drug candidate is intended to treat people with Parkinson's who develop LIDs, which is more than 30 percent of all people living with Parkinson's. In the eight major markets worldwide, this equates to one million affected individuals. 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.

In a 28-day Phase Ib study, mesdopetam was found to be safely administered and tolerable in patients with advanced Parkinson's. In mesdopetam-treated patients, a consistent numeric reduction in dyskinesia assessments scales was observed. In the subsequent 28-day Phase IIa study, mesdopetam demonstrated anti-dyskinetic effects using several dyskinesia assessment scales, although the primary efficacy endpoint, UDysRS was not met.

Thus, the Phase Ib and Phase IIa studies demonstrated a good safety and tolerability profile and proof-of-concept with potential for superior anti-dyskinetic efficacy, compared to current treatment options.

Completed Phase IIb study

The Phase IIb study of mesdopetam investigated the efficacy

and safety of three doses of mesdopetam (2.5, 5.0, and 7.5 mg bid), as compared to placebo, in people with Parkinson's experiencing troublesome dyskinesia caused by their levodopa treatment and supported dose selection for further clinical development.

The top-line results of the study were reported in January 2023 with further analysis of the full data currently ongoing.

The Phase IIb study's primary endpoint, change in daily ON-time without troublesome dyskinesia ("good ON"-time), did not reach statistical significance by mesdopetam compared to placebo. A secondary efficacy endpoint, UDysRS (part 1, 3 and 4, full analysis set), a comprehensive scale measuring ON-phase dyskinesia, showed significant anti-dyskinetic effects by mesdopetam already at four weeks (nominal p-value = 0.045), at eight weeks (nominal p-value = 0.004), continuing for the full twelve-week study period (nominal p-value = 0.026) at the 7.5 mg bid dose. This effect was corroborated by the numerical improvement in scales measuring disability associated with dyskinesia. Further, the daily time spent in OFF showed a dose-dependent pattern and a numerical decrease compared to placebo also favoring the 7.5 mg bid dose. The secondary endpoint MDS-UPDRS part II (motor aspects of experiences of daily living) was unchanged by mesdopetam treatment, which was the desired outcome as it shows that mesdopetam does not impair normal motor function in this study population.

Mesdopetam was shown to be well tolerated and has an acceptable safety profile. The adverse event profile of mesdopetam in the Phase IIb study was similar to placebo. Early withdrawal from the study due to any adverse events occurred in similar proportions in the mesdopetam treatment arms and the placebo arm, indicating good tolerability. Any reported adverse events were 56.9% in mesdopetam-treated subjects compared to 46.2% in placebo. The most common adverse events reported by system organ class (SOC) were nervous

"Our whole portfolio has steadily progressed during 2022 and, particularly so, during the past months. The preclinical and clinical development program for mesdopetam, now through Phase IIb, has shown that we have discovered a tolerable and efficacious potential treatment for people living with Parkinson's, with a novel mechanism of action. We are continuing the analyses of the full study data and look forward to presenting more results during the spring.

In our Phase IIb study of pirepemat, the number of activated sites is steadily increasing and the recruitment pace is expected to increase accordingly with the prognosis of having all study participants enrolled by year-end.

Our preclinical development candidates, IRL757 and IRL942, represent novel strategies to treat apathy and cognitive impairment, symptoms that are prevalent in people with Parkinson's where there are no available treatment alternatives, follow their plans toward Phase I studies in 2023 and 2024, respectively.

In our discovery organization, a full focus is on the P003 program where we recently nominated IRL1117 for further development towards Phase I with the aim to develop a new treatment for the hallmark symptoms of Parkinson's. Overall, we are making big and meaningful progress across our whole R&D portfolio."

NICHOLAS WATERS, EVP AND HEAD OF R&D

system disorders reported by 19.8% of mesdopetam-treated subjects and 23% of placebo-treated subjects. Parkinsonism was reported by 4.3% of mesdopetam-treated subjects and 10.3% of placebo-treated subjects. A small number of subjects treated with mesdopetam (6.9%), compared to 0% placebo, reported decreased mobility during the first month of treatment which was not seen during the second and third months of treatment. There were seven randomized patients reporting Serious Adverse Events (SAEs) of which four were in the mesdopetam treatment arms and three in placebo. One SAE was considered probably related to mesdopetam treatment. There were two deaths not considered related to mesdopetam. In the study, 195 patients were screened, 156 patients were randomized, and 125 patients completed the twelve-week treatment period.

Full disclosure of the detailed results from the Phase IIb trial will be made in abstracts at future scientific congresses and publications in scientific journals.

The study is conducted at 46 study sites in Europe, Israel and in the US. More information can be found on clinicaltrials.gov: NCT04435431, and EudraCT number: 2020-002010-41.

Preclinical studies

The pharmacological profile of mesdopetam has been further explored by independent investigators at Umeå University and Lund University, Sweden. These studies, combining advanced electrophysiological and behavioral recordings, aim to provide a deeper mechanistic understanding of the pharmacological effects of mesdopetam, on the level of brain activity patterns, mental and motor behavior. Results from these recently concluded studies was presented at the Society for Neuroscience conference in San Diego, November 12-16, 2022.

The first study "Behavioral and electrophysiological characterization of anti-psychotic treatments in a rodent model of Parkinson's disease psychosis", authored by Loredan Stan et al, describes a new method to characterize brain activity patterns associated with Parkinson's disease psychosis. They show that mesdopetam reverses these high frequency oscillations (HFOs), indicating antipsychotic properties. The second study, "Behavioral and electrophysiological characterization of the antidyskinetic treatments in a rodent model of PD-LID", by A. Ronaghi et al, investigates mesdopetam, and comparator compounds, in a preclinical PD-LID model, showing that mesdopetam suppresses LIDs as well as the aberrant electrophysiological oscillations in the brain, associated with LIDs.

Collaboration with Ipsen

In 2021, exclusive global rights to the development and commercialization of the mesdopetam program was licensed to global specialty pharma company Ipsen. IRLAB remained responsible for the completion of the Phase IIb study while Ipsen is responsible for any further clinical development and worldwide commercialization.

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, leading to 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 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.

As reported, and published in the Phase I and Phase IIa study publications (can be found through www.irlab.se), pirepemat was concluded to have an acceptable safety profile and to be well tolerated in the intended patient population i.e. patients with Parkinson's and dementia. Adverse events in this patient population were mainly related to the central nervous system (CNS), gastrointestinal systems and infections. These were of mild to moderate intensity and occurred predominantly during the initial 14-day titration phase. After the 28-day treatment period, a moderate transient increase in liver enzymes was seen in three patients in the pirepemat-treated group. No such effects were observed during the treatment period and these had all normalized at the study follow-up visit. A similar transient liver signal following the termination of active treatment has been observed in Phase I studies. The interpretation is that this is part of a rebound effect follwing an abrupt termination of treatment with pirepemat

The preclinical results and clinical studies suggest that pirepemat has the potential to strengthen frontal cortical function in the brain and that pirepemat could be developed into a highly valuable, first-in-class, treatment to prevent falls in people living with Parkinson's.

Ongoing Phase IIb study

The ongoing Phase IIb study with pirepemat is designed as a randomized, double-blind and placebo-controlled study 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 active at 28 of 39 planned study sites at present, all sites are expected to be activated by Q2 2023. Patient recruitment and randomization is expected to be completed by the year-end 2023. This is followed by the three-month treatment period, follow-up visits, data management and database lock. At this time, the top-line results are expected in H1 2024.

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

Preclinical phase

IRL942

Drug candidate IRL942 is targeting a once-daily oral tablet to treat cognitive deficits in Parkinson's and other neurological disorders with the aim to improve cognitive function. There are about 12 percent of adults aged 65 years or more experiencing cognitive decline, which greatly affect quality of life and it is more common in people living with neurological disorders.

Disruption of frontal cortical neurotransmission is implicated in the pathogenesis of cognitive decline and neuro-psychiatric 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.

Non-clinical development activities related to CMC (development of large scale synthesis and production of drug compound and manufacturing of drug product for regulatory studies), toxicology and safety studies are ongoing, in preparation for regulatory submission to start Phase I studies. IRL942 is expected to Phase I ready during H1 2024.

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 with Parkinson's and in 20–90 percent of people with disorders such as Alzheimer's disease and other disorders related to CNS.

Preclinical efficacy by IRL757 has been obtained in several pre-clinical models representing various aspects of cognitive function including potential signals of improved motivation. The efficacy by IRL757 observed, 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.

Non-clinical development activities related to CMC, toxicology and safety studies to prepare for regulatory submission to start Phase I studies are currently ongoing. IRL757 is expected to be Phase I ready by the year-end 2023.

IRL1117 (P003 project)

IRL1117 is intended to be developed as a once-daily oral treatment for the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay levodopa-based treatments in Parkinson's. IRL1117 is an orally available and 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 slowness of movement. Levodopa has been the mainstay treatment of Parkinson's since the 1960s and is currently the only medication that provides adequate 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 continues with inhouse activities in preparation for Phase I enabling toxicology and manufacturing activities in 2024.

The P003 project aims to discover and develop dopamine D1 and D2 receptor agonist compounds with once-daily oral administration and improved efficacy on Parkinson's core motor symptoms (tremor, rigidity, and slowness of movements) but are free from the limitations displayed by levodopa (i.e., the short duration of action and the motor complications). In addition to IRL1117, there are a number of follow-on compounds identified with differentiation relating to the onset of action and time to maximal efficacy.

Research technology platform 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 at that stage already predict which drug candidates that have the greatest potential to be developed into a promising drug with the lowest risks. ISP provides an improvement in probability of drug discovery success in translation between clinical phases, compared

with industry standard. This is also exemplified by higher probability to demonstrate positive clinical proof-of-concept in patients and reach later stages of clinical development for an ISP generated drug candidate compared with the industry standard target based screening methods for candidate drug identification.

This 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. New perspectives are also added through close cooperation with universities and academic researchers so that IRLAB can keep leading the development of cutting-edge technology.

The group's performance January – December 2022

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 transforming life for people with Parkinson's and other CNS disorders through novel treatments. The company's most advanced drug candidates are mesdopetam and pirepemat, both of which are intended to treat some of the most difficult symptoms related to Parkinson's.

The company's unique proprietary research platform ISP generates novel, high-potential drug substances that make up the company's pipeline. Generated by ISP, IRLAB's three promising preclinical drug candidates IRL942, IRL757 and IRL1117, are currently in developmet toward clinical studies in respective preclinical development programs.

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 work

The research and development work has advanced according to plan. In the period January to December, the total costs for research and development were SEK 146,178 thousand (129,748), corresponding to 84 percent (84) 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 – December 31, 2022 was SEK –113,406 thousand (51,781). Earnings per share were –2.19 SEK (1.00). The group's revenue during the period was SEK 61,277 thousand (207,906).

Of the SEK 239.6 million that was received up-front in 2021 under the mesdopetam license agreement, SEK 185.3 million was recognized as license revenue and SEK 54.3 million was recognized as deferred income for the finalization of the ongoing Phase IIb study and will be recognized as income during 2022 in parallel with the study's completion. In 2022, SEK 42,576 million was recognized as such income. Revenue for other services provided to Ipsen during 2022 was SEK 18,560 million.

In 2022, the group's operating expenses were SEK 174,387 thousand (155,330). The increase compared with the previous year was primarily due to increased clinical research activities and an increased organization.

Financing and cash flow

Cash flow from operating activites were during the period 1 january to 31 december 2022 SEK –142,612 thousand (128,641) and during the fourth quarter SEK –37,887 thousand (-28,388). Cash and cash equivalents were SEK 252,776 thousand (401,897) on December 31, 2022.

On December 31, 2022, equity was SEK 290,831 thousand (399,481) and the equity ratio was 90 percent (85).

The Board of Directors and CEO determines that there are sufficient cash and cash equivalents to cover working capital needs over the next twelve months, given the current business activities and financing plan.

Investments

Investments in intangible assets for the period January 1 – December 31, 2022 were SEK 5,257 thousand (0), 4,757 of which were paid through a share issue in kind. Investments in tangible assets during the period were SEK 2,876 thousand (708) and related mainly to tools and machinery in the laboratories.

Significant events January–March 2022

In March, new drug candidate IRL757 was nominated for the treatment of apathy in neurological diseases.

Significant events April–June 2022

In April, know-how was acquired to support a strong patent application for chemical matter claims related to the P003 research project. The P003 project aims to offer a once-daily Parkinson's treatment without any complications.

In June, it was announced that the management team was strengthened by appointing Richard Godfrey as new CEO and Nicholas Waters as Executive Vice President and Head of Research & Development, effective July 1, 2022.

Significant events July–September 2022

In July, it was reported that the Phase IIb PD-LIDs study with mesdopetam was expanded to include 154 patients, top-line data is anticipated around the year-end.

The share issue of 120,000 Class A shares relating to the acquisition of know-how related to the P003 discovery project was registered. After the registration in July, the total number of registered shares is 51,868,406 (51,748,406).

In September, it was reported that IRLAB's partner Ipsen initiates clinical studies in line with mesdopetam's development plan and that the recruitment in the ongoing Phase IIb study with mesdopetam has been concluded.

Significant events October–December 2022

The nomination committee was appointed ahead of the annual general meeting (AGM) 2023 and comprises Hans-Peter Ostler, Anders Vedin, Clas Sonesson, and Gunnar Olsson, chairperson of IRLAB Therapeutics AB.

In November, IRLAB shared that new preclinical data were published providing insight into the mechanisms underlying antipsychotic and antidyskinetic efficacy of drug candidate mesdopetam (IRL790) in PD-Psychosis and PD-LIDs. The research was conducted by an independent academic research group led by Prof. Per Petersson and presented at the premier congress Neuroscience 2022 in San Diego, CA, on November 12–16.

In mid-December, the final patient completed the treatment period and follow-up visit ("LPLV") in the Phase IIb study of mesdopetam in levodopa-induced dyskinesia in people with Parkinson's disease (PD-LIDs).

On December 21, IRLAB was informed by the Swedish Economic Crime Authority (ECA) that the investigation concerning suspected insider dealing in the company's share during 2021 has been closed. IRLAB has assisted fully with the authorities in their investigations.

Significant events after the end of the period

In early January, IRLAB was invited to participate at the 6th Neuroscience Innovation Forum hosted by Sachs Associates. The event was held in connection to the Annual J.P. Morgan Healthcare Conference, in San Francisco, US.

In early January, drug candidate IRL1117 was nominated from the P003 research project. IRL1117 will be developed as a once-daily oral treatment for the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay anti-Parkinson's levodopa treatments. IRL1117 continues with inhouse activities in preparation for Phase I enabling toxicology and manufacturing activities in 2024.

In mid-Jaunary, the top-line results from the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias (PD-LIDs) were announced. Mesdopetam demonstrated anti-dyskinetic effects in several dyskinetic assessment scales with an adverse event and tolerability profile similar to placebo, even though the study did not statistically meet the primary efficacy endpoint of "good ON"-time. Additional analysis of the full data is currently ongoing.

In mid-February, the company announced an update to the portfolio development milestones following an assessment of the operational priorities for 2023.

On February 20, IRLAB's CEO Richard Godfrey was replaced by Gunnar Olsson who was appointed as interim CEO. Carola Lemne, former Vice Chair, took over the role as Chair of the Board from Gunnar Olsson. The process to recruit a permanent CEO is initiated immediately.

As the new Chair of the Board of IRLAB, Carola Lemne takes over the membership in the nomination committee after Gunnar Olsson's resignation as Chair of the Board.

An van Es-Johansson has elected to leave her assignment as board member.

Consolidated income statement in summary

Amounts in SEK thousand	2022 Oct–Dec	2021 Oct–Dec	2022 Jan–Dec	2021 Jan–Dec
Operating income, etc.				
Net revenue	12,181	12,141	61,136	207,782
Other operating income	136	243	141	124
Total income	*12,317*	*12,384*	*61,277*	*207,906*
Operating expenses				
Other external expenses	−30,431	−24,389	−125,906	−81,737
Personnel expenses	−12,669	−9,600	−42,481	−31,024
Outlicensed balanced development projects	0	0	0	−39,091
Amortization, depreciation and impairment	-1,865	−996	−4,779	−3,474
Other operating expenses	-435	0	−1,220	−4
Total operating expenses	*−45,399*	*−34,986*	*−174,387*	*−155,330*
Operating profit/loss	**−33,083**	**−22,601**	**−113,110**	**52,576**
Profit/loss from financial items				
Finance income	0	1	0	1
Finance costs	-83	-516	−297	−796
Total financial items	*−83*	*−515*	*−297*	*−795*
Profit/loss after financial items	**−33,166**	**−23,117**	**−113,406**	**51,781**
Income tax	0	0	0	0
Profit/loss for the period	**−33,166**	**−23,117**	**−113,406**	**51,781**
Earnings per share before and after dilution (SEK)	−0,64	−0.45	-2,19	1,00
Average number of shares, before and after dilution	51,868,406	51,748,406	51,831,913	51,748,406
Number of shares at year-end	51,868,406	51,748,406	51,868,406	51,748,406

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	2022 Oct–Dec	2021 Oct–Dec	2022 Jan–Dec	2021 Jan–Dec
Result for the period	–33,166	–23,117	-113,406	51,781
Other comprehensive income	0	0	0	0
Comprehensive income for the period	**–33,166**	**–23,117**	**-113,406**	**51,781**

Consolidated statement of financial position in summary

Amounts in SEK thousand	12/31/2022	12/31/2021
ASSETS		
Non-current assets		
Intangible assets	46,862	42,661
Tangible fixed assets	8,009	8,348
Total non-current assets	**54,871**	**51,009**
Current assets		
Short-term receivables	15,908	19,542
Cash and cash equivalents	252,776	401,897
Total current assets	**268,684**	**421,440**
TOTAL ASSETS	**323,555**	**472,449**
EQUITY AND LIABILITIES		
Equity		
Share capital	1,037	1,035
Other contributed capital	690,204	685,450
Retained earnings including results for the period	-400,411	-287,004
Total equity	**290,831**	**399,481**
Long-term liabilitiess		
Leasing debt	381	3,566
Total long-term liabilities	**381**	**3,566**
Current liabilities		
Leasing debt	3,595	3,034
Other liabilities	28,748	66,367
Total short-term liabilities	**32,343**	**69,402**
TOTAL EQUITY AND LIABILITIES	**323,555**	**472,449**

Consolidated statement of changes in equity in summary

Amounts in SEK thousand	Share capital	Unregistered share capital	Other contributed capital	Retained earnings incl. total comprehen-sive income for the period	Total equity
Equity January 1, 2021	**970**	**65**	**685,630**	**–338,786**	**347,880**
Comprehensive income for the period				51 781	51 781
Transactions with owners in their capacity as owners:					
Rights issue	65	-65			
Issue costs			-180		-180
Equity December 31, 2021	**1,035**	**0**	**685,450**	**–287,005**	**399,481**
Equity January 1, 2022	**1,035**	**0**	**685,450**	**–287,005**	**399,481**
Comprehensive income for the period				-113,406	-113,406
Transactions with owners in their capacity as owners:					
Rights issue	2		4,754		4,757
Equity December 31, 2022	**1,037**	**0**	**690,204**	**–400,411**	**290,831**

Consolidated statement of cash flows in summary

Amounts in SEK thousand	2022 Oct–Dec	2021 Oct–Dec	2022 Jan–Dec	2021 Jan–Dec
Operating activities				
Operating profit/loss	-33,083	-22,601	-113,110	52,576
Adjustments for non-cash items	1,865	996	4,779	42,564
Interest received	0	0	0	0
Interest paid	-54	-516	-297	-796
Taxes paid	0	0	0	0
Cash flows from operating activities before changes in working capital	**-31,271**	**-22,121**	**-108,627**	**94,345**
Cash flows from changes in working capital				
Changes in operating receivables	5,073	-4,177	3,634	-12,811
Changes in operating liabilities	-11,689	-2,090	-37,619	47,107
Cash flows from operating activities	**-37,887**	**-28,388**	**-142,612**	**128,641**
Investing activities				
Acquisition of immaterial fixed assets	0	0	-500	0
Acquisition of property, plant and equipment	-214	-147	-2,876	-708
Cash flows from investing activities	**-214**	**-147**	**-3,376**	**-708**
Financing activities				
Repayment of financial liabilities	-872	-736	-3,134	-2,865
Rights issue	0	0	0	-180
Cash flows from financing activities	**-872**	**-736**	**-3,134**	**-3,045**
Cash flows for the period	**-38,973**	**-29,271**	**-149,121**	**124,888**
Cash and cash equivalents at the beginning of the period	291,719	431,168	401,897	277,009
Cash and cash equivalents at the end of the period	**252,746**	**401,897**	**252,776**	**401,897**

Parent company income statement in summary

Amounts in SEK thousand	2022 Oct–Dec	2021 Oct–Dec	2022 Jan–Dec	2021 Jan–Dec
Operating income, etc.				
Net sales	1,555	1,272	4,531	4,059
Total income	*1,555*	*1,272*	*4,531*	*4,059*
Operating expenses				
Other external expenses	-3,403	-2,149	-12,187	-16,805
Personnel expenses	-4,460	-3,135	-14,402	-8,705
Other operating expenses	-25	0	-25	0
Total operating expenses	*-7,888*	*-5,283*	*-26,614*	*-25,510*
Operating profit/loss	**-6,333**	**-4,012**	**-22,083**	**-21,451**
Profit/loss from financial items				
Interest expenses	-7	-2	-7	-3
Total financial items	*-7*	*-2*	*-7*	*-3*
Profit/loss after financial items	**-6,340**	**-4,014**	**-22,090**	**-21,454**
Group contributions made	0	0	0	0
Tax on profit/loss for the year	0	0	0	0
Profit/loss for the period	**-6,340**	**-4,014**	**-22,090**	**-21,454**

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2022 Oct–Dec	2021 Oct–Dec	2022 Jan–Dec	2021 Jan–Dec
Profit/loss for the period	-6,340	–4,014	–22,090	–21,454
Other comprehensive income	0	0	0	0
Comprehensive income for the period	**-6,340**	**–4,014**	**–22,090**	**–21,454**

Parent company balance sheet in summary

Amounts in SEK thousand	12/31/2022	12/31/2021
ASSETS		
Non-current assets		
Financial assets		
Participations in group companies	350,320	350,320
Total non-current assets	**350,320**	**350,320**
Current assets		
Other receivables	8,535	1,755
Cash and bank balances	92,814	112,970
Total current assets	**101,349**	**114,725**
TOTAL ASSETS	**451,669**	**465,045**
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	1,037	1,035
Unregistered share capital	0	0
	1,037	*1,035*
Non-restricted equity		
Share premium reserve	744,314	739,560
Retained earnings including comprehensive income for the period	-302,434	-280,345
	441,880	*459,215*
Total equity	**442,917**	**460,250**
Current liabilities		
Other liabilities	8,752	4,795
Total liabilities	**8,752**	**4,795**
TOTAL EQUITY AND LIABILITIES	**451,669**	**465,045**

Key financial ratios for the group

	2022 Jan-Dec	2021 Jan-Dec	2020 Jan-Dec	2019 Jan-Dec
Net sales, SEK thousand	61,136	207,782	0	26
Operating profit/loss, SEK thousand	-113,110	52,576	-91,458	-95,848
Profit/loss for the period, SEK thousand	-113,406	51,781	-91,653	-96,120
Profit/loss attributable to the parent company's shareholders, SEK thousand	-113,406	51,781	-91,653	-96,120
Earnings per share before and after dilution, SEK	-2,19	1.00	-1.92	-2.37
R&D costs, SEK thousand	146,178	129,748	75,989	79,381
R&D costs as a percentage of operating expenses, %	84	84	83	82
Cash and cash equivalents at the end of the period, SEK thousand	252,776	401,897	277,009	110,527
Cash flows from operating activities, SEK thousand	-142,612	128,641	-89,214	-91,201
Cash flows for the period, SEK thousand	-149,121	124,888	166,482	-23,915
Equity, SEK thousand	290,831	399,481	347,880	181,827
Equity attributable to the parent company's shareholders, SEK thousand	290,831	399,481	347,880	181,827
Equity per share, SEK	5.61	7.72	6.72	4.22
Equity ratio, %	90	85	94	87
Average number of employees	29	22	18	17
Average number of employees in R&D	25	20	17	16

Of the above key financial ratios, only the key ratio Earnings per share before and after dilution, and R&D costs, are defined in accordance with IFRS. Of the other key financial ratios, Result for the period, Liquid assets at the end of the period, Cash flow from operating activities, Cash flow for the period, and Equity are drawn from 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 IRLAB Therapeutics AB (publ) annual report 2021.

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 2021 Annual Report.

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

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.

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 258,704 thousand (412,658).

Transactions with related parties

With the exception of salaries and other remuneration to the executive management and board fees, in accordance with the resolution of the Annual General Meeting, no transactions with related parties have taken place.

Revenue in the fourth quarter 2022

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. At present, the primary revenue is related to the licensing agreement with specialty pharma Ipsen for the global exclusive development and commercialization rights to drug candidate mesdopetam.

Net sales by revenue category	2022 Oct–Dec	2021 Oct–Dec	2022 Jan–Dec	2021 Jan–Dec
Licensing revenue	0	0	0	185,261
Service revenue	12,181	12,141	61,136	22,521
Total revenue	**12,181**	**12,141**	**61,136**	**207,782**

Segment information

Net sales by geographic market	2022 Oct–Dec	2021 Oct–Dec	2022 Jan–Dec	2021 Jan–Dec
Sweden	0	0	0	0
United Kingdom	12,181	12,141	61,136	207,782
Total revenue	**12,181**	**12,141**	**61,136**	**207,782**

All invoicing was in EUR. Revenue is recognized in 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 77–78 and its risk management is described on page 110 of the 2021 Annual Report. No significant changes have occurred that affect the reported risks.

To date, the global Covid-19 pandemic has not had any significant direct effects on IRLAB's operational activities, results or financial position. Effects in the medium to long term cannot yet be assessed, but the company is monitoring and evaluating the situation. There are, however, indications that healthcare providers in certain countries and regions are under pressure, which affects certain hospitals' ability to participate in clinical trials. Additionally, interactions have shown that regulatory authorities currently have longer processing times. Combined, this may affect IRLAB's clinical programs if the Covid-19 outbreak continues to put a strain on global healthcare resources and if restrictions on individuals' freedom of movement are extended beyond what is known today. We are therefore monitoring the situation closely and evaluating measures to minimize the effects on our projects and schedules.

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 studies. The company is continuously monitoring the developments so that appropriate measures can be taken if necessary.

Nomination Committee

Prior to the 2023 Annual General Meeting and until a new nomination committee is elected, and pursuant to the instructions applicable to IRLAB's Nomination Committee, the nomination committee comprised Hans-Peter Ostler, Anders Vedin (Chair of the Nomination Committee), Clas Sonesson and Carola Lemne, the Chair of the Board. The members of the nomination committee represent about 43 percent of the votes and shares in IRLAB as per December 31, 2022.

Employees

The average number of employees in the group from January – December was 29 (22). At the end of the period, the number of full-time positions was 30 (24), distributed over 32 (26) people.

The number of full-time positions, including long-term contracted consultants, was 33 (27) at the end of the period, distributed over 36 (30) people.

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.

Financial calendar

Annual report 2022	Week of May 1-5, 2023.
Interim report Q1 2023	May 10, 2023.
Annual General Meeting	June 20, 2023
Interim report Q2 2023	August 30, 2023.
Interim report Q3 2023	October 25, 2023.
Year-end report 2023	February 7, 2024.

Glossary

Dyskinesias	Condition where the body or a part of the body performs uncontrolled involuntary movements. Dyskinesia occurs in neurodegenerative and psychiatric diseases, brain diseases where the nervous system is either exposed to a slowly decreasing nerve cell activity, such as Parkinson's disease, or diseases where the nerve cell activity in particular parts of the brain has become unbalanced, such as psychosis or depression.
Good ON-time	The part of the day when the patient does not have troublesome symptoms of Parkinson's disease.
ISP	Integrative Screening Process, IRLAB's proprietary research platform used to generate drug candidates.
PD-LIDs	Parkinson's Disease levodopa-induced dyskinesias, involuntary movements (dyskinesias) caused by long-term medication with levodopa.
PD-P	Parkinson's Disease Psychosis, psychic symptoms such as delusions and/or hallucinations caused by Parkinson's disease.
PD-Falls	Parkinson's Disease Falls, falls due to postural dysfunction (balance impairment) and impaired cognition in Parkinson's disease.
Preclinical Proof of Concept	Is achieved when a drug candidate has shown safety, tolerability and efficacy in preclinical model systems and when the effect shown can be connected to a medical need. At IRLAB, the preclinical development starts when these requirements are fulfilled.
Clinical Proof of Concept	Prove the effectiveness of a concept. At IRLAB, this means when a drug candidate has achieved clinical proof of concept after a successful Phase II program.
CNS disorders	Central nervous system (CNS) disease is a broad category of conditions in which the brain does not function as it should, limiting health and the ability to function.

Presentation to investors and media

A presentation will be held on February 23, 2023, at 10:00 CET via an online webcast. CEO Gunnar Olsson and EVP and Head of R&D Nicholas Waters will comment the year-end report for the period January-December 2022. The presentation will be held in English and followed by a Q&A session.

Follow the presentation online on:
https://www.youtube.com/watch?v=YbKsH6TDFqM

Review and the Board's assurance

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

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

Gothenburg, February 23, 2023

CAROLA LEMNE
Chair of the Board

REIN PIIR
Board member

CATHARINA GUSTAFSSON WALLICH
Board member

GUNNAR OLSSON
CEO,
Board member

IRLAB

IRLAB discovers and develops novel treatments of Parkinson's disease and other CNS disorders. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), are in Phase IIb and are designed to treat some of the most difficult symptoms related to Parkinson's. In 2021, Ipsen, a specialty pharma company, acquired exclusive global rights to the development and commercialization of mesdopetam.

IRLAB has discovered and generated all its drug candidates and continues to discover innovative drug candidates for the treatment of CNS disorders through its proprietary systems biology-based Integrative Screening Process (ISP) research platform. In addition to IRLAB's strong clinical pipeline, the company is also progressing three preclinical programs, IRL942, IRL757, and IRL1117, towards Phase I studies.

Contact information

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