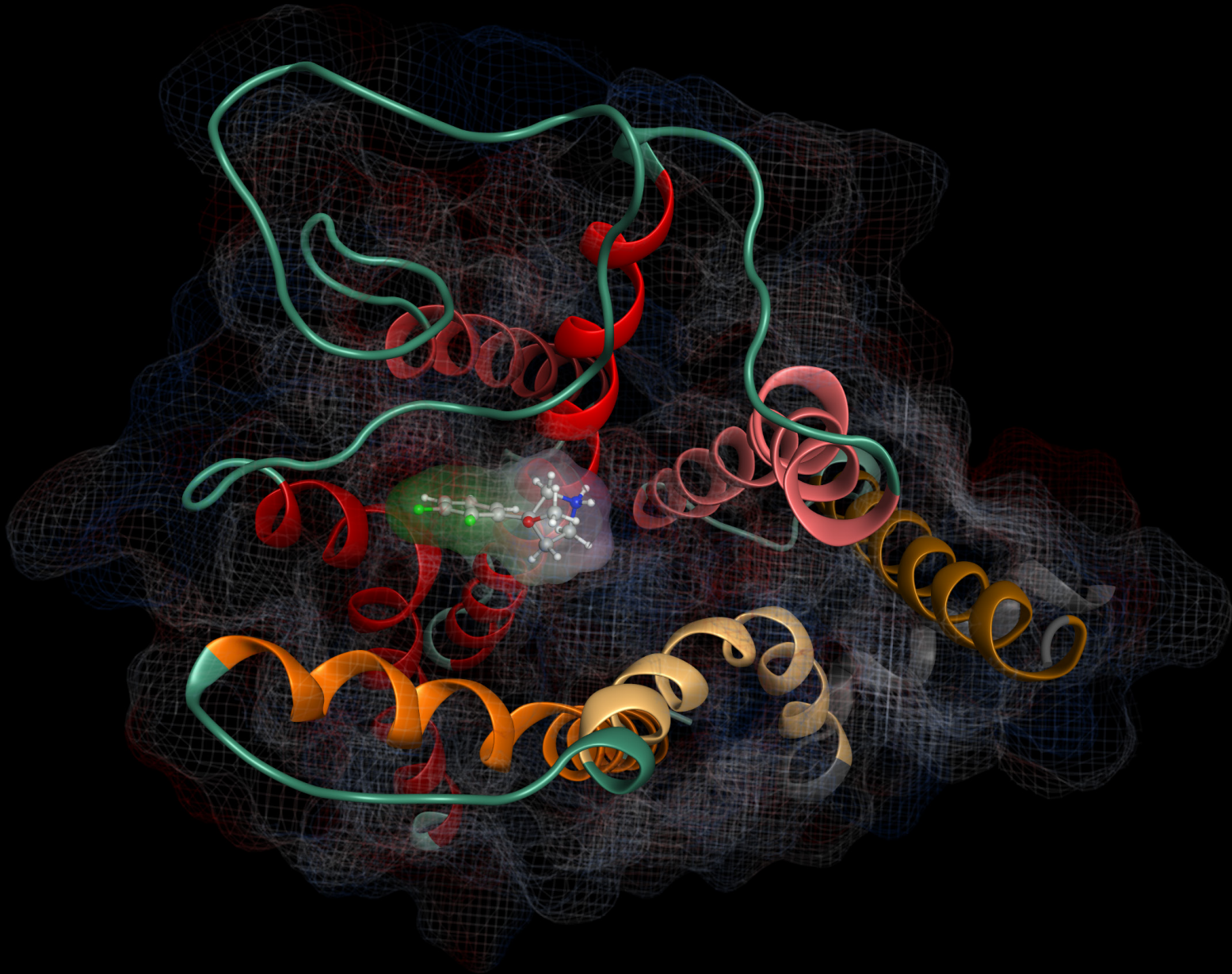


# Year-end Report January – December 2021



**Pirepemat:  
More time in balance for patients  
with Parkinson's**

# Year-end Report

## January – December 2021

### OCTOBER–DECEMBER 2021 compared with October–December 2020

	Oct–Dec 2021	Oct–Dec 2020
Net sales	12,141	0
Operating profit/loss	-22,601	-19,424
Profit/loss for the period	-23,117	-19,466
Earnings per share before and after dilution, attributable to the parent company's shareholders	-0.45	-0.40
Number of shares at the end of the period, including subscribed but not yet registered shares	51,748,406	51,748,406
Cash and cash equivalents	401,897	277,009
Equity per share	7.72	6.72
Average number of employees	22	18
Of which in R&D	20	17

### JANUARY–DECEMBER 2021 compared with January–December 2020

	Jan–Dec 2021	Jan–Dec 2020
Net sales	207,782	0
Operating profit/loss	52,576	-91,458
Profit/loss for the period	51,781	-91,653
Earnings per share before and after dilution, attributable to the parent company's shareholders	1.00	-1.92
Number of shares at the end of the period, including subscribed but not yet registered shares	51,748,406	51,748,406
Cash and cash equivalents	401,897	277,009
Equity per share	7.72	6.72
Average number of employees	22	18
Of which in R&D	20	17

*“The license agreement with Ipsen has resulted in a positive position that has allowed a major investment in our preclinical candidates and the hiring of new employees with new and important skills. In parallel, we have also been granted approval to begin the Phase IIb study with pirepemat.”*

NICHOLAS WATERS, CEO

## IRLAB in brief

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 Ipsen.

### Pirepemat

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

## 2021 in brief

- Ipsen and IRLAB entered into an exclusive global license agreement regarding mesdopetam, aiming to improve life for people with Parkinson's.
- IRLAB received regulatory approval for a Phase IIb study with pirepemat – which brought us one step closer to the possibility of improving balance and reducing injuries from falls in patients with Parkinson's.
- In 2021, IRLAB's operating profit was SEK 52.6 million, due to the licensing of the drug candidate mesdopetam to Ipsen.

*“After the capital contribution from the mesdopetam transaction, IRLAB is now better placed than ever to progress our projects and utilize the power of our ISP research platform.”*

VIKTOR SIEWERTZ, CFO



## 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.

### Integrative Screening Process

Our integrative Screening Process (ISP) includes specialized systems biology screening models, a database, software, analysis models that include AI and working methods. We are leading in technological development through the use of modern AI-based methods for developing new and better drugs. In addition to the clinical candidates, the ISP platform has also generated several programs for disorders of the central nervous system (CNS), which are now at the preclinical phase.

### Mesdopetam and pirepemat

Our most advanced candidates, mesdopetam (IRL790) and pirepemat (IRL752), both of which have gone through Phase IIa studies, are intended to treat some of the most difficult symptoms associated with Parkinson's disease: involuntary movements (PD-LIDs), psychosis (PD-P) and symptoms linked to cognitive decline, such as impaired balance and an increased risk of falls (PD-Falls). Through our proprietary development platform ISP (Integrative Screening Process), IRLAB discovers and develops drug candidates for CNS disorders, where there are significant growing medical needs.

## 9 MILLION

At present, nearly nine million people have Parkinson's. By 2040, this figure is expected to double. The need for new and better treatments is therefore huge. IRLAB focuses its research on developing new knowledge and designing and developing novel drugs which can do the greatest good for these patients.

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"We are leaders in technological development through the use of modern AI-based methods for developing new and better drugs."

NICHOLAS WATERS, CEO

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## IRLAB A

IRLAB Therapeutics has been listed on Nasdaq Stockholm's Mid Cap list since October 2020. The share was listed on Nasdaq First North Premier Growth Market in February 2017.



*"IRLAB's new positive position after the mesdopetam license transaction allowed us to invest in our preclinical candidates, obtain approval for a Phase IIb study with pirepemat, and recruit new and important talent to IRLAB.."*

NICHOLAS WATERS, CEO

## Comments from the CEO

I am very pleased with the company's development in 2021. During a period when the Covid-19 pandemic and the financial markets created major challenges for the biotech sector, we took major steps ahead, both in our clinical development projects and in the growth of the company.

Without a doubt, the most central event was the competitive negotiation that resulted in the mesdopetam license agreement with Ipsen, which gave us an initial milestone payment of USD 28 million, the potential payment of an additional USD 335 million and royalty on any sales.

During the year, we have leveraged our stronger position to accelerate the development in our preclinical projects and, in parallel, we have expanded our organization with new talent.

### The Ipsen transaction leads to greater opportunities for additional partnerships

IRLAB is engaged in long-term and purposeful conversations with a large group of pharmaceutical companies. In January 2021, IRLAB presented new and highly exciting preclinical data indicating that mesdopetam is capable of both treating and preventing the development of levodopa-induced dyskinesia (LID) in Parkinson's. Combined with the convincing clinical and preclinical results, this started off the process in the first quarter 2021 that led to the commercial license agreement with Ipsen.

In addition to placing mesdopetam at the heart of the hope for a new and better treatment for people with Parkinson's, the

deal has given IRLAB a strong financial basis, which has allowed us to vigorously develop the company towards the vision that is governing our work – to be a world-leading developer of innovative drugs for the treatment of Parkinson's and other disorders of the brain.

The transaction, which was one of the largest deals ever made in Swedish biotech, strengthened our conviction that we are developing IRLAB in the right direction. We are now acting in the international arena, with increased visibility and capacity. The 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, and we are proud to confirm that we have effective internal processes, controlled risk management and high operational quality. Our deal with Ipsen has also allowed us to accelerate the research and development in the P001 and P003 preclinical programs.

The fact that we reported a profit and positive cash flows in 2021 is an important milestone for IRLAB and an important consequence of our successful business development. Not only does this give us the conditions required to take the business to a higher level; it is also a highly important signal that our business model works, and that the organization delivers in line with our goals.

### Scalability

Our research and business model is scalable, and we are now expanding our organization with cutting-edge talent in key areas

to leverage the scalability of our research. We are currently focusing on important roles in strategy, research, artificial intelligence and communication.

In parallel with the scaling up of the business and the progression of our preclinical projects to clinical Phase I studies, our top priorities include conducting 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.

### **Our ISP platform gives us a clear competitive advantage**

ISP is an important element of IRLAB's competitiveness, as the research platform and the company's extensive and profound knowledge of brain disorders can generate new projects and drug candidates efficiently and quickly. Our research method gives us a major competitive advantage compared with our industry peers and sets the stage for major collaborations in product development and preclinical projects. Based on our technology development and experience, we can now state that our research and business development engine has been properly tuned.

### **We enter 2022 with confidence**

Covid-19 had a major impact on the pharmaceutical sector last year. For IRLAB, our 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.

From a global perspective, biotech companies had to delay the start of studies or interrupt studies prematurely in 2021, and delays in patient recruitment were not unusual. All companies

also experienced longer response times from regulatory authorities. We are therefore very happy that the mesdopetam study was able to progress, even though people with Parkinson's belong to the elderly at-risk group who were advised to isolate and avoid unnecessary medical appointments. In connection with the rapid spread of the omicron variant at end of the year, a slow-down in recruiting to clinical studies became clear.

Hospitals, where clinical studies are conducted, found it difficult to participate in starting up new studies, as they prioritised Covid-19 and its effects. These factors also affected IRLAB and we experienced delays 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. Now that lifting of restrictions seem to begin in Europe, we have an opportunity to get patient recruitment for this study off to a good start, and we hope that conditions will return to normal during 2022. The aim of the pirepemat study is to improve balance, thus reducing injuries from falls, in people with Parkinson's.

Last year, we received a great deal of positive feedback and external validation from our ongoing collaborations with British laboratories and Swedish research teams that are helping us evaluate our clinical drug candidates and the exciting compounds in the P001 and P003 projects. We enter 2022 with curiosity about new collaborations and a sense of confidence.



*Nicholas Waters, CEO, IRLAB*

# 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.

## Clinical phase

Tolerability, safety and efficacy studies in humans.

### 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).

An international phase IIb/III study has been conducted since the fall of 2020. In 2021, Mesdopetam was licensed to the international pharmaceutical company Ipsen.

### 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).

## Regulatory approval to start a trial

In the fourth quarter, IRLAB announced that the company had received regulatory approval by the Swedish Medical Products Agency on its application to begin a Phase IIb study with pirepemat. The treatment of the first patient in the Phase IIb trial is expected

to begin in the first quarter 2022. Recruitment is expected to take 18 months.

## Preclinical phase

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

IRLAB's P001 project is aimed at developing new drugs that improve the connection and signaling between nerve cells in the cortex to strengthen the patient's cognitive ability in a way that not only relieves symptoms, but also has the potential to slow down disease progression.

The aim of the drug candidates in P001 is to treat mental illness and cognitive and motor disorders associated with neurodegenerative and age-related CNS disorders.

## Discovery phase

Laboratory studies to discover drug candidates.

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

In the treatment of the hallmark symptoms of Parkinson's disease, the most effective drugs are currently based on levodopa or apomorphine in various forms. Both substances can be effective but their duration is short, which leads to poor treatment results.

Finding better, more long-acting alternatives to these two drug substances have long been an express goal.

IRLAB's P003 project aims to develop long-acting substances with better efficacy than levodopa or apomorphine. The project has achieved preclinical proof of concept.

	DISCOVERY	PRE CLINICAL	PHASE I	PHASE II A	PHASE II B	PHASE III
PARKINSON'S DISEASE – LEVODOPA-INDUCED DYSKINESIAS (LIDS)						
Mesdopetam* (IRL790)	D3 antagonist					
PARKINSON'S DISEASE – PSYCHOSIS						
Mesdopetam* (IRL790)	D3 antagonist					
PARKINSON'S DISEASE – FALLS						
Pirepemat (IRL752)	PFC enhancer					
PARKINSON'S DISEASE – DEMENTIA						
Pirepemat (IRL752)	PFC enhancer					
NEURODEGENERATIVE DISORDERS – AGING						
IRL942 + follow-up	P001 program					
PARKINSON'S DISEASE						
P003	Dopamin substitution					

PFC = prefrontal cortex

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

# The clinical drug candidate pirepemat aims to prevent injuries from falls

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 cognition, such as memory or the ability to think – an issue where existing Parkinson's drugs are ineffective.

Injuries related to falls are one of the major reasons why patients suffering from Parkinson's seek hospital care. Some 45 percent of all Parkinson's patients fall regularly. Pirepemat (IRL752) has the ability to increase the levels of the neurotransmitters norepinephrine and dopamine in the cortex, activating genes involved in strengthening the nerve cells' contacts. These effects help counteract the impaired balance and cognitive functions experienced by people with Parkinson's.

## 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.

## Phase IIb study

IRLAB has now obtained authorization to conduct a Phase IIb study, where pirepemat will be given for 12 weeks as adjunctive therapy to the patient's regular Parkinson's medication. The study's primary aim is to evaluate the effect on the frequency of

*“Treating impaired balance and reducing the risk of falls is the top priority in the effort to reduce complications from Parkinson's disease. These symptoms are the most severe consequences of Parkinson's disease, reducing the patients' quality of life.”*

JOAKIM TEDROFF, CHIEF MEDICAL OFFICER

falls and balance. The study also includes an evaluation of the effect on Parkinson's disease dementia (PD-D). The effect of pirepemat will be compared with placebo.

The study will be carried out in several countries in Europe and is estimated to include a total of 165 patients divided into three different groups: two dose levels of pirepemat and a placebo group. The recruitment period is estimated to be about 18 months.

After safety and efficacy data have been established in the Phase IIb study, pirepemat can progress to a more extensive Phase III clinical trial. The treatment of the first patient in the Phase IIb trial is expected to begin in the first quarter 2022.

There is currently no specific treatment that improves balance, which would reduce the risk of Parkinson's patients falling and hurting themselves. According to a global overview of the ongoing development project, there is no other drug under development with a similar mechanism of action. IRLAB therefore determines that pirepemat has a lead of approximately 4–5 years ahead of other projects.

## PATENT OVERVIEW FOR PIREPEMAT

Molecule	IRL752	RL752 fumarate
Type of patent	Substance	Substance and manufacturing process
WO No.	WO2010/058018	WO2020/211080
Status	Granted in all major markets (EU/US/JP/CN)	Patent applications submitted in all major markets
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* and PTE* in EU/US/JP)	No later than 2040, provided that the patent is granted and that the option to extend the patent period is used (SPC* and PTE* in EU/US/JP)

\* SPC = Supplementary Protection Certificate, PTE = Patent Term Extension

Source: The company's statement

# IRLAB’s competitive advantages

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.

## 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. Revenue is then received in the form of a payment when the agreement is signed, 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 current 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 excellent prerequisites for success are developed. To the extent that we identify additional resources within the ISP framework, these can be offered to external parties.

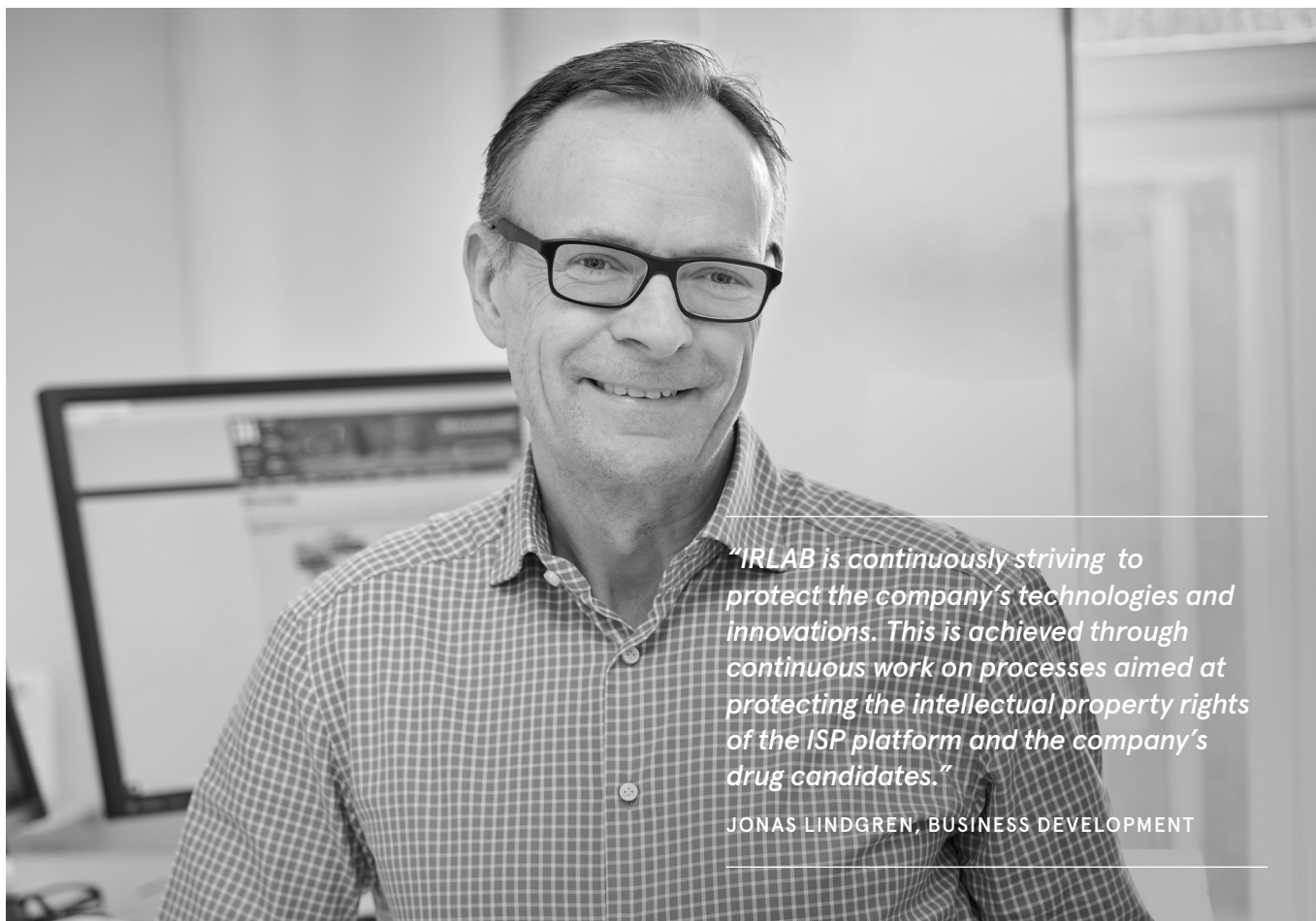
## What does IRLAB need to succeed?

### Innovative research

IRLAB needs to promote the continuous development of knowledge

2020–2023	2023–2025	2025–2027
Forming the basis for Parkinson’s disease treatments	Building for the future	Delivering first-in-class treatments for Parkinson’s disease
<b>MESDOPETAM</b> Successfully finalized Phase IIb/III studies	<b>MESDOPETAM</b> Phase III study initiated	<b>MESDOPETAM</b> Application for marketing authorization
<b>PIREPEMAT</b> Initiate Phase IIb study	<b>PIREPEMAT</b> Phase III study initiated	<b>PIREPEMAT</b> Application for marketing authorization
<b>DISCOVERY PIPELINE</b> Initiate Phase I study with preclinical candidate Upgrade ISP methodology	<b>DISCOVERY PIPELINE</b> Progress Phase I candidates to Phase II studies	<b>DISCOVERY PIPELINE</b>
<b>BUSINESS DEVELOPMENT</b>	<b>BUSINESS DEVELOPMENT</b>	<b>BUSINESS DEVELOPMENT</b>





*"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."*

JONAS LINDGREN, BUSINESS DEVELOPMENT

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

#### **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.

#### **Effective collaboration**

Good relations with partners and external experts are required to carry out the company's research and development, strategic and operational activities effectively. 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.

#### **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.

#### **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 constantly work 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.

# 45%

Some 45 percent of all Parkinson's patients fall regularly, and many need hospital care.

# The group's performance January – December 2021

IRLAB Therapeutics AB 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 are mesdopetam and pirepemat, both of which are intended to treat some of the most difficult symptoms related to Parkinson's disease. Mesdopetam is being developed for the treatment of levodopa-induced dyskinesia (PD-LID) and psychosis (PD-P). Pirepemat is being developed for the treatment of impaired balance leading to falls (PD-Falls). Both drug candidates have gone through Phase IIa studies.

In July 2021, a license agreement regarding the global and exclusive rights to develop and commercialize the drug candidate mesdopetam was entered into with the pharmaceutical company Ipsen. IRLAB will remain responsible for finalizing and financing the ongoing Phase IIb/III study but has no other material obligations.

According to the license agreement, IRLAB is eligible to receive up to USD 363 million in up-front and milestone payments, of which USD 28 million was paid in the third quarter 2021. In addition, IRLAB is eligible to receive tiered low double-digit royalties on worldwide net sales.

The company also has a unique and proprietary research platform (ISP) for developing new drug substances. IRLAB has several such substances at the preclinical phase that are intended improve motor function as well as the mental and cognitive health associated with age-related disorders of the central nervous system (CNS).

The parent company's operations mainly consist of providing management and administrative services to the group's operating companies. In addition, the parent company 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.

## 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 but will be taken up as income later in 2022, once the study is finalized. In 2021, SEK 11,759 thousand was recognized as revenue, of which SEK 6,382 thousand was recognized

in the fourth quarter. In 2021, revenue for services provided to Ipsen was SEK 10,762 thousand, of which SEK 5,759 thousand was recognized in the fourth quarter.

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. In the fourth quarter, the company's operating expenses were SEK 34,986 thousand (19,545). This increase is chiefly due to the cost of services provided to Ipsen, the higher number of employees and the greater activity in the rest of the operations.

## Financing and cash flow

In 2021, cash flows from operating activities were SEK 128,641 thousand (–89,214). 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%).

The executive management believes that there are sufficient cash and cash equivalents to cover working capital needs over the next twelve months, given the current business and development plan and financing plan. This mainly relates to activities within the scope of upcoming clinical studies for pirepemat (IRL752) and mesdopetam (IRL790), as well as costs for preclinical studies, new projects/drug candidates and other operating costs.

## Investments

Investments for the period January 1–December 31, 2021 were SEK 708 thousand (394).

*“Pirepemat has the potential to become the first treatment in a new class of drugs designed to improve balance and reduce injuries from falls for people suffering from Parkinson's disease. After obtaining advice from regulatory authorities and in cooperation with external experts, we have designed a study that supports the continuous development of pirepemat – a study for which we have now received regulatory approval.”*

NICHOLAS WATERS, VD

### Significant events January–September 2021

- In January, new preclinical data were presented that indicated that mesdopetam cannot only treat, but also prevent, the development of levodopa-induced dyskinesias (LIDs) in Parkinson's. These new results increase the commercial potential of mesdopetam.
- In January, results were also presented from a collaboration between Chalmers University of Technology, the AI company Smartr and IRLAB regarding the application of deep learning on multi-dimensional effects of CNS drugs. A summary of these interesting results were presented at the leading congress Society of Neuroscience (SfN) Global Connectome: A Virtual Event.
- In early March, it was announced that the first European patients had been dosed with mesdopetam in the Phase IIb/III clinical trial. Regulatory authorities across Europe have approved the study and Poland is the first European country where mesdopetam treatment has been initiated. The study is currently underway on two continents, both in the US and in Europe.
- At the end of March, it was announced that independent scientists have confirmed that the dopamine D3 receptor (D3R) is a highly promising drug target with therapeutic potential in levodopa-induced dyskinesia, especially when the receptor's unique signaling properties are taken into account. IRLAB's mesdopetam is currently the most advanced D3R antagonist in the global neurology pipeline. It is used in the scientific article to exemplify a compound that could have an impact on the management of a number of disorders marked by aberrant D3R activity. The article was published in the scientific journal *Biomedicines* in March 2021.
- During the quarter, the company entered into a new lease and extended the existing lease of the company's premises. The new premises are located in direct connection to the current premises. As a result, the right-of-use assets and lease liabilities in the company's balance sheet have increased.
- On May 6, the company's Annual General Meeting was conducted solely through postal voting due to the covid-19 pandemic.
- In May, a scientific article was published that described the results from the clinical Phase I study with the drug candidate mesdopetam in the journal *Pharmacology Research & Perspectives* (PR&P). The article strengthens the growing scientific evidence of the drug candidate mesdopetam's significant potential in Parkinson's.
- In June, it was announced that equity research company Edison initiated coverage of the company.
- In mid-June, a report of the results from the clinical first-in-human study with pirepemat was published in the journal *Clinical Pharmacology in Drug Development* (CPDD). The publication of results from preclinical and clinical studies are an important part of drug development and is at the center of the company's strategy to establish IRLAB's science and pipeline in academia and industry.
- 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 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, it was announced that IRLAB had been granted stronger patent protection for the Phase II candidate pirepemat. The granted patent describes a chemical process for the manufacturing of pirepemat in its pure form.

### Significant events in the fourth quarter October–December 2021

- In November, a Nomination Committee was appointed for IRLAB's 2022 Annual General Meeting.
- In November, IRLAB published its interim report for the third quarter 2021.
- In December, IRLAB obtained regulatory approval for the Phase IIb study with pirepemat.
- In December, board member Martin Nicklasson announced his intention to resign from the Board of Directors of IRLAB, in order to take on a new assignment.

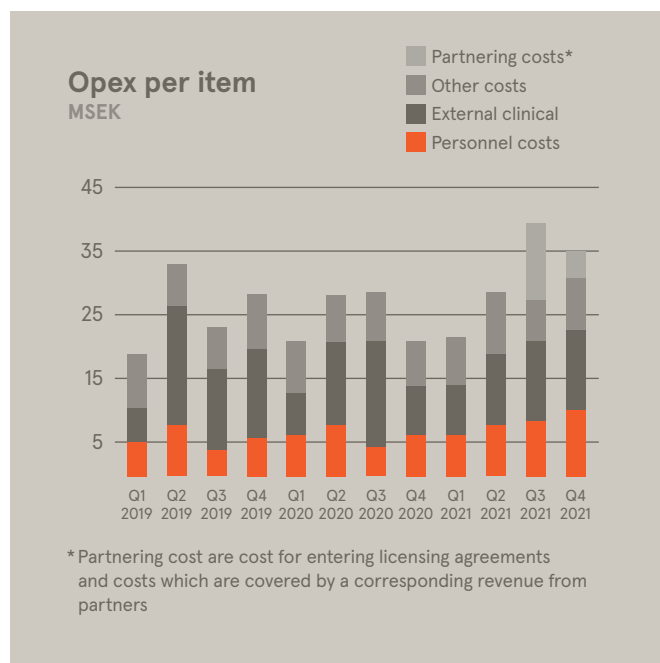
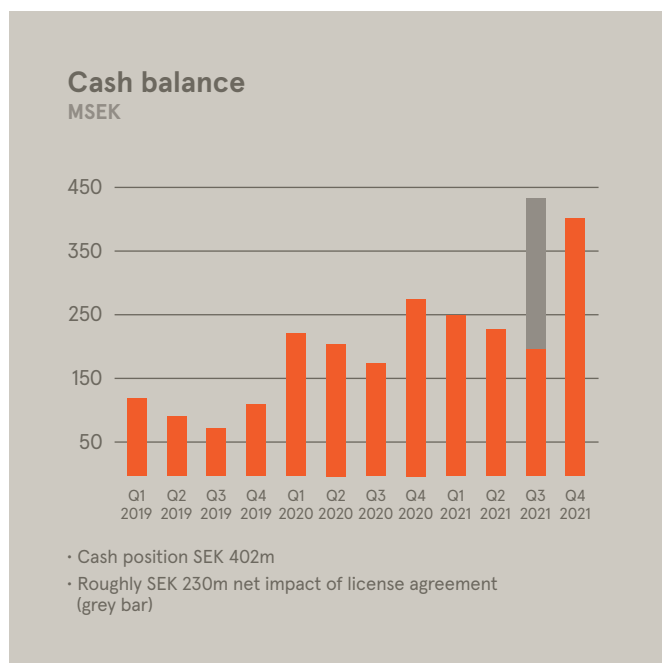
### Significant events after the end of the period

After the end of the period, there were no significant events that affected the group's financial results or position.



*“We have more cash and cash equivalents than ever before in the company’s history, and we will use this new position to expand the business and increase our investments in preclinical operations, so that we may progress new drug candidates to Phase I as quickly as possible.”*

VIKTOR SIEWERTZ, CFO



# Other

## The IRLAB share

IRLAB's Class A share has been listed on Nasdaq Stockholm's Mid Cap 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 A shares and 79,776 (79,776) were 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 shares.

The ten largest shareholders on December 31, 2021	Number of shares	%
Försäkringsbolaget Avanza Pension	4,040,845	7.8%
Ancoria Insurance Public Ltd	3,826,638	7.4%
FV Group AB	3,665,626	7.1%
Fourth Swedish National Pension Fund	3,280,366	6.3%
Johnsson, Daniel	2,690,000	5.2%
Pension, Futur	2,055,484	4.0%
Third Swedish National Pension Fund	1,847,994	3.6%
Nordnet Pensionsförsäkring AB	1,684,060	3.3%
Diklev, Philip	1,595,550	3.1%
Unionen	1,416,250	2.7%
<b>Total ten largest shareholders</b>	<b>26,102,813</b>	<b>50.4%</b>
<b>Other shareholders</b>	<b>25,645,593</b>	<b>49.6%</b>
<b>Total</b>	<b>51,748,406</b>	<b>100%</b>

## 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.

## 2021 Annual Report

IRLAB's Annual Report will be published on the company's website between April 4 and April 8, 2022.

## Management team

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.

## RISKS AND UNCERTAINTIES

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.

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.

With regard to risks, IRLAB's operations are based on continuous evaluations and analyses of available information to remain a step ahead and identify potential problems as early as possible.

As a step in IRLAB's internal control and operational governance efforts, any risks and uncertainties that may affect IRLAB's operations and earnings capacity are reviewed systematically on an annual basis. Risks have been divided into strategic, operational and financial risks, and compliance and reporting risks. All risks are then assessed based on the likelihood of their occurrence and the impact they may have on the company if they occur.

In 2021, the risks that were considered to be the highest in an overall assessment was the risk of IRLAB's pipeline not developing or delivering in line with expectations, the risk associated with IRLAB's patient situation, and the risk that the Covid-19 pandemic would have a negative effect on operations.

IRLAB has devised plans to monitor all risks and mitigate any effects.

The company's financial risk exposure and risk management are described on pages 93–94 and business risks are described on pages 99–100 of the 2020 Annual Report. No significant changes have occurred that affect the reported risks.

## 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. 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.

### Competition

A number of competing 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 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 share.

### 2022 Annual General Meeting

IRLAB's 2022 Annual General Meeting is planned to be held in Gothenburg, Sweden, on May 11, 2022. 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.

### Nomination Committee

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

### Sustainability

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

## Calendar

March 22, 2022	IRLAB's Capital Markets Day 2022 in Stockholm
April 4–8, 2022	2021 Annual Report
May 11, 2022	Annual General Meeting 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

*“Over the next 20–25 years, more than 14 million people all over the world will suffer from Parkinson’s disease, causing great human suffering and major costs to society. We aim to create new treatments for Parkinson’s disease, thus creating a better future for those affected.”*

MALIN EDLING, SENIOR RESEARCH SCIENTIST

### Presentation to investors and media

A conference call will be held on Wednesday February 23, 2022, at 10:30 CET where Nicholas Waters, CEO, and Viktor Siewertz, CFO, will present the report. The presentation will be held in Swedish and be followed by an opportunity to pose questions.

Those who wish to participate in the conference call may call in using the following numbers:

SE +46 850 558 364  
UK +44 333 300 9263  
US +1 646 722 4957

It will also be possible to follow the conference call via link:  
<https://financialhearings.com/event/43409>

### Review

This interim report has not been reviewed by the company’s auditors. The Board of Directors and the CEO assure that the interim report provides a fair overview of the parent company’s and the group’s operations, position and results and describes significant risks and uncertainties faced by the company and group companies.

### Gothenburg, February 23, 2021

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

# Consolidated income statement in summary

Amounts in SEK thousand	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
<b>Operating income, etc.</b>				
Net sales	12,141	0	207,782	0
Other operating income	243	121	124	404
<i>Total income</i>	<i>12,384</i>	<i>121</i>	<i>207,906</i>	<i>404</i>
<b>Operating expenses</b>				
Other external expenses	-24,389	-12,919	-81,737	-65,630
Personnel expenses	-9,600	-6,055	-31,024	-23,968
Outlicensed balanced development projects	0	0	-39,091	0
Amortization, depreciation and impairment	-996	-570	-3,474	-2,256
Other operating expenses	0	0	-4	-8
<i>Total operating expenses</i>	<i>-34,986</i>	<i>-19,545</i>	<i>-155,330</i>	<i>-91,862</i>
<b>Operating profit/loss</b>	<b>-22,601</b>	<b>-19,424</b>	<b>52,576</b>	<b>-91,458</b>
<b>Profit/loss from financial items</b>				
Finance income	1	0	1	1
Finance costs	-516	-41	-796	-196
<i>Total financial items</i>	<i>-516</i>	<i>-41</i>	<i>-795</i>	<i>-195</i>
<b>Profit/loss after financial items</b>	<b>-23,117</b>	<b>-19,466</b>	<b>51,781</b>	<b>-91,653</b>
Income tax	0	0	0	0
<b>Profit/loss for the period</b>	<b>-23,117</b>	<b>-19,466</b>	<b>51,781</b>	<b>-91,653</b>
Earnings per share before and after dilution (SEK)	-0.45	-0.40	1.00	-1.92
Average number of shares, before and after dilution	51,748,406	48,641,263	51,748,406	47,677,734
Number of shares at year-end	51,748,406	51,748,406	51,748,406	51,748,406

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



# Consolidated statement of comprehensive income in summary

Amounts in SEK thousand	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Profit/loss for the period	-23,117	-19,466	51,781	-91,653
Other comprehensive income	0	0	0	0
<b>Comprehensive income for the period</b>	<b>-23,117</b>	<b>-19,466</b>	<b>51,781</b>	<b>-91,653</b>

# Consolidated statement of financial position in summary

Amounts in SEK thousand	12/31/2021	12/31/2020
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets	42,661	82,011
Property, plant and equipment	8,348	4,317
<b>Total non-current assets</b>	<b>51,009</b>	<b>86,327</b>
<b>Current assets</b>		
Current receivables	19,542	6,732
Cash and cash equivalents	401,897	277,009
<b>Total current assets</b>	<b>421,440</b>	<b>283,741</b>
<b>TOTAL ASSETS</b>	<b>472,449</b>	<b>370,068</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>	Note 5	
Share capital	1,035	970
Unregistered share capital	0	65
Other contributed capital	685,450	685,630
Retained earnings including comprehensive income for the year	-287,005	-338,786
<b>Total equity</b>	<b>399,481</b>	<b>347,880</b>
<b>Non-current liabilities</b>		
Lease liabilities	3,566	1,270
<b>Total non-current liabilities</b>	<b>3,566</b>	<b>1,270</b>
<b>Current liabilities</b>		
Lease liabilities	3,034	1,657
Other liabilities	66,367	19,261
<b>Total current liabilities</b>	<b>69,402</b>	<b>20,918</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>472,449</b>	<b>370,068</b>

# Consolidated statement of changes in equity in summary

Amounts in SEK thousand	Share capital	Unregistered share capital	Other contributed capital	Retained earnings incl. total comprehensive income for the period	Total equity
<b>Equity January 1, 2020</b>	<b>862</b>	<b>0</b>	<b>428,097</b>	<b>-247,133</b>	<b>181,827</b>
Comprehensive income for the period				-91,653	-91,653
<i>Transactions with owners in their capacity as owners:</i>					
Rights issue	108	65	275,322		275,495
Issue costs			-17,789		-17,789
<b>Equity December 31, 2020</b>	<b>970</b>	<b>65</b>	<b>685,630</b>	<b>-338,786</b>	<b>347,880</b>
<b>Equity January 1, 2021</b>	<b>970</b>	<b>65</b>	<b>685,630</b>	<b>-338,786</b>	<b>347,880</b>
Comprehensive income for the period				51,781	51,781
<i>Transactions with owners in their capacity as owners:</i>					
Rights issue	65	-65			0
Issue costs			-180		-180
<b>Equity December 31, 2021</b>	<b>1,035</b>	<b>0</b>	<b>685,450</b>	<b>-287,005</b>	<b>399,481</b>

# Consolidated statement of cash flows in summary

Amounts in SEK thousand	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
<b>Operating activities</b>				
Operating profit/loss	-22,601	-19,424	52,576	-91,458
Adjustments for non-cash items	996	570	42,564	2,256
Interest received	0	0	0	1
Interest paid	-516	-41	-796	-196
Taxes paid	0	0	0	0
<b>Cash flows from operating activities before changes in working capital</b>	<b>-22,121</b>	<b>-18,895</b>	<b>94,345</b>	<b>-89,397</b>
<b>Cash flows from changes in working capital</b>				
Changes in operating receivables	-4,177	2,441	-12,811	2,620
Changes in operating liabilities	-2,091	941	47,107	-2,437
<b>Cash flows from operating activities</b>	<b>-28,389</b>	<b>-15,513</b>	<b>128,641</b>	<b>-89,214</b>
<b>Investing activities</b>				
Acquisition of property, plant and equipment	-147	0	-708	-394
<b>Cash flows from investing activities</b>	<b>-147</b>	<b>0</b>	<b>-708</b>	<b>-394</b>
<b>Financing activities</b>				
Repayment of financial liabilities	-736	-414	-2,865	-1,616
Rights issue	0	123,241	-180	257,706
<b>Cash flows from financing activities</b>	<b>-736</b>	<b>122,828</b>	<b>-3,045</b>	<b>256,091</b>
<b>Cash flows for the period</b>	<b>-29,271</b>	<b>107,315</b>	<b>124,888</b>	<b>166,482</b>
Cash and cash equivalents at the beginning of the period	431,168	169,693	277,009	110,527
<b>Cash and cash equivalents at the end of the period</b>	<b>401,897</b>	<b>277,009</b>	<b>401,897</b>	<b>277,009</b>

# Parent company income statement in summary

Amounts in SEK thousand	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
<b>Operating income, etc.</b>				
Net sales	1,272	889	4,059	3,274
<i>Total income</i>	<i>1,272</i>	<i>889</i>	<i>4,059</i>	<i>3,274</i>
<b>Operating expenses</b>				
Other external expenses	-2,149	-2,155	-16,805	-8,052
Personnel expenses	-3,135	-1,563	-8,705	-7,794
<i>Total operating expenses</i>	<i>-5,283</i>	<i>-3,717</i>	<i>-25,510</i>	<i>-15,845</i>
<b>Operating profit/loss</b>	<b>-4,011</b>	<b>-2,828</b>	<b>-21,451</b>	<b>-12,572</b>
<b>Profit/loss from financial items</b>				
Profit/loss from participations in group companies	0	0	0	-35,000
Interest income	0	0	0	1
Interest expenses	-2	0	-3	-1
<i>Total financial items</i>	<i>-2</i>	<i>0</i>	<i>0</i>	<i>-35,001</i>
<b>Profit/loss after financial items</b>	<b>-4,014</b>	<b>-2,828</b>	<b>-21,454</b>	<b>-47,572</b>
Group contributions made	0	-150,000	0	-150,000
Tax on profit/loss for the year	0	0	0	0
<b>Profit/loss for the period</b>	<b>-4,014</b>	<b>-152,828</b>	<b>-21,454</b>	<b>-197,572</b>

## Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Profit/loss for the period	-4,014	-152,828	-21,454	-197,572
Other comprehensive income	0	0	0	0
<b><i>Comprehensive income for the period</i></b>	<b><i>-4,014</i></b>	<b><i>-152,828</i></b>	<b><i>-21,454</i></b>	<b><i>-197,572</i></b>

# Parent company balance sheet in summary

Amounts in SEK thousand	12/31/2021	12/31/2020
<b>ASSETS</b>		
<b>Non-current assets</b>		
<b>Financial assets</b>		
Participations in group companies	350,320	350,320
<b>Total non-current assets</b>	<b>350,320</b>	<b>350,320</b>
<b>Current assets</b>		
Other receivables	1,755	1,232
Cash and bank balances	112,970	239,693
<b>Total current assets</b>	<b>114,725</b>	<b>240,926</b>
<b>TOTAL ASSETS</b>	<b>465,045</b>	<b>591,246</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
<b>Restricted equity</b>		
Share capital	1,035	970
Unregistered share capital	0	65
	1,035	1,035
<b>Non-restricted equity</b>		
Share premium reserve	739,560	739,740
Retained earnings including comprehensive income for the period	-280,345	-258,891
	459,215	480,849
<b>Total equity</b>	<b>460,250</b>	<b>481,884</b>
<b>Current liabilities</b>		
Other liabilities	4,795	109,362
<b>Total liabilities</b>	<b>4,795</b>	<b>109,362</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>465,045</b>	<b>591,246</b>

## The parent company's statement of cash flows

Amounts in SEK thousand	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Cash flows from operating activities	-1,930	2,391	-126,543	-12,179
Cash flows from investing activities	0	0	0	0
Cash flows from financing activities	0	73,241	-180	172,706
<b>Cash flows for the period</b>	<b>-1,930</b>	<b>75,632</b>	<b>-126,723</b>	<b>160,527</b>
Cash and cash equivalents at the beginning of the period	114,900	164,061	239,693	79,166
<b>Cash and cash equivalents at the end of the period</b>	112,970	<b>239,693</b>	<b>112,970</b>	<b>239,693</b>



## 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 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, SEK thousand	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 the other key financial ratios, Profit/loss for the period, Cash and cash equivalents at the end of the period, Cash flows from operating activities, Cash flows for the period, and Equity were obtained from a financial statement defined by IFRS. For the derivation of key financial ratios, as well as definitions and justifications for the selected key financial ratios, please refer to the IRLAB Therapeutics AB (publ) 2020 Annual Report.

# Notes

## Note 1. Accounting principles

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

As of January 1, 2019, shareholder contributions made to subsidiaries that are intended to cover the subsidiaries' costs for research are expensed in the parent company. The cost is reported in the income statement under Profit/loss from participations in group companies. Accordingly, the accounting in the parent company reflects the accounting in the group, where all costs for research are charged to profit or loss. The opening balance remains unchanged as the company found that there had been no impairment. The accounting principles applied correspond to those applied in the 2020 Annual Report.

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

New and amended standards adopted from 2020 have not had any significant impact on the group's financial position.

### 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 met:

- 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 compensation 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 recognized in the agreement. 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 the revenue when the group satisfies a performance obligation by transferring a product or service to a customer, i.e., when the customer obtains control of the asset. A performance obligation is fulfilled either over time or by a specific time.

IRLAB's income is made up primarily 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 income. The sale of products is recognized as income 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. Services are recognized over time as the services are provided. For services that are provided over a shorter period of time, the revenue is recognized in practice when the service has been completed.

## Note 2. Risks and uncertainties

IRLAB Therapeutics' financial risk exposure and risk management are described on pages 93–94 and business risks are described on pages 99–100 of the 2020 Annual Report. No significant changes have occurred that affect the reported risks.

## Note 3. Transactions with related parties

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

## Note 4. Covid-19

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. There are, however, indications that healthcare providers in certain countries and regions are under pressure, which affects certain hospitals' ability to participate in clinical trials.

Additionally, interactions have shown that regulatory authorities currently have longer processing times. Combined, this may affect IRLAB's clinical programs if the Covid-19 outbreak continues to put a strain on global healthcare resources and if restrictions on individuals' freedom of movement are extended beyond what is known today. We are therefore monitoring the situation closely and evaluating measures to minimize the effects on our projects and schedules.

### Note 5. Financial instruments

The group currently has no financial instruments that are valued at fair value, rather all financial assets and liabilities are valued at accrued acquisition value. It is judged that there are no significant differences between fair value and book value regarding the financial assets and liabilities. The carrying amount for financial assets on the closing date amounts to SEK 408,414 thousand (277,190).

### Note 6. Net sales

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

Net sales per revenue category	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Licensing revenue	0	0	185,261	0
Service revenue	12,141	0	22,521	0
<b>Total revenue</b>	<b>12,141</b>	<b>0</b>	<b>207,782</b>	<b>0</b>

### Note 7. Equity

#### Incentive programs

In April 2016, it was decided to offer warrants to key personnel, both employees and board members. A total of 39,355 warrants (196,775 after the split) were subscribed for in the program at a subscription price that corresponded to the market value.

Each warrant confers an entitlement on the holder to subscribe for one Class A ordinary share at a subscription price of SEK 82.70 after the split. The warrants may be exercised up to and including June 30, 2023. When the warrants are fully exercised, the share capital will increase by SEK 3,935.50 through the issue of 196,775 Class A ordinary shares.

### Note 8. Segment information

Net sales per geographic market	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Sweden	0	0	0	0
United Kingdom	12,141	0	207,782	0
<b>Total revenue</b>	<b>12,141</b>	<b>0</b>	<b>207,782</b>	<b>0</b>

### Note 9. Significant events after the balance sheet date

There were no significant events after the end of the period.

# Glossary

<b>API</b>	Active Pharmaceutical Ingredient, the active substance in a drug.
<b>Bad ON time</b>	The part of the day when the patient experiences troublesome dyskinesias.
<b>CMC</b>	Chemistry, Manufacturing and Controls, ensuring the production of the active substance and formulated drug.
<b>COMT inhibitors</b>	Drugs that work by slowing down the metabolism of levodopa and dopamine.
<b>CRO</b>	Clinical Research Organization, a contract research organization that conducts clinical studies.
<b>Dyskinesia</b>	Condition where the body or a part of the body performs uncontrolled involuntary movements. Dyskinesia occurs in neurodegenerative and psychiatric diseases, brain diseases where the nervous system is either exposed to a slowly decreasing nerve cell activity, such as Parkinson's disease, or diseases where the nerve cell activity in particular parts of the brain has become unbalanced, such as psychosis or depression.
<b>Good ON time</b>	The part of the day when the patient does not have troublesome symptoms of Parkinson's disease.
<b>IND</b>	Investigative New Drug Application is an application to conduct pharmaceutical studies in humans, usually referring to studies in the United States.
<b>INN</b>	An International Nonproprietary Name, also called a generic substance name, is assigned by the World Health Organization based on the substance's mechanism of action.
<b>ISP</b>	Integrative Screening Process, IRLAB's proprietary research platform used to generate drug candidates.
<b>MAO-B inhibitors</b>	Drugs that work by slowing down the breakdown of dopamine and have a certain symptom-relieving effect.
<b>NMDA receptor</b>	The N-methyl-D-aspartate receptor. A receptor in the brain that is likely to be inhibited by the drug amantadine.
<b>OFF time</b>	The part of the day when the patient experiences classic Parkinson's symptoms, such as muscle stiffness, mobility impairment and tremors.
<b>PD-LID</b>	Parkinson's Disease levodopa-induced dyskinesia, involuntary movements (dyskinesias) caused by long-term medication with levodopa.
<b>PD-P</b>	Parkinson's Disease Psychosis, psychic symptoms such as delusions and/or hallucinations caused by Parkinson's disease.
<b>PD-Fall</b>	Parkinson's Disease Falls, falls due to postural dysfunction (balance impairment) and impaired cognition in Parkinson's disease.
<b>Proof of Concept</b>	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.
<b>UDysRS</b>	(Unified Dyskinesia Rating Scale) – A standardized method for estimating movement patterns in dyskinesias.
<b>UPDRS</b>	(Unified Parkinson's Disease Rating Scale) – A method for qualitatively measuring the extent of the disease in a Parkinson's sufferer. The scale has 42 measuring points, including behavior, mood, movement patterns and the complications the patient may experience during treatment.
<b>Hauser diaries</b>	A standardized method for patients to evaluate their health status, also called patient diaries.



IRLAB is a Swedish research and drug development company that focuses on developing novel treatments in Parkinson's disease.

The company's most advanced candidates, mesdopetam (IRL790), licensed to Ipsen and pirepemat (IRL752), both of which have completed Phase IIa studies, are intended to treat some of the most difficult symptoms related to Parkinson's disease: involuntary movements (PD-LIDs), psychosis (PD-P) and symptoms linked to cognitive decline such as impaired balance and an increased risk of falls (PD-Falls).

Through its proprietary development platform ISP (Integrative Screening Process), IRLAB discovers and develops drug candidates for diseases related to the central nervous system (CNS), where there are significant growing medical needs.

In addition to the clinical candidates, the ISP platform has also generated several CNS programs, which are now at the preclinical phase.

## Contact information

FOR FURTHER INFORMATION, PLEASE CONTACT

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