

IRLAB Therapeutics AB 2021 Annual Report

"Our vision is to be a world-leading developer of innovative drugs for the treatment of Parkinson's and other disorders of the brain."

NICHOLAS WATERS, CEO

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"We have established a promising product portfolio with drug candidates at various stages of development, and our success in 2021 has allowed us to further increase the number of candidates in our pipeline."

NICHOLAS WATERS, CEO

IRLAB's positive development leads to new opportunities

After a successful 2021, IRLAB increases the pace even more. The company provides vital, worldclass pharmaceutical research that may increase the quality of life for millions of people who are living with Parkinson's disease.

As the world's population is ageing, the number of people with Parkinson's disease is also rising – but not much is happening on the treatment front. IRLAB is about to change this.

"We work targeted and with great dedication to discover and develop new drugs for the treatment of Parkinson's disease. The medical need for new, safe and effective treatments is immense, and IRLAB aims to improve everyday life for patients with symptoms who do not currently have any effective treatment options," says Nicholas Waters, CEO of IRLAB.

The proprietary research platform is an important advantage

The team behind IRLAB has been working together since the end of the 1980s. It arose out of Nobel Prize laureate Arvid Carlsson's research team and has made several ground-breaking discoveries over the years. An important success factor is the company's proprietary research platform, which sets it apart from other biotechnology companies: Innovative Screening Process (ISP) – phenotypic screening of substances based on systems biology combined with machine learning and artificial intelligence.

"We have a principle for effectively discovering and developing disorders of the central nervous system that is unique in the world, which has also been published in a highly ranked scientific journal. Thanks to ISP, the likelihood of positive results from our drug candidates is higher, which makes them more likely to reach Phase III compared with the rest of our industry, where the majority is relying on target-based screening. We are also able to get faster results at a considerably lower cost than other companies in our industry," says Nicholas Waters.

IRLAB currently has two drug candidates, mesdopetam and pirepemat, that have reached clinical "Proof of Concept" and are subject to Phase IIb studies. They are designed to treat some of the most severe symptoms associated with Parkinson's disease.

"With mesdopetam and pirepemat, we address symptoms that cannot be treated in a good way or cannot be treated at all. The discovery of entirely new classes of drugs is highly unusual, and the fact that WHO-INN has proposed names with new and unique suffixes prove that our new chemical substances represent new classes of drugs. It feels incredible that we succeeded with both mesdopetam and pirepemat," says Nicholas Waters.

A bright future with a promising product portfolio

In 2021, IRLAB and Ipsen entered into an exclusive global license agreement for the continued development of mesdopetam. This was one of the largest transactions for decades in Swedish biotechnology and has led to new opportunities for IRLAB. With a growing pipeline of interesting projects that are on their way to Phase I, the future seems bright.

"We have established a promising product portfolio with drug candidates in various stages of development, and our excellent performance last year has allowed us to add to the number of candidates in our pipeline. For IRLAB, this means excellent opportunities for additional commercial collaborations and a positive cash flow for a considerable period ahead. And for those who are living with Parkinson's, this increases the chances of better treatment and a higher quality of life," says Nicholas Waters, CEO of IRLAB.



Comments from the CEO

In 2021, IRLAB reached an important milestone: thanks to our successful business development, we reported a profit and positive cash flow. This is an important signal that our business model is viable, and that the organization delivers on our goals. It also creates the conditions we need to elevate our portfolio to the next level.

Without a doubt, the single most important event in 2021 was the major license transaction we entered into in the summer with the global pharmaceutical company Ipsen. The transaction gave us a strong position that we have been able to leverage to accelerate the development in our preclinical projects and, in parallel, we have expanded our organization with new talent.

We have taken giant leaps, both with regard to the growth of the company and in our clinical development projects, where the most important event was the regulatory approval for our Phase IIb study with pirepemat. We achieved this during a year when the entire biotech and pharmaceutical sector was particularly challenged by the effects of the Covid-19 pandemic and the turbulence in the financial markets. Over the year, we also experienced strong and growing interest in our development programs and drug candidates from potential new partners, new investors and the media.

One of the de largest transactions ever in Swedish biotech

IRLAB is continuously engaged in purposeful conversations with a large group of pharmaceutical companies. This summer, after competitive negotiations, Ipsen became the first major pharmaceutical company with which we entered into a commercial license agreement. The transaction involving mesdopetam, one of our most advanced drug candidates, is one of the largest ever made within Swedish biotech, and we are very proud of it. The agreement places IRLAB in a strong position and contributes the cash we need to vigorously develop the company towards our vision – to be a world-leading developer of innovative drugs for the treatment of Parkinson's and other disorders of the brain.

We are acting in the international arena, with increased visibility and capacity. The mesdopetam transaction has brought us valuable attention and opportunities for additional partnerships. The license negotiation and the new collaboration also subjected us to thorough scrutiny as a research company, which allows us to state with certainty that we have effective internal processes, controlled risk management and high operational quality.

We have a highly effective discovery operation through our ISP research platform, which forms an important element in IRLAB's competitiveness. In conjunction with the company's broad and profound knowledge of disorders of the brain and their causes, the ISP can effectively generate new projects and drug candidates with major commercial potential. The agreement with Ipsen has made it possible to accelerate the development in the preclinical PO01 and PO03 programs, which entail several exciting opportunities for new and improved drugs.

New drug candidates on the way to clinical development

The P001 project, which represents an entirely new class of drug candidates with major therapeutic and commercial potential,

"The fact that we were reported a profit and positive cash flows in 2021 was an important milestone for IRLAB."

NICHOLAS WATERS, CEO

includes two strong development candidates: IRL942, for the treatment of cognitive impairment, and the newly selected IRL757, for the treatment of apathy in neurological diseases. Today, some 12 percent of all people over the age of 65 suffer from cognitive impairment. Apathy is one of the most common, and currently untreated, complications in Parkinson's, Alzheimer's and other dementia-related illnesses. Between 20 and 80 percent of all those with neurological ill-health suffer from apathy. IRL942 and IRL757 have been tailored to treat these symptoms. There is no approved treatment for apathy at present which makes IRLAB a pioneer in this area as well.

In the PO03 project, we are working on a potentially revolutionary principle for the treatment of the hallmark symptoms of Parkinson's disease. Our vision in this project is to develop a drug that may replace levodopa altogether. Over the year, we have laid the foundation for this goal by forming connections with experts in this field, incorporating new experimental models in our ISP platform and discovering chemical leads that may result in the best drug candidates in this area.

Continued efforts to become a world-leading developer

Covid-19 affected the pharmaceutical sector severely last year. However, IRLAB's research organization was able to do its work, and we were able to adapt quickly to the new conditions imposed on us by increasing the digitalization of our work processes. We are also pleased that the mesdopetam study could proceed, even though people with Parkinson's belong to the risk group who were particularly vulnerable, even if the incredibly rapid spread of the omicron variant that hit us at the end of the year generally caused a significant reduction in the recruitment to clinical trials. We also experienced delays

caused by the pandemic when entering into agreements with hospitals.

In light of the situation in 2021, we were therefore very pleased to receive regulatory approval for our Phase IIb study with pirepemat in the fourth quarter, with the aim of improving balance, thus reducing injuries from falls in people with Parkinson's. We believe we have an opportunity to get patient recruitment off to a good start this spring.

Over the year, we strengthened our organization with cutting-edge talents, with a focus on important roles in strategy, research, artificial intelligence and communication. In parallel with the scaling up of the business, the development of IRL747 and IRL942 and the progression of P003 towards a Phase I clinical trial, our top priorities include finalizing the Phase IIb/III study with mesdopetam, ensuring that we have the best possible conditions for the Phase IIb study with pirepemat and increasing our visibility to investors and industry peers.

The next period, 2022 to 2024, will therefore be highly eventful, with topline results from the ongoing Phase IIb studies and the start of the clinical development of several of our new drug candidates. In this period, the most important thing will be the start of the Phase III studies with our drug candidates, in collaboration with Ipsen, and the transactions that will provide us with the resources required to keep progressing towards our vision and IRLAB's future - to be a world-leading developer of innovative drugs for the treatment of Parkinson's and other disorders of the brain.

Nicholas Waters, CEO. IRLAB

2021 in review

Presenting new preclinical data

In 2021, IRLAB presented new results from preclinical studies that indicate that the drug candidate mesdopetam also has the potential to prevent the development of levodopa-induced involuntary and troublesome movements (dyskinesias) in Parkinson's disease. This increases the commercial potential of mesdopetam. The substance had previously been found to be effective in the treatment of established dyskinesias, which is now being studied further in an ongoing Phase IIb/III clinical trial.

For decades now, the standard treatment for Parkinson's disease has been the drug levodopa, which is taken several times per day. The treatment makes many patients hypersensitive to levodopa, often referred to as sensitization, which is linked to the development of levodopa-induced dyskinesias. Dyskinesias strongly impair the patients' quality of life. Consequently, the prevention of levodopa sensitization has the potential to prevent the development of dyskinesias.

The first European patients have been dosed in IRLAB's Phase IIb/III clinical trial with mesdopetam

In early March 2021, it was announced that the first European patients had been dosed with mesdopetam in the Phase IIb/III clinical trial. Regulatory authorities across in Europe have approved the study and Poland is the first country where treatment with mesdopetam has been initiated.

Ipsen and IRLAB enters into a global license agreement

In mid July 2021, Ipsen and IRLAB announced that the companies had entered into a license agreement, providing Ipsen with exclusive worldwide development and commercial rights to mesdopetam, a novel and innovative dopamine D3 receptor antagonist. Mesdopetam is currently under evaluation in a Phase IIb clinical as a potential treatment option for patients with Parkinson's disease and levodopa-induced dyskinesia (LID). It is estimated that around 40–50 percent of patients with Parkinson's disease will experience LID after five years of dopamine replacement therapy. The treatment options for LID are limited at present. Mesdopetam is also at the early stages of development for the treatment of psychosis in Parkinson's disease (PD-P), a common symptom that affects some 50 percent of Parkinson's patients during the course of their illness.

Parkinson's disease is a common progressive neurodegenerative disease that affects more than ten million people globally. Parkinson's disease affects the nerve cells in the brain that govern movements. The disease affects patients differently. The most common motor symptoms are tremors, rigidity and slowness of movement (bradykinesia). People who suffer from Parkinson's disease also experience problems that are unrelated to mobility, such as anxiety, pain and depression. Symptoms of Parkinson's disease are usually treated with drugs such as levodopa, which aims to compensate for the loss of nerve cells that contain dopamine. A common adverse drug reaction caused by levodopa is dyskinesia, involuntary movements of the face, arms, legs or torso. In many individuals, the dyskinesia can be so severe that it affects their quality of life. Mesdopetam has also been found to have antipsychotic properties in preclinical studies.

IRLAB was granted increased patent protection for the Phase II candidate pirepemat

In September, IRLAB was granted a new patent for the manufacturing of the drug candidate pirepemat by the US Patent Office. Pirepemat, one of IRLAB's clinical drug candidates, is under development in Phase IIb for the treatment of impaired balance and falls in Parkinson's disease.

The granted patent, US 11 078 158 B2, describes a chemical process for the manufacturing of pirepemat in its pure form. The process is critical for assuring the future production of pirepemat on an industrial scale, which will become necessary once a drug based on pirepemat is approved for use and available in the market.

Regulatory approval for the Phase IIb study with pirepemat

In December, IRLAB received regulatory approval by the Swedish Medical Products Agency to begin a Phase IIb study with the drug candidate pirepemat. Subject to approval from additional authorities and ethics committees in other countries, the recruitment of patients will begin in the first quarter 2022. Recruitment is expected to take 18 months.

The application to perform a Phase IIb study was made using the Voluntary Harmonization Procedure (VHP). This procedure makes it possible to obtain a coordinated assessment of an application for a clinical trial that is planned to take place in several European countries. In addition to the Medical Products Agency in Sweden, which is the reference country for this study, Polish and Spanish authorities are also involved in the coordinated assessment. In parallel, IRLAB is submitting applications to the regulatory and ethical authorities in other selected European countries.

All figures refer to the group	2021	2020	2019	2018
Operating profit/loss, SEK thousand	52,576	-91,458	-95,848	-73,897
Profit/loss for the year, SEK thousand	51,781	-91,653	-96,120	-74,099
Earnings per share before and after dilution, SEK	1.00	-1.92	-2.37	-1.94
Cash and cash equivalents, SEK thousand	401,897	277,009	110,527	134,442
Equity per share, SEK	7.72	6.72	4.22	5.25
Equity ratio, %	85	94	87	94
Average number of employees	22	18	17	15
Of which in R&D	20	17	16	14

Financial Overview 2018–2021

"It is reassuring that our excellent financial situation makes our growth plan and aggressive investments in our promising projects possible."

VIKTOR SIEWERTZ, CFO

Comments from the CFO

As the CFO of IRLAB, I am very pleased with the company's financial performance in 2021. For IRLAB, the positive bottom line is a milestone of huge significance, but the very strong cash position gained from the mesdopetam transaction with Ipsen is even more important for a company such as ours.

As a research company, we are dependent on access to capital to carry out our research and clinical studies. We need stability for advance planning purposes so that we can maintain the efficiency in all that we do. Thanks to the partnership with Ipsen, we now have all this. Our financial goal is to be a company with sustainable profitability and a core business funded by milestone and royalty payments. We are now well on our way to realizing this goal. We add major value in the development of new drug candidates until "Proof of Concept"; we can then enter into partnerships like we did in the mesdopetam transaction. In the future, we may also develop projects that we take to market ourselves.

The upfront payment received for the mesdopetam license agreement was approximately SEK 240 million, of which just over SEK 50 million was earmarked for the completion of the ongoing Phase IIb/III study. We may also receive milestone payments totaling USD 335 million, which roughly corresponds to SEK 3.2 billion, if the project develops according to plan. We will also receive royalties in double digits on sales once mesdopetam reaches the market. The transaction also saves us a lot of money in the short term, as major resources are freed up when Ipsen assumes all future costs for the preparations for and implementation of the Phase III studies and marketing of mesdopetam.

Cost control and a strong financial position allows aggressive investments

It is still important to monitor costs. We remain cost-conscious, but it is only natural that our costs will rise, as we are a growing company that is investing in the future. For example, we have nearly doubled the number of employees since the end of 2018, which is rational; our research platform has the potential to produce even more promising drug candidates. This requires more people with sharp brains to drive IRLAB ahead and add value for our shareholders. The costs of mesdopetam will be assumed by Ipsen, but the costs for the Phase IIb study with pirepemat will affect cash flow in 2022 and 2023.

In other words, it is reassuring that our excellent financial situation makes our growth plan and aggressive investments in promising projects possible. So far, we have focused on the mesdopetam and pirepemat programs. We are now able to widen our view and expand our investments in substances in earlier development phases. The discovery of entirely new presumptive classes of drugs is our ISP platform's unique sweet spot, and we want to expand our pipeline by taking more substances from our wide P001 and P003 programs from the preclinical phase to phase I.

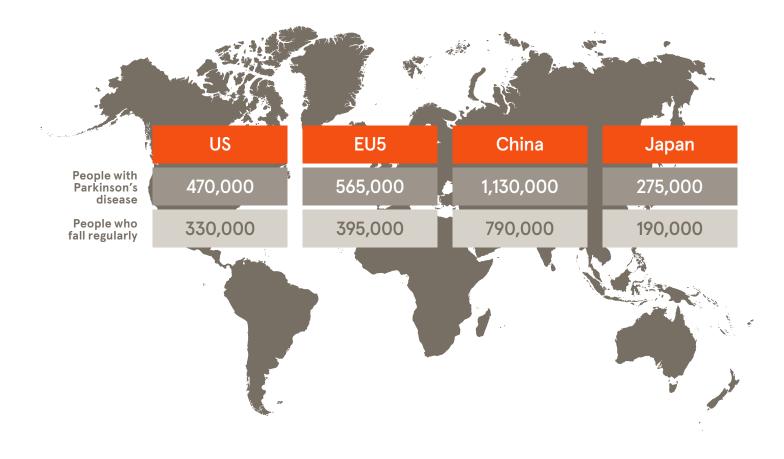
With regard to pirepemat, we still plan to carry out a structured license transaction based on the clinical data that will be generated in the Phase IIb study conducted by us. This is in accordance with the strategy that we have had since the company's inception – namely, to enter into cooperation agreements once clinical "Proof of Concept" has been achieved. Nevertheless, we now see major and increasing interest also in our early projects and are therefore open to initiating discussions that may allow transactions already in the preclinical phase or in Phase I.

A strong company with reduced risk

When we are looking at securing the company's continued capital requirements, we have been clear since the company was founded that we are relying on licensing and capital markets funding in parallel. This is still the case, and while our need for additional liquidity is not immediate, we are noting increased interest from international investors. Our transaction with a global pharmaceutical company such as Ipsen has drawn attention, which should allow us to take a more international approach to raising capital.

Finally, from my financial perspective, IRLAB has a new, strong position with excellent prospects. We have plenty of cash, we have a license deal for mesdopetam with the potential for further milestone payments. We note increased interest in our preclinical projects that increases the opportunities for new financially sound partnerships and the interest from international investors is strong, which will allow us to raise capital effectively should the need arise or if it would be strategically smart otherwise to do so. In light of this, we will leverage our strong position to ensure controlled growth, so that we can take additional projects to Phase I as quickly as possible and develop more preclinical projects on our ISP research platform.

Viktor Siewertz, CFO, IRLAB



Pirepemat - the market potential is excellent

What we do

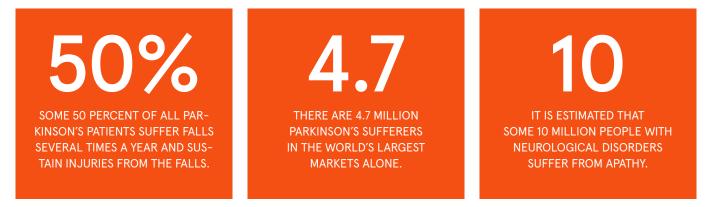
IRLAB strives to meet the need for new drugs to treat disorders of the central nervous systems with a focus on Parkinson's disease.

Why we do it

IRLAB seeks to change the lives of people with Parkinson's disease. The aim is to offer increased quality of life with fewer complications from the disease.

How we do it

IRLAB's cutting-edge expertise in modern research and development is used to create effective and successful drugs.



"There are no approved treatments for apathy at present, even if it is one of the most common and most troublesome symptoms in neurodegenerative diseases, both for patients and healthcare providers. We believe IRL757 has an important role to play in the treatment of people with apathy and neurological diseases."

JOAKIM TEDROFF, CMO OF IRLAB

About IRLAB

IRLAB uses a unique proprietary research platform called ISP to generate new drug candidates. The increased predictability of a drug candidate's potential is central to IRLAB's competitiveness. This is possible thanks to the ISP platform's comprehensive, high-quality and relevant data combined with effective machine learning methods.

Projects in clinical phase

IRLAB develops novel drugs for the treatment of Parkinson's disease, transforming the lives of those affected and their families. The company has two projects in the clinical phase, mesdopetam and pirepemat, both of which are undergoing Phase IIb studies. IRLAB also has a portfolio of preclinical projects that have all been generated by our proprietary research platform, ISP.

Mesdopetam

Mesdopetam is being developed to prevent and treat the involuntary movements that patients with Parkinson's often experience after long-term treatment with levodopa. In 2021, Mesdopetam was licensed to the global pharmaceutical company lpsen.

Pirepemat

Pirepemat is being developed to improve balance, thereby reducing falls and injuries from falls, in patients with Parkinson's.

Goals and strategy

IRLAB's strength lies in discovering new drug candidates with the help of ISP and developing them to reach clinical "Proof of Concept", when clear indications of efficacy, tolerability and safety are achieved. IRLAB's business model, expertise and experience have been designed to utilize this strength. By developing innovative drugs, IRLAB helps patients to a better life, which is a great benefit to society.

Two routes to shareholder value

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

Drug candidates

IRLAB's drug candidates can provide shareholder value through licensing/partnerships or the sale of projects. The revenue streams from sales differ from those associated with 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 are entered into for further development in Phase III, primarily in the form of license agreements with licensees who have the necessary resources to complete the development and market the drug once regulatory approval has been obtained.

The ISP research platform

In preclinical research, our ISP platform can be used in collaboration with other pharmaceutical companies. It creates opportunities for revenue in the form of market cooperation agreements and milestone payments and royalties on any products that the partner chooses to develop. IRLAB's strategy is to utilize internal resources to develop its own drug candidates and maximize their value. ISP has high precision and is resource and cost-efficient, which means that only molecules with an excellent chance of success are developed. To the extent that we identify additional resources, within the ISP framework, these can be offered to external parties.

What does IRLAB need to succeed?

Competent employees

Well-educated and motivated employees are a prerequisite for conducting research and development activities in the best possible manner. IRLAB's employees and external consultants must be highly qualified.

Well-planned clinical development

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

Innovative research

IRLAB needs to promote the continuous development of knowledge and methodology associated with the company's ISP research platform. IRLAB's drug candidates originate from the ISP platform, and it is important to keep developing the method continuously to maintain a high level of innovation in the company's future pipeline.

Effective collaboration

Good relations with partners and external experts are required to carry out the company's research and development effectively and drive strategic and operational activities. By using the best partner or expert in each important area, IRLAB can ensure the very best conditions.

Strong IP protection

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

Optimized organization

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

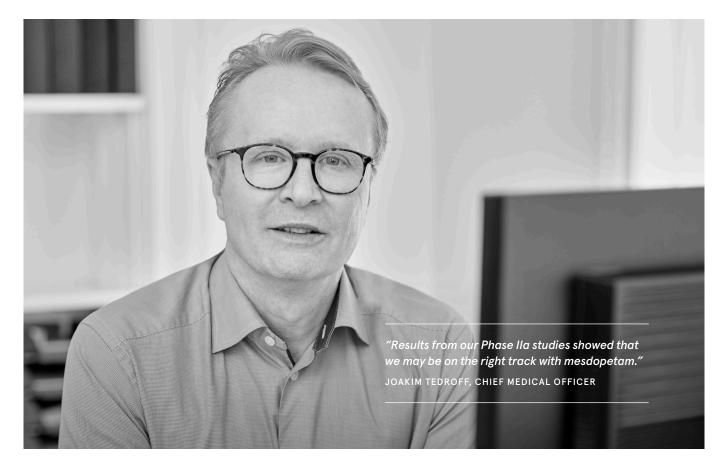
Strong financial position

IRLAB must work long-term on its capital structure to secure the development of the company's projects and pipeline. This also entails managing budgets and costs responsibly to manage the shareholders' trust in the best way possible.

By developing innovative drugs, IRLAB helps patients to a better life, which is a great benefit to society. This will, over time, lead to substantial value creation for our shareholders.

IRLAB's goal and vision

2020–2023	2023–2025	2025-2027
Treatments for Parkinson's	Building for the future	Delivering first-in-class treatments for Parkinson's disease
MESDOPETAM Successful completion of the Phase IIb/III study	MESDOPETAM Phase III study initiated	MESDOPETAM Application for marketing authorization
PIREPEMAT Successful completion of the Phase IIb study	PIREPEMAT Phase III study initiated	PIREPEMAT Application for marketing authorization
EARLY PROJECTS Initiate a Phase I study with preclinical candidates Upgrade the ISP method- ology	EARLY PROJECTS Progress Phase I candidates into Phase II studies	DISCOVERY PIPELINE Continued work on the ISP platform to generate new innovative drug candidates for the treatment of dis- orders of the brain.



"Few people value their time higher than Parkinson's patients and their families. Time spent together, and in balance."

Parkinson's disease is a neurological disease that causes nerve cells to atrophy prematurely. Parkinson's disease is the second most common primary neurodegenerative disease after Alzheimer's disease. It is believed nearly nine million people are living with the disease globally and that this number will more than double by 2040. The disease is both chronic and progressive; in other words, it is both lifelong and worsening over time. 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.

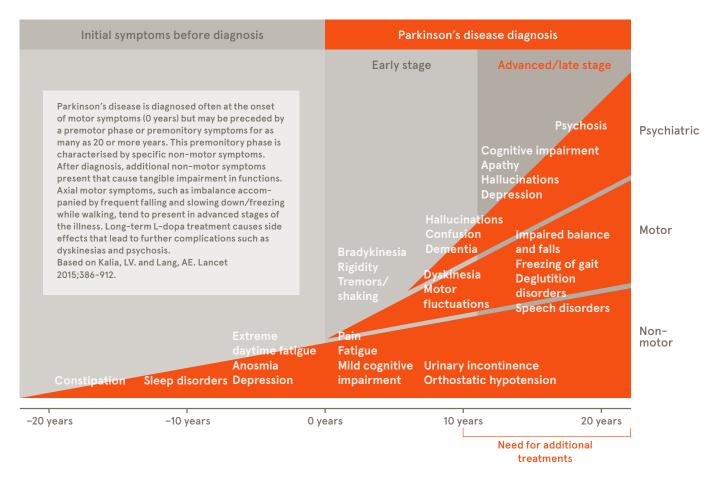
The disease starts with motor symptoms such as a slowness of movement (bradykinesia), tremors and rigidity. These symptoms are caused by a deficit of the neurotransmitter dopamine in the brain. The progression of the disease also affects other nerve cells and neurotransmitter systems, and with time, an increasingly difficult balance impairment emerges, along with symptoms from the autonomic nervous system and cognitive disorders.

Levodopa improves mobility but causes dyskinesia

A gigantic leap in the treatment 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. All of a sudden, patients who were previously bedridden or used wheelchairs were able to get up and walk! But nothing is all good. It was noticed early on that levodopa, which was so effective in reducing hypokinesia and tremors, eventually began to cause involuntary movements (dyskinesia). With time, the treatment became increasingly difficult to manage; patients fluctuated rapidly between reduced mobility and dyskinesia. The treatment may also cause the patient to hallucinate. People who suffer from this also often experience the feeling that someone else is present in the room, which can progress to visual hallucinations, and in severe cases, obvious psychotic symptoms with a distorted concept of reality.

Treatment options are still not optimal

Since the introduction of levodopa treatment in the 1970s, some new drugs have been introduced. These are based roughly on the same principle – the use of various methods to increase the transmission of dopamine, thereby improving mobility. To stabilize motor function, pump-controlled treatments with levodopa have been introduced, and the development of pumpcontrolled subcutaneous levodopa is still ongoing. An increasingly common method of treating Parkinson-related conditions that are difficult to treat is the surgical insertion of electrodes in the brain, referred to as deep brain stimulation (DBS). The method involves using high frequency electrical activity to disrupt any signals that contribute symptoms.



Nevertheless, treatment options for those who suffer from Parkinson's disease are currently far from optimal. At IRLAB, we are trying to find ways of addressing some of the greatest medical needs for those affected by the disease. Last year, we initiated a global Phase II study with mesdopetam aimed at investigating whether this potential drug, as an adjunctive treatment, can improve mobility in patients by reducing dyskinesias caused by the required levodopa treatment. Dyskinesia is a highly complex neurobiological disorder. How can we use pharmacology to reduce involuntary movements without affecting dopaminedriven voluntary movements? Our previously conducted Phase Ila study showed that we may be on the right track with mesdopetam. The addition of mesdopetam to the treatment reduced the daily time with troublesome involuntary movements without impairing voluntary motor function. A great many renowned doctors with an interest in Parkinson's disease have been engaged as investigators in the Phase IIb study, which is conducted in several countries (United States, France, Poland, Serbia, Israel and Italy). Mesdopetam, which is based on an entirely new pharmacological principle for the treatment of such symptoms, has the potential to also be used as an entirely new class of drugs for hallucinations caused by the symptomrelieving treatment. That way, mesdopetam has the potential to control undesired adverse drug reactions from the necessary treatment needed by all those who suffer from Parkinson's disease. It is estimated that the need, and therefore the market, for such a drug is substantial, and it would be a welcome addition to the arsenal of treatments.

No treatment to reduce the risk of falls

Parkinson's disease is a progressive disease and over time, motor and balance impairment becomes increasingly severe, causing an increased risk of falls. The increased risk of falls is particularly large if the patient suffers from cognitive impairment. Injuries related to falls are one of the most common reasons why people with Parkinson's disease seek emergency care in hospital. 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 results in higher health-care and social costs. In the United States, the estimated health-care cost of a fall injury in a person over the age of 65 is approximately SEK 250,000 (converted from USD 30,000). Complications associated with falls are fractures, reduced mobility and a lower quality of life. There is currently no treatment for balance impairment and the repeated falls that affect people with Parkinson's. Levodopa and other similar drugs have effect on reduced mobility and tremors, but they have no effect on balance and cognition.

It is therefore highly exciting that we received regulatory approval last year for another Phase IIb study with our drug candidate pirepemat. The aim of the study is to investigate whether pirepemat as an adjunctive treatment can reduce the risk of falls in people suffering from Parkinson's disease. We will also investigate whether pirepemat can improve cognitive impairment in patients who fall regularly. Pirepemat is an entirely new form of drug with a stimulating effect on the cortex, an area of the brain that is affected by a loss of neurotransmitters caused by Parkinson's disease, which contributes to both balance and cognitive impairment. This is a difficult field with few competitive products under clinical development. The need is immense, and the project is met with a great deal of positive attention from teachers and academics in the field.

"Immensely interesting data have been generated in a collaboration project between IRLAB and two world-leading Swedish Parkinson's researchers: professor Per Svenningson of the Karolinska Institute and professor Per Peterson of Lund University."

CLAS SONESSON, CHIEF SCIENTIFIC OFFICER (CSO)

"Time to save – both through patents and careful planning."

Mesdopetam, one of our candidate drugs in Phase IIb/III with blockbuster potential that is now being developed in collaboration with Ipsen, is facing exciting new opportunities. Immensely interesting data have been generated in a collaboration project between IRLAB and two world-leading Parkinson's researchers: professor Per Svenningson of the Karolinska Intitute and professor Per Peterson of Lund University. This research, which was partially funded in collaboration with SweLife, increases the understanding of how mesdopetam acts in the brain and how mesdopetam counteracts levodopa-induced dyskinesia and psychosis in Parkinson's.

P001 and P003 form the basis for IRLAB's early research

The P001 research project, which is based on IRLAB's discovery of an entirely new class of potential drugs developed with our research platform ISP, focuses on neurodegenerative diseases and ageing. The project has now advanced considerably due to a number of promising preclinical results developed in cooperation with international experts and research teams.

The neural tracts that govern executive functions such as working memory, problem solving and flexible thinking (cognitive functions) are located at the front of the brain, in the frontal lobe. These neural tracts are hugely important to our ability to manage everyday life. The frontal lobe is also involved in motivation and impulse control. According to new research, weak neural activity in this part of the brain, chiefly caused by low levels of the neurotransmitters dopamine and norepinephrine, leads to symptoms associated with cognitive impairment and apathy (indifference and insensitivity). These symptoms are pronounced in our most common neurodegenerative diseases, such as Parkinson's disease, vascular dementia and Alzheimer's disease, in which the treatment of cognitive impairment and apathy creates major medical needs. Even though an estimated 10 million patients in North America alone suffer from apathy, there is no treatment for apathy at present.

P001 focuses on increasing nerve activity in the frontal lobe

The aim of the P001 project is the development of substances capable of increasing, with precision, the neural activity in the frontal lobe synapses by increasing the levels of dopamine and norepinephrine, thereby counteracting cognitive impairment. IRL942, the investigative drug candidate in the P001 program that has had very promising results in preclinical studies in the field of dementia, is now being developed to improve cognitive function in dementia-related illnesses. We are now taking all the steps required to begin clinical Phase I studies with IRL942. The

required optimization and scaling up of the industrial process and the manufacturing of the substance for the Phase I trial have been initiated. The regulatory toxicological and safety studies will be conducted once the manufacturing of the active substance is complete. The work on compiling the documentation required by the authorities for the application for Phase I studies is carried out in parallel.

The P001 research team has also had the pleasure of selecting another development candidate, IRL757, with very promising characteristics. It is now likely that the P001 project will exceed its goal and deliver additional substances for the development of treatments for neurodegenerative diseases and ageing. Based on the effects identified in the preclinical studies, we are primarily aiming to use IRL757 as a treatment for apathy. Just like with IRL942, IRLAB is now developing industrial synthesis of IRL757 so that clinical Phase I studies may be initiated.

P003 may have the potential to replace levodopa

P003 is a research project striving to revolutionize the treatment of patients with Parkinson's. At present, the treatment of Parkinson's is based on levodopa, which has been the case since the 1960s. Medical research has long worked on finding an effective alternative to levodopa, which is usually combined with other medicines to optimize and improve the treatment and compensate for the weaknesses of levodopa.

In the P003 project, we have identified lead substances with hitherto unsurpassed potential to replace both levodopa and its adjunctive drugs in the treatment of Parkinson's disease. We are currently using a combination of advanced 3D computational chemistry and our ISP platform to optimize these leads quickly and effectively so that they meet the requirements posed on medicinal products. The receptors in the brain that we are seeking to affect are now available as a 3D model. This means that new chemical ideas can be evaluated in a rational manner in combination with our ISP strategy, which is unique in the world. For rapid progress, the research team has developed advanced preclinical models for Parkinson's disease, which are now being used to evaluate the most promising substances both in emergency and long-term treatment.

In 2021, IRLAB expanded its skills base by engaging additional key people in the fields of pharmacology, medicinal chemistry, analytical chemistry, computational biology and AI (artificial intelligence). Our premises were also expanded, and an extremely advanced analysis instrument was acquired for the examination of chemical structures and analyses of very low levels of medicinal substances.



"The more time we spend on quality work, the better the return in terms of time."

IRLAB is a growing and living company that is constantly breaking new ground in the research and development of new drugs. Our quality work must follow the same dynamics; that is, it must be living and flexible, so that we can guarantee compliance with applicable rules and regulations at all times and meet the requirements from a growing number of employees with new skills and fresh perspectives. At the same time, we are a pioneering research organization that is always striving for progress, so it is a matter of course for us to take a riskconscious approach throughout the entire organization, as part of our daily work. These dynamics mean that our work is constantly ongoing and immensely exciting but will never really reach an end destination.

We must keep developing our quality management system, relying on the same finesse and commitment that characterizes our research and development of new drugs.

As a company listed on Nasdaq Stockholm's main market, we have now come full cycle in our "annual wheel" of internal control procedures. We hold an annual event where our entire staff gathers to discuss risks and proposed improvements. In 2021, the event was largely held online due to the pandemic.

IRLAB's procedures for internal control and systematic quality are pillars for ensuring compliance with applicable laws and ordinances, excellent quality throughout all activities and effective operational governance. This is a prerequisite for our ability to achieve our goals, ensure the reliability of our internal and external financial reporting and, ultimately, protect our owners' investments.

Business goals are central

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

The other components of internal control, which cover 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 meeting its goals.

Risk awareness is the foundation

The internal work environment is based on a structured organization with well-defined areas of responsibility and reporting routes and on governing documents that set the framework for the business. The executive management works actively to create a work climate focused on integrity, ethical values and risk awareness that acts as the basis for how the organization's employees view and respond to risks and opportunities. By identifying "We are a pioneering research organization, so it is a matter of course for us to take a risk-based approach in our daily work, throughout the entire organization."

MARIA JALMELID, CHIEF OF CLINICAL OPERATIONS

risks and considering them in relation to the business, control mechanisms can be identified and implemented that make it possible to identify as early as possible the increased likelihood of a risk materializing. Measures aimed at preventing or mitigating the impact of the risk on the business can then be implemented.

Systematic quality work

IRLAB's system for quality assurance involves policy documents, standard operating procedures (SOPs) and work instructions that describe our core procedures and set the framework for how our operations are conducted and governed. A focus on quality and risk management is an integral part of the daily work at IRLAB and involves planning and monitoring the work so that possible areas of improvement can be identified, both in terms of preventing and detecting possible deficiencies. If necessary, changes are implemented in the business, so that our procedures improve continuously. Our dedicated employees make the process come alive, and our governing documents are subject to continuous development and improvements. 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

Our guidelines for the evaluation and approval of partners are an important aspect of our quality assurance. For example, IRLAB outsources a large part of the practical implementation of the

clinical studies to specialized collaboration partners (Clinical Research Organizations, CROs), which requires careful evaluation to ensure that our chosen partner has the appropriate expertise and experience. Our procedures also describe how IRLAB, during the implementation of clinical studies, ensures continuous control and review of the CROs' work and their deliveries.

Regular risk assessments

Established procedures for reporting and communication in the form of an annual cycle ensure that these procedures are kept alive and that the Board of Directors has an overview of the internal control and is kept informed of any risks and opportunities identified in the daily operations. Based on the company's updated goals, a risk assessment of the entire company is made. Governing documentation is reviewed and updated as required and control activities are identified and documented. At the end of the cycle, the processes and control activities are evaluated with a focus on their design and how effective they are at identifying at an early stage the increased likelihood of a risk.

"Through the systems that are built into our models, we obtain evidence early on that our molecules will work all the way. The ISP platform simply has a good track record."

PEDER SVENSSON, DIRECTOR OF COMPUTATIONAL CHEMISTRY & BIOLOGY/CIO

"IRLAB's unique ISP research platform reduces the development time to one-third – with higher precision and at a lower cost."

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 screening models, an extensive database and modern AI-based analyses. 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.

The most common method today to evaluate whether a molecule in a research lab will actually work as a drug in a real-life situation is target-based screening. To put it simply, the principle involves searching in vitro for molecules with a certain effect on a specific protein, based on the hypothesis that this will in turn affect a patient's condition. However, the long way from the test tube to the human body has many pitfalls.

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 Al-based methods.

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, broken down 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.

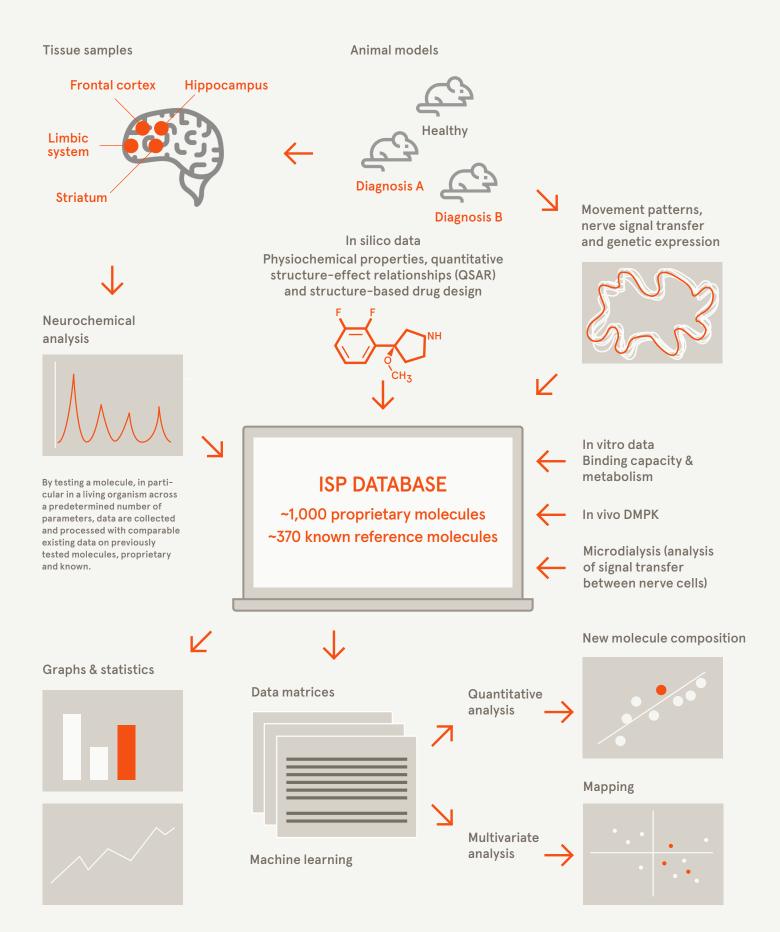
Continued investments in artificial intelligence (AI)

It is important to IRLAB to constantly refine and develop its research methods and always remain at the forefront of modern calculation methods, such as artificial intelligence, to further increase the efficiency in the development of drugs.

In 2021, IRLAB recruited two experienced AI experts, which reinforces the company's expertise and increases the focus on the application of artificial intelligence to the ISP platform.

New perspectives are also added through close cooperation with mathematicians, students and academic researchers so that the company can keep leading technology development.

Data flow in the ISP research platform



"We have been highly successful in our progression, as we have so much prior knowledge already."

PEDER SVENSSON, DIRECTOR OF COMPUTATIONAL CHEMISTRY & BIOLOGY/CIO





"For us, as a research company, a sustainable society begins with our employees."

IRLAB's operations are permeated by the goal and desire to have a positive impact on society and individuals through increased knowledge. By contributing research, knowledge building and drug development, IRLAB strives to make life better for disabled individuals, resulting in a more sustainable society.

IRLAB's sustainability work is based on those of the UN Sustainable Development Goals that are relevant to the operations. The company has chosen to focus its efforts on the following three areas:

Employees

IRLAB seeks to offer all its employees a good work environment

It is important to IRLAB that its corporate culture is inclusive on all levels of the operations. The company's research and development activities require specific expertise and training, but as a main principle, everyone should be offered equal opportunities in recruitment and career development. Years of experience are combined with new ideas and fresh perspectives.

IRLAB strives to create good conditions for the company's employees with a pleasant work environment, inspiring tasks that allow employees to take ownership and a clear link to the company's development. The well-being and safety of our employees have been the focus in the current Covid-19 pandemic. In 2021,

the company offered its employees the opportunity to work from home, according to government recommendations and guidelines. Digital communications with video conferencing were in frequent use, and outdoor activities were arranged to maintain the sense of community in the company.

Responsible dealings

IRLAB shall act responsibly in all relationships and partnerships

In addition to the company's own responsible behavior, IRLAB makes high demands on external suppliers and collaboration partners. If we are to create the best conditions for our drug development projects, our work must be permeated by transparency. This means that any suppliers and laboratories, contract research organizations and hospital clinics that we collaborate with must have documented solid experience and work in strict compliance with rules and regulatory requirements.

As and when needed, IRLAB seeks the support of area experts and Key Opinion Leaders (KOLs). These collaborations should be characterized by sincerity, respect and the pursuit of a common understanding of the goal so that they make a productive contribution to the development of our drug candidates.

Calendar for 2022

May 11, 2022	Interim report January–March 2022
August 24, 2022	Interim report April–June 2022
November 9, 2022	Interim report July-September 2022
February 22, 2023	2022 Year-end Report

"In 2021, we expanded our premises and strengthened our organization with additional expertise. IRLAB strives to create a work environment where all employees enjoy a high quality work environment and are able to influence their working pace, job quality and the contents of their work to the extent permitted by the operations."

CECILIA TIVERT STENBERG, FINANCE & HUMAN RESOURCES MANAGER

Community involvement

Knowledge-sharing is at the heart of the company's commitment

Research is IRLAB's core business, and knowledge is 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 that are open to the public in various research and development areas. Knowledge-sharing is at the heart of the company's commitment. The results and the knowledge produced by IRLAB are not only shared on the company's website, through presentations at public events and through the publication of articles in scientific journals; they are also shared in various networks. This way, IRLAB contributes to the development and visibility of the company's areas of expertise and raise awareness in society.

CNS disorders are a rapidly growing problem that steals time from societies and people. IRLAB has the potential to even out the odds in this race.

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

Global trends

The world's population is growing and ageing. 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 older generation must therefore be able to work up to the age of 70 and require less care.

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 ageing population, the already huge need for new and effective drugs for Parkinson's is believed to grow significantly in coming years. Drugs that address difficultto-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, especially for first-in-class substances, as the exclusive rights can then be leveraged to the maximum. With the high demands placed on drug development, this is a challenge at all stages. Due to its ISP research platform, IRLAB expects to minimize the time spent on preclinical development and estimates a time saving of two to three years compared with traditional drug development.

Market size

MESDOPETAM	

REGION	PD-LIDS	PD-P	
US	196,000	275,000	
EU5	235,000	329,000	
China	471,000	659,000	
Japan	115,000	160,000	

PIREPEMAT

REGION	PATIENT POPULATION (RISK OF FALLS)	PATIENT POPULATION (RECURRING FALLS)
US	470,000	366,000
EU5	565,000	418,000
China	1,130,000	878,000
Japan	275,000	190,000

In the US, drugs have been registered for the treatment of PD-LIDs (Gocovri[™]) and PD-P (Nuplazid[™]). Both have a price tag of approximately USD 30,000 per year. For pirepemat, external specialists have determined that a price of USD 40,000 per year in the USD may be a reasonable expectation.

Parkinson's disease is one of the fastest-growing diseases

The total economic burden of Parkinson's in the US is USD 51.9 billion per year.²

2040 According to forecasts, 16+ million people will live with Parkinson's globally²

2015 8.7 million people live with Parkinson's disease globally¹

¹ Based on market data in EU5, Japan, US and China.

² Yang, W., Hamilton, J.L., Kopil, C. et al. Current and projected future economic burden of Parkinson's disease in the U.S. npj Parkinsons Dis. 6, 15 (2020). https://doi.org/10.1038/s41531-020-0117-1

The market for IRLAB's drug candidates

IRLAB develops drug candidates with a unique mechanism of action for symptoms associated with Parkinson's in markets with great 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.

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. Newly introduced drugs in this sector have prices of around USD 30,000/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

Recent 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.

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.

The mechanism of action of mesdopetam indicates that the drug candidate may also have clinical potential in the neurological condition of tardive dyskinesia, which affects patients with psychosis and is caused by long-term treatment with antipsychotics. Globally, more than 3 million patients have tardive dyskinesia, which is approximately 25 percent of those treated with antipsychotic drugs.

Pirepemat

Pirepemat is intended to improve postural dysfunction (impaired balance), thus preventing falls in Parkinson's (PD-Falls). Some 60 percent of all Parkinson's patients 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. 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 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

Mesdopetam

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. Amantadine may work well for some patients but is associated with adverse drug reactions, with hallucinations being the most prominent. It is also questionable whether the drug works for more than 6-12 months. Amantadine ER, a reformulation of amantadine, is approved for the treatment of PD-LIDs, but it is only available in the US. There is therefore a great need for drugs that can help Parkinson's patients 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 ("good ON time"). 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

There is currently no approved drug that improves balance and reduces falls in Parkinson's. IRLAB only knows of a few development projects in the clinical phase that may compete with IRLAB's drug candidates. In addition to IRLAB's pirepemat, there is only one candidate in the preclinical phase (CM-PK) and one in the clinical phase (droxidopa, which is being developed for the treatment of falls in orthostatic hypertension and Parkinson's).

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.

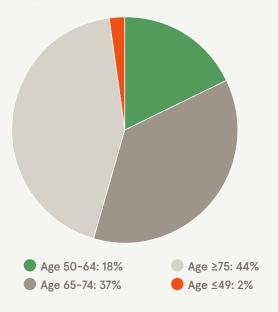
⁴ Adeyemi, A. et al. JBJS Open Access: March 28, 2019 - Volume 4 - Issue 1 - p e0045 doi: 10.2106/JBJS.OA.18.00045

⁵ Kalilani, L. et al. PLoS One. 2016;11(9):e0161689. Published 2016 Sep 1. doi: 10.1371/journal.pone.0161689

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



Parkinson's prevalence, age distribution in the US 2017.



Illustrates candidates in development for PD-LIDs and PD-Falls, including IRLAB's two candidates in orange.

	PRE- CLINICAL PHASE	PHASE I	PHASE II	PHASE III
PD-LIDs	••		••••	
PD-Falls	•		•	

Project portfolio

IRLAB's project portfolio consists of drug candidates in the clinical and preclinical development phases. The project portfolio is focused on developing new treatments for patients with Parkinson's disease. All drug candidates have been developed using the company's proprietary research platform, ISP.

Clinical phase

Tolerability, safety and efficacy studies.

Mesdopetam

Mesdopetam (IRL790) is being developed to prevent and treat levodopa-induced dyskinesias (troublesome involuntary movements, PD-LIDs) in Parkinson's disease. The aim is to reduce troublesome dyskinesias and then extend the daily time with good and controlled mobility, referred to as "good ON time". Mesdopetam also has antipsychotic properties and is being developed for Parkinson's psychoses (PD-P).

Pirepemat

Pirepemat (IRL752) is being developed to improve balance and reduce falls, and thus injuries from falls, in Parkinson's disease. Pirepemat is also being developed for the treatment of dementia in Parkinson's disease (PD-D).

Preclinical phase

Laboratory studies to meet the requirements for studies in the clinical phase.

IRL942

IRL942 is intended to treat mental illness and cognitive and motor disorders associated with neurodegenerative and age-related CNS disorders.

IRL757

The aim of IRL757 is to treat apathy in neurological diseases – which is an enormous problem for patients and their families – for which there is no treatment at present.

Discovery phase

Laboratory tests for discovering drug candidates.

The P003 research program includes a group of molecules with the potential to be developed into drugs for the treatment of newly diagnosed Parkinson's disease.

IRLAB's research and development portfolio

		DISCOVERY	PRE CLINICAL	PHASE I	PHASE IIA	PHASE IIB	PHASE III
PARKINSON'S DI	SEASE – LEVODOI	A-INDUCED DY	SKINESIAS (LID	S)			
Mesdopetam* (IRL790)	D3 antagonist						
PARKINSON'S DI	SEASE – PSYCHOS	IS					
Mesdopetam* (IRL790)	D3 antagonist						
PARKINSON'S DI	SEASE – FALLS						
Pirepemat (IRL752)	PFC enhancer						
PARKINSON'S DI	SEASE – DEMENTI	A					
Pirepemat (IRL752)	PFC enhancer						
NEURODEGENE	RATIVE DISORDER	s – Aging					
IRL942	P001 program						
NEURODEGENE	RATIVE DISORDER	S – APATHY					
IRL757	P001 program						
PARKINSON'S DI	SEASE						
P003	Dopamin substitution						

PFC = prefrontal cortex

*Developed in partnership with Ipsen, which has the global rights for development and commericialization

The clinical drug candidate mesdopetam

The drug candidate mesdopetam is being developed for the treatment of levodopa-induced dyskinesias (PD-LIDs) and psychosis (PD-P) in Parkinson's disease. The aim of mesdopetam is to increase the time of day when patients have an optimal effect of their standard treatment with levodopa, i.e., good mobility and control of hallmark symptoms, without being troubled by involuntary movements or psychoses. A Phase IIb/III study is currently being conducted in the US and Europe to investigate the effects of mesdopetam in patients with PD-LIDs. In 2021, IRLAB entered into a license agreement with the global pharmaceutical company Ipsen, which grants Ipsen exclusive global rights to develop and market mesdopetam globally.

Mesdopetam (IRL790) is an antagonist of the dopamine D3 receptor and reduces the overactivity which, via the D3 receptor, leads to dyskinesias (involuntary movements) in Parkinson's disease. See the mechanism of action of mesdopetam on the next page.

Clinical development of mesdopetam

IRLAB has completed clinical Phase I, Phase Ib and Phase IIa studies with mesdopetam. Following positive results in the Phase I and Phase Ib studies, a clinical Phase IIa study was carried out on patients with Parkinson's disease and dyskinesias. The aim was to study the efficacy, safety and tolerability of mesdopetam in approximately 70 patients. Analyses of efficacy data indicate that mesdopetam can reduce dyskinesias in Parkinson's disease (PD-LIDs) without affecting other mobility in patients. The study results indicate that mesdopetam has good potential to help patients with Parkinson's disease to optimize their treatment with levodopa without risking dyskinesias. This increases the daily time when levodopa treatment helps with the hallmark symptoms (good ON time) without the patient experiencing troublesome dyskinesias. Recent preclinical studies indicate that mesdopetam has further potential to be able to prevent the development of dyskinesias, which means that mesdopetam may be relevant for a larger group of patients.

Ongoing Phase IIb/III study

A Phase IIb/III study with mesdopetam in PD-LIDs was initiated at the end of 2020, and the initial top-line results are expected

during the first six months of 2022. In the study, a total of about 140 patients will be treated over three months, divided into four different groups: three dose levels of mesdopetam and a placebo group. The study's primary endpoint is the change in the daily number of hours with good mobility and no troublesome dyskinesias, good ON time, as measured through a patient diary. The study is conducted at clinics in Europe and the US. Through the start of the study, the company's clinical development work was expanded to the US, which was one of the company's important strategic goals.

Ipsen's development plan (Life Cycle Management) includes continued clinical studies to also evaluate the effect of mesdopetam on symptoms of psychosis (PD-P) and potentially also on tardive dyskinesia and other possible indications on which mesdopetam may have a great effect.

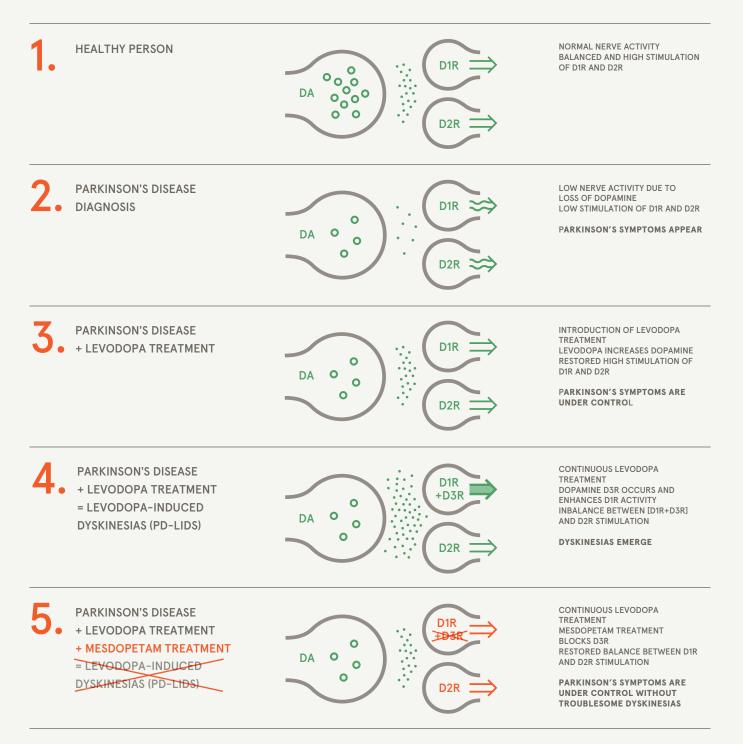
Patent overview for mesdopetam

Molecule	IRL790
WO No.	WO2012/143337
Granted patents	All major markets Asia, North America and Australia
Patent expiration	No later than 2037 in the EU/JP/US, provided that the option to extend the term of the patent is utilized (IND application, Supplementary Protection Certificate (SPC) and Patent Term Extension (PTE).

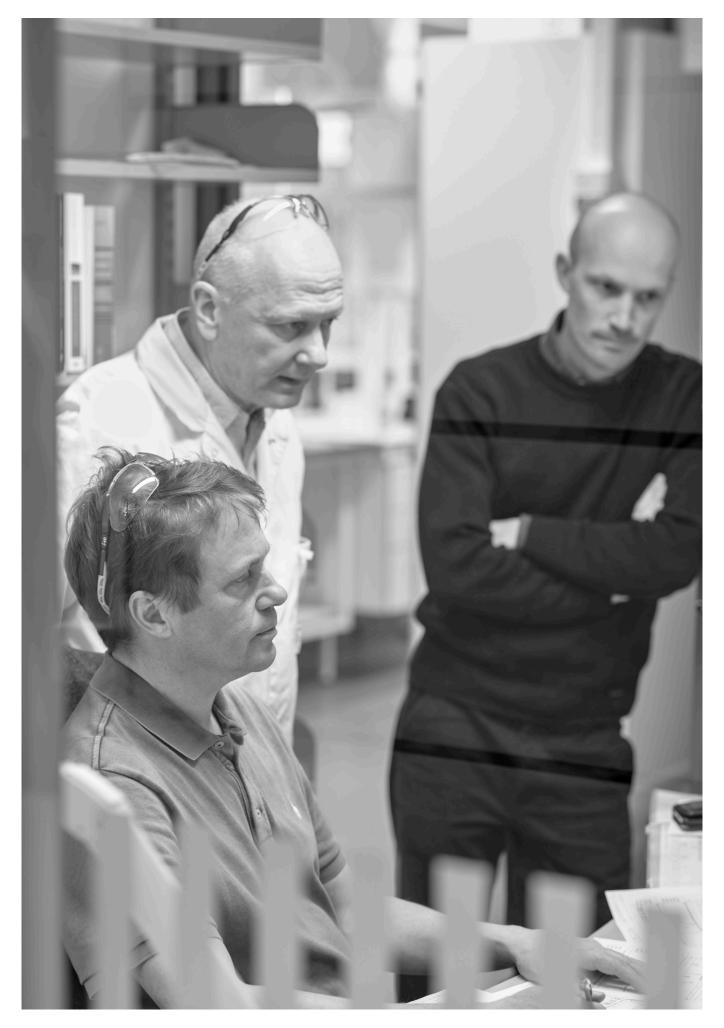
An additional patent application was published in 2020, which, if approved, could give mesdopetam exclusivity well into the 2040s.

Source: The company's statement

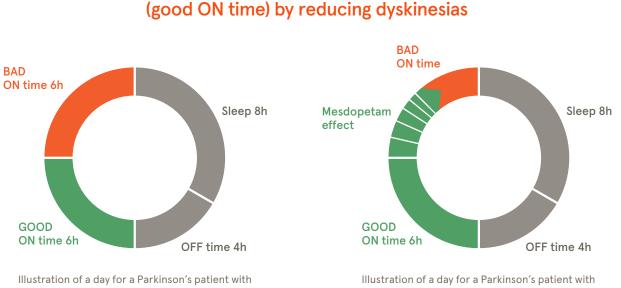
Mechanism of action for mesdopetam



DA = dopamine; D1R = dopamine receptor D1; D2R = dopamine receptor D2; D3R = dopamine receptor D3



The clinical drug candidate mesdopetam



Mesdopetam extends the daily time experienced as good

standard anti-Parkinson's medication (levodopa). The time is aggregated and grouped according to category. Illustration of a day for a Parkinson's patient with standard anti-Parkinson's medication (levodopa) and mesdopetam. The time is aggregated and grouped according to category.

Mesdopetam's main competitive advantages

- Indications of significantly better efficacy and a better safety profile than competitor drugs and projects.
- Ongoing Phase IIb/III study within PD-LIDs in the most important markets: US and Europe.
- First-in-class: Mesdopetam is a drug candidate with a new mechanism of action that has the potential to become the first in a completely new drug class for the treatment of complications in Parkinson's disease.
- Preclinical results also indicate the potential to prevent the development of dyskinesias, which distinguishes mesdopetam from currently available treatments.
- Mesdopetam has been obtained as the International Non-proprietary Name (INN, generic substance name).
- Development within two indications; dyskinesias and psychosis in Parkinson's. Development for additional indications, such as tardive dyskinesia, is also possible.
- Study results have been published in highly-ranked scientific journals.
- Strong IP protection: global patent protection and patent registrations may provide exclusivity until approximately 2042.

The clinical drug candidate pirepemat

Pirepemat is being developed to treat impaired balance and falls caused by Parkinson's disease (PD-Falls). Impaired balance and an increased risk of falls are strongly associated with impaired memory and thinking ability, issues where the existing Parkinson's drugs are ineffective. The aim of pirepemat is to give Parkinson's patients improved balance and fewer falls, thus improving the quality of their everyday lives. Pirepemat is also being developed for the treatment of dementia in Parkinson's disease (PD-D).

Injuries related to falls are one of the major reasons why patients suffering from Parkinson's seek hospital care. About 60 percent of all patients suffer falls each year, and about 70 percent of them fall regularly. Pirepemat (IRL752) has the ability to selectively improve the functions of the cerebral cortex by increasing the levels of the neurotransmitters norepinephrine and dopamine and activating genes involved in the nerve cell contacts. Pirepemat chiefly affects the cerebral cortex.

There is no specific treatment at present that reduces the risk of falls in Parkinson's patients. According to a global overview of the ongoing development project, there is no drug under development with a similar mechanism of action. IRLAB therefore determines that pirepemat has a lead of approximately 4–5 years compared with other projects.

Clinical development of pirepemat

IRLAB has carried out Phase I and Phase IIa clinical studies with pirepemat where the results indicate good tolerability for the doses studied. Exploratory analyses of efficacy data indicate that pirepemat improves symptoms that are strongly linked to cerebral cortex functions. These early indications of efficacy include improved balance, a decreased tendency to fall, decreased apathy (lack of motivation and reduced initiative) and improved results in cognitive tests (memory and thinking ability). The continued development program for pirepemat aims to demonstrate the safety and efficacy in Parkinson's patients with symptoms consistent with impaired signal transmission in the cerebral cortex.

The Phase IIb study

In December 2021, IRLAB received approval to begin the Phase IIb study where pirepemat will be given for twelve weeks as an

adjunctive therapy to the patient's regular Parkinson's medication, and the effect of pirepemat on the frequency of falls will be compared with placebo. The study is estimated to include a total of 150 patients divided into three different groups; two dose levels of pirepemat and a placebo group. After safety and efficacy data have been established in the Phase IIb study, pirepemat will progress to a more extensive Phase III clinical trial. The Phase IIb study began in the first quarter of 2022 and is conducted at clinics in Europe.

IRLAB's development plan also includes continued clinical studies to evaluate the effect of pirepemat in dementia in Parkinson's (PD-D). The plans for these studies are not as well developed as for the Phase IIb study in PD-Falls.

Patent overview for pirepemat

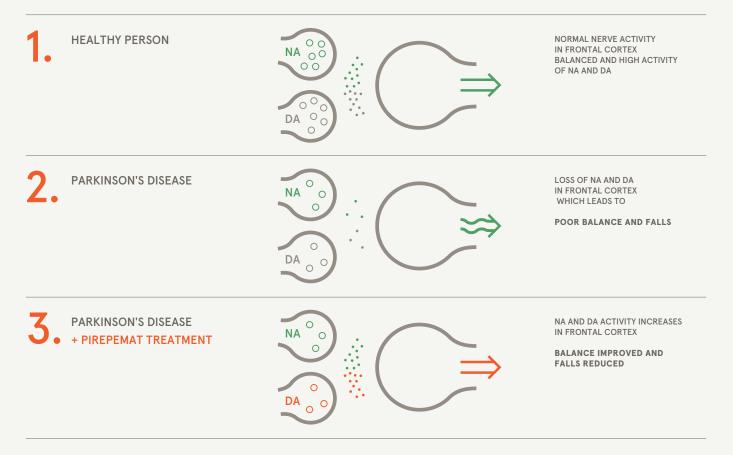
Molecule	IRL752
Type of patent	Substance
WO No.	WO2010/058018
Status	Granted in all major markets (EU/US/JP/CN)
Patent expiration	No later than 2034 in EU/JP and 2035 in the US provided that the option to extend the patent period is used (SPC* och PTE* i EU/US/JP)
Molecule	IRL752 fumarate
Type of patent	Substance and manufacturing process
WO No.	WO2020/211080
Status	Patent applications submitted in all major markets
Patent expiration	No later than 2040 provided that tha patent is granted and that the option to extend the patent period is used (SPC* och PTE* i EU/US/JP)

* SPC = Supplementary Protection Certificate

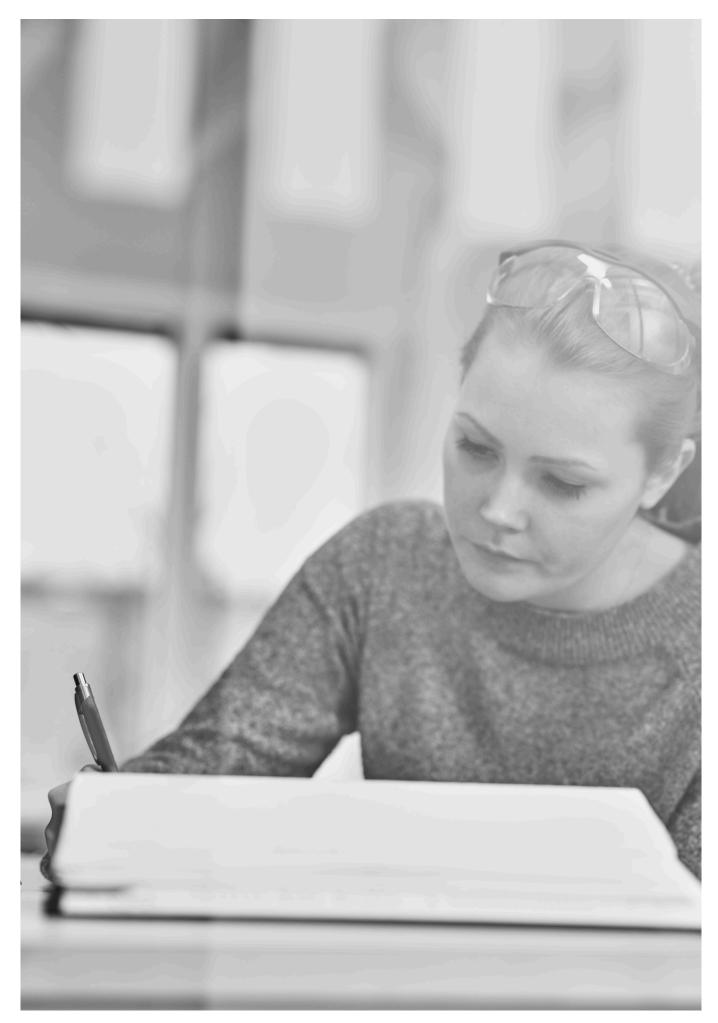
PTE = Patent Term Extension

Source: The company's statement

Mechanism of action for pirepemat



NA = noradrenergic; DA = dopamine



The clinical drug candidate pirepemat

Some 60 percent of all Parkinson's patients 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.



Pirepemat's main competitive advantages

- First-in-class treatment for impaired balance (postural dysfunction) and falls.
- A new, unique mechanism of action.
- Strong IP protection: global patent protection and patent registrations may provide exclusivity until approximately 2040.
- Good tolerability profile in Parkinson's patients.
- Pirepemat has been obtained as the International Nonproprietary Name (INN, generic substance name).
- Development within two indications; treatment of impaired balance and falls in Parkinson's (PD-Falls) and dementia in Parkinson's disease (PD-D).
- Developed for a new market with significant clinical needs and limited competition.
- Study results have been published in highly-ranked scientific journals.

Preclinical phase and discovery phase

In addition to the two main projects – the drug candidates mesdopetam and pirepemat – IRLAB is working on two preclinical programs and a research project. These are also generated by the proprietary research platform, ISP.

IRL942

The drug candidate IRL942 originated in the PO01 research program and is intended for the treatment of mental and cognitive disorders and impaired motor functions associated with neurodegenerative disorders and ageing. As a new drug candidate, IRL942 will, as a first step, progress through a preclinical development program to meet the regulatory requirements for obtaining a permit to conduct Phase I clinical studies. If the results of the preclinical program are positive, clinical studies will be initiated.

The P001 research program will continue, in part to support the continued development of IRL942 and in part to identify additional substances with similar properties.

IRL757

The drug candidate IRL757 also originated in the P001 research program. It will be developed as a treatment of apathy in patients with neurological diseases. Between 20 and 80 percent of all those with neuropsychological diseases suffer from apathy, and there are no approved treatments at present.

P003

The P003 research program includes a group of substances with the potential to be developed into drugs for the treatment of newl diagnosed Parkinson's disease. The program aims to develop new drug candidates that IRLAB can develop further, towards clinical studies.

Overview of portfolio development

		DISCOVERY	PF	RECLINICAL	RECLINICAL PHASE I
NEURODEGEN	IERATIVE DISORDER	S – AGEING			
IRL942	P001 program				
NEURODEGEN	IERATIVE DISORDER	S – APATHY			
IRL757	P001 program				
PARKINSON'S I	DISEASE			_	
P003	Dopamine substitution				



Organization

IRLAB was created by skilled employees in all parts of the business. This applies to the laboratory, the business functions, the clinical operations and the work on the ISP platform – all the elements that form the core of the organization. The business makes its progress in collaboration with external consultants and area experts.

IRLAB's operations are based at the Biotech center in Gothenburg, but the company operates in many parts of the world. The premises in Gothenburg contain both laboratory and office space. The company's clinical development group expanded over the year and premises were obtained in Stockholm. In 2021, IRLAB's employees mostly worked from home in accordance with the guidelines and recommendations from the authorities during the various phases of the Covid-19 pandemic. At the end of the first quarter of 2021, the business had 30 employees, five of whom joined in the last six months. 60 percent are women and 40 percent are men. Our employees have extensive experience from the pharmaceutical and biotech industry. All are university educated and a 49 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 in practice, the company is a much larger organization than the figures show.

Scientific experts

IRLAB collaborates with several scientific experts:

- Dr. Bastiaan Bloem, Netherlands, Professor of Neurology, MD, PhD
- Dr. Camille Carroll, UK, Assistant Professor of 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

Regulatory issues are highly important for successful drug development, so IRLAB collaborates with experienced consultants in the US and Europe. In the US, IRLAB collaborates with Clintrex, which provides advise on both regulatory issues and matters involving the design of the clinical studies. Clintrex is an integrated team of internationally renowned experts, including former senior employees of the FDA. Clintrex collaborates with development companies to identify, clarify and resolve preclinical, clinical, biostatistical and regulatory issues that are important for product development and market authorization. Clintrex is chiefly active in the US.

In Europe, IRLAB has entered into cooperation with Consilium Salmonson and Hemmings for support with the development and approval of drugs and life cycle management. They have over 50 years of collective 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

IRLAB's business development activities are supported by Hjalmarsson & Partners, an independent financial advisor specializing in mergers and acquisitions (M&A) and capital raising.

The law firm MAQS Advokatbyrå supports IRLAB with legal advice and participates in all corporate procedures of a legal nature.

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



49%

49 percent of IRLAB's employees have doctorates. All have a university degree. 30 employees, 60 percent women, 40 precent men.

60%

Partners for drug development

Toxicity studies, preclinical

Clinical studies Production of active substances for preclinical studies Animal laboratory (rats) Cognition tests on rats Production of drugs, manufacturing of API – Cambrex Licensing issues and business development Project forecasting software Patent registration Laboratory partner for metabolism studies Contract issues and legal advice Certified advisor, Nasdaq Stockholm Investor relations Regulatory, US Regulatory, EU/EMEA

TKT SVERIGE SELECTED INTERNATIONAL CLINICAL RESEARCH ORGANIZATIONS ARDENA UNIVERSITY OF GOTHENBURG UNIVERSITY OF MANCHESTER AND ST ANDREWS CATALENT NOTTINGHAM HJALMARSSON & PARTNERS CAPTARIO POTTER CLARKSON ADMESCOPE MAQS ADVOKATBYRÅ FNCA MSC NORDICS CLINTREX CONSILIUM SALMONSON AND HEMMINGS

The share

The IRLAB share

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

Share capital and number of votes

At year-end, IRLAB's share capital was SEK 1,034,968 divided into 51,748,406 shares with a quota value of SEK 0.02. Each share, including shares in Class B, gives the holder one vote.

Share data

The number of registered shares at the end of the financial year was 51,748,406 (48,498,406) shares, of which 51,668,630 (48,418,630) were Class A shares and 79,776 (79,776) were Class B shares.

Shareholder structure

The number of shareholders was 3,706 on December 31, 2021 – an increase of approximately 9 percent compared with the end of 2020. The ten largest shareholders held 50.4 percent of the total number of shares.

Dividends

IRLAB is in a phase that requires the preclinical and clinical development of drug candidates to be prioritized, which is why no dividend is deemed to be relevant in the coming years. The Board of Directors has proposed that no dividend be paid for the 2021 financial year.

Employees

The average number of employees in the group from January– December was 22 (18). At the end of the period, the number of full-time positions was 24 (18), distributed over 26 (21) people. The number of full-time positions, including long-term contracted consultants, was 27 (20) at the end of the period, distributed over 30 (25) people.

Executive management

The management team comprises Nicholas Waters – Chief Executive Officer, Maria Jamelid – Chief of Clinical Operations, Viktor Siewertz – Chief Financial Officer, Clas Sonesson – Chief Scientific Officer, Cecilia Stenberg – Finance and Human Resources Manager, Peder Svensson – Director of Computational Chemistry & Biology and Chief Information Officer, Joakim Tedroff – Chief Medical Officer and Susanna Waters – Director of Biology & Biostatistics.

https://irlab.se/sv/bolagsstyrning/management/

Impact from the Covid-19 pandemic

As of December 31, 2021, the global pandemic has not had any significant direct effects on IRLAB's operational activities, results or financial position.

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





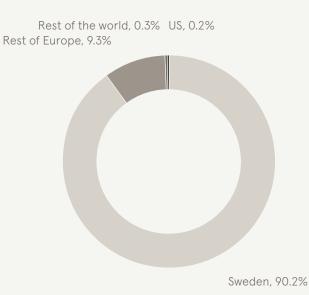


Breakdown by class of shares December 31, 2021

	Number of shareholders	Number of Class A shares	Number of Class B shares	Total number of shares	Votes and capital (%)
1-500	2,042	289,186	0	289,186	0.56%
501-1000	587	453,805	0	453,805	0.88%
1,001-5,000	652	1,461,236	0	1,461,236	2.82%
5,001-10,000	158	1,123,425	5,567	1,128,992	2.18%
10,001-25,000	121	1,909,082	1,861	1,910,943	3.69%
25,001-100,000	89	4,519,187	13,089	4,532,276	8.76%
100,001-	57	41,912,709	59,259	41,971,968	81.11%
Total	3,706	51,668,630	79,776	51,748,406	100.00%

Source: Euroclear Sweden AB

Shares per region December 31, 2021



Source: Euroclear Sweden AB

The 20 largest shareholders December 31, 2021

	Number of Class A shares	Number of Class B shares	Total number of shares	Votes (%)	Capital (%)
Försäkringsaktiebolaget,					
Avanza Pension	4,040,845	0	4,040,845	7.81%	7.81%
Ancoria Insurance Public Ltd	3,826,638	0	3,826,638	7.39%	7.39%
		0		7.08%	7.08%
Fv Group AB	3,665,626	0	3,665,626	1.00%	7.00%
Fourth Swedish National Pension Fund	3,280,366	0	3,280,366	6.34%	6.34%
Daniel Johnsson	2,690,000	0	2,690,000	5.20%	5.20%
Pension, Futur	2,055,484	0	2,055,484	3.97%	3.97%
Third Swedish National Pension Fund	1,847,994	0	1,847,944	3.57%	3.57%
Nordnet Pensionsförsäkring AB	1,684,060	0	1,684,060	3.25%	3.25%
Diklev, Jens Philip	1,595,550	0	1,595,550	3.08%	3.08%
Unionen	1,416,250	0	1,416,250	2.74%	2.74%
Marinvest Holding AB	1,208,250	0	1,208,250	2.33%	2.33%
Handelsbanken Hälsovård	1,136,311	0	1,136,311	2.20%	2.20%
Second Swedish National					
Pension Fund	1,008,493	0	1,008,493	1.95%	1.95%
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%
Ekerholm, Lennart	689,505	0	689,505	1.33%	1.33%
Sandesjö, Claes	640,000	0	640,000	1.24%	1.24%
Holm Waters, Susanna	604,704	8,946	613,650	1.19%	1.19%
Tedroff, Joakim	552,839	8,946	561,785	1.09%	1.09%
20 largest shareholders, tota	34,122,704	35,784	34,157,488	66.01%	66.01%
Other shareholders	17,545,926	43,992	17,589,918	33.99%	33.99%
Total	51,668,630	79,776	51,748,406	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.

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 efficacy.

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. "For IRLAB, the positive bottom line is a milestone of huge significance, but for a company such as ours, the very strong cash position gained from the mesdopetam transaction with Ipsen is even more important."

VIKTOR SIEWERTZ, CFO

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Administration report

The Board of Directors and the CEO hereby submit the annual report and consolidated financial statements for IRLAB Therapeutics AB, corporate identity number 556931-4692, for the January 1, 2021–December 31, 2021 financial year.

Operations

IRLAB Therapeutics AB ("IRLAB") 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 transforming life for patients with Parkinson's through novel treatments.

The company's most advanced drug candidates, mesdopetam and pirepemat, are intended to treat some of the most difficult and severe symptoms related to Parkinson's: levodopainduced dyskinesias (PD-LIDs), psychosis (PD-P) and impaired balance leading to falls (PD-Falls). Both drug candidates are currently undergoing Phase IIb studies. The company also has a unique and proprietary research platform (ISP) for developing new drug substances. The two most recently generated drug substances, IRL757 and IRL942, are both in the preclinical phase. IRL757 is being developed for the treatment of apathy in neurological diseases and IRL942 is being developed to improve cognitive function and brain health.

The parent company's operations mainly consist of providing management and administrative services to the group's operating companies. The parent company also manages group-wide issues, such as activities and information related to the stock market and other group management issues. The research and development operations are conducted in the wholly owned subsidiary Integrative Research Laboratories Sweden AB.

Research and development work

The research and development work has advanced according to plan. In the period January to December, the total costs for research and development were SEK 129,748 thousand (75,989), corresponding to 84% (83%) of the group's total operating expenses. Development costs vary over time, depending on where in the development phase the projects are.

Significant events during the 2021 financial year

In January 2021, IRLAB presented new results from preclinical studies that indicate that the drug candidate mesdopetam also has the potential to prevent the development of levodopainduced dyskinesias (involuntary and troublesome movements) in Parkinson's disease. This increases the commercial potential of mesdopetam. The substance had previously been found to be effective in the treatment of established dyskinesias, which is now being studied further in an ongoing Phase IIb/III clinical trial.

In July, it was announced that the global biopharmaceutical company Ipsen and IRLAB had entered into a license agreement, providing Ipsen with exclusive worldwide development and commercial rights to mesdopetam, IRLAB's novel investigational drug candidate for the treatment of dyskinesia and psychosis in Parkinson's. IRLAB will remain responsible for the ongoing Phase IIb/ III trial that started in the autumn of 2020. Ipsen will take over and drive the preparatory activities for the upcoming Phase III trial and will be responsible for all remaining clinical development and worldwide commercialization. IRLAB is eligible to receive up to USD 363 million and royalties. Payments include an initial up-front payment of USD 28 million and up to USD 335 million in potential development, regulatory and sales-based milestone payments, plus tiered low double-digit royalties on worldwide net sales.

In September, IRLAB was granted a new patent for the manufacturing of the drug candidate pirepemat by the US Patent Office. Pirepemat, one of IRLAB's clinical drug candidates, is under development in Phase IIb for the treatment of impaired balance and falls in Parkinson's disease.

In December, IRLAB received regulatory approval by the Swedish Medical Products Agency to begin a Phase IIb study with the drug candidate pirepemat. Having received approval from additional authorities and ethics committees in other countries, the study began in the first quarter 2022. Recruitment is expected to take 18 months.

Financial overview - group

	2021	2020	2019	2018
Net sales (SEK thousand)	207,782	0	26	18
Profit/loss after net financial items (SEK thousand) Equity ratio (%)	51,781 85	-91,653 94	-96,120 87	-74,099 94
R&D costsas a percentage of operating expenses (%)	84	83	82	80

Financial overview - parent company

	2021	2020	2019	2018
Net sales (SEK thousand)	4,059	3,274	2,828	2,321
Profit/loss after net financial items (SEK thousand) Equity ratio (%)	-21,454 99	-47,572 82	-38,201 98	-10,672 99

Appropriation of profit/loss

Amounts in SEK thousand

Proposal for the appropriation of the company's profit/loss

At the disposal of the Annual General Meeting:	
Share premium reserve	739,559,971
Accumulated deficit	-258,890,718
Loss for the year	-21,453,794
	459,215,459
The Board of Directors propose that the following be carried forward:	459,215,459 459,215,459

Comments on the income statement

Profit/loss for the period January 1–December 31, 2021 was SEK 51,781 thousand (–91,653). Earnings per share were SEK 1.00 (–1.92). The company's revenue during the period was SEK 207,906 thousand (404).

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 will be expensed over the remainder of 2021 and 2022, when the study is finalized. In 2021, SEK 11,759 thousand was expensed.

In addition, revenue from services provided to Ipsen in 2021 was SEK 10,762 thousand.

The group's operating expenses were SEK 155,330 thousand (91,862) in 2021. The increase was chiefly due to the cost of sold development projects related to the licensing of mesdopetam, which had an effect of SEK 39,091 thousand (0) on costs. The rest of the increase compared with the previous year was due to increased activity in ongoing studies and an increased number of employees, which means that other operational activity increased as well, and costs for the services provided to Ipsen, which resulted in higher costs compared with the same period in 2020.

Financing and cash flow

Cash flows from operating activities in 2021 were SEK 128,641 thousand (-89,214) and cash flows for the year were SEK 124,888 thousand (166,482). Cash and cash equivalents were SEK 401,897 thousand (277,009) on December 31, 2021. On December 31, 2021, equity was SEK 399,481 thousand (347,880) and the equity ratio was 85% (94%).

Given the current business and development plan, the executive management is of the view that there are sufficient cash and cash equivalents to cover the working capital required to carry out the development plans over the next twelve months. This mainly relates to activities within the scope of the Phase II studies with mesdopetam and pirepemat and costs for preclinical studies, new projects/drug candidates and other operating expenses.

Investments

Investments for the year were SEK 708 thousand (394).

Personnel

The average number of employees in the group from January– December was 22 (18). At the end of the year, the number of fulltime positions, including consultants with long-term contracts, was 27 (20), distributed over 30 (25) people.

Share data

The number of registered shares at the end of the financial year was 51,748,406 (48,498,406) shares, of which 51,668,630 (48,418,630) were Class A shares and 79,776 (79,776) were Class B shares. At year-end, IRLAB's share capital was SEK 1,034,968 and the quota value was SEK 0.02. Each share, including shares in Class B, gives the holder one vote.

Nomination Committee

Prior to the 2022 Annual General Meeting, and pursuant to the instructions applicable to IRLAB's Nomination Committee, the Nomination Committee comprised Daniel Johnsson (chair), Bo Rydlinger, Clas Sonesson and Gunnar Olsson, the Chair of the Board. They represent approximately 46 percent of the votes and capital in IRLAB as of August 31, 2021.

2022 Annual General Meeting

IRLAB's 2022 Annual General Meeting is planned to be held in Gothenburg, Sweden, on May 11, 2022. The Annual General Meeting will be held physically in Gothenburg with the possibility of voting in advance by post. All documents for the Annual General Meeting, including the annual report, will be made available on the company's website no later than three weeks before the Annual General Meeting.

Parent company

The parent company in the group is IRLAB Therapeutics AB, corporate identity number 556931-4692. The parent company's loss for the financial year was SEK -21,454 thousand (-197,572). Personnel expenses were SEK 8,705 thousand (7,794).

Risks and uncertainties

General information on risks in IRLAB's operations

Operations in the field of research and development of pharmaceuticals are associated with high risks, and the effects of these risks on the company's earnings and financial position cannot always be controlled by the company. 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 they should be compared with the opportunities that are inherent in projects and operations. IRLAB's operations are based on continuous evaluations and analyses of available information on risks to remain a step ahead and identify potential problems as early as possible.

Risks related to the clinical projects

Safety, tolerability and efficacy

Drug development is associated with the risk that drug candidates do not achieve an acceptable profile in terms of safety, tolerability and efficacy. Results from early preclinical and clinical studies do not always correspond to results in more extensive studies, which may lead to requirements for further studies or, in the worst case, the conclusion 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, to the extent 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 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 possibility of obtaining the necessary approvals. To remain up to date at all times regarding current regulations, guidelines and authorities' assessments, IRLAB collaborates with experienced players and advisers.

Impact of the covid-19 pandemic

As of December 31, 2021, the global pandemic has not had any significant direct effects on IRLAB's operational activities, results or financial position.

Effects in the medium to long term cannot yet be assessed,

but the company is monitoring and evaluating the situation on an ongoing basis. The circumstance that is considered to be the highest potential risk is that the recruitment of patients for future clinical trials may be delayed if the Covid-19 outbreak continues to put a strain on global healthcare resources and if restrictions on individuals' freedom of movement are extended beyond what is known today. A delay in the recruitment of patients could lead to increased costs for the company for the duration of the studies and have a negative effect on the company's possibility of carrying out rights issues, which may have an impact on the company's financial position. There are indications that healthcare providers in certain countries and regions are under pressure, which affects certain hospitals' ability to participate in clinical trials. Additionally, interactions have shown that regulatory authorities currently have longer processing times. We are therefore monitoring the situation closely and evaluating measures to minimize the effects on our projects and time schedules.

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 their 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.

Operational risks

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 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.

Financing risks

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.

Outlook for 2022

The company intends to expand the Phase IIb study with pirepemat to additional countries in Europe and additional clinics in 2022. For mesdopetam, the focus is to complete the ongoing Phase IIb/III study.

The preclinical work on the drug candidates IRL942 and IRL1009 will be accelerated according to plan so that Phase I studies can begin as soon as possible, and for the P003 program, the aim is to identify a drug candidate also in this research program in 2022.

In 2022, the company will also expand and make further use of the ISP research platform's unique discovery capacity; additional staff have been hired to further increase the activity.

The company does not expect any significant revenue in 2022 in addition to the revenue from the mesdopetam license transaction that was entered into in 2021 and additional revenue for the development of mesdopetam in collaboration with Ipsen.

Share and owners

The largest owners as at December 31, 2021 are listed in the table on page 49. 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 propose that no dividend be paid for the 2021 financial year.

Consolidated income statement

Amounts in SEK thousand	Note	2021 Jan-Dec	2020 Jan-Dec
Operating income, etc.			
Net sales	5	207,782	0
Other operating income	7	124	404
Total operating income		207,906	404
Operating expenses			
Other external expenses	8, 9	-81,737	-65,630
Personnel expenses	10	-31,024	-23,968
Unlicensed capitalized development projects		-39,091	0
Amortization, depreciation and			
impairment	8	-3,474	-2,256
Other operating expenses		-4	-8
Total operating expenses		-155,330	-91,862
Operating profit/loss		52,576	-91,458
Profit/loss from financial items			
Finance income		1	1
Finance costs	8, 11	-796	-196
Total financial items		-795	-195
Profit/loss after financial items		51,781	-91,653
Income tax	12	0	0
Profit for the year		51,781	-91,653
Earnings per share before and after dilution (SEK)		1.00	-1.92
Average number of shares before dilution		51,748,406	47,677,734
Average number of shares after dilution		51,748,406	47,677,734
Number of shares at year-end		51,748,406	51,748,406

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

Consolidated statement of comprehensive income

Amounts in SEK thousand	2021 Jan-Dec	2020 Jan-Dec
Profit/loss for the year	51,781	-91,653
Other comprehensive income	0	0
Comprehensive income for the year	51,781	-91,653

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

Consolidated statement of financial position

Amounts in SEK thousand	Note	12/31/2021	12/31/2020
ASSETS			
Non-current assets			
Intangible assets			
Research database	13	259	518
Acquired development projects	14	42,402	81,492
		42,661	82,011
Property, plant and equipment			
Leasehold improvements	15	92	95
Equipment, tools, fixture and fittings	16	1,224	1,006
Right-of-use assets	17	7,033	3,216
		8,348	4,317
Total non-current assets		51,009	86,328
Current assets			
Current receivables			
Trade receivables		4,470	0
Other receivables		6,274	4,711
Prepaid expenses and accrued income	19	8,799	2,020
		19,543	6,732
Cash and cash equivalents		401,897	277,009
Total current assets		421,440	283,741
TOTAL ASSETS		472,449	370,068

Amounts in SEK thousand	Note	12/31/2021	12/31/2020
EQUITY AND LIABILITIES			
Equity			
Share capital	20	1,035	970
Unregistered share capital		0	65
Other contributed capital		685,450	685,630
Retained earnings including comprehensive income for the year		-287,004	-338,785
Total equity		399,481	347,880
Non-current liabilities			
Lease liabilities	21	3,566	1,270
Total non-current liabilities		3,566	1,270
Current liabilities			
Lease liabilities	21	3,034	1,657
Trade payable		12,302	3,683
Other liabilities		5,645	3,773
Accrued expenses and deferred income	22	48,420	11,805
Total current liabilities		69,402	20,918
TOTAL EQUITY AND LIABILITIES		472,449	370,068

Consolidated statement of changes in equity

Amounts in SEK thousand	Share capital	unregistered share capital	Other contributed capital	Retained earnings incl. profit for the year	Total equity parent company shareholders
Amount at the beginning of 01/01/2020	the year 862	0	428,097	-247,133	181,827
Comprehensive income for the year				-91,653	-91,653
New issue Issue costs	108	65	275,322 -17,789		275,495 –17,789
Amount at year-end 12/31/2020	970	65	685,630	-338,785	347,880
Amount at the beginning of the year					
01/01/2021	970	65	685,630	-338,785	347,880
Comprehensive income for the year				51,781	51,781
New issue Issue costs	65	-65	-180		0 -180
Amount at year-end 12/31/2021	1,035	0	685,450	-287,004	399,481

Consolidated statement of cash flows

Amounts in SEK thousand	Note	2021 Jan-Dec	2020 Jan-Dec
Operating activities			
Operating profit/loss		52,576	-91,458
Adjustments for non-cash items	23	42,564	2,256
Interest received		0	1
Interest paid		-796	-196
Taxes paid		0	0
Cash flows from operating activities before changes in working capital		94,345	89,397
Cash flows from changes in working capital			
Decrease (+) /increase (-) in operating receivables		-12,811	2,620
Decrease (-) /increase (+) in operating liabilities		47,107	-2,437
Cash flows from operating activities		128,641	-89,214
Investing activities			
Acquisition of property, plant and equipment		-708	-394
Cash flows from investing activities		-708	-394
Financing activities			
Repayment of financial liabilities, lease liabilities	21	-2,865	-1,616
New issue		0	275,495
Issue costs		-180	-17,789
Cash flows from financing activities		3,045	256,091
Cash flows for the year		124,888	166,482
Cash and cash equivalents at the beginning of the year		277,009	110,527
Cash and cash equivalents at year-end	24	401,897	277,009

Parent company income statement

Amounts in SEK thousand	Note	2021 Jan-Dec	2020 Jan-Dec
Operating income, etc.	6		
Net sales		4,059	3,274
Total equity		4,059	3,274
Operating expenses	6		
Other external expenses	9	-16,805	-8,052
Personnel expenses	10	-8,705	-7,794
Total operating expenses		-25,510	-15,845
Operating profit/loss		-21,451	-12,572
Profit/loss from financial investments			
Profit/loss from participations			
in group companies		0	-35,000
Interest income and similar items		0	1
Interest expenses and similar items	11	-3	-1
Total financial items		-3	-35,000
Profit/loss after financial items		-21,454	-47,572
Appropriations			
Group contributions made		0	-150,000
Total appropriations		0	-150,000
Profit/loss before tax		-21,454	-197,572
Tax on profit/loss for the year	12	0	0
Profit/loss for the year		-21,454	-197,572

Parent company statement of comprehensive income

Amounts in SEK thousand	2021 Jan-Dec	2020 Jan-Dec
Profit/loss for the year	-21,454	-197,572
Other comprehensive income	0	0
Comprehensive income for the year	-21,454	-197,572

Parent company balance sheet

Amounts in SEK thousand	Note	12/31/2021	12/31/2020
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		465	447
Other receivables	10	655	506
Prepaid expenses and accrued income	19	636	280
		1,755	1,232
Cash and bank balances		112,970	239,693
Total current assets		114,725	240,926
TOTAL ASSETS		465,045	591,246

Amounts in SEK thousand	Note	12/31/2021	12/31/2020
EQUITY AND LIABILITIES			
Equity	20		
Restricted equity			
Share capital		1,035	970
Unregistered share capital		0	65
		1,035	1,035
Non-restricted equity			
Share premium reserve		739,560	739,740
Retained earnings		-258,891	-61,319
Profit/loss for the year		-21,454	-197,572
		459,215	480,849
Total equity		460,250	481,884
Current liabilities			
Trade payable		1,442	461
Liabilities to group companies		626	100,120
Other liabilities		753	194
Accrued expenses and deferred income	22	1,974	8,587
Total current liabilities		4,795	109,362
TOTAL EQUITY AND LIABILITIES		465,045	591,246

Parent company statement 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					
01/01/2020	862	0	482,207	-61,319	421,750
Comprehensive income for the year				-197,572	-197,572
New issue	108	65	275,322		275,495
Issue costs			-17,789		-17,789
Amount at year-end					
12/31/2020	970	65	739,740	-258,891	481,884
Amount at year-end					
01/01/2021	970	65	739,740	-258,891	481,884
Comprehensive income for the year				-21,454	-21,454
Rights issue	65	-65			0
Issue costs			-180		-180
Amount at year-end					
12/31/2021	1,035	0	739,560	-280,345	460,250

Parent company statement of cash flows

Amounts in SEK thousand	Note	2021 Jan-Dec	2020 Jan-Dec
Operating activities			
Operating profit/loss		-21,451	-12,572
Interest received		0	1
Interest paid		-3	-1
Cash flows from operating activities before changes in working capital		-21,454	12,572
Cash flows from changes in working capital			
Decrease (+) /increase (-) in operating receivables		-523	-18
Decrease (-) /increase (+) in operating liabilities		-104,567	411
Cash flows from operating activities		-126,543	-12,179
Investing activities			
Cash flows from investing activities		0	0
Financing activities			
New issue		0	275,495
Issue costs		-180	-17,789
Shareholder and group contributions made		0	-85,000
Cash flows from financing activities		-180	172,706
Cash flows for the year		-126,723	160,527
Cash and cash equivalents at the beginning of the year		239,693	79,166
Cash and cash equivalents at year-end	24	112,970	239,693

Key financial ratios for the group

	2021 Jan-Dec	2020 Jan-Dec	2019 Jan-Dec	2018 Jan-Dec
Net sales, SEK thousand	207,782	0	26	18
Operating profit/loss, SEK thousand	52,576	-91,458	-95,848	-73,897
Profit/loss for the period, SEK thousand	51,781	-91,653	-96,120	-74,099
Profit/loss for period attributable to the parent company's shareholders, SEK thousand	51,781	-91,653	-96,120	-74,099
Earnings per share before and after dilution, SEK	1.00	-1.92	-2.37	-1.94
R&D costs, SEK thousand	129,748	75,989	79,381	58,927
R&D costs as a percentage of operating expenses, %	84	83	82	80
Cash and cash equivalents at the end of the period, SEK thousand	401,897	277,009	110,527	134,442
Cash flows from operating activities, SEK thousand	128,641	-89,214	-91,201	-70,790
Cash flows for the period, SEK thousand	124,888	166,482	-23,915	59,733
Equity, SEK thousand	399,481	347,880	181,827	212,476
Equity attributable to the parent company's shareholders,	399,481	347,880	181,827	212,476
Equity per share, SEK	7.72	6.72	4.22	5.25
Equity ratio, %	85	94	87	94
Average number of employees	22	18	17	15
Average number of employees in R&D	20	17	16	14

Of the key financial ratios above, Earnings per share before and after dilution is the only key financial ratio that is mandatory and defined in accordance with IFRS. Of other key financial ratios, Profit/loss for the period, Cash and cash equivalents at the end of the period, Cash flows from operating activities, Cash flows for the period and Equity attributable to the parent company's shareholders were obtained from a financial statement defined by IFRS.

The table below derives the calculation of key financial ratios, both for the key performance measures that are mandatory according to IFRS, 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 expenses, 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 expenses 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 do not generate a steady flow of revenue; instead, revenue is generated irregularly in connection with the signing of license agreements and achieved milestones. The company therefore uses the key financial ratios 'Equity' and 'Equity attributable to the parent company's shareholders per share' to assess the company's financial position and stability. In addition to these key financial ratios, the various cash flow measures in the Consolidated statement of cash flows are used. For definitions, see the section Definitions below.

	2021	2020
Profit/loss attributable to the parent company's		
shareholders (SEK thousand)	51,781	-91,653
Average number of shares before and after dilution	51,748,406	47,677,734
Earnings per share before and after dilution (SEK)	1.00	-1.92
Operating expenses (SEK thousand)	155,330	91,862
Unlicensed capitalized development projects	-39,091	0
Administration expenses (SEK thousand)	16,982	-13,617
Amortization and depreciation (SEK thousand)	-3,474	-2,256
R&D costs (SEK thousand)	129,748	75,989
R&D costs as a percentage of operating expenses (%)	84	83
Equity attributable to the parent company's shareholders (SEK thousand)	399,481	347,880
Number of shares as at the balance sheet date, including not yet registered issues	51,748,406	51,748,406
Equity attributable to the parent company's		
shareholders per share (SEK)	7.72	6.72
Equity (SEK thousand)	399,481	347,880
Total assets (SEK thousand)	472,449	370,068
Equity ratio (%)	85	94

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 shar 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 no 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 IRL 626 AB, IRL 752 AB and IRL 790 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 control was obtained over Integrative Research Laboratories Sweden AB. On April 8, 2022, the Board of Directors approved these annual accounts and consolidated financial statements for publication.

The group's operations

The group's operations are conducted in the subsidiary Integrative Research Laboratories Sweden AB, which is a research company that develops new treatment principles for neurological and mental disorders with the aim of transforming life for patients with Parkinson's through novel treatments. The company's most advanced drug candidates, mesdopetam and pirepemat, are intended to treat some of the most difficult and severe symptoms associated with Parkinson's disease: levodopainduced dyskinesias (PD-LIDs), psychosis (PD-P) and impaired balance leading to Falls. Both drug candidates have completed Phase IIa studies. The company also has a unique and 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 to the group's operating companies. The parent company also manages group-wide issues, such as activities and information related to the stock market and 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 (IFRIC), as adopted by the EU.

The parent company's annual accounts were 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 of preparation

The consolidated financial statements were prepared in accordance with the historical cost convention. 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 reporting currency is Swedish kronor (SEK). The consolidated financial statements are stated in thousands of Swedish kronor (SEK thousand) unless otherwise stated.

New and amended standards adopted by the group

No new standards that shall be applied by the group for the first time on January 1, 2021 have had or are expected to have a material impact on the consolidated financial statements.

New standards and interpretations yet to be applied by the group

Several new accounting standards and interpretations will enter into force for accounting years beginning after January 1, 2021 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 consolidated financial statements.

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 ability 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;
- 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 consisting of a research database and 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 neces-

sary. 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 forwardlooking 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.

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:

- 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 that are intended to cover costs are reported under the heading Other revenue 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.

The parent company's accounting policies

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 straightline basis over the term of the lease.

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 the 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, 2021, currency exposure from trade payables were GBP 209 thousand, USD 29 thousand and EUR 487 thousand. 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, 2021 would have been SEK 892 thousand (159) 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 64 thousand (0).

Currency	2021 Income	2021 Costs	2021 Net exposure	2020 Income	2020 Costs	2020 Net exposure
SEK	124	112,968	-112,844	300	46,197	-45,897
USD	0	8,805	-8,805	0	3,009	-3,009
EUR	190,638	71,159	119,479	0	21,351	-21,351
GBP	124	19,455	-19,331	0	15,954	-15,954
Total expressed in SEK thousand	190,886	212,387	-21,501	300	86,511	-86,211

Less than Between 3 months Between 1 year Between 2 years Over 3 months and 5 years and 1 year and 2 years 5 years Lease liabilities 816 2,448 3.264 393 0 Trade payables 12,302 0 0 0 0 Other liabilities and accrued expenses 11,489 0 0 0 0 393 0 Total 24,607 2,448 3,264

Maturity of inancial liabilities as at December 31, 2021 (referring to undiscounted cash flows):

Interest rate risk in the cash flows

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 are in the form of bank balances and the only interest-bearing liabilities are in the form of lease liabilities.

Calculated on the basis of financial interest-bearing assets and liabilities that had a variable interest rate as at December 31, 2021, a single percentage point change in the market rate would affect the group's profit or loss after tax by SEK 3,953 thousand (2,740). The corresponding effect on the parent company would have been SEK 1,130 thousand (2,397).

Credit risk

Credit risk is the risk that a party to a transaction with a financial instrument will not be able to meet its obligations. The maximum exposure to credit risks relating to financial assets as at December 31, 2021 was SEK 412,889 thousand (277,009). The corresponding figure for the parent company was SEK 113,435 thousand (240,140). 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.

Liquidity risk

Caution in managing liquidity risk means holding sufficient cash or cash equivalents or, alternatively, holding agreed credit facilities that allow market positions to be closed. In the preparation of this financial report, the Board of Directors estimates that there is sufficient capital to complete the planned implementation of the Phase IIb study with pirepemat and the Phase II/III study with mesdopetam, which means that the capital requirement is secured for at least 12 months from the balance sheet date. The maturity structure for the group's financial liabilities is shown above.

Capital risk management

The 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.

Debt to equity ratio	12/31/2021	12/31/2020
Total interest-bearing liabilities	6,601	2,927
Less: interest-bearing assets	401,897	277,009
Net debt(+)/Net cash(-)	-395,297	-274,082
Total equity	399,481	347,880
Net debt to equity ratio	-99.0%	-78.8%

Net debt: Net debt: Interest-bearing liabilities less interest-bearing assets (including 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 was reversed, and as at December 31, 2021, it was SEK 0 (39,091 thousand). 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 42,661 thousand (82,011), of which acquired development accounted for SEK 42,402 thousand (81,492) and the research platform accounted for SEK 259 thousand (519). Changes in the assumptions made by the executive management when testing for impairment could have a material impact on the company's results and financial position.

Tax loss carry-forwards in the group were SEK 377,389 thousand (466,711) as at December 31, 2021. For the parent company, tax loss carry-forwards were SEK 266,706 thousand (245,102). 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.

The allocation of transaction prices for studies or other services associated with the sale or licensing of the drug candidate is based on the executive management's adopted budget and the market markup.

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 207,782 thousand 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)	2021	2020
Sweden United Kingdom	0 207,782	0 0
Total	207,782	0

Net sales by revenue category (SEK thousand)2021		2020
Licensing revenue Service revenue	185,261 22,521	0 0
Total	207,782	0

Note 6. Intra-group purchases and sales

Of the parent company's net revenue, SEK 4,059 thousand (3,274) was made up of invoicing to group companies. The parent company's procurement of services from group companies in 2021 amounted to SEK 939 thousand (486).

Note 7. Other operating income

The group	2021	2020
Public grants: Planning grants, EU	0	300
Exchange rate gains	0	104
Other	124	0
Total	124	404

Note 8. Leases

The group has leases, chiefly in the form of agreements for the use of office premises and certain medical equipment. When discounting future lease payments, the group's incremental borrowing rate was been used, which currently amounts to 5%.

The following amounts were reported in the income statement.

The group	2021	2020
Amounts reported in profit/loss		
Depreciation of right-of-use assets	-2,722	-1,664
Interest expenses for lease liabilities	-367	-193
Costs associated with leases of low-value assets	0	0
Costs associated with variable fees not included in the valuation of the lease liability	-187	-130

Total cash flows for leases were SEK -3,232 thousand (-1,818).

Note 9. Remuneration to auditors

	Group		Parent company	
	2021	2020	2021	2020
Fees and expense allowances				
Öhrlings PricewaterhouseCoopers AB				
Audit assignment	435	290	453	290
Audit activities outside the audit assignment	88	102	88	102
Tax advice	3	5	3	5
Other assignments	69	298	57	298
Total	613	695	613	695

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.

Other assignments refer to services provided in connection with the company's new issues.

Note 10. Employees and personnel costs

		021	= -	2020		
Average number of employees	Number of employees	Of which are men	Number of employees	Of which are men		
Parent company						
Sweden	2	2	2	2		
Subsidiary						
Sweden	20	7	16	6		
Group total	22	9	18	8		
Gender distribution.		2021		2020		

Senior executives Women Men	Women	Men
Board of Directors 2 3	3	3
CEO and other executive management 0 2	0	2
Subsidiary		
Board of Directors 2 3	3	3
CEO and other executive management 3 3	3	3

Salaries and other remuneration (SEK thousand)	2021	Group 2020	Parent 2021	company 2020
Salaries and other remuneration				
Chairman of the Board	450	450	450	450
Other board members	1,172	1,235	1,172	1,235
Chief Executive Officer	2,599	2,008	2,599	2,008
Other senior executives	6,738	5,861	1,503	1,235
Other employees	10,502	6,706	0	0
Pensions	21461	16260	5724	4928
Board of Directors	0	0	0	0
Chief Executive Officer	682	602	682	602
Other senior executives	2,122	1,871	411	344
Other employees	1,264	573	0	0
	4068	3046	1093	946
Social security contributions	4,421	3,839	1,790	1,612
	29,950	23,145	8,606	7,486

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

Fees to board members elected at a general meeting are determined by the general meeting. Remuneration to the CEO is determined by the Board of Directors. The number of board members wax six in both 2020 and 2021. Remuneration levels for board and committee work have not increased compared with the previous year.

Senior executives refer to the people who, together with the CEO, form the executive management. The executive management consists of eight people, including the CEO. Remuneration to senior executives consists of a basic salary, pension benefits, other benefits, and terms and severance pay.

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

2021 (SEK)	Position	Salary and benefits /board fee	Variable remun- eration	Pension costs	Other remun- eration	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 Dire	ectors	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 Execut and senior execut		8,154,802	1,182,080	3,484,602	1,178,017	13,999,501

2020 (SEK)	Salary an Position	d benefits/ board fee	Variable remuneratio	Pension n 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
Eva Lindgren	board member	250,000	0	0	0	250,000
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 Dir	rectors	1,685,000	0	0	0	1,685,000
Nicholas Waters	Chief Executive Officer	1,878,486	130,000	748,433	0	2,756,919
Other senior executives, 7 people		5,619,029	241,490	2,325,261	926,606	9,112,386
Total Chief Execu and senior execut		7,497,515	371,490	3,073,694	926,606	11,869,305

The notice period for the CEO is twelve months, regardless of which party gives the notice; however, the CEO has a notice period of eighteen months in certain situations. The notice period for the CSO, the Director of Biology & Biostatistics and the Director of Computational Chemistry & Biology/CIO is six months, regardless of which party gives the notice. For other senior executives who are employees, the notice period that applies is that provided in the applicable collective agreement, which currently ranges from one to three months. Cecilia Tivert Stenberg's consulting agreement 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. For defined contribution plans, the group makes fixed contributions to insurance companies. The retirement age is 65. 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 premium is 28% of his regular salary. The pension costs reported above include special employer's contribution.

Martin Nicklasson was elected to the Board of Directors at the Annual General Meeting on May 6, 2021. On December 31, 2021, he resigned from the Board of Directors.

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

	Group		Parent company	
	2021	2020	2021	2020
Interest expenses, group companies	0	0	0	0
Interest expenses, lease liability	-367	-193	0	0
Interest expenses, other	-3	-2	-1	-1
Exchange rate losses	-426	0	-2	0
Total	-796	-196	-3	-1

Note 12. Income tax

	c	Group		company
	2021	2020	2021	2020
Current tax	0	0	0	0
Deferred tax	0	0	0	0
Total	0	0	0	0
Theoretical tax				
Reported profit/loss before tax	51,781	-91,653	-21,454	-197,572
Tax according to the applicable tax rate, 20.6% (21.4%)-10,667	19,614	4,419	42,281
Reconciliation of reported tax				
Effect of expenses that are not deductible	-29	-9	-6	-7,496
Effect of loss carry-forwards not valued	-15,807	-53,831	-4,450	-38,592
Effect of utilized loss carry-forwards not previously valued	26,466	30,420	0	0
Effect of costs reported in equity	37	3,807	37	3,807
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 377,389 thousand (466,711) as at December 31, 2021. For the parent company, tax loss carry-forwards as at December 31, 2021 were SEK 266,706 thousand (245,102). None of the loss carry-forwards are limited in time. Of the tax loss carry-forwards, SEK 39,716 thousand (77,325) were valued in the group, and SEK 0 (0) were valued in the parent company.

Group	Deferred tax assets		Deferred tax liability	
	2021	2020	2021	2020
Opening reported value	15,929	15,976	-15,929	-15,976
Change via the income statement for the year	-6,244	-47	6,244	47
Reported value	9,685	15,929	-9,685	-15,929

Temporary differences are found in the following items:

	Group	
	2021	2020
Intangible assets	-8,236	-15,963
Right-of-use assets	-1,449	-688
Current receivables	144	95
Lease liabilities	1,360	627
Tax loss carry-forwards	8,181	15,929
Carrying amount	0	0

Note 13. Research database

	Group	
	2021	2020
Opening cost	1,036	1,036
Closing accumulated cost	1,036	1,036
Opening amortization	-518	-259
Amortization for the year	-259	-259
Closing accumulated amortization	-777	-518
Carrying amount	259	518

Note 14. Acquired development projects

	2021	Group	2020
Opening cost	81,492		81,492
Sales and disposals	-39,091		0
Closing accumulated cost	42,402		81,492
Carrying amount	42,402		81,492

Note 15. Leasehold improvements

	2021	Group 2020
Opening cost	116	116
Closing accumulated cost	116	116
Opening depreciation	-21	-15
Translation differences for the year	-3	-6
Closing accumulated depreciation	-24	-21
Carrying amount	92	95

Note 16. Equipment, tools, fixtures and fittings

	Group		
	2021	2020	
Opening cost	2,941	2,547	
Acquisitions	708	394	
Closing accumulated cost	3,651	2,941	
Opening depreciation	-1,936	-1,609	
Depreciation for the year	-490	-327	
Closing accumulated depreciation	-2,426	-1,936	
Carrying amount	1,224	1,006	

Note 17. Right-of-use assets

	Group	
	2021	2020
Opening cost, IFRS 16	6,544	6,544
Acquisitions	6,539	0
Terminated over the year	-143	
Closing accumulated cost	12,940	6,544
Opening depreciation	-3,328	-1,664
Depreciation for the year	-2,722	-1,664
Terminated over the year	143	
Closing accumulated depreciation	-5,907	-3,328
Carrying amount	7,033	3,216

Note 18. Participations in group companies

	Corporate	•		Share of		Carrying amount	
Company	identity No.	Seat	Number	capital	2021	2020	
Integrative Resea Laboratories	arch						
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	2021	2020
Opening cost	350,320	350,320
Shareholder contributions	0	35,000
Impairment of participations in subsidiaries	0	-35,000
Carrying amount	350,320	350,320

Note 19. Prepaid expenses and accrued income

	Group P		Parent o	Parent company	
	2021	2020	2021	2020	
Prepaid insurance	393	531	370	242	
Other prepaid expenses	1,886	1,489	266	38	
Accrued R&D deductions	231	0	0	0	
Other accrued income	6,288	0	0	0	
Reported value	8,799	2,020	636	280	

Note 20. Equity

Number of shares	2021	Group 2020
Registered number of shares	51.748.406	48.498.406
	51,748,406	48,498,406
Average number of shares, before and after dilution	51,748,406	47,677,734
	51,748,406	47,677,734

The registered number of shares comprises 51,748,406 (48,416,630) Class A shares and 79,776 (79,776) Class B shares. Class A and Class B shares confer a right to one vote each. The quota value for all shares is SEK 0.02 per share. Only Class A shares have been admitted to trading on Nasdaq Stockholm.

Share capital development

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
At the	e end of the period	1 784,593,373	1,034,968		51,748,406		0.02

The issued amount above is the total issued amount, including share premiums 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)

The Board of Directors proposes that SEK 459,215,459 be carried forward	459,215,459
	459,215,459
Loss for the year	-21,453,794
Accumulated deficit	-258,890,718
Share premium reserve	739,559,971
At the disposal of the Annual General Meeting:	

Note 21. Lease liabilities

	G 2021	roup 2020	
Opening carrying amount	2,927	4,543	
Added over the year		6,538 0	
Repayments over the year, affecting cash flows		-2,865 -1,616	
Carrying amount	6,600	2,927	
Non-current part	3,566	1,270	
Current part	3,034	1,657	

Note 22. Accrued expenses and deferred income

	Group		Parent company	
	2021	2020	2021	2020
Personnel-related expenses	4,495	4,226	1,365	1,717
Other prepaid expenses	1,349	7,025	610	6,870
Contract liability	42,576	0	0	0
Reported value	48,420	11,250	1,974	8,587

Note 23. Non-cash items

	Group
2021	2020
Amortization and depreciation 3,474	2,256
Licensed capitalized development projects 39,090	0
Total 42,564	2,256

Note 24. Cash and cash equivalents

	G	iroup	Parent	ent company	
	2021	2020	2021	2020	
Cash in hand	4	4	1	1	
Bank deposits	401,893	277,005	112,969	239,692	
Total cash and cash equivalents	401,897	277,009	112,970	239,693	

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 465 thousand and a liability to a group company of SEK 626 thousand.

Information on sales to and purchases from group companies is provided in Note 6.

Note 26. Financial instruments by category

		Group	Paren	t company
	2021	2020	2021	2020
Financial assets at amortized cost				
Trade receivables	4,470	0	0	0
Other Receivables	3	81	465	447
Accrued income	6,288	0	0	0
Cash and cash equivalents	401,897	277,009	112,970	239,693
	412,658	277,090	113,435	240,140
Financial liabilities at amortized cost				
Lease liabilities	6,600	2,927	0	0
Trade payables	12,302	3,683	1,442	461
Other liabilities and accrued expenses	11,489	7,089	3,353	106,990
	30,391	13,699	4,795	107,452

Financial assets 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 4,470 thousand (0).

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

In March, it was announced that the company had selected a new drug candidate, IRL757, from the P001 research program. The intention is to develop IRL757 for the treatment of apathy in neurological diseases.

In March, the company held a capital markets day for owners, investors, analysts and the media.

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 faithful representation of the group's financial position and results of operations.

The financial statements of 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, April 8, 2022

GUNNAR OLSSON Chair of the Board CAROLA LEMNE Vice Chair

REIN PIIR Board member LARS ADLERSSON Board member

LENA TORLEGÅRD Board member

NICHOLAS WATERS CEO

Our audit report was submitted on April 14, 2022 Öhrlings PricewaterhouseCoopers AB

Johan Rippe Authorized Public Accountant Auditor-in-charge Martin Oscarsson Authorized Public Accountant

Auditor's report

Report on the annual report and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of IRLAB Therapeutics AB for the year 2021. The annual accounts and consolidated accounts of the company are included on pages 54–95 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 the parent company and the group as at December 31, 2021 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 at December 31, 2021 and its financial position of the group as at December 31, 2021 and its financial position of the group as at December 31, 2021 and its 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 income statement and the statement of financial position for 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 Article 11 of the Audit Regulation (537/2014).

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 Article 5.1 of the Audit Regulation (537/2014) have been provided to the audited com any 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

The scope of the audit

We designed our audit by determining materiality and assessing the risks of material misstatement in the consolidated accounts. 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 audits, we also addressed the risk that the Board of Directors and CEO override 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 accounts 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 financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall group materiality for the consolidated accounts as a whole. 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 judgement, were of most significance in our 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.

Key audit matter

How this matter was considered in the audit

Revenue recognition

The group reported net sales of SEK 207.8 million in 2021 that refer to revenue from the licensing of the drug candidate mesdopetam and associated services. The revenue was recognized in accordance with *IFRS 15 Revenue from contracts with customers*, and based on this standard, the executive management have allocated transaction price based on the various performance obligations in the contract and determined the extent to which these performance obligations were met during the financial year. The company's accounting policies for revenue recognition are explained in Note 2.

We have reviewed the agreement for the licensing and associated services to determine the reasonableness of the executive management's estimates and assumptions related to revenue recognition.

We have evaluated whether the transaction price has been allocated to identifiable performance obligations and evaluated the executive managements assessment of the extent to which these performance obligations were met during the financial year.

We have finally evaluated whether the disclosures made in the annual accounts meet the disclosure requirements in *IFRS 15 Revenue from Contracts with Customers* in a satisfactory manner.

Valuation of acquired development projects

The group's assets include intangible assets regarding acquired development projects totaling SEK 42.4 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 valuation of the development projects is based on the executive management's estimates of future cash flows and assumptions on required returns, etc., which means that the nature of the valuation is subject to uncertainty, as it may be affected by unexpected future events.

Based on the impairment testing performed, the executive management has determined that there is no impairment loss.

A description of the essential estimates and assumptions made when testing for impairment can be found in Note 4.

Our review of the executive management's impairment testing of acquired development projects included a review of the company's documentation, where we assessed whether the impairment testing was performed in accordance with applicable accounting policies and generally accepted valuation models.

We have discussed the methods, estimates and assumptions on which the company's impairment testing was based. We have reviewed and assessed the reasonableness of assumptions of future cash flows, discount rates and other essential estimates presented to us by the Board of Directors. When applicable, we have checked indata against relevant documentation and reviewed the executive management's sensitivity analyses.

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.

Other information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts which is found on pages 1–53. 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 Directors and the CEO

The Board of Directors is responsible for ensuring that the annual accounts and consolidated accounts are drawn up and provide a fair view according to the Swedish Annual Accounts Act. 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 board of director's 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 where such a material misstatement 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.

As part of an audit according to ISA, we use our professional judgment and maintain a professionally skeptical attitude throughout the audit process. We also:

- identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and purpose according to its to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud – is higher than for one resulting from mistakes, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of the company's internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors and the CEO.
- conclude on the appropriateness of the board of directors' CEO's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate-,

to modify our opinion about the annual accounts consolidated accounts financial statements. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company to cease to continue as a going concern.

- evaluate the overall presentation, structure and content of the annual report and consolidated accounts, including the disclosures, and whether the annual report and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit.We remain solely responsible for our audit opinion.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence and, where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the risks deemed most important for material misstatements, and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter.

Report on other legal and regulatory requirements

Report on the audit of the administration 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 Directors and the CEO of IRLAB Therapeutics AB for the year 2021 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 Directors 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 Directors and the CEO

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's 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.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined the Board of Directors' reasoned statement and a selection of supporting evidence in order to be able to assess whether the proposal is in accordance with the Companies Act.

The auditor's examination of the ESEF report

Opinions

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 (publ) for the financial year 2021.

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

In our opinion, the ESEF report #[checksumma] has been prepared in a format that, in all material respects, enables uniform electronic reporting.

Basis for opinions

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 (publ) 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 Directors and the CEO

The Board of Directors and the CEO are responsible for the preparation of the ESEF report in accordance with 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 Swed-ish 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 firms apply 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 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 audit 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 technical validation of the ESEF report, i.e., if the file containing the ESEF report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 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 ESEF report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, financial position, changes in equity and cash flow. Öhrlings PricewaterhouseCoopers AB, 113 97 Stockholm, was appointed auditor of IRLAB Therapeutics ABs by the general meeting of the shareholders on May 6, 2021 and has been the company's auditor since December 9, 2016.

IRLAB Therapeutics AB has been a public-interest entity since September 30, 2020, when the shares of IRLAB Therapeutics AB were admitted to trading on a regulated market.

Gothenburg, April 8, 2022

Öhrlings PricewaterhouseCoopers AB

Johan Rippe Authorized Public Accountant Auditor-in-charge

Martin Oscarsson Authorized Public Accountant



2021 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 complies with 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 2021 financial year and has been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Corporate Governance Code. The report has been reviewed by the company's auditor.

Deviations from the Code

In 2021, Clas Sonesson was a member of the Nomination Committee. Sonesson is a member of the company's executive management, one of the company's founders and represents a group of founders, who are also shareholders, in the Nomination Committee. It is therefore reasonable that he is allowed to exercise influence on the Nomination Committee on behalf of the founders.

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 of Directors and the executive management, where the bodies exercise their responsibility, influence, and control in relation to each other.

Shareholders

The shareholders' influence is primarily exercised through the right to vote at General Meetings 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 May 11, 2022, owners were invited to submit proposals no later than the January 15, 2022. For information on the share and the owners, please refer to IRLAB's Annual Report.

General Meetings

The Annual General Meeting is the company's highest decisionmaking 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 adopts the company's income statement and balance sheet, resolves on the appropriation of the company's profit or loss, discharges the board members and the CEO from liability, appoints the Board of Directors, the Chair of the Board and the auditor and resolves on the remuneration to the Board of Directors and the auditor. The General Meeting also decides on issues of shares, convertibles, options and other financial instruments and authorizes the Board of Directors to pass resolutions on such issues.

The Annual General Meeting shall also adopt instructions for the appointment and work of the Nomination Committee and resolve on 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.

Annual General Meetings and Extraordinary General Meetings are convened by publishing a notice in *Post- och Inrikes Tidningar* and making the notice available on the company's website. The fact that a meeting has been convened shall also be advertised in the Swedish business daily, *Dagens industri*.

2021 Annual General Meeting

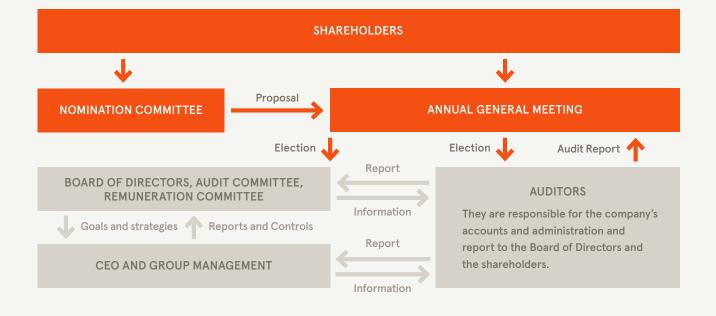
IRLAB's 2021 Annual General Meeting was held in Gothenburg on May 6. The following resolutions were passed at the Annual General Meeting:

- Resolution that the General Meeting should be held in an open format in such a way that the General Meeting could be webcast in the form of audio and video recordings.
- Resolution on the adoption of the income statement and balance sheet for both the parent company and the group.
- Resolution that the company's profit/loss should be carried forward.
- Resolution to discharge the Board of Directors and the CEO from liability for the 2019 financial year.
- Resolution authorizing the Board of Directors to issue a maximum of 10,000,000 Class A shares.
- Resolution on the re-election of Lars Adlersson, Gunnar Olsson, Rein Piir, Lena Torlegård and Carola Lemne as board members and the election of Martin Nicklasson as a new board member. Resolution on the election of Gunnar Olsson as Chair of the Board and Carola Lemne as Vice-chair.
- Resolution on the re-election of the firm of auditors Öhrlings PricewaterhouseCoopers AB as auditor, with a note that Johan Rippe has been appointed auditor-in-charge.
- 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.

The minutes from the 2021 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.

2022 Annual General Meeting

IRLAB's 2022 Annual General Meeting will be held on May 11, 2022. The Annual General Meeting will be held physically in Gothenburg with the possibility of voting in advance by post. For the right to participate or to obtain more information, please refer to the notice on the company's website, once it has been



INTERNAL GOVERNING INSTRUMENTS

- Business concept, strategies and goals
- Articles of Association
- Rules of Procedure for the Board of Directors
- Instructions to the Audit and Remuneration Committees
- $\boldsymbol{\cdot}$ CEO instruction
- Internal control systems

EXTERNAL GOVERNING INSTRUMENTS

- The Swedish Companies Act
- The Swedish Annual Accounts Act
- The Swedish Corporate Governance Code
- Nasdaq Stockholm's Rulebook for Issuers

published. 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 at August 31 in 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 held on May 6, 2021 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 5, 2021, 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 evaluate submitted proposals for new board members to ensure that the Board has the appropriate expertise, experience and background. The Nomination Committee's proposals for the Board of Directors and the Chair of the Board shall be submitted to the owners no later than in connection 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 deputy board members
- Remuneration to the members of the board and to members of any committees
- The number of auditors and deputy auditors
- The auditor
- The auditor's fee

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

The Nomination Committee's work prior to the 2022 AGM

The Nomination Committee held meetings in addition to a number of telephone calls. The evaluation of the incumbent Board of Directors' work, expertise, experience and composition was 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 the board members, conducted by an external independent party
- Interviews with individual board members
- The Chair of the Board's, the CEO's and the executive management's reports on the company's operations, goals and strategy.

Prior to the 2022 Annual General Meeting, the Nomination Committee consisted of the Chair of the Board and representatives for the three largest owners or groups of owners, according to Euroclear Sweden AB on August 31, 2021, which represented approximately 46 percent of the number of shares and votes in the company. The three largest owners or owner groupings were 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, 2021). 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 measures on its own, 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 and the Board of Directors' and the CEO's administration in accordance with an audit plan established together with the Board of Directors or the Audit Committee. In connection with the audit, the auditors shall report their observations to the group management and 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 give an account of their audit and their recommendations in the auditor's report.

The Company's auditors

Since the Extraordinary General Meeting on November 30, 2016, the company's auditor has been the registered firm of auditors, Öhrlings PricewaterhouseCoopers AB ("PwC"), which was also re-elected at the Annual General Meeting on May 6, 2021. PwC 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 Martin Oscarsson.

The auditor has audited the annual report and the consolidated accounts for the January 1, 2021–December 31, 2021 financial year and reviewed the interim 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 Auditor's Report but also through specific opinions on the Corporate Governance Report, the reviewed interim report and compliance with the guidelines for remuneration to senior executives. These are presented to the Annual General Meeting.

The auditor 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 was made to the Board of Directors without the executive management being present.

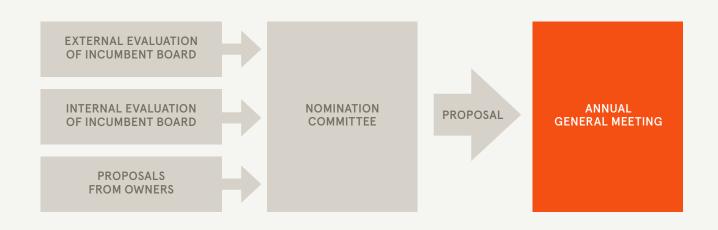
The fees invoiced by the auditor in the last two financial years are reported in Note 9 in the 2021 Annual Report.

Board of Directors

The Board of Directors' responsibilities and work

The Board of Directors is the company's highest decisionmaking body after the Annual General Meeting, and pursuant to the Swedish Companies Act, it is responsible for the company's administration and organization.

NOMINATION COM	NOMINATION COMMITTEE FOR THE 2022 ANNUAL GENERAL MEETING							
Board member	Appointed by							
1) Daniel Johnsson	Group of owners who represent approximately 21% of the shares and votes							
2) Bo Rydlinger	Group of owners who represent approximately 15% of the shares and votes							
3) Clas Sonesson	Group of owners, consisting of the company's founders, who represent approximately 10% of the shares and votes							
4) Gunnar Olsson	Chair of the Board							



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, making decisions on particularly important issues after preparation by the executive management, ensuring and monitoring procedures and systems for risk management and evaluating the operational management.

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

Composition and independence of the Board of Directors

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

After the Annual General Meeting on May 6, 2021, IRLAB's Board of Directors has consisted of six board members and no deputy board members: Gunnar Olsson (Chair of the Board), Lars Adlersson, Carola Lemne, Martin Nicklasson, Rein Piir and Lena Torlegård. At the end of 2021, Nicklasson notified his intention to resign from the Board of Directors. Thereafter, the Board of Directors comprised the remaining five board members elected at the Annual General Meeting. Information about the board members, with information on their year of birth, year of election to the Board, education, experience, Current assignments and shareholdings in the company as at March March 31, 2022, can be found on pages 112–113. 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 himself 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 so that they can familiarize themselves with IRLAB's operations and have the conditions needed 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's tasks include maintaining and improving the efficiency of the contact with the group's auditors, supervising the procedures for accounting and financial reporting and supervising the internal audit of 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.

Rules of Procedure for the Board of Directors

At the Statutory Board Meeting, which is held after the Annual General Meeting, the Board of Directors adopts the 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 adopted after the Annual General Meeting on May 6, 2021, 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 significant events in 2021

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 must 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 improve 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 participates as rapporteur in matters that fall within his area of responsibility. The company's legal counsel also attends regularly and keeps the minutes.

In 2021, the Board of Directors held fifteen meetings, relatively evenly spread over the year.

The most important resolution passed in 2021 was the approval of the license agreement for mesdopetam. Otherwise, the year was dominated by strategic issues, contacts with the international capital market, financing matters and business development, including licensing matters. The Board of Directors was also involved in strategic issues regarding the company's research portfolio and business development and continuously received reports on the company's operations.

The Board of Directors continuously evaluates its work internally and engages an independent external party to carry out an annual survey-based evaluation. Based on the results of the survey, the Board of Director'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 adminis-

Annual cycle for internal control at IRLAB



IRLAB THERAPEUTICS 2021 ANNUAL REPORT

tration. 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 of Directors and the CEO is primarily governed by the instruction to the CEO as adopted by the Board of Directors on the Statutory Board Meeting.

To summarize, the instruction states that the CEO is responsible for the following:

- Leading the business according to the Board of Directors' guidelines
- Ensuring that the company's accounting is kept in accordance with law
- Ensuring that taxes and fees are paid on time
- Ensuring that the company keeps to the budget and implementing plans so that established goals are met
- Ensuring that the company complies with 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 the 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' 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 2021, in addition to the CEO, the executive management comprised the Chief Scientific Officer (CSO), the Chief Medical Officer (CMO), the Director of Biology and Biostatistics, the Director of Computational Chemistry and Biology (CIO), the Finance and Human Resource Manager, the Chief Financial Officer (the CFO) and the Director of Clinical Operations. Accordingly, the executive members comprise eight individuals. For more information about IRLAB's senior executives such as when they took up their positions, their year of birth, education, experience, shareholding in the company and Current assignments, please see pages 114–116.

Remuneration of 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 6, 2021, resolved that a fee of SEK 1,685,000 be paid to the Board of Directors, of which SEK 400,000 is shall be paid to the Chair of the Board and SEK 200,000 shall be paid 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 shall be paid to the Chair of the Committee and SEK 50,000 shall be paid to the Board's Remuneration Committee, of which SEK 50,000 shall be paid to the Daird's Remuneration for the Committee and SEK 50,000 shall be paid to the Chair of the Chair of the Chair of the Committee, of which SEK 50,000 shall be paid to the Chair of the Chair of the Committee and SEK 50,000 shall be paid to the Chair of the Committee and SEK 50,000 shall be paid to the Chair of the Committee and SEK 30,000 shall be paid to each of the other committee members.

Name	Lars Adlersson	Carola Lemne	Martin Nicklasson	Gunnar Olsson	Rein Piir	Lena Torlegård
Board function	Board member	Vice Chair of the Board	Board member	Chair of the Board	Board member	Board member
Elected in	2017	2019	2021	2017	2016	2018
Independent in rela- tion to the company and the executive management	Yes	Yes	Yes	Yes	Yes	Yes
Independent in relation to the major owners	Yes	Yes	Yes	Yes	Yes	Yes
Board fees ¹	200,000	200,000	150,000	400,000	200,000	200,000
Fee for the Remun- eration Committee ¹	-	30,000 (member)	-	50,000 (chair)	-	30,000 (member)
Fee for the Audit Committee ¹	50,000 (member)	_	37,500 (member)	-	75,000 (chair)	-
Presence at board meetings ²	15	15	9	15	15	15
Presence at committee meetings ³	4	4	2	4	4	4

¹ Fees refer to remuneration decided by the Annual General Meeting, excluding social security contributions, for the period from the 2021 Annual General Meeting to the 2022 Annual General Meeting.

Martin Nicklasson's fee has been adjusted to reflect his active time on the Board of Directors

² The Board of Directors held six meetings before the 2021 Annual General Meeting and nine meetings after the 2021 Annual General Meeting. Eva Lindgren was present at all six meetings prior to the Annual General Meetings.

³ The Audit Committee held four meetings, and the Remuneration Committee held four meetings, in 2021.

The company is a party to a collective agreement and complies with applicable agreements and rules. The CEO and the company's executive management 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. In accordance with the guidelines adopted at the Annual General Meeting on May 6, 2021, the remuneration shall consist of a fixed salary, pension and other benefits.

Internal control and risk management

The Board of Directors' responsibility for internal control is governed by the Swedish Companies Act, the Swedish Annual Accounts Act and the Swedish Corporate Governance Code. The Board of Directors shall ensure that the company has good internal control and formalized procedures that 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 internal control procedures for financial reporting have been designed 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 2021. These systems include not only risk assessments and control procedures for financial reporting, but for the entire business.

Control environment

Good internal control is based on a functioning control environment. At IRLAB, the control environment includes 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 financial reporting. The Board of Directors' instructions to the CEO and an adopted reporting instruction determine how the financial reporting to the Board should 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 required to assess risks on an ongoing basis and meet the requirements for correct financial reporting.

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

Risk assessment

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

The identified most significant risks related to financial reporting are managed through control structures based on the reporting of deviations from the established goals or from established standards.

Control activities

The design of IRLAB's control activities is based on clear roles in the organization that allow an effective division of responsibilities for specific control activities, such as authorization control in IT systems, business systems and certification procedures. The continuous analysis of the financial reporting is highly important to ensure that the financial reporting does not contain any material misstatements.

Information and communication

Internal information and communication involve ensuring that those of 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. If required, the executive management deals with such issues at management group meetings, and other employees are regularly informed of any changes that affect their ability to make decisions or affect the impact of their decisions on the financial reporting. The company has adopted a system that ensures that all employees receive the relevant documents.

The external information aims to keep the market up to date regarding the company's development and ensure that IRLAB complies with the requirements on the correct provision of information 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 is able to monitor 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.

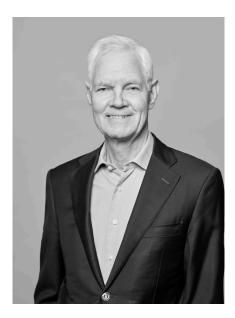
The external auditors, the company's finance function and the Audit Committee have regular contact throughout the financial year to identify any risks at an early stage and deal with any issues that may affect the financial reporting. The auditors also report regularly to the Board of Directors, chiefly 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 skills and qualifications, and the main principle is that everyone with the relevant expertise 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



Gunnar Olsson, born in 1953

Chair of the Board since 2020. Board member since 2017. Independent in relation to the company, the executive management and the company's major shareholders.

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

Current assignments: Chair of the Board of Betagenon AB and Betagenon Bio AB. Board member of Olsson Solutions AB, Gesynta Pharma AB and Hjärt-Lungfonden.

Holding: 4,000 Class A shares.



Carola Lemne, born in 1958

Board member and Vice-chair. Board member since 2018. 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, 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 Försäkringar, and has also been a board member of the Swedish Foundation for Strategic Research, the State Delegation for Clinical Research, Stockholm University, the Research Institute of Industrial Economics and the Swedish Corporate Governance Board and has been the Chair of the Swedish Education Council for Clinical Trials at Uppsala University.

Current assignments: Chair of the Board of UF Support AB, Internationella Engelska Skolan i Sverige AB, Internationella Engelska Skolan i Sverige Holdings AB, Internationella Engelska Skolan i Sverige Holdings I AB, Internationella Engelska Skolan i Sverige Holdings II AB and Art Clinic Holding AB. Board member of Arjo AB, Calgo Enterprise AB, Ramatuelle Holdings III AB, IES Skolfastigheter AB and Bostadsrättsföreningen Munklägret nr 14. Principal and board member of King Gustav V's anniversary fund.

Holding: 9,000 Class A shares.



Rein Piir, born in 1958

Board member since 2016. Independent in relation to the company, the executive management and the company's major shareholders.

Education and background: Many years of experience advising publicly held 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.

Current assignments: Chair of the Board of Piir & Partner AB. Board member of L. E. Svensson Snickeri AB 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, held directly and via companies/related parties.



Lars Adlersson, born in 1964

Board member since 2017. Independent in relation to the company, the executive management and the company's major shareholders.

Education and background: Master of Business Administration from Uppsala University and has also completed strategy and management training at Duke University, London Business School and IFL Executive Education. 30 years of experience from the life science industry, including as CEO of Medivir, Managing Director of GlaxoSmith-Kline, Austria and Sweden, and Senior Analyst at Handelsbanken Capital Markets. Lars Adlersson is currently a Partner and Senior Advisor at Adlersson Heath AB.

Current assignments: Chair of the Board of Adlersson Heath AB and Bostadsrätts-föreningen Östbra.

Holding: 3,000 Class A shares.



Lena Torlegård, born in 1963

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

Education and background: Master of Business Administration from the Stockholm School of Economics. Lena Torlegård has been an advisor in financial and corporate communications to a large number of companies, including in the life sciences sector.

Current assignments: Board member of Codesign Sweden AB, Nanologica AB (publ), Annexin Pharmaceuticals AB (publ), Synartro AB and Lena Torlegård AB.

Holding: 10,000 Class A shares.

Current assignments refer to assignments registered with the Swedish Companies Registration Office as of March 29, 2022 and do not include assignments within the IRLAB group. Shareholdings refer to holdings registered in the Euroclear Sweden AB share register as of February 28, 2021.

Management



Nicholas Waters, born in 1962

Chief Executive Officer since 2013.

Education and background: He worked in the Nobel laureate Arvid Carlsson's research group at the Department of Pharmacology at the University of Gothenburg from 1987-2000. He received his doctorate in 1995. In 1996, he was a Swedish Brain Foundation fellow. In 1998, he co-founded A Carlsson Research AB (CR) and then worked as the Head of Research in the company until 2006, when he was appointed CEO. He worked as CEO of CR and Neurosearch Sweden AB from 2006-2012. He was a board member of A Carlsson Research AB from 1998-2002 and of NeuroSearch Sweden AB from 2006-2012. From 2010-2012. he was also the Executive Vice President Research at NeuroSearch A/S. From 2007-2010, he was a board member of Sweden BIO. 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 held directly and the others are held via related parties.



Viktor Siewertz, born in 1971

Chief Finance Officer (CFO) of IRLAB since 2017. Prior to that, he was the Chief Operating Officer (COO) from 2016.

Education and background: He has worked as an accountant, a financial advisor and in his own business as support to senior managements in small and medium-sized companies and has experience in strategy, financing, raising

capital and company transfers, including at Deloitte, Speed Ventures, HSH Nordbank, Handelsbanken and the company he co-owns, Investigium AB.

Current assignments: Board member of Vestigium AB, Investigium AB, FTT Holding AB, Slavestigium AB and Ignavia AB. Deputy board member of HyrMax Rental AB, Moorgate Investment AB, Töreboda Vind AB, FTT Sweden AB, DB Mat AB, ContentMap Holding AB, Gris & Kalv i Sjöbo AB and Traxmitech AB.

Holding: 223,465 Class A shares, held directly and via companies/related parties.



Clas Sonesson, born in 1961

Chief Scientific Officer (CSO) since 2013.

Education and background: He worked as a medicinal chemist and doctoral student in the Nobel Laureate Arvid Carlsson's research group at the Department of Pharmacology at the University of Gothenburg from 1989-2000. In 1998, he co-founded A Carlsson Research AB, which was sold to NeuroSearch Sweden A/S in 2006 and changed its name to NeuroSearch Sweden AB, At A Carlsson Research AB/NeuroSearch Sweden AB, he was a board member from 1998-2002. Head of Medicinal Chemistry from 2000-2002, Director of Chemistry & IP from 2002-2009, Head of Discovery from 2009-2011 and Vice President Chemistry & IP from 2011-2012. During his 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 Class B shares.



Joakim Tedroff, born in 1961

Chief Medical Officer (CMO) since 2013.

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

Current assignments: Board member of Tedroff NeuroCare AB and Linnea Pharma AB. Deputy board member in Palette Film AB.

Holding: 656,339 Class A shares, 8,946 Class B shares and 8,049 subscription warrants, corresponding to 40,245 Class A shares, held directly and via companies/related parties.



Peder Svensson, born in 1962

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

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

Holding: 252,979 Class A shares and 8,946 Class B shares, held directly and via companies/related parties.



Susanna Holm Waters, born in 1966

Director of Systems Pharmacology since 2013.

Education and background: She worked in the Nobel laureate Arvid Carlsson's research group at the Department of Pharmacology at the University of Gothenburg from 1993–2000. In 1998, she co-founded A Carlsson Research AB. At A Carlsson Research/NeuroSearch Sweden AB, she was Director of Computational Biology & Biostatistics from 2000–2006, Director of Molecular Biology & Pharmacokinetics from 2007–2010 and Director of Biology from 2011–2012. In 2013, she co-founded IRLAB Sweden. She also worked clinically, as a doctor at Sahlgrenska University Hospital, from 2015 to 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 held directly and the others are held via related parties.



Maria Jalmelid, born in 1979

Chief of Clinical Operations since 2018.

Education and background: Master's degree in Medical Biology from Linköping University, specializing in clinical trials. She has 15 years of experience from the pharmaceutical industry and clinical trials in various phases, mainly from AstraZeneca but also from academic research projects.

Holding: 2,752 Class A shares.



Cecilia Tivert Stenberg, born in 1957

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

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

Current assignments: Board member of Terzett Konsult Aktiebolag and Tivert Konsult AB. Deputy board member of 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, held directly and via companies/related parties.

Current assignments refer to assignments registered with the Swedish Companies Registration Office as at March 29, 2022 and do not include assignments within the IRLAB group. Shareholdings refer to holdings registered in the Euroclear Sweden AB share register as at February 28, 2021. Gothenburg, April 8, 2022

GUNNAR OLSSON Chair of the Board

REIN PIIR Board member

LENA TORLEGÅRD Board member

NICHOLAS WATERS

CAROLA LEMNE Vice Chair

LARS ADLERSSON Board member

Auditor's report on the corporate governance report

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

Engagement and responsibility

The Board of Directors is responsible for the 2021 Corporate Governance Report on pages 103-117 and it has been prepared in accordance with the Annual Accounts Act.

The scope of the audit

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the Corporate Governance Report. This means that our examination of the Corporate Governance Report 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 Report has been prepared. Disclosures in accordance with Chapter 6, Section 6, second paragraph, items 2-6 of the Annual Accounts Act and Chapter 7, Section 31, second paragraph of the same act are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

Gothenburg, April 8, 2022

Öhrlings PricewaterhouseCoopers AB

Johan Rippe Authorized Public Accountant Auditor-in-charge

Martin Oscarsson Authorized Public Accountant



IRLAB discovers and develops new drugs for the treatment of Parkinson's disease and other disorders of the brain. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), both of which are currently subject to Phase IIb studies, have been designed to treat some of the most difficult symptoms associated with Parkinson's disease. In 2021, IRLAB entered into an exclusive global license agreement with Ipsen regarding the development and marketing of mesdopetam. Through its proprietary development platform, ISP (Integrative Screening Process), IRLAB has discovered and developed all its projects and keeps discovering innovative drug candidates for the treatment of disorders of the central nervous system (CNS). In addition to IRLAB's strong clinical pipeline, IRLAB runs several preclinical programs, with IRL942 and IRL747 in development for Phase I.

Contact information

FOR FURTHER INFORMATION, PLEASE CONTACT

Nicholas Waters, CEO +46 730 75 77 01 nicholas.waters@irlab.se Viktor Siewertz, CFO +46 727 10 70 70 viktor.siewertz@irlab.se

HEAD OFFICE

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