IRLAB

Annual Report 2022

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

IRLAB THERAPEUTICS AB (PUBL)

Contents

IRLAB in brief

IRLAB discovers and develops novel treatments to transform the lives of people living with Parkinson's disease and other CNS disorders.

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).

Focused strategy

IRLAB discovers and develops treatments for people with Parkinson's throughout their whole disease journey.

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 positive Phase II data in patients.
- First program out-licensed to major pharma company.

Organization positioned for success

IRLAB is an experienced organization.

IRLAB is listed on the Nasdaq Stockholm main market (IRLAB A).

IRLAB A

Broad & solid portfolio

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

Phase IIb

- Mesdopetam: to counteract Parkinson's levodopa-induced dyskinesias (PD-LIDs).
- Pirepemat: to improve balance and reduce falls in Parkinson's (PD-Falls).

Preclinical

- IRL757: to treat apathy.
- IRL942: to improve cognitive function and brain health.
- IRL1117: a new technology for the treatment of Parkinson's hallmark symptoms with potential to replace levodopa.

The operations

IRLAB is a Swedish research and development company developing novel drugs for the treatment of Parkinson's disease and other disorders related to the central nervous system (CNS) with the aim of transforming the lives of those affected and their families. 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, especially Parkinson's. The company has a well-defined, strategically focused R&D pipeline of powerful new treatments targeting the various stages of Parkinson's as the symptoms develop over time. Having a full range of effective disease management options for Parkinson's 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 increases due to an aging global population. The treatment alternatives are few despite the major unmet medical needs.

World-unique research platform ISP

IRLAB has developed the unique, disruptive research platform Integrative Screening Process (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 the probability of success. Based on advanced machine learning-based techniques, ISP first interrogates the company's extensive proprietary CNS pharmacology database, then informs IRLAB's medicinal chemists on the optimal molecule design for potential drug candidates with the desired therapeutic effect and safety.

Five drug candidates in development

Today, IRLAB has five drug candidates at different stages of development from preclinical through Phase IIb, generated by the ISP platform.

The 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-response, identify dose regime for Phase III and generate additional safety data. The company's second clinical candidate pirepemat (IRL752) has also completed Phase I safety, Phase IIa efficacy proof-of-concept studies and is currently 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, IRLAB is developing two preclinical drug candidates to treat neuropsychiatric symptoms: cognitive impairment (IRL942) and apathy (IRL757) in Parkinson's, which represent great unmet medical needs. The company's third preclinical candidate IRL1117 is a once-daily treatment to treat the hallmark symptoms of Parkinson's without causing fluctuations in efficacy or inducing the troublesome complications caused by today's mainstay anti-Parkinson's levodopa-based treatments.

Mesdopetam is out-licensed to the global specialty care company Ipsen and, in addition to potential revenue, brings further validation to the commercial value of the company's portfolio. The anticipation is that the potential of the five drug candidates for the treatment of people with Parkinson's and other neurological disorders will make them attractive targets for the pharmaceutical industry and in turn, yield substantial value for shareholders.

Transforming lives of patients with Parkinson's

An article published in *The BMJ* identified ten prioritized areas in the management of Parkinson's. These included treatment of motor complications, such as levodopa-induced dyskinesias (LIDs), non-motor symptoms, such as psychosis, anxiety, impaired balance, and falls, as well as cognitive impairment. This study strongly supports the major clinical needs in the treatment of Parkinson's and the difference IRLAB's drug candidates can potentially make for affected patients.

KARIN ÖNNHEIM, works with evaluation of the effect of the drug candidates we synthesize and test in various model systems.

Highlights during the past year

Portfolio expanded with drug candidate IRL757

A new drug candidate, IRL757, was nominated at the beginning of 2022 for the treatment of apathy in people with Parkinson's and other neurological disorders. There are no approved treatments for apathy today even though it is one of the most common and troublesome neuropsychiatric symptoms in neurodegenerative disorders, both for patients and their caregivers.

IRL757 has the potential to be the first treatment in a new class of drugs designed to treat apathy in people living with Parkinson's and other neurological disorders. Positive efficacy by IRL757 has been obtained in several preclinical models of impaired cognitive function including signals of improved motivation. The drug candidate is now being taken through all the necessary steps, i.e. IND/CTA-enabling studies, in preparation to start clinical studies.

Restructuring the company management

In the summer of 2022, the company's management structure underwent a change. The previous combined role of CEO and Head of Research & Development (R&D) was split into two distinct roles. The purpose behind this restructuring was to allow the Head of R&D to focus solely on research-related matters, providing dedicated support to the development of our five substances currently in development. Meanwhile, the CEO's role was redefined to focus more strategically on financing, business development, and fostering collaborations with other companies. This change is a critical step towards facilitating growth in our commercial activities and preparing to run multiple clinical development programs concurrently.

In July, Richard Godfrey was recruited as new CEO for the company. In February 2023, the board took the decision to dismiss Richard Godfrey and install Gunnar Olsson to the role as interim CEO for the time until a new CEO has been recruited. Recruitment activities are ongoing.

IRL1117 – new nominerad drug candidate

At the beginning of 2023, the drug candidate IRL1117 was nominated as a new addition to the company's portfolio. IRL1117 is a potent orally available dopamine D1 and D2 receptor agonist that is currently in development as an innovative once-daily treatment for the hallmark symptoms of Parkinson's. In preclinical studies, IRL1117 has shown to be free of fluctuations in efficacy and troublesome complications, unlike the mainstay anti-Parkinson's treatment levodopa. Preclinical studies have demonstrated that IRL1117 exhibits rapid onset and more than 10 hours of sustained efficacy. Successful clinical development of IRL1117, derived from the P003 research project, could significantly change the current treatment paradigm for Parkinson's disease and become a crucial drug for managing its hallmark symptoms.

Furthermore, the acquisition of know-how related to the P003 project in 2022, combined with the ongoing development of the project, has further strengthened IRLAB's preclinical project portfolio.

New data presented at scientific conferences and in publications

IRLAB has been active and participated at several medical and scientific conferences during the year to share knowledge by showcasing new results and to give further understanding about our drug candidate projects and our research platform ISP.

New preclinical data providing insight into the mechanisms underlying antipsychotic and anti-dyskinetic efficacy of drug candidate mesdopetam (IRL790) in PD-P and PD-LIDs were presented at the congress Neuroscience 2022 in San Diego, US, in November. The new data provide further clarity on how mesdopetam differentiates from current therapies in Parkinson's.

Furthermore, study results from the Phase I study with pirepemat (IRL752) have also been published in the high ranked scientific journals Clinical Pharmacology in Drug Development (CPDD) and Pharmacology Research & Perspectives (PR&P).

Regarding the research platform ISP, a collaboration between the Department of Mathematical Sciences was presented at Chalmers University of Technology, Smartr – a company specialized in artificial intelligence (AI), and IRLAB related to the application of deep learning on multidimensional effects of CNS drugs. A summary of the results was presented at SfN Global Connectome: A Virtual Event Society of Neuroscience (SfN), one of the world's leading conferences in neuroscience.

Clear anti-dyskinetic effects demonstrated by mesdopetam in Phase IIb study

The top-line results of the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias were reported in the middle of January 2023. While the study did not reach statistical significance in the primary endpoint, it achieved its purpose of confirming dose-dependent effects and the selection of best dose for further clinical studies. Mesdopetam demonstrated clear anti-dyskinetic effects during the full 12-week treatment period with an adverse event and tolerability profile at the same level as placebo. The anti-dyskinetic effects were achieved without reducing normal motor function and are further strengthened by a clear reduction of OFF-time. Detailed analyses of the full data set from the study are ongoing in collaboration with our partner Ipsen.

There is now 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 a continued Phase III program and toward future marketing registration of a new drug.

Symposium at a leading medical congress

An industry symposium, organized by IRLAB, at the AD/PD™ 2023 International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders was held on Friday, March 31, 2023. It was an official symposium at the congress, supported by IRLAB, with the title The management dilemma of Parkinson's disease progression and emerging treatment approaches. The symposium had a distinguished panel of leading experts addressing the challenges in managing Parkinson's disease. A recording of the symposium can be found on IRLAB's web page, www.irlab.se.

Financial overview

All figures refer to the group	2022	2021	2020	2019
Operating result, tSEK	–113 406	52 576	-91 458	-95 848
Result for the year, tSEK	-113 406	51 781	-91 653	-96 120
Earnings per share before and after dilution, SEK	-2,19	1,00	-1,92	-2,37
Cash and cash equivalents, tSEK	252 776	401 897	277 009	110 527
Equity per share, SEK	5.61	7.72	6.72	4.22
Solidity, %	90	85	94	87
Average number of employees	29	22	18	17
of which are within R&D	25	20	17	16

Conversation between the CEO, Head of R&D and Chairperson

Gunnar Olsson, Nicholas Waters and Carola Lemne talk about IRLAB's research, development projects, and future to improve the lives of those living with Parkinson's disease.

If you were to summarize, how was 2022 for IRLAB?

– ***Gunnar Olsson (GO):*** Looking back on 2022, it was a tremendously important year for IRLAB. We expanded our research portfolio and now have five different substances in the development phase, all with a blockbuster potential. We nominated the new candidates IRL757 and IRL1117 and initiated subsequent preclinical development work, which is now running in parallel with preclinical development for IRL942. We began the Phase IIb study with pirepemat and completed patient recruitment in the Phase IIb study with mesdopetam. In order to effectively manage our five pharmaceutical projects, which will be in clinical phase in the next few years, we made the decision to strengthen our management team. Overall, it was a year full of exciting developments for IRLAB.

How has IRLAB been strengthened by the last year's changes in management and board?

– ***GO:*** The most important organizational change in 2022 was that we created separate CEO and head of research roles within the company management instead of having these tasks in one role as before. The effect has been that the Head of Research & Development (R&D) can focus on research-related issues and provide support for the development work around our five substances in the development phase, while the CEO's role is now directed more towards strategic issues around financing, company development and creating collaborations with other companies.
– ***Nicholas Waters (NW):*** The fact that we are now separating out areas of responsibility to more employees with clear focus is an important change in the preparations for growth in both our commercial activities and in the preparation to run more clinical projects in parallel. In our research organization, we have strengthened our in-depth competence in handling data, statistics and we continue to strengthen and develop our effective research platform, ISP, in order to be able to deliver additional new drug candidates within our focus areas.

– ***Carola Lemne (CL):*** As we continue to develop our unique portfolio, the demand for expertise in various areas has increased. Our investments this year were all geared towards enhancing our ability to effectively advance our substances and to determine the optimal path towards their commercialization.

How do you perceive the process of hiring a permanent CEO for the company? What are the key qualities you are seeking?

– ***GO:*** TWe are looking for a person with broad knowledge of pharmaceutical development/commercialization, and who has good leadership skills to be able to continue developing the company. We must take into account here that IRLAB today has a world-leading portfolio of research projects, and the goal for a new CEO will be to ensure that this position can be further developed to the benefit of both patients and shareholders.

– ***CL:*** I also believe that an important task for our CEO is to build the strongest possible team for the exciting challenges and opportunities we have ahead of us. Developing and commercializing medicines is a very complex, regulated and, time-consuming business, and success is based on strong teams where each individual contributes their unique skills to a creative and efficient whole.

Conversation between the CEO, Head of R&D and Chairperson

Are there any risks or challenges that you are keeping an extra close eye on in 2023?

– ***GO:*** At IRLAB, we are engaged in researching and developing first-in-class medicines, which entails being prepared for unexpected findings and having the ability to make sound judgments and identify opportunities in such situations. This necessitates close monitoring of developments across our entire research portfolio.

In 2023, we are focusing particularly on two areas: our collaboration with Ipsen and our cost management. Following the completion of the Phase IIb study with mesdopetam, the project's further planning and execution has been handed over to Ipsen. We have gone through all the study results in the Phase IIb study with Ipsen, who are now evaluating the situation and then decide on the next step. Cost management has always been a top priority for us, and with the addition of two new substances to our development pipeline, we will need to maintain our focus on cost efficiency. We are continuously exploring various funding activities to secure the necessary resources to drive forward our portfolio of innovative drug candidates. Nonetheless, should we face any setbacks in this, it may impede the progress of our projects and lead to delays.

– ***NW:*** In the field of research, technical risks are always at the forefront, closely followed by implementation risks in both preclinical and clinical studies. At IRLAB, we continuously work to identify and mitigate these risks. Technical risks have historically posed a significant challenge in drug development. However, our unique research platform, ISP, allows us to address these risks early on in the discovery phase. We have observed that drug candidates developed using the ISP platform have a higher likelihood of success, from preclinical to Phase III studies.

In R&D, the major risks and challenges are related to the implementation of international clinical studies in indication areas where we are pioneers in developing medicines that work via new mechanisms. As we explore uncharted territory, it requires significant effort and expertise from our organization to make quick and informed decisions. We are focused on addressing these challenges to ensure that our innovative drug candidates can benefit patients in need.

– ***CL:*** From the board's perspective, in addition to the aforementioned points, it is crucial to closely collaborate with Gunnar in his new position, to provide both guidance and constructive criticism to him and the entire team, and to initiate a fresh search process to secure a permanent CEO.

How does IRLAB differentiate itself from competitors – and other drug development companies?

– ***GO:*** IRLAB is in many respects unique. We have a world-leading portfolio of drug candidates in Parkinson's/CNS and we have a unique research platform (ISP) to identify new innovative drug candidates for the treatment of brain diseases. Our selected candidates have a higher probability of success than drug candidates selected through the traditional methodology used by the majority of pharmaceutical companies. Our research has a strong focus on Parkinson's, which is based on world-leading knowledge about the causes of the disease, which originates from Nobel Prize-winning research in Arvid Carlsson's laboratory. All this gives us a very strong position in our field.

– ***NW:*** Our success lies in our ability to identify and develop drug candidates that address real needs for patients, utilizing the unique capabilities of our ISP platform to generate drug candidates for the most immediate clinical needs. Our extensive experience in basic research and development of drug candidates for brain diseases is a key factor in this success.

– ***CL:*** Through its unique ISP platform and its successful long-term approach, IRLAB has achieved something quite rare in our industry: a "small" pharmaceutical company with a "big" portfolio. It is the quality of our research, combined with a long-term perspective and the support of our shareholders over the years, that has made this possible. We are now entering an incredibly exciting development phase for the company.

What is the most important thing for IRLAB in 2023 to continue delivering on the long-term vision of taking-first-in-class drug candidates towards market approval?

– ***GO:*** We have a clear set of priorities for 2023, which includes providing full support for mesdopetam Phase III planning, completing patient recruitment in the ongoing Phase IIb trial with pirepemat, advancing IRL757 through preclinical development for future clinical trials, and progressing IRL942 and IRL1117 through preclinical development in preparation for clinical studies.

– ***NW:*** In 2023, one of our top priorities is to provide full support for the Phase III planning of the mesdopetam program. Additionally, it is crucial that we successfully recruit all patients for the ongoing Phase IIb trial with pirepemat, which has the potential to bring hope to those living with Parkinson's who experience recurrent falls. Our preclinical projects IRL757 and IRL942 target indications with high unmet needs and we aim to advance them to Phase I trials.

Our latest drug candidate, IRL1117, addresses a critical need in the treatment of Parkinson's. Although levodopa-based drugs are available to treat the hallmark symptoms, large international studies have shown that patients and their families are still dissatisfied with the control of stiffness, tremors, and slow movements. IRL1117 has the potential to provide an effective, long-acting treatment for these symptoms without the complications, such as strong fluctuations in effect, that arise from levodopa treatment.

"IRLAB is in many respects unique. We have a world-leading portfolio of drug candidates in Parkinson's/CNS and we have a unique research platform (ISP) to identify new innovative drug candidates for the treatment of brain diseases. Our selected candidates have a higher probability of success than drug candidates selected through the traditional methodology used by the majority of pharmaceutical companies. "

Goals & Strategy

IRLAB's strength is in discovering new drug candidates with the help of the research platform ISP and developing them into so-called clinical proof-of-concept when clear indications of efficacy, tolerability, and safety are achieved. IRLAB's business model, competence, and experience are designed to utilize this strength. By developing innovative drugs, IRLAB helps people living with Parkinson's to a better life, which is a great benefit to society. This can, over time, lead to substantial value creation for our shareholders.

Two routes to shareholder value

IRLAB's business model has the potential to generate revenue by out-licensing drug candidates and by entering into collaborations based on the ISP platform.

Drug candidates

IRLAB's drug candidates can provide shareholder value through licensing/partnership or sale of projects. Revenue is then received in the form of a payment when signing an agreement, milestone payments, and royalties. IRLAB's main focus is to develop unique drug candidates up to and including Phase II studies and achieve clinical "proof-of-concept". After that, collaboration agreements will be entered into for further development in Phase III, primarily through license agreements with licensees who have the necessary resources to complete development and to commercialize the drug after regulatory approval.

The ISP research platform

IIn preclinical research, the ISP platform can be used in collaboration with other pharmaceutical companies. It creates opportunities for revenue in the form of research collaboration agreements, as well as milestone payments and royalties on the products that the partner chooses to develop. IRLAB's current strategy is to utilize internal resources in order to develop its own drug candidates and thereby maximize the value in those. ISP has high precision and is resource and cost-efficient, which means that only the development of molecules with very good prerequisites for success takes place. To the extent that the company believes that there are additional resources within the framework of the ISP, these can be offered to external parties.

What does IRLAB need to succeed?

Competent employees

Well-educated and motivated personnel is a prerequisite for conducting research and development activities in the best possible manner. IRLAB needs to maintain a high level of competence of employees and external consultants.

Well-planned clinical development

Successful studies are necessary in order to move forward with the company's drug candidates. Good prerequisites for this are created through careful and detailed work on development plans and design of studies, which are validated together with area experts and through interactions with regulatory authorities.

Innovative research

IRLAB needs to promote continuous development of knowledge and methodology around the company's research platform, ISP. IRLAB's drug candidates have originated from ISP, and it is important to continuously develop the method in order to maintain a continued high level of innovation in the creation of the company's future pipeline.

Effective collaboration

Good relationships with partners and external expertise are needed to be able to effectively carry out the company's research and development activities, as well as strategic and operational activities. By using the best partners or area experts in each important area, IRLAB can obtain the best prerequisites.

Strong IP protection

IRLAB works continuously to protect the company's technologies and innovations. This is performed through continuous work in processes aimed at protecting the intellectual property rights of the ISP platform and our drug candidates.

Optimized organization

In order to create the best prerequisites for developing new treatments for Parkinson's patients, IRLAB needs to maintain a continuous focus on constantly optimizing the organization with regard to effectiveness, quality, and flexibility.

Strong financial position

IRLAB needs to constantly work with the capital structure to secure the development of the company's projects and pipeline. This also entails managing budgets and costs responsibly in order to best manage shareholders' trust.

What?

IRLAB strives to meet the need for novel drugs for the treatment of Parkinson's disease and other CNS-disorders.

Why?

IRLAB wants to transform the lives of people with Parkinson's disease and other CNS disorders. The aim is to provide these people with the possibility of increased quality of life.

How?

With IRLAB's cutting-edge expertise in modern research and development, effective and successful medicines are created.

Financing

IRLAB is a research and development company with no regular income. The company is primarily financed via the capital market or through out-licensing or sales of projects. The financing strategy is to continuously ensure that the company is sufficiently financed via the capital market to be able to operate the business efficiently and make rational business decisions. Activities to obtain financing via the capital market are ongoing in parallel with processes to be able to enter into agreements on out-licensing or sales.

Viktor Siewertz, CFO, on the company's financing:

Can you comment on the current situation in the financial markets and how it affects IRLAB?

– Financial markets are currently challenging with many uncertainties leading to high interest rates and geopolitical instability, much due to the ongoing war in Ukraine. This has led to capital being allocated away from high-risk investments, including those in the biotech industry. Also, there is significant competition for investors' money with so many biotech companies needing funding right now.

As a biotech company, we require continuous capital injections as part of our business model. Although we are currently relatively well capitalized, we need to continue to be vigilant about our financial stability. The high-cost base for biotech companies, especially in research and development, means that we need access to the capital markets to support our operations and would benefit from stable capital markets before we need to seek new financing.

Are there any alternative financing methods that you have explored?

- Yes, definitely. For example, another valuable financing method for our company is licensing agreements or other types of collaborations, which we actively work to secure. In 2021, we entered into a license agreement with Ipsen, which has had a very positive effect on our company. The agreement not only provided us with additional funding but also helped us support our research and development efforts in a meaningful way.

IRLAB also has the advantage of having five different substances in development, which means we have our eggs in different baskets, which is good and gives us more options than many other companies. It is also important that we remain flexible and have the ability to act quickly when necessary. We must be able to adapt to changing market conditions and take advantage of opportunities as they arise.

How do you ensure that your financial strategies are in line with your long-term goals?

– We constantly monitor the financial markets and strive to make strategic decisions that benefit our company and our shareholders. We understand that we have a responsibility to our shareholders to ensure that we run the business efficiently and that our finances are stable. We will continue to work hard to secure the necessary financing to support our operations and achieve our long-term goals in the manner most beneficial to our shareholders.

How does IRLAB plan to manage its costs in light of the challenges that exist in the financial markets?

- Cost control is always a top priority for us as a biotech company. Given the challenges that now exist in the financial markets, we have had to look closely at our spending and identify areas where we can reduce costs without compromising the quality of our research and development.

VIKTOR SIEWERTZ, CFO

Drug development is complex and the road to approval of a new drug can be perplexing. There is no single route forward, but rather many possibilities where, among other things, aspects such as chemical structure, mechanisms of action, analytical methods and regulatory requirements govern. The illustration below shows IRLAB's vision of the development process and where IRLAB's project is in this process.

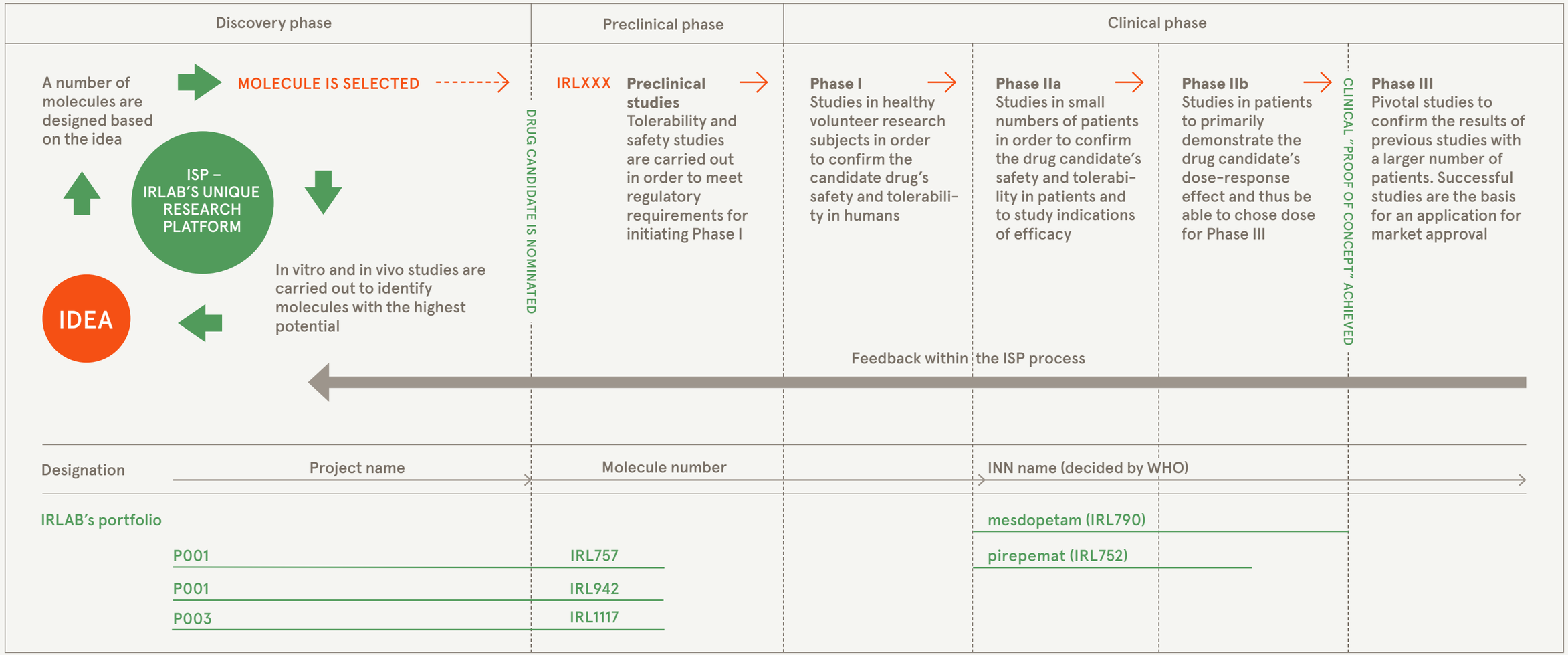


Illustration by IRLAB, April 2023

Parkinson's disease

Parkinson's disease is the second most common neurodegenerative disease after Alzheimer's disease. Globally, it is believed nearly nine million people are living with the disease, and that the number will more than double by 2040. Today's available treatments are insufficient and the need for new, effective drugs that can improve the quality of life of Parkinson's patients is significant and urgent.

In Parkinson's disease, nerve cells that use the neurotransmitter dopamine slowly disappear and cause a reduced level of dopamine in the brain. Parkinson's develops slowly and is usually not diagnosed until close to 80 percent of the dopamine cells have disappeared.

The disease is both chronic and progressive, in other words, it is both lifelong and worsens over time. Parkinson's symptoms usually appear after the age of 60 but can also affect younger people. The onset of Parkinson's disease is usually after the age of 60, but it can also affect younger people. The exact cause of the disease is not known, and at present, there is no way to prevent the onset or slow down its progress. In recent years, several genetic defects have been identified, but overall, these only account for a minor share of all diagnosed cases.

Motor and non-motor symptoms

Parkinson's is primarily associated with characteristic motor symptoms, such as tremors, muscle stiffness, mobility impairment, and balance problems (so-called postural dysfunction). These symptoms result in difficulty in walking, starting movements, and performing repeated motions (such as writing or brushing teeth), decreased facial expressions, weakened voice, impaired balance, and recurring falls. The movements become less automated, slower, and require more mental effort.

Parkinson's also causes so-called non-motor symptoms, such as problems related to cognition (for example, memory, the ability to think or plan, decision-making, and learning), or to mental health, such as depression, apathy, anxiety, fatigue, and sleep problems. The so-called autonomic nervous system may also be affected, which can cause problems such as a drop in blood pressure, impotence, and incontinence.

Neuropsychiatric symptoms

In later stages of Parkinson's, people often develop neuropsychiatric symptoms such as psychotic symptoms in the form of hallucinations and delusions. People with Parkinson's also suffer from cognitive decline, which gradually worsens over the course of the disease with difficulties with attention, memory and executive function.

Apathy is another complex symptom that people with Parkinson's and other neurodegenerative diseases can develop over time and which significantly reduces the quality of life for both the patient and relatives.

Hallmark symptoms of Parkinson's

Parkinson's affects the nervous system and causes gradual changes in the body's ability to move and function. The symptoms of Parkinson's vary from person to person, but there are three hallmark symptoms: tremor, rigidity and bradykinesia. People with Parkinson's are treated with the anti-Parkinson drug levodopa, which reduces these particular symptoms.

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 fluctuations in effect and excessive involuntary movements and periods with low effect of the medication, so called OFF-periods, which may be due in part to fluctuating medication and dopamine levels.

There is currently no anti-Parkinson treatment that is simple to dose and that exhibits a long-lasting anti-Parkinson effect without inducing the troublesome fluctuations in effect or other complications during long-term treatment.

Dyskinesias, involuntary movements

A common and difficult-to-treat complication of chronic levodopa treatment is dyskinesias, often referred to as PD-LIDs (Parkinson's Disease Levodopa-Induced Dyskinesias). Dyskinesias refers to involuntary movements which are caused by the levodopa treatment the patient has to take to stay mobile. Dyskinesias are often very troublesome, and as such overshadow the benefit of the levodopa treatment that is necessary to treat the underlying symptoms. The resulting dyskinesias consequently reduce the time patients have good mobility and can control the symptoms. More than 30 percent of people with Parkinson's develop such dyskinesias within five years and about 60 percent after 10 years after starting treatment with levodopa.[1] The concern of increasing the time with troublesome dyskinesias often leads to doctors being forced to prescribe a lower dose of levodopa than would have been optimal for the treatment of the underlying symptoms.

In Europe, there is no approved drug for the treatment of PD-LIDs. The drug amantadine has long been used to control PD-LIDs, although it is not approved for that indication. In 2017, amantadine ER, a long-acting formulation of amantadine, was approved for the treatment of PD-LIDs in the United States. Amantadine can work well for some patients who tolerate the side effects. Amantadine treatment is associated with complicating side effects, primarily psychiatric. Other options for patients with PD-LIDs are surgical methods, such as deep brain stimulation (DBS), but these are only considered for the most severe cases due to side effects and high costs.

Impaired balance and falls

Impaired balance and a fear of falling substantially impair the daily lives of many Parkinson's patients. Linked to a balance impairment, there is a markedly increased risk of falls. People with Parkinson's have a two to three times greater risk of falling compared to healthy people of the same age. Injuries related to falls are one of the biggest reasons people with Parkinson's seek hospital care. About 60 percent of people with Parkinson's suffer falls each year, and about 70 percent of them fall regularly. This leads to significant increases in injuries and consequently increased healthcare and social costs. In the United States, healthcare costs are estimated at approximately SEK 300 000 (recalculated from USD 30 000) for each fall injury in people over the age of 65 leading to hospitalization. Complications that can be associated with falls are fractures and soft tissue injuries resulting in reduced mobility and a lower quality of life.

Levodopa and other similar drugs have therapeutic effects on reduced mobility and tremors, but they have no effect on balance and cognition.

Cognitive impairment

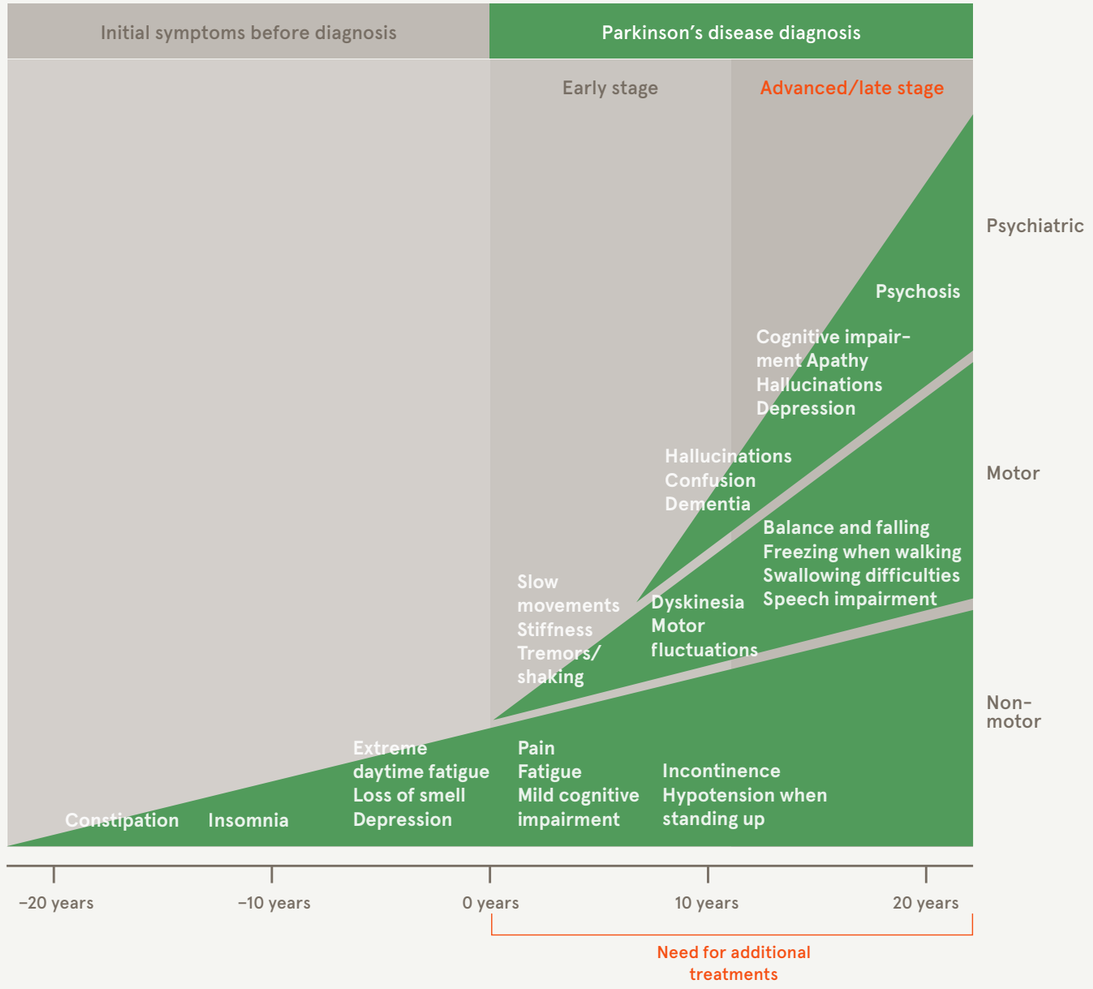
Cognitive impairment is considered a severe complication in Parkinson's because it can affect the person's ability to perform everyday tasks, think, plan and make decisions.

About 12 percent of adults age 65 or older experience cognitive decline. This figure is even higher among people living with a neurological disease. Cognitive impairment can include problems with attention, memory, learning, language, thinking, spatial awareness, and executive functions. The person with Parkinson's may experience difficulty concentrating, forget things, have difficulty managing multiple tasks at once, trouble finding words, and lose the ability to perform daily tasks such as dressing or cooking.

Furthermore, the individual's quality of life is also affected by limiting independence and their ability to participate in social activities. It can also increase the risk of falls and other accidents. In addition, it can be a source of anxiety and stress for the patient and their relatives.

The cause of cognitive impairment and neuropsychiatric symptoms in Parkinson's and other neurological diseases is assumed to be a weakening of nerve signaling in the cerebral cortex.

Diagnosis of Parkinson's disease



Parkinson's disease is diagnosed often at the onset of motor symptoms (0 years) but may be preceded by a premotor phase or premonitory symptoms for as many as 20 or more years. This premonitory phase is characterised by specific non-motor symptoms. After diagnosis, additional non-motor symptoms present that cause tangible impairment in functions. Axial motor symptoms, such as imbalance accompanied by frequent falling and slowing down/freezing while walking, tend to present in advanced stages of the illness. Long-term L-dopa treatment causes side effects that lead to further complications such as dyskinesias and psychosis.
Based on Kalia, LV. and Lang, AE. Lancet 2015;386-912.

Parkinson's disease

Apathy

Apathy is common in people with Parkinson's and can affect motivation, initiative and engagement in daily activities. Apathy is considered a disabling condition reaching over 10 million people in the US and an equal number in Europe. The prevalence is high and apathy is estimated to occur in 20-70 percent of people with Parkinson's and in 20-90 percent of people with Alzheimer's and other CNS disorders.

People with Parkinson's affected by apathy may experience a lack of interest or enjoyment in activities. They may also feel tired, exhausted and without energy, which can make it difficult to complete daily tasks. In addition, apathy can contribute to social isolation and reduced quality of life.

An additional important aspect is that apathy can also change the person's adherence to medication and treatment plans, which can lead to poorer effectiveness of treatment and worsen the individual's health.

The cause of apathy in neurological diseases is not fully known, but it has been suggested that it may be due to a weakening of nerve signaling from the cerebral cortex to deeper brain regions.

Psychosis

People living with Parkinson's often develop psychotic symptoms (PD-P) in the form of hallucinations and delusions. It is estimated that 20 – 40 percent of people with Parkinson's are at risk of developing psychotic symptoms over time.[2] This means more than 750 000 patients in the United States, the EU5 (France, Germany, Italy, Spain and the United Kingdom) and Japan.

There is currently one approved drug for the treatment of PD-P. This drug is approved in the United States for the treatment of hallucinations and delusions, but not in Europe. In the absence of approved drugs, patients are often treated with antipsychotic drugs used in the management of psychotic symptoms in schizophrenia, even though they are not documented for the treatment of PD-P.

Current treatments for Parkinson's

The aim of all current Parkinson's treatments is to achieve good symptom control with as few treatment complications as possible.

Levodopa – efficacious but clear limitations with remaining great medical need

A gigantic leap in the treatment of Parkinson's was made in the 1960s, when the dopamine deficiency was identified, and levodopa treatment was introduced. Levodopa, a precursor to dopamine, is converted to dopamine in the brain, replacing the dopamine that has been lost due to the disease. It was noticed early on that levodopa, which was so effective in reducing reduced mobility and tremors, eventually began to cause involuntary movements (dyskinesia). With time, the treatment becomes increasingly difficult to manage; patients fluctuate rapidly between reduced mobility, OFF, and dyskinesia. The treatment may also cause the patient to hallucinate.

Since the 1970s, almost all people with Parkinson's are treated with levodopa. However, as the disease progresses, it will be necessary to add additional drugs to manage the unwanted side effects caused by the long-term treatment with levodopa.

A further significant limitation is the short duration of action that levodopa has which means that the individual must take a new dose at intervals, sometimes as short as 20 minutes, to achieve optimal effect.

Levodopa and other similar drugs have effect on reduced mobility and tremors, but they have no effect on balance and cognition.

Available add-on to the standard levodopa-based treatments with the aim to improve the management of the hallmark symptoms currently consist of enzyme inhibitors (for example, COMT inhibitors and MAO-B inhibitors), dopamine receptor agonists (mainly D2 type receptors), and amantadine, a compound that inhibits NMDA receptors. However, these have additional side effects and are not fully effective in controlling the symptoms.

[1] Turcano et al. 2018. Neurology 91:1-6
[2] Spears C. (n.d.) Hallucinations/Delusions. Parkinson's Foundation https://www.parkinson.org/Understanding-Parkinsons/Symptoms/Non-Movement-Symptoms/Hallucinations-Delusions

FREDRIK WALLNER, works in our computational group, develops analysis methods for ISP.

Research platform ISP

The Integrative Screening Process (ISP) platform is the core of the resource-effective method used by IRLAB to develop new drug candidates. The ISP methodology combines systems biology-based screening models, an extensive database and the use of machine learning (ML) methodology. This means that IRLAB obtains unique insights into the overall effect of the studied molecules at an early stage of the process. This development strategy gives IRLAB strong competitive advantages in the development of new treatments for disorders of the brain.

ISP looks at the overall effekt

The most common method today to identify new molecules as candidate drugs (CDs) in a research lab is target-based screening. To put it simply, the principle involves searching in vitro for molecules with a certain effect on a single unique specific target protein assumed to be related to the disease in question. However, this approach has many pitfalls since most vital functions have many reserve systems (redundancy systems), that may counteract a single target interaction when tested in real life, and thus result in "no efficacy" finding when tested in patients with the disease in question.

The use of the ISP platform compared to a target-based methodology allows IRLAB to capture the entire complex interaction of the brain's signaling system. By studying the effects of the molecules in a living system (phenotypic screening), new profiles and unexpected mechanisms of action may be discovered using detailed analysis methods. It is extremely difficult to make such findings with a target-based methodology. The ISP platform will also reveal early on whether it is even possible to turn a promising substance into a drug. Many molecules have undesired characteristics that make them impossible to use as a drug, even though they deliver promising results in a test tube. It may involve anything from the inability to enter the body to safety issues. The ability to immediately remove such substances saves considerable resources, both in time and money.

To summarize, the structured systems biology screening models mean that the ISP produces a powerful basis for finding new effective drugs in less time, where previous research results can be reused over and over again to create synergies in combination with new discoveries and AI-based methods. This results in a higher probability of success of the ISP generated candidate drugs compared to industry standard.

More about the systems biology approach

During every experiment, hundreds of variables are measured in every animal – data which is constantly reused in future analyses and comparisons. The ISP platform also means that the selected drug candidates have a much greater chance of passing the future development stages, which reduces the risk of carrying out major in vivo safety programs unnecessarily. All in all, this means that the number of animals required to create an entirely new drug for the treatment of severe diseases can be kept to a minimum.

More about the database

IRLAB's database constitutes a constantly growing reference library that currently contains data on approximately 1,100 proprietary substances and close to 400 known reference substances. Building the databases into the unique source of knowledge that it is today has required long-term, dedicated, and stringent work. It includes high-quality data of measured and calculated profiles on:

- Chemical structure and chemical properties
- Binding affinity to target proteins
- Neurochemical and gene expression effects in different brain regions
- Effect on specified behavioral patterns
- Pharmacokinetics, i.e. how substances are absorbed, distributed, metabolized, and eliminated from the body

Using machine learning processes, these data profiles are analyzed in parallel to capture the underlying connections in the huge amount of data.

Leading in technology development

At IRLAB, research is a fundamental pillar, and it is crucial to consistently enhance and advance our methodologies, remaining at the forefront of modern computational methods. By employing machine learning (ML) techniques, we can boost the efficacy of drug discovery and development via the ISP platform. IRLAB is a technology development leader in the CNS field for systems biology-based drug discovery using these techniques. Multiple ML and artificial intelligence (AI) experts are employed at IRLAB, specifically working towards expanding the utilization of ML and AI within the ISP platform..

Sebastian Oleszko, Research Scientist in AI/ML, about his role and work at IRLAB:

How do you work with AI/machine learning at IRLAB?

– As part of my work, I focus on various aspects related to AI, machine learning, and statistics. Currently, we are developing techniques for collecting and managing the large amounts of information generated by the ISP platform once our measurement methods have been established. To achieve this, we are incorporating behavioral analytics by leveraging video data. Specifically, we are developing algorithms that can detect and analyze specific behaviors using image analysis, providing us with a greater degree of precision when evaluating the efficacy of drug candidates or experimental substances.

What is your background, and why was IRLAB an interesting company for you to join?

– My background is in physics and mathematics, and I became familiar with IRLAB through a project course during my master's studies. The engineer in me quickly became convinced of the working method here at IRLAB, to collect data in a highly standardized manner over a long period of time. As data is a prerequisite for machine learning, I immediately saw the potential of the business and joined the company in 2021.

Is there a specific project or result that you would like to share?

– We are constantly finding new ways to use machine learning in the company to solve problems that would otherwise have been difficult and costly. In a special experiment targeted toward Parkinson's, we recently used algorithms that identify body parts in an animal to count how much they rotate during a treatment experiment. Traditionally, these assessments have been done with a physical machine, but now we have been able to speed up testing, eliminate complex equipment while getting more data, and as an added bonus, reduce costs through machine learning analysis.

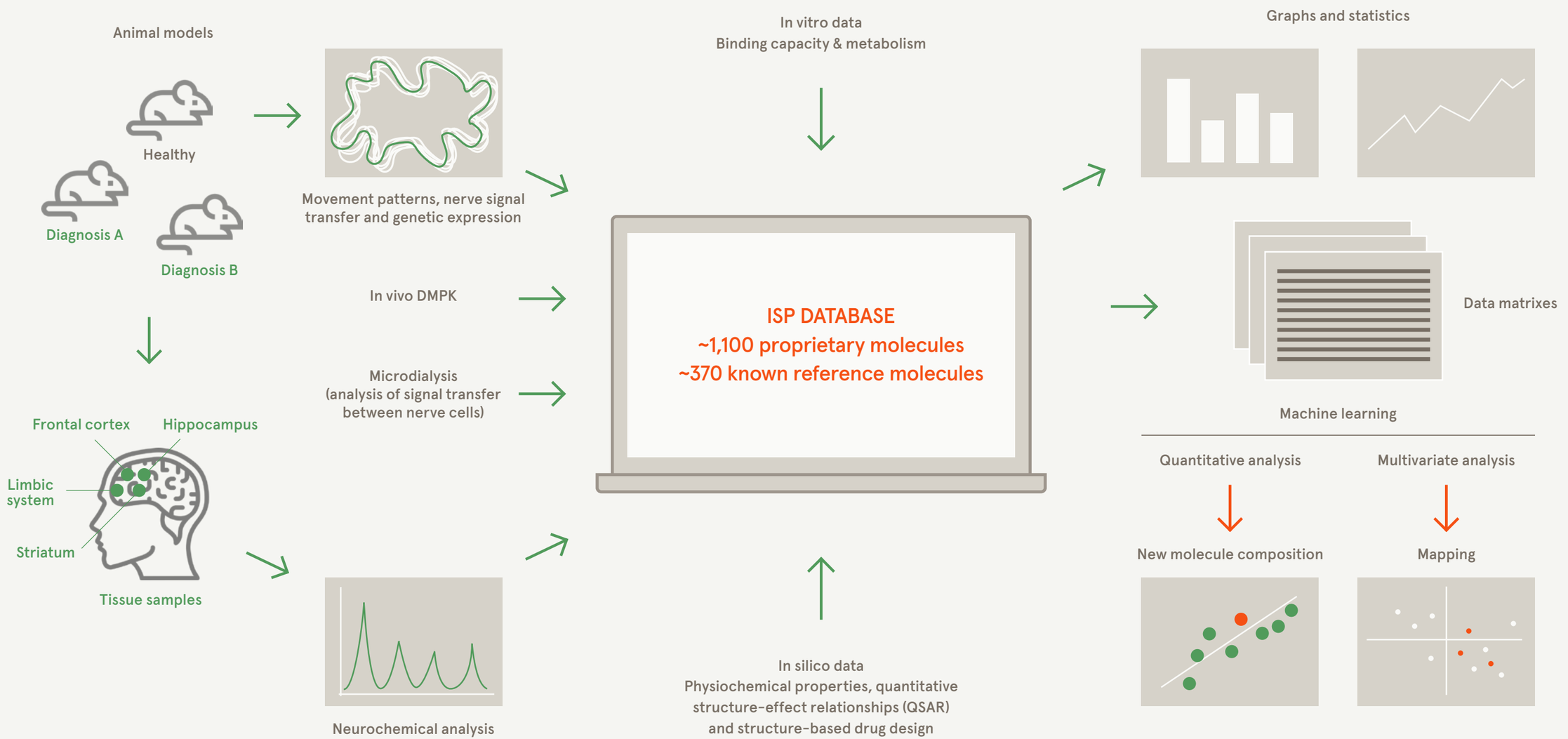
How do you think AI can change drug development in the future?

– Biological systems, such as the human body, can be very complex and often difficult to model accurately with mathematical formulas. I believe that machine learning is the perfect tool for studying such systems where we allow the computer to find relationships in the available data without having to model every little aspect separately. Therefore, I think that machine learning has all the possibilities to completely change drug discovery and the development process when we have enough data to model the mechanisms that are crucial for disease and biological function.

AI (Artificial Intelligence) is a broader concept that includes various techniques and methods of making computers intelligent and autonomous. Machine learning is one of these techniques and is about teaching computers to do tasks by training them on data, instead of explicitly programming them.

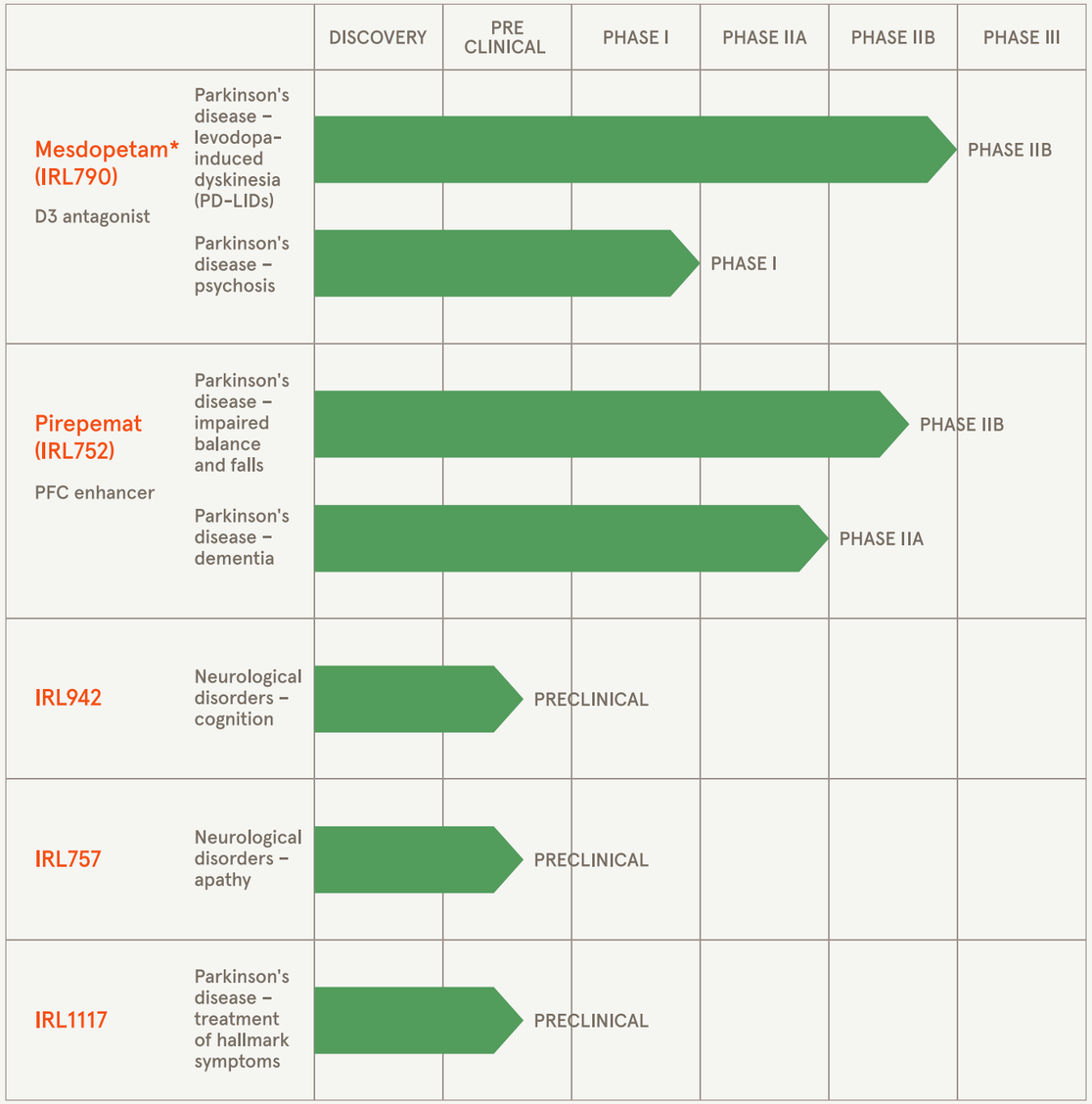
SEBASTIAN OLESZKO, works with machine learning and development of methods for analysis of data.

Data flow in the ISP research platform



By testing a molecule, in particular in a living organism across a predetermined number of parameters, data is collected and processed with comparable existing data on previously tested molecules, proprietary and known.

IRLAB's research and development portfolio



PFC enhancer = noradrenaline and serotonin antagonists In the prefrontal cortex

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

Project portfolio

IRLAB's project portfolio is specifically aimed at discovering and developing novel drug candidates for the treatment of Parkinson's disease, covering the entire disease progression. The portfolio comprises drug candidates in various stages of clinical and preclinical development, all of which have been developed using the company's proprietary research platform, ISP.

Clinical phase

Mesdopetam

Mesdopetam (IRL790) is a dopamine D3 receptor antagonist in development as a treatment for Parkinson's disease levodopa-induced dyskinesias (PD-LIDs). The project is run in a partnership with Ipsen. The primary objective of mesdopetam is to improve the quality of life of individuals with Parkinson's by reducing PD-LIDs, a debilitating condition characterized by involuntary movements that frequently develop in patients who receive prolonged/chronic levodopa treatment.

Pirepemat

Pirepemat (IRL752) has the potential to become 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. Pirepemat is designed to strengthen nerve cell signaling in the prefrontal cortex via reducing activity at 5HT7 and alpha-2 receptors, which leads to increased dopamine and noradrenaline levels in this brain region. Falls represent one of the most significant untreated issues in Parkinson's and can lead to severe complications, including fractures and soft tissue injuries. These injuries often require hospital care and result in reduced mobility and a lower quality of life for patients.

Preclinical phase

IRL942

IRL942 is one of IRLAB's two programs in preclinical development targeting neuropsychiatric symptoms in neurological disorders. IRL942 is targeting a once-daily oral dose to improve cognitive function in Parkinson's and other neurological disorders. There is about 12 percent of adults aged 65 years or more experiencing cognitive decline, which greatly affects the quality of life. The condition is more common in people living with neurological disorders.

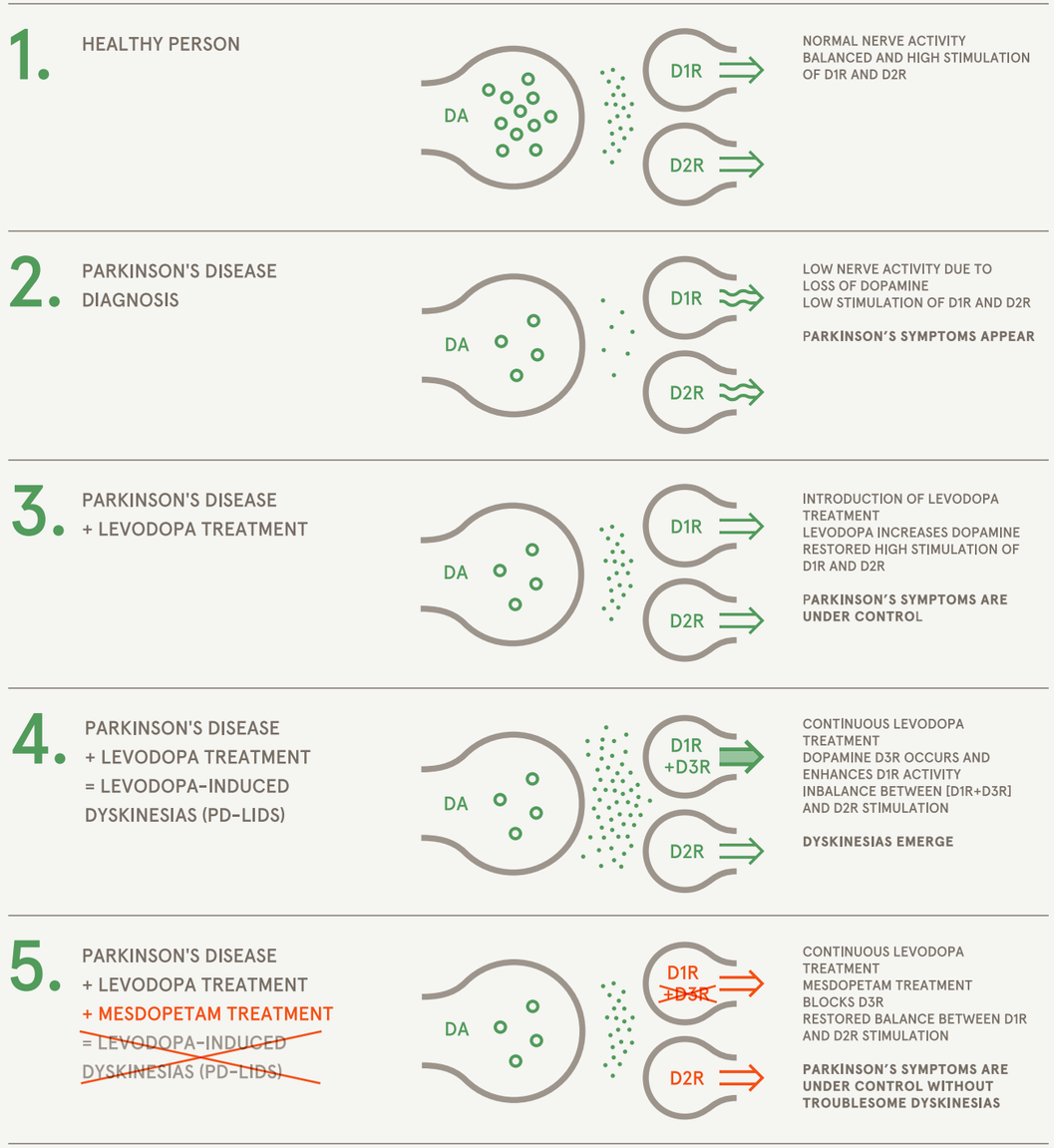
IRL757

IRL757 is IRLAB's second program in preclinical development targeting neuropsychiatric symptoms in neurological disorders. 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, and apathy is estimated to occur 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.

IRL1117

The drug candidate IRL1117 is under development as a once-daily treatment for the hallmark symptoms of Parkinson's without inducing fluctuations in efficacy or the troublesome complications caused by today's mainstay levodopa-based treatments. In preclinical studies, IRL1117 has shown to produce a long lasting antiparkinsonian effect, be free of efficacy fluctuations and the troublesome complications occurring during chronic treatment with levodopa (i.e., short duration of action and fluctuations in effect).

Mechanism of action (MoA) of mesdopetam



DA = dopamine ; D1R = dopamine receptor D1; dopamine receptor D2; D3R = dopamine receptor D3

Clinical drug candidate mesdopetam

The investigational drug mesdopetam (IRL790) is a dopamine D3 receptor antagonist in development as a treatment of Parkinson's disease levodopa-induced dyskinesias (PD-LIDs). The development is conducted in partnership with the global specialty pharma company Ipsen. The primary objective of mesdopetam is to improve the quality of life of individuals with Parkinson's by reducing PD-LIDs, a debilitating condition characterized by involuntary movements that frequently develop in patients who receive prolonged/chronic levodopa treatment. The Phase I and Phase II clinical studies necessary for initiation of further development into Phase III were completed at the beginning of 2023.

Overall, the results of the completed clinical studies in the Phase I and Phase II programs demonstrate a consistent anti-dyskinetic effect of mesdopetam, good safety, and it is assessed as offering significantly better tolerability compared to existing treatment. Mesdopetam is considered an easily controlled treatment due to its predictable relationship between administered dose and the amount of substance absorbed in the body, which are crucial pharmacokinetic properties for a drug intended to be used by a larger population of individuals with Parkinson's than the current options available for treating PD-LIDs.

Mesdopetam, an antagonist of the dopamine D3 receptor, reduces the neuronal overactivity induced by levodopa treatment which, via the D3 receptor, leads to dyskinesias (involuntary movements) in Parkinson's disease. See the image describing the mechanism of action of mesdopetam on the left.

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.

Clinical development of mesdopetam

IRLAB has completed clinical Phase I, Phase Ib and Phase IIa studies with mesdopetam. The successful completion of Phase Ib and Phase IIa studies demonstrated a very good safety and tolerability profile and proof-of-concept with potential for better anti-dyskinetic efficacy, compared to current treatment options.

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

Recent preclinical studies indicate that mesdopetam has further potential also to prevent the development of dyskinesia, and may therefore be relevant for a larger group of patients, i.e. those on chronic treatment with levodopa who have not yet developed dyskinesia.

Anti-dyskinetic effect showed in Phase IIb study

The Phase IIb study of mesdopetam investigated the efficacy and safety of three doses of mesdopetam (2.5, 5, and 7.5 mg twice daily), as compared to placebo, in people with Parkinson's experiencing troublesome dyskinesia caused by their levodopa treatment.

The top-line results of the study were reported in January 2023 with further analysis of the full data currently ongoing together with IRLAB's partner Ipsen.

JENNY GUNNERGREN, works with analysis of how our substances are handled by the body (pharmacokinetics and metabolism).

Clinical drug candidate mesdopetam

The purpose of the study was to evaluate anti-dyskinetic effect and safety/tolerability of different doses of mesdopetam to be able to choose the right dose of the drug in Phase III.

The Phase IIb study's primary endpoint was change in daily ON-time without troublesome dyskinesia ("good ON"-time). Mesdopetam showed dose dependent changes, which did not reach statistical significance compared to placebo. However, in the measurement scale 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 twice daily 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 twice daily 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 have an acceptable safety profile. The adverse event profile of mesdopetam in the Phase IIb study was similar to placebo.

The study was 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.

Partnerhip with Ipsen

In 2021, exclusive global rights to the development and commercialization of the mesdopetam program was licensed to global specialty pharma company Ipsen. In the agreement, responsibility for completing the Phase IIb study remained with IRLAB, while Ipsen has responsibility for all other Phase III preparatory activities, including a series of regulatory Phase I studies aimed at expanding the knowledge of mesdopetam uptake, distribution, metabolism and excretion from the body, the continued clinical development and worldwide commercialization.

Key competitive advantages

- Clear anti-dyskinetic effect with a first-in-class mechanism of action.
- Good tolerability at all doses (can therefore be used by more patients than today's treatment alternatives).
- Simple dose titration.
- Predictable uptake in the body (linear pharmacology and no known drug interactions).
- Strong IP protection: global patent protection and patent registrations can provide exclusivity into the early 2040s.

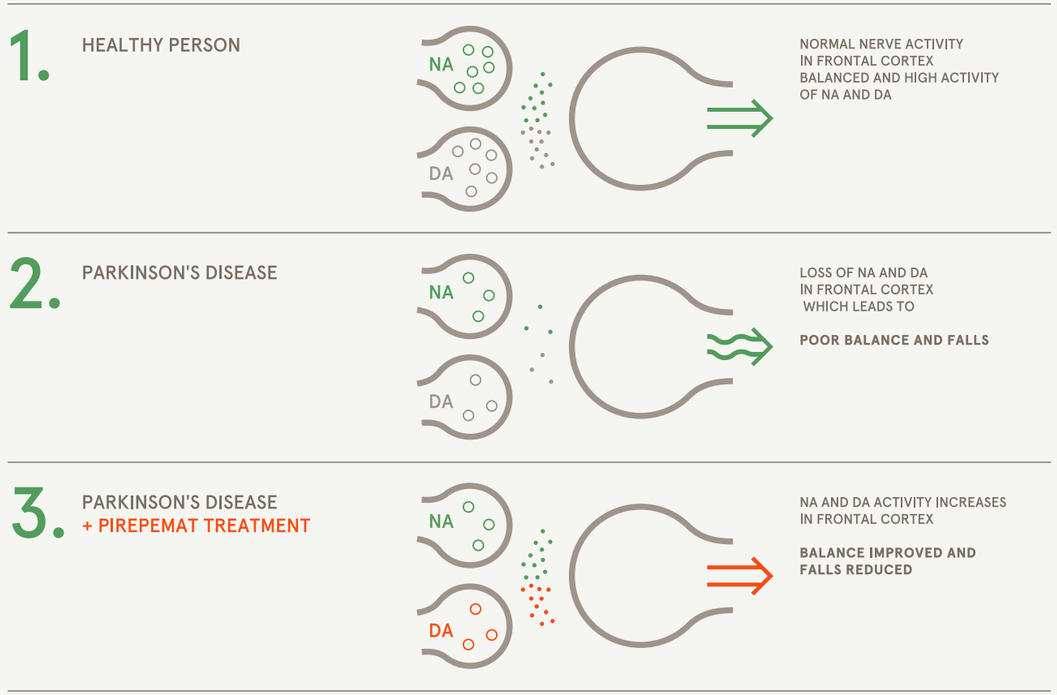
Patent overview for mesdopetam

Molecule	**IRL790**
WO No.	WO2012/143337
Granted patents	All major markets in Europe, US, Canada, Australia and China
Patent expiration	Until 2037 in EU/JP/US based on: · IND application strategies · Supplementary Protecton Certificate (SPC) · Patent Term Extension (PTE)

Additional patent applications have been published during 2020, which, if approved, could give mesdopetam exclusivity well into the 2040s.

Source: The company's statement

Mechanism of action (MoA) of pirepremat



NA = noradrenergic; DA = dopamine

Clinical drug candidate pirepemat

Pirepemat (IRL752) has the potential to become 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. 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 reduced quality of life.

Impairment of balance and increased risk of falls is strongly associated with weakened cognitive capacity, such as executive function, a problem where existing Parkinson's medications do not help. The goal of pirepemat is to provide Parkinson's patients improved balance and fewer falls and give them the opportunity to experience an increased quality of life in everyday 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 to reduce the risk of falls in people with Parkinson's, despite the great medical need. Injuries related to falls are one of the major reasons why patients suffering from Parkinson's seek hospital care. The cost for hospital treatment of a fall injury in the US is estimated to be USD 30 000 for people over age 65.

There is currently no specific treatment to reduce the risk of falls for Parkinson's patients. An overview of ongoing development projects globally shows that there is no drug with a similar mechanism of action under development. IRLAB thereby estimates that with pirepemat the company is approximately 4–5 years ahead of other projects.

Clinical development of pirepemat

IRLAB has successfully completed a Phase I program and an exploratory Phase IIa study in 32 patients with advanced Parkinson's and cognitive impairment (dementia). Exploratory analyses of efficacy data indicate that pirepemat improves symptoms that are strongly linked to functions of the cerebral cortex. These early indications of efficacy include improved balance, decreased risk of falls, and favorable cognitive and psychiatric effects. The results of these studies indicate that pirepemat has an acceptable safety profile and was well tolerated in the intended patient population..

The continued development program for pirepemat aims to demonstrate the safety and efficacy in people living with Parkinson's experiencing symptoms consistent with a weakened nerve signaling in the cerebral cortex.

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 two doses of pirepemat on falls frequency in people with Parkinson's over a three-month treatment period. Other study objectives include assessments of efficacy on cognitive function and safety/tolerability. The study is designed to randomize 165 patients distributed across three groups (55 people in each group); two groups with different dose levels of pirepemat and one placebo group. All clinical sites in the study is expected to be activated during Q2 2023. Patient recruitment 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. Present estimation is that the top-line results can be expected in H1 2024.

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

Clinical drug candidate pirepemat

Patent overview for pirepemat

Molecule	**IRL752**
Patent type	Substance
WO No.	WO2010/058018
Status	Granted in all major markets in (EU, US, JP/ CN)
Patent expiration	Until 2034 in EU/JP and 2035 in the US given that possible patent extensions are leveraged (SPC and PTE in EU/US/JP)

Source: The company's statement

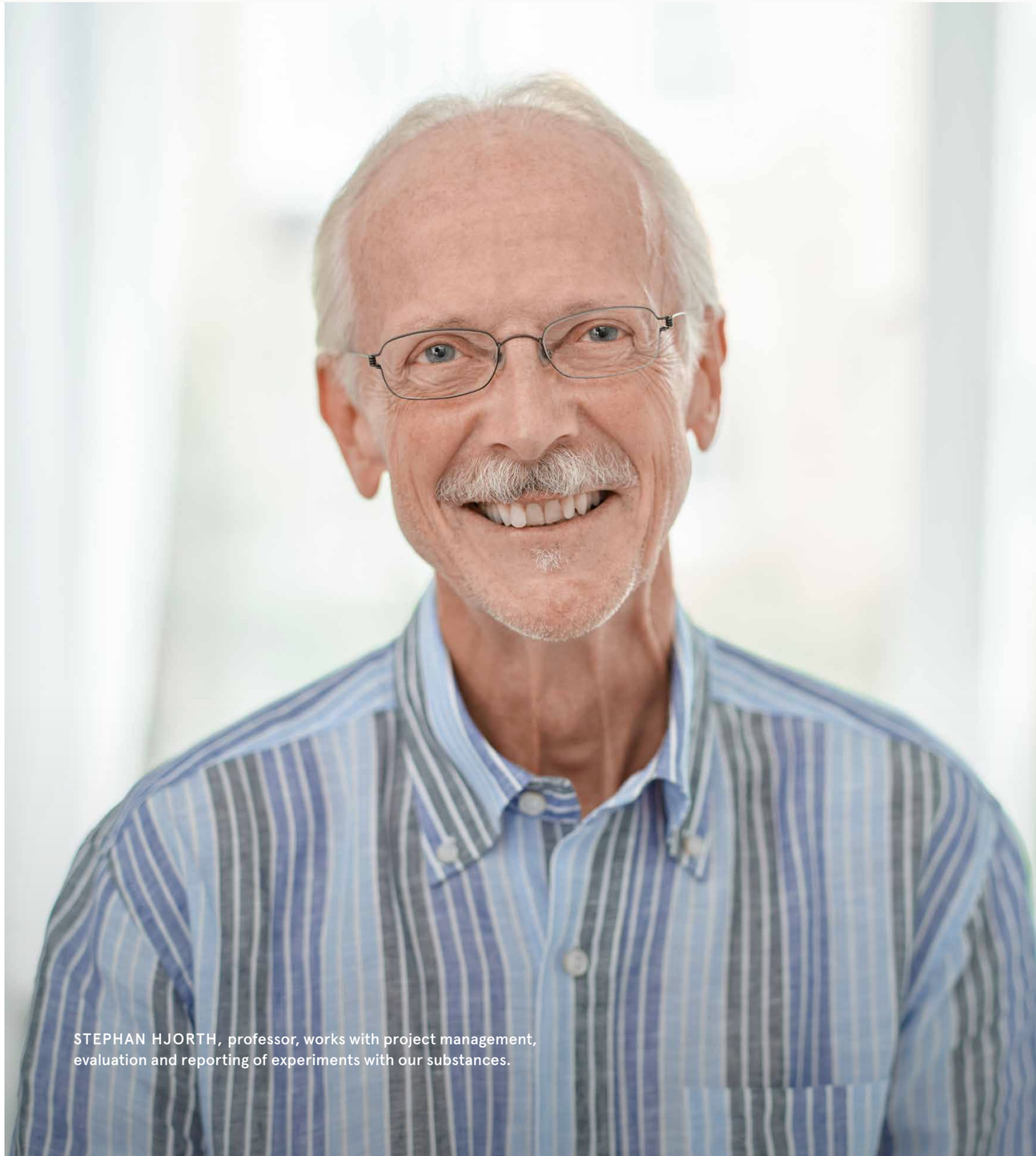
Patent overview for pirepemat

Molecule	**IRL752 fumarat**
Patent type	Substance and manufacturing
WO No.	WO2010/058018
Status	Patent application submitted in all major markets
Patent expiration	Until 2040 in EU/JP assuming the patent is granted and possible patent extensions are leveraged (SPC and PTE in EU/US/JP)

Source: The company's statement
SPC = Supplementary Protecton Certificate
PTE = Patent Term Extension

Competitive advantage

- First-in-class treatment with a unique mechanism of action for impaired balance and reduced risk of falls.
- Good tolerability.
- Being developed for a new market with significant clinical need and limited competition.
- Strong IP protection; global patent protection and patent registrations can provide exclusivity into the 2040s.



STEPHAN HJORTH, professor, works with project management, evaluation and reporting of experiments with our substances.

Preclinical phase

In the project portfolio there are three strong drug candidates in the preclinical phase in addition to the clinical drug candidates mesdopetam and pirepemat. Our aim is to have two of the preclinical drug candidates ready for clinical development within about a year. All candidates have been generated by the proprietary research platform ISP.

IRL942

Drug candidate IRL942 is being developed to improve the cognitive function in people with Parkinson's and other neurological disorders. The future medicine is intended to be administered orally once daily. There are about 12 percent of adults aged 65 years or more experiencing cognitive impairment, which greatly affects 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 neuropsychiatric symptoms in Parkinson's and other neurological disorders. IRL942 displays a unique ability to activate frontal cortical neurotransmission, synaptic gene expression, and associated circuits, resulting in improvements in cognitive function in several preclinical models of impaired cognitive function.

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. Providing positive outcomes from the preparatory studies and approvals from authorities, IRL942 is expected to be Phase I ready during H1 2024.

IRL757

IRL757 is in preclinical development and aims to treat apathy in Parkinson's and other neurological disorders with a once-daily oral administration. 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 observed positive effects of IRL757, is hypothesized to be associated with IRL757's unique pharmacology to restore weakened cortical to sub-cortical nerve signaling, a proposed mechanism underlying apathy in neurological disorders.

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, assuming positive results from the preparatory studies and obtained approvals from authorities.

IRL1117

The drug candidate IRL1117 is under development as a once-daily treatment for the hallmark symptoms of Parkinson's without inducing fluctuations in efficacy or the troublesome complications caused by today's mainstay levodopa-based treatments.

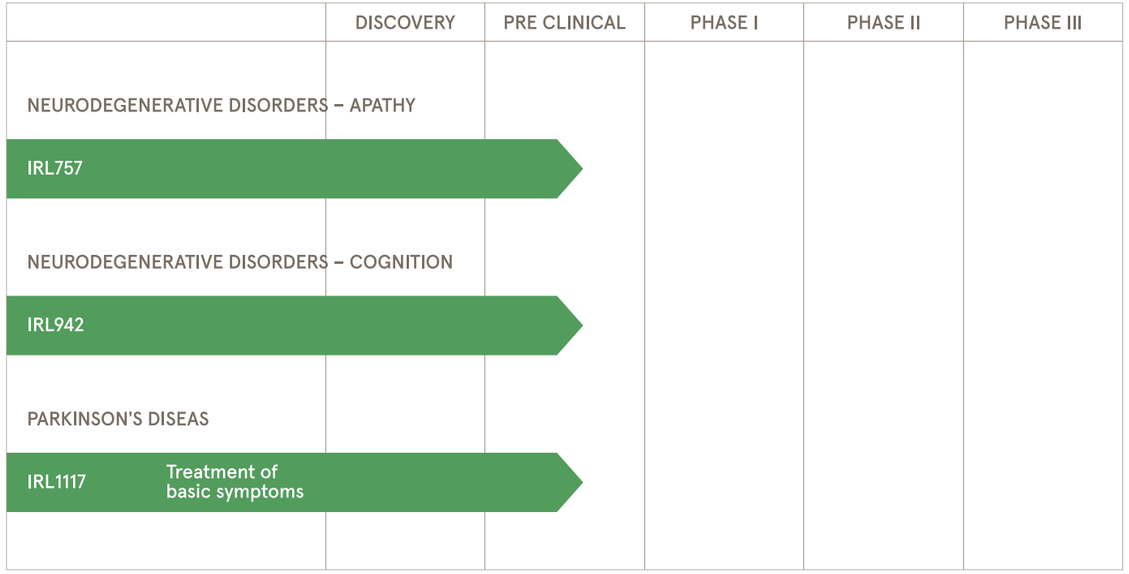
IRL1117 is an orally available and potent dopamine D1 and D2 receptor agonist that has demonstrated rapid onset and more than 10 hours of sustained efficacy in preclinical studies.

At present, people with Parkinson's disease are prescribed the anti-Parkinson's treatment levodopa to treat the hallmark symptoms of the disease - tremor, rigidity, and bradykinesia. 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 fluctuations in effect and excessive involuntary movements. By comparison, IRL1117 offers a clearly differentiating alternative being orally available, significantly more potent and displaying a long duration of effect without fluctuations in the effect, as well as having anti-Parkinson efficacy without inducing the troublesome complications during long-term treatment with levodopa.

IRLAB continues to develop IRL1117 with inhouse activities in preparation for Phase I enabling toxicology and manufacturing activities in 2024.

IRL1117 was nominated as a development candidate from the P003 project in early 2023. 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.

Overview of the candidate's development



HENRIK GRADÉN, works with development of synthesizing methods for our candidate drugs and manufacturing of them in our laboratories.

Market & competition

IRLAB focuses on areas in Parkinson's disease where there is a significant need for new, effective treatments that can improve the quality of life for patients. Parkinson's is the second most common primary neurodegenerative disease after Alzheimer's, and the number of affected persons is expected to rise as the world's population is aging.

Global trends

The world's population is growing and aging. Globally, the fastest-growing part comprises people above the age of 65. From 2019 to 2050, the number of people over 65 in the US and Europe will grow by as much as 48 percent.[1]

The increase in the proportion of older people also leads to a reduction in the proportion of younger and able-bodied people, which is predicted to cause problems in many countries around the world. In Europe, it is estimated that the number of able-bodied people in relation to older people is estimated to fall from four in 2015 to two in 2050.

The onset of Parkinson's disease is usually after the age of 60, but it can also affect younger people. In 2017, it was estimated that over 40 percent of Parkinson's patients were 75 years old or older, and only two percent were aged 49 or younger. Due to the high societal costs and the aging population, the already huge need for new and effective drugs for Parkinson's is believed to grow significantly in coming years. Drugs that address difficult-to-treat symptoms that occur in Parkinson's can provide valuable improvements in the patients' ability to function, as well as significant reductions in the societal costs associated with the disease.

The market for drugs related to the central nervous system (CNS) is one of the largest in the pharmaceutical industry. As the financial burden and the medical needs are considerable for various adjunctive treatments to the current standard treatment of Parkinson's, the market potential for IRLAB's drug candidates is significant.

The success of a drug candidate largely depends on how quickly it enters the market as the exclusive rights can then be leveraged to the maximum. For innovative first-in-class substances, the time to market is often challenging because the development programs need to be designed without a previous template from previous experiences. Within IRLAB, we have opportunities to predict treatment effects in humans on the basis of results generated from our research platform ISP. Furthermore, this information provides better conditions to generate strong IP protections that last for a long time. This provides opportunities to avoid long development times and opportunities to have long patent periods remaining upon market introduction. Our current assessment is that we will have long periods of market exclusivity for our new medicines. In addition to these advantages, we also see that drug candidates generated with our ISP platform have a higher probability of success compared to what is stated for the "industry average".

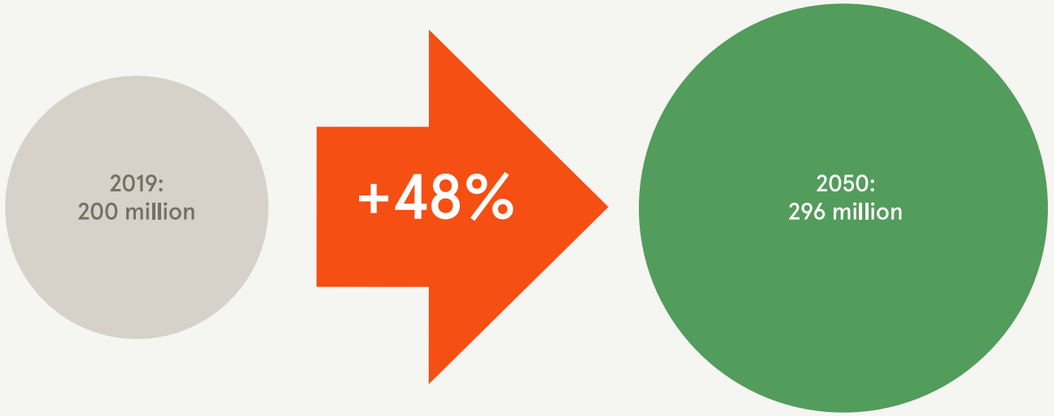
Market for IRLAB's drug candidates

IRLAB develops drug candidates with a unique mechanism of actions for Parkinson's in markets with great unmet needs. The global market for Parkinson's is estimated at approximately USD 5 billion, where the majority is generic drugs. Growth is expected to be around 6.5 percent annually. Mesdopetam and pirepemat are candidates in the clinical phase that have shown promise for the treatment of several Parkinson's-related symptoms. The company's preclinical portfolio comprises the two neuropsychiatric drug candidates IRL942 and IRL757 as well as drug candidate IRL1117, a new anti-Parkinson treatment for the hallmark symptoms.

Mesdopetam

Mesdopetam is being developed to treat some of the most severe symptoms associated with Parkinson's: levodopa-induced dyskinesias (PD-LIDs) and psychosis (PD-P). Today, about 1 million patients are affected by PD-LIDs, and for Parkinson's psychosis (PD-P), the number of patients is about 1.5 million in the eight major markets. Recently introduced drugs in this sector have prices of around USD

The growth of people over 65 in the US and Europe.



Market size

MESDOPETAM, PD-LIDs

REGION	PATIENT POPULATION [1]	TREATMENT PRICE
US 200 000	28 500 USD per year (amantadin ER)	
EU5	230 000	No approved drug available
China	470 000	No approved drug available
Japan	115 000	No approved drug available

PIREPEMAT, PD-FALLS

REGION	PATIENT POPULATION (RISK FOR FALLS) [2]	PATIENT POPULATION (RECURRING FALLS) [2]
US 470 000	330 000	
EU5	565 000	395 000
China	1 130 000	790 000
Japan	275 000	190 000

[1] GlobalData, Epidemiology database, 2020. Regards treatment of established LIDs, not preventative.
[2] Adamas Pharmaceuticals Annual Report, 2019.

Market & competition

40,000/patient and year. In the US, there is currently one treatment with market authorization that is specifically targeted at PD-LIDs; in other geographical regions, there are no authorized drugs. The treatment that has been approved in the US is usually associated with several disabling side effects that impact the patient's quality of life.

Wider potential in neurological diseases

Preclinical studies indicate that mesdopetam also has the potential to prevent the development of dyskinesias, which means that mesdopetam may be relevant for a larger group of patients and a longer duration of treatment, i.e. both patients that will start treatment and patients with ongoing chronic levodopa treatment.

Mesdopetam has also shown antipsychotic properties and is therefore being evaluated as a potential treatment for Parkinson's psychosis (PD-P), which approximately 35 percent of Parkinson's patients are at risk of developing over time.

Competition

The competitive situation for mesdopetam is assessed as being good. In addition to the standard treatment with levodopa, several drugs are available to Parkinson's patients. These are used to support the effect of levodopa on the hallmark symptoms. For the treatments of PD-LIDs, amantadine in an extended release formulations that has received market authorization in the US. Amantadine may work well for some patients but is associated with adverse drug reactions, with hallucinations being the most prominent. Therefore, there is a great need for drugs that can help Parkinson's patients to reduce dyskinesias, or at best slow down the development of symptoms, and thus provide increased daily time where patients have good mobility without being troubled by dyskinesias. There are several development programs aimed at treating PD-LIDs in the global pipeline, both in the clinical and preclinical phases, but none of them has the same mechanism of action as mesdopetam.

Pirepemat

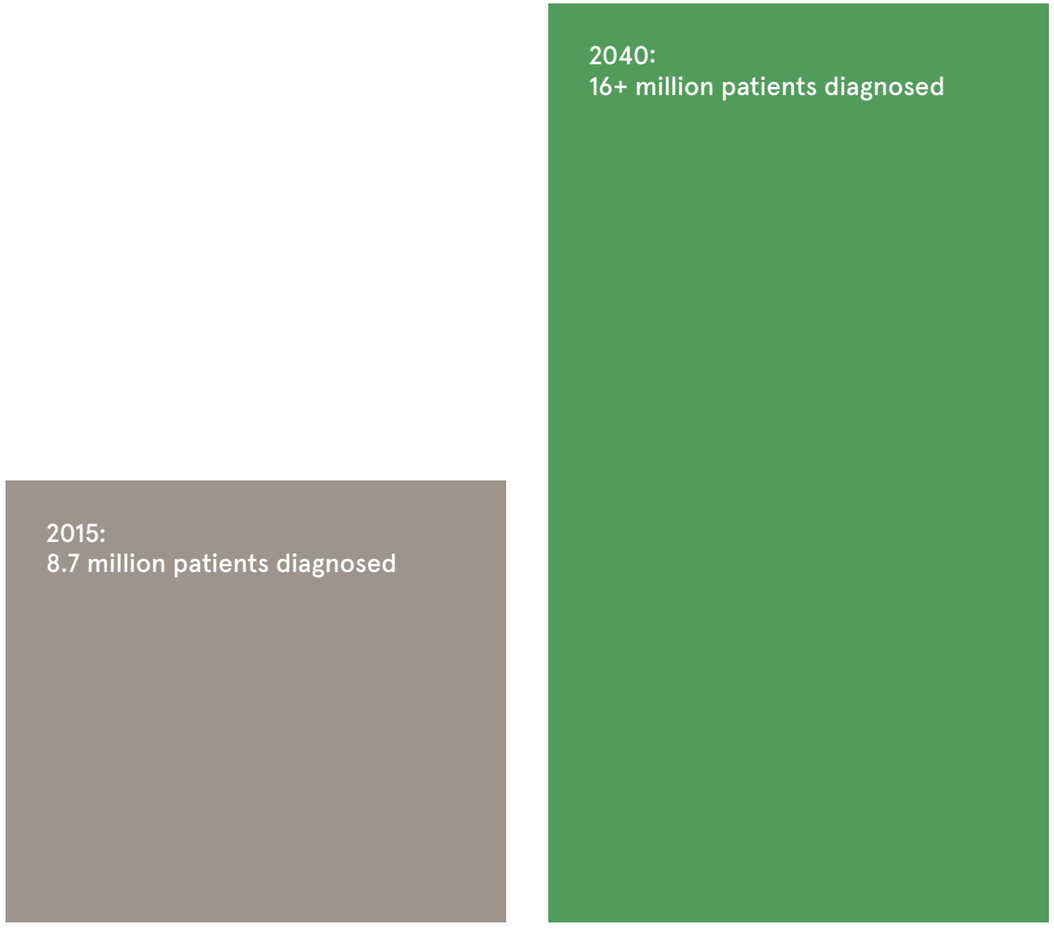
Pirepemat is intended to improve impaired balance and reduce the risk of falls in Parkinson's (PD-Falls). Some 60 percent of all people with Parkinson's suffer falls every year, which leads to fractures, limited mobility and a lower quality of life. About 76 percent of all falls in Parkinson's patients require hospital care, and 33 percent of falls result in fractures. For people over 65, the cost of medical care for falls is estimated at USD 30,000.[2] Balance impairment with its associated risk of falling has been found to be strongly linked to impaired cognition. There is currently no approved treatment for this major clinical problem.

As there is no approved drug, estimates of the market for balance impairment should be based on the cost of Parkinson's patients who fall and sustain fractures and other injuries. Approximately 30 percent of all Parkinson's patients will suffer a fall that causes a hip fracture in the first ten years after diagnosis.[3] The cost of treating a hip fracture is estimated at about USD 50,000.[4] Today, about 1 million patients in the US have been diagnosed with Parkinson's, and the number of patients is expected to rise steadily. Accordingly, falls and fractures will place a significant burden on healthcare systems in the future.[5] From a health economic perspective, the market potential for a balance-improving treatment is huge.

Competition

The competitive situation for pirepemat is assessed as being good. There is currently no approved drug that improves balance and reduces falls in Parkinson's. To the best of IRLAB's knowledge there are few development activities in this area, one candidate in the preclinical phase (CM-PK) and one in clinical Phase II, TAK071 a muscarinic acetylcholine receptor 1 (M1R) agonist. In addition droxidopa, marketed in the US as a treatment for orthostatic hypotensionhas been evaluated for the treatment of falls in orthostatic hypotension in Parkinson's.

Parkinson's disease is one of the fastest growing diseases



IRL942

The preclinical drug candidate IRL942 is being developed to improve the cognitive function in people with Parkinson's and other neurological disorders. The future medicine is intended to be administered orally once daily. There are about 12 percent of adults aged 65 years or more experiencing cognitive impairment which greatly affects quality of life, and it is more common in people living with neurological disorders.

Among the patients diagnosed with mild cognitive impairment (according to the definition of MCI), 30–50 percent develop Alzheimer's dementia. Additionally, other neuropsychiatric disorders, such as schizophrenia, are strongly associated with cognitive impairment.

Currently, there's no specific treatment for MCI, and the treatment of dementia depends on its underlying cause. Pharmacologic options include acetylcholinesterase inhibitors and memantine. Antipsychotic medications show only modest beneficial effects on cognitive functioning in people with psychotic disorders.

The competitive situation for IRL942 is assessed as being good. Despite high prevalence of cognitive impairment, only a few projects are in clinical development focusing on dementia and cognitive function associated with Parkinson's, all of them in Phase II trials.

IRL757

IRL757 is in preclinical development and aims to treat apathy in both Parkinson's and other neurological disorders with a once-daily oral administration. 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. It means that around 25 million patients are affected. Apathy is associated with poorer cognitive function in people with Parkinson's.

Despite the large number of people with apathy and the great need for treatments for apathy in neurological disorders, there is currently no specific drug approved to treat the condition. Drugs used for other neurological symptoms, e.g dementia, are prescribed to this patient population to address other symptoms, but there are clinical limitations related to medical contraindications (e.g., severe cardiovascular disease or gastrointestinal problems)

The competitive situation for IRL757 is assessed as being good. Studies aiming to successfully target apathy have not been able to provide evidence of improvement in apathy in neuropsychiatric disorders. One Phase II study currently ongoing targeting apathy in dementia is investigating the compound CVL-871. Study completion is expected in 2024.

IRL1117

People with Parkinson's disease are today prescribed the anti-Parkinson's treatment levodopa treating the hallmark symptoms of tremor, rigidity, and bradydyskinesia. 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 fluctuations in effect and excessive involuntary movements. By comparison, IRL1117 offers a clearly differentiating alternative being orally available, significantly more potent and displaying a long duration of effect without fluctuations in effect, as well as having antiparkinsonian efficacy without inducing the troublesome complications during long-term treatment with levodopa.

The competitive situation for IRL1117 is assessed as being good.

[1] United Nations, Department of Economic and Social Affairs, Population Division (2019). World Population Ageing 2019: Highlights (ST/ESA/SER.A/430)
[2] US CDC
[3] Watts, JJ. et al. BMC Geriatr. 2008;8:23. Published 2008 Sep 30. doi:10.1186/1471-2318-8-23.
[4] Adeyemi, A. et al. JBJS Open Access: March 28, 2019 – Volume 4 – Issue 1 – p e0045 doi: 10.2106/JBJS.OA.18.00045
[5] Kalilani, L. et al. PLoS One. 2016;11(9):e0161689. Published 2016 Sep 1. doi: 10.1371/journal.pone.0161689

THERESE KNUBBE, works with analythical chemistry to better understand how our candidate drugs are handled by the body.

Sustainability

IRLAB's organization is permeated by the goal and the desire to contribute to a positive impact on society and individuals through increased knowledge. IRLAB does this through research, knowledge building, and drug development in order to contribute to a better life for individuals affected by impaired function, and consequently to a more sustainable society.

IRLAB's sustainability efforts are based on the UN's global sustainability goals that are relevant to the company. The company has chosen to focus primarily on the following areas:

Employees

IRLAB is committed to providing a positive working environment

IRLAB strives to create an inclusive working environment for all its employees, at every level of the organization. The company recognizes that its research and development activities require specialized skills and training, and therefore, it is essential to provide equal opportunities for recruitment and professional growth to all employees. The company values the combination of experience and fresh perspectives, fostering an environment where employees are engaged in challenging tasks and have a clear connection to the company's development. IRLAB prioritizes the well-being and safety of its employees, recognizing that their satisfaction and health are essential to the success of its operations.

Responsible dealings

IRLAB shall act responsibly in all relationships and partnerships

In addition to the company's own responsible behavior, IRLAB also places high demands on external suppliers and collaboration partners. They are required to meet and work according to the same guidelines as IRLAB. It is important that transparency permeates IRLAB's work in order to create the best conditions for the company's drug development projects. This means that suppliers and laboratories, contract research organizations and hospital clinics with which IRLAB collaborates shall have documented experience and strictly follow current regulations and regulatory requirements.

Where necessary, IRLAB receives support from area experts and Key Opinion Leaders (KOLs). These collaborations shall be characterized by sincerity, respect and the pursuit of a common understanding of the goal to productively contribute to the development of our drug candidates.

Community involvement

Knowledge sharing is at the center of the company's commitment

Research is IRLAB's core business, and knowledge is a key to innovation in drug development. IRLAB regularly offers university students the opportunity to carry out degree work within the business and holds regular seminars in various research and development areas, which are open to everyone. The results and knowledge IRLAB produce are shared via its own website, through presentations at public events, and through the publication of articles in scientific journals.

In this way, IRLAB wishes to contribute to the development and visibility of the company's areas of expertise and raise awareness in society.

Organization

IRLAB is established on competent employees in all parts of the business. This applies to the laboratory, the business functions, the clinical operations and the work with the ISP platform – everything that forms the core of the organization. The business is driven forward together with external consultants and area experts..

IRLAB's operations are based at the office in the Biotech center in Gothenburg but have activities on all the world's continents. The premises in Gothenburg contain both a laboratory and office space. The company also have a smaller office in Stockholm. At the end of 2022, the business consists of 36 employees including long-term consultants. About 60 percent are women and 40 percent are men. The staff has a long experience in the pharmaceutical and biotech industry. All are university educated and a total of 41 percent have a doctorate.

In addition to the direct employees of the company, IRLAB has formalized collaborations with clinical research organizations (CROs), consultants and subject matter experts so the company is in practice a much larger organization than the figures show.

Scientific experts

IRLAB collaborates with a number of scientific experts:

- Dr. Bastiaan Bloem, Netherlands, Professor of Neurology, MD, PhD
- Dr. Camille Carroll, UK, Assistant professor in Neurology, MD, PhD
- Dr. Per Svenningsson, Sweden, Professor of Neurology, MD, PhD
- Dr. Anette Schrag, UK, Professor of Clinical Neuroscience, MD, PhD
- Prof. Alan Whone, UK, Assistant Professor and Consultant in Movement Disorders, MD, PhD

Regulatory experts

Clintrex is a clinical research company that collaborates with pharmaceutical organizations to establish development pathways for new treatments for CNS diseases. Clintrex is an integrated team of internationally renowned experts who collaborate with clients to identify, clarify and resolve preclinical, clinical, biostatistical and regulatory issues that are important for product development and approval. Mainly active in the US.

Consilium Salmonson and Hemmings support the development, approval and life cycle of drugs. Together, they have over 50 years of experience working with drug development and regulation. They offer unique insights into the science of drug development, regulatory standards, and processes for regulatory assessment and decision-making in the EU.

Long-term collaborations

Hjalmarsson & Partners supports IRLAB's business development activities and is an independent financial advisor within mergers and acquisitions (M&A) and raising capital.

MAQS Advokatbyrå (legal firm) supports IRLAB with all legal services and participates in all company processes. MAQS is one of Sweden's leading law firms specializing in business law.

MSC Nordics works with IRLAB's IR and communications and are specialized in Nordic life science. MSC has experience from 80+ biotech companies.

DANIEL ANDERSSON, works with development of preclinical models for parkinson's and leads the work with testing of our candidate drugs.

Quality work

IRLAB's processes for internal control and systematic quality work are the pillar for ensuring compliance with applicable laws and ordinances, good quality throughout all activities, and effective governance of the operations. This is a prerequisite for being able to achieve our goals, in both the short and long term, ensure the reliability of internal and external financial reporting and, ultimately, protect our owners' investments.

Business goals at the center

IRLAB works continuously with the processes for internal control in accordance with the requirements set out in the Swedish Companies Act, the Swedish Annual Accounts Act and the Swedish Corporate Governance Code. A cornerstone in the process is the company's defined operational goals, which cover the entire business from research and clinical operations to control of financial data. Risks are defined as circumstances that may affect the likelihood that the company will achieve its goals.

The other components of internal control, which, among other things, deal with the internal work environment, systematic quality work and risk management, aim to ensure that the goals are achieved through efficient and effective operations, and that the Board of Directors has an overview of the company's path towards fulfilled goals.

Risk awareness are the foundation

The internal work environment is built on a structured organization with well-defined areas of responsibility and reporting routes, and with governing documents that provide the business with a framework. The management team works actively to create a work climate with focus on integrity, ethical values and risk awareness, which determines the basis for how the organization's employees view and respond to risks and possibilities. By identifying risks and considering them in relation to the business, control mechanisms can be identified and implemented in order to be able to identify as early as possible when the probability of a risk increases, and then be able to take measures to prevent or mitigate the impact on the business.

Systematic quality work

IRLAB's system for quality assurance involves policy documents, standard operating procedures (SOPs) and work instructions that describe our core processes and form the framework for how our operations are conducted and governed. Focus on quality and risk management is an integral part of the daily work at IRLAB, and relates to planning and monitoring the work and thereby identifying possible areas for improvement, both in terms of preventing and detecting possible deficiencies. If necessary, changes are implemented in the business, and as such our processes are continuously improved. Employee commitment makes the process come alive, and our governing documents are under constant development and improvement. The management team is also responsible for regularly reviewing and evaluating the system for control activities and quality assurance to ensure efficiency and results in relation to established goals.

Evaluation of partners

An important aspect of quality assurance is our guidelines for evaluation and approval of our partners. For example, IRLAB outsources a large part of the practical implementation of the clinical studies to specialized collaboration partners (so-called Clinical Research Organizations, CRO), which requires careful evaluation to ensure that the partner we choose has the right competence and experience. Our processes also describe how IRLAB, during the implementation of the clinical studies, ensures continuous control and review of work and deliveries from the CRO.

Regular risk assessments

Within the framework of the systematic quality work, an assessment is regularly made of the most significant risks to the business and the opportunities to achieve our goals. All employees are involved in the work of identifying the risks that arise in the operations, and it is the management team's responsibility to assess how likely it is that the risk will occur and how harmful the consequences of the risk may be. Based on the assessment, a plan is created to ensure that the risks are managed and/or eliminated in an appropriate and effective manner. The risks that are currently considered to be the most significant are presented on pages 88–90.

Annual cycle for internal control at IRLAB

Ultimately, the Board of Directors is responsible for internal control and risk management. Established procedures for reporting and communication in the form of an annual cycle ensure that the processes are kept alive and that the Board of Directors has an overview of internal control, and is kept up to date with risks and opportunities identified in daily operations.

The annual cycle of the company's internal control can be briefly described as beginning with an evaluation of the previous year and deciding on a strategy, as well as establishing goals for the coming year together with the Board of Directors. Based on the updated company goals, a risk assessment is performed on the entire company, governing documentation is reviewed and updated as necessary, and control activities are identified and documented. At the end of the cycle, the processes and control activities are evaluated with a focus on how they are designed and how effective they are at identifying when the likelihood of a risk increases at an early stage. This is done together with the Board of Directors and feeds into the discussions and decisions on strategy for the coming year. More about this can be found in the Corporate Governance Report on pages 114–131.

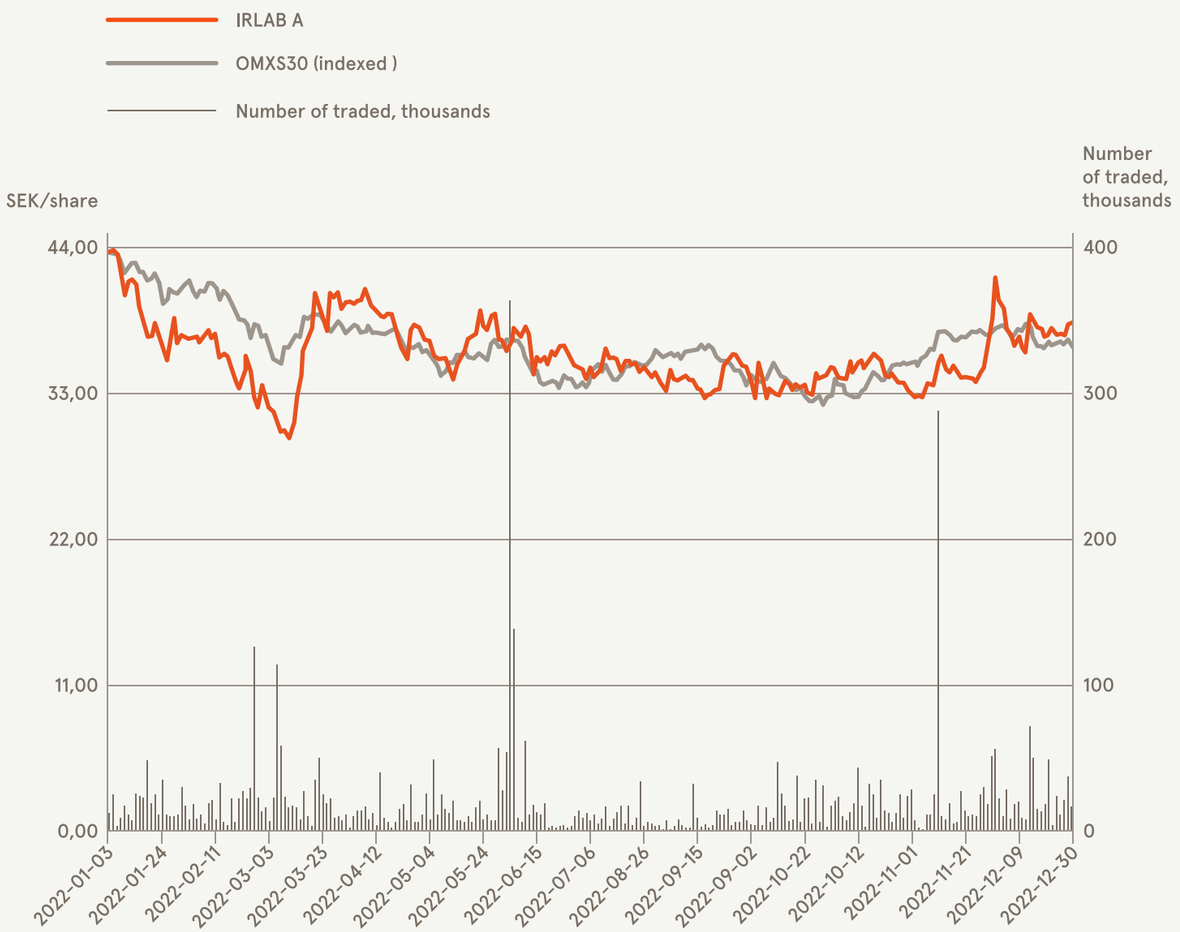
SOP

IRLAB's system for quality assurance involves policy documents, standard operating procedures (SOPs) and work instructions that describe our core processes and form the framework for how our operations are conducted and governed.

IRLAB outsources a large part of the practical implementation of the clinical studies to specialized collaboration partners (Clinical Research Organizations, CRO).

CRO

IRLAB share price development in 2022



Source: Infront

The share

IRLAB's Series A share has been listed on Nasdaq Stockholm's Main Market since September 30, 2020, following a move from Nasdaq First North Premier Growth Market, where the company has been listed since February 28, 2017. At the turn of the year, the share capital in IRLAB amounted to SEK 1,037,368, divided into 51,868,406 shares with a quota value of SEK 0.02. All shares, including Series B shares, carry one vote. The number of shareholders with regard registered shares amounted to 3,663 as of December 31, 2022, a decrease of just about 1 percent compared with the end of 2019. The ten largest shareholders held 52.6 percent of the number of shares.

Directed share issue in April 2022

In April, a share issue of 120,000 Class A shares was directed as a payment for know-how relating to the P003 project. The share issue, which was registered in July 2022, increased the number of shares in IRLAB from 51,748,406 to 51,868,406, whereof 51,788,630 Class A shares and 79,776 Class B shares. The company's share capital increased with SEK 2,400 from 1,034,968.12 to 1,037,368.12.

Incentive program

In April 2016, a decision was made on a share and subscription warrant program for key personnel, both employees and board members. A total of 71,551 Series B ordinary shares (357,755 after split) and 39,355 subscription warrants (196,775 after split) were subscribed for in the program. The subscription price for the shares and the subscription warrants corresponded to the market value. Proceeds from the issue of the shares was paid by the group as a benefit to the key personnel.

Class B shares

During July 2019, a conversion of Class B shares into Class A shares was called for by holders of B shares. 277,979 Class B shares were converted into Class A shares. The remaining 79,776 Class B shares are not subject to conversion as the holders may only convert Class B shares on one occasion, and all holders have now exercised this and carried out a conversion.

Subscription warrant program

Each subscription warrant entitles the holder to subscribe for one Series A ordinary share at a subscription price of SEK 82.70 after split. The subscription warrants can be exercised up to and including June 30, 2023. Upon full exercise of the subscription warrants, share capital increases by SEK 3,935.50 through the issue of 196,775 Series A ordinary shares and IRLAB will receive roughly SEK 16.3 million in cash.

Trading volume

In 2022, approximately 4.9 million IRLAB shares were traded on Nasdaq Stockholm's Main Market. This corresponds to a turnover rate of approximately 10 percent.

Dividend

IRLAB is in a phase that requires the preclinical and clinical development of drug candidates be prioritized, which is why no dividend is deemed to be relevant in the coming years. The board recommends that no dividend should be paid for the fiscal year 2022.

Analysts who follow IRLAB

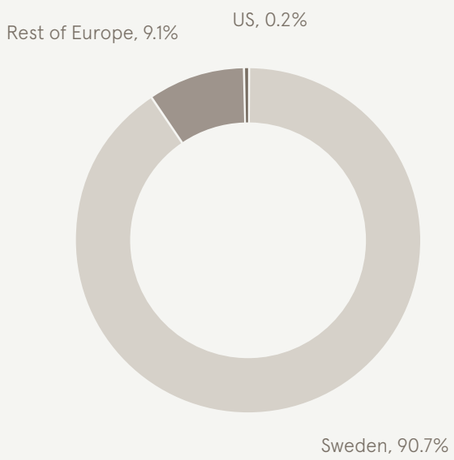
Fredrik Thor, RedEye
Gonzalo Artiach, ABG Sundal Collier
Soo Romanoff, Edison Investment Research

Breakdown by class of shares at 31 December 2022

	Number of shareholders	Number of class A shares	Number of class B shares	Totalt number of shares	Votes and capital (%)
1 - 500	2 013	284 033	0	284 033	0.55%
501 - 1000	554	425 376	0	425 376	0.82%
1001 - 5000	661	1 485 690	0	1 485 690	2.86%
5001 - 10000	159	1 120 081	5 567	1 125 648	2.17%
10001 - 25000	133	2 110 195	1 861	2 112 056	4.07%
25001 - 100000	87	4 279 810	13 089	4 292 899	8.28%
100001 -	56	42 083 445	59 259	42 142 704	81.25%
Total	**3 663**	**51 788 630**	**79 776**	**51 868 406**	**100.00%**

Source: Euroclear Sweden AB

Shares per region 31 December 2022



The 20 largest shareholders at 31 December 2022*

	Number of class A shares	Number of class B shares	Total number of shares	Votes (%)	Capital (%)
Avanza Pension	4 765 464	0	4 765 464	9.19%	9.19%
Ancoria Insurance Public Ltd	3 826 638	0	3 826 638	7.38%	7.38%
Fv Group AB	3 665 626	0	3 665 626	7.07%	7.07%
Fjärde AP-fonden	3 495 420	0	3 495 420	6.74%	6.74%
Johnsson, Daniel	2 690 400	0	2 690 400	5.19%	5.19%
Pension, Futur	2 055 384	0	2 055 384	3.96%	3.96%
Tredje AP-fonden	1 847 994	0	1 847 994	3.56%	3.56%
Unionen	1 691 452	0	1 691 452	3.26%	3.26%
Nordnet Pensionsförsäkring AB	1 664 466	0	1 664 466	3.21%	3.21%
Diklev, Jens Philip	1 556 629	0	1 556 629	3.00%	3.00%
Marinvest Holding AB	1 208 250	0	1 208 250	2.33%	2.33%
Handelsbanken Hälsovård Tema	1 136 311	0	1 136 311	2.19%	2.19%
Sonesson, Clas	748 589	8 946	757 535	1.46%	1.46%
Waters, Nicholas	736 200	8 946	745 146	1.44%	1.44%
Olsson, Lars-Erik	695 000	0	695 000	1.34%	1.34%
Sandesjö, Claes	635 000	0	635 000	1.22%	1.22%
Holm Waters, Susanna	604 704	8 946	616 650	1.18%	1.18%
Andra AP-fonden	598 684	0	598 684	1.15%	1.15%
Baretten Invest AB	550 000	0	550 000	1.06%	1.06%
Victor, Hans	508 110	0	508 110	0.98%	0.98%
20 largest shareholders, total	34 680 321	26 838	34 707 159	66.91%	66.91%
Other shareholders	17 108 309	52 938	17 161 247	33.09%	33.09%
Total	**51 788 630**	**79 776**	**51 868 406**	**100.00%**	**100.00%**

Source: Euroclear Sweden AB

Glossary

API – Active Pharmaceutical Ingredient, the active substance in a drug.

Bad ON-time – The part of the day the patient experiences troublesome dyskinesias.

CMC – Chemistry, Manufacturing and Controls, ensuring the production of the active substance and formulated drug.

COMT-inhibitors – Drugs that work by slowing down the metabolism of levodopa and dopamine.

CRO – Clinical Research Organization, contract research organization that conducts clinical studies.

Dyskinesia – Condition where the body or a part of the body performs uncontrolled involuntary movements. 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.

First-in-class – A drug candidate or drug that is the first one in a new class of drugs.

Good ON-time – The part of the day the patient does not have troublesome symptoms of Parkinson's disease.

IND – Investigative New Drug Application is an application to conduct drug studies in humans, usually referring to studies in the United States.

INN-name – International Nonproprietary Name, also called a generic substance name, is assigned by the World Health Organization based on the substance's mechanism of action.

ISP – Integrative Screening Process, IRLAB's proprietary research platform used to generate drug candidates.

MAO-B-inhibitors – Drugs that work by slowing down the breakdown of dopamine and have a certain symptom-relieving effect.

NMDA-receptor – The N-methyl-D-aspartate receptor. A receptor in the brain that is likely to be inhibited by the drug amantadine.

OFF-time – The part of the day the patient experiences classic Parkinson's symptoms, such as muscle stiffness, mobility impairment and tremors.

PD-LIDs – Parkinson's Disease levodopa-induced dyskinesia, 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.

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.

UDysRS (Unified Dyskinesia Rating Scale) – A standardized method for estimating movement patterns in dyskinesias.

UPDRS (Unified Parkinson's Disease Rating Scale) – A method for qualitatively measuring the extent of the disease in a Parkinson's sufferer, which consists of 42 measuring points, including behavior, mood, movement patterns and the complications they may experience during treatment.

Hauser diaries – A standardized method for patients to evaluate their health status, also called patient diaries.

Development process for drugs

Discovery phase

The early research phase is usually the stage where researchers have ideas on how to cure a disease or block processes that lead to a disease, or improve the efficacy of drugs, and where several tests in a laboratory environment are performed. A number of substances are developed to evaluate which has the best effect. A promising substance (drug candidate) then continues into the preclinical development phase.

Preclinical phase

The preclinical studies include a number of stages before studies on humans can begin, and evaluate chemistry (for example, possible manufacturing methods, the candidate's solubility and stability, and the type of drug formulation to be used in clinical studies), toxicity and effects via studies in appropriate laboratory experiments and animal models. When the preclinical requirements on the substance are met, the substance can proceed to clinical development following a specific permit from the authorities.

Clinical phase

In the clinical phase, studies are carried out on humans. The clinical development is typically implemented in four phases, where each phase needs to show promising results, including safety, in order for the substance to be allowed to proceed to the next phase:

Phase I

Phase I studies are usually carried out on healthy study participants, but may, in some cases, include patients with the disease in question. The aim is to determine how the drug is tolerated, and how it is absorbed, distributed, metabolized and excreted in humans. The initial doses are often low and are gradually increased.

Phase II

The Phase II program often includes several studies and is carried out on a small number of patients with the relevant disease in order to study safety and tolerability, and to determine an appropriate dose for the Phase III studies. Phase II studies also aim to obtain preliminary but statistically reliable information on the efficacy of the substance, which usually occurs in the latter part of the Phase II program.

Phase IIa: Studies in patients with the aim of confirming the safety and tolerability of the drug candidate in patients, as well as obtaining indications of efficacy.

Phase IIb: Studies in patients to primarily demonstrate the drug candidate's dose-response effect and thus be able to select dose for Phase III.

Phase III

The Phase III program, also known as the pivotal program, often consists of at least two independent studies and forms the basis of an application for market approval, and is carried out on a larger number of patients than in Phase II in order to confirm and document statistically significant efficacy of the treatment, as well as safety and tolerance in a large number of patients.

Phase IV

After approval of a new drug, the development of the drug usually continues through so-called Phase IV studies. There, additional information is collected from large patient groups over a long period of time, whereby unusual side effects can be detected and additional treatment effects evaluated. Sometimes the efficacy and tolerance between different drugs for a certain disease are compared.

LISA HELGESON, works with bioanalysis to better understand how our candidate drugs are handled by the body.

Financial statements

Administration report

The Board of Directors and the CEO hereby submit the annual report and consolidated financial statements for IRLAB Therapautics AB, Org. No. 556931-4692, for the financial year 2022-01-01 – 2022-12-31.

Operations

IRLAB Therapeutics AB, 556931-4692, is a Swedish public limited company with its seat in Gothenburg, Sweden. The Company's Class A share is listed on Nasdaq Stockholm's Main Market. IRLAB is the parent company in a group that carries out research and development with the aim of developing life-altering treatments for patients with Parkinson's and other CNS illnesses.

With its unique and proprietary research platform, ISP, the Company generates novel candidate drugs with high potential that constitute the Company's pipeline. IRLAB has two candidate drugs in clinical phase, mesdopetam where data from a Phase IIb-study was reported in January 2023 and pirepemat where a Phase II-study is ongoing. In addition, IRLAB has three promising candidate drugs in preclinical development, IRL942, IRL757 and IRL1117, all of which, like mesdopetam and pirepemat, has been discovered using the ISP. The preclinical candidate drugs are currently in preclinical development in preparation for Phase I-studies.

The parent company's operations mainly consist of providing management and administrative services for the group's operative companies. In addition, the parent company manages group-wide issues, such as activities and information related to the stock market, as well as other group management issues. The research and development operations are conducted in the wholly owned subsidiary Integrative Research Laboratories Sweden AB. The company has offices in Gothenburg (head office) and Stockholm.

Research and development work

The research and development work has advanced according to plan. Total costs for research and development during the period January to December amounts to SEK 146,178 k (129,748), corresponding to 84% (84%) of the group's total operating costs. Development costs vary over time, depending on where in the development phase the projects are.

Significant events during the financial year

In March, IRL757 was nominated a new drug candidate for the treatment of apathy in neurological diseases. In April, know-how to support a strong patent application for chemical matter claims related to the P003 research program was acquired.

In June it was reported 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.

In July, the share issue of 120,000 Class A shares was registered. The shares were relating to the acquisition of know-how related to the research program P003. Subsequent to the registration, the number of registered shares is 51,868,406 (51,748,406).

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

Financial overview – the group

	2022	2021	2020	2019
Net revenue (TSEK)	61,136	207,782	0	26
Result after net financial items (TSEK)	–113,406	51,781	–91,653	–96,653
Equity ratio (%)	90	85	94	87
R&D costs as a percentage of operating costs (%)	84	84	83	82

Financial overview – the parent company

	2022	2021	2020	2019
Net revenue (TSEK)	4,531	4,059	3,274	2,828
Result after net financial items (TSEK)	–22,090	–21,454	–47,572	–38,201
Equity ratio (%)	98	99	82	98

Appropriation of profit/loss

Amount in SEK	
Proposal for appropriation of the company's profit at the disposal of the Annual General Meeting are:	
premium fund	744,314,371
accumulated loss	–280,344,512
result for the year	–22,089,866
	441,879,993
The Board of Directors proposes that:	
is carried forward	441,879,993
	441,879,993

Comments on the income statement

The result for the period January 1 – December 31, 2022 was SEK –113,406k (51,781). Earnings per share were SEK –2,19 (1.00). The company's revenue during the period was SEK 61,136k (207,906). Of the SEK 239,596 thousand that was paid up-front under the mesdopetam license agreement, SEK 185,262 thousand was recognized as license revenue and SEK 54,335 thousand was recognized as deferred income for the finalization of the ongoing Phase IIb/III study and has been expensed during 2022. In 2022, SEK 42,576k (11,759) was expensed. In addition, revenue from services provided to Ipsen in 2022 was SEK 18,560k (10,762). The group's operating expenses were SEK 174,387k (155,330) in 2022. The increase was chiefly due to increased activity in ongoing studies and an increased number organization.

Financing and cash flow

Cash flow from operating activities in 2022 amounts to SEK -142,612k (128,641) and the cash flow for the period amounts to SEK -142,121k (128,888). Liquid assets as of December 31, 2022 amount to SEK 252,776k (401,897). On December 31, 2022, equity was SEK 290,831k (399,481) and the equity/assets ratio was 90% (85%).

The management makes the assessment that there are sufficient liquid assets to cover working capital needs, given the current business and development plan, to carry out the development plans over the next twelve months. This mainly relates to activities within the framework of Phase II studies for pirepemat, as well as costs for preclinical studies, the new projects/drug candidates, and other operating costs.

Investments

Investments in intangible assets for the period January 1 – December 31, 2022 amounted to SEK 5,257k (0) whereof 4,757 was paid via an issue in kind. Investments in other assets, mainly machinery for the Company's laboratories, during the period amounted to SEK 2,876k (708).

Personnel

The number of employees in the group during the period January - December averaged 29 (22). At the end of the period, the number of full-time positions, including long-term contracted consultants, was 33 (27), distributed over 36 (30) people.

Share data

The number of registered shares at the end of the reporting period was 51,868,406 (51,748,406) shares, of which 51,788,630 (51,668,630) were A shares and 79,776 (79,776) were B shares. At year-end, IRLAB's share capital was SEK 1,037,368 and the quota value was SEK 0.02. Each share, including Class B shares, gives the holder one vote.

Corporate governance

IRLAB has decided to have the corporate governance report as a document separated from the annual report according to Chapter 6, Section 8(1) of the Swedish Annual Accounts Act and is available on pages 114-131.

Administration report

Nomination committee

Prior to the 2023 Annual General Meeting, and pursuant to the instructions that apply to IRLAB's Nomination Committee, the Nomination Committee comprised Anders Vedin (Chair), Hans-Peter Ostler, Clas Sonesson, and the Chair of the Board Carola Lemne, who together represent approximately 40 percent of the votes and capital in IRLAB as of March 31, 2023.

Annual general meeting 2023

IRLAB's Annual General Meeting 2023 is planned to be held on June 20, 2023 in Gothenburg. The Annual General Meeting will be held physically in Gothenburg with the possibility of voting in advance by post. For the right to participate and more information, please refer to the notice. The minutes from the Annual General Meeting will be available on the company's website. All general meeting documents, including the annual report, will be available on the company's website no later than three weeks before the general meeting.

Parent company

The parent company in the group is IRLAB Therapeutics AB, organization number 556931-4692. The parent company's loss for the period January 1 – December 31, 2022 was SEK –22,090k (–21,454). Personnel expenses were SEK 14,402k (8,705).

Risks and uncertainties

General information on risks in IRLAB's operations

Operations in the field of research and development of pharmaceuticals is 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. IRLAB's business model entails high development costs that do not generate potential revenues connected to licensing, sales or partnerships until a large part of the development has been completed. It is important to take risks into account when assessing IRLAB's future potential, and are to be compared with the opportunities that are inherent in projects and operations. IRLAB's operations are based on continuous evaluation and analysis of available information with regard to risks in order to stay one step ahead and identify any problems as early as possible.

Risks related to the clinical projects

Safety and tolerability, as well as efficacy

Drug development is associated with the risk that drug candidates do not achieve an acceptable profile in terms of safety and tolerability, and efficacy. Results from early preclinical and clinical studies do not always correspond to results in more extensive studies, which may, for example, lead to requirements for further studies or, in the worst case, an evaluation that the project should not be pursued further.

Large-scale production

Development of large-scale production of a drug is a complicated process, with high demands on reproducibility, robustness and quality. IRLAB continuously develops and improves its methods, but there is a risk that a production method will become unreasonably costly or provide unacceptable quality or efficacy, which may lead to a risk of increased costs, delays, or abandoned projects. IRLAB has established close collaborations with partners who have the necessary expertise to develop large-scale production and, as far as possible, identify and mitigate the risks.

Regulatory approvals

Clinical studies and the manufacturing, marketing and sales of drugs are subject to approvals from or registrations with relevant authorities in each geographical market in which IRLAB intends to be active. There is a risk that authorities' arrive at a conclusion that differs from IRLAB's conclusion, that requirements may differ between countries or that authorities arrive at different conclusions internally. Furthermore, the rules and interpretations that currently apply to the approval of drugs may change in the future, which may affect the time frames or the possibilities of obtaining the necessary approvals. To remain up to date at all times regarding current regulations, guidelines and authorities' assessments, IRLAB collaborates with ex perienced players and advisers.

Impact of the war in Ukraine

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.

Competition

Several drug candidates are under development that aim to treat the same or similar symptoms as IRLAB's drug candidates. There is a risk that these competing drug candidates receive marketing authorization before IRLAB's drug candidates or have advantages regarding the effect and/or adverse drug reactions compared with IRLAB's drug candidates, which may make it more difficult for IRLAB's drugs to take market shares.

Risks related to operations

Product liability and insurance

Participants in clinical trials with IRLAB's drug candidates may experience adverse drug reactions, which may lead to claims for damages or other claims, including claims based on product liability, being directed at IRLAB. IRLAB has taken out product liability insurance, but there is a risk that any claims will exceed IRLAB's insured amount or that IRLAB will not be able to obtain or maintain insurance cover on reasonable terms in the future.

Partnership agreements

IRLAB's business model is largely based on entering into agreements in the form of licensing or collaboration agreements regarding the remaining development and commercialization of its drug candidates. There is a risk that expected revenues will fall or disappear completely for IRLAB if a partnership agreement cannot be reached or if the partners do not succeed in taking a drug candidate to market.

Trade secrets, patents and intellectual property rights

IRLAB is dependent on protecting business and trade secrets. There is a risk that competitors will succeed in obtaining sensitive information and will use this in a way that has a negative impact on IRLAB. The company's intellectual property rights are primarily protected through patents and patent applications. There is a risk that IRLAB's patent applications will not be granted and/or that granted patents will be challenged by third parties, and/or that third parties will intentionally or unintentionally infringe on patents, trademarks or other intellectual property rights. Patent litigation can entail significant legal costs, and if a patent is not granted, conditions may deteriorate, and revenues may be significantly reduced.

IRLAB maintains an active and continuous dialogue with our external patent attorney and works proactively to be well prepared in the event of a patent dispute. Internally, IRLAB carries out systematic quality work continuously, including policies and governing documents that describe how each employee shall handle and protect the company's sensitive information. There is also a continuous review of the IT environment and associated security procedures to ensure that IRLAB has updated and sufficient protection.

Dependence on personnel and key people

IRLAB is dependent on its highly qualified and experienced personnel and leading key employees. There is a risk that personnel losses and potential difficulties recruiting the corresponding experience and expertise may have a negative impact on the ability to maintain time schedules and quality in research and development. At IRLAB, ensuring adequate skills and resources to meet the business goals is a focus area. IRLAB is continuously striving

Administration report

to ensure that knowledge is shared and does not remain isolated with individual employees and to gradually rejuvenate the personnel without losing competence and experience.

Dependence on suppliers

IRLAB has a limited internal organization and is highly dependent on collaborations with suppliers in various areas. There is a risk that manufacturers and suppliers do not deliver in accordance with agreements and changing suppliers can be both costly and time-consuming; the quality, quantity and terms and conditions may differ from those of the original suppliers.

IRLAB's quality processes include a thorough evaluation to ensure the skills and experience before collaborations are initiated to reduce the risk of problems. Ongoing collaborations are subject to continuous follow-up to ensure that deliveries are made with the expected quality and in accordance with the agreed time schedule. The wording agreements is also a focus area where IRLAB collaborates with legal experts.

Risks related to financing

Future financing

The financing of IRLAB's operations is dependent on the possibility to generate revenue or carry out new issues. There is a risk that revenue will not be generated and that new issues cannot be carried out when the need arises or cannot be carried out on terms acceptable to IRLAB.

IRLAB maintains an active and continuous dialogue with advisors and potential investors to ensure the best model for IRLAB.

Currency fluctuations

The company's reporting and functional currency is Swedish kronor (SEK). Over the next few years, however, a large part of IRLAB's operating expenses will primarily be denominated in foreign currencies. There is a risk that currency fluctuations will impact future results. IRLAB works actively to analyze the impacts of this risk and to evaluate tools to manage it in the best possible way.

For a further description of financial risks, see Note 3.

Management changes during 2022 and 2023

In July, Richard Godfrey was recruited as new CEO. In February 2023, the board decided to dismiss Richard Godfrey and appoint Gunnar Olsson as interim CEO until a new CEO has been recruited. Recruitment activities are ongoing.

Remuneration to management

Guidelines for remuneration of senior executives was adopted at the annual general meeting on May 11, 2022. The guidelines in full is found on www.irlab.se

Outlook for 2023

The company's strategic priorities and outlook for 2023 are carefully designed and focused on enabling continued effective and value-enhancing research and development of its project portfolio.

This includes fully describing the potential of mesdopetam to be an effective treatment for people with Parkinson's disease. Furthermore, it is of great importance to publish and present the extensive results from the Phase IIb-study of mesdopetam in Parkinson's disease at scientific congresses and in scientific publications during 2023.

IRLAB will effectively complete the Phase IIb study of pirepemat in PD-Falls on schedule with top-line results in H1 2024.

The company will continue to develop our three preclinical drug candidates IRL942, IRL757 and IRL1117 towards clinical Phase I studies.

The company does not expect to have any significant revenue in 2023 beyond revenue that is a result of the license deal regarding mesdopetam entered into in 2021 with Ipsen.

Shares and owners

The largest owners on December 31, 2022 are shown in the table on page 55 and refer to registered shares. No individual owner has more than 10 percent of the capital or votes in the company.

The development of the share capital is shown in Note 20.

Proposed dividend

The Board of Directors proposes that no dividend be paid for the 2022 financial year.

MARCUS MALO, works in our computational group with computational chemistry and design of new drug candidates.

Consolidated financial statements

Consolidated income statement in summary

Amounts in SEK thousand	Note	2022 Jan–Dec	2021 Jan–Dec
Operating income, etc.			
Net revenue	5	61,136	207,782
Other operating income	7	141	124
Total income		*61,277*	*207,906*
Operating expenses			
Other external expenses	8, 9	–125,906	–81,737
Personnel expenses	10	–42,481	–31,024
Outlicensed balanced development projects		0	–39,091
Amortization, depreciation and impairment	8	–4,779	–3,474
Other operating expenses		–1,220	–4
Total operating expenses		*–174,387*	*–155,330*
Operating profit/loss		**–113,110**	**52,576**
Profit/loss from financial items			
Finance income		0	1
Finance costs	8, 11	–297	–796
Total financial items		*–297*	*–795*
Profit/loss after financial items		**–113,406**	**51,781**
Income tax	12	0	0
Profit/loss for the year		**–113,406**	**51,781**
Earnings per share before and after dilution (SEK)		-2,19	1,00
Average number of shares before dilution		51,831,913	51,748,406
Average number of shares after dilution		51,831,913	51,748,406
Number of shares at year-end		51,868,406	51,748,406

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

Consolidated statement of comprehensive income in summary

Amounts in SEK thousand	2022 Jan–Dec	2021 Jan–Dec
Result for the year	**–113,406**	**51,781**
Other comprehensive income	0	0
Comprehensive income for the year	**–113,406**	**51,781**

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

Consolidated financial statements

Consolidated balance sheet

Amounts in SEK thousand	Note	12/31/2022	12/31/2021
ASSETS			
Non-current assets			
Intangible assets			
Research database	13	0	259
Acquired development projects	14	46,862	42,402
		46,862	42,661
Property, plant and equipment			
Leasehold improvements	15	86	92
Equipment, tools, fixture and fittings	16	3,369	1,224
Right-of-use assets	17	4,555	7,033
		8,009	8,348
Total non-current assets		**54,871**	**51,009**
Current assets			
Current receivables			
Trade receivables		3,322	4,470
Aktuella skattfordring		231	0
Other receivables	6,367	6,274	
Prepaid expenses and accrued income	19	5,989	8,799
		15,908	19,543
Cash and cash equivalents		252,776	401,897
Total current assets		**268,684**	**421,440**
TOTAL ASSETS		**323,555**	**472,449**

Amounts in SEK thousand	Note	12/31/2022	12/31/2021
EQUITY AND LIABILITIES			
Equity			
Share capital	20	1,037	1,035
Unregistered share capital		0	0
Other contributed capital		690,205	685,450
Retained earnings including results for the period		-400,411	-287,004
Total equity		**290,831**	**399,481**
Long-term liabilitiess			
Leasing debt	21	381	3,566
Total long-term liabilities		**381**	**3,566**
Current liabilities			
Leasing debt	21	3,595	3,034
Trade payable		10,031	12,302
Other liabilities		5,282	5 645
Accrued expenses and deferred income	22	13,435	48,420
Total short-term liabilities		**32,343**	**69,402**
TOTAL EQUITY AND LIABILITIES		**323,555**	**472,449**

Consolidated financial statements

Consolidated statements 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			0
Issue costs			-180		-180
Equity December 31, 2021	**1,035**	**0**	**685,450**	**–287,004**	**399,481**
Equity January 1, 2022	**1,035**	**0**	**685,450**	**–287,004**	**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**	**690,205**	**–400,411**	**290,831**

Consolidated statements of cash flows in summary

Amounts in SEK thousand	Note	2022 Jan–Dec	2021 Jan–Dec
Operating activities			
Operating profit/loss		-113,110	52,576
Adjustments for non-cash items	23	4,779	42,564
Interest paid		-297	–796
Taxes paid		0	0
Cash flows from operating activities before changes in working capital		**-108,627**	**94,345**
Cash flows from changes in working capital			
Changes in operating receivables		3,634	–12,811
Changes in operating liabilities		-37,619	47,107
Cash flows from operating activities		**-142,612**	**128,641**
Investing activities			
Acquisition of immaterial fixed assets		-500	0
Acquisition of property, plant and equipment		-2,876	–708
Cash flows from investing activities		**-3,376**	**–708**
Financing activities			
Repayment of financial liabilities	21	-3,134	–2,865
Rights issue		0	-180
Cash flows from financing activities		**-3,134**	**–3,045**
Cash flows for the period		**-149,121**	**124,888**
Cash and cash equivalents at the beginning of the period		401,897	277,009
Cash and cash equivalents at year end	24	**252,776**	**401,897**

Financial statement of the parent company

Parent company income statement in summary

Amounts in SEK thousand	Note	2022 Jan–Dec	2021 Jan–Dec
Operating income, etc.	6		
Net sales		4,531	4,059
Total income		*4,531*	*4,059*
Operating expenses	6		
Other external expenses	9	–12,187	–16,805
Personnel expenses	10	–14,402	–8,705
Other operating expenses		–25	0
Total operating expenses		*–26,614*	*–25,510*
Operating profit/loss		***–22,083***	***–21,451***
Profit/loss from financial items			
Interest expenses	11	–7	–3
Total financial items		*–7*	*–3*
Profit/loss after financial items		***–22,090***	***–21,454***
Tax on profit/loss for the year	12	0	0
Profit/loss for the year		**–22,090**	**–21,454**

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2022 Jan–Dec	2021 Jan–Dec
Profit/loss for the year	–22,090	–21,454
Other comprehensive income	0	0
Comprehensive income for the year	**–22,090**	**–21,454**

Financial statement of the parent company

Parent company balance sheet in summary

Amounts in SEK thousand	Note	12/31/2022	12/31/2021
ASSETS			
Non-current assets			
Financial assets			
Participations in group companies	18	350,320	350,320
Total non-current assets		**350,320**	**350,320**
Current assets			
Current receivables			
Receivables from group companies		6,059	465
Other receivables		1,07	655
Prepaid expenses and accrued income	19	1,405	636
		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**

Amounts in SEK thousand	Note	12/31/2022	12/31/2021
EQUITY AND LIABILITIES			
Equity	20		
Restricted equity			
Share capital		1,037	1,035
		1,037	*1,035*
Non-restricted equity			
Share premium reserve		744,315	739,560
Retained earnings		-280,345	-258,981
Profit/loss for the year		-22,090	-21,454
		441,880	*459,215*
Total equity		**442,917**	**460,250**
Current liabilities			
Trade payable		826	1,442
Liabilities to group companies		382	626
Other liabilities		565	753
Accrued expenses and deferred income	22	6,978	1,974
Total liabilities		**8,752**	**4,795**
TOTAL EQUITY AND LIABILITIES		**451,669**	**465,045**

Financial statement of the parent company

Parent company statements of changes in equity

Amounts in SEK thousand	Share capital	Unregistered share capital	Share premium reserve	Retained earnings including profit/loss for the year	Total equity
Amount at the beginning of the year 01/01/2021	**970**	**65**	**739,740**	**–258,891**	**481,884**
Comprehensive income for the year				-21,454	-21,454
New issue	65	-65			0
Issue costs			-180		-180
Amount at year-end 12/31/2021	**1,035**	**0**	**739,560**	**–280,345**	**460,250**
Amount at the beginning of the year 01/01/2022	**1,035**	**0**	**739,560**	**–280,345**	**460,250**
Comprehensive income for the year				-22,090	-22,090
New issue	2		4,755		4,757
Amount at year-end 12/31/2022	**1,037**	**0**	**744,315**	**–302,435**	**442,917**

Parent company statements of cash flows in summary

Amounts in SEK thousand	Note	2022 Jan–Dec	2021 Jan–Dec
Operating activities			
Operating profit/loss		-22,083	-21,451
Interest received		0	0
Interest paid		-7	-3
Cash flows from operating activities before changes in working capital		**-22,090**	**-21,454**
Cash flows from changes in working capital			
Decrease (+) /increase (-) in operating receivables		-6,780	-523
Decrease (-) /increase (+) in operating liabilities		8,713	-104,567
Cash flows from operating activities		**-20,156**	**-126,543**
Investing activities		0	0
Cash flows from investing activities		**0**	**0**
Financing activities			
Issue costs		0	-180
Cash flows from financing activities		**0**	**-180**
Cash flows for the year		**-20,156**	**-126,723**
Cash and cash equivalents at the beginning of the year		112,970	239,693
Cash and cash equivalents at year-end	24	**92,814**	**112,970**

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 key financial ratios above, only the key financial ratio 'Earnings per share before and after dilution' is mandatory and defined in accordance with IFRS. Of the other key financial ratios, Profit for the period, 'Cash and cash equivalents at the end of the period', 'Cash flow from operating activities', 'Cash flow for the period' and 'Equity attributable to the Parent Company's shareholders' are drawn from a financial statement defined by IFRS.

The table below derives the calculation of key financial ratios, both for the IFRS mandatory key financial ratio 'Earnings per share before and after dilution', but also for the key financial ratios 'R&D costs', 'R&D costs as a percentage of operating costs', 'Equity attributable to the Parent Company's shareholders per share' and 'Equity ratio'.

The company's business is to conduct research and development (R&D), which is why R&D costs as a percentage of operating costs are a significant key financial ratio as a measure of efficiency and the proportion of the company's costs used in R&D.
The company's operations are such that it does not have a steady flow of revenue, but rather this comes irregularly in conjunction with the signing of license agreements and achieved milestones. Therefore, the company follows the key financial ratios 'Equity' and 'Equity attributable to the Parent Company's shareholders per share' in order to be able to assess the company's financial position and stability. Together with these key financial ratios, the various measures of cash flows that follow from the Group's report on cash flow are also followed.

For definitions, see the section Definitions below.

	2022	2021
Profit/loss attributable to the parent company's shareholders (SEK thousand)	-113,406	51,781
Average number of shares before and after dilution	51,831,913	51,748,406
Earnings per share before and after dilution (SEK)	**-2,19**	**1.00**
Operating expenses (SEK thousand)	174,387	155,300
Unlicensed capitalized development projects	0	-39,091
Administration expenses (SEK thousand)	-23,429	16,982
Amortization and depreciation (SEK thousand)	-4,779	-3,474
R&D costs (SEK thousand)	**146,178**	**129,748**
R&D costs as a percentage of operating expenses (%)	**84**	**84**
Equity attributable to the parent company's shareholders (SEK thousand)	290,831	399,481
Number of shares as at the balance sheet date, including not yet registered issues	51,868,406	51,748,406
Equity attributable to the parent company's shareholders per share (SEK)	**5,61**	**7,72**
Equity (SEK thousand)	290,831	399,481
Total assets (SEK thousand)	323,555	472,449
Equity ratio (%)	**90**	**85**

Definitions

Key financial ratio	Definition	Reasons for using a key performance measure that is not defined according to IFRS
Net revenue	Revenues for goods and services sold in the main business during the current period.	
Operating profit/loss	Profit/loss before financial items and tax.	Operating profit/loss provides a picture of the results generated in the company's regular operations.
Earnings per share before and after dilution	Profit/loss attributable to the parent company's shareholders divided by the weighted average number of shares during the period before and after dilution, respectively.	
Average number of shares before and after dilution	Average number of shares outstanding during the period before and after dilution, respectively.	
R&D costs as a percentage of operating expenses	R&D costs divided by operating expenses, which include other external costs, personnel costs, amortization and depreciation.	Management believes that the company's R&D costs in relation to total costs are an important parameter to follow as an indicator of how great a proportion of the total costs are used for the company's main operations.
Cash and cash equivalents	Cash and bank balances.	

Key financial ratio	Definition	Reasons for using a key performance measure that is not defined according to IFRS
Cash flows from operating activities	Cash flows before cash flows from investing and financing activities.	
Cash flows for the period	The period's change in cash and cash equivalents excluding the effect of unrealized exchange rate gains and losses.	
Equity per share	Equity attributable to the parent company's shareholders divided by the number of shares at the end of the period.	Management uses this number in order to monitor how much equity is per share.
Equity ratio	Equity as a percentage of total assets.	Management monitors this figure as an indicator of the company's financial stability.
Average number of employees	The average number of employees is calculated as the sum of hours worked during the period divided by normal working hours for the period.	
Average number of employees in R&D	The average number of employees in the company's research and development departments.	

Notes

Note 1. General information

IRLAB Therapeutics AB (publ) with its registered office in Gothenburg, registered in Sweden with corporate identity number 556931-4692, is the parent company of Integrative Research Laboratories Sweden AB and its subsidiaries IRL626 AB, IRL752 AB and IRL790 AB. These companies are collectively referred to as the Group.

The address is Arvid Wallgrens backe 20, 413 46 Gothenburg, Sweden. The Group was formed in July 2014 when a controlling influence was obtained over Integrative Research Laboratories Sweden AB. On April 28, 2023, the Board of Directors approved this annual report and consolidated financial statements for publication.

The group's operations

The group's operations are conducted in the subsidiary Integrative Research Laboratories Sweden AB, a research company with the objective to offer life-altering treatments for patients with Parkinson's disease. The company's most advanced drug candidates are mesdopetam which has concluded Phase IIb-studies and is intended to treat PD-LIDs and psychosis (PD-P), and pirepemat where a Phase IIb-study is ongoing and which is intended to treat impaired balance leading to falls (PD-Falls). The company also has a unique, proprietary research platform (ISP) for developing new drug substances.

The parent company's operations

The parent company's operations mainly consist of providing management and administrative services for the group's operative companies. In addition, the parent company manages group-wide issues, such as activities and information related to the stock market, as well as other group management issues.

Note 2. Accounting principles

The consolidated financial statements are prepared in accordance with the Swedish Annual Accounts Act, RFR 1 Supplementary Accounting Rules for Groups, International Financial Reporting Standards (IFRS) and interpretations from the IFRS Interpretations Committee (IFRS IC), as adopted by the EU.

The parent company's annual report has been prepared in accordance with the Swedish Annual Accounts Act and RFR 2 Accounting for Legal Entities. The recommendation means that the parent company applies the same accounting principles as the group, except in cases where the Swedish Annual Accounts Act or applicable tax rules limit the possibilities of applying IFRS. Differences between the parent company's and the group's accounting principles are reported under the parent company's accounting principles below.

Basis for the report

The consolidated financial statements have been prepared in accordance with the acquisition value method. The balance sheet items that are classified as current assets and current liabilities are expected to be recovered and paid within 12 months. All other balance sheet items are expected to be recovered or paid later. The group's functional accounting currency is Swedish kronor (SEK). The consolidated financial statements are stated in thousands of Swedish kronor (TSEK), unless otherwise stated.

New and amended standards adopted by the group

No standards to be applied by the group for the first time on 1 January 2022 have had or are expected to have any impact on the consolidated accounts.

New standards and interpretations that have not yet been applied by the group

Several new standards and interpretations enter into force for financial years beginning after January 1, 2022 and have not been applied in the preparation of this annual report. The new standards and interpretations that have not yet entered into force are not expected to have any impact on the group's financial reports.

Consolidated financial statements

Subsidiaries are all companies over which the group has control. The group controls a company where the group is exposed to, or has rights to, variable returns from its holdings in the company, and has the opportunity to affect those returns through its control over the company. Subsidiaries are fully consolidated from the date on which control is transferred to the group. They are deconsolidated from the date when control ceases.

The acquisition method of accounting is used to account for business combinations by the group. The consideration transferred for the acquisition of a subsidiary comprises the fair value of the assets transferred and liabilities incurred to the former owners of the acquired business and shares issued by the group. The consideration also includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Identifiable assets acquired and liabilities assumed in a business acquisition are measured initially at their fair values at the acquisition date. Acquisition-related costs are expensed as incurred.

Intra-group transactions, balances and unrealized gains and losses on transactions between group companies are eliminated.

Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the group.

Translation of foreign currency

Functional currency and reporting currency

Items included in the financial statements of each of the group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in Swedish kronor (SEK), which is the group's reporting currency.

Transactions and balance sheet items

Foreign currency transactions are translated into the functional currency using the exchange rates on the dates of the transactions or on the date when the items are revaluated. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are recognized in profit or loss.

Foreign exchange gains and losses that relate to borrowings and cash and cash equivalents are presented in income statement, within finance costs. All other foreign exchange gains and losses are presented in the income statement on a net basis within Other operating income or Other operating expenses in the income statement.

Intangible assets and property, plant and equipment

Intangible assets and property, plant and equipment are recognized at cost less amortization and depreciation. Cost includes expenditure that is directly attributable to the acquisition of the asset. Additional expenses are added to the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the asset will benefit the group and the cost of the asset can be measured reliably. Expenditure for repair and maintenance are expensed in the income statement in the period in which they are incurred.

Depreciation is calculated using the straight-line method:

- Leasehold improvements, 20 years
- Equipment, tools, fixtures and fittings, 5 years
- Research databases, 5 years

Development expenditure that adds functionality and value is reported as intangible assets when the following criteria are met, which is normally the case when a development project is in Phase III.

- It is technically and financially feasible to complete the asset;

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- Adequate technical, financial and other resources to complete the development and to use or sell the asset are available;
- There is an intention and ability to sell or use the asset;
- It is likely that the asset will generate revenue or lead to cost savings; and
- The expenditure can be reliably measured.

Directly attributable costs that are capitalized as part of an intangible asset include employee costs and an appropriate portion of relevant overheads. Other development expenditure that does not meet the criteria above are recognized as an expense as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period. The group does not currently have any development project in Phase III or in any later Phase, which is why no development expenditure has yet been capitalized. The intangible assets reported in the balance sheet refer to acquired intangible assets consisting of a research database and acquired development projects. Acquired development projects consist of five patent families, which are not written off but are tested for impairment as they are not yet ready for use.

The residual value and useful life of the assets are tested at the end of every reporting period and adjusted where necessary. The carrying amount of an asset is immediately written down to its recoverable value if the carrying amount of the asset exceeds its estimated recoverable value.

Impairment

Intangible assets that are not ready for use are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Assets that are subject to amortization are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. When estimating the value in use, the estimated future cash flow is discounted to present value using a discount rate before tax that reflects the current market assessments of the time value of money and the risks specific to the asset.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are essentially independent cash flows (cash-generating units). Assets that have suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

Earnings per share

The calculation of earnings per share before dilution is based on profit/loss for the period attributable to the parent company's shareholders divided by the weighted average number of shares outstanding in the parent company during the financial year. The calculation of earnings per share after dilution is based on profit/loss for the period attributable to the parent company's shareholders divided by the weighted average number of shares outstanding after dilution.

Financial assets

The group classifies and measures its financial assets based on the business model for managing the asset's contractual cash flows and the nature of the asset. Financial assets are classified in one of the following categories: financial assets measured at amortized cost, financial assets measured at fair value through other comprehensive income, and financial assets measured at fair value through profit or loss.

At present, the group only has financial assets that are not normally sold outside the group and where the purpose of the holding is to obtain contractual cash flows.

Financial assets measured at amortized cost

All financial assets are classified as financial assets measured at amortized cost using the effective interest method. IRLAB applies the simplified approach to measuring expected credit losses, which is based on historical data regarding payment patterns and the solvency of the counterparty. The method uses a lifetime expected loss allowance for trade receivables. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of customers to settle the receivables. Based on historical data, the expected credit losses are considered to be extremely limited.

Cash and cash equivalents

In the balance sheet and the cash flow statement, cash and cash equivalents include cash, bank balances and other current investments with a due date within three months of the time of acquisition.

Equity

Share capital

Ordinary shares are classified as share capital.

Issue costs

Transaction costs that can be directly attributed to the issue of new ordinary shares or options are reported, net after tax, in equity as a deduction from the issue proceeds.

Financial liabilities

Financial liabilities measured at amortized cost

The group only has financial liabilities that are classified and measured at amortized cost using the effective interest method. They are initially recognized at fair value, net of transaction costs.

Provisions

Legal and informal obligations are reported as provisions that are attributable to the financial year or previous financial years and which on the balance sheet date are certain or likely to occur, but uncertain as to the amount or time when they shall be honored.

Income tax

Reporting of income tax includes current tax and deferred tax. The tax is reported in the income statement, except in cases where it relates to items that are reported directly in equity. In such cases, the tax is also reported in equity. Deferred tax is reported according to the balance sheet method for all significant temporary differences. A temporary difference exists when the book value of an asset or liability differs from the tax value. Deferred tax is calculated with the application of the tax rate that has been decided or announced on the balance sheet date and is expected to apply when the tax claim in question is realized or the tax liability is settled.

Deferred tax assets are reported to the extent that it is probable that future tax surpluses will exist against which the temporary differences can be utilized.

Revenue recognition

Net sales consist of revenue from the sale or licensing of products, e.g., in the form of drug development projects (candidate drugs) and services. In accordance with IFRS 15, revenue is recognized when control of the goods/services is transferred to the customer based on a five-step model:

- Identify the contract with the customer
- Identify the various performance obligations in the contract
- Determine the transaction price
- Allocate the transaction price to each performance obligation
- Recognize revenue when a performance obligation is satisfied.

At the start of a customer contract, IRLAB determines whether the goods and/or services to be delivered constitute a performance obligation or several separate performance obligations. A performance obligation is defined as a distinct promise to provide a product or service. A product or service that has been promised is distinct if both of the following criteria are fulfilled:

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- The customer can benefit from the product or service separately or together with other resources that are available for the customer; and
- The group's promise to transfer the product or service to the customer can be distinguished from other promises in the agreement.

When determining the transaction price, which is the consideration that is promised in the agreement, the group considers potential variable compensation. The transaction price includes variable consideration only if it is highly probable that a significant reversal of the revenue is not expected to occur in a future period.

When entering into a drug candidate license agreement, the revenue is allocated between the various performance obligations that are identified in the agreement. Service revenue from the completion of studies and other commitments were calculated based on a cost-plus model based on estimated costs for these commitments and licensing revenue was calculated based on the residual method. Revenue for agreed but not yet performed services are reported as contract liabilities. No customer agreements within the group are considered to include a significant financing component; IRLAB allocates the transaction price for each performance obligation on the basis of a stand-alone selling price. The standalone selling price is the price at which the group would sell the product or service separately to the customer. IRLAB recognizes revenue when the group satisfies a performance obligation by transferring a good or service to a customer, i.e., when the customer obtains control of the asset.

A performance obligation is satisfied either over time or at a point in time.

IRLAB's revenue is primarily made up of the sale or licensing of products in the form of drug development projects or candidate drugs, but services related to the sold products are often an important part of the revenue. The sale and licensing of products is recognized as revenue when control of the product is transferred to the customer, which normally occurs in conjunction with the transfer of rights to use IRLAB's patents, study results and other rights connected to the product to the customer. Services are recognized over time as the services are provided. For services that are provided over a brief period, revenue is recognized in practice when the service has been completed.

Revenue from future milestones and royalties are recognized when it is determined that more or less certain that these have been reached or will be received.

Reporting of public grants

Public grants are reported at fair value as soon as there is reasonable assurance that the conditions associated with the grant will be met and thereby that the grant will be received. Grants received to cover costs are reported under the heading 'other income' in the same period as the costs arise.

Leases

When new leases are entered into, a right-of-use asset and a lease liability are recognized in the balance sheet. The cost comprises the discounted remaining lease payments during any lease terms that cannot be terminated. Potential options to extend the term of the lease are included if the group is reasonably certain that these options will be used. The group's incremental borrowing rate is used for discounting. The lease may be amended during the term of the lease, in which case the lease liability and right-of-use asset will be revaluated. Lease payments are allocated to repayments of the lease liability and payments of interest.

The company applies the exemption for leases of low-value assets and short-term leases. These leases are recognized as an expense in the period when the use takes place.

Remuneration to employees

Liabilities for salaries, benefits and paid absences that are expected to be settled wholly within 12 months after year-end are recognized as current liabilities with the amount expected to be paid when the liabilities are settled, without discounting. The cost is recognized when the services are provided by the employees.

The group has both defined benefit plans and defined contribution plans. For defined contribution plans, the group pays fixed contributions to an independent pension institution. Once the fee is paid, the company has no additional obligations. Defined benefit plans are available in the form of ITP1 and ITP2 from the insurer Alecta. Alecta cannot provide a distribution of the group's total plan assets and pension commitments, so these pension plans are also reported as defined contribution plans. The cost of pensions is reported in the period when the employees performed the duties to which the remuneration relates.

Statement of cash flows

The statement of cash flows is prepared using the indirect method, which means that the operating profit or loss is adjusted for the effects of transactions of a non-cash nature during the period and for any income or expense associated with cash flows from investing or financing activities. Cash and cash equivalents include cash and immediately available banks balances.

Parent company's accounting principles

The parent company applies the same accounting principles as the group, except in the respects set out below. The parent company's accounting principles are unchanged compared with the previous year.

Participations in subsidiaries

Participations in subsidiaries are recognized at cost less any impairment losses. The cost includes acquisition-related costs and potential earnouts.

When there is indication that participations in subsidiaries have decreased in value, an estimate is made of the recoverable amount. If recoverable is lower than the carrying amount, an impairment loss is applied. Impairment is reported in the item Profit/loss from participations in group companies.

Financial instruments

The company does not apply IFRS 9, except for the rules on assessing and calculating the impairment of financial assets. In the parent company, non-current financial assets are measured at cost less any impairment and current financial assets are measured at the lowest of the cost and the fair value less the cost of disposal.

Leases

The parent company uses the exemption from IFRS 16 Leases, which means that all leases are reported as a cost on a straight-line basis over the term of the lease.

Currency	2022 Income	2022 Costs	2022 Net exposure	2021 Income	2021 Costs	2021 Net exposure
SEK	**0**	32,737	**-32,737**	124	112,968	-112,844
CHF	**0**	235	-235	0	**0**	0
DKK	**0**	2	**-2**	0	0	0
EUR	**22,550**	72,579	-50,029	190,638	71,159	119,479
GBP	**0**	21,437	-21,437	**124**	19,455	-19,331
USD	**0**	3,154	**-3,154**	08,005		-8,005
Total	**22,550**	**130,144**	**-107,594**	**190,886**	**212,387**	**-21,501**

Notes

Note 3. Financial risk management and capital risk

FINANCIAL RISK MANAGEMENT

Through its operations, the group is exposed to various financial risks, such as market risk (including currency risk and interest rate risk in the cash flows), credit risk and liquidity risk. The group's overall risk management policy, which has been established by the Board of Directors, is to strive for minimal adverse effects on financial results and position.

Market risk

Currency risk

The group operates both nationally and internationally, which entails exposure to fluctuations in various currencies, especially with regard to GBP, USD and EUR. Currency risk arises through future business transactions as well as reported assets and liabilities. As at December 31, 2022, currency exposure from trade payables were DKK 2k, GBP 165k, USD 18k and EUR 542k. Interest-bearing liabilities comprised liabilities in SEK only. It is the group's currency policy not to hedge flows in foreign currency.

If the Swedish krona had become weaker or stronger by 10% compared with the currencies mentioned above, with all other variables constant, the recalculated profit/loss after tax as of December 31, 2022 would have been SEK 631k (777) higher or lower, largely as a result of gains or losses when translating current receivables and liabilities. The corresponding impact on the parent company would have been SEK 7k (64).

Interest rate risk in the cash flow

Interest rate risk is the risk that the value of financial instruments varies due to changes in market rates. The group's only interest-bearing financial assets in the form of bank balances and interest-bearing liabilities in the form of lease liabilities.

Calculated on the basis of financial interest-bearing assets and liabilities that have a variable interest rate as of December 31, 2022, a single percentage point change in the market rate would affect the group's profit or loss after tax by SEK 2,488k (3,953). The corresponding effect on the parent company would have been SEK 928k (1,130).

Credit risk

Credit risk is the risk that a party to a transaction with a financial instrument will not be able to fulfill its obligations. The maximum exposure to credit risks relating to financial assets as of December 31, 2022 amounted to SEK 264,622k (412,435). The corresponding figure for the parent company was SEK 99,032k (SEK 113 435). To minimize credit risk, cash and cash equivalents are only deposited in a cash account or similar, and the group only uses credit institutions with a high credit rating. See also Note 26.

Financial liabilities as of December 31, 2022 due for payment:

	Within 3 months	Between 3 months and 1 year	Between 1 year and 2 years	Between 2 years and 5 years	Later than 5 years
Leasing debt	920	2,761	277	115	0
Accounts payable	10,031	0	0	0	0
Other liabilities and accrued expenses	11,731	0	0	0	0
Total	**22,682**	**2,791**	**277**	**115**	**0**

Liquidity risk

Caution in managing liquidity risk means holding sufficient cash or cash equivalent, or alternatively agreed credit facilities to be able to close market positions. In preparing this financial report, the Board of Directors estimates that there is sufficient capital to complete the planned implementation of the Phase IIb study for pirepemat. The maturity structure for the group's financial liabilities is shown below.

Capital risk management

he group's objectives when managing capital, defined as equity, are to safeguard the company's ability to continue as a going concern, so that it can continue to provide returns for shareholders and benefits for other stakeholders, and maintain an optimal capital structure considering the cost of capital. Dividends to shareholders, the redemption of shares, issues of new shares or the sale of assets are examples of measures that the company can use to adjust the capital structure. The company deems that the current debt to equity ratio is satisfactory based on the company's current operations.

The group's debt to equity ratio	**2022-12-31**	**2021-12-31**
Total interest-bearing liabilities	3,976	6,601
Deduct: interest-bearing assets	252,776	401,897
Net debt	**–248,800**	**–395,297**
Total equity	290,880	399,481
Net debt to equity ratio	**–85,5%**	**–99,0%**

Net debt: Interest-bearing liabilities less interest-bearing assets (incl. cash and cash equivalents).
Net debt to equity ratio: Net debt in relation to equity.

Note 4. Important estimates and assessments for accounting purposes

The most important assumptions about the future, and other important sources of uncertainty in estimates as at the balance sheet date, which entail a significant risk of material adjustments in the reported values of assets and liabilities the following financial year, are described below. The greatest uncertainty is found in intangible assets. Intangible assets are held by the subsidiary and the sub-subsidiaries and were acquired by the group through operational acquisitions. Intangible assets are tested annually for impairment.

After the licensing of mesdopetam, the entire carrying value of mesdopetam has been reversed. Thereafter, acquired development projects chiefly refer to pirepemat, which was acquired when IRLAB Therapeutics AB became the parent company of the group in 2014. As the project has not yet been completed, no amortization has been made yet; instead, it is tested annually for impairment.

The impairment testing is based on a review of the recoverable value, which is estimated based on the assets' value in use. The executive management calculates the present value of future cash flows according to internal business plans and forecasts as well as future growth rates beyond established budgets and forecasts for the acquired development projects. Valuations are only made for pirepemat, the value of which makes up the vast majority of the value of the acquired development projects.

A discount rate of 30 percent before tax was used in the calculation. This discount rate is probability-adjusted according to the general industry-based probability that projects will the market.

Only cash flows calculated for the period when the project is expected to have market exclusivity are discounted, without terminal value. The calculations include sensitivity analyses regarding the discount rate (+/- 5 percent), pricing (+/- USD 15 thousand per year), time to market authorization (+/- 3 years) and the maximum penetration rate (+/- 6%) without any expected impairment.

The carrying value of intangible assets was SEK 46,862k (42,661), of which acquired development accounted for SEK 46,862k (42,402) and the research platform accounted for SEK 0k (259). Changes in the assumptions made by the executive management when testing for impairment could

Notes

have a material impact on the company's results and financial position.

Tax loss carry-forwards in the group were SEK 489,805k (377,389) as at December 31, 2022. For the parent company, tax loss carry-forwards were SEK 288,683k (266,706). Before the group shows a stable profit, it is considered that tax loss carry-forwards will only be valued to the extend that the deferred tax assets meet the deferred tax liability that arose in the acquisition of the intangible assets.

Note 5. Segment information

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker is the function responsible for allocating resources and assessing the performance of the operating segments. In the group, this function has been identified as the executive management, which consists of eight people, including the CEO. The management team has determined that the group as a whole constitutes a single segment based on the information that is processed and which, in consultation with the Board of Directors, is used as a basis for allocating resources and evaluating performance.

All non-current assets are located in Sweden.

The group's net sales were SEK 61,136k (207,782) and consist entirely of consideration for the licensing of drug development projects or drug candidates and revenue linked to ongoing studies, invoicing of work performed on behalf of customers and other service revenue. All of the net sales were related to a single customer.

Net sales by geographic market (SEK thousand)	2022	2021
Sweden	0	0
United Kingdom	61,136	207,782
Total	**61,136**	**207,782**

Net sales by revenue category (SEK thousand)	2022	2021
Licensing revenue	0	185,261
Service revenue	61,136	22,521
Total	**61,136**	**207,782**

Note 6. Purchases and sales within the group

Of the parent company's net revenues, SEK 4,531k (4,059) was made up of invoicing to group companies. The parent company's procurement of services from group companies in 2022 amounted to SEK 913k (939).

Note 7. Other operating income

The group	2022	2021
Insurance payment	215	0
Exchange rate gains	293	124
Total	**504**	**124**

Note 8. Leasing agreements

The group has leases, chiefly in the form of agreements for the use of office premises and certain medical equipment. When discounting future leasing payments, the group's marginal borrowing rate has been used, which is estimated to 5%.

The following amounts were reported in the income statement.

The group	2022	2021
Amounts reported in the result		
Depreciation of usufruct assets	–2,987	–2,722
Interest expenses for leasing liabilities	–265	–367
Costs attributable to leasing agreements of low value	0	0
Costs attributable to variable fees that are not included	–310	–187

Total cash flows for leases were SEK –3,398k (–3,232).

Note 9. Remuneration to auditors

	Group		Parent company	
	2022	2021	2022	2021
Fees and expense allowances				
Öhrlings PricewaterhouseCoopers AB				
Audit assignment	542	453	542	453
Audit activities outside the audit assignment	122	88	122	88
Tax advice	0	3	0	3
Other assignments	0	69	0	69
Total	**664**	**613**	**664**	**613**

The audit assignment includes auditing the Annual Report and accounts as well as the administration of the company by the Board of Directors and CEO, other duties that the company auditor must perform as well as advice and other assistance arising from the audit or in carrying out these duties.

Audit activities outside the audit assignment chiefly include reviewing interim reports.

Tax advice includes tax advice related to income tax and value-added tax.

Note 10. Employees and personnel costs

Average number of employees	2022 Number of employees	2022 Of which are men	2021 Number of employees	2021 Of which are men
Parent company				
Sweden	3	3	2	2
Subsidiary				
Sweden	26	9	20	7
Group total	**29**	**12**	**22**	**9**

Notes

Note 10. Employees and personnel costs

Gender distribution, senior executives	2022 Women	2022 Men	2021 Women	2021 Men
Parent company				
Board of Directors	3	2	2	4
CEO and other executive management	0	3	0	2
Subsidiary				
Board of Directors	3	2	2	4
CEO and other executive management	3	3	3	3

Salaries and other remuneration (SEK thousand)	Group 2022	Group 2021	Parent company 2022	Parent company 2021
Salaries and other remuneration				
Chairman of the Board	517	450	517	450
Other board members	1,257	1,172	1,257	1,172
Chief Executive Officer	3,318	2,599	3,318	2,599
Other senior executives	6,519	6,738	1,436	1,503
Other employees	15,203	10,502	8	0
	26,813	**21,461**	**6,535**	**5,724**
Pensions				
Board of Directors	0	0	0	0
Chief Executive Officer	1,080	682	1,080	682
Other senior executives	2,190	2,122	753	411
Other employees	3,469	1,264	6	0
	6,762	**4,068**	**1,839**	**1,093**
Social security contributions	6,264	4,421	2,731	1,790
	39,840	**29,951**	**11,106**	**8,607**

Remuneration to the Board of Directors, the CEO and senior executives

Remuneration to board members elected by the general meeting is decided by the Annual General Meeting. The CEO's remuneration is decided by the Board of Directors. In relation to the previous year, the number of board members has decreased to 5 (6). Remuneration levels for board and committee work have increased in relation to the previous year.

Senior executives refer to the people who, together with the CEO, form the company's management. The management team consists of eight people, including the CEO. Remuneration to senior executives consists of a basic salary, pension benefit, other benefits, and conditions upon termination.

Remuneration to the Board of Directors, the CEO and senior executives of the group is shown in the tables below.

2022 (SEK)	Position	Salary and benefits /board fee	Variable remun-eration	Pension costs	Other remun-eration	Total
Gunnar Olsson	Chair of the Board	516,666	0	0	0	**516,666**
Carola Lemne	board member	310,001	0	0	0	**310,001**
An van EsJohansso	board member	295,166	0	0	0	**295,166**
Catharina Gustavsson Wallich	board member	326,667	0	0	0	**326,667**
Rein Piir	board member	325,000	0	0	0	**325,000**
Total Board of Directors		**1,773,500**	**0**	**0**	**0**	**1,773,500**
Richards Godfrey fr o m 1 july	Chief Executive Officer	2,070,000	0	894,672	0	2,964,672
Nicholas Waters t o m 30 june	Chief Executive Officer	1,248,090	0	447,724	0	**1,695,814**
Other senior executives, 7 people		6,518,579	0	2,721,064	1,003,790	**10,243,433**
Total Chief Executive Officer and senior executives		**9,836,669**	**0**	**4,063,460**	**1,003,790**	**14,903,919**

Notes

Note 10. Employees and personnel costs

2021 (SEK)	Position	Salary and benefits/ board fee	Variable remuneration	Pension costs	Other remuneration	Total
Gunnar Olsson	Chair of the Board	450,000	0	0	0	**450,000**
Lars Adlersson	board member	250,000	0	0	0	**250,000**
Carola Lemne	board member	230,000	0	0	0	**230,000**
Martin Nicklasson	board member	187,500	0	0	0	**187,500**
Rein Piir	board member	275,000	0	0	0	**275,000**
Lena Torlegård	board member	230,000	0	0	0	**230,000**
Total Board of Directors		**1,622,500**	**0**	**0**	**0**	**1,622,500**
Nicholas Waters	Chief Executive Officer	2,285,281	314,000	847,220	0	**3,446,501**
Other senior executives, 7 people		5,869,521	868,080	2,637,382	1,178,017	**10,553,000**
Total Chief Executive Officer and senior executives		**8,154,802**	**1,182,080**	**3,484,602**	**1,178,017**	**13,999,501**

The notice period for the interim CEO is thirty days. For the Executive Vice President & Head of R&D the notice period is twelve months, regardless of which party gives the notice, however, the notice period is eighteen months in certain situations. The notice period for CSO, Director of Biology & Biostatistics and Director of Computational Chemistry & Biology/CIO is six months, regardless of which party gives the notice. For other senior executives who are employed, the notice period that applies is that according to the applicable collective agreement, which currently means 1-3 months. The consulting agreement regarding Cecilia Tivert Stenberg runs until further notice with a mutual notice period of three months. Remuneration according to this agreement is reported under "Other remuneration". No employee is entitled to severance pay.

The group only has pension obligations that are managed as defined contribution plans. In defined contribution plans, the company pays fixed fees to insurance companies. Retirement age is 65 years. For the CEO, Nicholas Waters, the company shall pay a fixed premium corresponding to 30% of his regular salary, and for the CFO, the corresponding 28% of his regular salary applies. The pension costs reported above include separate income tax.

An van Es-Johansson was elected board member at the Annual General Meeting on May 11, 2022. On February 21, 2023, she elected to resign from the Board of Directors.

Note 11. Financial expenses/ interest expenses and similar income statement items

	Group		Parent company	
	2022	2021	2022	2021
Interest expenses, group companies	0	0	0	0
Interest expenses, lease liability	–265	–367	0	0
Interest expenses, other	–32	–3	–7	–1
Exchange rate losses	0	–426	0	–2
Total	**–297**	**–796**	**–7**	**–3**

Note 12. Income tax

	Group		Parent company	
	2022	2021	2022	2021
Current tax	0	0	0	0
Deferred tax	0	0	0	0
Total	**0**	**0**	**0**	**0**
Theoretical tax				
Reported profit/loss before tax	–113,406	51,781	–22,090	–21,454
Tax according to the applicable tax rate, 20.6%	23,362	–10,667	4,551	4,419
Reconciliation of reported tax				
Effect of expenses that are not deductible	–205	–29	–23	–6
Effect of loss carry-forwards not valued	0	–15,807	–4,527	–4,450
Effect of utilized loss carry-forwards not previously valued	23,157	26,466	0	0
Effect of costs reported in equity	0	37	0	37
Effect of loss carry-forwards valued in previous years	0	0	0	0
Total	**0**	**0**	**0**	**0**

Tax loss carry-forwards in the group were SEK 489 ,805k (377,389) as at December 31, 2022. For the parent company, tax loss carry-forwards were SEK 288,683k (266,706). None of the loss carry-forwards are limited in time. Of the tax loss carry-forwards, SEK 39,752k (39,716) were valued in the group, and SEK 0 (0) were valued in the parent company.

Notes

Note 12. Income tax

Group	Deferred tax assets 2022	Deferred tax assets 2021	Deferred tax liability 2022	Deferred tax liability 2021
Opening reported value	9,685	15,929	–9,685	–15,929
Change via the income statement for the year	–611	–6,244	611	6,244
Årets förändring via tillkommande leasing	105	0	105	0
Reported value	**9,179**	**9,685**	**–9,179**	**–9,685**

Temporary differences are found in the following items:

	Group 2022	Group 2021
Intangible assets	–8,241	–8,236
Right-of-use assets	–938	–1,449
Current receivables	171	144
Lease liabilities	819	1,360
Tax loss carry-forwards	8,189	8,181
Carrying amount	**0**	**0**

Note 13. Research database

	Group 2022	Group 2021
Opening cost	1,036	1,036
Closing accumulated cost	**1,036**	**1,036**
Opening amortization	–777	–518
Amortization for the year	–259	–259
Closing accumulated amortization	**–1,036**	**–777**
Carrying amount	**0**	**259**

Note 14. Acquired development projects

	Group 2022	Group 2021
Opening cost	81,492	81,492
Övertaget vid förvärv	5,257	0
Closing accumulated cost	**86,749**	**81,492**
Opening depreciation	-39,091	0
Impairment for the year	-796	0
Sales and disposals	0	-39,091
Closing accumulated cost	**–39,887**	**39,091**
Carrying amount	**46,862**	**42,402**

Note 15. Improvements to someone else's property

	Group 2022	Group 2021
Opening cost	116	116
Closing accumulated cost	**116**	**116**
Opening depreciation	–24	–21
Translation differences for the year	–6	–3
Closing accumulated depreciation	**–30**	**–24**
Carrying amount	**86**	**92**

Notes

Note 16. Equipment, tools and installations

	Group 2022	2021
Opening cost	3,651	2,941
Acquisitions	2,876	708
Closing accumulated cost	**6,527**	**3,651**
Opening depreciation	–2,426	–1,936
Depreciation for the year	–730	–490
Closing accumulated depreciation	**–3,156**	**–2,426**
Carrying amount	**3,369**	**1,224**

Note 17. Utilized assets

	Group 2022	2021
Opening cost, IFRS 16	12,940	6,544
Acquisitions	509	6,539
Terminated over the year	0	-143
Closing accumulated cost	**13,449**	**12,940**
Opening depreciation	–5,907	–3,328
Depreciation for the year	–2,987	–2,722
Terminated over the year	0	143
Closing accumulated depreciation	**–8,894**	**–5,907**
Carrying amount	**4,555**	**7,033**

Note 18. Shares in group companies

Company	Corporate identity No.	Seat	Number	Share of capital	Carrying amount 2022	2021
Integrative Research Laboratories Sweden AB	556922-0444	Gothenburg	150,995	100%	350,320	350,320
IRL 626 AB	559041-8389	Gothenburg	50,000	100%	–	–
IRL 752 AB	559041-8371	Gothenburg	50,000	100%	–	–
IRL 790 AB	559041-8405	Gothenburg	50,000	100%	–	–
					350,320	**350,320**

Parent company	**2022**	**2021**
Opening cost	350,320	350,320
Carrying amount	**350,320**	**350,320**

Note 19. Prepayments and accrued income

	Group 2022	2021	Parent company 2021	2020
Prepaid insurance	564	393	311	370
Other prepaid expenses	2,780	1,886	1,055	266
Accrued R&D deductions	347	231	39	0
Other accrued income	2,298	6,288	0	0
Carrying amount	**5,989**	**8,799**	**1,405**	**636**

Notes

Note 20. Equity

Number of shares	Group 2022	2021
Registered number of shares	51,868,406	51,748,406
	51,868,406	**51,748,406**
Average number of shares, before and after dilution	51,831,913	51,748,406
	51,831,913	**51,748,406**

The registered number of shares comprises 51,788,630 (51,478,406) Series A shares and 79,776 (71 ,776) Series B shares. Both A and B shares confer a right to one vote each. The quota value for all shares is SEK 0.02 per share. Only A shares are admitted to trading on Nasdaq Stockholm.

Year	Event	Amount issued (SEK)	Total share capital (SEK)	Change (SEK)	Total number of shares	Change shares	Quota value (SEK)
2013	Formation	25,000,000	50,000	50,000	100,000	100,000	0.50
2015	New issue	24,106,969	84,473	34,473	168,946	68,946	0.50
2015	New issue	14,772,000	104,169	19,696	208,338	39,392	0.50
2015	New issue	8,407,125	115,379	11,210	230,757	22,419	0.50
2015	Stock split	0	115,379	0	2,307,570	2,076,813	0.05
2015	Non-cash issue	54,515,644	181,358	65,980	3,627,162	1,319,592	0.05
2016	New issue	41,350,000	231,358	50,000	4,627,162	1,000,000	0.05
2016	New issue	15,350,195	249,919	18,561	4,998,388	371,226	0.05
2016	New issue	726,243	253,497	3,578	5,069,939	71,551	0.05
2016	Stock dividend issue	0	506,994	253,497	5,069,939	0	
2017	New issue	115,800,000	699,994	193,000	6,999,939	1,930,000	0.10
2018	New issue	138,600,000	809,994	110,000	8,099,939	1,100,000	0.10
2019	Stock split 5:1	0	809,994	0	40,499,695	32,399,756	0.02
2019	New issue	70,470,000	862,194	52,200	43,109,695	2,610,000	0.02
2020	New issue	145,495,197	969,968	107,774	48,498,406	5,388,711	0.02
2020	New issue	130,000,000	1,034,968	65,000	51,748,406	3,250,000	0.02
2022	Non-cash issue	0	1,089,968	120,000	51,868,406	120,000	0,02
At the end of the period		**784,593,373**	**1,089,968**		**51,868,406**		**0.02**

The issued amount above is the total issued amount including a premium but before issue costs.

Incentive programs

In April 2016, it was decided to offer warrants to key personnel, both employees and board members. A total of 71,551 Class B ordinary shares (357,755 after the split) and 39,355 subscription warrants (196,775 after the split) were subscribed for in the program. The subscription price for the shares and the subscription warrants corresponded to the market value. Proceeds from the issue of the shares was paid by the group as a benefit to key personnel.

In July 2019, a conversion of Class B shares into Class A shares was called for by all holders of Class B shares. 277,979 Class B shares were converted into Class A shares. The remaining 79,776 Class B shares are not subject to conversion as the holders are only allowed convert B shares once, and all holders have now exercised this possibility and carried out the conversion.

Subscription warrant program

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. Upon full exercise of the warrants, the share capital will increase by SEK 3,935.50 through the issue of 196,775 Class A ordinary shares.

Proposal for the appropriation of the company's profit/loss (SEK)	
At the disposal of the Annual General Meeting:	
Share premium reserve	744,314,371
Accumulated deficit	–280,344,512
Loss for the year	–22,089,866
	441,879,993
The Board of Directors proposes that SEK 441,879,993 be carried forward	
	441,879,993

Notes

Note 21. Leasing debt

	Group 2022	Group 2021
Opening carrying amount	6,601	2,928
Added over the year	509	6,538
Repayments over the year, affecting cash flows	-3,134	-2,865
Carrying amount	**3,976**	**6,601**
Non-current part	381	3,566
Current part	3,595	3,034

Note 22. Accrued expenses and prepaid income

	Group 2022	Group 2021	Parent company 2022	Parent company 2021
Personnel-related expenses	6,986	4,495	2,502	1,365
Other prepaid expenses	6,449	1,349	4,477	610
Contract liability	0	42,576	0	0
Reported value	**13,435**	**48,420**	**6,978**	**1,974**

Note 23. Items that do not affect cash flow

	Group 2022	Group 2021
Amortization and depreciation	3,982	3,474
Impairment	797	0
Licensed capitalized development projects	0	39,090
Total	**4,779**	**42,564**

Note 24. Cash and cash equivalents

	Group 2022	Group 2021	Parent company 2022	Parent company 2021
Cash in hand	4	4	1	1
Bank deposits	252,772	401,893	92,813	112,969
Total cash and cash equivalents	**252,776**	**401,897**	**92,814**	**112,970**

Note 25. Transactions with related parties

Remuneration to the Board of Directors and senior executives is reported in Note 10. All transactions with related parties have been on market terms.

As at the balance sheet date, the parent company has a receivable from a group company of SEK 6,059k and a liability to a group company of SEK 382k.
Information on sales to and purchases from group companies is provided in Note 6.

Note 26. Financial instruments by category

	Group 2022	Group 2021	Parent company 2022	Parent company 2021
Financial assets at amortized cost				
Trade receivables	3,322	4,470	0	0
Group receivables	0	0	6,058	465
Other Receivables	170	3	160	0
Accrued income	2,298	6,288	0	0
Cash and cash equivalents	252,776	401,897	92,814	112,970
	258,566	**412,658**	**99,032**	**113,435**
Financial liabilities at amortized cost				
Lease liabilities	3,976	6,601	0	0
Trade payables	10,031	12,302	826	1,442
Other liabilities and accrued expenses	11,731	11,486	5,423	3,353
	25,738	**30,392**	**6,429**	**4,795**

Notes

Note 26. Financial instruments by category

Financial assets valued at amortized cost

The group's operations currently give rise to very few trade receivables; historically, trade receivables have never reached any significant amounts. Historically, there have been no credit losses related to trade receivables. As at the balance sheet date, trade receivables were SEK 3,322k (4,470).

Cash and cash equivalents comprise a small amount of cash at hand and bank deposits.

The group applies the simplified approach to measuring expected credit losses. The method uses a lifetime expected loss allowance for trade receivables.

The group's trade receivables are very limited, so no loss allowance has been made.

The parent company has receivables from subsidiaries, which are not deemed to be subject to any significant credit risk.

As at the balance sheet date, no impaired receivables had been identified. Trade receivables are in EUR. Group receivables are in SEK.

In all essentials, the fair value of financial assets is deemed to be commensurate with their carrying value.

Financial liabilities measured at amortized cost

The group's only borrowings are in the form of lease liabilities for leases of premises and medical equipment. These are secured by the right-of-use to the premises and the instruments.

The maturity structure of the financial liabilities is provided in Note 3.

In all essentials, the fair value of financial liabilities is deemed to be commensurate with their carrying value

Note 27. Significant events after the end of the financial year

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 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 a Board member at IRLAB.

Notes

The Board of Directors and the CEO declare that the consolidated financial statements have been prepared in accordance with IFRS as adopted by the EU and give a true and faithful representation of the group's financial position and results of operations.

The financial statements for the parent company have been prepared in accordance with generally accepted accounting principles in Sweden and give a true and fair view of the parent company's financial position and results of operations.

Gothenburg 28 April 2023

CAROLA LEMNE
Chair of the Board

REIN PIIR
Board member

CATHARINA GUSTAVSSON WALLICH
Vice Chair

GUNNAR OLSSON
CEO and Board member

Our audit report was submitted on 14 April 2021
Öhrlings PricewaterhouseCoopers AB

Johan Rippe
Authorized Public Accountant
Lead Partner

Sophie Damborg
Authorized Public Accountant

SABINA BRANDIN, works with studying the effects of our candidate drugs in different model systems.

Auditor's report

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of IRLAB Therapeutics for the year 2022. The annual accounts and consolidated accounts of the company are included on pages 60-106 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 December 2022 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2022 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Our audit approach

Overview

Audit scope

We designed our audit by determining materiality and assessing the risks of material misstatement in the consolidated financial statements. In particular, we considered where management made subjective judgements; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits, we also addressed the risk of management override of internal controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud.

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the consolidated financial statements as a whole, taking into account the structure of the Group, the accounting processes and controls, and the industry in which the group operates.

Materiality

The scope of our audit was influenced by our application of materiality. An audit is designed to obtain reasonable assurance whether the financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the consolidated financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall group materiality for the consolidated financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Key audit matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our

Key audit matters	How our audit addressed the Key audit matter
Valuation of acquired development projects The Group's assets include intangible assets regarding acquired development projects totaling SEK 46.9 million, which make up a considerable part of all assets in the Group. The acquired development projects comprise development projects acquired by the group when IRLAB Therapeutics AB became the parent company of the group in 2014. The initial cost from the acquisition has been reduced, for example due to the licensing of mesdopetam in 2021. Intangible assets that have not yet been completed are not amortized; instead, they are subject to annual impairment testing. The carrying value of intangible assets is supported by the higher of either value in use calculations, which are based on discounted future cash flow forecasts, or fair value less cost of disposal (recoverable amount). The assessment to identify potential impairment indicators and to perform impairment tests requires management to exercise significant judgment where there is a risk that the valuation of intangible assets and any potential impairment charge or reversal of impairment may be incorrect. Management's test requires consideration of a number of factors, including but not limited to, the Group's intention to proceed with a portfolio of development candidates, the probability of success of future candidates, future prices and costs as well as the discount and inflation rates. Following the analysis of potential impairment indicators for the intangible assets during the year and as per 31 December 2022 it was concluded that there were no impairment indicators identified and no impairment was recorded. Refer to pages 83 to 84 in the Accounting Policies and note 4 and 14 in the financial statements for more information.	We have examined management's assessment for determining the impairment indicators and concluded that there are no impairment indicators identified. The assumptions that underpin management's calculation of the recoverable amount of intangible assets are inherently judgmental. Our audit work therefore assessed the reasonableness of management's key judgements of the recoverable amount of intangible assets. Specifically, our work included, but was not limited to, the following procedures: · comparison of management's price assumptions along with external data to number of potential patients; · verification of estimated future costs by agreement to budgets and where applicable, third party data; · benchmarking of inflation and discount rates applied; · testing of the mathematical accuracy of the model to calculate the recoverable amount We finally evaluated whether the disclosures provided describe in a satisfactory manner how the impairment testing was performed, and on which estimates and assumptions it was based on

Auditor's report

audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1 – 59. This other information also includes the remuneration report, which we received before the date of this auditor's report. The Board of Directors and the CEO are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Director's and the Managing Director

The Board of Directors and the CEO are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the CEO are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the CEO are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the CEO intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

A further description of our responsibility for the audit of the annual accounts and consolidated accounts is available on Revisorsinspektionen's website:

www.revisorsinspektionen.se/revisornsansvar.

This description is part of the auditor's report.

Report on other legal and regulatory requirements

The auditor's audit of the administration of the company and the proposed appropriations of the company's profit or loss

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Director's and the CEO of IRLAB Therapeutics AB for the year 2022 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Director's and the CEO be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Director's and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group' equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The CEO shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the CEO in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

Auditor's report

A further description of our responsibility for the audit of the administration is available on Revisorsinspektionen's website:

www.revisorsinspektionen.se/revisornsansvar.

This description is part of the auditor's report.

The auditor's examination of the ESEF report

Opinion

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the CEO have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4 a of the Swedish Securities Market Act (2007:528) for IRLAB Therapeutics AB for the financial year 2022.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

Basis for Opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of IRLAB Therapeutics AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of the Board of Director's and the CEO

The Board of Directors and the CEO are responsible for the preparation of the Esef report in accordance with the Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the CEO determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the CEO, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of assumptions made by the Board of Directors and the CEO.

The procedures mainly include a validation that the Esef report has been prepared in a valid XHTML format and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the Esef report has been marked with iXBRL in accordance with what follows from the Esef regulation.

Öhrlings PricewaterhouseCoopers AB, 113 97 Stockholm, was appointed auditor of IRLAB Therapeutics AB by the general meeting of the shareholders on the 7 May 2020 and has been the company's auditor since the 9 December 2016.

IRLAB Therapeutics AB has been a public interest entity since 30 September 2020 when the shares of IRLAB Therapeutics AB began trading on a regulated market.

Göteborg den 28 april 2023

Öhrlings PricewaterhouseCoopers AB

Johan Rippe
Authorized Public Accountant
Lead Partner

Sophie Damborg
Authorized Public Accountant

Corporate governance report

IRLAB Therapeutics AB (publ) is a Swedish public limited company with its registered office in Gothenburg, Sweden. The company's Class A shares have been listed on Nasdaq Stockholm's Main Market since September 30, 2020. The company follows Nasdaq Stockholm's regulatory framework for issuers and has applied the Swedish Corporate Governance Code ("the Code") since January 1, 2017. The Code can be found on the Swedish Corporate Governance Board's website, www.bolagsstyrning.se.

The corporate governance report refers to the financial year 2022, and has been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Corporate Governance Code. The report is reviewed by the company's auditor.

Deviations from the Code

Clas Sonesson was a member of the Nomination Committee during 2020. Sonesson is part of the company's management team, is one of the company's founders, and represents a group of founders, who are owners, on the Nomination Committee. It is therefore reasonable that he, on behalf of the founders, is given the opportunity to exercise influence in the Nomination Committee.

As a result of a shortcoming in the design of the postal voting form for the 2022 AGM (the nomination committee's proposal on the election of Gunnar Olsson as chairman of the board in the company was not explicitly stated in the form) came Gunnar Olsson to be elected chairman of the board by the board instead of by the general meeting.

IRLAB's fundamental principles for corporate governance

IRLAB's corporate governance is based on the Swedish model for corporate governance as defined by the Swedish Companies Act, the Swedish Annual Accounts Act, the Swedish Corporate Governance Code and practice. The purpose is to create a clear division of roles and responsibilities between the owners, the board and the executive management, where the bodies exercise their responsibility, influence, and control in relation to each other.

Shareholders

The shareholders' influence is exercised primarily through the right to vote at the Annual General Meeting and appoint members to the company's Nomination Committee. All shareholders also have the right to propose new board members to the Nomination Committee. However, this must be done well in advance of the General Meeting so that the Nomination Committee has the opportunity to make relevant evaluations of the proposed candidates. Prior to the Annual General Meeting on June 20, 2023, owners were invited to submit proposals no later than the end of January 2023. For information on the stock and the owners, please refer to IRLAB's annual report.

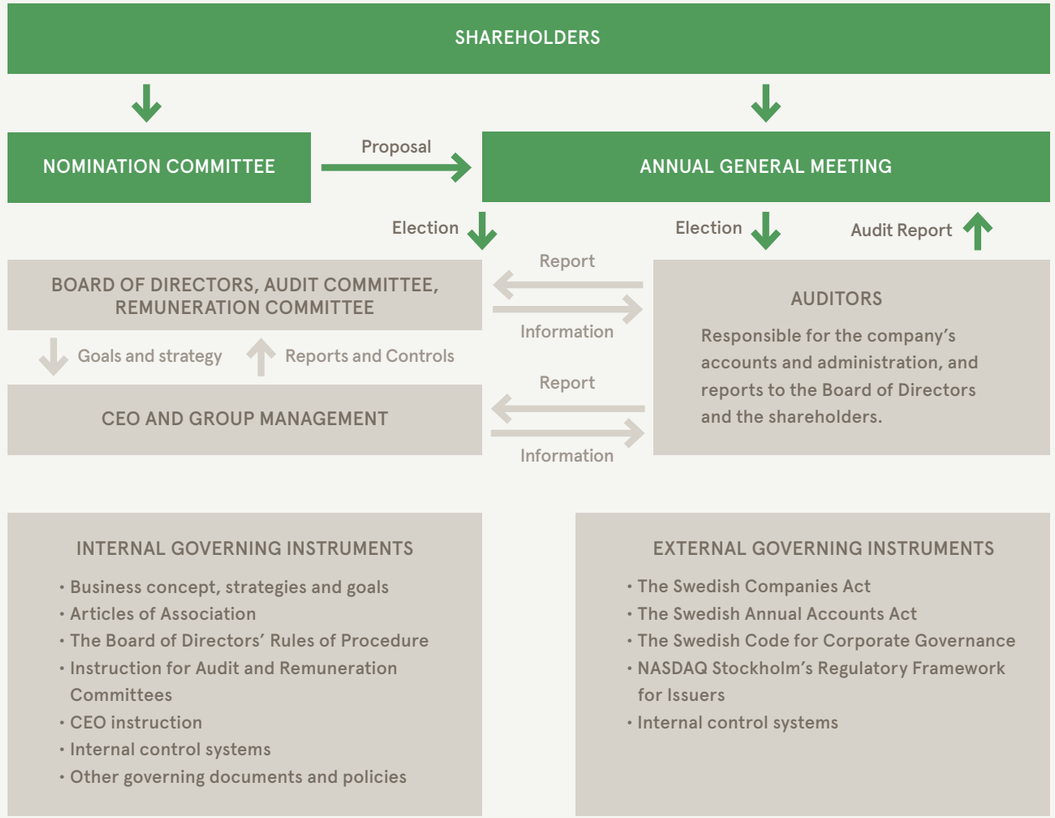
Annual General Meeting

The Annual General Meeting is the company's highest decision-making body and shall be held in Gothenburg or Stockholm. The shareholders' influence is exercised at the Annual General Meeting, which decides on key issues. The Annual General Meeting shall, among other things, decide on approving the company's income statement and balance sheet, appropriation of the company's profit or loss, discharge of liability for the board members and the CEO, appointment of Board of Directors, Chair of the Board and auditor, and decide on remuneration to the Board of Directors and auditor. The Annual General Meeting also decides on issues of shares, convertibles, options and other financial instruments, as well as authorization for the Board of Directors to make decisions on such issues.

The Annual General Meeting shall also decide on the instructions for the appointment and work of the Nomination Committee, as well as the principles for remuneration and terms of employment for the CEO and other senior executives. In addition to the Annual General Meeting, Extraordinary General Meetings may be held.

Notice of both an Annual General Meeting and an Extraordinary General Meeting shall be given by advertising in *Post- och Inrikes Tidningar* and by making the notice available on the company's website. The fact that notice has been given shall be simultaneously published in *Dagens Industri*.

ERIK WERNER, works with development of machine learning and AI methods for analysis of data generated within ISP.



Corporate governance report

Annual General Meeting 2022

IRLAB's Annual General Meeting 2022 was held on May 11 in Gothenburg. At the general meeting, the following resolutions were passed:

- Resolution that the general meeting should be held in open format in such a way that webcasting of the general meeting shall be permitted in the form of recording of audio and video.
- Resolution on the adoption of the income statement and balance sheet for both the parent company and the group.
- Resolution to dispose of the company's results by transfer to a new account.
- Resolution to grant discharge from liability to the Board of Directors and CEO for the financial year 2021.
- Resolution on the re-election of Gunnar Olsson, Rein Piir and Carola Lemne as board members and the election of Catharina Gustafsson Wallich and An van Es Johansson as new board members.
- Resolution on the re-election of Öhrlings PricewaterhouseCoopers AB as auditor, with a note that Johan Rippe has been appointed principal auditor.
- Resolution on fees to the Board of Directors and auditors.
- Resolution on instructions to the Nomination Committee.
- Resolution on guidelines for remuneration to senior executives.
- Resolution on adoption of new articles of association to facilitate advance voting for future general meetings.
- Resolution authorizing the Board of Directors to issue a maximum of 5 166 630 Series A shares.

The minutes from the 2022 Annual General Meeting, instructions for the Nomination Committee's work, guidelines for salaries and remuneration to senior executives, and other information, are available on the company's website.

Annual General Meeting 2023

IRLAB's Annual General Meeting 2023 will be held on June 20, 2023. The Annual General Meeting will be held physically in Gothenburg with the possibility of voting in advance by post. For the right to participate and more information, please refer to the notice. The minutes from the Annual General Meeting will be available on the company's website.

Nomination committee

The Nomination Committee's work is governed by the instructions adopted at the General Meeting. In addition to the Chair of the Board, it is composed by representatives for the three largest owners or groups of owners, according to Euroclear Sweden AB, as of August 31 the year prior to the General Meeting. The instructions for the Nomination Committee's work have been available in both the minutes from the Annual General Meeting of May 11, 2022, and separately on the company's website. The composition of the Nomination Committee was announced, together with contact details to enable shareholders to contact the Nomination Committee, on November 15, 2022, after which the information has also been available on the company's website.

The Nomination Committee's task is to evaluate the existing Board of Directors, and to evaluate submitted proposals for new board members, in order to ensure that the Board has appropriate expertise, experience and background. The Nomination Committee's proposals for the Board of Directors, and who shall be the Chair of the Board, shall be submitted to the owners no later than in conjunction with the publication of the notice of the Annual General Meeting. In addition to proposals for the Board and the Chair of the Board, the Nomination Committee shall submit proposals for the following:

- Chair of the general meeting
- The number of board members and deputies
- Remuneration to the members of the board and to members of any committees
- The number of auditors and deputy auditors
- Auditor
- Fee to auditor

NOMINATION COMMITTEE FOR THE 2023 ANNUAL GENERAL MEETING

Board member	Appointed by
1) Clas Sonesson	Group of owners including the company's founders who represent approximately 13.7 percent of the shares and votes*
2) Hans-Peter Ostler	Group of owners who represent approximately 13.5 percent of the shares and votes*
3) Anders Vedin	Group of owners who represent approximately 13.0 percent of the shares and votes.* Vedin has been elected chair of the nomination committee.
4) Carola Lemne	Chair of the Board. Replaced Gunnar Olsson on February 20, 2023 as chair of the board and thus also in the nomination committee.

* Ownerships are based on information from Euroclear as per March 31, 2023.

Corporate governance report

The Nomination Committee shall also, if they deem it necessary, submit proposals for amendments to the instructions to the Nomination Committee.

The Nomination Committee's work prior to the AGM 2023

The Nomination Committee has had five meetings in addition to a number of telephone calls. The evaluation of the incumbent Board of Directors' work, competence, experience and composition has been based on the following information:

- The Chair of the Board's report on the Board of Directors' work
- An anonymous survey-based evaluation of the Board of Directors' work from board members, conducted by an external independent party
- Interviews with individual board members
- The Chair of the Board's, CEO's and the executive management's reports on the company's operations, goals and strategy.

Prior to the 2023 Annual General Meeting, the Nomination Committee has consisted of the Chair of the Board and representatives for the three largest owners or groups of owners, first appointed based on ownership information from Euroclear Sweden AB as per August 31, 2022.The three largest owners or owner-groupings have been evaluated based on the ownership statistics obtained from Euroclear Sweden AB, sorted by voting power (grouped by ownership as owner-groupings were reported to the company before August 31, 2022). In the event that there are nominee-registered shareholdings in these ownership statistics, these have only been taken into account if the nominee has stated the identity of the underlying shareholders to Euroclear Sweden AB, or if the company, without taking any own measures, receives other information showing shareholders' identities.

Auditor

The external auditor is elected by the Annual General Meeting for a period of one year at a time. The auditors review the annual report and accounts, as well as the Board of Directors' and the CEO's administration, in accordance with an audit plan that is established together with the Board of Directors or the Audit Committee. In conjunction with the audit, the auditors shall report their observations to the group management, as well as the Board of Directors or the Audit Committee. At least once a year, the auditors shall report their observations directly to the Board of Directors without the presence of the executive management. The auditors also participate in the Annual General Meeting, where they go through their audit and their recommendations in the auditor's report.

The company's auditor

Since the Extraordinary General Meeting on November 30, 2016, the company's auditor has been the registered auditing company Öhrlings PricewaterhouseCoopers AB ("PwC"), which was also re-elected at the Annual General Meeting on May 11, 2022. PwC has announced that they have appointed the authorized public accountant Johan Rippe as the auditor in charge, and that the annual report shall also be signed by the authorized public accountant Sophie Damborg.

The auditor has audited the annual report and the consolidated accounts for the financial year 2022-01-01 to 2022-12-31, and also reviewed the quarterly report for the third quarter. The auditor has also stated that this corporate governance report has been prepared, and that certain information herein is consistent with the annual report and consolidated accounts.

The auditor's review is reported primarily through the audit report but also through specific opinions on the corporate governance report, the reviewed quarterly report, and compliance with guidelines for remuneration to senior executives. These are presented to the Annual General Meeting.

The auditor has also provided more detailed reports on both the audit's planning and the observations made to the Audit Committee and the Board of Directors. In the parts concerning the review of the executive management's administration, the reporting has been to the Board of Directors without the executive management being present.

Corporate governance report

The fees invoiced by the auditor for the last two financial years are reported in Note 9 in the 2022 annual report.

The Board of Directors

The Board of Directors' responsibilities and work

The Board of Directors is the company's highest decision-making body after the Annual General Meeting, and is responsible for the company's administration and organization in accordance with the Swedish Companies Act.

The Board of Directors' responsibilities and tasks are regulated in the Swedish Companies Act, the Articles of Association, the Swedish Corporate Governance Code, and the Board of Directors' written Rules of Procedure. This means that the Board of Directors is responsible for determining goals and strategies, for making decisions on particularly important issues, following preparation by the executive management, for ensuring and monitoring procedures and systems for risk management, and for evaluating operational management.

The Board of Directors is also responsible for ensuring that the annual report, consolidated accounts and interim reports are prepared in a timely manner. The Board of Directors is also tasked with appointing and dismissing the CEO.

The Board of Directors' composition and independence

In accordance with the Articles of Association, the Board of Directors is to comprise no less than three and no more than ten members. In accordance with the Swedish Corporate Governance Code, the company shall not appoint any deputies.

At the Annual General Meeting on May 11, 2022, Gunnar Olsson, Carola Lemne, An van Es-Johansson, Catharina Gustafsson Wallich and Rein Piir was elected members. At the following statutory board meeting, Gunnar Olsson was elected chair and Carola Lemne elected vice chair, according to the Nomination Committees proposal. On February 20, 2023, the current CEO was dismissed and Gunnar Olsson was appointed interim CEO. At the same time, the board elected Carola Lemne as chair of the Board. Gunnar Olsson remained as member of the Board. On February 21, 2023, An van Es-Johansson elected to leave her assignment. Information about the board members, with information on year of birth, year of election to the Board, education, experience, current assignments and shareholdings in the company as at March 31, 2023, can be found on pages 134-135. Other assignments in the group are not specified.

The Board of Directors has established an Audit Committee and a Remuneration Committee, which prepare and make decisions on specific issues.

Chair of the Board

The Chair of the Board is proposed by the Nomination Committee and elected by the Annual General Meeting. In addition to the regular responsibilities as a board member, the Chair of the Board shall lead the Board's work, convene board meetings, compile agendas and ensure that adequate follow-up takes place, and that the Board's work is carried out in the most organized and efficient manner possible. The Chair of the Board shall also keep themself informed on an ongoing basis about the company's operations through regular contact with the CEO and other executive management, also in addition to board meetings and committee work.

The Chair of the Board shall also ensure that both incumbent and new board members receive sufficient information to be able to familiarize themselves with IRLAB's operations, and that they have the prerequisites to continuously update and deepen their knowledge in issues concerning IRLAB and its operations.

Committee work

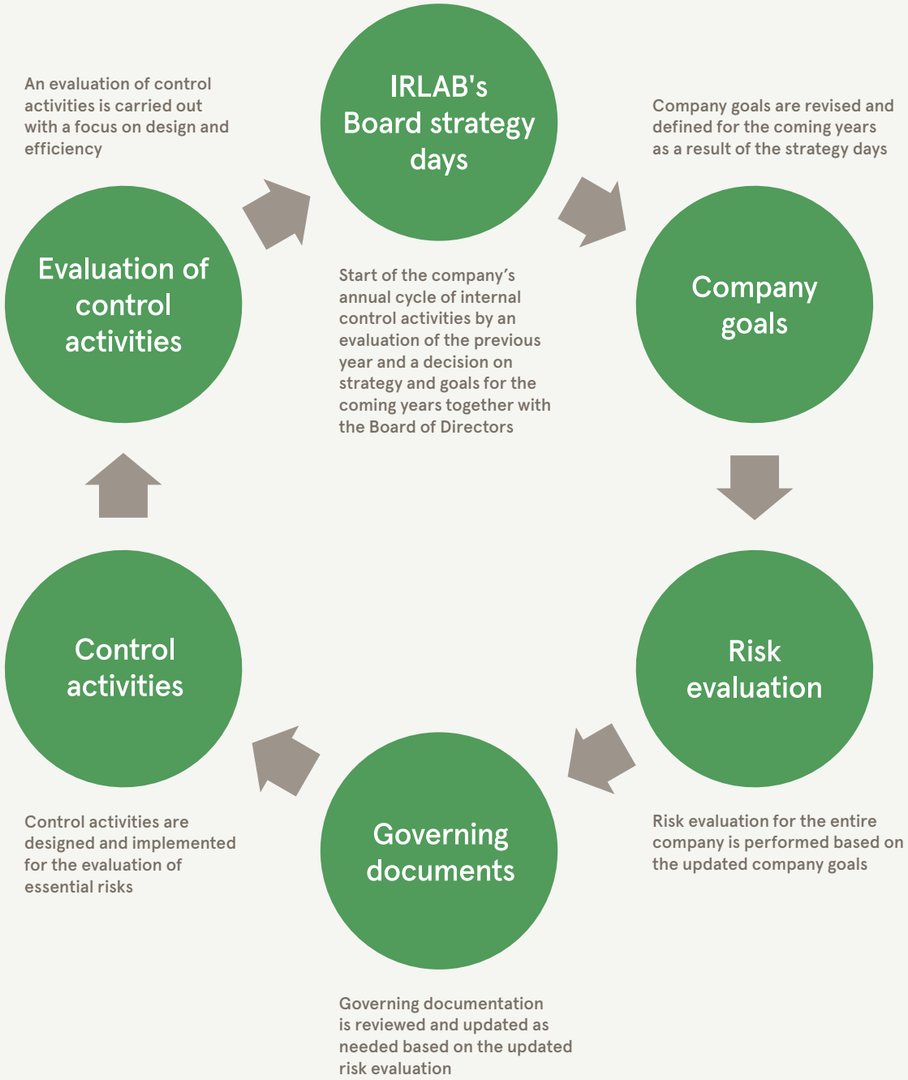
The Board of Directors has established two formal committees, the Audit Committee and the Remuneration Committee, in accordance with a decision at the annual general Meeting on May 16, 2018. The Remuneration Committee is tasked with preparing issues on remuneration and terms of employment for the group's management. The Audit Committee tasks include maintaining and improving the efficiency of contact with the group's auditors, supervising the procedures for accounting and financial reporting, and the risk management in the group. The Board of Directors has adopted rules for the work of both committees.

In addition to the work of the formal committees, special working groups were formed during the year that made use of the board members' special expertise in areas such as financing, IR and clinical development.

Name	Board function	Elected	Independent in relation to the company and the executive management	Independent in relation to large owners	Board fees [1]	Fee remuneration committee [1]	Fee audit committee [1]	Attendance board meetings [2]	Attendance committee meetings [3]
An van Es-Johansson	Board member	2022	Yes	Yes	250 000	30 000 (member)	50 000 (member)	14	4
Catharina Gustafsson Wallich	Board member	2022	Yes	Yes	250 000	–	50 000 (member)	13	2
Carola Lemne	Vice-chair	2019	Yes	Yes	250 000	30 000 (member)	–	21	2
Gunnar Olsson	Chair	2017	No	Yes	500 000	50 000 (chair)	–	21	2
Rein Piir	Board member	2016	Yes	Yes	250 000	–	75 000 (chair)	21	4

[1] Fees refer to remuneration decided by the Annual General Meeting excluding social security contributions for the period from the AGM 2022 to the AGM 2023. Subsequent to management changes in February 2023, the composition of the committees have changed which has induced a corresponding change in fees.
[2] The board held seven meetings before the Annual General Meeting and 14 meetings after the Annual General Meeting 2022.
Regarding meetings before the Annual General Meeting, the outgoing board members Lars Adlersson and Lena Torlegård attended all seven meetings.
[3] The Audit Committee held four meetings, and the Remuneration Committee held two meetings in 2022. Remuneration issues have also been handled during board meetings during the year.

Annual cycle for internal control at IRLAB



Corporate governance report

The Board of Directors' Rules of Procedure

At the Statutory Board Meeting, which is held after the Annual General Meeting, the Board of Directors adopts Rules of Procedure which, among other things, regulate the division of work and responsibilities between the Board, the Chair of the Board, and the company's CEO. According to the Rules of Procedure decided after the Annual General Meeting on May 11, 2022, the Board of Directors shall hold five to ten meetings per year, where the regular meetings are held in the following months: May, August, November, January and March.

The Board of Directors' work and important events during 2020

The Board of Directors convenes in part on dates scheduled for the year and in part when it is deemed necessary depending on the provision of information or when specific decisions are to be made. The Board of Directors has also decided to separate meetings from decisions related to the publishing of interim reports from meetings dedicated to other issues. The reason for this is to achieve a more even distribution of work and impove the quality of the preparation of the meetings. In addition to the board members, the company's CEO participates in the board meetings as rapporteur, and the company's CFO as rapporteur in matters that fall within their area of responsibility. The company's legal counsel also attends regularly and keeps the minutes.

During 2022, the Board of Directors held 21 meetings, relatively evenly spread over the year.

During the year, the Board of Directors' work was dominated by strategic issues, contact with the international capital market, financing matters, and business development. In addition, the Board has been involved in strategic issues regarding the company's research portfolio and has continuously received reports on the company's operations. In June 2022, a decision was made to appoint a new CEO and after tha balance date, in February 2023, a decision was made to dismiss the CEO.

The Board of Directors continuously evaluates its work internally, and allows an independent external party carry out a survey-based evaluation annually. Based on the results of the survey, the Board's working methods are discussed and adjusted.

CEO and executive management

The CEO is subordinate to the Board of Directors and is primarily responsible for day-to-day operations and the regular administration. In connection with the rest of the executive management, the CEO prepares matters prior to resolutions by the Board of Directors. The CEO has statutory obligations and the division of work between the Board and the CEO is regulated primarily in the instruction to the CEO, which the Board of Directors decided on the Statutory Board Meeting.

In summary, the instruction states that the CEO is responsible for the following:

- Lead the business according to the Board of Directors' guidelines
- Ensure that the company's accounting is discharged in accordance with law
- Ensure that taxes and fees are paid on time
- Ensure that the company follows the budget, and implementing plans so that established goals are met
- Ensure that the company follows its information and insider policy

The CEO shall prepare and participate in board meetings in accordance with good order and the special instructions specified by the Chair of the Board. The Board of Directors shall prepare an agenda for board meetings, and the CEO shall present the matters to the Board of Directors so that the Board can make well-informed decisions. The CEO shall also continuously keep the Board informed of the business's development, financial position, liquidity and credit status and of all important business events.

The CEO shall also lead the work of the executive management. In 2022, the executive management, in addition to the CEO, consisted of the Executive Vice President & Head of R&D (CEO until June 30, 2022), Chief Scientific

Corporate governance report

Officer (CSO), Chief Medical Officer (CMO), Director of Biology and Biostatistics, Director of Computational Chemistry and Biology (CIO), Finance and Human Resource Manager, Chief Financial Officer (CFO) and Director of Clinical Operations. The executive management accordingly consists of eight or nine individuals. For more information about the senior executives in IRLAB such as when they took up their positions, their year of birth, education, experience, shareholding in the company and current assignments, please see pages 136–138.

Remuneration to board members and senior executives

Fees to board members and members of board committees are decided by the Annual General Meeting. The Annual General Meeting on May 1, 2022 resolved that a fee of SEK 1 785 000 be paid to the Board of Directors, of which SEK 500 000 should be paid to the Chair of the Board and SEK 250 000 to each of the other board members, and that a fee shall be paid to the Board's Audit Committee, of which SEK 75 000 should be paid to the Chair of the Committee and SEK 50 000 to each of the other committee members, and that a fee shall be paid to the Board's Remuneration Committee, of which SEK 50 000 should be paid to the Chair of the Committee and SEK 30 000 to each of the other committee members.

The company is a party to a collective agreement, and as such follows applicable agreements and rules. The CEO and the company's management team constitute the company's senior executives. These shall be offered market compensation, which shall take into account the individual's areas of responsibility and experience. The remuneration shall, in accordance with the guidelines established at the Annual General Meeting on May 11, 2022, consist of a fixed salary, pension, and other benefits.

Internal control and risk management

The Board of Directors' responsibility for internal control is regulated by the Swedish Companies Act, the Swedish Annual Accounts Act, and the Swedish Corporate Governance Code. The board shall ensure that the company has good internal control and formalized procedures which ensure that established principles for financial reporting and internal control are complied with and that there are appropriate systems for follow-up and control of the company's operations and the risks associated with the company and its operations.

The procedures for internal control for financial reporting have been designed in order to ensure reliable overall financial reporting and external reporting in accordance with IFRS, applicable laws and regulations, and other requirements applicable to companies listed on Nasdaq Stockholm's main market.

The internal control systems introduced in 2020 were maintained in 2022. These systems include not only risk assessments and control procedures for financial reporting, but for the entire operation.

Control environment

Good internal control is based on a functioning control environment. At IRLAB, the control environment consists of, among other things, an organizational structure, instructions, policies, guidelines, reporting, and defined areas of responsibility.

The Board of Directors has the overall responsibility for internal control with regard to financial reporting. The board's instructions to the CEO and an adopted reporting instruction have determined how the financial reporting to the Board is to be devised. The Board of Directors has also delegated the responsibility for maintaining an effective control environment to the CEO, even though the Board of Directors remains ultimately responsible. Established systems and procedures have been created to provide management with the necessary reports in order to be able to assess risks on an ongoing basis and meet the requirements for correct financial reporting.

The Board of Directors has, based on an assessed good control environment, deemed that there are no special circumstances in the business or other circumstances that justify the establishment of a function for internal audit.

Risk assessment

IRLAB's risk assessment aims to identify and evaluate the most significant risks that affect internal control with regard to both the company's operations and financial reporting throughout the group.

The identified most significant risks with regard financial reporting are managed through control structures based on deviation reporting from the established goals or from established standards.

Control activities

The design of control activities within IRLAB is based on clear roles in the organization that enable an effective division of responsibilities for specific control activities such as authorization controls in IT systems, business systems and certification procedures. The continuous analysis made of the financial reporting is very important to ensure that the financial reporting does not contain any significant inaccuracies.

During 2022, the ERP-system implemented during 2021 has been used to manage supplier invoices and attestations completely digitally, which further increases the security of the controls and raises the quality of the control environment.

Information and communication

Internal information and communication involve ensuring that the company's employees who can influence the financial information or manage identified risks are kept up to date on any changes to policies, guidelines, laws or regulations. The executive management deals with such issues at management group meetings, and other employees are regularly informed about such changes that affect their ability to make decisions, or that affect the impact of their decisions on financial reporting. The company has adopted a system that ensures that all employees recieve the relevant documents.

The external information aims to keep the market up to date on the company's operational development, and ensure that IRLAB meets the requirements for correct information provision to the market. This is also governed by the company's established information policy.

Follow-up, evaluation and reporting

The Board of Directors receives continuous operational and financial reporting from the executive management, and can follow the operational and financial development of the company. The group's financial position, capital requirements, investments and cost base are discussed at each board meeting. Reconciliations against budgets and outcomes from previous years are made on an ongoing basis, and major deviations are also reported to the Board of Directors at each board meeting.

The internal control is evaluated regularly and new procedures are set up continuously to increase the internal control of the company's financial reporting further and manage the risks identified.

The external auditors, the company's finance function, and the Audit Committee have ongoing contact throughout the financial year in order to identify any risks at an early stage and deal with any issues that may affect the financial reporting. The auditors also report regularly to the Board of Directors, primarily through meetings with the Audit Committee.

Diversity initiatives

IRLAB's organization promotes an inclusive corporate culture at all levels. The company, which conducts research and development activities, usually needs very specific competencies and education, and the main principle is that everyone with relevant competencies and education shall have the same opportunity during recruitment, and to career development. By investing in diversity and supporting employees with different genders, ages, ethnic backgrounds, religions and personalities, IRLAB achieves better conditions for conducting better business, where many years of experience are combined with new ideas and fresh perspectives to best help patients in need of effective treatments.

Board of directors

Carola Lemne
born 1958

Board member since 2018. Chair since February 20, 2023. Independent in relation to the company, the executive management and the company's major shareholders.

Education and background: Former CEO of the Confederation of Swedish Enterprise and Danderyds Sjukhus AB, and former group CEO of Praktikertjänst AB, Head of Clinical Research and Head of Global Strategic Drug Development and Regulatory Strategy at Pharmacia Corp. Carola Lemne has held board positions in Getinge, Apoteket, MEDA, Investor and AFA Insurance, and has also been a board member of the Swedish Foundation for Strategic Research, the State Delegation for Clinical Research, Stockholm University, the Swedish Institute for Business Research, and the Swedish Corporate Governance Board, as well as Chair of the Swedish Education Council for Clinical Trials at Uppsala University.

Ongoing assignments: Chair of Ung Företagsamhet Sverige and UF Support AB. Board member of Arjo AB, Calgo Enterprise AB, Ramatuelle Holdings III AB, Brf Munklägret nr 14 Terveystalo Oyj and Hjärt-Lungfonden.

Holding: 10 000 Class A shares.

Gunnar Olsson
born 1953

Board member since 2017. Chair of the board from AGM 2020 until February 20, 2023. Interim CEO since February 20, 2023. Independent in relation to the company's major shareholders but not to the company or the executive management (employed).

Education and background: 25 years' experience in senior positions within Astra Zeneca, including in the management team for the Cardiovascular and Gastro-intestinal therapy areas within Global R&D, of which 10 years was as head of the same unit. Gunnar Olsson has participated in the development and launch of seven global blockbusters/mega-brands.

Ongoing assignments: Board member in Amplifier Tx AB, Betagenon AB, Betagenon Bio AB, Gesynta Pharma AB and Olsson Solutions AB. Vice chair in Hjärt-Lungfonden and Bundy Academy at Lund's University.

Holding: 4 000 Class A shares.

Rein Piir
born 1958

Board member since 2015. Independent in relation to the company, the executive management and the company's major shareholders.

Education and background: Many years of experience in advising stock market companies, including as Head of Analysis at Carnegie Investment Bank AB and Strategist at Alecta. Other experience includes CFO/Head of Investor Relations at listed Medivir Aktiebolag and auditor at PricewaterhouseCoopers AB. He is Vice President Investor Relations in listed Camurus AB and Alligator Bioscience AB.

Ongoing assignments: Chair of the Board of Piir & Partner AB. Board member of L. E. Svensson Snickeri Aktiebolag and Cereno Scientific AB.

Holding: 36 333 Class A shares, 5 567 Class B shares and 5 009 subscription warrants, corresponding to 25 045 Class A shares, personally and via companies/related parties.

Catharina Gustafsson Wallich
born 1964

Board member since 2022. Independent in relation to the company, the executive management and the company's major shareholders.

Education and background: Bachelor's degree in business administration and studies in political science. 30 years of experience in life science. Experience in international corporate management with senior positions within AstraZeneca, Amgen International and Shire Pharmaceuticals. Knowledge in business and product development, R&D, market access, marketing and development of commercial strategies. Co-founder of PCW Consultants AB. Currently mentor at The Nordic Mentor Network for Entrepreneurship and consultant at PCW Consultants AB..

Ongoing assignments: Board member of Mevia AB and Deputy Board Member of PCW Consultants AB.

Holding: No.

Ongoing assignments refer to assignments registered with the Swedish Companies Registration Office as of April 21, 2023 and do not include assignments within the IRLAB group. Shareholdings refer to holdings registered in the Euroclear Sweden AB share register as of March 31, 2023, adjusted for changes known by the company up to April 21, 2023.

Ledningsgrupp

Gunnar Olsson
born 1953

Board member since 2017. Chair of the board from AGM 2020 until February 20, 2023. Interim CEO since February 20, 2023. Independent in relation to the company's major shareholders but not to the company or the executive management (employed).

Education and background: 25 years' experience in senior positions within Astra Zeneca, including in the management team for the Cardiovascular and Gastro-intestinal therapy areas within Global R&D, of which 10 years was as head of the same unit. Gunnar Olsson has participated in the development and launch of seven global blockbusters/mega-brands.

Ongoing assignments: Board member in Amplifier Tx AB, Betagenon AB, Betagenon Bio AB, Gesynta Pharma AB and Olsson Solutions AB. Vice chair in Hjärt-Lungfonden and Bundy Academy at Lund's University.

Holding: 4 000 Class A shares.

Clas Sonesson
born 1961

Chief Scientific Officer (CSO) since 2013.

Education and background: Worked as a pharmaceutical chemist and doctoral student in the Nobel Laureate Arvid Carlsson's research group at the Department of Pharmacology at the University of Gothenburg 1989-2000. In 1998, he co-founded A Carlsson Research AB, which was sold to NeuroSearch Sweden A/S in 2006, and in conjunction with that changed company to NeuroSearch Sweden AB. In A Carlsson Research AB/NeuroSearch Sweden AB, he was a board member from 1998-2002, Head of Medicinal Chemistry 2000-2002, Director of Chemistry & IP 2002-2009, Head of Discovery 2009-2011 and Vice President Chemistry & IP 2011-2012. During the years at A Carlsson Research AB/NeuroSearch Sweden AB, he was also responsible for CMC in a number of development projects. In 2013, he was a co-founder of IRLAB Sweden.

Holding: 748 589 Class A shares and 8 946 Series B shares.

Joakim Tedroff
born 1961

Chief Medical Officer (CMO) since 2013.

Education and background: Co-founded A Carlsson Research AB in 1998, which was sold to NeuroSearch A/S in 2006, and in conjunction with that changed company to NeuroSearch Sweden AB. In A Carlsson Research/NeuroSearch Sweden AB, Joakim Tedroff was Vice President Clinical Science. In 2013, he was a co-founder of IRLAB Sweden. Joakim Tedroff is a practicing neurologist specializing in neurodegenerative diseases, and an Associate Professor at Karolinska Institutet. He has more than 15 years' experience in the pharmaceutical industry. As a consultant, he has performed services for a number of pharmaceutical companies in the field of neurology, including for Allergan, Orion, Pfizer, Teva, Novartis and Lundbeck, and for venture capital companies in various life science projects.

Ongoing assignments: Board member: Tedroff NeuroCare AB. Deputy board member: Palette Film AB.

Holding: 681 339 Class A shares, 8 946 Class B shares, and 8 049 subscription warrants, corresponding to 40 245 Class A shares, in person and via companies/related parties.

Susanna Holm Waters
born 1966

Director of Biology & Biostatistics of IRLAB Therapeutics since 2013.

Education and background: Worked in the Nobel laureate Arvid Carlsson's research group at the Department of Pharmacology at the University of Gothenburg 1993-2000. In 1998, she co-founded A Carlsson Research AB. In A Carlsson Research/NeuroSearch Sweden AB she was Director of Computational Biology & Biostatistics 2000-2006, Director of Molecular Biology & Pharmacokinetics 2007-2010 and Director of Biology 2011-2012. In 2013, Susanna Holm Waters co-founded IRLAB Sweden. She also works clinically, as a doctor at Sahlgrenska University Hospital 2015-2019.

Holding: 1 340 904 Class A shares and 17 892 Class B shares, of which 604 704 Class A shares and 8 946 Class B shares are owned directly and the others via related parties.

Peder Svensson
born 1962

Director of Computational Chemistry & Biology and Chief Information Officer (CIO) since 2013.

Education and background: Over 25 years' experience in research and research management in the pharmaceutical industry. He started at A Carlsson Research AB in 2000, the company later changed to NeuroSearch Sweden AB. In A Carlsson Research AB/NeuroSearch Sweden AB he was Head of Computational Chemistry & Chief Information Officer 2000-2011 and Director of Computational Chemistry & Biology, IT 2011-2012. In 2013, he co-founded IRLAB Sweden.

Holding: 252 979 Class A shares and 8 946 Class B shares in person and via companies/related parties.

Cecilia Tivert Stenberg
born 1957

Head of Finance and Human Resources Manager (HRM) since 2013.

Education and background: Has been CFO and Human Resources Manager at Spectrogon AB and A Carlsson Research/NeuroSearch Sweden AB. In 2013, she co-founded IRLAB Sweden.

Ongoing assignments: Board member: Terzett Konsult AB and Tivert Konsult AB. Deputy board member: Bohini AB.

Holding: 356 264 Class A shares, 8 946 Class B shares, and 8 049 subscription warrants, corresponding to 40 245 Class A shares, in person and via companies/related parties.

Ledningsgrupp

Viktor Siewertz
born 1971

Chief Finance Officer (CFO) since 2017 and Chief Operating Officer (COO) since 2016.

Education and background: International experience from auditing, venture capital, corporate finance and financial adviser in own business with support to management in small and medium-sized companies. Experience from board work, strategy issues, financing issues, capital acquisitions, mergers and aquisitions, negotiations as well as accounting and financial statements. Degree of Masters of Law from the School of Business, Economics and Law in Gothenburg with specialization in company law, contract law, tax law and m&a as well as a master's degree in accounting and finance from the School of Business, Economics and Law in Gothenburg.

Ongoing assignments: Board member in his own companies Vestigium AB, Investigium AB, Slavestigium AB and Ignavia AB and in FTT Holding AB. Deputy board member in HyrMax Rental AB, Moorgate Investment AB, Töreboda Vind AB, FTT Sweden AB and ContentMap Holding AB.

Holding: 233 965 Class A shares in person and via companies/related parties.

Nicholas Waters
born 1962

Executive vice president & Head of R&D since July 1, 2023. CEO of IRLAB since 2013.

Education and background: Worked in the Nobel laureate Arvid Carlsson's research group at the Department of Pharmacology at the University of Gothenburg 1987-2000. He defended his dissertation in 1995. In 1996, he was a brain trust fellow. In 1998, he co-founded A Carlsson Research AB (CR), and then worked as Head of Research in the company until 2006 when he was appointed CEO. He worked as CEO of CR and Neurosearch Sweden AB 2006-2012. He was a board member of A Carlsson Research AB 1998-2002, and at NeuroSearch Sweden AB he was a board member 2006-2012. During 2010-2012, he was also Executive Vice President Research at NeuroSearch A/S. During the years 2007-2010, he was a board member of SwedenBIO. In 2013, he co-founded IRLAB Sweden.

Holding: 1 340 904 Class A shares and 17 892 Class B shares, of which 736 200 Class A shares and 8 946 Class B shares are owned directly and the others via related parties.

Gothenburg 28 April 2023

CAROLA LEMNE
Chair of the Board

CATHARINA GUSTAFSSON WALLICH
Board member

GUNNAR OLSSON
Board member
CEO

REIN PIIR
Board member

Ongoing assignments refer to assignments registered with the Swedish Companies Registration Office as of April 21, 2023 and do not include assignments within the IRLAB group. Shareholdings refer to holdings registered in the Euroclear Sweden AB share register as of March 31, 2023, adjusted for changes known by the company up to April 21, 2023.

DAVID BLIMAN, works with design of new candidate drugs and the manufacturing of them in our laboratories.

Auditor's report on the Corporate Governance Statement

To the general meeting of the shareholders in IRLAB Therapeutics AB (publ.), corporate identity number 556931-4692.

Engagement and responsibility

It is the board of directors who is responsible for the corporate governance statement for the year 2022 on pages 114-131 and that it has been prepared in accordance with the Annual Accounts Act.

The scope of the audit

Our examination has been conducted in accordance with FAR's auditing standard RevR 16 *The auditor's examination of the corporate governance statement*. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

Opinions

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Gothenburg, 28 April 2023

Öhrlings PricewaterhouseCoopers AB

Johan Rippe
Authorized Public Accountant
Lead Partner

Sophie Damborg
Authorized Public Accountant

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

FOR FURTHER INFORMATION, PLEASE CONTACT

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