IRLAB

Q1.2025
Interim report
January – March 2024

MALIN EDLING AND KARIN ÖNNHEIM, studies the effect of our candidate drugs in different model systems

"The first quarter of 2025 has been one of our most dynamic to date, marked by significant regulatory progress, promising clinical results, and the deepening of strategically important partnerships, all collectively strengthening our position."

KRISTINA TORFGÅRD, CEO

Interim report January–March 2025

Highlights during and after the first quarter 2025

POSITIVE FEEDBACK FROM THE EMA – CONFIRMS ALIGNMENT WITH THE FDA ON PHASE III FOR MESDOPETAM.

POSITIVE PHASE I TOP-LINE RESULTS SUPPORT CONTINUED DEVELOPMENT OF IRL757.

IRL757 STUDY IN PARKINSON'S TO BE INITIATED, FULLY FUNDED BY DEVELOPMENT PARTNER MSRD.

PHASE IIB STUDY WITH PIREPEMAT INDICATES, BASED ON IN-DEPTH ANALYSIS, A SIGNIFICANT AND CLINICALLY MEANINGFUL REDUCTION IN FALL FREQUENCY.

Financial summary

SEK thousand	January–March 2025	January–March 2024	January–December 2024
Net sales	4,360	-	94,628
Operating profit	–28,641	–37,636	–75,111
Earnings per share before and after dilution, SEK	–0.65	–0.75	–1.60
Cash and cash equivalents	88,605	73,140	66,917
Cash flow from operating activities	6,332	–38,211	–65,590
Average number of employees	31	32	31
Share price at the end of period, SEK	7.94	15.60	10.75

Presentation for investors and media about the Q1 2025

Wednesday May 7, 2025, at 11.30 CET is the presentation of the Q1 interim report through a digital webcast. Access via link or view after the event: https://www.youtube.com/watch?v=RWNIkYDnHWg

Financial calendar

Annual general meeting 2025	June 11, 2025
Interim report Q2 2025	August 27, 2025
Interim report Q3 2025	October 29, 2025
Year-end report 2025	February 11, 2026

"We have a strong and broad project portfolio with five unique first-in-class candidates. Our main focus is currently on establishing partnerships for mesdopetam and pirepemat, as well as advancing IRL757 through to Proof-of Concept."

KRISTINA TORFGÅRD, CEO

Comments from the CEO

The first quarter of 2025 has been one of our most dynamic to date, marked by significant regulatory progress, promising clinical results, and the deepening of strategically important partnerships, all collectively strengthening our position. Following an in-depth analysis of the topline data for pirepemat presented during the quarter, we can confidently affirm that all of our development programs continue to make evident progress and bring us closer to our goal - to provide new, effective treatments for people living with Parkinson's disease.

Regulatory progress paves the way for the next stage in the development of mesdopetam

In January, the EMA granted us a waiver from the requirement to conduct pediatric studies with mesdopetam in Parkinson's disease. This decision is in line with the previous approval from the FDA. It means that we can now fully focus our resources and energy on developing mesdopetam for the treatment of levodopa-induced dyskinesias (LIDs) in adults- an area with a significant unmet medical need.

In early 2025, we also received positive feedback from the EMA, confirming alignment with the FDA regarding the Phase III program for mesdopetam. Based on our previously successful End-of-Phase 2 meeting with the FDA and the positive dialogue with the EMA, we are now preparing for registration-enabling Phase III studies of this drug candidate.

These regulatory advances reinforce our conviction that we are on the right track and add weight to our ongoing discussions with potential partners. We look forward to offering a treatment that has the potential to address one of the most pressing needs in the Parkinson's field - to effectively treat LIDs and thereby improve the quality of life for affected patients worldwide.

Promising results with pirepemat – one step closer to a new treatment

In March, we presented topline results from the Phase IIb study (REACT-PD) of pirepemat in patients with Parkinson's disease. The initial analysis showed that treatment with 600 mg of pirepemat daily reduced the fall rate by 42 percent—a clear effect, even though the outcome did not reach statistical significance in the overall population.

However, in the in-depth analyses of the efficacy data, we could clearly see that patients with medium plasma concentrations of pirepemat showed a fall reduction of as much as 51.5 percent after three months of treatment. This outcome is both clinically meaningful and statistically significant. These insights are highly valuable and provide essential guidance for optimizing dosing and study design in the next development phase. At the same time, the results strengthen our belief in pirepemat as a potential treatment to reduce fall risk and improve the quality of life for patients with Parkinson's.

I am proud of our team's work and look forward to continuing the development of pirepemat, which has the potential to become the world's first treatment targeting the severe balance problems – resulting in falls and injuries – that affect people with Parkinson's disease.

Strategic partnerships and positive results support the development of IRL757

We have made significant progress in developing our drug candidate IRL757, with two completed clinical Phase I studies. The most recent study, conducted in healthy elderly individuals, showed positive results earlier this year. The study demonstrated that IRL757 is well absorbed, provides good systemic exposure, and has a favorable safety profile. These results represent an important milestone for us, as they form the basis for the next

development step – initiating a clinical study in patients with Parkinson's disease who suffer from apathy. We expect to begin recruiting the first patients during the second half of 2025.

I would also like to highlight our strong partnership with MSRD/Otsuka, which provides full funding for the development of IRL757 through proof-of-concept (PoC). Combined with our collaboration with the Michael J. Fox Foundation for Parkinson's Research (MJFF), this not only ensures critical financial support but also serves as a strong validation of our scientific platform and our position as a leading innovator in treating apathy in neurological disorders.

We now look forward with confidence to continuing the development of IRL757, with the goal of offering a treatment for apathy where the medical need for effective therapies is very high.

New insights into drug candidates with the potential to become first-in-class treatments

During the first quarter, a scientific article on mesdopetam was published in the medical journal European Journal of Neuroscience. The article is based on preclinical studies and provides new insights into the mechanisms behind levodopa-induced dyskinesia. The data provide f fresh perspectives into the system-level mechanisms behind the antidyskinetic effect of mesdopetam and suggest potential additional benefits in the treatment of Parkinson's related psychosis (PD-P). Given resources, clinical studies in psychosis could broaden and strengthen the compound's future commercial potential.

In April, we participated in the international conference on Alzheimer's and Parkinson's diseases (ADPD) in Vienna, where we presented progress on pirepemat and IRL757. Both drug candidates are so-called "cortical enhancers," acting by directly strengthening neural signaling in the cerebral cortex. Cortical dysfunction is a key factor in neurodegenerative diseases, including Alzheimer's and Parkinson's. The presentation on pirepemat, featuring new and compelling data on fall frequency, attracted significant interest and was well received by key opinion leaders and leading experts in the field.

We view participation in international congresses and publications in scientific journals as important steps forward, as they reinforce the scientific foundation for our continued development of these drug candidates. It is gratifying to see our research efforts being recognized and continuing to build value.

Enhanced opportunities, priorities for value creation at IRLAB

We have taken several important actions to ensure financial sustainability during this critical phase. We have extended the maturity of the existing loan from Fenja Capital, with the possibility of further expanding it under certain conditions. In addition, we have secured new loans from some of our largest shareholders. In the short term, these measures strengthen our financial position and provide the resources needed to focus on reaching several potentially value-creating milestones in the near future.

We have a strong and broad project portfolio with five unique first-in-class candidates. Our main focus is currently on establishing partnerships for mesdopetam and pirepemat, as well as advancing IRL757 through to PoC. For the benefit of these prioritized projects, along with IRL1117, we will slow the development pace of IRL942 and not proceed with toxicology studies at CROs, which means that we will not be ready for Phase I during 2025. At the same time, we are reviewing our costs to ensure we can focus our resources on the activities most critical to our continued development.

During the quarter, I had the pleasure of meeting many of our investors and other stakeholders. These meetings have been very rewarding—not only as an opportunity to share our progress and strategy but also to gain valuable insights, understand expectations, and gain experience and commitment for the future of IRLAB. I appreciate the open and constructive dialogue and look forward to continuing this journey together with our committed owners and our competent, dedicated team.

Thank you for your continued trust!

Kristina Torfgård, CEO, IRLAB

Key Milestones During the Quarter:

- Promising results from the Phase I study with IRL755 enable the next step in clinical development – a study in patients with Parkinson's and apathy. Our strategic collaboration with MSRD/Otsuka and the Michael J. Fox Foundation plays an important role in advancing the development of IRL757.
- The regulatory progress for mesdopetam lays a strong foundation for the upcoming Phase III program and deepened discussions with potential partners.
- Study data on pirepemat show a statistically significant and clinically meaningful reduction in fall rate, linked to the plasma concentrations of the drug.

Together, these advances demonstrate that we are well on our way to realizing our vision and creating value for patients, partners and shareholders

IRLAB's unique offering and position

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

Pioneering biology & ISP

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

Focused strategy

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

Validated proof-of-concept

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

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

Organization positioned for success

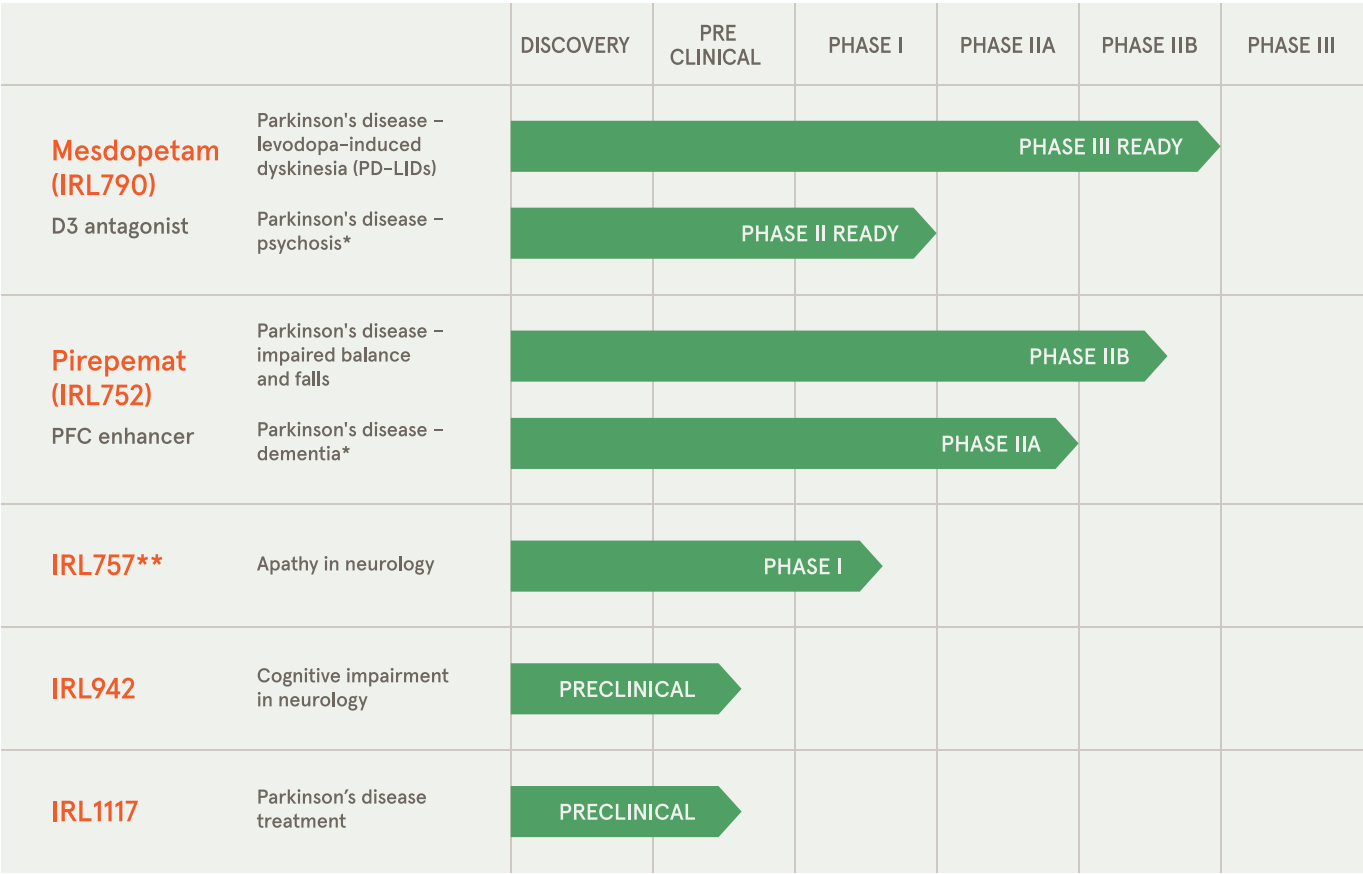
IRLAB is an organization with an experienced team. IRLAB is listed on the Nasdaq Stockholm main market (IRLAB A).

Broad & solid portfolio

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

IRLAB's portolio

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



* Currently no active clinical development in this indication.

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

R&D update

"We have made important progress during the quarter – with regulatory alignment around mesdopetam, strong results for pirepemat, and our collaboration with MSRD now entering its next phase through the decision to initiate a large patient study."

NICHOLAS WATERS, EVP OCH HEAD OF R&D

Highlights during and after the first quarter of 2025

The first quarter of the year has been very eventful. In the discussions we had with the FDA, and now also with EMA, about how the phase III program for mesdopetam should be designed, we now have agreement between the regional regulatory bodies. The Phase III program, with two parallel efficacy studies and a separate safety study, now has a design that can lead to market authorization in both the US and Europe.

The results from the Phase IIb study with pirepemat, completed during the period, where we see that medium plasma concentrations of pirepemat reduce the frequency of falls by 51.5%, statistically significant (p<0.05 compared to placebo), provide conditions to continue the work of developing a treatment to reduce falls in Parkinson's disease.

The preclinical studies we conducted with IRL1117 show that we have a potential "blockbuster" for the treatment of Parkinson's with the possibility of a better treatment effect than levodopa. We are now continuing the necessary development of IRL1117 to allow for clinical studies.

The collaboration with MSRD/Otsuka is now intensified. We have now completed a successful Phase I program with IRL757 in parallel with the preclinical studies required to be able to start 3-month studies in patients. We are aiming to start recruitment, in a larger study, focused on the treatment of apathy in Parkinson's, during the autumn

We have been very successful in developing the patent portfolio and expanded with additional composition of matter patents allowing exclusivity for both mesdopetam and pirepemat into the 2040ies.

About IRLAB's drug candidates

Mesdopetam

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

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

Mesdopetam also has potential as a treatment for Parkinson's disease Psychosis (PD-P), which affects about 1.5 million people across the eight major markets worldwide. Further, mesdopetam has poten-

tial to treat other neurological conditions such as tardive dyskinesia, representing an even larger market.

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

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

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

Current status

The company has successfully completed an End-of-Phase 2 meeting with the American pharmaceutical authority, FDA, and has now also received scientific advice from the European pharmaceutical authority EMA (February 2025). Both authorities consider that the studies and the data generated so far are adequate to move the program into Phase III. The authorities' assessment is based on the completed preclinical studies, toxicological studies, CMC development and the clinical studies from Phase I through Phase IIb. It has also been confirmed that the FDA, EMA and IRLAB are in agreement regarding the design of the Phase III program's studies and the key components for evaluation of efficacy ("endpoints") and safety. The company has also taken in scientific advice from national European medicine authorities in Germany (BfArM) and Portugal (Infarmed), with the aim of ensuring that mesdopetam's development program also meets specific national requirements.

In short, the Phase III program will include double-blind treatment with mesdopetam or placebo in approx. 250-270 patients over 3 months divided into two studies of approx. 130 patients/study, which are carried out in parallel. Those who participate in the studies and have undergone the double-blind treatment phase will be offered continued open treatment with mesdopetam in a so-called Open Label Extension (OLE). In parallel with the efficacy and OLE studies, a separate safety study of 6-12 months will run. This is done to fulfill the FDA's requirement to achieve at least 100 patients treated with mesdopetam during a year, as well as to meet EMA's guidelines which indicate that a safety population should amount to 300-600 patients treated for at least 6 months.

During the past year, work has been carried out to develop the market strategy for mesdopetam, through structured interviews with managers in healthcare organizations to better understand medical needs from the perspective of healthcare and those who finance healthcare. By having insight into the needs of patients, regulatory authorities and healthcare providers, we ensure that the design of the Phase III program fulfills expectations and requirements from all stakeholders and thereby can become a successful and appreciated treatment.

During the period, the company received a waiver from the European Medicines Agency (EMA) regarding pediatric studies with mesdopetam, which means that IRLAB does not need to conduct studies with mesdopetam in children. A basic principle is that drug development companies need to submit pediatric trial plans for all new drugs. The waiver enables IRLAB to concentrate its efforts on developing mesdopetam for patient groups where Parkinson's disease is more common and thus avoid resource-demanding and lengthy studies in the pediatric population.

During the past year, the company has been granted a, so-called, composition of matter patent in Europe that covers the salt of mesdopetam, used during the clinical development, and the granted patent also protects the production process. The granted patent expands the already strong patent protection for mesdopetam. There is thus potential for market exclusivity well into the 2040s in the large and important markets.

Pirepemat

Pirepemat (IRL752) has potential to be the first treatment in a new class of drugs designed to reduce falls and fall injuries in people living with Parkinson's disease through strengthening of nerve cell signalling in the prefrontal cortex. This is obtained through antagonism at 5HT7 and alpha-2 receptors leading to increased dopamine and noradrenaline levels in this brain region, an effect that cannot be achieved with the drugs currently prescribed to people living with Parkinson's.

Falls are a significant consequence of Parkinson's that has severe complications such as fractures, impaired mobility and reduced quality of life. About 50 percent of all people living with Parkinson's fall recurrently, which approximates to 2.6 million people suffering from a significantly reduced quality of life also driven by fear of falling. There are currently no treatments available, despite the great medical need. The societal burden due to falls is also significant with the cost for hospital treatment of a fall injury in the US estimated to be around USD 30 000 for people over age of 65. The costs to society are also significant. In the United States alone, injuries related to falls in the elderly (>65 years) are estimated to cost up to $80 billion/year (doi: 10.1136/ip-2023-045023).

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

Current status

In the recently completed Phase IIb study (REACT-PD), the effect on fall frequency in Parkinson's patients at two doses of pirepemate or placebo was evaluated in a randomized, double-blind, placebo-controlled clinical trial with a three-month treatment period. Secondary objectives include cognitive and neuropsychiatric evaluations and continued studies of safety and tolerability. The study recruited patients at clinics in France, Poland, the Netherlands, Spain, Sweden and Germany.

Patient recruitment was completed in autumn 2024 and in January 2025 all patients had completed the Phase IIb study. After a month-long baseline period, three-month treatment period, follow-up visits, data management, database locking, and analysis of study data, topline data were presented in March 2025. The results showed that treatment with pirepemat (600 mg daily) reduces the frequency of falls by 42 percent in people with Parkinson's disease, but that the effect did not reach statistical

significance compared to placebo. At the end of March, additional results were presented based on predefined in-depth analyzes of efficacy data from the dose-defining Phase IIb study. The analysis shows that medium-high plasma concentrations of pirepemate reduce the frequency of falls by as much as 51.5% after three months of treatment. This effect is highly clinically meaningful and statistically significant ($p<0.05$ compared to placebo). A treatment that leads to a reduction in falls in Parkinson's, a clinically meaningful reduction is considered to be approximately 20-25% (DOI:10.1016/j.parkreldis.2018.11.008).

Based on these significant results, the company continues the analysis of the study data before a decision on the optimal design of future studies in the continued development program for the drug candidate. More information can be found at EudraCT: 2019-002627-16 and clinicaltrials.gov: NCT05258071.

During the past year, a new patent was granted for a salt of the drug candidate pirepemat in the USA. The patent covers the active pharmaceutical ingredient used in the ongoing clinical development of pirepemat. The new patent has previously been granted in Europe, Japan and China, with the granted patent term adjustment (PTA), US exclusivity will extend into the early 2040s.

IRL757

In May 2024, Phase I clinical development began with IRL757. IRL757 aims to treat apathy in Parkinson's and other neurological disorders. Apathy is a debilitating condition affecting over 10 million people in the US and equally many in Europe. The prevalence is high, occurring in 20–70 percent of people being treated with Parkinson's, which equates to 1.1-4.0 million people on the eight major markets. Apathy is also prevalent in 43–59 percent of people being treated for Alzheimer's disease, which equates to 4.9-6.7 million people in the ten major markets globally (Canada, China, France, Germany, Italy, Japan, Spain, South Korea, the UK and the US).

Preclinical efficacy by IRL757 has been obtained in several preclinical models representing various aspects of impaired cognitive function and reduced motivation. The efficacy of IRL757 observed in these models is hypothesized to be associated with IRL757's unique pharmacology to reverse disruption in cortical to sub-cortical nerve signalling, a proposed mechanism underlying apathy in neurological disorders.

Current status

In the spring of 2024, the drug candidate IRL757 received approval from regulatory authorities to begin Phase I after successfully completing the required preclinical studies and development work. In collaboration with a CRO, the Phase I program is carried out, which is financed through a research grant from The Michael J. Fox Foundation. In May 2024, a collaboration agreement was also entered into with the McQuade Center for Strategic Research and Development (MSRD), part of the global pharmaceutical company Otsuka, to develop IRL757 further after Phase I up to and through Proof-of-Concept for the treatment of apathy in both Parkinson's and Alzheimer's. The project is thus fully funded for the coming years.

During the past year, we have successfully completed the first part of the Phase I clinical study where the drug candidate IRL757 was administered in ascending doses (Single Ascending Dose, SAD). The results show that IRL757 is well absorbed, provides good exposure in the body and has a good tolerability and safety profile. In the second part of Phase I, repeated and ascending doses are administered (Multiple Ascending Dose, MAD). The SAD and MAD studies are carried out with funding from the Michael J. Fox foundation.

During the previous period, an additional Phase I clinical study with IRL757 was initiated, this time in a group of research subjects aged 65 and over. The results show that IRL757 is well absorbed and provides good exposure in the body also in this age group. All participants completed the study, and no serious adverse events occurred. Overall, safety, tolerability and pharmacokinetic profile support the continued development of IRL757. This study in the elderly is the first clinical study within the framework of the collaboration with MSRD/Otsuka.

In collaboration with the McQuade Center for Strategic Research and Development (MSRD), preparations are now being made for a clinical study in patients with Parkinson's disease and apathy. The first patients are expected to be recruited in the second half of 2025.

IRL942

The ultimate goal for the preclinical drug candidate IRL942 is an orally administered drug improving cognitive function in people living with Parkinson's, but also in other neurological diseases. Approximately 12 percent of everyone aged 65 or older experiences cognitive decline, which greatly affects quality of life. The condition is even more common in people living with neurological diseases.

Weakening of neural signaling in the cerebral cortex is believed to be a cause of cognitive impairment and of neuropsychiatric symptoms in Parkinson's and other neurological diseases. IRL942 has a unique ability to enhance frontal cortex nerve signaling, activate genes important for the function of neural connections and the associated neural pathways in the cerebral cortex, which counteracts impaired cognitive function. This has been shown in several preclinical models.

IRL942 could thus become a drug that can improve the cognitive function of the 1.5 million people treated for Parkinson's and the 3 million people treated for Alzheimer's calculated in the ten largest markets.

Current status

The development continues according to plan for GMP manufacturing of drug substance and the development of the drug product, i.e. the pharmaceutical formulation, has begun. However, the pace of development for IRL942 will be reduced during 2025 and we will therefore not conduct the preclinical regulatory toxicology and safety studies required to allow for start of clinical development in Phase I during the year.

IRL1117

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

At present, people with Parkinson's disease are prescribed the anti-Parkinson's treatment levodopa to treat the hallmark symptoms of tremor, rigidity, and bradykinesia (slowness of movement). Levodopa has been the mainstay treatment for Parkinson's since the 1960s and is currently the only medication that provides symptomatic relief of the disease during its progression. Levodopa has, however, significant treatment related limitations, especially the short duration of action and the occurrence of troublesome treatment-related complications such as excessive involuntary movements. By comparison, in preclinical studies IRL1117 offers a clearly differentiating alternative being more potent and displaying a full anti-parkinsonian efficacy during long-term treatment, administered only once daily, and without inducing the troublesome complications during long-term treatment in preclinical models of Parkinson's. IRL1117, as a potentially superior alternative to levodopa, could be administered to all individuals currently being treated for Parkinson's, which amounts to 5.7 million people across the eight largest markets.

Current status

Development activities are ongoing with IRL1117. The preclinical results in long-term treatment show that IRL1117 has full anti-parkinsonian effect and at the same time does not cause the well-known complications, such as strong fluctuations in effect, that occur in long-term treatment with levopdopa. The results are very promising and indicate that IRL1117 has the potential to significantly improve the treatment of Parkinson's. In parallel, the development of substance manufacturing on a larger scale (CMC) and preparations for the preclinical regulatory studies that are necessary to initiate Phase I, are ongoing.

Integrative Screening Process (ISP)

IRLAB's portfolio is generated with the unique proprietary drug discovery platform Integrative Screening Process, called ISP, which has proven to enable the discovery of truly novel first-in-class compounds. The ISP methodology combines systems biology screening models, an extensive database, and modern machine learning-based analytical methods. This means that IRLAB obtains unique insights into the overall effect of the studied molecules at an early stage.

The platform can already at the discovery phase predict the drug candidates with the greatest potential in a certain indication, as well as the lowest technical risks. ISP provides an improvement in probability of drug discovery success in clinical phase transition, compared with industry standard. This is also exemplified by higher probability to demonstrate clinical proof-of-concept in patients and reach later stages of clinical development for an ISP generated drug candidate compared with industry standard.

Our discovery and development strategy provides IRLAB with a strong competitive advantage in the discovery of novel treatments for Parkinson's and other CNS disorders. It is important to IRLAB to constantly refine and develop this technology-base to remain at the forefront of modern drug discovery. A close cooperation with universities and academic researchers also contribute to IRLAB being able to keep leading the development of cutting-edge technology.

The group's performance January – March 2025

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 parent company's operations mainly consist of providing management and administrative services to the group's operating companies, and activities related to the stock market. The research and development operations are conducted in the wholly-owned subsidiary Integrative Research Laboratories Sweden AB. IRLAB has offices in Gothenburg (main) and Stockholm, Sweden.

Research and development costs

In the period January 1 to March 31, 2025 the total costs for research and development were SEK 27,517k (28,937), corresponding to 75 percent (77) of the group's total operating expenses. Development costs vary over time, depending on where in the development phase the projects are.

Comments on the income statement

The loss for the period January 1 to March 31, 2025 was SEK −33,969k (-39,019). Earnings per share were −0.65 SEK (-0.75). The group's revenue during the period was SEK 8,057k (-) whereof 4,360k (-) is net revenue and the remainder is other operating income, which consists of the the share of the total grant from The Michael J. Fox Foundation which has been recognized as revenue.

The personnel costs during the period January 1 – March 31, 2025 was SEK 11,689k (10,953).

During th first quarter 2025 the group's operating expenses were SEK 36,698k (37,636).

Financing and cash flow

Cash flow from operating activites were during the period January 1 - March 31, 2025, SEK 6,332k (-38,211). Cash and cash equivalents were SEK 88,605k (73,140) on March 31, 2025.

On March 31, 2025, group equity was SEK 4,632k (76,745) and the equity ratio was 3 percent (56). In the parent company, the equity was 365,183k (410,109) and the equity ratio was 85 (93) percent. The decline is mainly attributable to operating profit

IRLAB is a research and development company with no regular income. The company is primarily financed via the capital market or through the sale or out-licensing of projects, with an initial payment at signing of the agreement, as another financing option. In addition to revenues from operations, the financing strategy is based on continually ensuring that the company is adequately financed through the capital market to effectively run the operations and make rational business decisions.

The Board and the CEO assess that, given the company's current financial position and the current conditions on the capital market, material uncertainty (related to events or conditions) which may cast significant doubt on the entity's ability to continue as a going concern. In order to meet future financing needs, the company runs active processes to achieve partnerships, licensing agreements, share issues or other capital market transactions for example through a new licensing agreement regarding mesdopetam, license agreements with pirepemat and IRL1117 or financing through various forms of share issues or other capital market transactions.

During the first quarter of 2025, the previous loan agreement with Fenja Capital A/S (Fenja) was terminated and replaced by a new loan agreement. The total loan amount is SEK 55,000 thousand, and the agreement initially included an option to increase the loan to SEK 75,000 thousand under certain conditions. However, these conditions were not met, and the option to increase the loan was no longer available at the end of the quarter. Fenja retains the right to convert up to SEK 10,000 thousand of the loaned amount into shares until May 22, 2025. Fenja has also received a total of approximately 1.6 million warrants, entitling them to subscribe for shares at SEK 19.25 per share.

During the first quarter, additional loans totaling approximately SEK 22,400 thousand were also raised from four of the company's largest shareholders. The loans from both Fenja and the shareholders mature on December 31, 2025, with an option for IRLAB to extend the maturity to June 30, 2026, subject to a fee. Transaction costs related to the loans have been capitalized and are amortized over the term of the loans as interest expenses, with no impact on cash flow. The value of the warrants received is treated in the same way and recognized as an interest expense, also without affecting cash flow. The debt to Fenja will increase over the term of the facility to reach SEK 55,000 thousand at maturity.

Between January 1 and March 31, 2025, the Group received one disbursement of approximately SEK 3,600 thousand, representing a partial payment for the ongoing Phase I study with IRL757. During the quarter, IRLAB also invoiced MSRD USD 4.4 million, corresponding to approximately SEK 45,221 thousand, intended to cover costs for the upcoming study with IRL757..

Investments

The group did not make any investments in either the first quarter of 2025 or 2024.

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	2025 Jan–Mar	2024 Jan–Mar	2024 Jan–Dec
Operating income, etc.			
Net sales	4,360	-	94,628
Other operating income	3,697	-	19,455
Total income	*8,057*	*-*	*114,083*
Operating expenses			
Other external expenses	–21,170	–25,256	–136,289
Personnel costs	–11,689	–10,953	–46,179
Amortization, depreciation and impairment	–1,122	–1,152	-4,583
Other operating expenses	-2,717	-275	-2,143
Total operating expenses	*–36,698*	*–37,636*	*–189,194*
Operating profit/loss	**–28,641**	**–37,636**	**–75,111**
Profit/loss from financial items			
Finance income	238	715	2,459
Finance costs	–5,566	–2,098	–10,477
Total financial items	*–5,328*	*–1,383*	*–8,018*
Profit/loss after financial items	**–33,969**	**–39,019**	**–83,129**
Income tax	-	-	-
Profit/loss for the period	**–33,969**	**–39,019**	**–83,129**
Earnings per share before and after dilution (SEK)	–0.65	–0.75	-1.60
Average number of shares, before and after dilution	51,868,406	51,868,406	51,868,406
Number of shares at the end of the period	51,868,406	51,868,406	51,868,406

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

Consolidated statement of comprehensive income in summary

Amounts in SEK thousand	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Result for the period	-33,969	-39,019	-83,129
Other comprehensive income	-	-	-
Comprehensive income for the period	**-33,969**	**-39,019**	**-83,129**

Consolidated statement of financial position in summary

Amounts in SEK thousand	03/31/2025	03/31/2024	12/31/2024
ASSETS			
Non-current assets			
Intangible assets	46,862	46,862	46,862
Tangible fixed assets	8,670	5,520	9,793
Total non-current assets	**55,532**	**52,381**	**56,654**
Current assets			
Short-term receivables	15,585	11,146	12,641
Cash and cash equivalents	88,605	73,140	66,917
Total current assets	**104,191**	**84,285**	**79,558**
TOTAL ASSETS	**159,723**	**136,667**	**136,212**
EQUITY AND LIABILITIES			
Equity			
Share capital	1,037	1,037	1,037
Other contributed capital	696,172	690,205	690,205
Retained earnings including result for the period	-692,577	-614,497	-658,608
Total equity	**4,632**	**76,745**	**32,635**
Non-current liabilities			
Long-term debt	-	25,494	-
Lease liabilities	2,674	46	3,536
Total non-current liabilities	**2,674**	**25,540**	**3,536**
Current liabilities			
Short-term debt	60,381	-	53,466
Lease liabilities	3,407	2,067	3,419
Other liabilities	88,628	32,314	43,156
Total current liabilities	**152,416**	**34,381**	**100,041**
TOTAL EQUITY AND LIABILITIES	**159,723**	**136,667**	**136,212**

Consolidated statement of changes in equity in summary

Amounts in SEK thousand	Share capital	Other contributed capital	Retained earnings incl. total comprehen-sive income for the period	Total equity
Equity January 1, 2024	**1,037**	**690,605**	**–575,478**	**115,764**
Comprehensive income for the period			–39,019	–39,019
Equity March 31, 2024	**1,037**	**690,605**	**–614,497**	**76,745**
Comprehensive income for the period			-44,110	-44,110
Equity December 31, 2024	**1,037**	**690,605**	**–658,608**	**32,635**
Equity January 1, 2025	**1,037**	**690,605**	**-658,608**	**32,635**
Comprehensive income for the period			–33,969	–33,969
Warrant premiums paid		5,967		5,967
Equity March 31, 2025	**1,037**	**696,172**	**–692,577**	**4,632**

Consolidated statement of cash flows in summary

Amounts in SEK thousand	2025 Jan–Mar	2024 Jan–Mar	2024 Jan–Dec
Operating activities			
Operating profit/loss	–28,641	–37,636	–75,111
Adjustments for non-cash items	1,122	1,152	4,583
Interest received	238	715	2,459
Interest paid	–5,566	–2,098	–6,522
Cash flows from operating activities before changes in working capital	**–32,847**	**–37,867**	**–74,591**
Cash flows from changes in working capital			
Changes in operating receivables	–2,944	2,070	2,792
Changes in operating liabilities	42,124	–2,414	6,209
Cash flows from operating activities	**6,332**	**–38,211**	**–65,590**
Investing activities			
Acquisition of property, plant and equipment	–	–	–199
Cash flows from investing activities	**–**	**–**	**–199**
Financing activities			
New financial debts	10,263	983	25,000
Repayment of financial liabilities	–874	–942	–3,604
Option premiums	5,967	–	–
Cash flows from financing activities	**15,356**	**–42**	**21,396**
Cash flows for the period	**21,688**	**–38,169**	**–44,394**
Cash and cash equivalents at the beginning of the period	66,917	111,309	111,309
Cash and cash equivalents at the end of the period	**88,605**	**73,140**	**66,917**

Parent company income statement in summary

Amounts in SEK thousand	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Operating income, etc.			
Net sales	1,411	1,252	5,521
Total income	*1,411*	*1,252*	*5,521*
Operating expenses			
Other external expenses	–2,137	–2,059	–9,387
Personnel expense	–3,676	–3,380	–14,395
Other operating expenses	–	–5	–17
Total operating expenses	*–5,813*	*–5,443*	*–23,799*
Operating profit/loss	***–4,402***	***–4,191***	***–18,277***
Profit/loss from financial items			
Results from impairment losses in group companies	-	-	-20,000
Interest incomes	137	602	1,690
Interest expenses	-5,450	-2,049	-10,228
Total financial items	*-5,313*	*1,447*	*-28,538*
Profit/loss after financial items	***–9,715***	***–5,638***	**–46,815**
Tax on profit/loss for the period	–	–	–
Profit/loss for the period	**–9,715**	**–5,638**	**–46,815**

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec
Profit/loss for the period	-9,715	-5,638	-46,815
Other comprehensive income	-	-	-
Comprehensive income for the period	**-9,715**	**-5,638**	**-46,815**

Parent company balance sheet in summary

Amounts in SEK thousand	03/31/2025	03/31/2024	12/31/2024
ASSETS			
Non-current assets			
Financial assets			
Participations in group companies	350,320	350,320	350,320
Total non-current assets	**350,320**	**350,320**	**350,320**
Current assets			
Other receivables	43,047	7,942	27,862
Cash and cash equivalents	49,961	85,909	49,991
Total current assets	**93,008**	**93,851**	**77,853**
TOTAL ASSETS	**443,328**	**444,171**	**428,173**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1,037	1,037	1,037
	1,037	*1,037*	*1,037*
Non-restricted equity			
Share premium reserve	744,314	744,314	744,314
Option premium	5,967	-	-
Retained earnings including comprehensive income for the period	-386,135	-335,242	-376,420
	364,146	*409,072*	*367,894*
Total equity	**365,183**	**410,109**	**368,932**
Long-term liabilities			
Long-term interest bearing debt	-	25,494	-
Total long-term liabilities	**-**	**25,494**	**-**
Current liabilities			
Short-term interest bearing debt	60,381	-	53,466
Other liabilities	6,327	7,725	5,776
Total liabilities	**66,709**	**7,725**	**59,241**
TOTAL EQUITY AND LIABILITIES	**431,892**	**443,328**	**428,173**

Key financial ratios for the group

	2025 Jan-Mar	2024 Jan-Mar	2024 Jan-Dec	2023 Jan-Dec	2022 Jan-Dec
Net sales, SEK thousand	4,360	-	94,628	5,678	61,136
Operating profit/loss, SEK thousand	-28,641	-37,636	-75,111	-180,765	-113,110
Profit/loss for the period, SEK thousand	-33,969	-39,019	-83,129	-177,839	-113,406
Profit/loss attributable to the parent company's shareholders, SEK thousand	-33,969	-39,019	-83,129	-177,839	-113,406
Earnings per share before and after dilution, SEK	-0.65	-0.75	-1.60	-3.43	-2.19
R&D costs, SEK thousand	27,517	28,937	163,669	151,312	146,178
R&D costs as a percentage of operating expenses, %	75	77	87	81	84
Cash and cash equivalents at the end of the period, SEK thousand	88,605	73,140	66,917	111,309	252,776
Cash flows from operating activities, SEK thousand	6,332	-38,211	-65,590	-164,860	-146,612
Cash flows for the period, SEK thousand	21,688	-38,169	-44,394	-141,467	-149,121
Equity, SEK thousand	4,632	76,745	32,635	115,764	290,831
Equity attributable to the parent company's shareholders, SEK thousand	4,632	76,745	32,635	115,764	290,831
Equity per share, SEK	0.09	1.48	0.63	2.23	5.61
Equity ratio, %	3	56	24	65	90
Average number of employees	31	32	31	31	29
Average number of employees in R&D	27	28	27	26	25

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

Other information

Accounting principles

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

The accounting principles applied correspond to those applied in the 2024 Annual Report with the addition that income from MJFF and MSRD are reported as a prepaid income and will be recognized as income in line with the costs of the activites they are intended to cover.

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

Financial instruments

The group currently has no financial instruments that are valued at fair value, rather all financial assets and liabilities are valued at accrued acquisition value. It is judged that there are no significant differences between fair value and book value regarding the financial assets and liabilities. On the closing date, the carrying amount of financial assets was SEK 88,967k (73,385). The financial assets consist mostly of cash and cash equivalents.

Transactions with related parties

IRLAB has during the period January 1 - March 31, 2025 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 been considered not significant for neither IRLAB nor the recipient, and has been on market conditions.

Revenue January - March 2025

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

Net sales by revenue category	2025 Jan–Mar	2024 Jan–Mar	2024 Jan–Dec
Service revenue	4,360	-	94,628
Total revenue	**4,360**	**-**	**94,628**

Segment information

Net sales by geographic market	2025 Jan–Mar	2024 Jan–Mar	2024 Jan–Dec
USA	4,360	-	94,628
Total revenue	**4,360**	**-**	**94,628**

All invoicing was in American dollars (USD). Revenue is recognized in Swedish krona (SEK). In the tables above, all amounts are in thousand SEK.

Risks and uncertainties

The nature of research and development of pharmaceuticals are associated with high risks, and the effects of these risks on the company's earnings and financial position cannot always be controlled by the company. It is therefore important to take the risks into account when assessing IRLAB's future potential in addition to the opportunities that are inherent in both projects and operations. IRLAB's business model entails high development costs that do not generate potential revenues connected to licensing, sales or partnerships until the majority of the drug development has been completed.

The company's financial risks are described on pages 88–89 and its risk management is described on page 125–127 of the 2024 Annual Report. No significant changes have occurred that affect the reported risks.

The wars in Ukraine and the Middle East, along with the resulting geopolitical instability in nearby regions, may impact both the pace of patient recruitment and the ability of already recruited patients to attend required clinic visits. IRLAB's upcoming study with IRL757 may be conducted in areas geographically close to Ukraine, which entails a potentially increased risk of disruptions. However, in previous studies, only minor impact has been observed, and we are continuously monitoring the situation to take appropriate measures if needed.

The ongoing uncertainty in the United States—marked by economic instability and trade-related tensions—continues to contribute to increased volatility in the global capital markets. For a research-driven company without marketed products, both financing and operations may be affected by the changing investment climate, access to research materials, and regulatory processes. It may also complicate or delay discussions and agreements with potential partners.

Employees

During the quarter, work corresponding to 30 (31) full-time equivalents was performed. This work has been distributed among 32 (33) people.

Annual General Meeting

The 2025 Annual General Meeting will be held on June 11, 2025 in Gothenburg.

Sustainability

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

Events during the period

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

In January, the company was granted a waiver by the EMA regarding pediatric studies with mesdopetam for Parkinson's disease.

At the end of January, the company reported positive topline results from the Phase I study with IRL757 in healthy elderly subjects.

In February, the company's loan financing was refinanced and expanded.

Also in February, the company received positive feedback from the EMA confirming alignment with the FDA regarding the Phase III program for mesdopetam.

In March, topline results from the Phase IIb study with pirepemat were first reported, followed by additional positive efficacy data from the same study.

Preclinical data for mesdopetam were also published in March in the journal European Journal of Neuroscience.

At the end of March, the company announced the launch of a study with IRL757 in Parkinson's disease, fully funded by its development partner MSRD..

Events after the period

No events has occured after the period.

Review by the auditors

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

Board's assurance

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

Gothenburg, May 7, 2025

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

Glossary

API
API stands for Active Pharmaceutical Ingredient, and it refers to the primary ingredient in a medication that provides its therapeutic effect.

CNS disorders
Central Nervous System (CNS) disorders are a broad category of conditions in which the brain does not function as it should, leading to a decline in health and the ability to function.

CRO
Clinical Research Organization (CRO) conducts clinical studies on behalf of biotech companies that may not have the internal capacity, as in larger pharmaceutical companies.

Drug Product
Refers to the medication to be used in clinical trials. The Drug Product contains Active Pharmaceutical Ingredients (API) and additional ingredients to ensure beneficial properties of the entire medication, such as bioavailability, proper shelf life, stability, or formulations with slow release.

DSMB
Data Safety Monitoring Board (DSMB) is an independent safety committee responsible for continuously reviewing clinical study data during an ongoing study to ensure the safety of study participants and the validity and integrity of data. DSMB provides recommendations regarding the continuation, modification, or termination of the clinical study based on the results of the predefined data review.

End-of-Phase 2 meeting
The purpose of an end-of-Phase 2 meeting is to determine the safety of proceeding to Phase III, to evaluate the Phase III plan and protocols and the adequacy of current studies and plans, and to identify any additional information necessary to support a marketing application for the uses under investigation.

GMP manufacturing
GMP stands for Good Manufacturing Practice, which describes how pharmaceutical companies should manufacture drug substances to ensure that regulatory authorities and patients can always be confident they are receiving the right product of high quality.

ISP
Integrative Screening Process (ISP) is IRLAB's proprietary research platform used to generate drug candidates.

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

IRLAB

IRLAB discovers and develops a portfolio of transformative treatments for all stages of Parkinson's disease. The company originates from Nobel Laureate Prof Arvid Carlsson's research group and the discovery of a link between brain neurotransmitter disorders and brain diseases. Mesdopetam (IRL790), under development for treating levodopa-induced dyskinesias, has completed Phase IIb and is in preparation for Phase III. Pirepemat (IRL752), currently in Phase IIb, is being evaluated for its effect on balance and fall frequency in Parkinson's disease. IRL757, a compound being developed for the treatment of apathy in neurodegenerative disorders, is in Phase I. In addition, the company is also developing two preclinical programs, IRL942 and IRL1117, towards Phase I studies. IRLAB's pipeline has been generated by the company's proprietary systems biology-based research platform Integrative Screening Process (ISP). Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A).

Contact information

FOR FURTHER INFORMATION, PLEASE CONTACT:

Kristina Torfgård, CEO
+46 730 60 70 99
kristina.torfgard@irlab.se

Viktor Siewertz, CFO
+46 727 10 70 70
viktor.siewertz@irlab.se

HEAD OFFICE

IRLAB Therapeutics AB, Corporate identity No. 556931-4692
Arvid Wallgrens Backe 20
413 46 Gothenburg
Sweden
+46 31 757 38 00
www.irlab.se
info@irlab.se